5 510(k) Summary

5.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Contact Person: Jennifer M. Jackson, MS

Date of Submission: 20-Feb-2014

5.2 Name of the Device

Trade Name: Straumann® Variobase™ Abutments

Common Name: Dental Implant Abutment

Classification Name: Abutment, Implant, Dental, Endosseous

Regulation Number: §872.3630

5.3 Predicate Device(s)

- K120822, Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC (Institut Straumann AG)
- K111935, Ti-Base Abutment (NT-Trading GmbH & Co. KG)

5.4 Device Description

The Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments, sometimes referred to as "Ti-bases". Straumann® Variobase™ Abutments are available to fit Straumann® dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit®), and RC (Regular CrossFit®). A dental laboratory technician would design the corresponding coping and/or crown (the second component of the Variobase two-piece abutment) and/or prosthetic restoration in the

dental laboratory using either a burnout coping or STL model for open CAD software. The coping and/or crown would be manufactured via validated Straumann milling.

5.5 Intended Use

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments intended to be placed onto Straumann dental implants to provide support for customized prosthetic restorations such as crowns and bridges. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

5.6 Technological Characteristics

Straumann® Variobase™ Abutments are two-piece abutments consisting of a pre-manufactured (stock) abutment made from a titanium-aluminum-niobium alloy and a coping and/or crown which is designed in the dental laboratory by a dental technician using open CAD software and manufactured via validated Straumann milling.

The Ti-base components of the Straumann® Variobase™ Abutments are identical to the Ti-base components of the Straumann predicate (K120822). The Ti-base components are also equivalent to the Ti-base components identified in K111935.

The materials which may be used to manufacture the coping/crown component of the Straumann® Variobase™ Abutments are identical to the identified predicate devices and include:

Milling: Polycon® ae (temporary restorations – K120822)

Zerion® (K120822)

5.7 Performance Testing

The material used in the manufacture of Straumann® Variobase™ Abutments is a titanium-aluminum-niobium alloy which meets the requirements of ISO 5832-11. Bench testing was performed with Polycon® ae and Zerion® to evaluate the fatigue load limits of the proposed Straumann® Variobase™ Abutments. Dynamic fatigue tests were conducted in according to the FDA guidance document *"Guidance for Industry and FDA*

Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments".

5.8 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase™ Abutments are substantially equivalent to the predicate devices and do not pose new issues of safety and effectiveness when used as labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Straumann USA, Limited Liability Company
Jennifer M. Jackson, MS
60 Minuteman Road
Andover, MA 01810

Re: K132219
Trade/Device Name: Straumann® Variobase ™Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Abutment, Implant, Dental, Endosseous
Regulatory Class: II
Product Code: NHA
Dated: January 23, 2014
Received: January 24, 2014

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132219

Device Name: Straumann® Variobase™ Abutments

Indications for Use:

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.10.21
-05'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Straumann USA, Limited Liability Company
Jennifer M. Jackson, MS
60 Minuteman Road
Andover, MA 01810

Re: K132219
Trade/Device Name: Straumann® Variobase ™Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Abutment, Implant, Dental, Endosseous
Regulatory Class: II
Product Code: NHA
Dated: January 23, 2014
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We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K132219

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Michael Mendelson
Branch Chief Sign-Off	Susan Runner
Division Sign-Off	Kwame O. Ulmer -S 2014.02.21 14:00:59 -05'00'

Template Name: K1(A) – SE after 1996

(b)(4) Trade Secret Process

[redacted]

Indications for Use

510(k) Number (if known): K132219

Device Name: Straumann® Variobase™ Abutments

Indications for Use:

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2014.02.21
10:22:22 -05'00'

K132219

straumann®

July 16, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: Traditional 510(k) Premarket Notification: Straumann® Variobase™ Abutments

Dear Sir or Madam:

On behalf of Institut Straumann AG, Straumann USA, LLC submits this Traditional 510(k) Premarket Notification for the Straumann® Variobase™ Abutments in accordance with 21 CFR 807.81. The intended use and fundamental operating principles of the proposed devices are substantially equivalent to previously cleared devices as detailed in this premarket submission.

Submitter:
Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Primary Contact:
Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager
Straumann USA, LLC
60 Minuteman Road
Andover, MA 01810
Telephone: 800-448-8168 x2509
Fax: 978-747-0023

Classification Name of Device:

Classification Name:	Abutment, Implant, Dental, Endosseous
Device Product Code:	NHA
Product Classification:	Class II
Panel:	Dental
Regulation Number:	§872.3630

straumann

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

The term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence from an FDA-regulatory point of view under the Federal Food, Drug and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to, and does not diminish, any patent claim related to this product or the technology used to manufacture the product.

Information in this premarket notification is considered proprietary or trade secret or confidential commercial information. The company requests that all such information not be disclosed pursuant to 18 U.S.C. §1905, 5 U.S.C. §552, 21 U.S.C. §331(j), and all other applicable laws and regulations.

Two copies of the Traditional 510(k) Premarket Notification are enclosed. The second copy is being provided in PDF format on CD and is an exact duplicate of the hardcopy. Further, in accordance with the Medical Device User Fee and Modernization Act of 2001 ("MDUFMA"), Straumann USA, LLC has submitted the appropriate application fees. A copy of the User Fee Cover Sheet is provided with the enclosed 510(k) Premarket Notification.

We trust that the foregoing information will be sufficient to permit FDA to make a finding of substantial equivalence for the proposed Straumann® Variobase™ Abutments to the currently marketed devices as presented in this premarket notification.

Please address any questions regarding this 510(k) Premarket Notification to the undersigned.

Sincerely,

Jennifer M. Jackson

Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager

Enclosures

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Table of Contents

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

(b)(4) Trade Secret Process

(b)(4) Trade Secret

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Table of Tables

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Table of Figures

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

1 Medical Device User Fee Cover Sheet (Form FDA 3601)

Payment Identification Number: (b)(4) Trade Secret

The Medical Device User Fee Cover Sheet (Form FDA 3601) begins on the next page.

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

STRAUMANN USA
60 MINUTEMAN ROAD
ANDOVER
MA 01810
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
Jennifer Jackson
2.1 E-MAIL ADDRESS
jennifer.jackson@straumann.com
2.2 TELEPHONE NUMBER (include Area code)
978-747-2509
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
978-747-0023

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distr buted commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 03-Jul-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

2 CDRH Premarket Review Submission Cover Sheet

The CDRH Premarket Review Submission Cover Sheet begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
07-16-2013	(b)(4) Trade	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Straumann USA, LLC	1222315		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	978-747-2509		
Street Address	FAX Number *(including area code)*		
60 Minuteman Road	978-747-0023		
City	State / Province	ZIP/Postal Code	Country
Andover	MA	01810	USA
Contact Name			
Jennifer M. Jackson, MS			
Contact Title	Contact E-mail Address		
Senior Regulatory Affairs Project Manager	jennifer.jackson@straumann.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NHA	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached

☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K120822	1	Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC	1	Straumann
2	K111935	2	Ti-Base Abutment	2	NT-Trading GmbH & Co. KG
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Endosseous dental implant abutment

	Trade or Proprietary or Model Name for This Device		Model Number
1	(b)(4) Trade Secret Process	1	(b)(4)
2	(b)(4) Trade Secret Process	2	(b)(4)
3	(b)(4) Trade Secret Process	3	(b)(4)
4	(b)(4) Trade Secret Process	4	(b)(4)
5	(b)(4) Trade Secret Process	5	(b)(4)

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NHA	21 CFR 872.3630	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Dental

Indications *(from labeling)*

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: Institut Straumann AG		Establishment Registration Number: 9613348	
Division Name *(if applicable)*		Phone Number *(including area code)*: 978-747-2509	
Street Address: Peter Merian-Weg 12		FAX Number *(including area code)*: 978-747-0023	
City: Basel	State / Province	ZIP Code: CH-4052	Country: Switzerland
Contact Name: Jennifer M. Jackson, MS	Contact Title: Senior Regulatory Affairs Project Manager	Contact E-mail Address: jennifer.jackson@straumann.com	

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	(b)(4) Trade Secret Process				
2	(b)(4) Trade Secret Process				
3	(b)(4) Trade Secret Process				
4	(b)(4) Trade Secret Process				
5	(b)(4) Trade Secret Process				
6	(b)(4) Trade Secret Process				
7	(b)(4) Trade Secret Process				

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	(b)(4) Trade Secret Process				
	Standards No.	Standards	Standards Title	Version	Date
	(b)(4) Trade Secret Process				
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

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1350 Piccard Drive, Room 400
Rockville, MD 20850

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3 510(k) Cover Letter

The 510(k) Cover Letter begins on the next page.

straumann®

July 16, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: Traditional 510(k) Premarket Notification: Straumann® Variobase™ Abutments

Dear Sir or Madam:

On behalf of Institut Straumann AG, Straumann USA, LLC submits this Traditional 510(k) Premarket Notification for the Straumann® Variobase™ Abutments in accordance with 21 CFR 807.81. The intended use and fundamental operating principles of the proposed devices are substantially equivalent to previously cleared devices as detailed in this premarket submission.

Submitter:
Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Primary Contact:
Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager
Straumann USA, LLC
60 Minuteman Road
Andover, MA 01810
Telephone: 800-448-8168 x2509
Fax: 978-747-0023

Classification Name of Device:

Classification Name:	Abutment, Implant, Dental, Endosseous
Device Product Code:	NHA
Product Classification:	Class II
Panel:	Dental
Regulation Number:	§872.3630

straumann

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

The term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence from an FDA-regulatory point of view under the Federal Food, Drug and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to, and does not diminish, any patent claim related to this product or the technology used to manufacture the product.

Information in this premarket notification is considered proprietary or trade secret or confidential commercial information. The company requests that all such information not be disclosed pursuant to 18 U.S.C. §1905, 5 U.S.C. §552, 21 U.S.C. §331(j), and all other applicable laws and regulations.

Two copies of the Traditional 510(k) Premarket Notification are enclosed. The second copy is being provided in PDF format on CD and is an exact duplicate of the hardcopy. Further, in accordance with the Medical Device User Fee and Modernization Act of 2001 ("MDUFMA"), Straumann USA, LLC has submitted the appropriate application fees. A copy of the User Fee Cover Sheet is provided with the enclosed 510(k) Premarket Notification.

We trust that the foregoing information will be sufficient to permit FDA to make a finding of substantial equivalence for the proposed Straumann® Variobase™ Abutments to the currently marketed devices as presented in this premarket notification.

Please address any questions regarding this 510(k) Premarket Notification to the undersigned.

Sincerely,

Jennifer M. Jackson

Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager

Enclosures

4 Indications for Use Statement

The Indications for Use Statement associated with this 510(k) is located on the following page in the required format.

Indications for Use

510(k) Number (if known):

Device Name: Straumann® Variobase™ Abutments

Indications for Use:

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5 510(k) Summary

5.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Contact Person: Jennifer M. Jackson, MS

Date of Submission: 16-Jul-2013

5.2 Name of the Device

Trade Name: Straumann® Variobase™ Abutments

Common Name: Dental Implant Abutment

Classification Name: Abutment, Implant, Dental, Endosseous

Regulation Number: §872.3630

5.3 Predicate Device(s)

K120822 – Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC

K111935 – Ti-Base Abutment (NT-Trading GmbH & Co. KG)

5.4 Device Description

The Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments, sometimes referred to as "bonding bases". Straumann® Variobase™ Abutments are available to fit Straumann® dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit®), and RC (Regular CrossFit®).

5.5 Intended Use

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments intended to be placed onto Straumann dental implants to provide support for customized prosthetic restorations such as crowns and bridges. Straumann® Variobase™ Abutments are

indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

5.6 Technological Characteristics

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments made from a titanium-aluminum-niobium alloy.

5.7 Performance Testing

The material used in the manufacture of Straumann® Variobase™ Abutments is a titanium-aluminum-niobium alloy which meets the requirements of ISO 5832-11. Bench testing was performed to evaluate the fatigue load limits of the proposed Straumann® Variobase™ Abutments. Dynamic fatigue tests were conducted in according to the FDA guidance document *"Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"*.

5.8 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase™ Abutments are substantially equivalent to the predicate devices.

6 Truthful and Accuracy Statement

As Required by 21 CFR 807.87(k)

I certify that, in my capacity as Senior Regulatory Affairs Project Manager of Straumann USA, LLC, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Jennifer M. Jackson

(Signature)

Jennifer M. Jackson, MS

(Typed Name)

16-Jul-2013

(Date)

(Premarket Notification Number)

7 Class III Summary and Certification

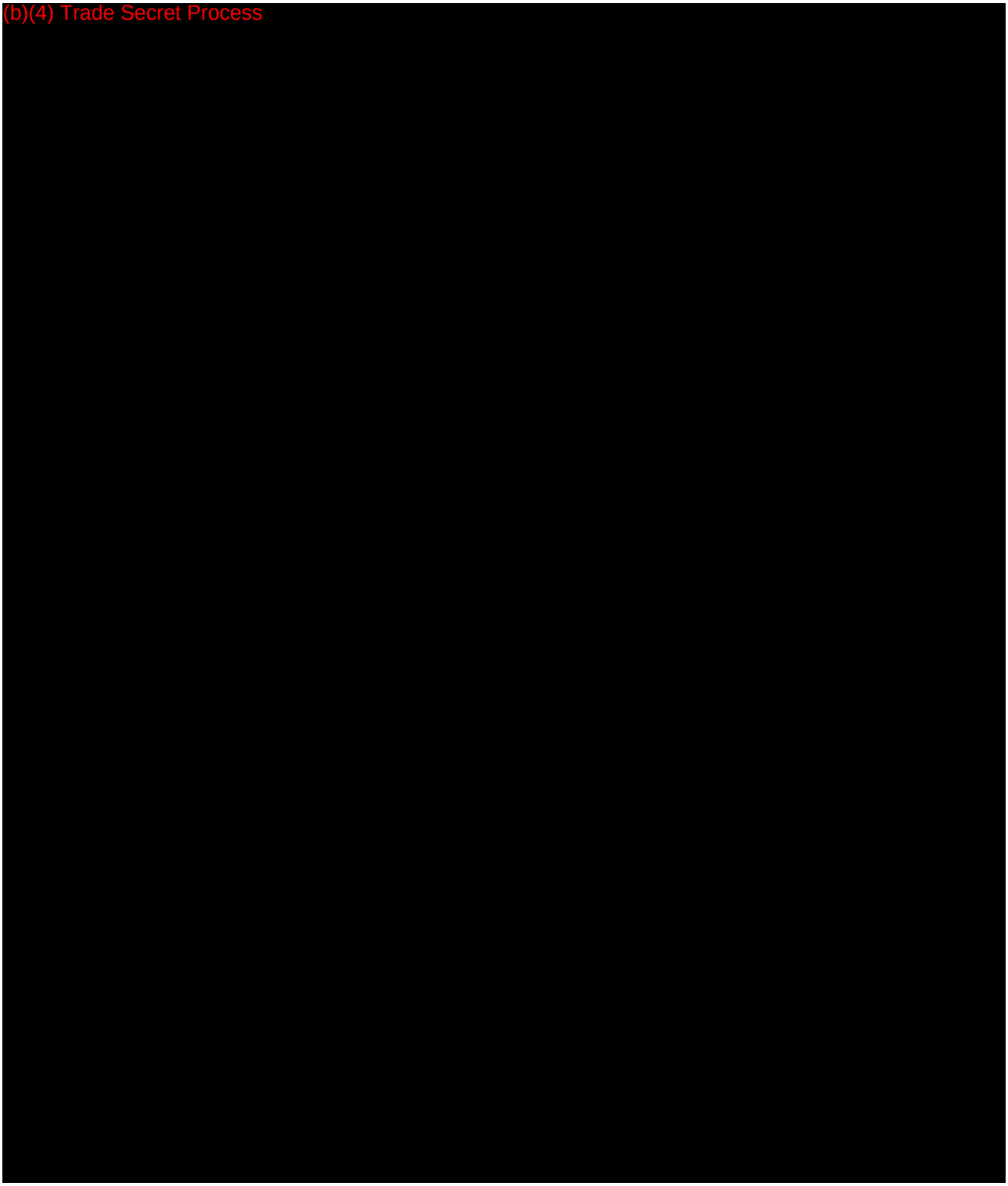
This section is not applicable as the subject devices have been determined to be Class II per 21 CFR 872.3630.

8 Financial Certification or Disclosure Statement

This section is not applicable as there is no clinical data being submitted to support this premarket notification.

9 Declarations of Conformity and Summary Reports

(b)(4) Trade Secret Process



Traditional 510(k) Submission

Straumann® Variobase™ Abutments

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)?	☒	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?	☒	☐
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo), May 1, 1995

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo), May 1, 1995

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#2-135	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)?	☒	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?	☒	☐
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
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Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

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[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process

Department of Health and Human Services

Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☐	☒
FDA Recognition number[3]	#_____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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If yes, was the guidance document followed in preparation of this 510k?	☒	☐

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[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#8-63	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: ___		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☐	☒
FDA Recognition number[3]	#____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: ___		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process [redacted]

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☒
FDA Recognition number[3]	#14-261	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)?	☒	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?	☒	☐
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: ___		

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[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process

(b)(4) Trade Secret Process

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☐	☒
FDA Recognition number[3]	#____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: ___		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#4-195	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)?	☒	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?	☒	☐
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for Industry and FDA Staff 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseious Dental Implant Abutments', May 12, 2004

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

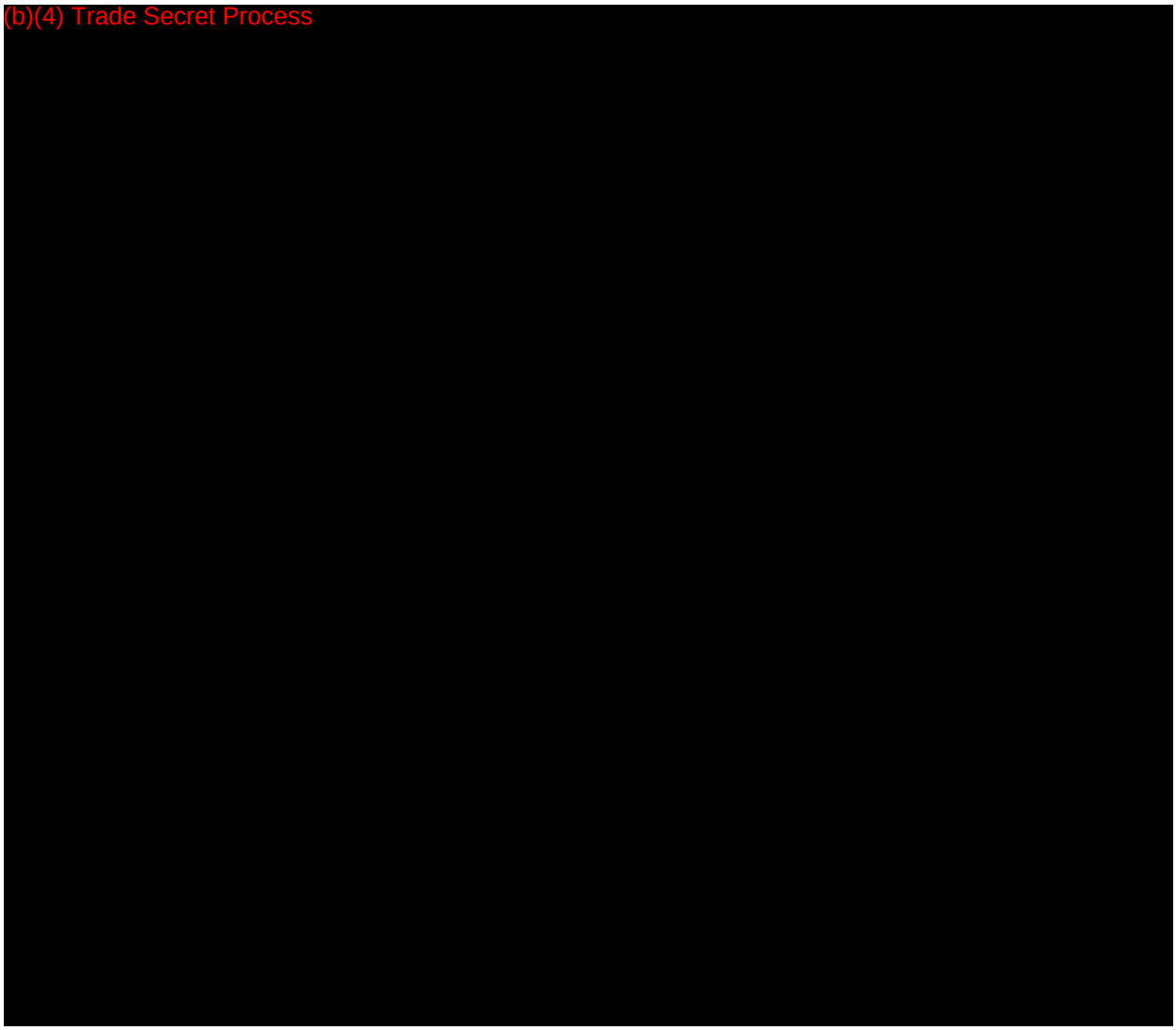
[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

10 Device Description

The modification proposed in this premarket notification is to the Indications for Use for the previously cleared Straumann® CARES® Variobase™ Abutments for NNC, RN, WN, NC, and RC (K120822). The modified Indications for Use would allow Straumann to market the Straumann® Variobase™ Abutment as a stand-alone component. The dental laboratory would then manufacture the respective coping and/or prosthetic restoration using a burnout coping or STL model for open CAD software.

10.1 Straumann® Variobase™ Abutments

(b)(4) Trade Secret Process



(b)(4) Trade Secret Process

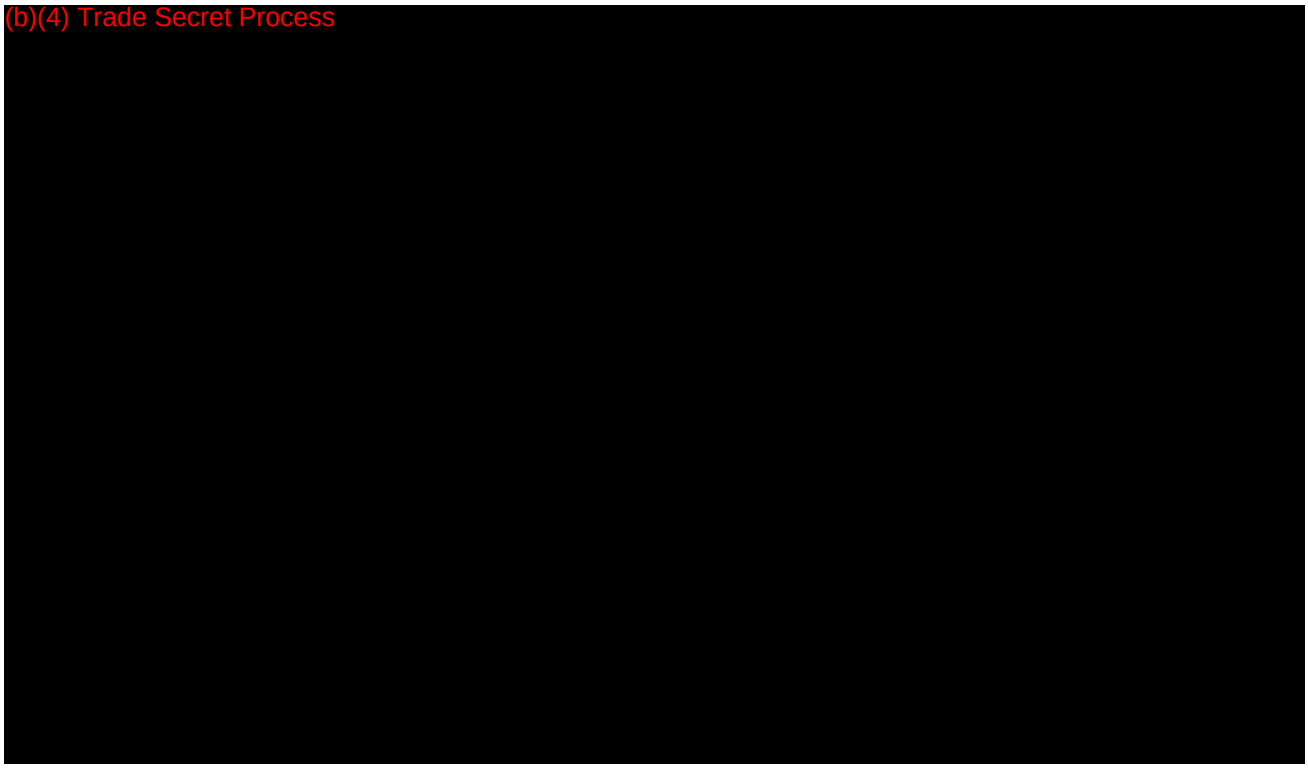
[redacted]

10.2 Basal Screws

(b)(4) Trade Secret Process

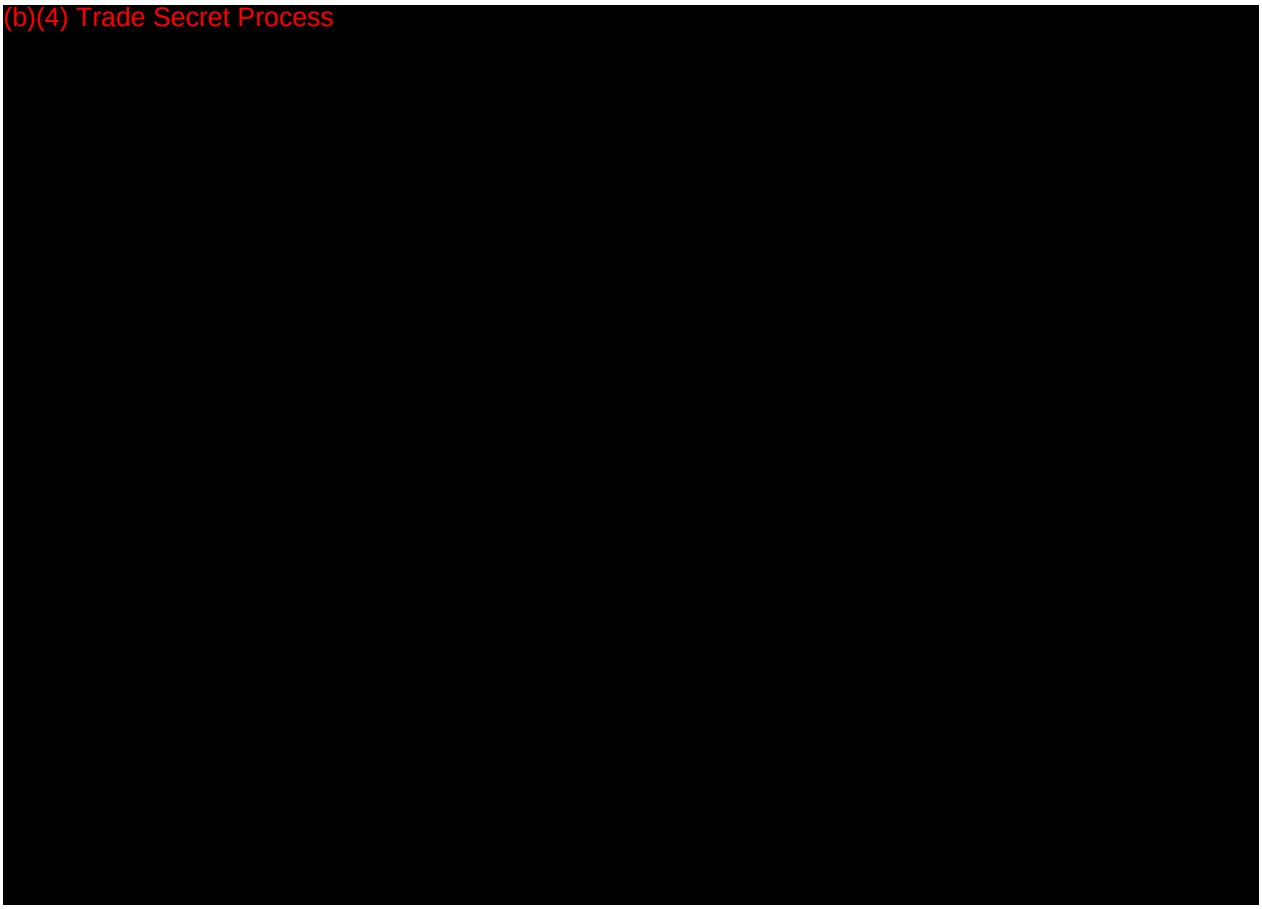
[redacted]

(b)(4) Trade Secret Process



10.3 Accessories

(b)(4) Trade Secret Process



10.4 Procedure

10.4.1 Restoration Design

(b)(4) Trade Secret Process

10.4.2 Dental Laboratory and Prosthetic Procedures

(b)(4) Trade Secret Process

[redacted]

10.5 Conclusion

(b)(4) Trade Secret Process

[redacted]

11 Substantial Equivalence Discussion

Within the meaning of the Medical Device Amendments Act of 1976, the proposed change to the Indications for Use for the Straumann® Variobase™ Abutments in this 510(k) premarket notification are substantially equivalent to the medical devices currently in commercial distribution listed below:

- K120822, Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC
- K111935, Ti-Base Abutment (NT-Trading GmbH & Co. KG)

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments intended to be placed onto Straumann dental implants to provide support for customized prosthetic reconstructions such as crowns and bridges. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

The NT-Trading Ti-Base Abutment is a pre-manufactured abutment supplied in two parts, the abutment and screw, for fixation onto dedicated endosseous dental implants and is intended for use as an aid in prosthetic restoration. The Ti-Base is compatible with commercially available dental CAD/CAM systems, such as 3Shape, Exocad, and Dental Wings. Such systems must be validated by the user.

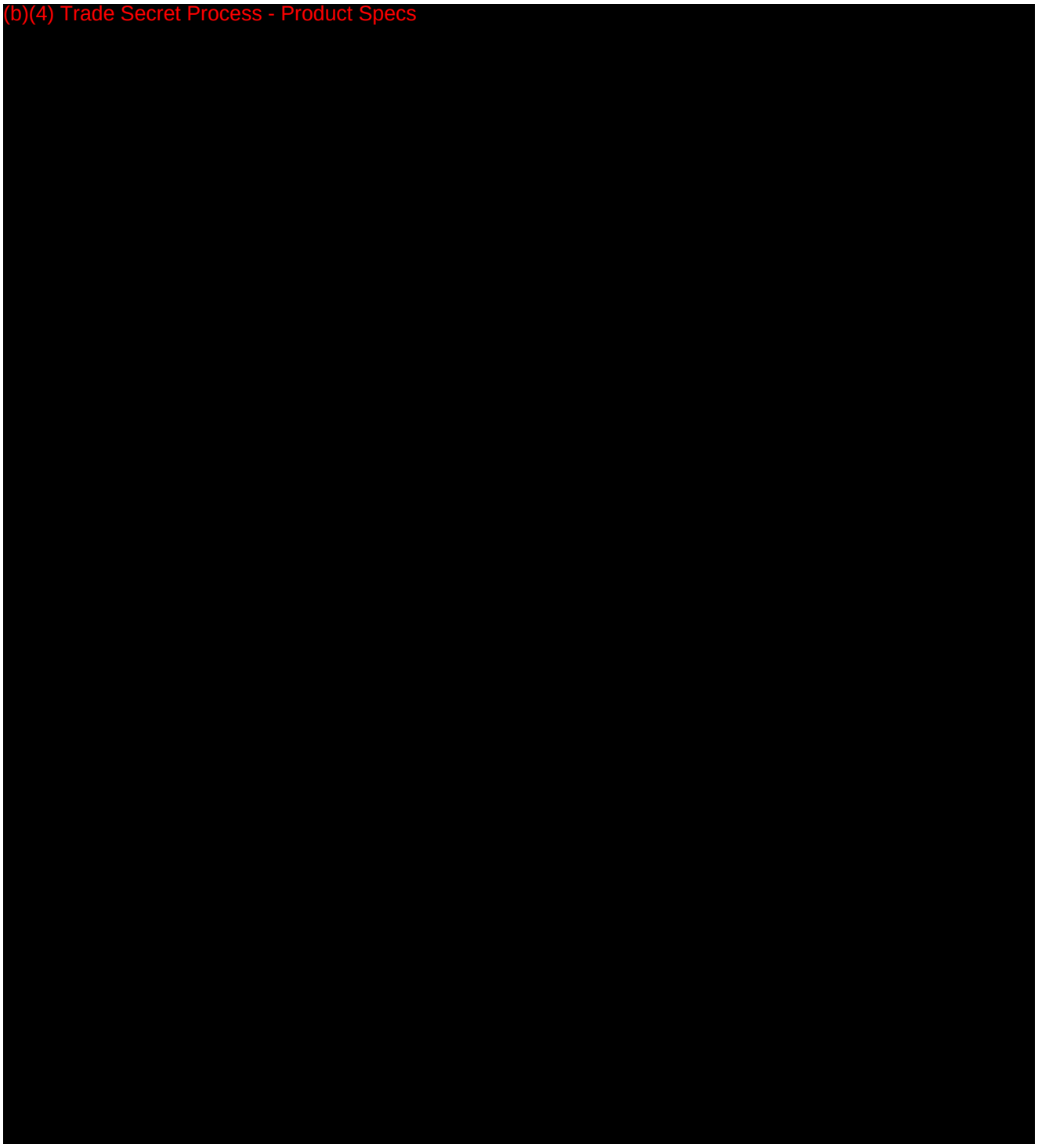
The NT-Trading catalog and package insert are included in this submission in Appendices 2 and 3, respectively. The products that were cleared in premarket notification K111935 are outlined in Table 5 (the 510(k) Summary is included in Appendix 4). Specifically, the L-Serie and N-Serie abutments are compatible with implants of the Straumann Dental Implant System.

(b)(4) Trade Secret Process - Product Specs

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

(b)(4) Trade Secret Process - Product Specs



Traditional 510(k) Submission

Straumann® Variobase™ Abutments

The table below provides a comparison matrix of the proposed and predicate devices (K120822):

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Straumann® CARES® Variobase™ Abutments (K120822)**	
Indications for Use	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.	The Straumann® CARES® Variobase™ Abutment is a two-piece dental abutment consisting of the Straumann® Variobase™ Abutment and the Straumann® CARES® Variobase™ Coping which is intended to be placed onto Straumann dental implants to provide support for prosthetic reconstruction such as crown and bridges. Straumann® CARES® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. The Straumann® CARES® Variobase™ Coping polycon® ae in combination with the Straumann® CARES® Variobase™ Abutment is indicated for temporary (up to 180 days) dental restoration of a Straumann dental implant.	The indications for use are being modified to allow Straumann to market the Straumann® Variobase™ Abutment as a stand-alone component. The dental laboratory would then manufacture the respective coping and/or prosthetic restoration using a burnout coping or STL model for open CAD software.
Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Identical
Abutment Diameter	(b)(4) Trade Secret	(b)(4) Trade Secret Process - Product	Identical
Abutment Height	(b)(4) Trade Secret	(b)(4) Trade Secret Process - Product	Identical

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Straumann® CARES® Variobase™ Abutments (K120822)**	
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Identical
Reusable	No	No	Identical

Table 6 - Comparison Matrix: Proposed Device versus Predicate Devices (K120822)

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

The table below provides a comparison matrix of the proposed and predicate devices (K111935):

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Ti-Base Abutment (K111935)**	
Indications for Use	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.	Ti-Base for individual Zirconium Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base for individual Zirconium Abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Nobel Biocare NobelActive™ • Biomet 3i® Osseotite® • Biomet 3i® Osseotite® Certain® • Nobel Biocare Branemark® • Straumann® synOcta® • Straumann® Bone Level® • Zimmer® Tapered Screw-vent® • Astra Tech OsseoSpeed® • Dentsply-Friadent® Frialit®	Equivalent

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

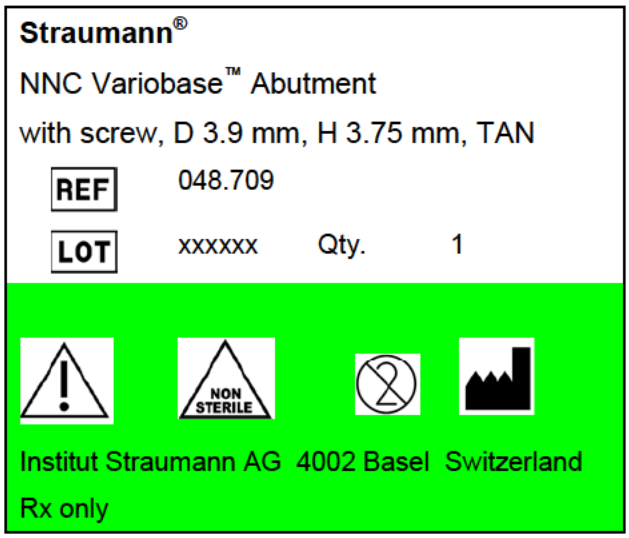
FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Ti-Base Abutment (K111935)**	
Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V)	Equivalent
Abutment Diameter	(b)(4) Trade Secret Process - Product	(b)(4) Trade Secret Process - Product Specs	Equivalent
Abutment Height	(b)(4) Trade Secret Process - Product S	(b)(4) Trade Secret Process -	Equivalent
Mode of Action	Screw-retained or cement retained S	Screw-retained or cement retained	Identical
Reusable	No	No	Identical

Table 7 - Comparison Matrix: Proposed Device versus Predicate Devices (K111935)

12 Proposed Labeling

12.1 Package Label

There are no changes to the package label as a result of the proposed change in this premarket notification. To aid in the review of the submission, an example of the label is shown in Figure 1.



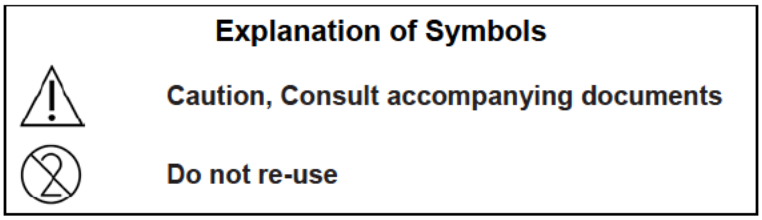


Figure 1 - Example label for Straumann® Variobase™ Abutment

12.2 Proposed Package Insert/Instructions for Use for Straumann® Variobase™ Abutments

Instructions for use: Straumann® Variobase™ Abutments

Institut Straumann AG, Peter-Merian-Weg 12, CH-4002 Basel/Switzerland, www.straumann.com

English

CAUTION: Federal law restricts this device to sale by or on the order of a dental professional.

Straumann® Variobase™ Abutments				
				
NNC	RN	WN	NC	RC

1. Product Description

Abutments

Abutments are placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

Basal Screws

Basal screws are used for the fixation of the abutment to the dental implant.

2. Intended use

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

3. Indications

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

4. Contraindications

Allergies or hypersensitivity to materials used, which are indicated in the following table:

Straumann Variobase™ abutments, Screws	Titanium alloy, Ti-6Al-7Nb (titanium-aluminum-niobium or TAN).

5. Warnings and Precaution

Our products must be secured against aspiration when used intraorally. Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications:

- Aspiration or swallowing of a component
- Breakage
- Infection

The Straumann® Variobase™ abutments are single use devices.

Place implant-borne restorations only in occlusion when the implant is completely osseointegrated.

Angled abutments should not be used in areas of high mechanical loads on small diameter implants.

Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer.

Implants are only to be restored with the corresponding original abutment compatible with that specific implant.

The Straumann® Variobase™ abutments have not been evaluated for safety and compatibility in the magnetic resonance environment. The Straumann® Variobase™ abutments have not been tested for heating or migration in the magnetic resonance environment.

6. Compatibility information

Straumann® implants and the prosthetic components are available in a variety of configurations to meet your clinical needs. The label on each product uses abbreviations to help you identify whether a particular abutment or coping is compatible with the implant that you are restoring. The implant as well as the prosthetic component contains an identifier for the connection type, summarized in the table below.

Implant connection type	Compatible prostheses
NC (Narrow CrossFit®)	parts labeled NC
RC (Regular CrossFit®)	parts labeled RC
NNC (Narrow Neck CrossFit®)	parts labeled NNC
RN (Regular Neck)	parts labeled RN
WN (Wide Neck)	parts labeled WN

7. Cleaning and Disinfection

Straumann® Variobase™ abutments and components are non-sterile when delivered. Before placing the restoration in the patient's mouth, the product must be cleaned, disinfected and sterilized. Straumann recommends the following procedure for cleaning, disinfection and sterilization of abutments prior to use.

1) Clean rinsing under flowing water while brushing outer and inner side with adequate brushes.

2) The pre-treated product is to be cleaned/disinfected in an automated washer disinfector. Select the appropriate program according to the manufacturer’s instructions.

8. Sterilization

Material	Method	Conditions
Variobase™ Abutment, TAN Screw, TAN	Autoclave (moist heat) Displacement: gravity or fractionated vacuum	134 °C (273 °F) 5 minutes

Please note: User should ensure the use of the appropriate biological indicator for the sterilizer and parameters used.

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

9. Procedure

Use and handling of the Straumann® Variobase™ abutments for the Dental Technician

Restoration design

Make a coping or crown following standard procedure according to the material manufacturer's instructions. When using pressing or casting techniques via wax-up, use the burn-out coping for Variobase™ abutments which supports a clean and sharp-edged finish of the screw channel and a good fit to the Straumann® Variobase™ abutment.

Processing

Process the coping or crown following standard procedure according to the material manufacturer's instructions. Always finalize the crown or coping prior to bonding to the Straumann® Variobase™ abutments.

Bonding

Please note: It is not necessary to sandblast the Straumann® Variobase™ abutment.

1) Fix the abutment to the implant analog with a screw (hand-tight).

2) Seal the screw channel with wax.

3) Apply self-adhesive dental cement on the abutment. Only suitable self-adhesive cementation systems for the material used shall be used. Follow the instructions for use of both the dental material and cement/bonding material manufacturer. (Straumann® recommends Panavia™ F2.0 resin cement by Kuraray)

4) Bond the coping to the abutment.

5) Immediately remove excess cement from the abutment and polish the lower margin of the coping after the cement is set.

6) Clean the restoration prior to sending it to the dentist.

7) Include this instruction for use when sending the restoration to the dentist.

Use and handling of the Straumann® Variobase™ Abutments for the Dentist

Remove the restoration from the master cast or the analog.

Clean, disinfect and sterilize the device as described in sections 7 and 8 of this Instructions for Use document.

Placing the restoration

a) Remove the healing cap or temporary restoration.

b) Clean and dry the interior of the implant and the abutment thoroughly.

c) Place the sterilized restoration into the patient's mouth.

d) Make sure that the retentive elements of the implant abutment connection are properly aligned.

e) Use the screw delivered with titanium base or abutment to screw the final restoration into the dental implant.

Please note: Always ensure that the surfaces of threads and screw heads are clean and that a new screw is used for the restoration.

f) Straumann® abutments are fixed to the implant using the Straumann® SCS screwdriver, ratchet and torque control device. Use the respective torque according to the table below:

Device type	Tightening torque	Special considerations
Abutments (permanent)	35 Ncm	n/a
Temporary abutments	15 – 35 Ncm	Tighten only to 35 Ncm if the implant is fully osseointegrated
Components on implant analogs	Hand-tight	n/a

Warning

Torques greater than 35 Ncm may result in failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

Please note

Once the Straumann® abutment has been secured to the implant using the indicated torque, it should not be removed.

10. Further Information

For additional information about the use of Straumann® products, call Straumann's customer service department or visit www.straumann.com.

For additional information, consult:

Basic information on the Straumann® Variobase™ abutment

11. Please note

Practitioners must have appropriate knowledge and instruction in the handling of the Straumann product described herein ("Straumann Product") for using the Straumann Product safely and properly in accordance with these instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Product is part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Institut Straumann AG, its ultimate parent company and all affiliates or subsidiaries of such parent company ("Straumann"), except if stated otherwise in these instructions for use. If use of products made by third parties is not recommended by Straumann in these instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann.

12. Validity

Upon publication of these instructions for use, all previous versions are superseded.

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Availability

Some items of the Straumann® Dental Implant System are not available in all countries.

CE 0123	Straumann Products with the CE mark fulfill the requirements of the Medical Devices Directive 93/42 EEC /
	Refer to package insert
	Manufacturer
REF	Article number
LOT	Lot Number
	Do not re-use
	Non-sterile
Rx only	Federal law restricts this device to sale by or on the order of a dental professional.

13 Sterilization and Shelf Life

13.1 Sterilization

(b)(4) Trade Secret Process - Product Specs

[redacted]

7. Cleaning and Disinfection

(b)(4) Trade Secret Process - Product Specs

[redacted]

8. Sterilization

Material	Method	Conditions
(b)(4) Trade Secret Process - Product Specs		

(b)(4) Trade Secret Process - Product Specs

[redacted]

13.2 Shelf Life

(b)(4) Trade Secret Process - Product Specs

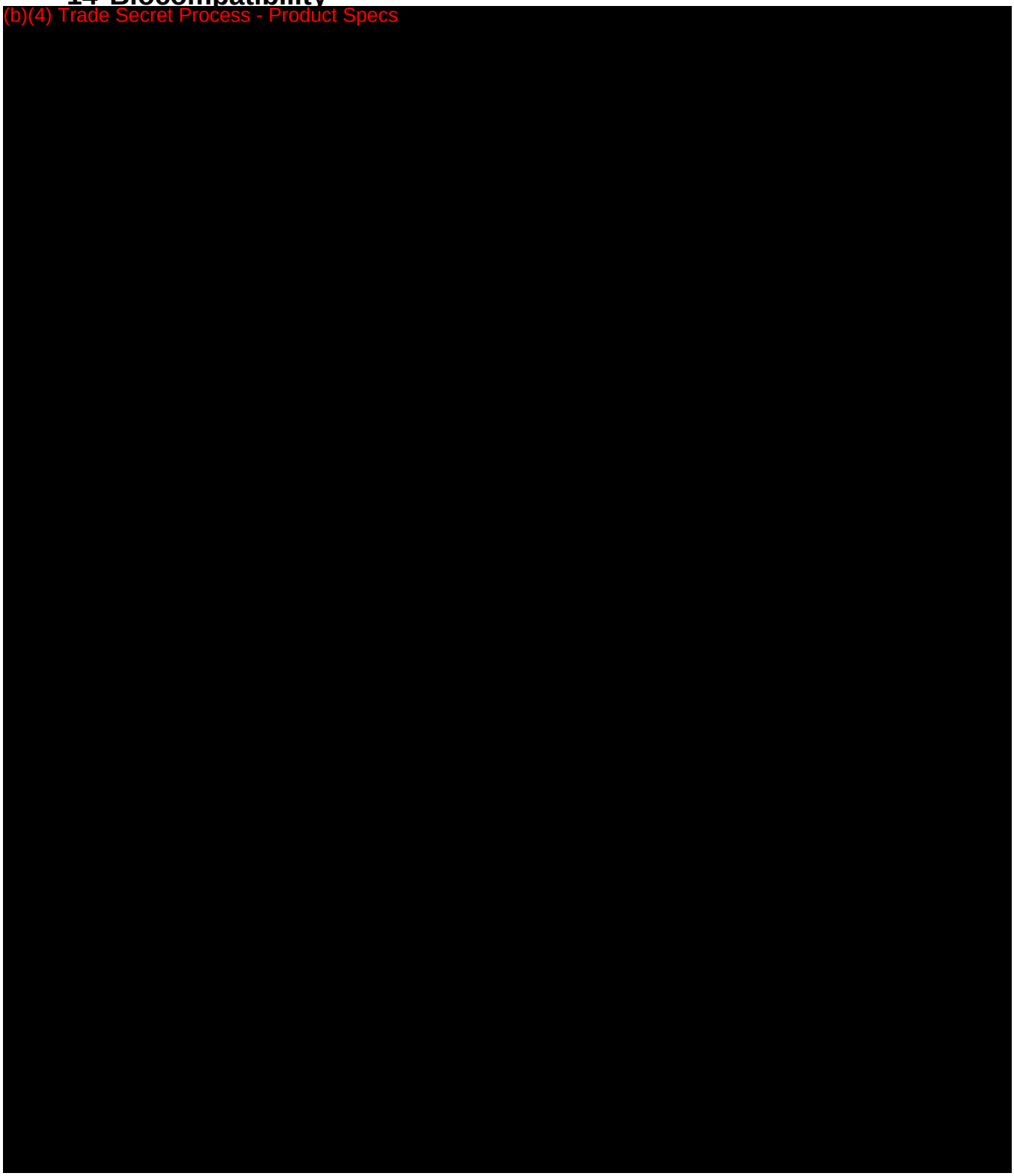
[redacted]

13.3 Packaging

(b)(4) Trade Secret Process - Product Specs

14 Biocompatibility

(b)(4) Trade Secret Process - Product Specs



Traditional 510(k) Submission

Straumann® Variobase™ Abutments

(b)(4) Trade Secret Process - Product Specs

15 Software

Software requirements do not apply to Straumann® Variobase™ Abutments and basal screws because these are standard stock products that do not contain software. Therefore, this section is not applicable as the proposed change does not contain and is not dependent on the use of software.

16 Electromagnetic Compatibility and Electrical Safety

(b)(4) Trade Secret Process - Product Specs

17 Performance Testing – Bench

(b)(4) Trade Secret Process - Testing

17.1 Design Control

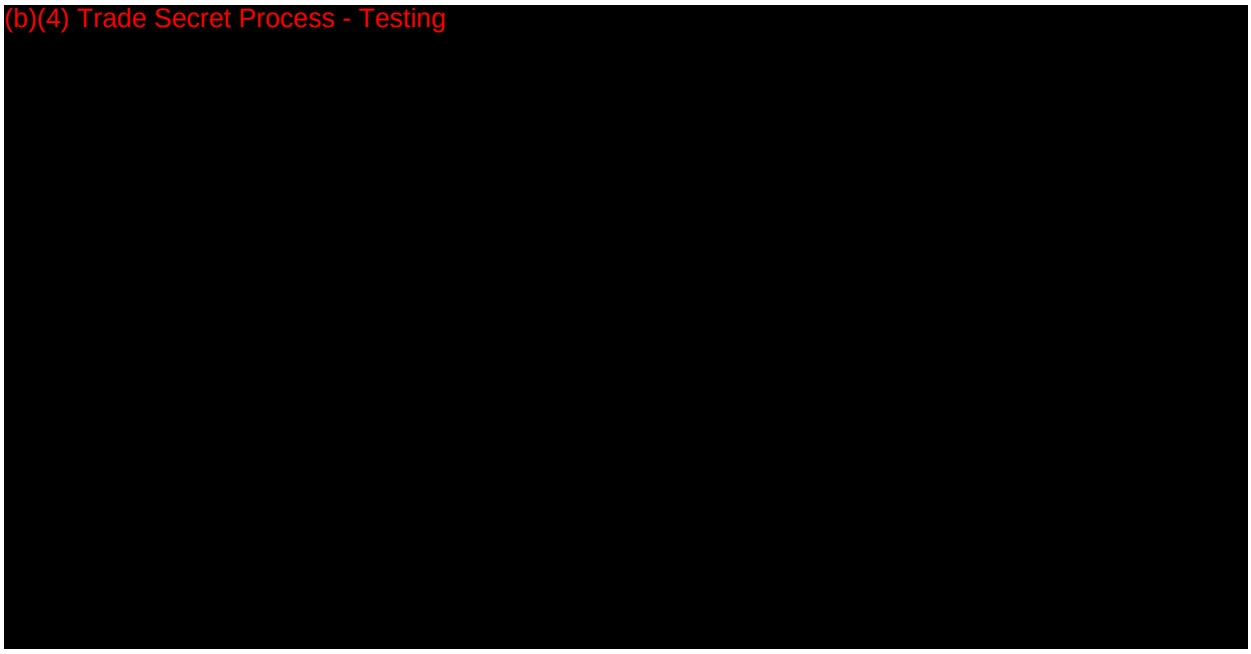
(b)(4) Trade Secret Process - Testing

17.2 Straumann® Variobase™ Abutments Material Properties

(b)(4) Trade Secret Process - Testing

17.2.1 Chemical Composition TAN

(b)(4) Trade Secret Process - Testing

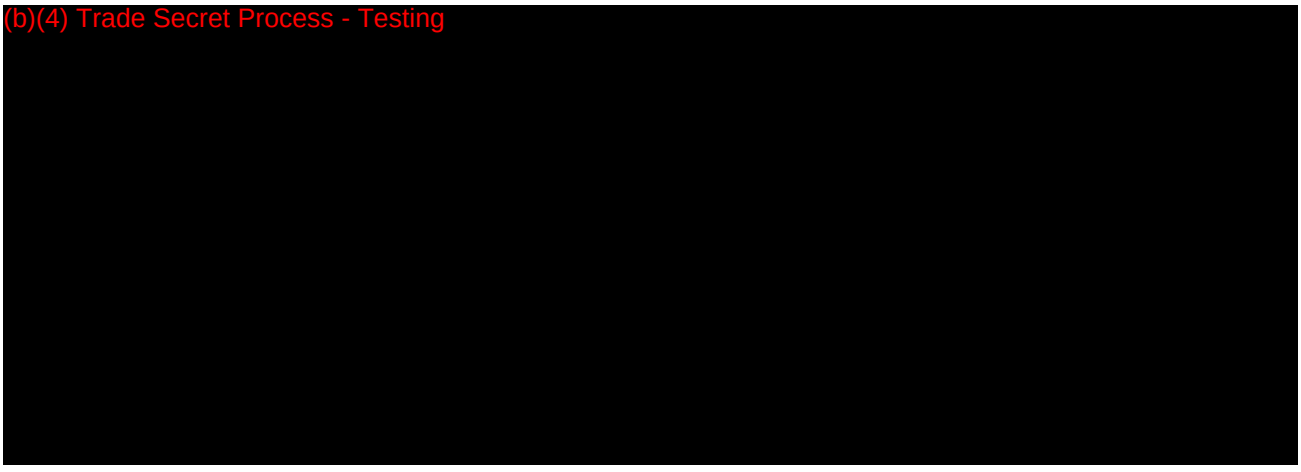


17.2.2 Mechanical Characteristics TAN

(b)(4) Trade Secret Process - Testing

17.3 Dynamic Fatigue Testing

(b)(4) Trade Secret Process - Testing



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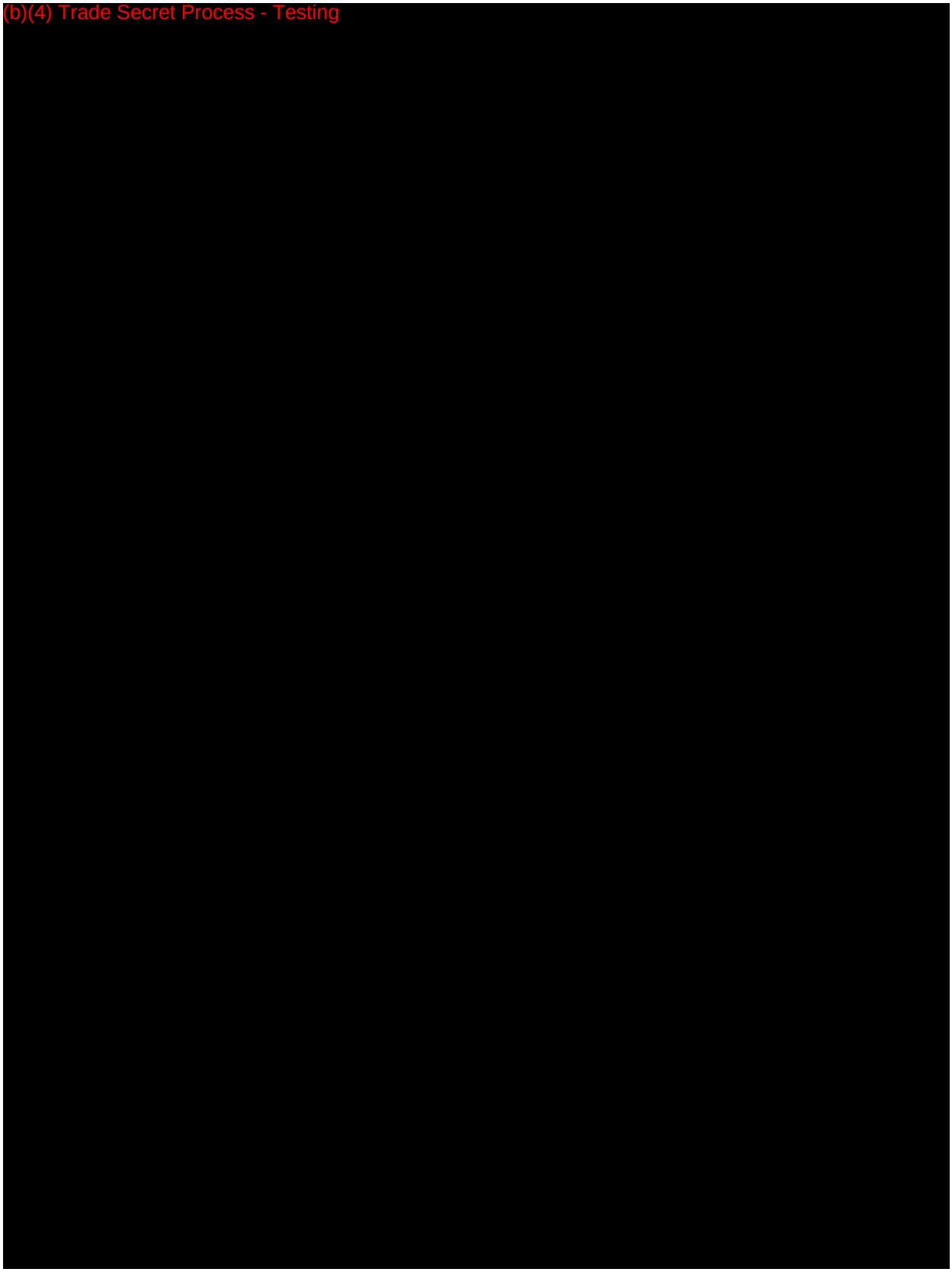

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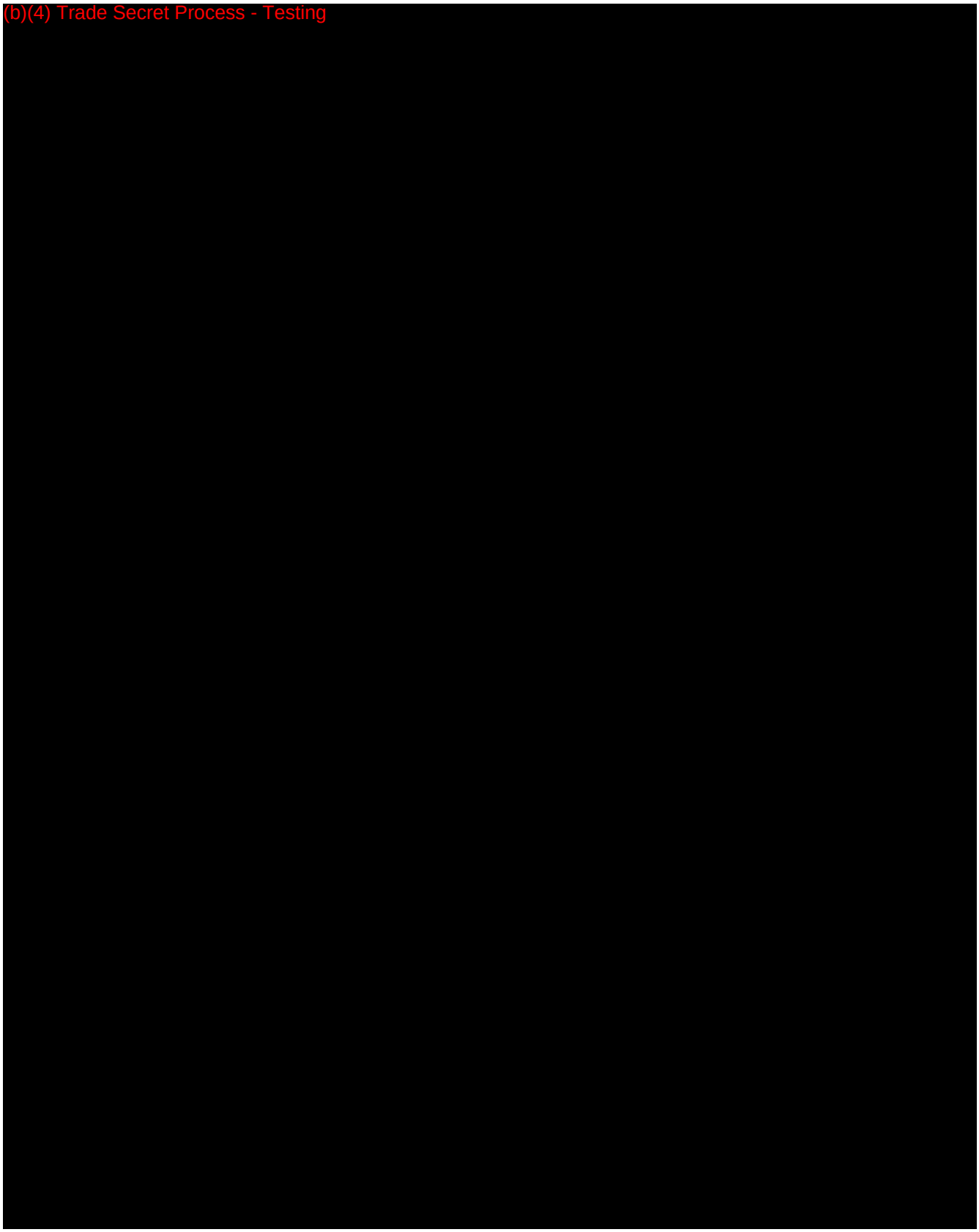

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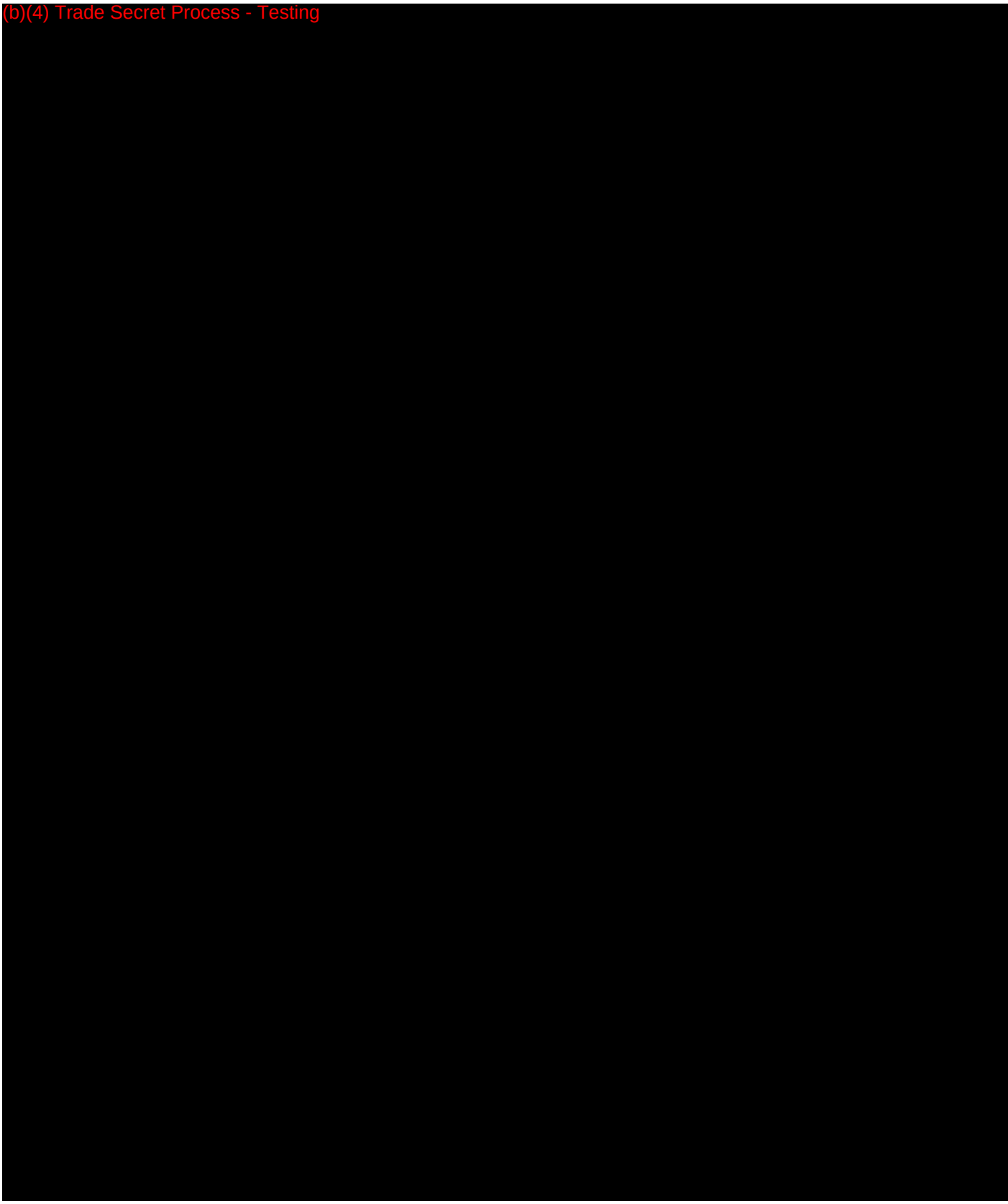

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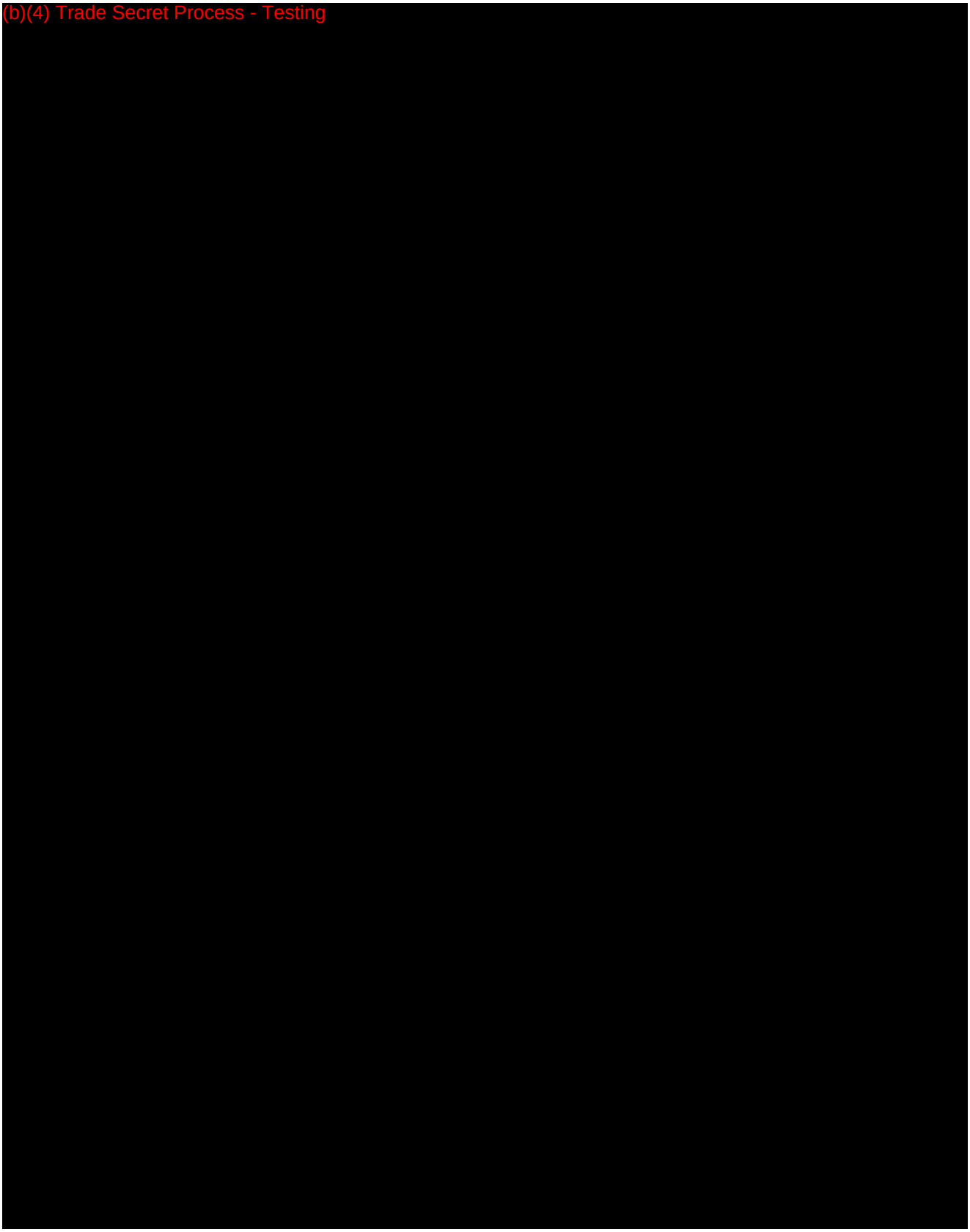
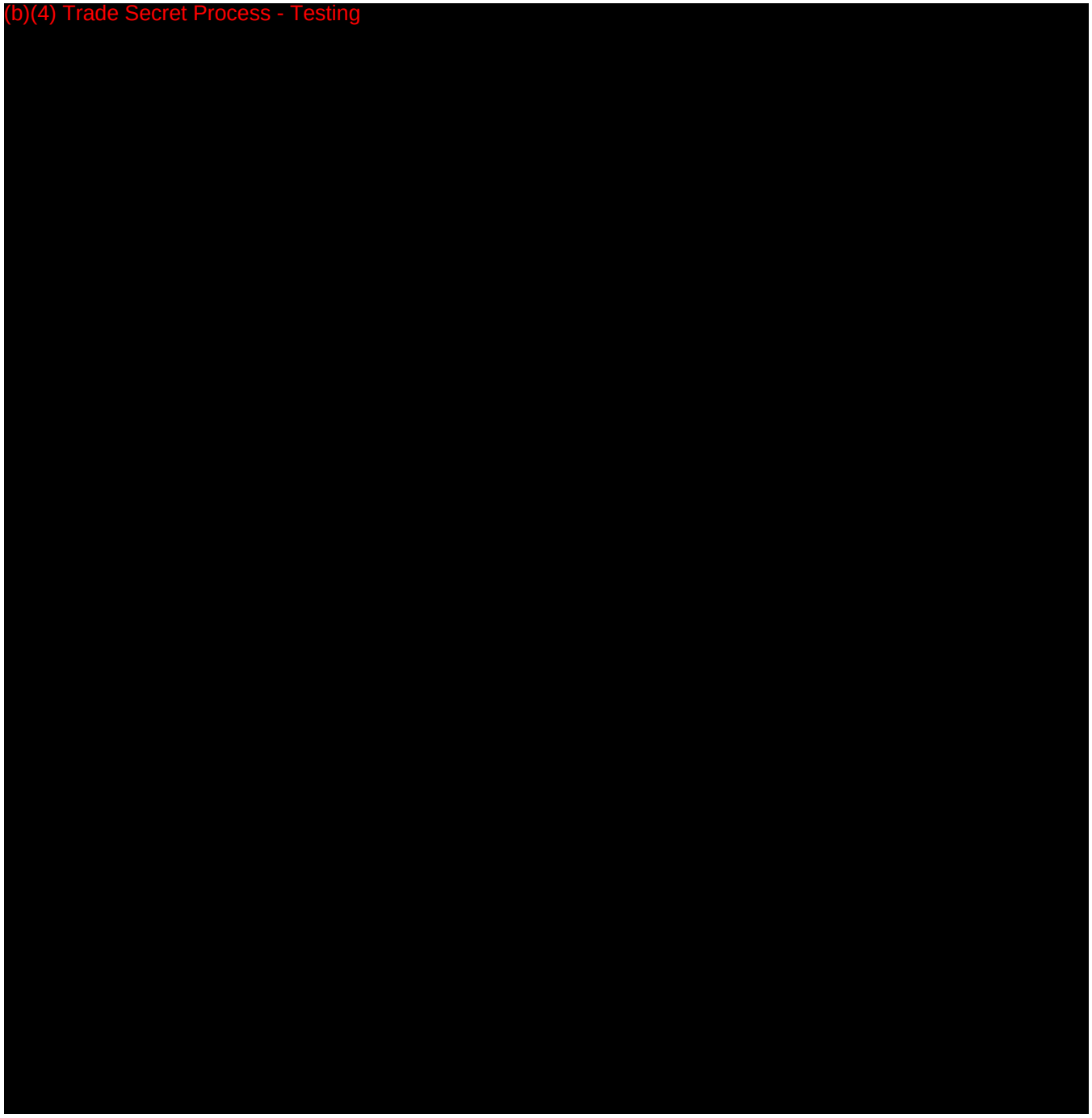


Traditional 510(k) Submission

Straumann® Variobase™ Abutments

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing



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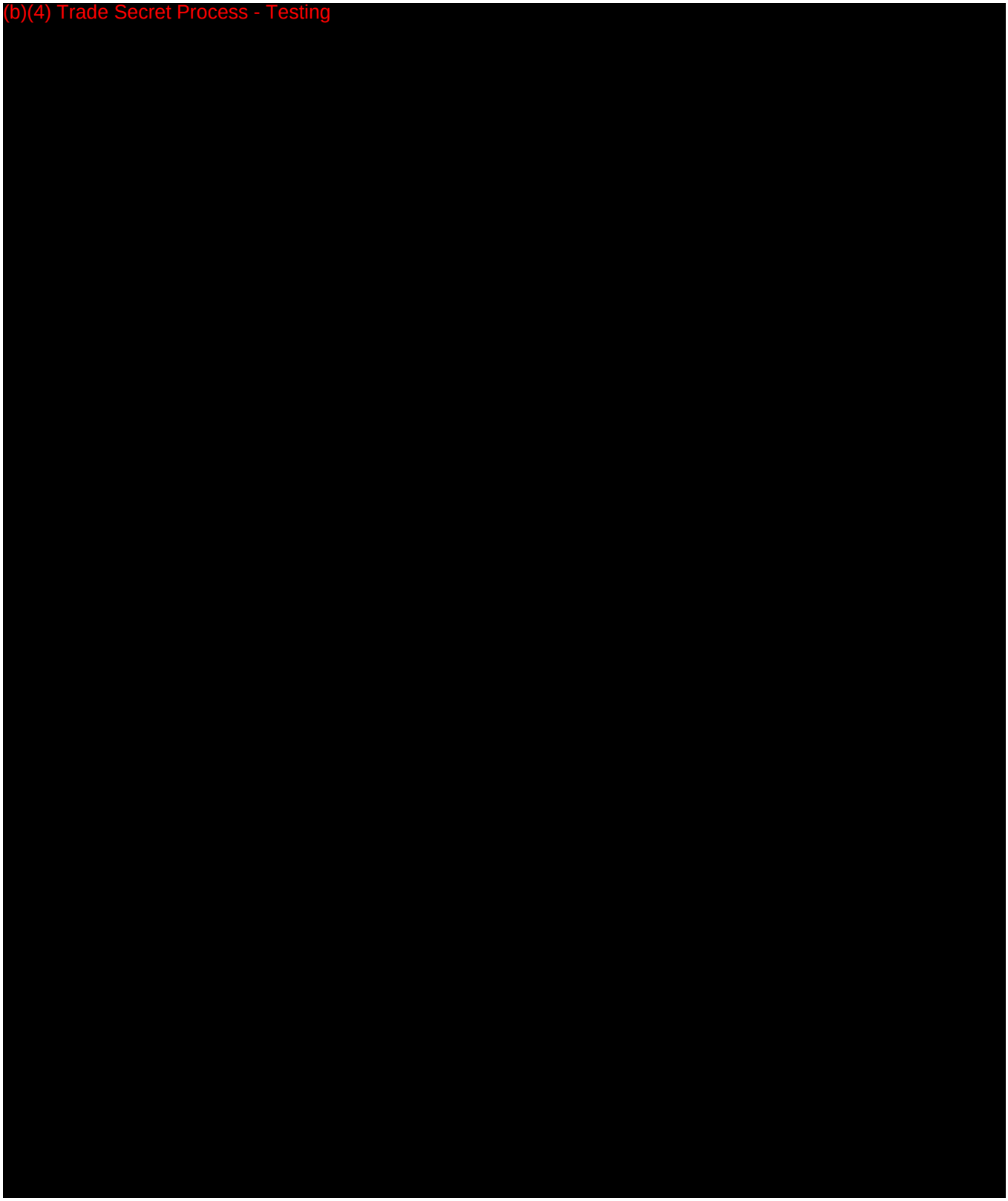

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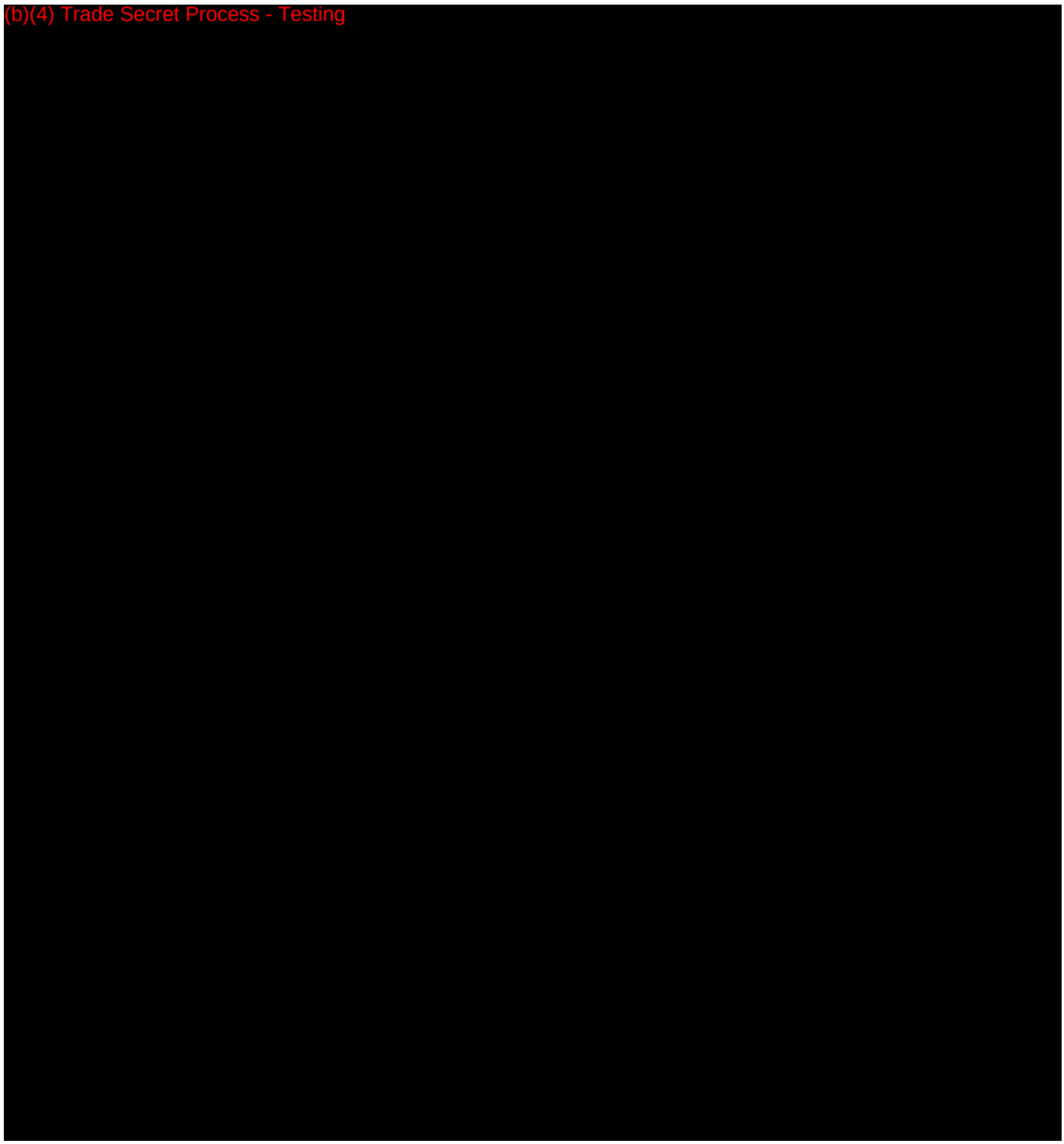


18 Performance Testing – Animal

This section is not applicable as no animal testing was performed in the development of the proposed devices.

19 Performance Testing – Clinical

This section is not applicable as clinical study results are not being submitted in this premarket notification.

Appendix 1 – Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

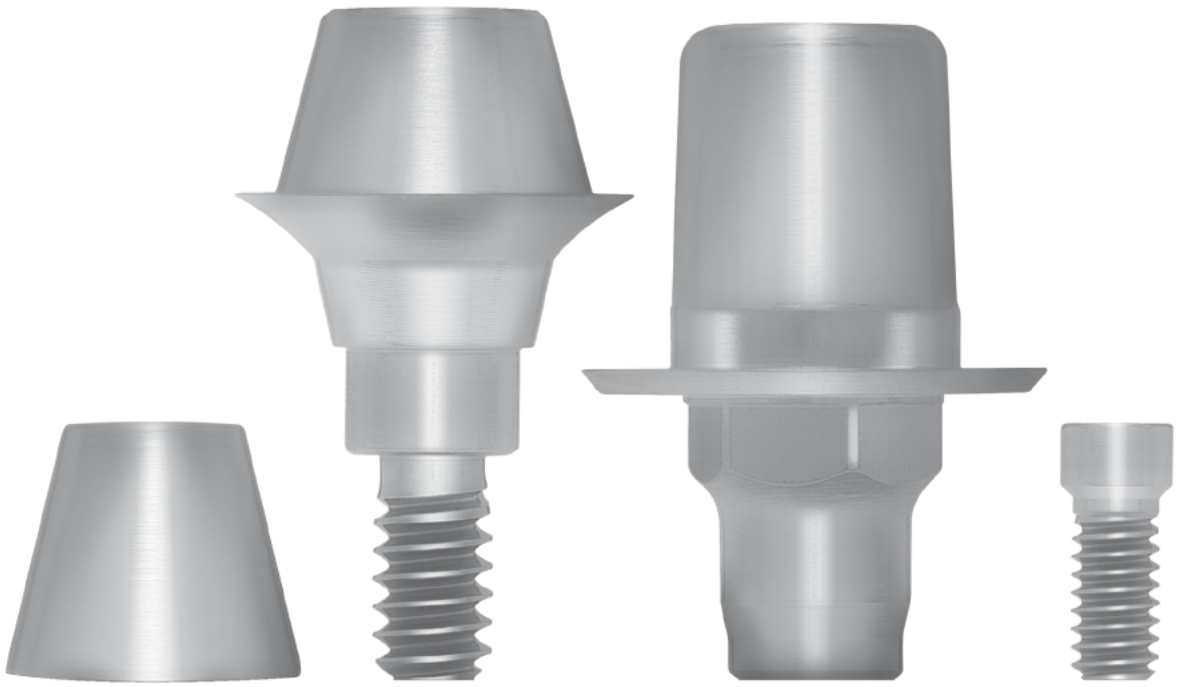
Appendix 2 – NT-Trading Product Catalog

nt-trading

www.nt-trading.com

MORE THAN ABUTMENT'S

CATALOGUE 2012/1



MORE THAN ABUTMENT

OPTIMIZED SAFETY AND QUALITY
CONSTANT LOAD ACCORDING TO DIN EN ISO 14801

To analyze the behavior of the material and the design of the implants on so many of these force effects and to determine the load limits, they will be reproduced in simulations. The international standard ISO 14801 describes the test setup and the implementation of such a test of fatigue limit endosseous dental implants.

We have had constant load tests for endosseous dental implants carried out for nt-trading abutments by the National Institute of Research and Development and Measurement Technique in accordance with standard DIN EN ISO 14801. The load corresponded to 30° angle to the implant axis. In addition, we have, in conformity with DIN EN ISO 14801 had a finite element analysis test carried out.

INCDMTM

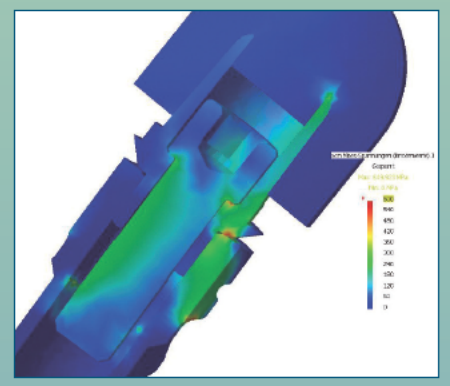
NATIONAL INSTITUTE OF RESEARCH AND DEVELOPMENT FOR MECATRONICS AND MEASUREMENT TECHNIQUE

TESTING REPORT

No. 113 from 24.06.2010

F.POS – 8.2.4 – 2

APROVED,
GENERAL MANAGER
Univ.Prof.PhD.eng.Gh.Ion GHEORGHE



nt-trading GmbH & Co. KG meets the requirements of ISO 13485:2007 and the EU Directive 93/42/EEC Health Canada Recognized Registrar CMDCAS.

TÜV SÜD CE -0123

CONTENTS

IMPLANT SYSTEMS

E-SERIE

COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®

Platform 3,5 mm NP	Platform 4,3 mm RP	Platform 5,0 mm WP	Platform 6,0 mm

Titanium Base

for individual milled Zirconium Abutment
incl. screw
Titan Grade 5

E 800	E 810	E 820	E 830

Scan Body

for Titanium Base
PEEK

E 00 W	E 10 W	E 20 W	E 30 W

Scan Body 3D Guide

for Titanium Base + 2-CONnect
PEEK

E 9.3D3.500	E 9.3D4.300	E 9.3D5.000	E 9.3D6.000

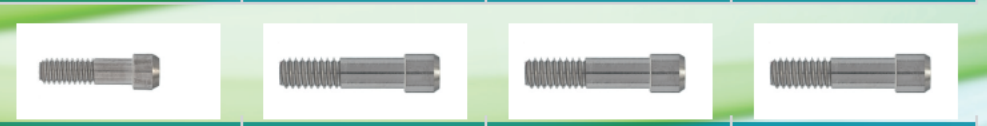
Lab Analog

Stainless Steel

E 50	E 51	E 52	E 53

Abutment Screw

Titan Grade 5
Recommended tightening torques 35 Ncm



E 60	E 61	E 61	E 61

E-SERIE

COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®

Platform 4,3 mm RP	Platform 5,0 mm WP

2-CONnect-Base Set

incl. 2-CONnect Cap and Cap-Screw
Titan Grade 5

E 810 S	E 820 S

2-CONnect-Base

Titan Grade 5
Recommended tightening torques 35 Ncm

E 810 M	E 820 M

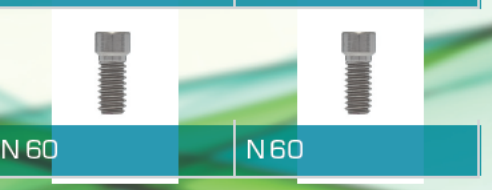
2-CONnect Cap

Titan Grade 5

E 810 F	E 820 F

Cap-Screw

Titan Grade 5
Recommended tightening torques 30 Ncm



N 60	N 60

Scan Body 3D Guide

for Titanium Base + 2-CONnect
PEEK

E 9.3D4.300	E 9.3D5.000

Lab Analog

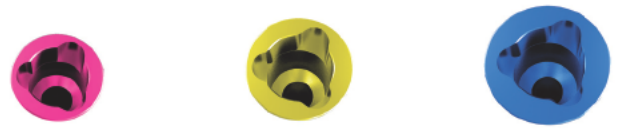
Stainless Steel

E 51	E 52

Notice: Products indicated with ® are registered brand names of the respective manufactures.

E-SERIE

COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®



Platform 3,5 mm NP | Platform 4,3 mm RP | Platform 5,0 mm WP

Straight Abutment

incl. Screw
GH 1,0 mm

E 100-1	E 110-1	E 120-1

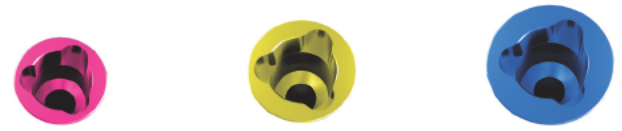
Straight Abutment

incl. Screw
GH 2,5 mm

E 100	E 110	E 120

E-SERIE

COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®



Platform 3,5 mm NP | Platform 4,3 mm RP | Platform 5,0 mm WP

Angled Abutment 16°

angled over surface
GH 1,0 mm
incl. Screw

E 200-1-1	E 210-1-1	E 220-1-1

Angled Abutment 16°

angled over edge
GH 1,0 mm
incl. Screw

E 200-2-1	E 210-2-1	E 220-2-1

Angled Abutment 16°

angled over surface
GH 2,5 mm
incl. Screw

E 200-1	E 210-1	E 220-1

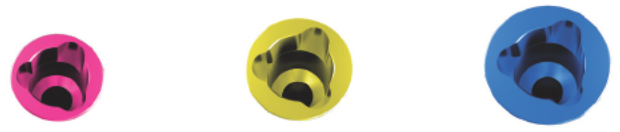
Angled Abutment 16°

angled over edge
GH 2,5 mm
incl. Screw

E 200-2	E 210-2	E 220-2

E-SERIE

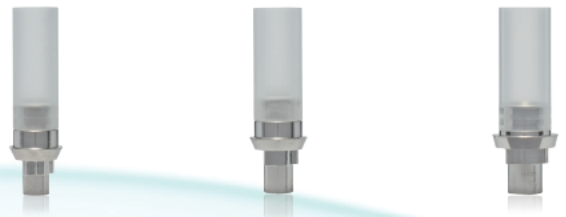
COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®



Platform 3,5 mm NP | Platform 4,3 mm RP | Platform 5,0 mm WP

HSL Abutment

rotation indexed
incl. Screw



E 11.CA3.500	E 11.CA4.300	E 11.CA5.000

Implant Pic-Up

incl. screw

E TR-NP013.5	E TR-RP024.3	E TR-WP035.0

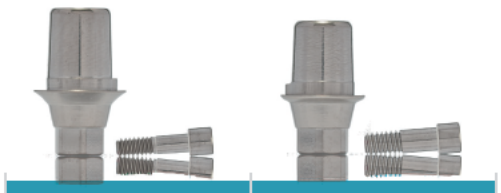
F-SERIE

COMPATIBLE TO NOBEL BIOCARE™ NOBEL ACTIVE™

Platform 3,5 mm NP | Platform 4,3 mm / 5,0 mm RP

Titanium Base

for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5



F 800	F 810

Scan Body

for Titanium Base
PEEK

F 00 W	F 10 W

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

F 9.3D3.500	F 9.3D4.350

Lab Analog

Stainless Steel

F 50	F 51

Abutment Screw

Titan Grade 5
Recommended tightening
torques 35 Ncm

F 60	F 61

F-SERIE

KOMPATIBEL ZU NOBEL BIOCARE™ NOBEL ACTIVE™

Platform
3,5 mm NP

Platform
4,3 mm / 5,0 mm RP

2-CONnect-Base Set

incl. 2-CONnect Cap and
Cap-Screw
Titan Grade 5

F 800 S	F 810 S

2-CONnect-Base

Titan Grade 5
Recommended tightening
torques 35 Ncm

F 800 M	F 810 M

2-CONnect Cap

Titan Grade 5

F 800 F	F 810 F

Cap-Screw

Titan Grade 5
Recommended tightening
torques 30 Ncm

N 60	N 60

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

F 9.3D3.500	F 9.3D4.350

Lab Analog

Stainless Steel

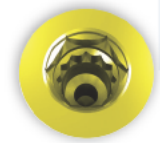
F 50	F 51

H-SERIE

KOMPATIBEL ZU BIOMET 3I CERTAIN®

Platform
3,4 mm

Platform
4,1 mm



Platform
5,0 mm

Titanium Base

for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5

H 800	H 810	H 820

Scan Body

for Titanium Base
PEEK

H 00 W	H 10 W	H 10 W

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

H 9.3D3.400	H 9.3D4.150	H 9.3D4.150

Lab Analog

Stainless Steel

H 50	H 51	H 52

Abutment Screw

Titan Grade 5
Recommended tightening
torques 20 Ncm

H 60	H 60	H 60

H-SERIE

COMPATIBLE TO BIOMET 3I CERTAIN®

Platform
3,4 mm

Platform
4,1 mm

2-CONnect-Base Set

incl. 2-CONnect Cap and
Cap-Screw
Titan Grade 5

H 800 S	H 810 S

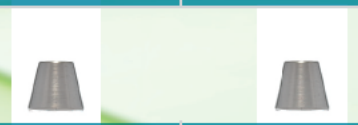
2-CONnect-Base

Titan Grade 5
Recommended tightening
torques 20 Ncm

H 800 M	H 810 M

2-CONnect Cap

Titan Grade 5



H 800 F	H 810 F

Cap-Screw

Titan Grade 5
Recommended tightening
torques 15 Ncm

KS 60	KS 60

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

H 9.3D3.400	H 9.3D4.150

Lab Analog

Stainless Steel

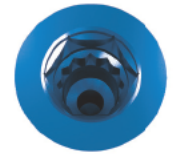
H 50	H 51

I-SERIE

COMPATIBLE TO BIOMET 3I OSSEOTITE®

Platform
3,4 mm

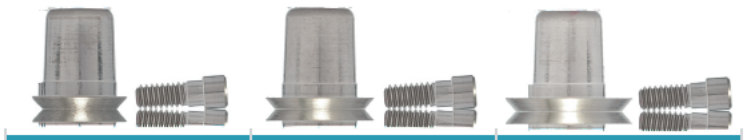
Platform
4,1 mm



Platform
5,0 mm

Titanium Base

for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5



I 800	I 810	I 820

Scan Body

for Titanium Base
PEEK

I 00 W	I 10 W	I 10 W

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

I 9.3D3.400	I 9.3D4.150	I 9.3D4.150

Lab Analog

Stainless Steel

I 50	I 51	I 52

Straight Abutment

incl. Screw
GH 2,5 mm

	I 110	

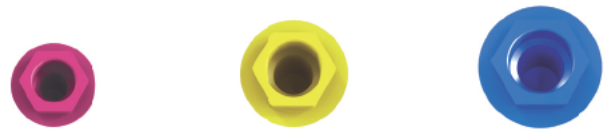
Abutment Screw

Titan Grade 5
Recommended tightening
torques 35 Ncm

I 61	I 61	I 61

K-SERIE

COMPATIBLE TO NOBEL BIOCARE BRÅNEMARK®



Platform 3,5 mm	Platform 4,1 mm	Platform 5,1 mm

Titanium Base

for individual milled Zirconium Abutment
incl. screw
Titan Grade 5

K 800	K 810	K 820

Scan Body

for Titanium Base
PEEK

K 00 W	K 10 W	K 20 W

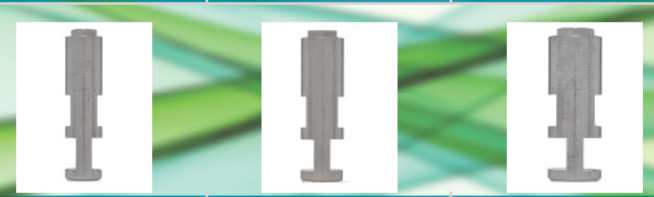
Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

K 9.3D3.500	K 9.3D4.100	K 9.3D5.100

Lab Analog

Stainless Steel



K 50	K 51	K 52

Straight Abutment

incl. Screw
GH 2,5 mm

	K 110	

Abutment Screw

Titan Grade 5
Recommended tightening torques 35 Ncm

K 60	K 61	K62

L-SERIE

COMPATIBLE TO STRAUMANN BONE LEVEL®

Platform 3,3 mm NC	Platform 4,1 mm / 4,8 mm RC

Titanium Base

for individual milled Zirconium Abutment
incl. screw
Titan Grade 5

L 800	L 810

Scan Body

for Titanium Base
PEEK

L 00 W	L 10 W

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

L 9.3D3.300	L 9.3D4.148

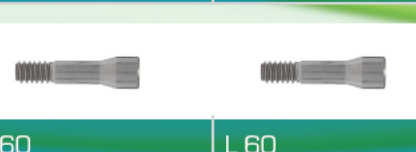
Lab Analog

Stainless Steel

L 50	L 51

Abutment Screw

Titan Grade 5
Recommended tightening torques 35 Ncm



L 60	L 60

L-SERIE

COMPATIBLE TO STRAUMANN BONE LEVEL®

Platform
3,3 mm NC

Platform
4,1 mm / 4,8 mm RC

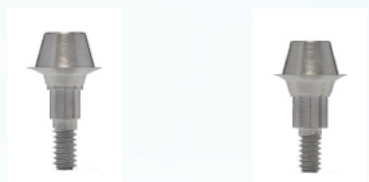
2-CONnect-Base Set

incl. 2-CONnect Cap and
Cap-Screw
Titan Grade 5

L 800 S	L 810 S

2-CONnect-Base

Titan Grade 5
Recommended tightening
torques 35 Ncm



L 800 M	L 810 M

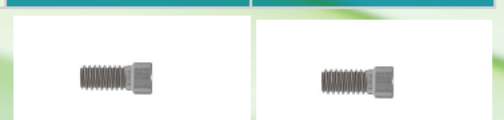
2-CONnect Cap

Titan Grade 5

L 800 F	L 810 F

Cap-Screw

Titan Grade 5
Recommended tightening
torques 30 Ncm



N 60	N 60

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

L 9.3D3.300	L 9.3D4.148

Lab Analog

Stainless Steel

L 50	L 51

L-SERIE

COMPATIBLE TO STRAUMANN BONE LEVEL®

Platform
3,3 mm NC

Platform
4,1 mm / 4,8 mm RC

Straight Abutment

incl. Screw
GH 2,5 mm

L 100	L 110

Straight Abutment

incl. Screw
GH 3,0 mm

L 100-3	L 110-3

Angled Abutment 18°

angled over surface
GH 1,5 mm
incl. Screw

L 200-1	L 210-1

Angled Abutment 18°

angled over edge
GH 1,5 mm
incl. Screw

L 200-2	L 210-2

Notice: Products indicated with ® are registered brand names of the respective manufactures.

L-SERIE

COMPATIBLE TO STRAUMANN BONE LEVEL®

Platform
3,3 mm NC

Platform
4,1 mm / 4,8 mm RC

Angled Abutment 18°

angled over surface
GH 3,0 mm
incl. Screw

L 200-1-3	L 210-1-3

Angled Abutment 18°

angled over edge
GH 3,0 mm
incl. Screw

L 200-2-3	L 210-2-3

HSL Abutment

rotation indexed
incl. Screw

L 11.CA3.300	L 11.CA4.148

Implant Pic-Up

incl. screw

L TR-NC013.3	L TR-RC024.1

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform
3,5 mm NN

Platform
4,8 mm RN

Platform
6,5 mm WN

Titanium Base

for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5

N 800	N 810	N 820

Scan Body

for Titanium Base
PEEK

N 00 W	N 10 W	N 20 W

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

N 9.3D3.500	N 9.3D4.800	N 9.3D6.500

Lab Analog

Stainless Steel

N 50	N 51	N 52

Abutment Screw

Titan Grade 5
Recommended tightening
torques 35 Ncm

N 60	N 62	N 62

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform
4,8 mm RN

Platform
6,5 mm WN

2-CONnect-Base Set

incl. 2-CONnect Cap and
Cap-Screw
Titan Grade 5

[illegible]	N 820 S

2-CONnect-Base

Titan Grade 5
Recommended tightening
torques 35 Ncm

N 810 M	N 820 M

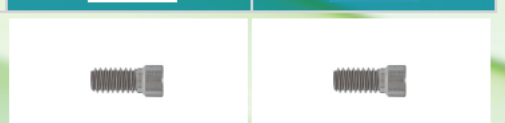
2-CONnect Cap

Titan Grade 5

N 810	N 820 F

Cap-Screw

Titan Grade 5
Recommended tightening
torques 30 Ncm



N 60	N 60

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

N 9.3D4.800	N 9.3D6.500

Lab Analog

Stainless Steel

N 51	N 52

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform
4,8 mm RN

Platform
4,8 mm RN

Platform
6,5 mm WN

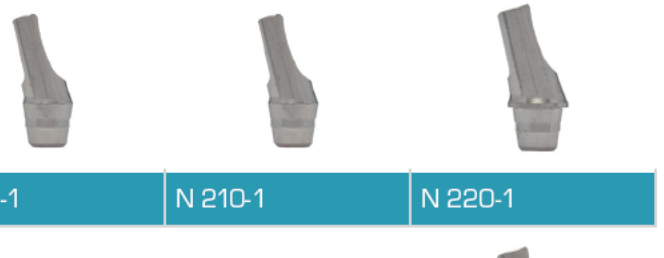
Straight Abutment

incl. Screw

N 110	N 110 L	N 120

Angled Abutment 16°

angled over surface
incl. Screw



N 210-1	N 210-1	N 220-1

Angled Abutment 16°

angled over edge
incl. Screw

N 210-2	N 210-2	N 220-2

Abutment Screw

Titan Grade 5
Recom. tight. torques 35 Ncm

N 61	N 61	N 61

Platform 4,8 mm RN

Total height 4,0 mm	Total height 5,5 mm	Total height 7,0 mm

RN-Massiv Abutment

only for Dentist

N 110-40	N 110-55	N 110-70

Platform 6,5 mm WN

		Total height 5,5 mm

WN-Massiv Abutment

only for Dentist

		N 120-55

Notice: Products indicated with ® are registered brand names of the respective manufactures.

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform
3,5 mm NN

Platform
4,8 mm RN

Platform
6,5 mm WN

Straight Abutment
incl. Screw

N 100

Angled Abutment 16°
incl. Screw

N 200

Abutment Screw

N 60

HSL Abutment
rotation indexed
incl. Screw

N 300	N 310	N 320

HSL Abutment
rotating
incl. Screw

N 300 R	N 310 R	N 320 R

Abutment Screw
Titan Grade 5
Recommended tightening
torques 35 Ncm

N 60	N 62	N 62

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform
3,5 mm NN

Platform
4,8 mm RN

Platform
6,5 mm WN

Angled Abutment 21°
angled over surface
incl. Screw

N 210	N 210-1-21

Angled Abutment 21°
angled over edge
incl. Screw

N 210-2-21

WN-Massiv Abutment
Height 4,0 mm

N 120-40	N 120-40

Implant Pic-Up
incl. screw

N TR-NN013.5	N TR-RN024.8	N TR-WN036.5

Notice: Products indicated with ® are registered brand names of the respective manufactures.

R-SERIE

COMPATIBLE TO ZIMMER TAPERED SCREW-VENT®

Platform 3,5 mm | Platform 4,5 mm | Platform 5,7 mm

Titanium Base

for individual milled Zirconium Abutment
incl. screw
Titan Grade 5

R 800	R 810	R 820

Scan Body

for Titanium Base
PEEK

R 00 W	R 10 W	R 20 W

Scan Body 3D Guide

for Titanium Base + 2-CONnect
PEEK

R 9.3D3.500	R 9.3D4.500	R 9.3D5.700

Lab Analog

Stainless Steel

R 50	R 51	R 52

Abutment Screw

Hex 0,50" (1,26 mm)
Recommended tightening torques 30 Ncm

R 60	R 60	R 60

R-SERIE

COMPATIBLE TO ZIMMER TAPERED SCREW-VENT®

Platform 3,5 mm | Platform 4,5 mm

2-CONnect-Base Set

incl. 2-CONnect Cap and Cap-Screw
Titan Grade 5

R 800 S	R 810 S

2-CONnect-Base

Titan Grade 5
Recommended tightening torques 30 Ncm

R 800 M	R 810 M

2-CONnect Cap

Titan Grade 5

R 800 F	R 810 F

Cap-Screw

Titan Grade 5
Recommended tightening torques 25 Ncm

KS 60	KS 60

Scan Body 3D Guide

for Titanium Base + 2-CONnect
PEEK

R 9.3D3.500	R 9.3D4.500

Lab Analog

Stainless Steel

R 50	R 51

Notice: Products indicated with ® are registered brand names of the respective manufactures.

R-SERIE

COMPATIBLE TO ZIMMER TAPERED SCREW-VENT®

Platform 3,5 mm | Platform 4,5 mm | Platform 5,7 mm

Straight Abutment
incl. Screw
GH 2,5 mm

R 100	R 110	R 120

Angled Abutment 16°
angled over surface
incl. Screw
GH 2,5 mm

R 200-1	R 210-1	R 220-1

Angled Abutment 16°
angled over surface
incl. Screw
GH 2,5 mm

R 200-2	R 210-2	R 220-2

Massiv Abutment
Titan Grade 5

R 400	R 410	R 420

HSL Abutment
rotation indexed
incl. Screw

R 300	R 310	R 320

Abutment Screw
Hex 0,50" (1,26 mm)
Recommended tightening
torques 30 Ncm

R 60	R 60	R 60

R-SERIE

COMPATIBLE TO ZIMMER TAPERED SCREW-VENT®

Platform 3,5 mm | Platform 4,5 mm

Implant Pic-Up
incl. screw

R TR-00013.5	R TR-00024.5

S-SERIE

COMPATIBLE TO ASTRA TECH OSSEOSPEED®

Platform
3,5 mm / 4,0 mm

Platform
4,5 mm / 5,0 mm

Titanium Base

for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5

S 800	S 820

Scan Body

for Titanium Base
PEEK

S 00 W	S 20 W

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

S 9.3D3.540	S 9.3D4.550

Lab Analog

Stainless Steel

S 50	S 52

Straight Abutment

incl. Screw
GH 1,5 mm

S 100

Abutment Screw

Titan Grade 5
Recommended tightening
torques 25 Ncm

S 60	S 61

S-SERIE

COMPATIBLE TO ASTRA TECH OSSEOSPEED®

Platform
3,5 mm / 4,0 mm

Platform
4,5 mm / 5,0 mm

2-CONnect-Base Set

incl. 2-CONnect Cap and
Cap-Screw
Titan Grade 5

S 800 S	S 820 S

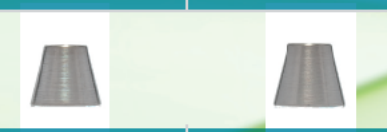
2-CONnect-Base

Titan Grade 5
Recommended tightening
torques 25 Ncm

S 800 M	S 820 M

2-CONnect Cap

Titan Grade 5



S 800 F	S 820 F

Cap-Screw

Titan Grade 5
Recommended tightening
torques 20 Ncm

N 60	N 60

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

S 9.3D3.540	S 9.3D4.550

Lab Analog

Stainless Steel

S 50	S 52

S-SERIE

COMPATIBLE TO ASTRA TECH OSSEOSPEED®

Platform 3,5 mm / 4,0 mm	Platform 3,5 mm / 4,0 mm	Platform 4,5 mm / 5,0 mm

Straight Abutment

incl. Screw
GH 1,5 mm

	S 110	S 120

Angled Abutment 16°

incl. Screw
GH 1,5 mm

S 200	S 210	S 220

HSL Abutment

rotation indexed
incl. Screw

S 11.CA3.540		S 11.CA4.550

Implant Pic-Up

incl. screw

S TR-00013.5		S TR-00024.5

T-SERIE

COMPATIBLE TO DENTSPLY-FRIADENT FRIALIT/XIVE®

Platform 3,4 mm	Platform 3,8 mm	Platform 4,5 mm	Platform 5,5 mm

Titanium Base

for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5

T 800	T 805	T 810	T 820

Scan Body

for Titanium Base
PEEK

T 00 W	T 05 W	T 10 W	T 10 W

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

T 9.3D3.400	T 9.3D3.800	T 9.3D4.555	T 9.3D4.555

Lab Analog

Stainless Steel

T 50	T 55	T 51	T 52

Abutment Screw

Titan Grade 5
Recommended tightening
torques 25 Ncm

T 60	T 60	T 60	T 60

T-SERIE

COMPATIBLE TO DENTSPLY-FRIADENT FRIALIT/XIVE®

Platform
3,4 mm

Platform
3,8 mm

Platform
4,5 mm

2-CONnect-Base Set

incl. 2-CONnect Cap and Cap-Screw
Titan Grade 5

T 800 S	T 805 S	T 810 S

2-CONnect-Base

Titan Grade 5
Recommended tightening torques 25 Ncm

T 800 M	T 805 M	T 810 M

2-CONnect Cap

Titan Grade 5

T 800 F	T 805 F	T 810 F

Cap-Screw

Titan Grade 5
Recommended tightening torques 15 Ncm

KS 60	N 60	N 60

Scan Body 3D Guide

for Titanium Base + 2-CONnect
PEEK

T 9.3D3.400	T 9.3D3.800	T 9.3D4.555

Lab Analog

Stainless Steel

T 50	T 55	T 51

T-SERIE

COMPATIBLE TO DENTSPLY-FRIADENT FRIALIT/XIVE®

Platform
3,8 mm

Platform
4,5 mm

Angled Abutment 16°

angled over edge
GH 1,0 mm

T 205-2-1

Angled Abutment 16°

angled over surface
GH 1,0 mm

T 205-1-1

Angled Abutment 16°

angled over surface
GH 2,5 mm

T 205-1

Straight Abutment

incl. Screw
GH 1,0 mm

T 105-1	T 110-1

Straight Abutment

incl. Screw
GH 2,5 mm

T 105	T 110

Abutment Screw

Hex 0,50" (1,26 mm)
Recommended tightening torques 25 Ncm

T 60	T 60

T-SERIE

COMPATIBLE TO DENTSPLY-FRIADENT FRIALIT/XIVE®

	Platform 3,4 mm	Platform 3,8 mm	Platform 4,5 mm
Implant Pic-Up incl. screw	T TR-00013.4	T TR-00023.8	T TR-00034.5

	T 11.CA3.400	T 11.CA3.800	T 11.CA4.500
HSL Abutment rotation indexed incl. Screw			

PROSTHETIC TOOLS

Torque Ratchet
continuously adjustable
to max. 40 Ncm
ISO-Shaft Connection

W 11.000.000

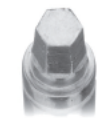
Laboratory
Screwdriver
for changeable inserts
(without ISO-Shaft)
ISO-Shaft Connection

W 11.100.000

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for S-, I- and R-Series
Hex 0,50" (1,26 mm)

W 11.IRS.G10

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for T- and H-Series
Hex 1,20 mm



W 11.TH0.G20

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for Ankylos®
Hex 1,00 mm

W 11.Y00.G30

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for L- and N-Series
Torx T6

W 11.LN0.G40

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for E-, F- and
K-Serie UG

W 11.EFK.G50

Insert
for Laboratory Screwdriver
and Torque Ratchet ISO-Shaft
for 2-CONnect-Base-Primary

W 11.005.G60

DENTOKEEP PEEK DISC

Dentokeep

nt-trading Dentokeep Disc PEEK are blanks for technical milling manufacture of permanent dentures and prosthetic brace in the CAM process. The derived prosthetic designs are available on the remaining teeth, - can be attached to stumps and / or implant abutment and provide a basic functional and aesthetic care.

1. PEEK Disc 98.5 mm, pearl white, 14 mm and 18 mm thick
2. For CAD / CAM Technology for CAD/CAM Technology
3. Clip in prosthetics CAD/CAM
4. Class II product for permanent prosthetic restorations

Dentokeep
PEEK Disc
Size 14 mm

12.000.P14

Dentokeep
PEEK Disc
Size 18 mm

12.000.P18

SCAN EQUIPMENT

nt-OptiScan™ Spray

nt-OptiScan™ Spray a new product development of nt-trading GmbH & Co. KG.

nt-OptiScan™ Spray

Advantages:

- Optimize composition
- Perfect dosage with proven applicator
- Optimize preparation of your working model for optical scanning with modern dental scanner
- Economical application
- Water soluble
- Handy size: Volume 75 ml brutto
- Superior scanning results
- Special attractive price

NT-MILLING AND GRINDING TOOLS

nt-trading tools are specially developed for dental CAD/CAM systems. They are up to the high mark to process dental materials and are constant liable to quality checks.
Tools coated with tax are especially qualified for process of dental high-capacity plastics, as well as for process of milling wax.
Tools coated with diamand are especially qualified for process of abrasive materials like zirconium dioxide.

nt-Diaburr			
Ø	0,6 mm	1,0 mm	2,5 mm
Art.-Nr.	11100	11101	11102

The milling tool coated with diamonds nt-Diaburr offers you a lifetime of at least 350 units while process of ZrO2 with the milling machine.

nt-Uburr		
Ø	1,0 mm	2,5 mm
Art.-Nr.	11201	11202

Universal milling tools are qualified for process of plastics, waxes and ZrO2 with the milling machine. Depending on choice of material the lifetime is at least 175 unites.

nt-PEEKburr		
Ø	1,0 mm	2,5 mm
Art.-Nr.	11301	11302

Special milling tools are qualified for process of PEEK materials like Dentokeep, plastics and waxes.

SINTER COMPONENTS

nt-pearls

Sinterization of Zr-oxide substructures.

Sinter pearls for dental CAD/CAM technology

Advantages:
Sinterization of Zr-oxide substructures. Full ceramics are the answer to patients demands for highly esthetic, metal-free and durable restaurations Zr-oxide became a common substructure for dental restaurations alreadi quite a while ago. This material features outstanding biocompatibility and mechanical properties Zr-oxide is mechanically machined in its greenstage, taking into consideration the specific shrinkage of this material. The sinterization is optimized for the specific material and its overzised milling relative to the material properties, thus assuring the best possible fit.
Another important factor contributing to a perfect fit is the right choice of support for this to be sintered substructure. Every manufacturer has his own recommendations concerning these supports. Some suggest to sinter on special „pearls", unfortunately particle size and quality are not always right to by example avoid getiing pinched between the interproximals and thus distorting the bridge.
Other solutions favour the use of „drops", resting on very expensive and fragile support discs. The necessary preparations for this type of support are always time consuming, sometimes even cumbersome and allways generating additional costs.
A viable alternative are special hi- density and quality sinterization pearls from nt-trading, optimized for crowns and bridges and therefore avoiding the common „pinching" and distortion problems especially known to bridges.



INSTRUCTION FOR USE

Indication:

For manufacturing of individual abutments on dental implants. The individual abutments can be combined with copings, crowns or suprastructures made of dental ceramics.

Contraindication:

The Ti-Bases of each Series can only be combined with the matching implant, e.g. the E-Series shall be combined exclusively with Replace Select® Implants. They cannot be combined with implants of a different implant type or manufacturer. The diameter of the Ti-base must correspond in size to the used implant in order to prevent a peri-implant tissue irritation.
The Ti-Bases are indicated for single use only. If they are use multiple times, they might damage the implants.
For fixation of the Ti-Bases on the implant, the correct torque force, recommended by the implant manufacturer, has to be considered carefully to avoid the damage of the implant-bone connection.

Ncm	Abutment				
20	H-Serie				
25	S-Serie	T-Serie	F-Serie		
30	R-Serie				
35	I-Serie	K-Serie	N-Serie	E-Serie	L-Serie

Mechanical treatment of the connection part of the Ti-Base will damage the correct fitting of the Ti-Base on the implant.

Handling method:

Ceramic abutments:
Milling with CAD/CAM-machines of zirconium oxide- or aluminum oxide- ceramics according to the anatomic form of a crown or coping. The ceramic copings or crowns shall be milled or polished with diamond instruments and with minimal pressure and watercooling. The minimal thickness shall be 0.5 mm Sharpe edges must be avoided.

Veneering:
Copings shall be veneered with appropriate ceramics before cementing onto the Ti-Base. The instructions for use of the ceramic manufacturers have to be considered. Treatment of the Ti-Base and the ceramic abutment before cementing: Sandblasting of the contact surfaces with Al2O3, 50 µm, 2 bar and intensive cleaning of dust and grease. It is recommended to protect the connection part of the Ti-Base with an implant analog during handling.

Cementing:
It is recommended to cement the ceramic abutment onto the Ti-Base with Panavia® F2.0 (Kuraray) with RelayXUnicem® (3M Espe) ore other equivalent cements. The instructions for use of the cements shall be followed carefully. The Ti-Base shall be fixed onto an implant analog with the abutments screw. The head of the screw has to be covered with wax or resin. The mixed cement is applied onto the contact part of the Ti-Base. The abutment is pressed onto the Ti-Base. The final position is evaluated by slight rotation. The gap between abutment and the Ti-Base must be as small as possible. Remaining cement shall be removed immediately.

Polishing:
After hardening the remaining cement shall be removed with rotating silicon instruments. The cement inside the screw channel has to be removed carefully.

Scan Body:

Indication:

Scan Body:
For the CAD/CAM scanning of the model, the Scan Body is used to indicate the position of the implant. The size of the Scan Body shall be corresponding to the original Implant system, implant diameter and Ti-Base Series.
The chamfer of the Scan Body prevents the rotation of the ceramic abutment. The Scan Body is fixed on the implant analogue with the abutment screw. After correct positioning, there is no gap visible between implant and Scan Body. Rotation of the Scan Body is impossible

Tightening torques

Ncm	2-CONnect-M-Abutment			
20	H-Serie			
25	S-Serie	T-Serie		
30	R-Serie			
35	E-Serie	F-Serie	L-Serie	N-Serie

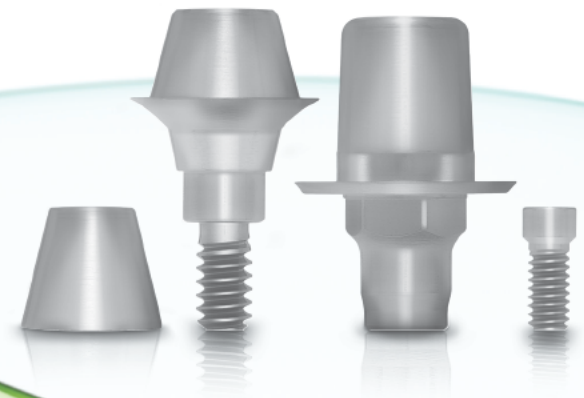
Ncm	2-CONnect Cap-Screw N 60			
20	S-Serie	T 805, T 810		
30	E-Serie	F-Serie	L-Serie	N-Serie

Ncm	2-CONnect Cap-Screw KS 60			
15	H 800, H 810	T 800	R 800	R 810

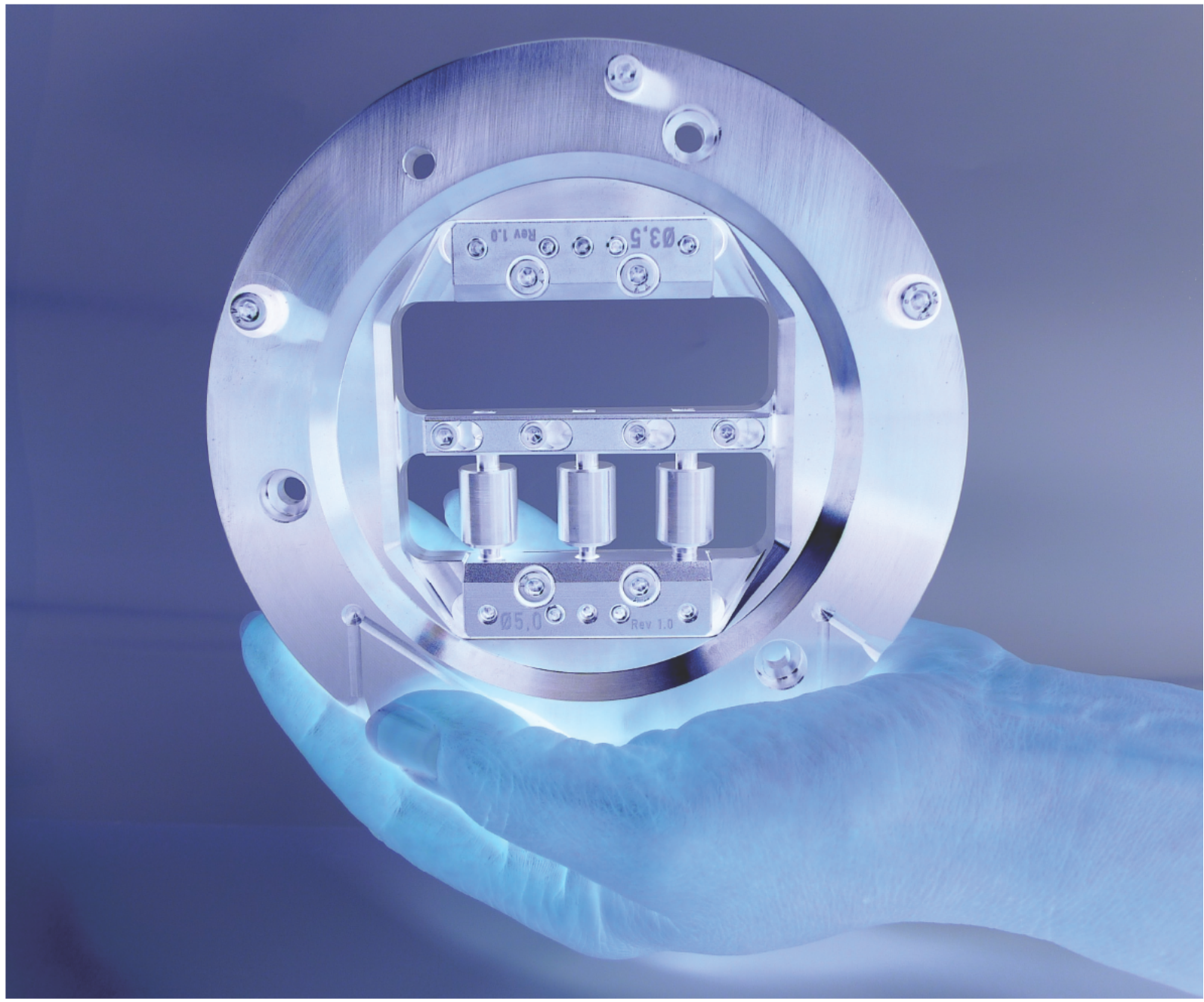
Conditions of warranty

Within our general terms of sale and warranty we ensure the perfect quality of our products. Due to our high production standards can offer you a 10-years' warranty on our prosthetic components.
We offer you a warranty on our nt-trading components according to the conditions of warranty.
The warranty includes all material and manufacturing defects which may occur within the 10-years' time of warranty. We only give warranty for our contracting/purchasing partners (dentists, dental hospitals, laboratory). Any other persons besides those mentioned cannot lay claims to the warranty. It is not possible to assign the warranty claims.

NOTES



NT-PREFORM



The new address from February 2013:

nt-trading GmbH & Co. KG
Nördliche Uferstraße 8
76189 Karlsruhe
Germany

nt-trading GmbH & Co. KG | Esso-Straße 16 | 76187 Karlsruhe | Germany
Phone: +49 (0)721 / 91 54 71 - 60 | info@nt-trading.com | www.nt-trading.com

PCE/D-2012-12

Appendix 3 – NT-Trading Ti-Base Package Insert

Instruction for use

Ti- Base-, for Individual Abutments, Scan Base and Scan Body E-, I-, K-, N-, R-, S-, T-, H-, L-, and F- Series

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INDICATION:
The Ti-Base, is intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The Ti-Base are for manufacturing of individual abutments on dental implants. The individual abutments can be combined with restorations such as, crowns or superstructures made of dental ceramics.

The Ti-Bases of the E-Series are indicated for Replace select® implants, manufactured by Nobel Biocare®.

The Ti-Base of the I-Series are indicated for Osseotite® implants manufactured by Biomet 3i®.

The Ti-Bases of the K-Series are indicated for Brånemark® implants, manufactured by Nobel Biocare®.

The Ti-Bases of the N-Series are indicated for synOcta® implants, manufactured by Straumann®.

The Ti-Bases of the R-Series are indicated for Tapered Screw-vent® implants, manufactured by Zimmer®.

The Ti-Bases of the S-Series are indicated for OsseoSpeed® implants, manufactured by Astra Tech®.

The Ti-Bases of the T-Series are indicated for Frialit® implants, manufactured by Dentsply-Friadent®.

The Ti-Bases of the H-Series are indicated for Biomet 3i Certain® implants, manufactured by Biomet 3i®.

The Ti-Bases of the L-Series are indicated for Bone Level implants, manufactured by Straumann®.

The Ti-Bases of the F-Series are indicated for NobelActive™ implants, manufactured by Nobel Biocare®.

ARTICLE NO. OF TI-BASES AND ABUTMENT SCREWS

The Abutments Ti-Base E-Series is compatible with Nobel Biocare Replace Select® Implant.

Nobel Replace Select®	3.5 mm	4.3 mm	5.0 mm	6.0 mm
Ti-Base E-Series	E 800	E 810	E 820	E 830
Abutment screw	E 60	E 61	E 61	E 61

The Abutment Ti-Base I-Series is compatible with Biomet 3i Osseotite®.

Biomet 3i Osseotite®	3.4 mm	4.1 mm	5.0 mm
Ti-Base I-Series	I 800	I 810	I 820
Abutment screw	I 61	I 61	I 61

The Abutment Ti-Base K-Series is compatible with Nobel Biocare Brånemark® Implant.

Brånemark®	3.5 mm	4.1 mm	5.1 mm
Ti-Base K-Series	K 800	K 810	K 820
Abutment screw	K 60	K 61	K 62

The Abutment Ti-Base N-Series is compatible with Straumann SynOcta® Implant.

Straumann SynOcta®	3.5 mm	4.8 mm	6.5 mm
Ti-Base N-Series	N 800	N 810	N 820
Abutment screw	N 60	N 62	N 62

The Abutment Ti-Base R-Series is compatible with Zimmer Tapered Screw-vent® (Sulzer) Implant.

Zimmer (Sulzer) Tapered Screw-vent®	3.5 mm	4.5 mm	5.7 mm
Ti-Base R-Series	R 800	R 810	R 820
Abutment screw	R 60	R 60	R 60

The Abutment Ti-Base S-Series is compatible with Astra Tech OsseoSpeed® Implant.

Astra Tech Osseo-Speed®	3.5 / 4.0 mm	4.5 / 5.0 mm
Ti-Base S-Series	S 800 / 810	S 820
Abutment screw	S 60	S 61

The Abutment Ti-Base T-Series is compatible with Dentsply-Friadent Frialit® Implant.

Dentsply-Friadent Frialit®	3.4 mm	3.8 mm	4.5 mm	5.5 mm
Ti-Base T-Series	T 800	T 805	T 810	T 820
Abutment screw	T 60	T 60	T 60	T 60

The Abutment Ti-Base H-Series is compatible with Biomet 3i Osseotite® Certain®.

Biomet 3i Osseotite®Certain®	3.4 mm	4.1 mm	5.0 mm
Ti-Base H-Series	H800	H810	H 820
Abutment screw	H 60	H 60	H 60

The Abutment Ti-Base L-Series is compatible with Straumann® Bone Level Implant.

Straumann® BoneLevel	3.3 mm	4.1 / 4.8 mm
Ti-Base L-Series	L 800	L 810
Abutment screw	L 60	L 61

The Abutment Ti-Base F-Series is compatible with Nobel Biocare NobelActive™ Implant.

NobelActive™	3.5 mm	4.3 / 5.0 mm
Ti-Base F-Series	F 800	F 810
Abutment screw	F 60	F 61

Each Ti-Base is delivered with an abutment screw for fixation on the implant. The article number is the order number.

COMPOSITION:
Ti-Base and Abutment Screw: Ti6Al4V, medical grade 5, ASTM 136
Scan Body: Polyether-ether-ketone, PEEK

CONTRAINDICATION:
The Ti-Bases of each Series can only be combined with the matching implant, e.g. the E-Series shall be combined exclusively with Replace select® implants. They cannot be combined with implants of a different implant type or manufacturer. The diameter of the Ti-base must correspond in size to the used implant in order to prevent a peri-implant tissue irritation.
The Ti-Bases are indicated for single use only. If they are used multiple times, they might damage the implants.
For fixation of the Ti-Bases on the implant, the correct torque force, recommended by the implant manufacturer, has to be considered carefully to avoid the damage of the implant-bone connection.
Mechanical treatment of the connection part of the Ti-Base will damage the correct fitting of the Ti-Base on the implant.

Ncm	Abutment				
20	H-Series				
25	S-Series	T-Series	F-Series		
30	R-Series				
35	I-Series	K-Series	N-Series	E-Series	L-Series

Mechanical treatment of the connection part of the Ti-Base will damage the correct fitting of the Ti-Base on the implant.

HANDLING METHOD FOR FURTHER PROCESSING:
The following instruction describes possible steps in the Laboratory for further processing to design the prosthetic components. The ceramic crown is an example for a possible aid prosthetic.

Ceramic crown: Milled with CAD/CAM-machines for zirconium oxide- or aluminum oxide- ceramic according to the anatomic form of a crown.
The ceramic crown shall be grinded or polished with diamond instruments and with minimal pressure and water-cooling. The minimal thickness shall be 0.5 mm. Sharpe edges must be avoided.

VENEERING:
Crowns shall be veneered with appropriate ceramics before cementing onto the Ti-Base. The instructions for use of the ceramic manufacturers have to be considered.
Before cementing the Ti-Base and the ceramic crown: Sandblasting the contact surfaces with Al_2O_3, 50 µm, 2 bar and ensure intensive cleaning of dust and grease.
It is recommended to protect the connection part of the Ti-Base with an implant analog during handling.

CEMENTING:
It is recommended to cement the ceramic abutment onto the Ti-Base with Panavia® F2.0 (Kuraray) with RelayXUnicem® (3M Espe) are other equivalent cements. The instructions for use of the cements shall be followed carefully.
The Ti-Base shall be fixed onto an implant analog with the abutments screw. The head of the screw has to be covered with wax or resin. The mixed cement is applied onto the contact part of the Ti-Base. The abutment is pressed onto the Ti-Base. The final position is evaluated by slight rotation. The gap between abutment and the Ti-Base must be as small as possible. Remaining cement shall be removed immediately.

POLISHING:
After hardening the remaining cement shall be removed with rotating silicon instruments. The cement inside the screw channel has to be removed carefully.

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SCAN BODY INDICATIONS:
The Scan Body can be used as auxiliary component, to determine the exact position and insertion angle of the implant. This is helpful for the further process to design the prosthetics.

SCAN BODY:
For the CAD/CAM scanning of the model, the Scan Body is used to indicate the position of the implant. The size of the Scan Body shall be corresponding to the original Implant system, implant diameter and Ti-Base Series.
The chamfer of the Scan Body prevents the rotation of the ceramic abutment.
The Scan Body is fixed on the implant analogue with the abutment screw. After correct positioning, there is no gap visible between implant and Scan Body. Rotation of the Scan Body is impossible.

ARTICLE NO.:
The article number of Scan Body and Titanium Base is a combination of the code for the Series: E, I, K, N, R, S, T, H, L and F (→ X) with the code W for Scan Body and for Titanium Base.

Titanium-Base	X 800	X 805	X 810	X 820	X 830
Scan-Body	X 00W	X 05W	X 10W	X 20W	X 30W

WARNING:
Safety hint: metal dust is harmful to your health. When milling and sandblasting use a suction extraction system and a breathing mask.

SECONDARY EFFECTS:
Allergies to the alloy or contents of the alloy or electrochemically based reactions may very rarely occur.

REACTIONS:
In case of occlusal or approximal contact of different alloys electrochemically based reactions may very rarely occur.

WARRANTY:
10 Years on the mechanical stability of the Ti-Base, if it was processed according to the Instruction for use. Whether given verbally, in writing or by practical instructions, our recommendation for use is based upon own experience and trials and can only be con sidered as standard values. Our products are subject to a constant further development. Therefore alternations in construction and composition are reserved.

CLEANING, DISINFECTION AND STERILIZATION:
The nt-trading abutments and screws of the series E, I, K, N, R, S and T are supplied in non-sterile condition. The components should be cleaned, disinfected and in specific clinical procedures and cases be sterilized, prior to use after they are received from the dental laboratory (no liability on disregard). Effective cleaning and disinfection is an indispensable requirement for effective sterilization of the abutments. Prior to sterilization, please keep implants and screws clean when handling in the laboratory and operatory.
Additionally, please pay attention to legal regulations valid for your local areas as well as to the hygienic instructions of your dental practice. This applies particularly to the different guidelines regarding the inactivation of prions.

1. Pre-disinfection (avoidance of cross contaminations)
Place the abutments and screws in a germicidal bath* immediately after use. Remove all residues and disassemble demountable products.

2. Cleaning
Please use distilled water and neutral cleaning agents* only. The internal irrigation tube has to be cleaned with a Miller needle and must be rinsed with distilled water at the beginning and end of the exposure time using a disposable syringe (min. 10 ml). The products must be cleaned with a plastic instrument cleaning brush and then rinsed with distilled water. Please control all products after cleaning in order to avoid either damaging or corrosion. Damaged products must be replaced.

3. Rinsing and Drying
After removal of the products from the germicidal bath, all components must be rinsed 3 times with distilled water /e.g. Aqua purificata). Please dry all components thoroughly with a lint-free disposable cloth. For the cleaning of the internal irrigation tube oil-free compressed air is mandatory. Please re-check all parts for damage or corrosion afterwards.

4. Disinfection
We recommend a high level disinfectant such as, Cidex OPA (Johnson & Johnson) for disinfection of the abutments and screws.

a) Soak the abutments and screws in the disinfectant solution for the required amount of time. See instructions for use of Cidex OPA.
b) Remove the abutments and screws from the disinfectant solution.
c) Rinse at least three times with highly purified water.
d) Air dry and package the abutments and screws immediately.

5. Sterilization:
If no sterilization device is available in the laboratory, this information should be forwarded to the dentist so proper sterilization can occur. Please use only validated sterilization procedures for the sterilization of the abutments and screws. Other sterilization procedures must not be used.

Reusability:
You may only sterilize the abutments one time. In case of inadvertent contamination, you may re-sterilize one time after cleaning and disinfection.

Steam sterilization:
- fractionated vacuum procedure or gravity procedure (with sufficient product drying)
- steam sterilizer according to ISO 17665: 2006 or EN 13060 and EN 285 respectively or equivalent national standards
- validated according to EN ISO/ANSI AAMI 17665 (in past: EN 554/ANSI AAMI ISO 11134) (valid IQ/OQ) (commissioning and product specific performance qualification)
- sterilization time 20 minutes at 121 °C (250 °F) (listed exposure times are at sterilization temperature)

7. Storage
Store the sterilized parts dry and dust-free at room temperature.

* Please observe all manufacturers guidelines for disinfection and cleaning agents with special regard to the concentration, exposure time and temperature. Only neutral disinfection solutions without chlorine, ammoniac and aldehydes and with a proven effectiveness against HBV, HCV, and HIV must be used. The products have to meet the respective national regulations for disinfectants. If disinfectants containing aldehydes are used, this might lead to a possible fixation of proteins. Please use only freshly prepared solutions.

Rev. A/ 2012-03-20

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Appendix 4 – NT-Trading Ti-Base 510(k) Summary

510(k) Summary K111935 FEB 17 2012

Submitter Name: Submitter Address:	**NT-Trading GmbH & Co. KG** Essostrasse 16 76187 Karlsruhe Germany
Phone Number: Fax Number:	+49-721-915471 60 +49-721-915471 61
Contact Person:	Dirk Jahn
Date Prepared:	June 29, 2011
Device Trade Name:	Ti-Base Abutment 2-CONnect Abutment
Common Name:	Dental Abutments
Classification Name, Number & Product Code:	Abutment, Implant, Dental, Endosseous 872.3630 NHA
Predicate Devices:	**(K100152)** Sirona Dental Systems Sirona Dental CAD/CAM System, **(K083871)** Atlantis™ Straumann Bone Level Abutment, **(K093483)** Atlantis™ Abutment for Nobel Active Implant, **(K072642)** Biomet 3I Dental Abutments And Restorative Components, **(K990342)** synOcta® Prosthetics, **(K080239)** P.004 Abutments, **(K072570)** NobelActive™Multi Unit Abutment
Device Description and Statement of Intended Use	The Ti-Base Abutment is a premanufactured prosthetic component supplied in two parts, the abutment and screw, for fixation onto dedicated endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. The 2-CONnect Abutment consists of 1 Abutment with screw (for fixation of abutment to the implant) and 1 titanium cap with 1 tiny screw (fixed into the hollow Abutment screw). The cap on top fits exactly to the abutment-geometry and does not have a rotation fixation, so it is easier to work with (not indicated for single crowns but strictly for bridges). The 2-CONnect is intended for use as an aid in prosthetic rehabilitation. The NT-Trading Ti-Base and 2-CONnect is compatible with commercially available dental CAD/CAM systems, such as 3Shape, Exocad, Dental Wings. Such systems must be validated by the user. Indication for use: **Ti-Base Abutments**: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Nobel Biocare NobelActive™
- Biomet 3i® Osseotite®
- Biomet 3i® Osseotite® Certain®
- Nobel Biocare Branemark®
- Straumann® synOcta®
- Straumann® Bone Level®
- Zimmer® Tapered Screw-vent®
- Astra Tech OsseoSpeed®
- Dentsply-Friadent® Frialit®

2-CONnect Abutments: 2-CONnect abutment is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction.
The 2-CONnect abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Straumann® synOcta®
- Straumann® BoneLevel®

Summary of Technological Characteristics

The proposed Ti-Base abutments and 2-CONnect abutments are substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each individual diameter and connection type. Comparison Demonstrating Substantial Equivalence follows at the end of this section.

Testing Summary
In order to demonstrate compatibility of Ti-Base and 2-CONnect abutments to each implant system, fatigue testing was performed according to ISO 14801 Dentistry-Implants-Dynamic fatigue test for endosseous implants. Testing was performed on the abutments in this submission with the implants that they are intended to fit. See section 18.

Conclusion

The information discussed above demonstrates that the NT-Trading Ti-Base Dental Abutments and 2-CONnect Abutments are substantially equivalent to the predicate devices.

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Ti-Base and 2-CONnect	Sirona Dental Systems Sirona Dental CAD/CAM System	Atlantis™ Straumann Bone Level Abutment	Atlantis™ Abutment for Nobel Active Implant	Biomet 3I Dental Abutments And Restorative Components	synOcta® Prosthetics	P.004 Abutments	NobelActive™ Multi Unit Abutment
510(k) Number		K100152	K083871	K093483	K072642	K990342	K080239	K072570
Manufacturer	Nt-Trading GmbH & Co. KG	Sirona Dental Systems GmbH	Astra Tech Inc.	Astra Tech Inc.	Biomet 3I, Inc.	Straumann® USA	Straumann® Manufacturing, Inc	Nobel Biocare® AB
Classification # & Product Code	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA
Intended Use	Ti-Base Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function	The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic reconstruction. The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement	The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	BIOMET 3i Dental Abutments and Overdenture Bars are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. These are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.	ITI Dental implants are intended to be placed in the maxillary and/or mandibular arch to support crowns, bridges or overdentures in edentulous or partially edentulous patients. The prosthetic accessories to dental implants are used either in the process of fabricating the prosthetic restoration for the implant or as part of the prosthetic restoration.	Abutments are placed into dental implants to provide support for prosthetic restorations such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations. The subject abutments are for permanent screw-retained bridges and bar-retained implant-borne dentures. Permanent copings are intended to	Nobel Biocare's Multi-Unit is a premanufactured prosthetic component directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.

	intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Nobel Biocare NobelActive™ • Biomet 3i® Osseotite® • Biomet 3i® Osseotite® Certain® • Nobel Biocare Branemark® • Straumann® synOcta® • Straumann® Bone Level® • Zimmer® Tapered Screw-vent® • Astra Tech OsseoSpeed® • Dentsply-Friadent® Frialit® **2-CONnect Abutments**: 2-CONnect abutment is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be	and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems: • Nobel Biocare Replace • Nobel Biocare Branemark • Friadent Xive • Biomet 3i Osseotite • Astra Tech Osseospeed • Zimmer Tapered Screw-Vent • Straumann SynOcta	retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.				serve as a base for multi-unit bar or bridge restorations. Temporary Copings are intended to serve as a base for temporary restorations for up to 6 month. Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.	

	used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction. The 2-CONnect abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Straumann® synOcta® • Straumann® BoneLevel®							
Abutment Diameter min. Diameter max.	3.5 mm 6.5 mm	Same	Same	Same	Same	Same	Same	Same
Abutment Height	Ti-Base: 4 mm 2-CONnect: 2.3 / 4.3 mm	Same	4 / 5.5 mm	6.6 mm	7.0	1.5 / 6.0	1.5 / 6.0	1.0 / 5.5 mm
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw retained	Screw retained	Screw retained
Reusable	No	No	No	No	No	No	No	No
Material	Ti-6Al-4V	Ti-6Al-4V	Ti-6A1-4V ELI	Ti-6A1- 4V ELI	Ti-6Al-4V	Titanium, Titanium alloy	Ti-6Al-4V	Titanium Alloy

For the reasons stated above, we believe a determination of substantial equivalence between the Ti-Base and 2-CONnect and these predicate devices is appropriate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NT-Trading GmbH & Company AG
C/O Mr. William Greenrose
President
Qserve America, Inc.
220 River Road
Claremont, New Hampshire 03743

FEB 17 2012

Re: K111935
Trade/Device Name: Ti-Base for Individual milled Zirconium Abutment, 2-CONnect Abutment for Bridges and Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 28, 2011
Received: February 14, 2012

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111935

Device Name: Ti-Base for individual milled Zirconium Abutment, 2-CONnect Abutment for Bridges and Bars

Indications For Use:

Ti-Base for individual Zirconium Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration.

The Ti-Base for individual Zirconium Abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The Ti-Base abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Nobel Biocare NobelActive™
- Biomet 3i® Osseotite®
- Biomet 3i® Osseotite® Certain®
- Nobel Biocare Branemark®
- Straumann® synOcta®
- Straumann® Bone Level®
- Zimmer® Tapered Screw-vent®
- Astra Tech OsseoSpeed®
- Dentsply-Friadent® Frialit®

2-CONnect Abutment for Bridges and Bars: 2-CONnect Abutment for Bridges and Bars is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction.
The 2-CONnect abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Straumann® synOcta®
- Straumann® BoneLevel®

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K111935

Appendix 5 – Biocompatibility Test Report for Straumann® Variobase™ Abutments

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

NOTE: This form is REQUIRED for holds and for final decisions.

Reviewer Name Michael Mendelson

510(k) Number K132219

Please list CTS decision code: SE - Substantially Equivalent

☐ Hold (Additional Information or Telephone Hold) Hold Date

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

☐ Incomplete Response - Convert Supplement to Amendment (attach email sent to firm)

☐ Add to File

(review staff should follow the instructions and complete the memo/routing sheet at: http://eroom.fda.gov/eRoom/CDRH3/CDRHPremarketNotification510kProgram/0_3bba7. DCC should refer to that documentation for the close-out code and mail any provided letter.)

The remainder of this form must be filled out for close-outs only

Class:	II
Regulation Number:	872.3630
Product Code:	NHA
Additional Product Codes:	

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Is this a combination product?		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X

DCC 2121

Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Susan Runner DDS, MA Mary S. Runner -S 2014.02.21 10:44:07 -05'00'
Division Sign-Off	Kwame O. Ulmer -S 2014.02.21 14:01:22 -05'00'

straumann

K132219/S 001

FDA CDRH DMC

AUG 07 2013

Received

August 6, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: K132219 Response to RTA Letter dated August 5, 2013

Dear Sir or Madam:

On behalf of Institut Straumann AG, Straumann USA, LLC submits this response to the Refuse to Accept Letter received on 05-Aug-2013 for K132219 Traditional 510(k) Premarket Notification for the Straumann® Variobase™ Abutments in accordance with 21 CFR 807.81.

(b)(4) Trade Secret Process - Product Specs

[redacted]

Straumann USA ▪ 60 Minuteman Road ▪ Andover, MA 01810
Phone 800/448 8168 ▪ 978/747 2500 ▪ Fax 978/747 2490 ▪ www.straumannusa.com

3

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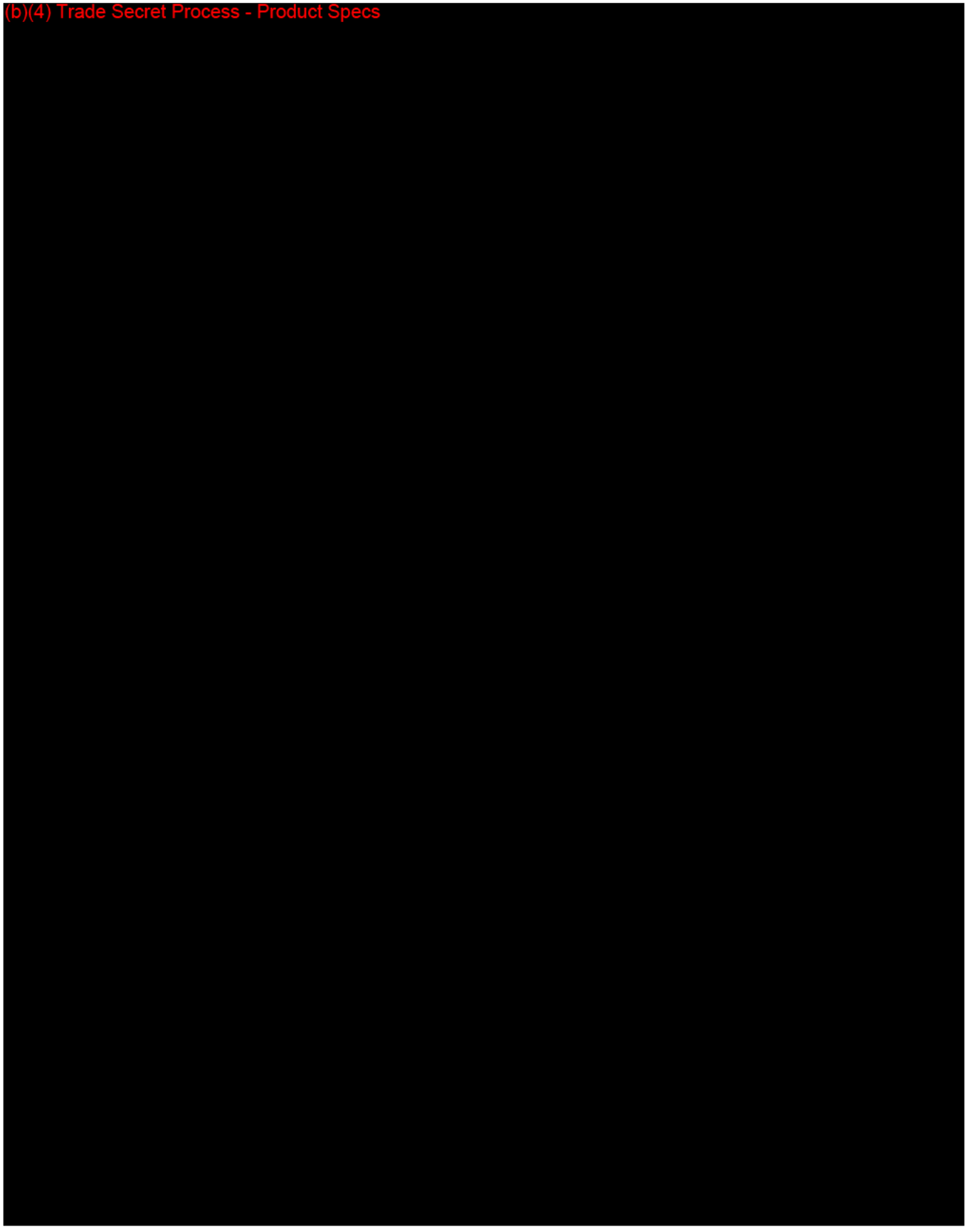
(b)(4) Trade Secret Process - Product Specs



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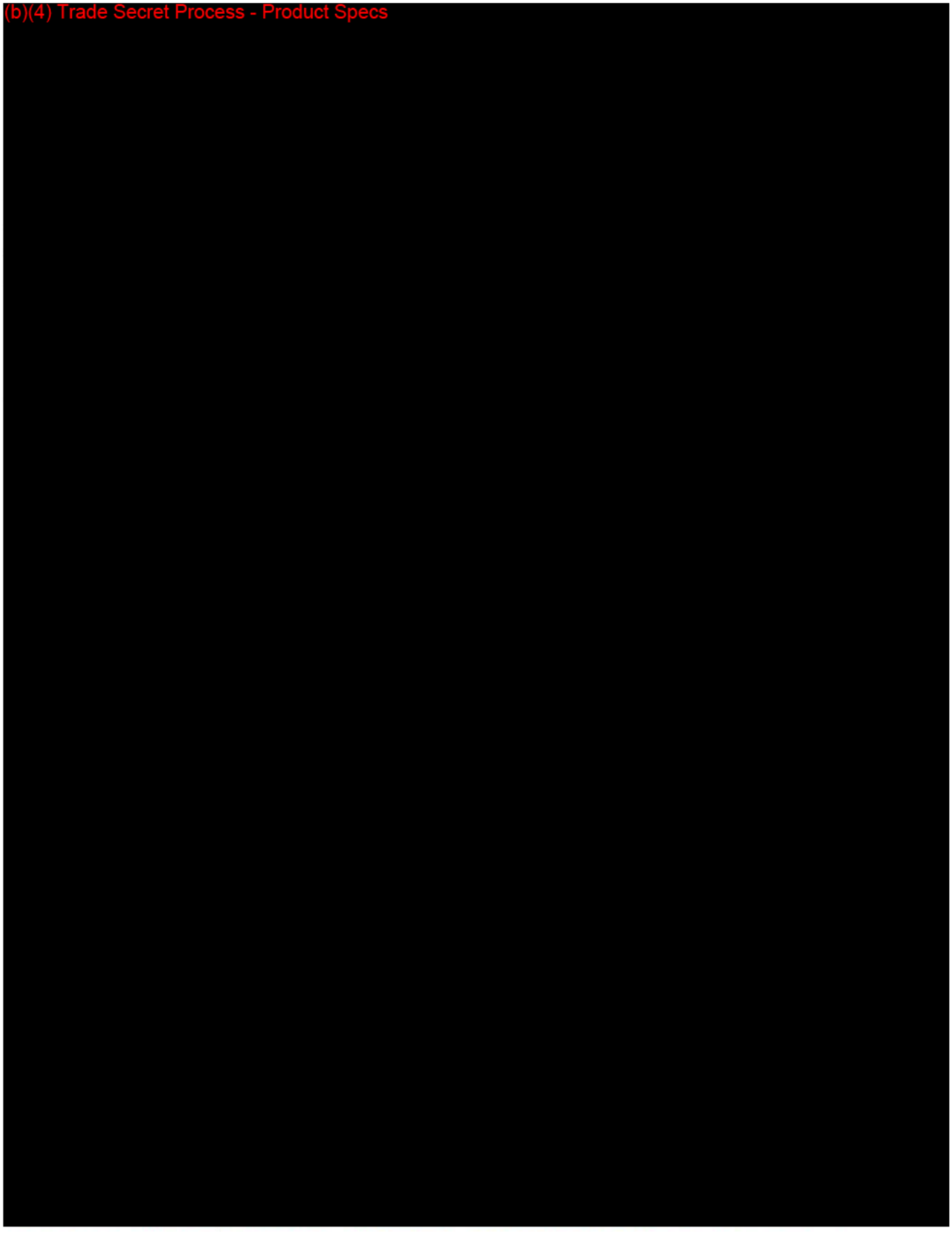
(b)(4) Trade Secret Process - Product Specs



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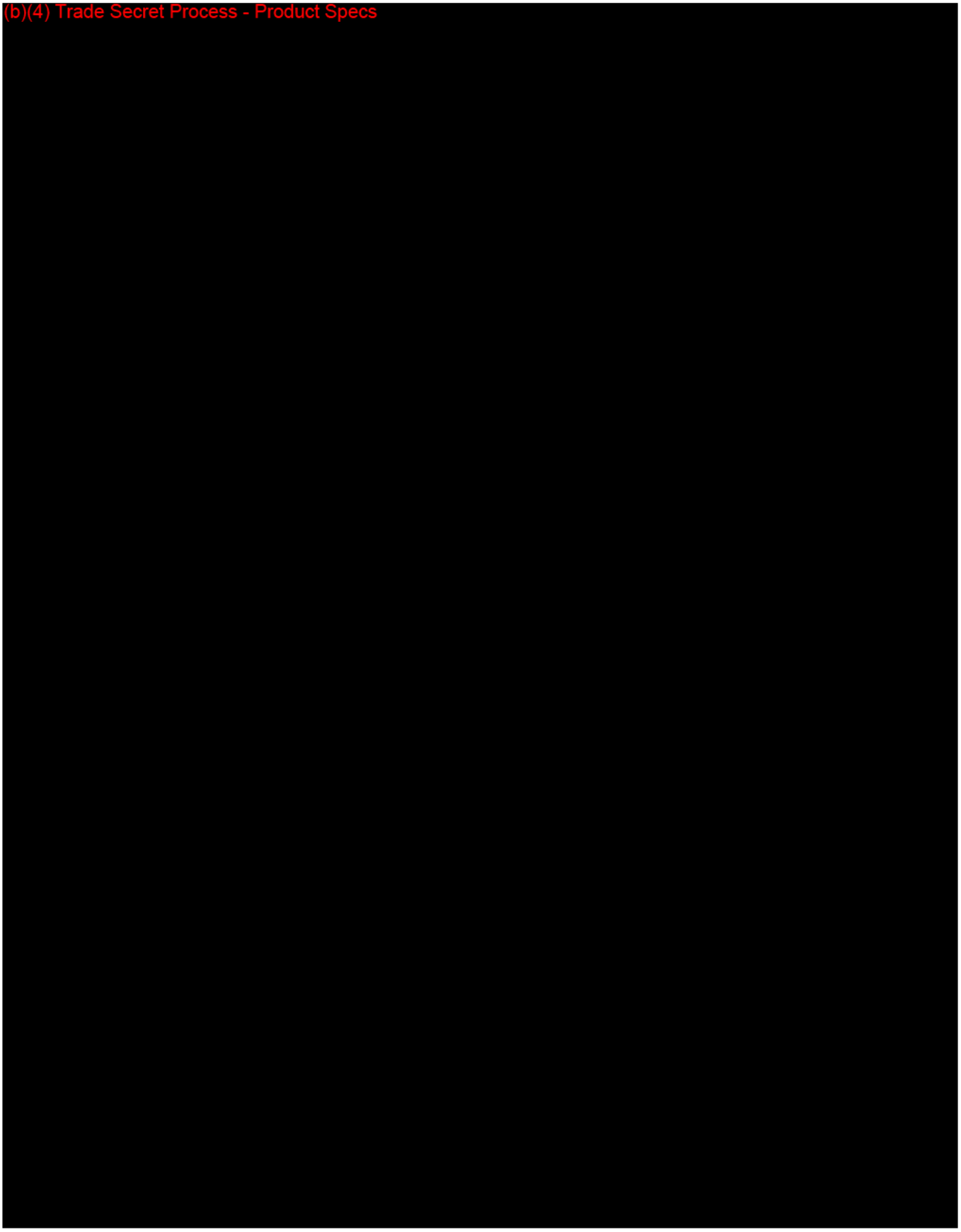

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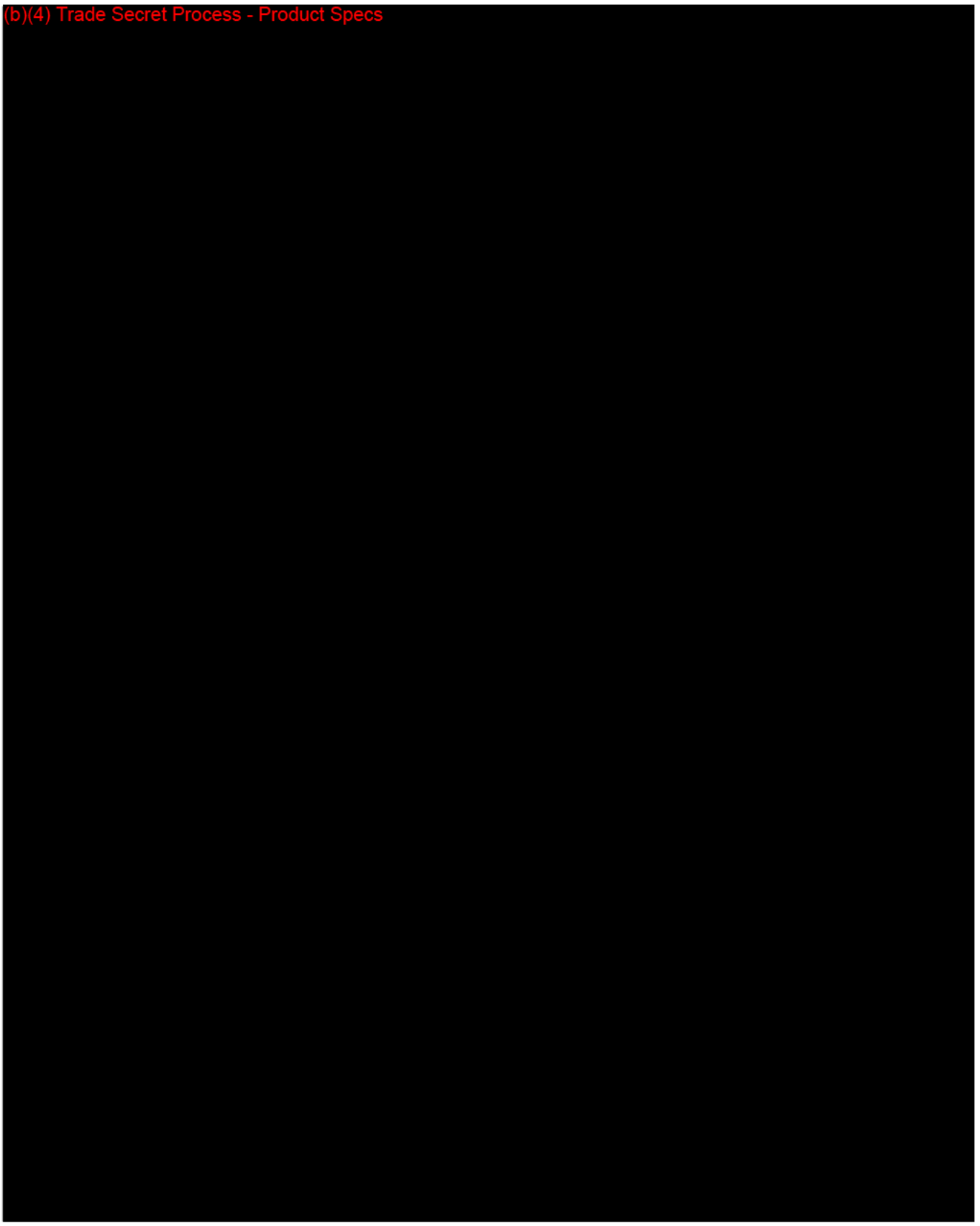

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(b)(4) Trade Secret Process - Product Specs

[redacted]

Sincerely,

Jennifer M. Jackson

Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager

Enclosures

straumann

August 6, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: K132219 Response to RTA Letter dated August 5, 2013

Dear Sir or Madam:

On behalf of Institut Straumann AG, Straumann USA, LLC submits this response to the Refuse to Accept Letter received on 05-Aug-2013 for K132219 Traditional 510(k) Premarket Notification for the Straumann® Variobase™ Abutments in accordance with 21 CFR 807.81.

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[redacted]

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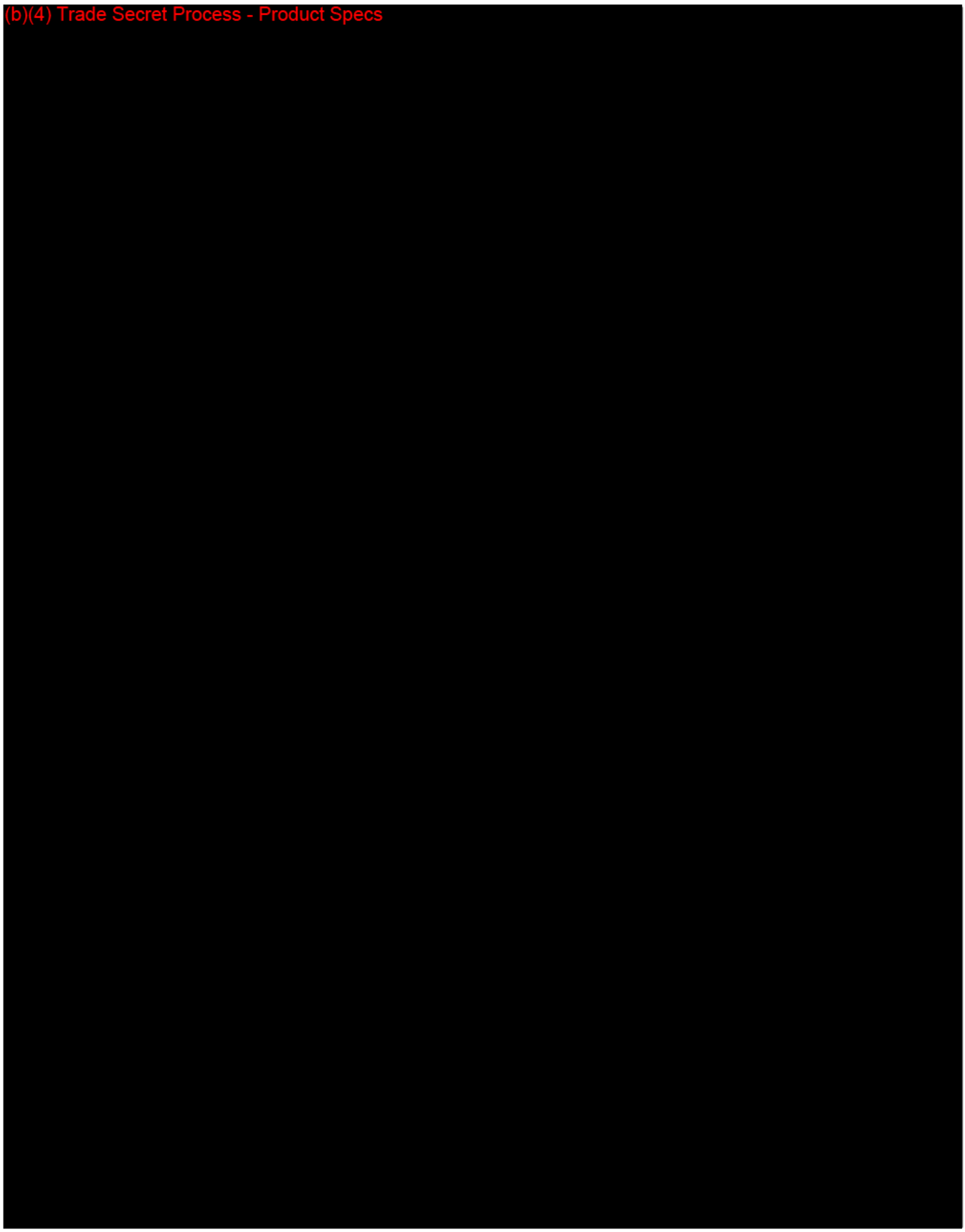
Phone 800/448 8168 ▪ 978/747 2500 ▪ Fax 978/747 2490 ▪ www.straumannusa.com

straumann



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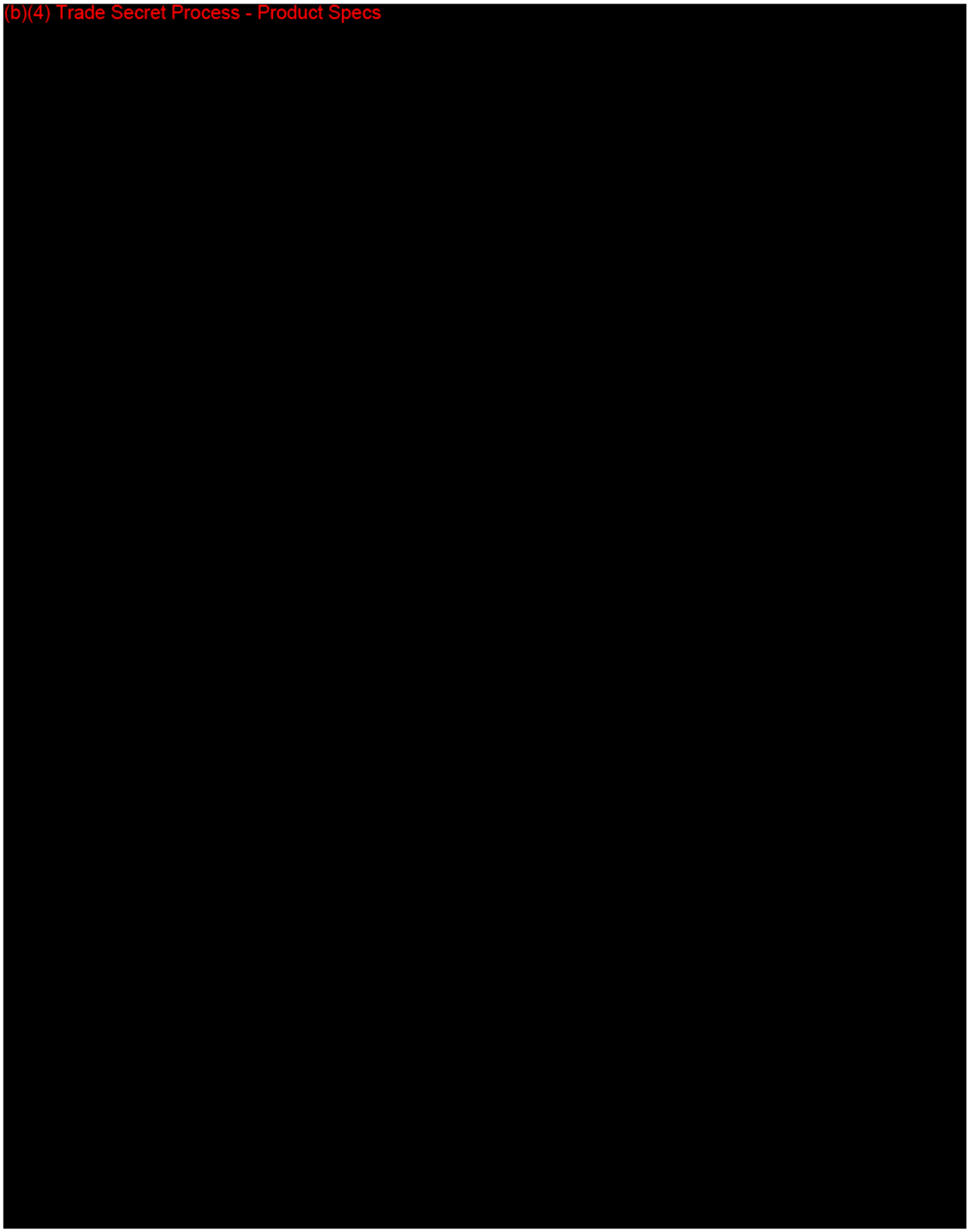

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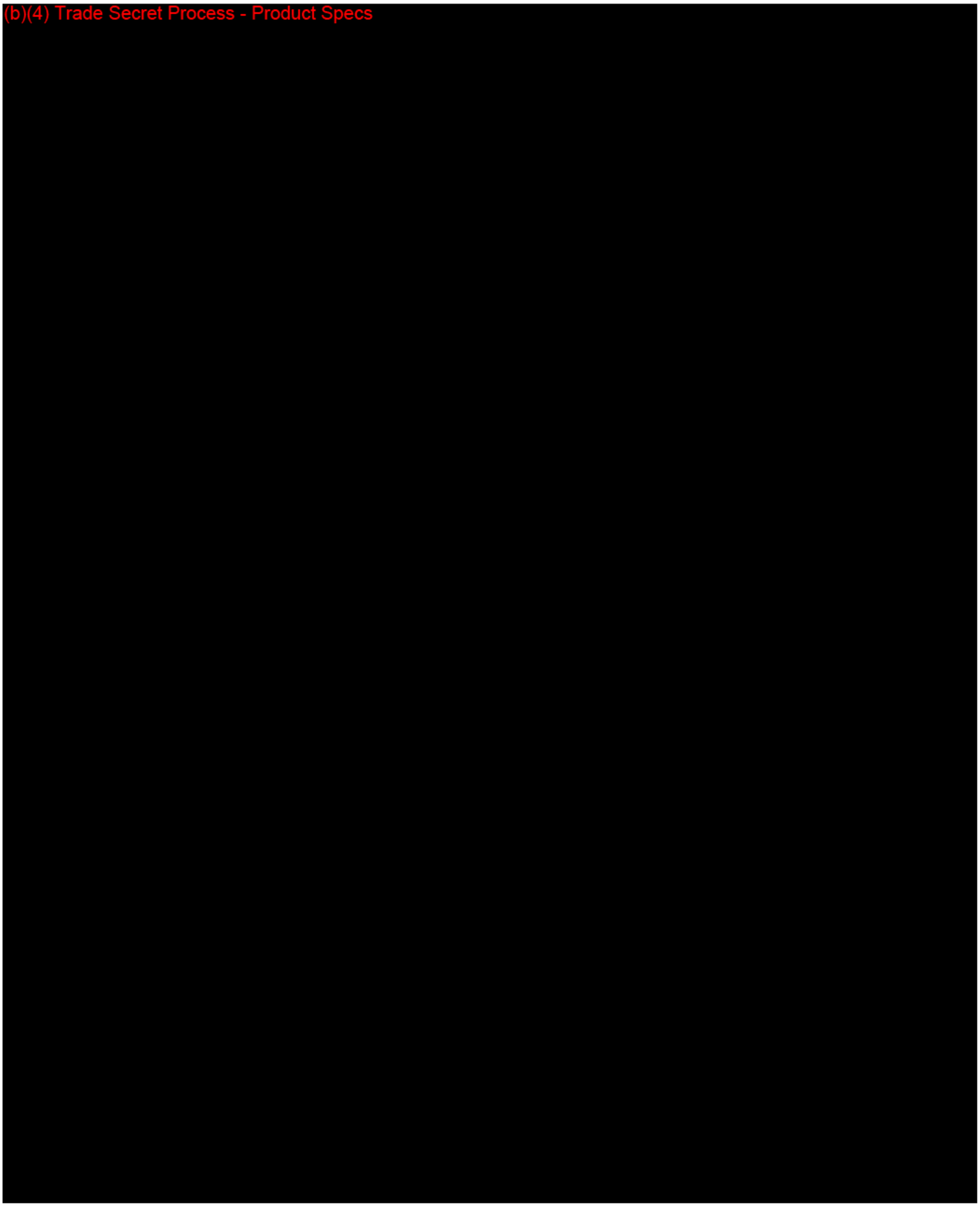

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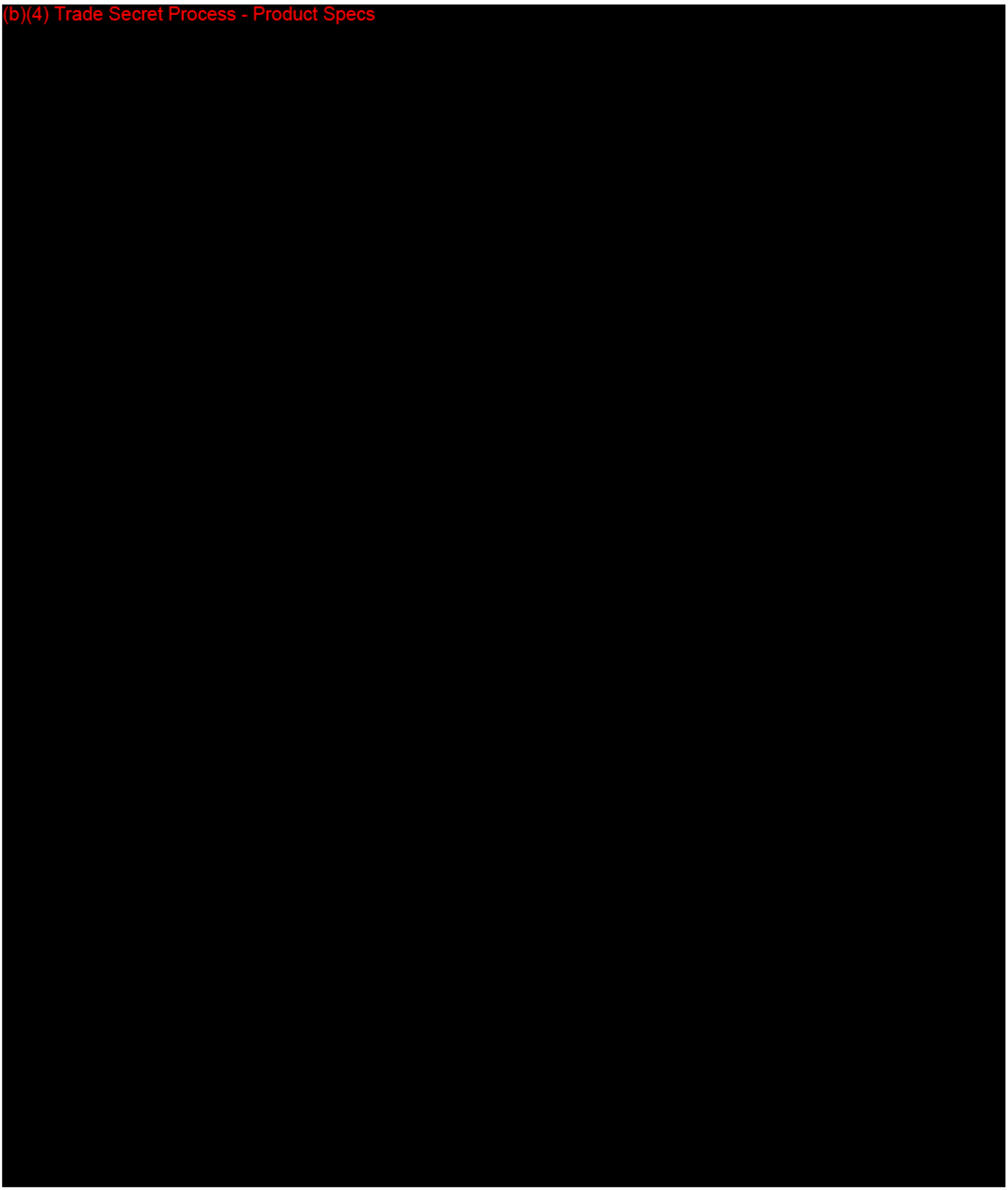

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Two copies of the response are enclosed. The second copy is being provided in PDF format on CD and is an exact duplicate of the hardcopy with the exception that the eCopy does not contain original signatures.

We trust that the foregoing information will be sufficient to permit FDA to make a finding of substantial equivalence for the proposed Straumann Dental Implant System to the currently marketed devices as presented in this premarket notification.

Please address any questions regarding this 510(k) Premarket Notification to the undersigned.

Sincerely,

Jennifer M. Jackson

Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager

Enclosures

straumann®

K132219/S2

FDA CDRH DMC
SEP 16 2013
Received

September 13, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: K132219 Response to RTA Letter dated August 16, 2013

Dear Sir or Madam:

On behalf of Institut Straumann AG, Straumann USA, LLC submits this response to the Refuse to Accept Letter received on 16-Aug-2013 for K132219 Traditional 510(k) Premarket Notification for the Straumann® Variobase™ Abutments in accordance with 21 CFR 807.81.

(b)(4) Trade Secret Process - Product Specs

[redacted]

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Phone 800/448 8168 ▪ 978/747 2500 ▪ Fax 978/747 2490 ▪ www.straumannusa.com

1/1

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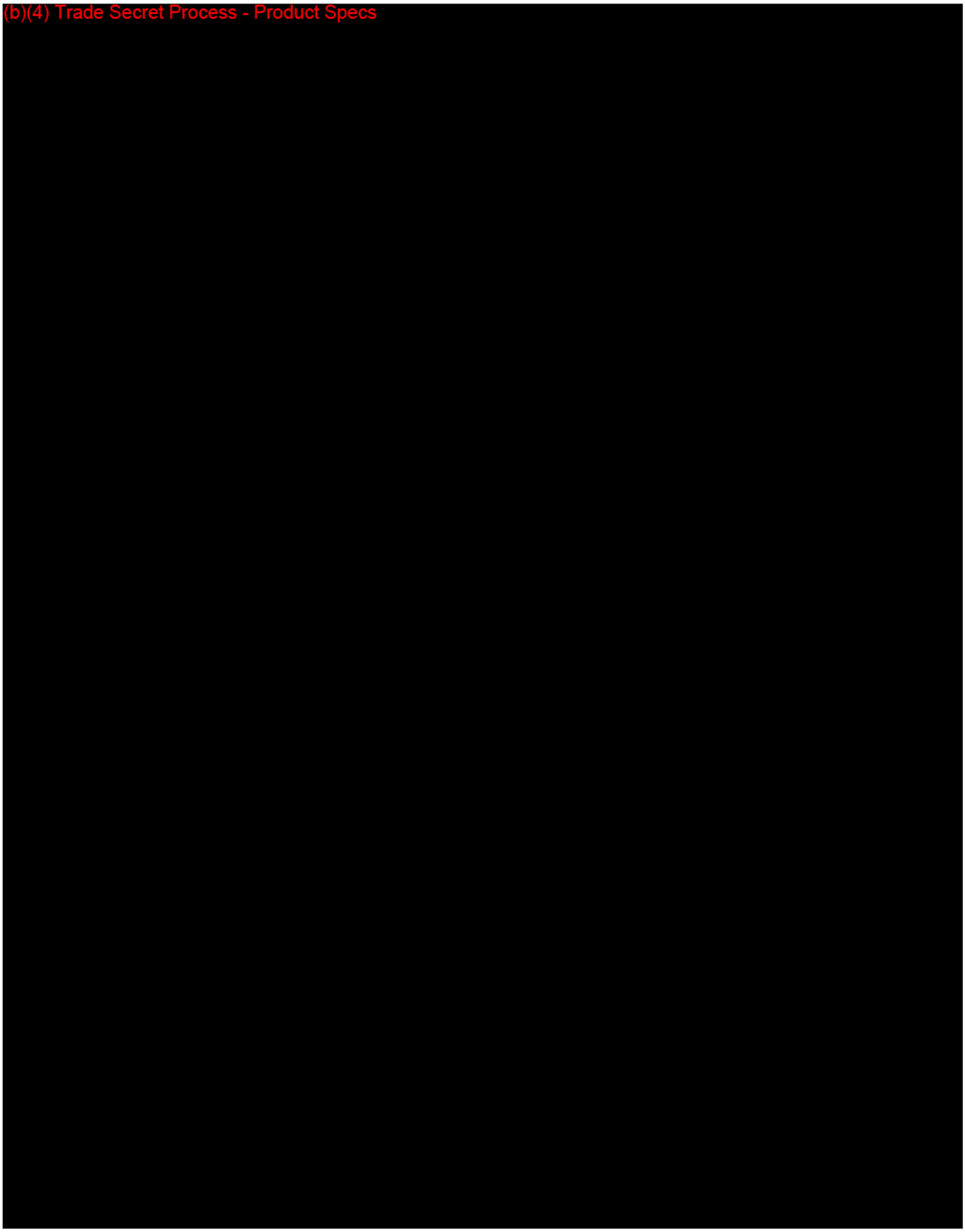
(b)(4) Trade Secret Process - Product Specs



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(b)(4) Trade Secret Process - Product Specs

Sincerely,

Jennifer M. Jackson

Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager

Enclosures

straumann

September 13, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: K132219 Response to RTA Letter dated August 16, 2013

Dear Sir or Madam:

On behalf of Institut Straumann AG, Straumann USA, LLC submits this response to the Refuse to Accept Letter received on 16-Aug-2013 for K132219 Traditional 510(k) Premarket Notification for the Straumann® Variobase™ Abutments in accordance with 21 CFR 807.81.

(b)(4) Trade Secret Process - Product Specs

[redacted]

Straumann USA ▪ 60 Minuteman Road ▪ Andover, MA 01810
Phone 800/448 8168 ▪ 978/747 2500 ▪ Fax 978/747 2490 ▪ www.straumannusa.com

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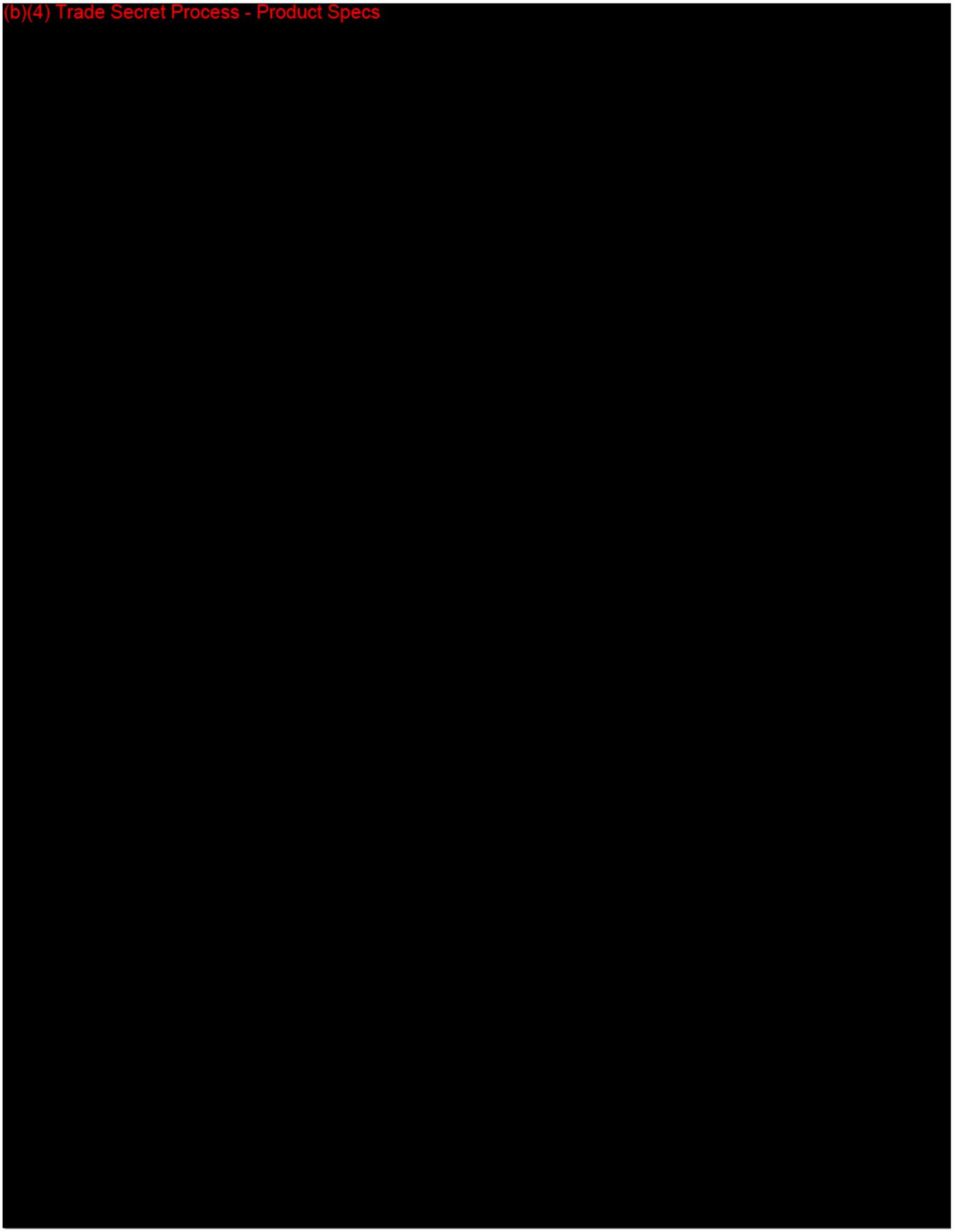


straumann

(b)(4) TS/CCI

Information in this premarket notification is considered proprietary or trade secret or confidential commercial information. The company requests that all such information not be disclosed pursuant to 18 U.S.C. §1905, 5 U.S.C. §552, 21 U.S.C. §331(j), and all other applicable laws and regulations.

We trust that the foregoing information will be sufficient to permit FDA to make a finding of substantial equivalence for the proposed Straumann® Variobase™ Abutments to the currently marketed devices as presented in this premarket notification.

Please address any questions regarding this 510(k) Premarket Notification to the undersigned.

Sincerely,

Jennifer M. Jackson

Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager

Enclosures

Table of Contents

(b)(4) Trade Secret Process - Product Specs

[redacted]

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Table of Contents

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Table of Contents

(b)(4) Trade Secret Process - Product Specs

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Table of Contents

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Table of Contents

Table of Tables

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Table of Contents

Table of Figures

1 Medical Device User Fee Cover Sheet (Form FDA 3601)

Payment Identification Number: (b)(4) Trade Secret Process Product

The Medical Device User Fee Cover Sheet (Form FDA 3601) begins on the next page.

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda gov/oc/mdufma/coversheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) STRAUMANN USA 60 MINUTEMAN ROAD ANDOVER MA 01810 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Jennifer Jackson 2.1 E-MAIL ADDRESS jennifer.jackson@straumann.com 2.2 TELEPHONE NUMBER (include Area code) 978-747-2509 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 978-747-0023

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instruc ions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government en ity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the applica ion is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining he data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 03-Jul-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

2 CDRH Premarket Review Submission Cover Sheet

The CDRH Premarket Review Submission Cover Sheet begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
09-13-2013	(b)(4) Trade	K132219

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Straumann USA, LLC	1222315		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	978-747-2509		
Street Address	**FAX Number *(including area code)***		
60 Minuteman Road	978-747-0023		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Andover	MA	01810	USA
Contact Name			
Jennifer M. Jackson, MS			
Contact Title	**Contact E-mail Address**		
Senior Regulatory Affairs Project Manager	jennifer.jackson@straumann.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NHA	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K120822	1	Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC	1	Straumann
2	K111935	2	Ti-Base Abutment	2	NT-Trading GmbH & Co. KG
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Endosseous dental implant abutment

(b)(4) Trade Secret Process - Product Specs

[redacted]

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 None	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NHA	21 CFR 872.3630	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Dental		

Indications *(from labeling)*

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Institut Straumann AG		Establishment Registration Number: 9613348
Division Name *(if applicable)*		Phone Number *(including area code)*: 978-747-2509
Street Address: Peter Merian-Weg 12		FAX Number *(including area code)*: 978-747-0023
City: Basel	State / Province	ZIP Code: CH-4052 / Country: Switzerland
Contact Name: Jennifer M. Jackson, MS	Contact Title: Senior Regulatory Affairs Project Manager	Contact E-mail Address: jennifer.jackson@straumann com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 10993-1:2009	ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009	10/04/2010
	Standards No.	Standards Organization	Standards Title	Version	Date
2	ISO 10993-5:2009	ISO	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	2009	05/05/2010
	Standards No.	Standards Organization	Standards Title	Version	Date
3	ISO 10993-12:2007	ISO	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials	2007	10/04/2010
	Standards No.	Standards Organization	Standards Title	Version	Date
4	ISO 10993-18:2005	ISO	Biological evaluation of medical devices -- Part 18: Chemical characterization of materials	2005	07/01/2005
	Standards No.	Standards Organization	Standards Title	Version	Date
5	ISO 5832-11:1994	ISO	Implants for surgery - Metallic materials -- Part 11: Wrought titanium 6-aluminum 7-niobium alloy	1994	09/09/2008
	Standards No.	Standards Organization	Standards Title	Version	Date
6	ISO 17665-1:2006	ISO	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices	2006	09/08/2009
	Standards No.	Standards Organization	Standards Title	Version	Date
7	ISO/TS 17665-2:2009	ISO	Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1	2009	01/05/2009

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 17664:2004	ISO	Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices	2004	10-12-2012
	Standards No.	Standards Organization	Standards Title	Version	Date
2	ISO 14801:2007	ISO	Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants	2007	04-25-2012
	Standards No.	Standards Organization	Standards Title	Version	Date
3					
	Standards No.	Standards Organization	Standards Title	Version	Date
4					
	Standards No.	Standards Organization	Standards Title	Version	Date
5					
	Standards No.	Standards Organization	Standards Title	Version	Date
6					
	Standards No.	Standards Organization	Standards Title	Version	Date
7					

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

3 510(k) Cover Letter

The 510(k) Cover Letter begins on the next page.

straumann

September 13, 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: Traditional 510(k) Premarket Notification: Straumann® Variobase™ Abutments

Dear Sir or Madam:

On behalf of Institut Straumann AG, Straumann USA, LLC submits this Traditional 510(k) Premarket Notification for the Straumann® Variobase™ Abutments in accordance with 21 CFR 807.81. The intended use and fundamental operating principles of the proposed devices are substantially equivalent to previously cleared devices as detailed in this premarket submission.

Submitter:
Straumann USA, LLC (on behalf of Institut Straumann AG)
60 Minuteman Road
Andover, MA 01810

Primary Contact:
Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager
Straumann USA, LLC
60 Minuteman Road
Andover, MA 01810
Telephone: 800-448-8168 x2509
Fax: 978-747-0023

Classification Name of Device:

Classification Name:	Abutment, Implant, Dental, Endosseous
Device Product Code:	NHA
Product Classification:	Class II
Panel:	Dental
Regulation Number:	§872.3630
Prior Related Submissions:	None

straumann

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

The term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence from an FDA-regulatory point of view under the Federal Food, Drug and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to, and does not diminish, any patent claim related to this product or the technology used to manufacture the product.

Information in this premarket notification is considered proprietary or trade secret or confidential commercial information. The company requests that all such information not be disclosed pursuant to 18 U.S.C. §1905, 5 U.S.C. §552, 21 U.S.C. §331(j), and all other applicable laws and regulations.

Two copies of the Traditional 510(k) Premarket Notification are enclosed. The second copy is being provided in PDF format on CD and is an exact duplicate of the hardcopy with the exception that the eCopy does not contain original signatures. Further, in accordance with the Medical Device User Fee and Modernization Act of 2001 ("MDUFMA"), Straumann USA, LLC has submitted the appropriate application fees. A copy of the User Fee Cover Sheet is provided with the enclosed 510(k) Premarket Notification.

We trust that the foregoing information will be sufficient to permit FDA to make a finding of substantial equivalence for the proposed Straumann® Variobase™ Abutments to the currently marketed devices as presented in this premarket notification.

Please address any questions regarding this 510(k) Premarket Notification to the undersigned.

Sincerely,

Jennifer M. Jackson

Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager

Enclosures

4 Indications for Use Statement

The Indications for Use Statement associated with this 510(k) is located on the following page in the required format.

Indications for Use

510(k) Number (if known):

Device Name: Straumann® Variobase™ Abutments

Indications for Use:

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5 510(k) Summary

5.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Contact Person: Jennifer M. Jackson, MS

Date of Submission: 13-Sep-2013

5.2 Name of the Device

Trade Name: Straumann® Variobase™ Abutments

Common Name: Dental Implant Abutment

Classification Name: Abutment, Implant, Dental, Endosseous

Regulation Number: §872.3630

5.3 Predicate Device(s)

K120822 – Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC

K111935 – Ti-Base Abutment (NT-Trading GmbH & Co. KG)

5.4 Device Description

The Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments, sometimes referred to as "bonding bases". Straumann® Variobase™ Abutments are available to fit Straumann® dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit®), and RC (Regular CrossFit®).

5.5 Intended Use

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments intended to be placed onto Straumann dental implants to provide support for customized prosthetic

restorations such as crowns and bridges. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

5.6 Technological Characteristics

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments made from a titanium-aluminum-niobium alloy.

5.7 Performance Testing

The material used in the manufacture of Straumann® Variobase™ Abutments is a titanium-aluminum-niobium alloy which meets the requirements of ISO 5832-11. Bench testing was performed to evaluate the fatigue load limits of the proposed Straumann® Variobase™ Abutments. Dynamic fatigue tests were conducted in according to the FDA guidance document *"Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"*.

5.8 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase™ Abutments are substantially equivalent to the predicate devices.

6 Truthful and Accuracy Statement

As Required by 21 CFR 807.87(k)

I certify that, in my capacity as Senior Regulatory Affairs Project Manager of Straumann USA, LLC, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Jennifer M. Jackson

(Signature)

Jennifer M. Jackson, MS

(Typed Name)

13-Sep-2013

(Date)

K132219

(Premarket Notification Number)

7 Class III Summary and Certification

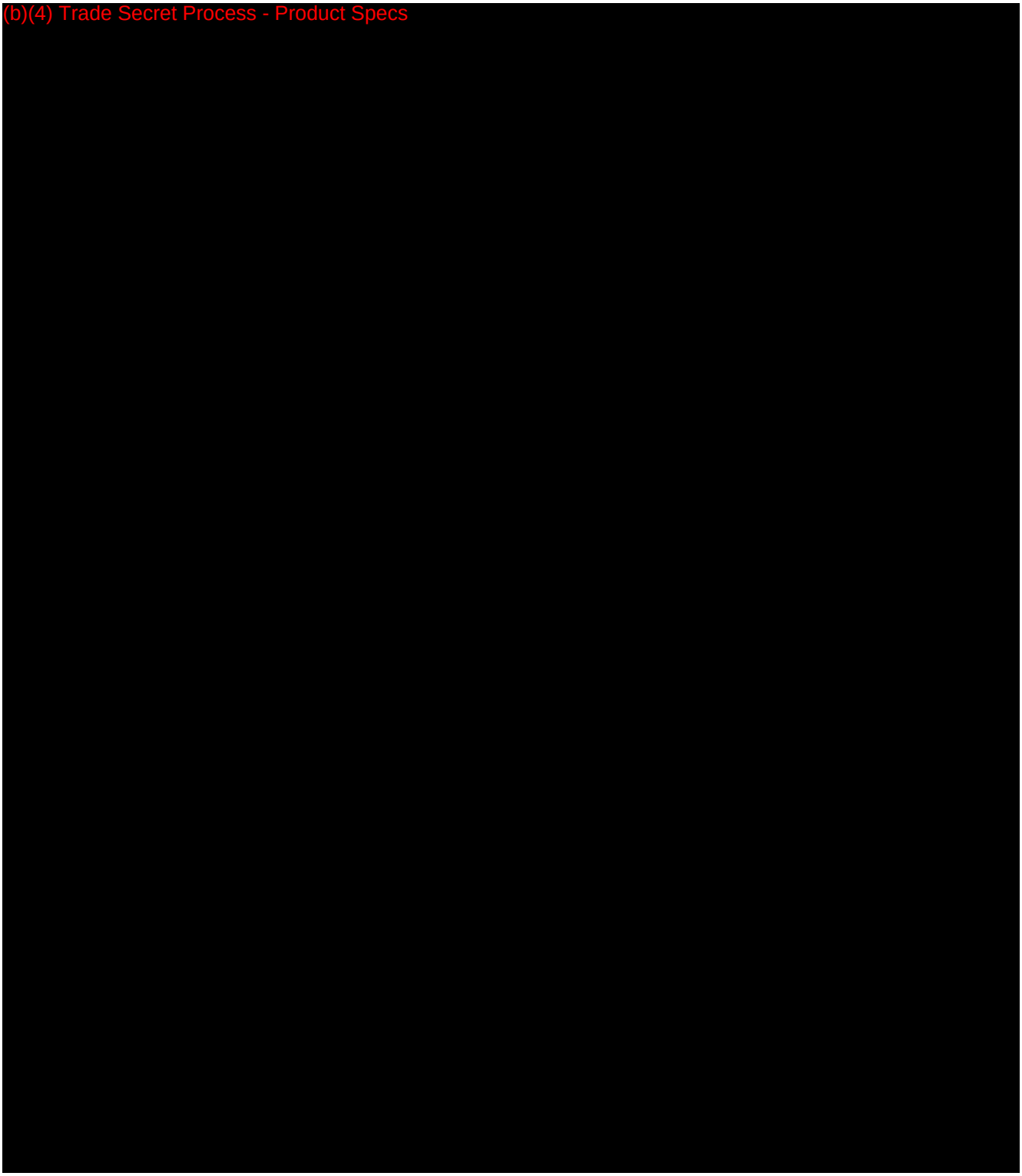
This section is not applicable as the subject devices have been determined to be Class II per 21 CFR 872.3630.

8 Financial Certification or Disclosure Statement

This section is not applicable as there is no clinical data being submitted to support this premarket notification.

9 Declarations of Conformity and Summary Reports

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process - Product Specs
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process - Product Specs

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process - Product Specs

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐
Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo), May 1, 1995		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to he device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certifica ion body involved in conformance assessment to his standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional informa ion which is necessary before FDA recognizes he standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) [redacted]		(b)(4) Trade Secret Process - Product Specs [redacted]
A.	Applicable recognized consensus standard:	
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process - Product Specs [redacted]

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process - Product Specs

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo), May 1, 1995

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process - Product Specs

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process - Product Specs
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process - Product Specs

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process - Product Specs

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#2-135	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
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Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo), May 1, 1995

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during he development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process - Product Specs

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process - Product Specs
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process - Product Specs

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process - Product Specs

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☐	☒
FDA Recognition number[3]	#____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo), May 1, 1995

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during he development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process - Product Specs

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process - Product Specs
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process - Product Specs

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process - Product Specs

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#8-63	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)?	☒	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?	☒	☐
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: ___		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during he development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

9.6 ISO 17664:2004

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process - Product Specs
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process - Product Specs

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process - Product Specs

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☐	☒
FDA Recognition number[3]	#____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)?	☒	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?	☒	☐
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: ___		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during he development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process - Product Specs

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process - Product Specs
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process - Product Specs

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process - Product Specs

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☒
FDA Recognition number[3]	#14-261	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: ___		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process - Product Specs

A.	Applicable recognized consensus standard:	(b)(4) Trade Secret Process - Product Specs
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process - Product Specs

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☐	☒
FDA Recognition number[3]	#____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)?	☒	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?	☐	☒
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance[6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: ___		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during he development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4) Trade Secret Process - Product Specs

A.	Applicable recognized consensus standard:	**ISO 14801:2007, Dentistry – Implants – Dynamic fatigue test for endosseous dental implants**
B.	Requirements met?	Yes
C.	Way(s) in which the standard may have been adapted (such as change in test method):	No change
D.	Requirements that were not applicable to the device:	N/A
E.	Deviations from each applicable standard that were met including justification:	N/A
F.	Differences exist, if any, between the tested device to be marketed:	No
G.	Test laboratory:	(b)(4) Trade Secret Process - Product Specs

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE[1]

(b)(4) Trade Secret Process - Product Specs

Please answer the following questions	Yes	No
Is this standard recognized by FDA[2]?	☒	☐
FDA Recognition number[3]	#4-195	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance[6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for Industry and FDA Staff 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseious Dental Implant Abutments', May 12, 2004

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during he development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

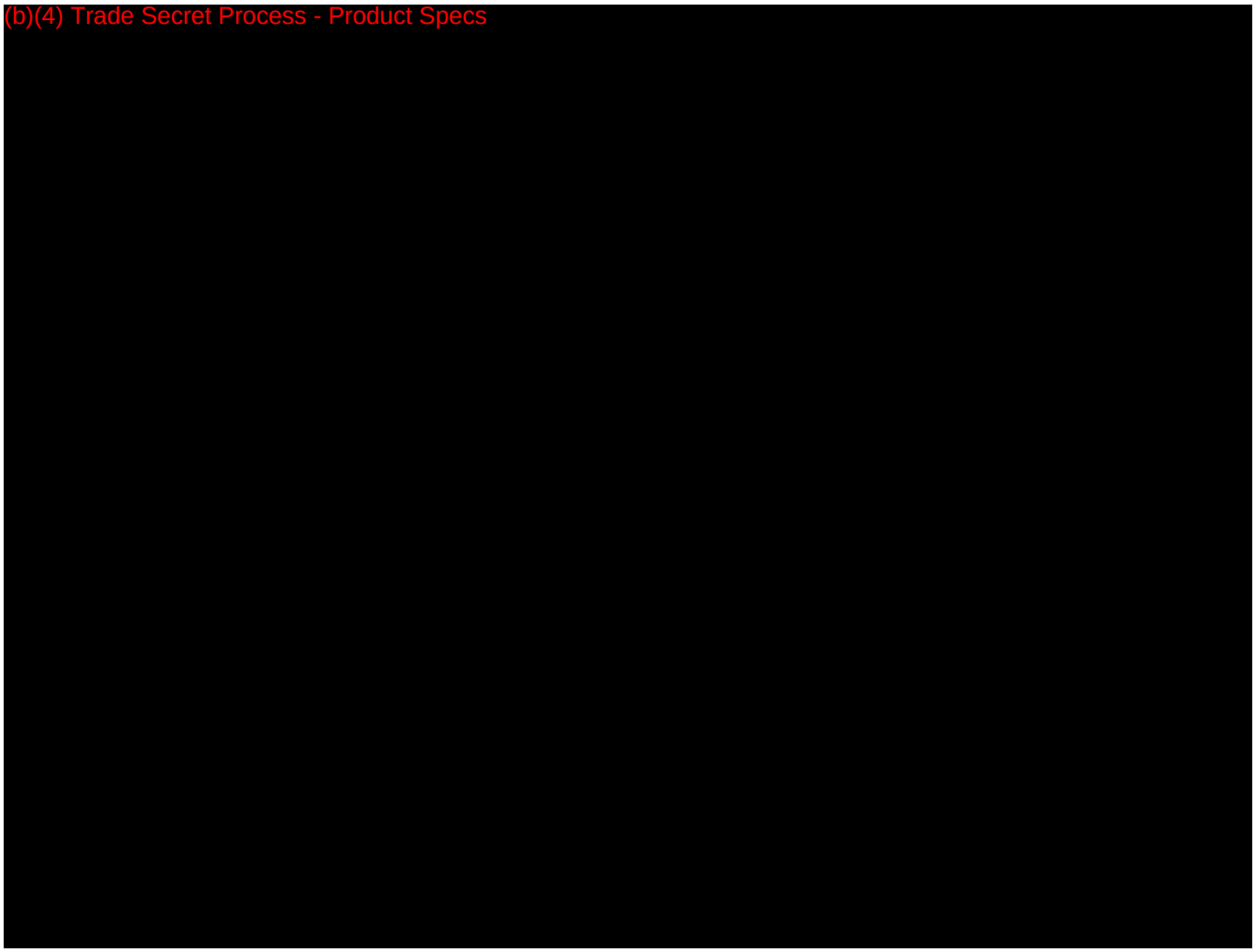
[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

10 Device Description

The modification proposed in this premarket notification is to the Indications for Use for the previously cleared Straumann® CARES® Variobase™ Abutments for NNC, RN, WN, NC, and RC (K120822). The modified Indications for Use would allow Straumann to market the Straumann® Variobase™ Abutment as a stand-alone component. The dental laboratory would then manufacture the respective coping (the second component of the Variobase two-piece abutment) and/or prosthetic restoration via their preferred workflow of pressing, casting, or in-lab milling using a burnout coping or STL model for open CAD software.

10.1 Straumann® Variobase™ Abutments

(b)(4) Trade Secret Process - Product Specs

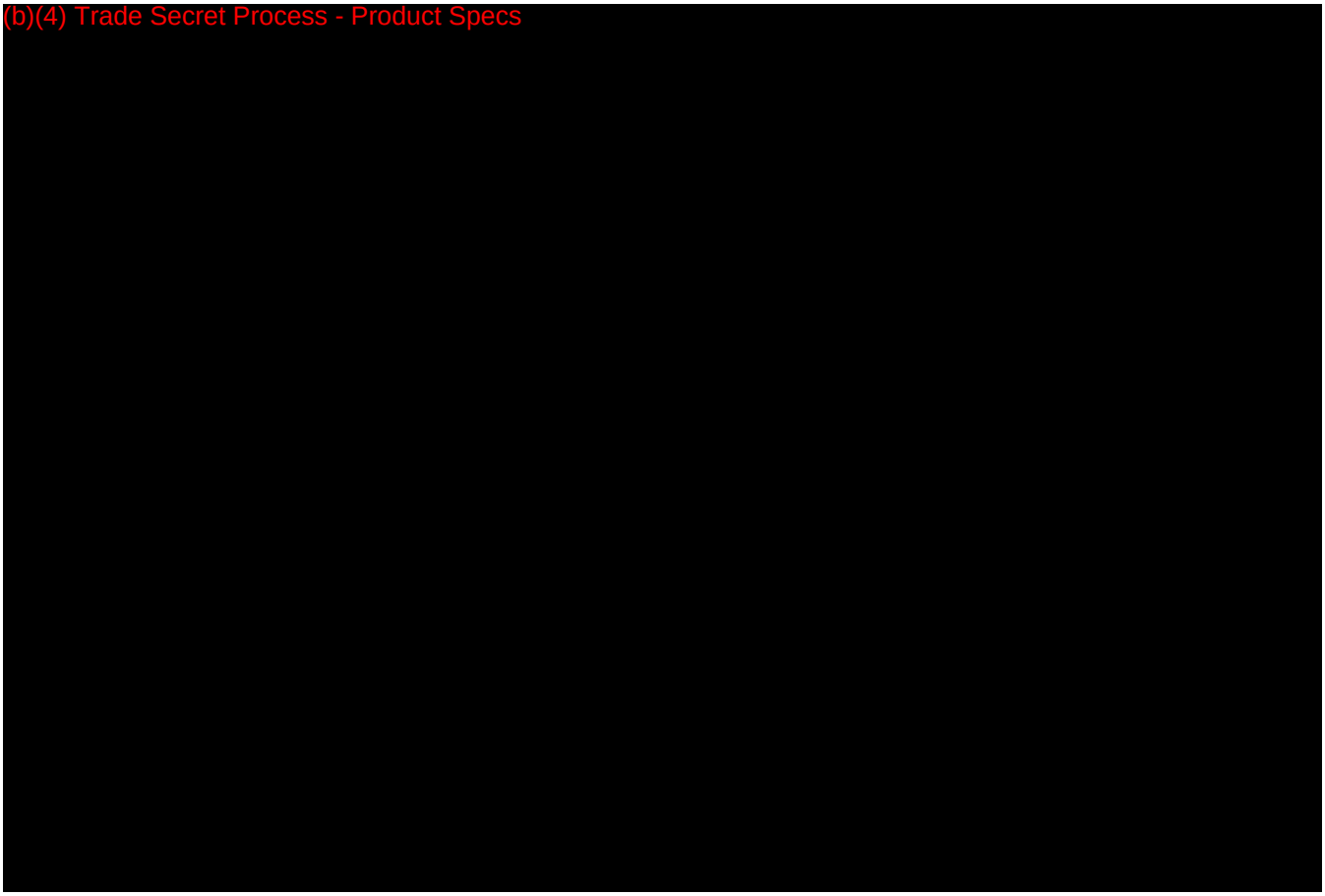


Traditional 510(k) Submission

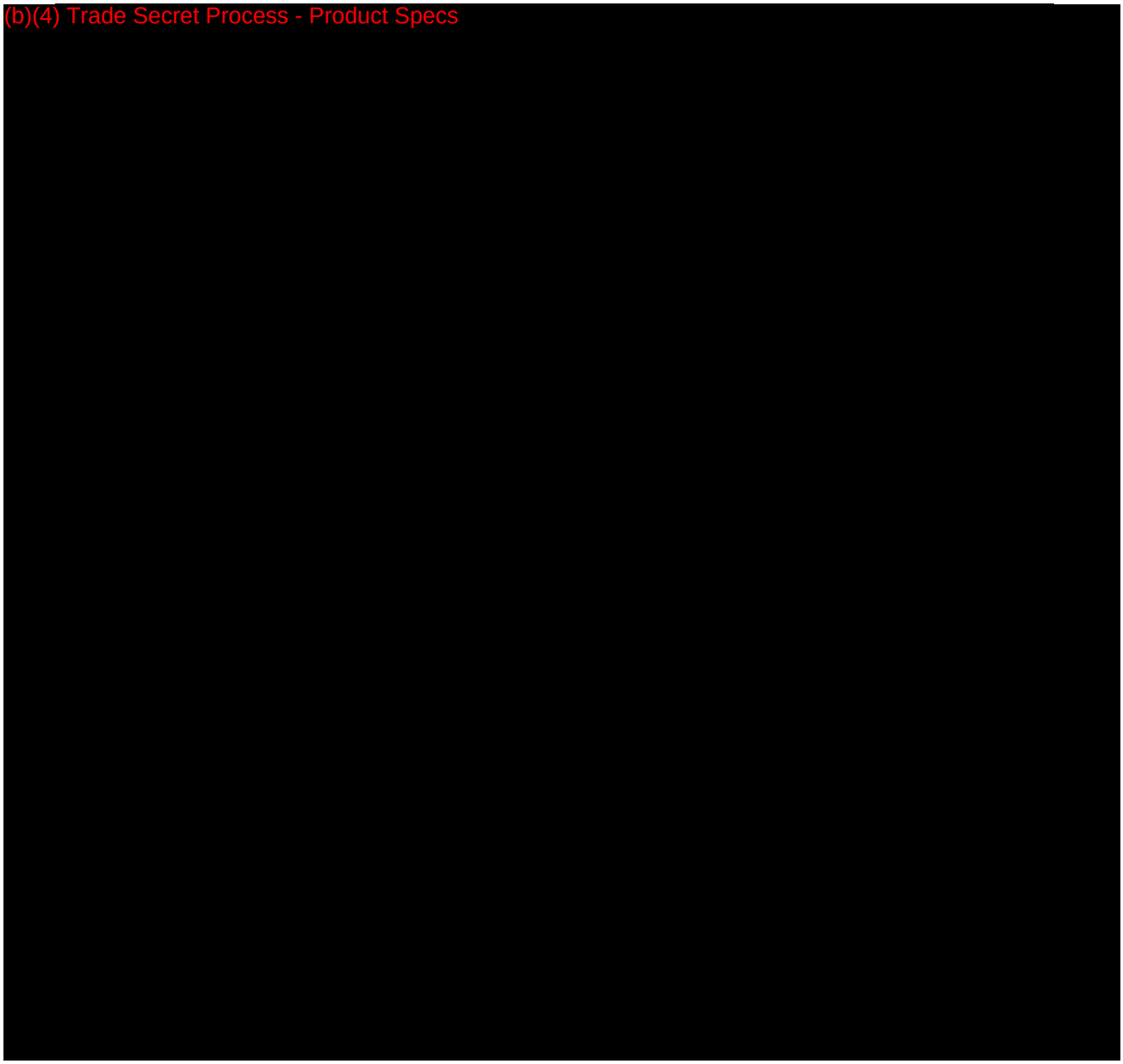
Straumann® Variobase™ Abutments

Device Description

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



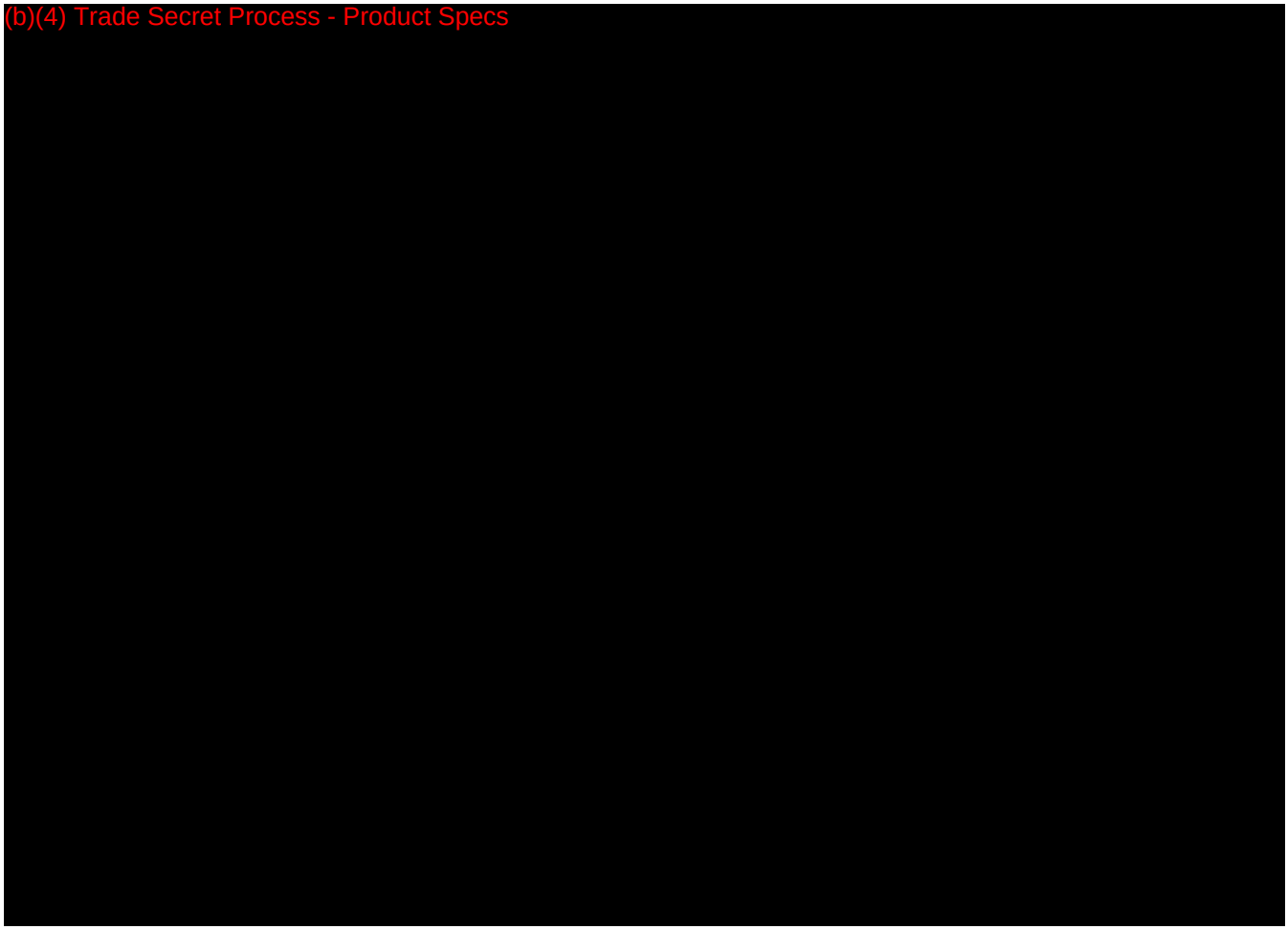
10.2 Basal Screws

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

10.3 Accessories

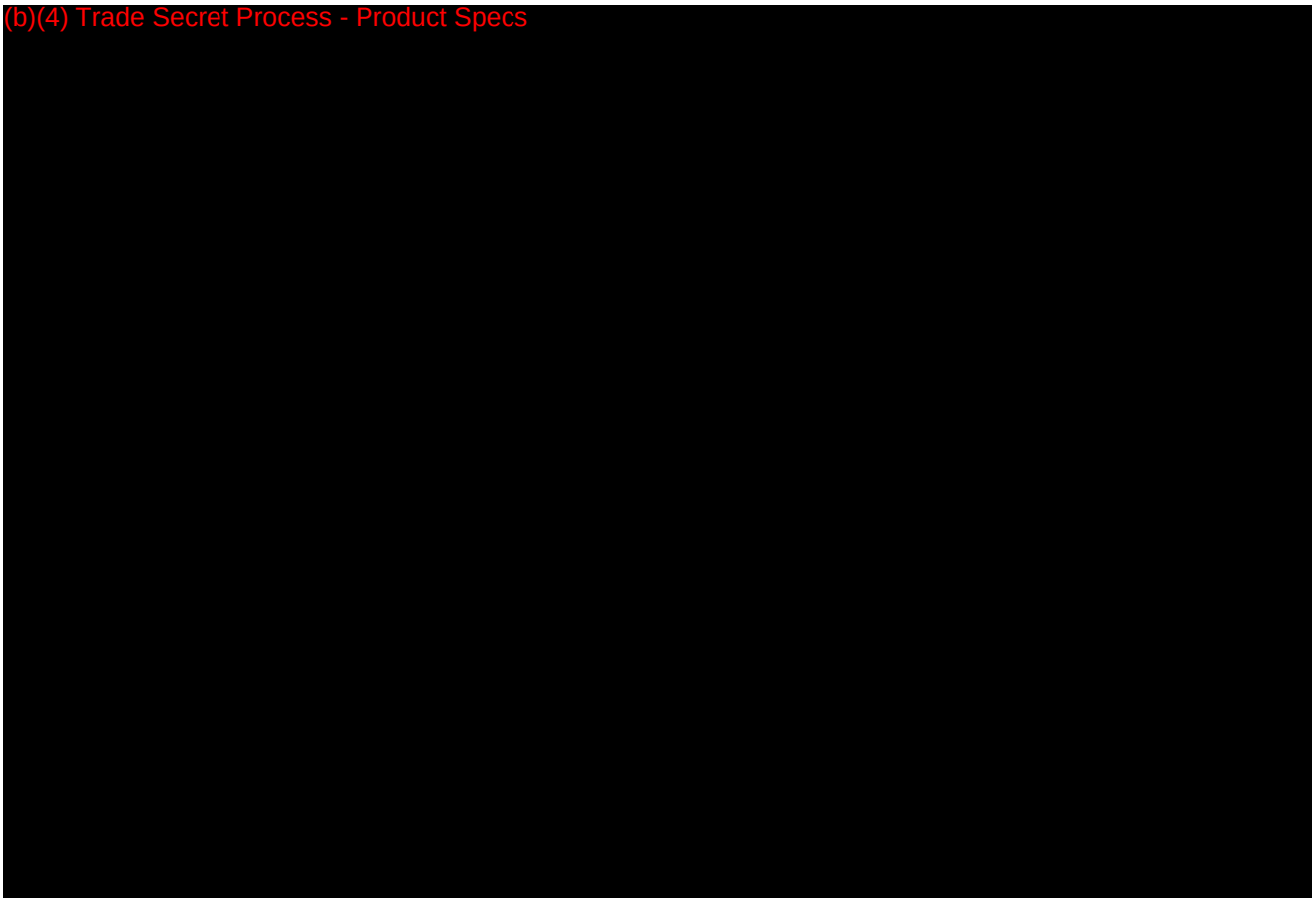
(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

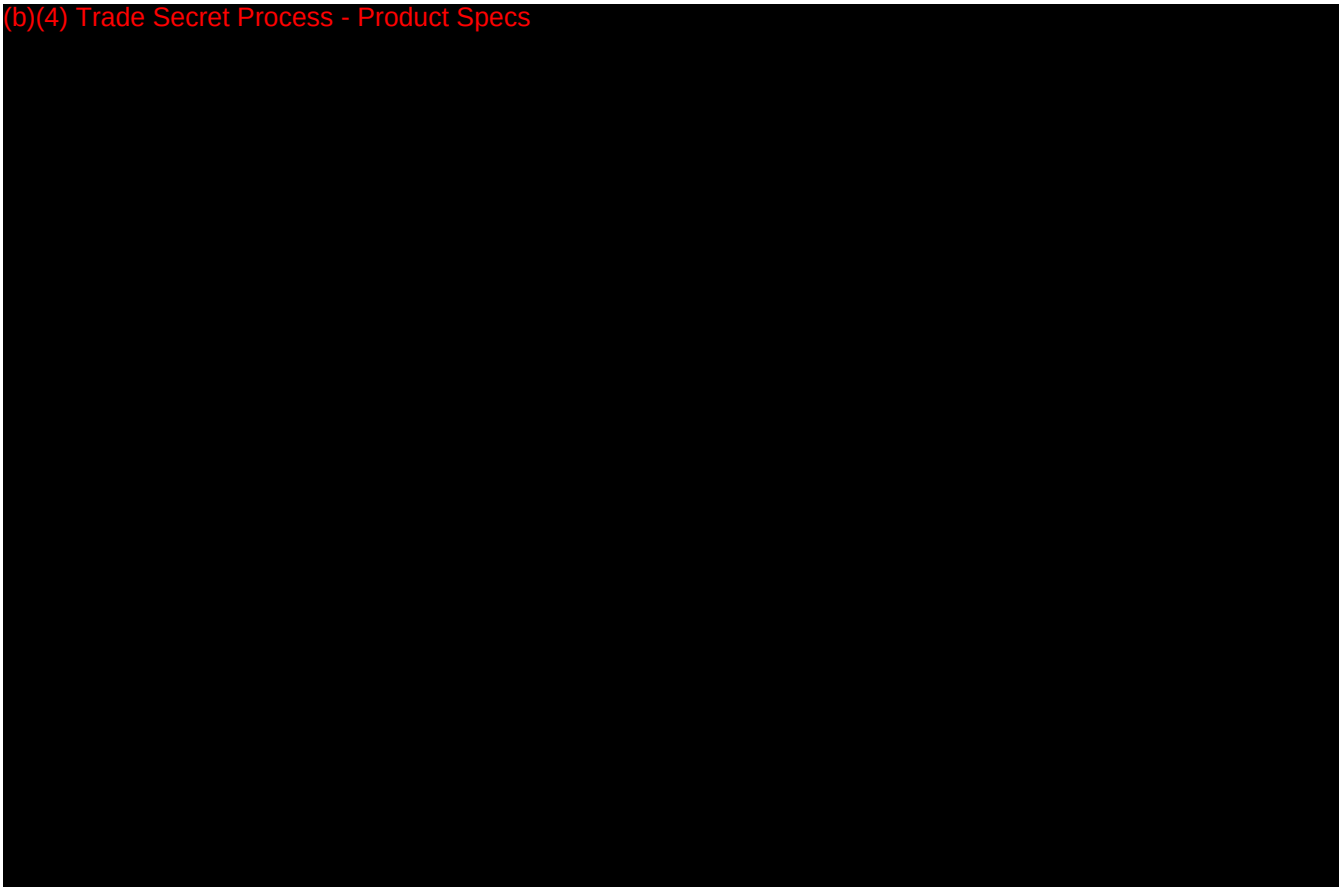
10.4 Procedure

(b)(4) Trade Secret Process - Product Specs



Device Description

(b)(4) Trade Secret Process - Product Specs



11 Substantial Equivalence Discussion

Within the meaning of the Medical Device Amendments Act of 1976, the proposed change to the Indications for Use for the Straumann® Variobase™ Abutments in this 510(k) premarket notification are substantially equivalent to the medical devices currently in commercial distribution listed below:

- K120822, Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC
- K111935, Ti-Base Abutment (NT-Trading GmbH & Co. KG)

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments intended to be placed onto Straumann dental implants to provide support for customized prosthetic reconstructions such as crowns and bridges. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

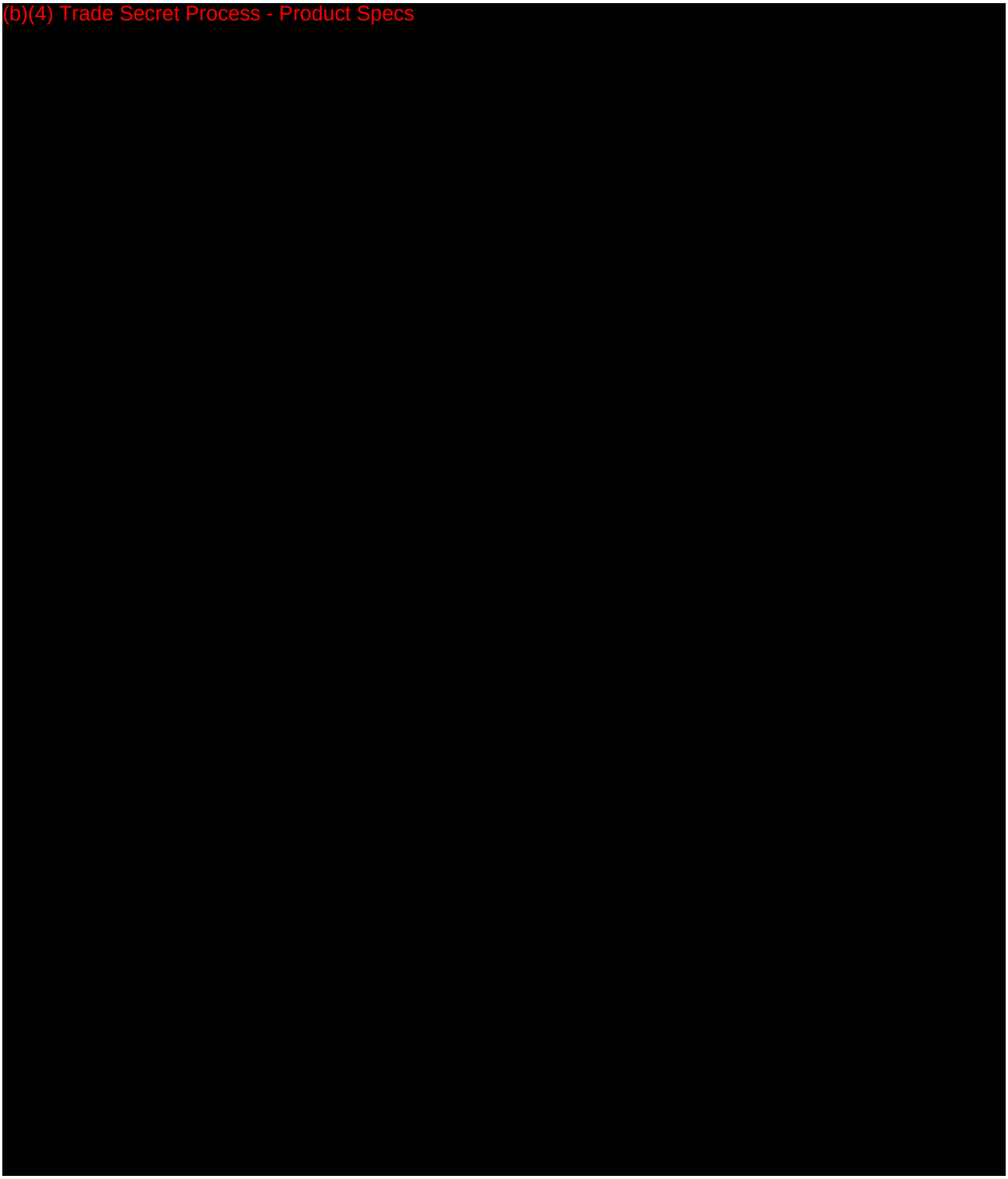
The NT-Trading Ti-Base Abutment is a pre-manufactured abutment supplied in two parts, the abutment and screw, for fixation onto dedicated endosseous dental implants and is intended for use as an aid in prosthetic restoration. As with the subject device, the coping/restoration is provided by the dental laboratory. The Ti-Base is compatible with commercially available dental CAD/CAM systems, such as 3Shape, Exocad, and Dental Wings. Such systems must be validated by the user.

The NT-Trading catalog and package insert are included in this submission in Appendices 3 and 4, respectively. The products that were cleared in premarket notification K111935 are outlined in Table 7 (the 510(k) Summary is included in Appendix 5). Specifically, the L-Series and N-Series abutments are compatible with implants of the Straumann Dental Implant System as shown in Table 7.

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs



Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

The table below provides a comparison matrix of the proposed and predicate devices (K120822):

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Straumann® CARES® Variobase™ Abutments (K120822)**	
Indications for Use	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.	The Straumann® CARES® Variobase™ Abutment is a two-piece dental abutment consisting of the Straumann® Variobase™ Abutment and the Straumann® CARES® Variobase™ Coping which is intended to be placed onto Straumann dental implants to provide support for prosthetic reconstruction such as crown and bridges. Straumann® CARES® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. The Straumann® CARES® Variobase™ Coping polycon® ae in combination with the Straumann® CARES® Variobase™ Abutment is indicated for temporary (up to 180 days) dental restoration of a Straumann dental implant.	The indications for use are being modified to allow Straumann to market the Straumann® Variobase™ Abutment as a stand-alone component. The dental laboratory would then manufacture the respective coping and/or prosthetic restoration using a burnout coping or STL model for open CAD software.
Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Identical
Abutment Diameter	(b)(4) Trade Secret Process - Product Specs	(b)(4) Trade S t	Identical
Abutment Height	(b)(4) Trade Secret Process - Product Specs	(b)(4) Trade S t	Identical

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Straumann® CARES® Variobase™ Abutments (K120822)**	
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Identical
Reusable	No	No	Identical

Table 8 - Comparison Matrix: Proposed Device versus Predicate Devices (K120822)

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

The table below provides a comparison matrix of the proposed and predicate devices (K111935):

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Ti-Base Abutment (K111935)**	
Indications for Use	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.	Ti-Base for individual Zirconium Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base for individual Zirconium Abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Nobel Biocare NobelActive™ • Biomet 3i® Osseotite® • Biomet 3i® Osseotite® Certain® • Nobel Biocare Branemark® • Straumann® synOcta® • Straumann® Bone Level® • Zimmer® Tapered Screw-vent® • Astra Tech OsseoSpeed® • Dentsply-Friadent® Frialit®	Equivalent – Both the subject and predicate devices are designed to interface with the Straumann Bone Level or the Straumann Tissue Level implants.

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

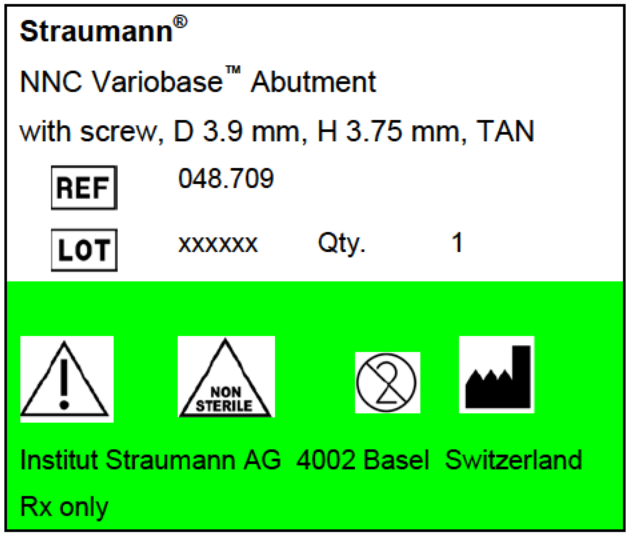
FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Ti-Base Abutment (K111935)**	
Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V)	Equivalent
Abutment Diameter	(b)(4) Trade S t	(b)(4) Trade S t	Equivalent
Abutment Height	(b)(4) Trade S t	(b)(4) T d	Equivalent
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Identical
Reusable	No	No	Identical

Table 9 - Comparison Matrix: Proposed Device versus Predicate Devices (K111935)

12 Proposed Labeling

12.1 Package Label

There are no changes to the package label as a result of the proposed change in this premarket notification. To aid in the review of the submission, an example of the label is shown in Figure 1.



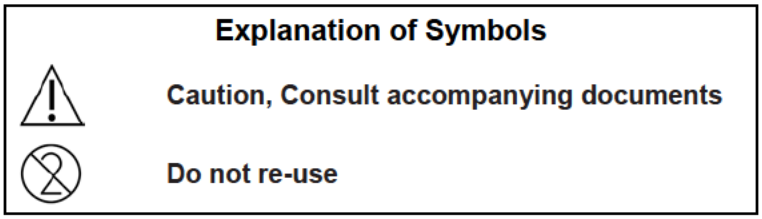


Figure 1 - Example label for Straumann® Variobase™ Abutment

12.2 Proposed Package Insert/Instructions for Use for Straumann® Variobase™ Abutments

Instructions for use: Straumann® Variobase™ Abutments

Institut Straumann AG, Peter-Merian-Weg 12, CH-4002 Basel/Switzerland, www.straumann.com

English

CAUTION: Federal law restricts this device to sale by or on the order of a dental professional.

Straumann® Variobase™ Abutments				
				
NNC	RN	WN	NC	RC

1. Product Description

Abutments

Abutments are placed into dental implants to provide support for prosthetic reconstructions such as crowns and bridges.

Basal Screws

Basal screws are used for the fixation of the abutment to the dental implant.

2. Intended use

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

3. Indications

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

4. Contraindications

Allergies or hypersensitivity to materials used, which are indicated in the following table:

Straumann Variobase™ Abutments, Screws	Titanium alloy, Ti-6Al-7Nb (titanium-aluminum-niobium or TAN).

5. Warnings and Precaution

Our products must be secured against aspiration when used intraorally. Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications:

- Aspiration or swallowing of a component
- Breakage
- Infection

The Straumann® Variobase™ Abutments are single use devices.

Place implant-borne restorations only in occlusion when the implant is completely osseointegrated.

Angled abutments should not be used in areas of high mechanical loads on small diameter implants.

Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer.

Implants are only to be restored with the corresponding original abutment compatible with that specific implant.

The Straumann® Variobase™ Abutments have not been evaluated for safety and compatibility in the magnetic resonance environment. The Straumann® Variobase™ Abutments have not been tested for heating or migration in the magnetic resonance environment.

6. Compatibility information

Straumann® implants and the prosthetic components are available in a variety of configurations to meet your clinical needs. The label on each product uses abbreviations to help you identify whether a particular abutment or coping is compatible with the implant that you are restoring. The implant as well as the prosthetic component contains an identifier for the connection type, summarized in the table below.

Implant connection type	Compatible prostheses
NC (Narrow CrossFit®)	parts labeled NC
RC (Regular CrossFit®)	parts labeled RC
NNC (Narrow Neck CrossFit®)	parts labeled NNC
RN (Regular Neck)	parts labeled RN
WN (Wide Neck)	parts labeled WN

7. Cleaning and Disinfection

Straumann® Variobase™ Abutments and components are non-sterile when delivered. Before placing the restoration in the patient's mouth, the product must be cleaned, disinfected and sterilized. Straumann recommends the following procedure for cleaning, disinfection and sterilization of abutments prior to use.

1) Clean rinsing under flowing water while brushing outer and inner side with adequate brushes.

2) The pre-treated product is to be cleaned/disinfected in an automated washer disinfector. Select the appropriate program according to the manufacturer’s instructions.

8. Sterilization

The restoration may be sterilized unwrapped or can be placed in an accessory cassette and packaged twice in common sterilization wraps (paper/film bags). Steam sterilize according to the parameters below:

Material	Method	Conditions
Variobase™ Abutment, TAN Screw, TAN	Autoclave (moist heat) Displacement: gravity or fractionated vacuum	134 °C (273 °F) 5 minutes

Please note: User should ensure the use of the appropriate biological indicator for the sterilizer and parameters used.

Please note: User should consult the coping/restoration material manufacturer's recommendations regarding sterilization.

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

9. Procedure

Use and handling of the Straumann® Variobase™ Abutments for the Dental Technician

Restoration design

Make a coping or crown following standard procedure according to the material manufacturer's instructions. When using pressing or casting techniques via wax-up, use the burn-out coping for Variobase™ Abutments which supports a clean and sharp-edged finish of the screw channel and a good fit to the Straumann® Variobase™ Abutment. When using a digital workflow, use the Straumann Variobase Implant Kit with any software platform, to facilitate the precise design of the interface between the Straumann® Variobase™ Abutment and the coping. The kit consists of an STL file containing the required milling template for the inner coping geometry.

Please note: The following framework wall thickness guidelines must be followed:

For ceramic materials a framework wall thickness ≥ 0.4 mm

For polymer materials a framework wall thickness ≥ 0.5 mm

Please note: The materials used to fabricate the coping must have a flexural strength between 91.5 MPa and 1007 MPa.

Processing

Process the coping or crown following standard procedure according to the material manufacturer's instructions. Always finalize the crown or coping prior to bonding to the Straumann® Variobase™ Abutments.

Bonding

Please note: It is not necessary to sandblast the Straumann® Variobase™ Abutment.

1) Fix the abutment to the implant analog with a screw (hand-tight).

2) Seal the screw channel with wax.

3) Apply self-adhesive dental cement on the abutment. Only suitable self-adhesive cementation systems for the material used shall be used. Follow the instructions for use of both the dental material and cement/bonding material manufacturer. (Straumann® recommends Panavia™ F2.0 resin cement by Kuraray)

4) Bond the coping to the abutment.

5) Immediately remove excess cement from the abutment and polish the lower margin of the coping after the cement is set.

6) Optional: For cement retained-restorations: Make a crown following standard procedure according to the material manufacturer's instructions and finalize it.

7) Clean the restoration prior to sending it to the dentist.

8) Include this instruction for use when sending the restoration to the dentist.

Use and handling of the Straumann® Variobase™ Abutments for the Dentist

Remove the restoration from the master cast or the analog.

Clean, disinfect and sterilize the device as described in sections 7 and 8 of this Instructions for Use document.

Placing the restoration

a) Remove the healing cap or temporary restoration.

b) Clean and dry the interior of the implant and the abutment thoroughly.

c) Place the sterilized restoration into the patient's mouth.

d) Make sure that the retentive elements of the implant abutment connection are properly aligned.

e) Use the screw delivered with the abutment to screw the abutment into the dental implant.

Please note: Always ensure that the surfaces of threads and screw heads are clean and that a new screw is used for the restoration.

f) Straumann® abutments are fixed to the implant using the Straumann® SCS screwdriver, ratchet and torque control device. Use the respective torque according to the table below:

Device type	Tightening torque	Special considerations
Abutments (permanent)	35 Ncm	n/a
Temporary abutments	15 – 35 Ncm	Tighten only to 35 Ncm if the implant is fully osseointegrated
Components on implant analogs	Hand-tight	n/a

For cement-retained restorations (optional):

g) Close the screw channel with cotton and sealing compound (i.e., gutta-percha)

h) Apply self-adhesive dental cement on the two-piece abutment. Only suitable self-adhesive cementation systems for the used materials shall be used. Follow the instructions for use of the cement/bonding material manufacturer (Straumann recommends Panavia™ F2.0 resin cement by Kuraray).

i) Bond the crown to the two-piece abutment.

j) Immediately remove excess cement from the two-piece abutment.

Warning

Torques greater than 35 Ncm may result in failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

Please note

Once the Straumann® abutment has been secured to the implant using the indicated torque, it should not be removed.

10. Further Information

For additional information about the use of Straumann® products, call Straumann's customer service department or visit www.straumann.com.

For additional information, consult:

Basic information on the Straumann® Variobase™ Abutment

11. Please note

Practitioners must have appropriate knowledge and instruction in the handling of the Straumann product described herein ("Straumann Product") for using the Straumann Product safely and properly in accordance with these instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Product is part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Institut Straumann AG, its ultimate parent company and all affiliates or subsidiaries of such parent company ("Straumann"), except if stated otherwise in these instructions for use. If use of products made by third parties is not recommended by Straumann in these instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann.

12. Validity

Upon publication of these instructions for use, all previous versions are superseded.

Availability

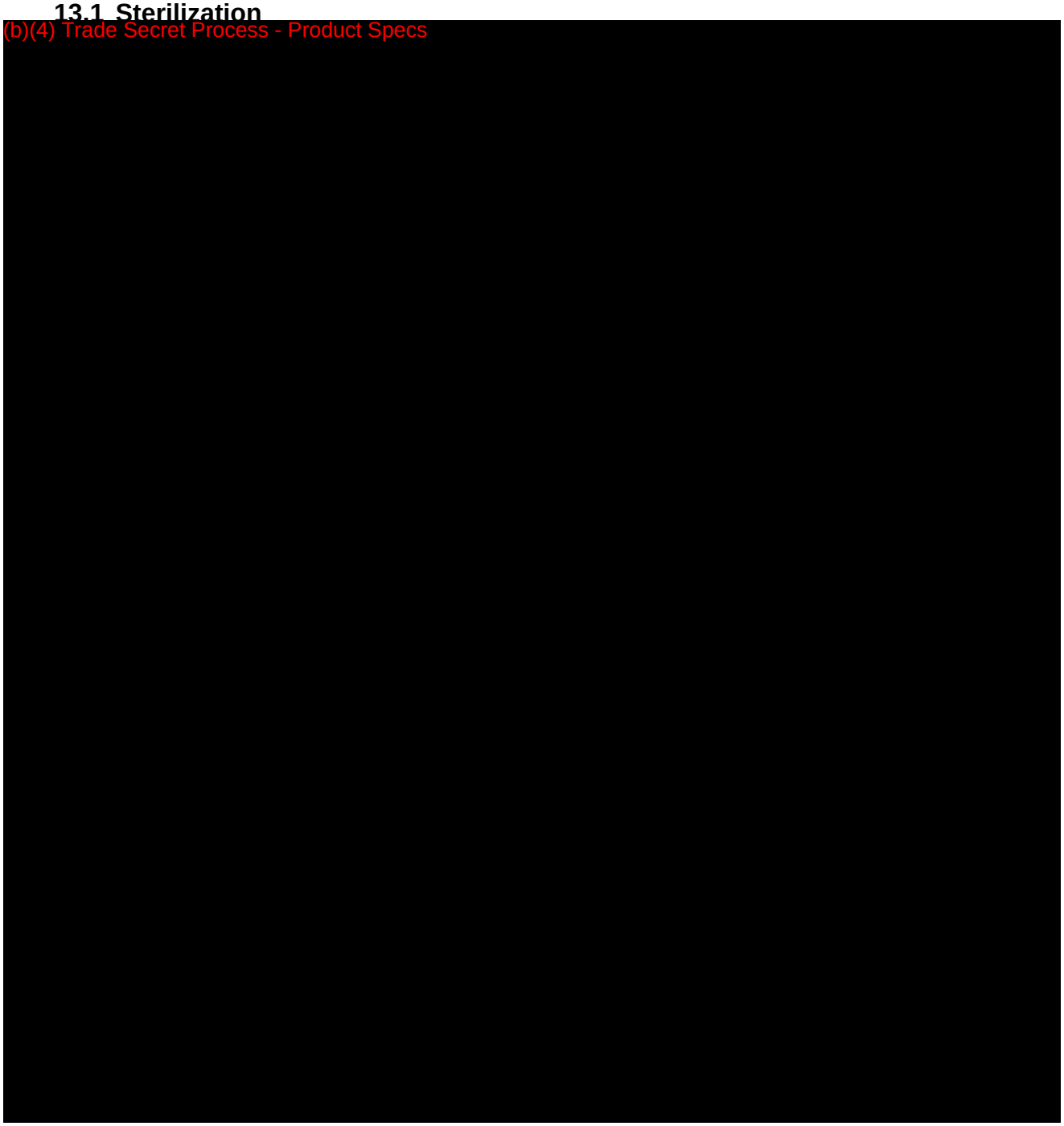
Some items of the Straumann® Dental Implant System are not available in all countries.

CE 0123	Straumann Products with the CE mark fulfill the requirements of the Medical Devices Directive 93/42 EEC /
	Refer to package insert
	Manufacturer
REF	Article number
LOT	Lot Number
	Do not re-use
	Non-sterile
Rx only	Federal law restricts this device to sale by or on the order of a dental professional.

13 Sterilization and Shelf Life

13.1 Sterilization

(b)(4) Trade Secret Process - Product Specs

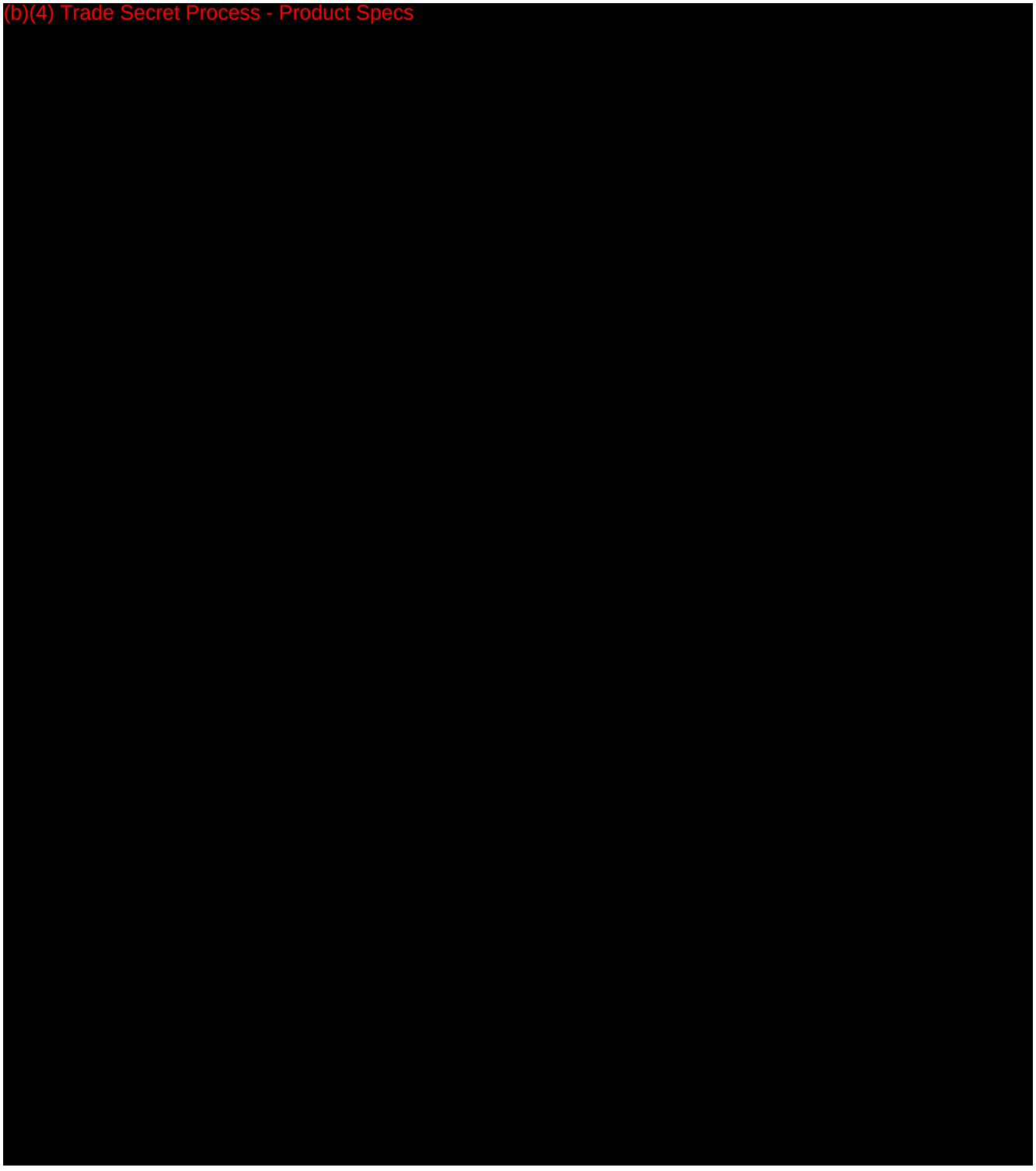


Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Sterilization and Shelf Life

(b)(4) Trade Secret Process - Product Specs



13.2 Shelf Life

(b)(4) Trade Secret Process - Product Specs

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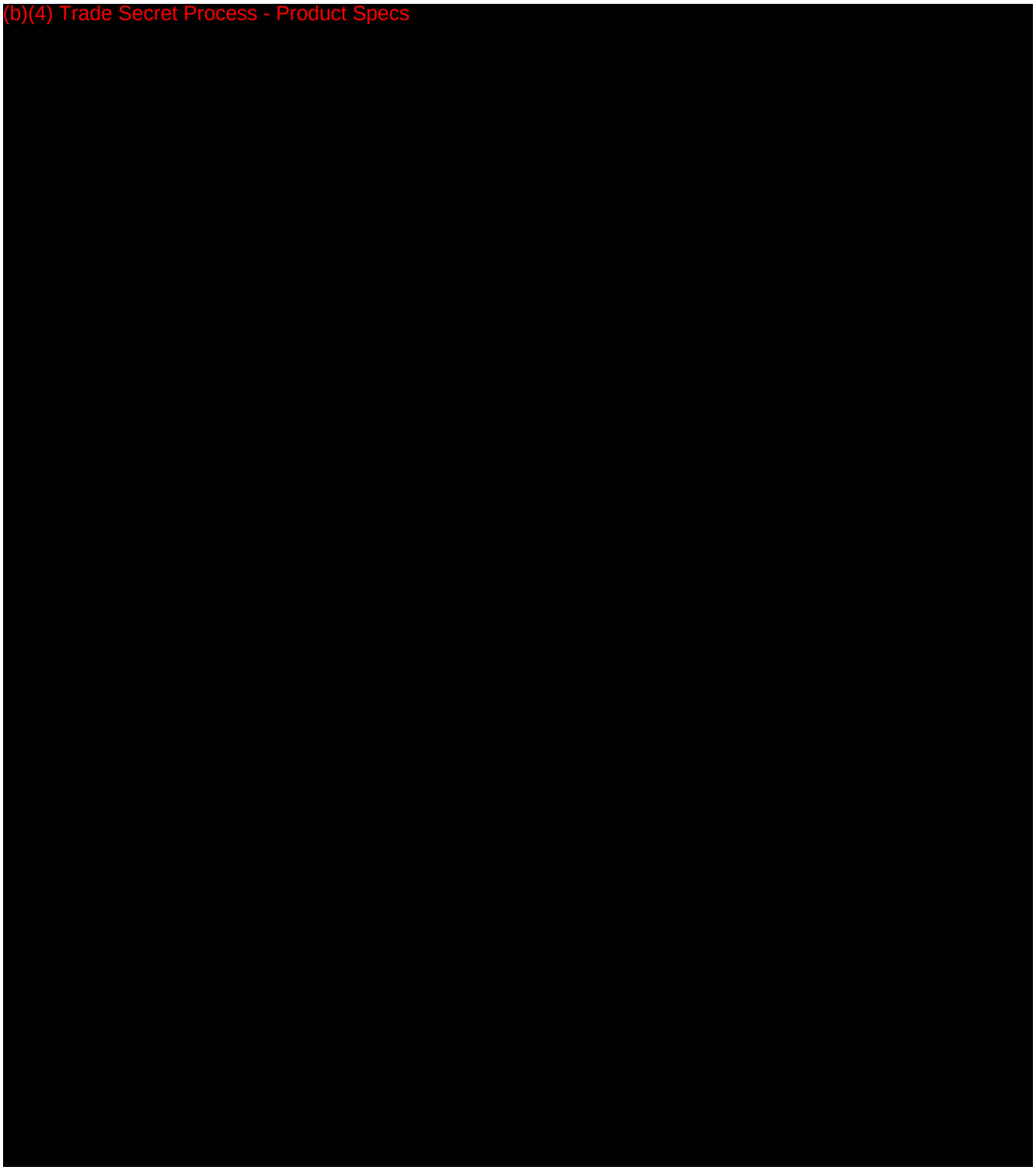
13.3 Packaging

(b)(4) Trade Secret Process - Product Specs

[redacted]

14 Biocompatibility

(b)(4) Trade Secret Process - Product Specs



Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Biocompatibility

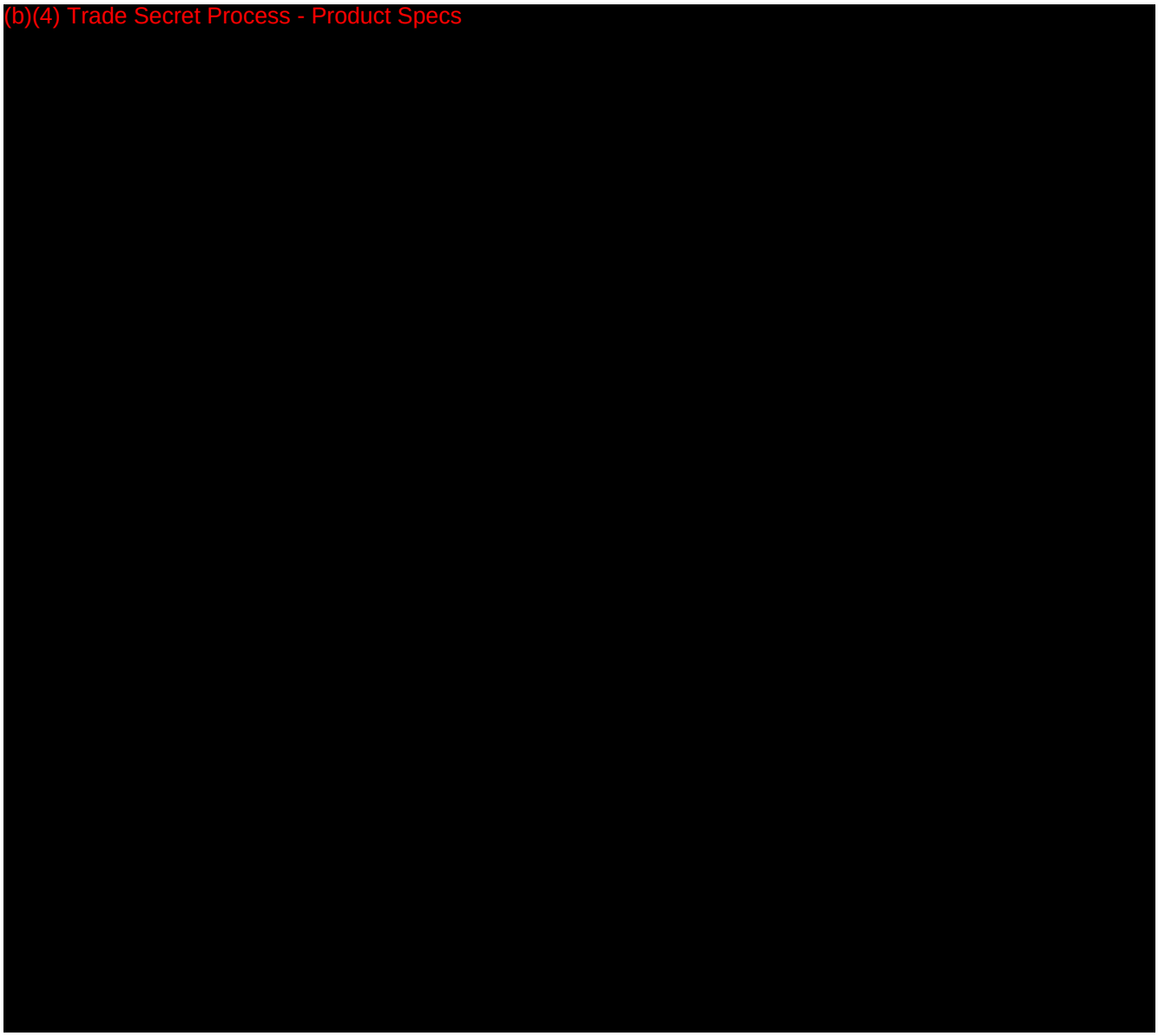
(b)(4) Trade Secret Process - Product Specs

15 Software

Software requirements do not apply to Straumann® Variobase™ Abutments and basal screws because these are standard stock products that do not contain software. The elements of the Straumann predicate device (K120822) that are designed using the referenced CAD software are the zirconia copings. These copings are not included in the subject submission. Therefore, this section is not applicable as the proposed change does not contain and is not dependent on the use of software.

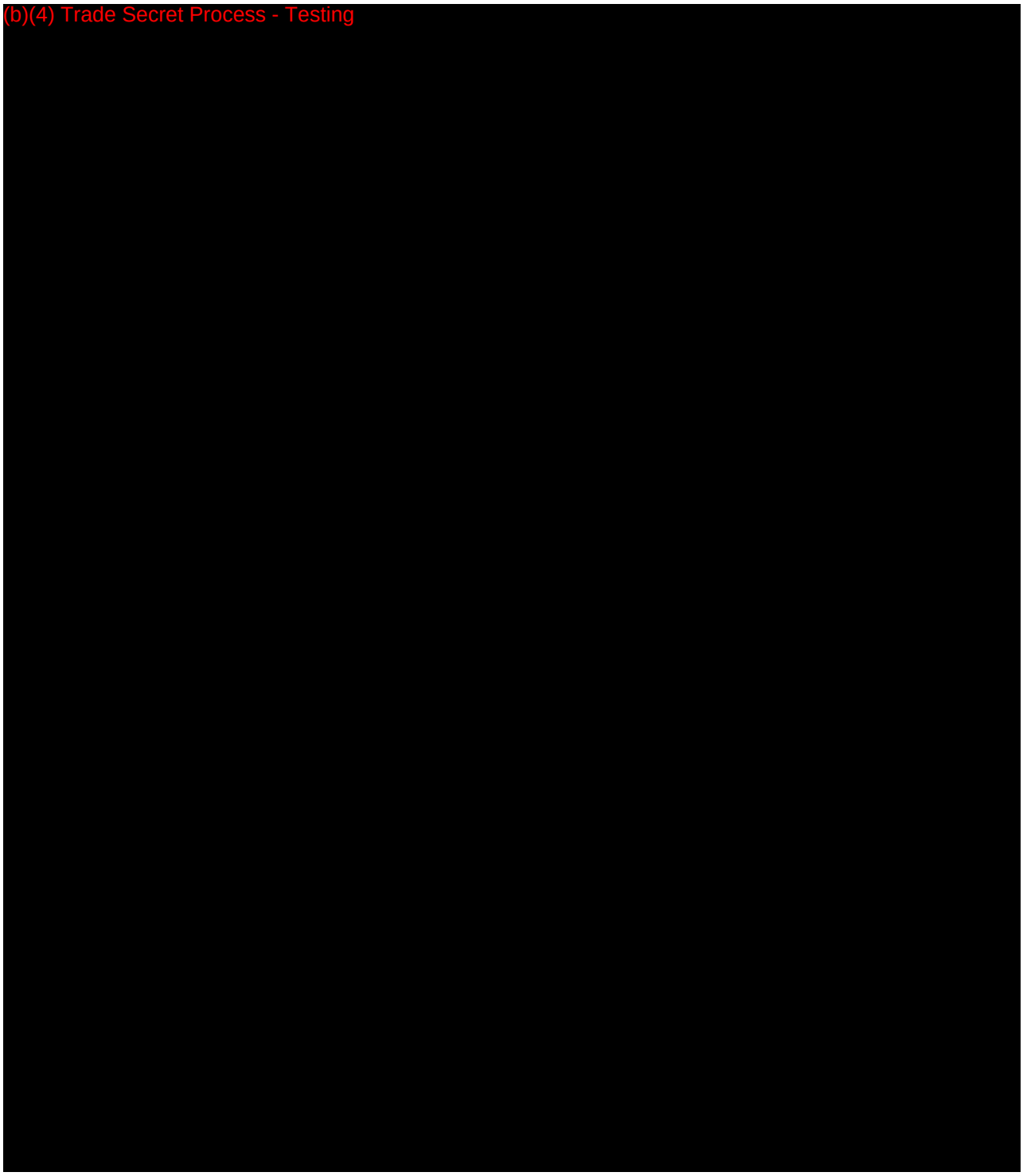
16 Electromagnetic Compatibility and Electrical Safety

(b)(4) Trade Secret Process - Product Specs



17 Performance Testing – Bench

(b)(4) Trade Secret Process - Testing

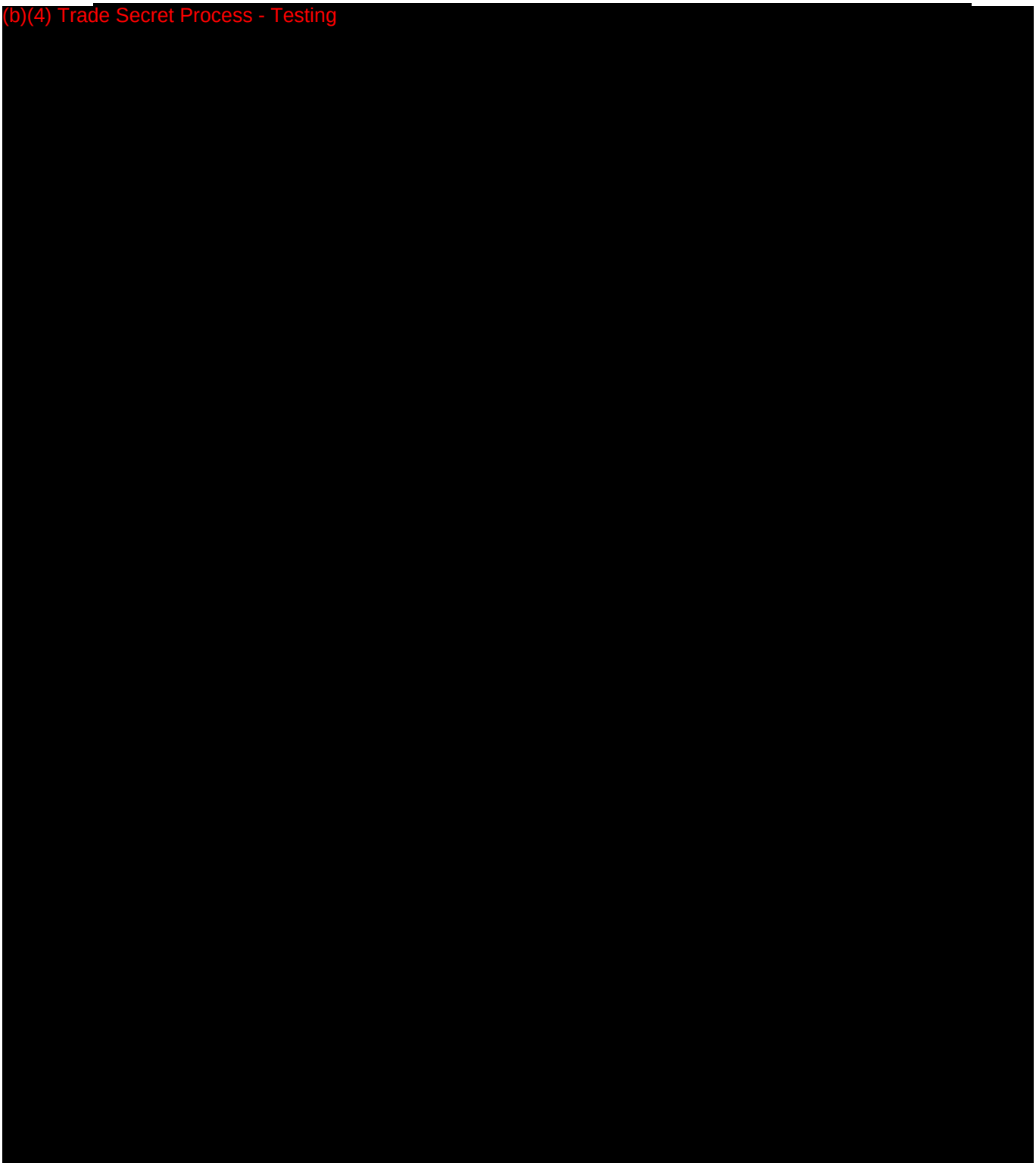


Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Performance Testing – Bench

(b)(4) Trade Secret Process - Testing



Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Performance Testing – Bench

(b)(4) Trade Secret Process - Testing

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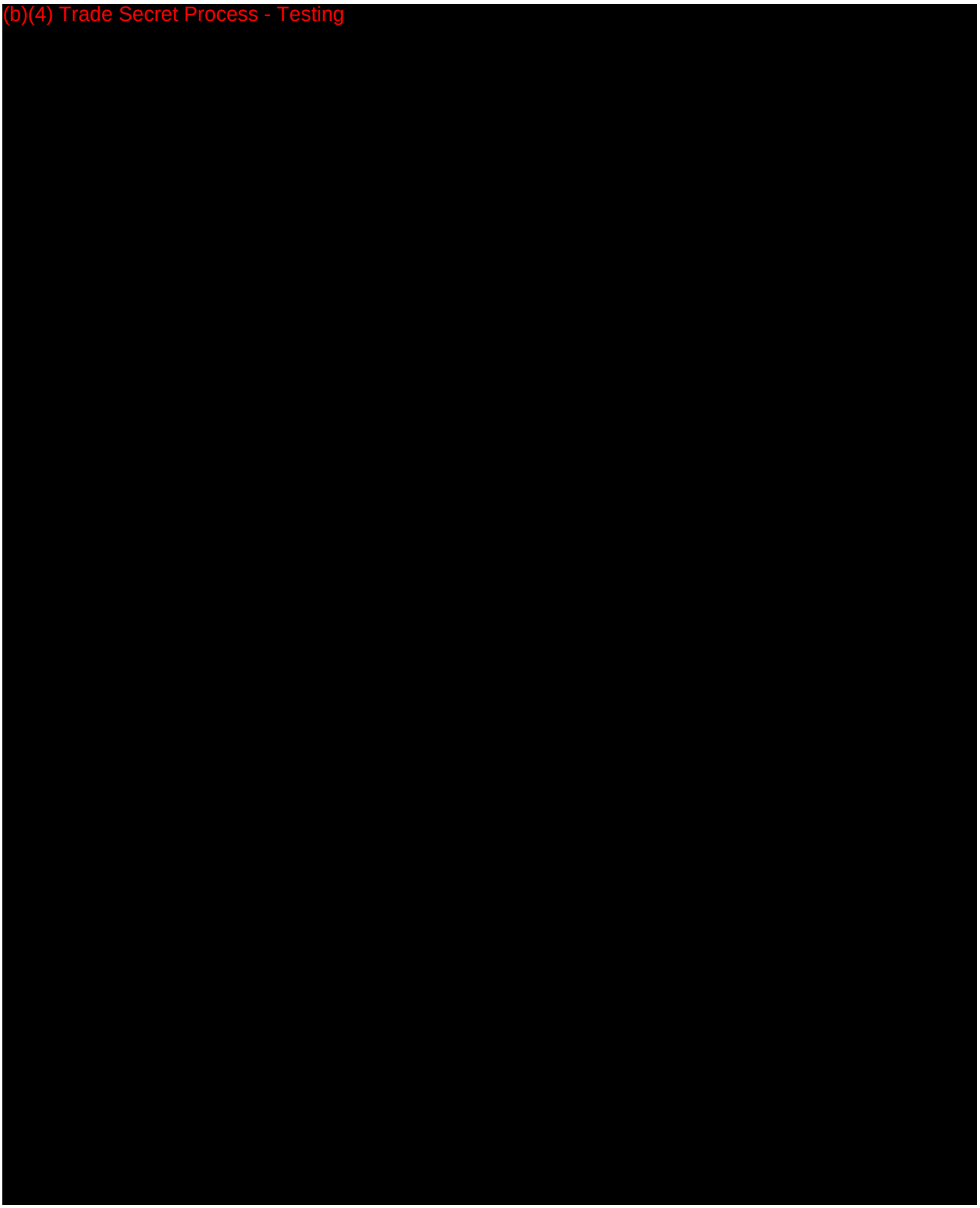
Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Performance Testing – Bench

(b)(4) Trade Secret Process - Testing

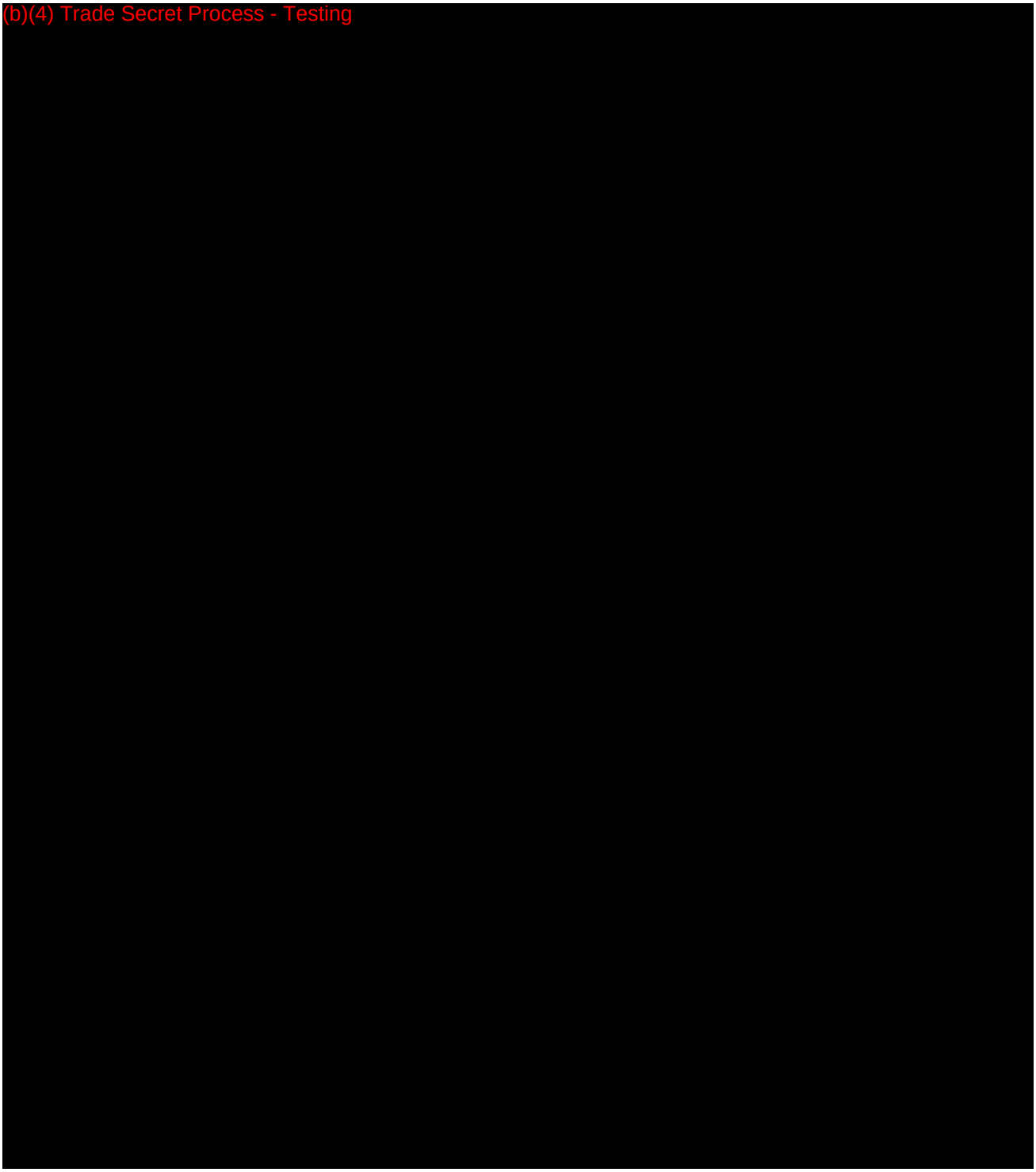


Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Performance Testing – Bench

(b)(4) Trade Secret Process - Testing



Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Performance Testing – Bench

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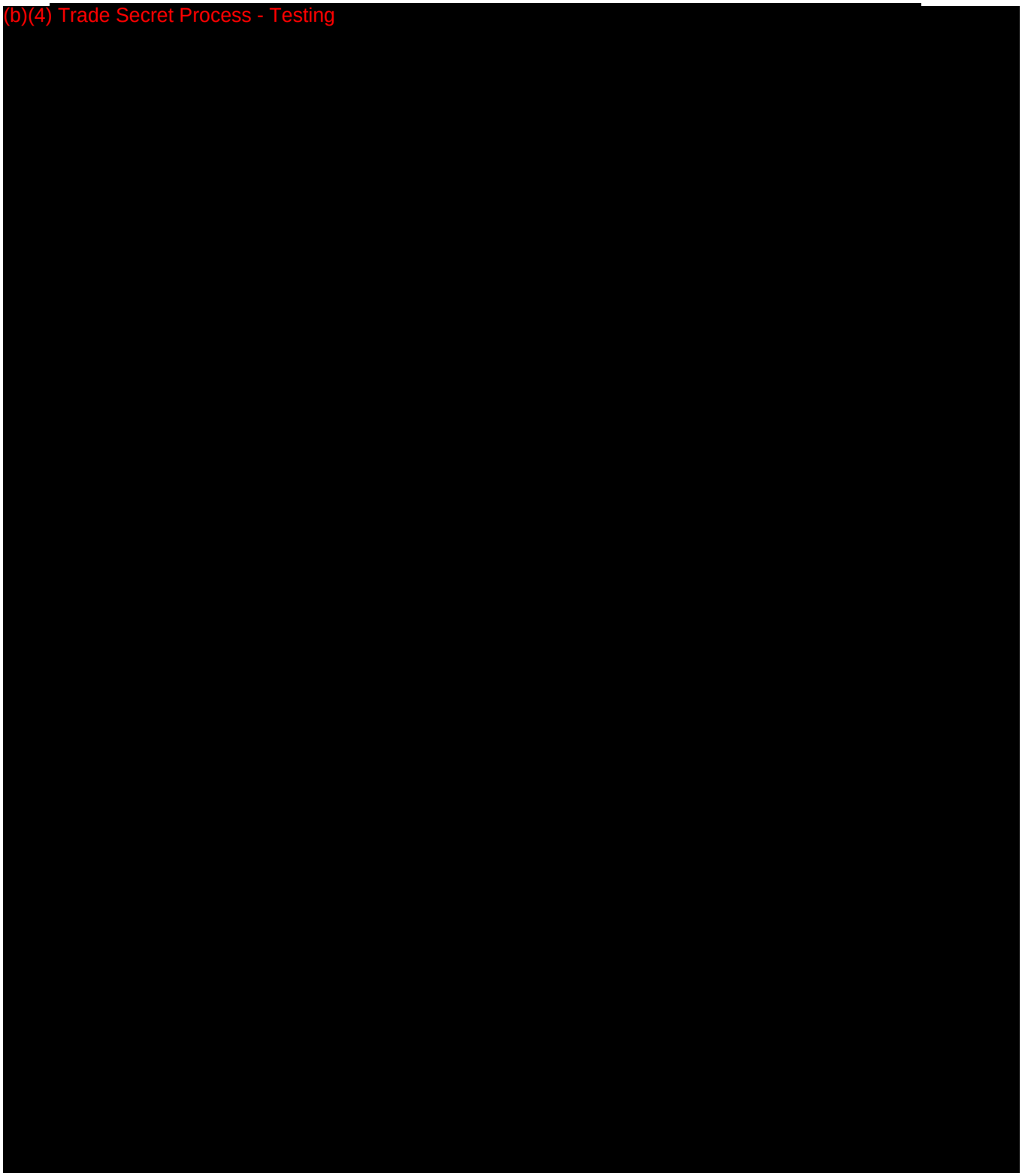

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Performance Testing – Bench

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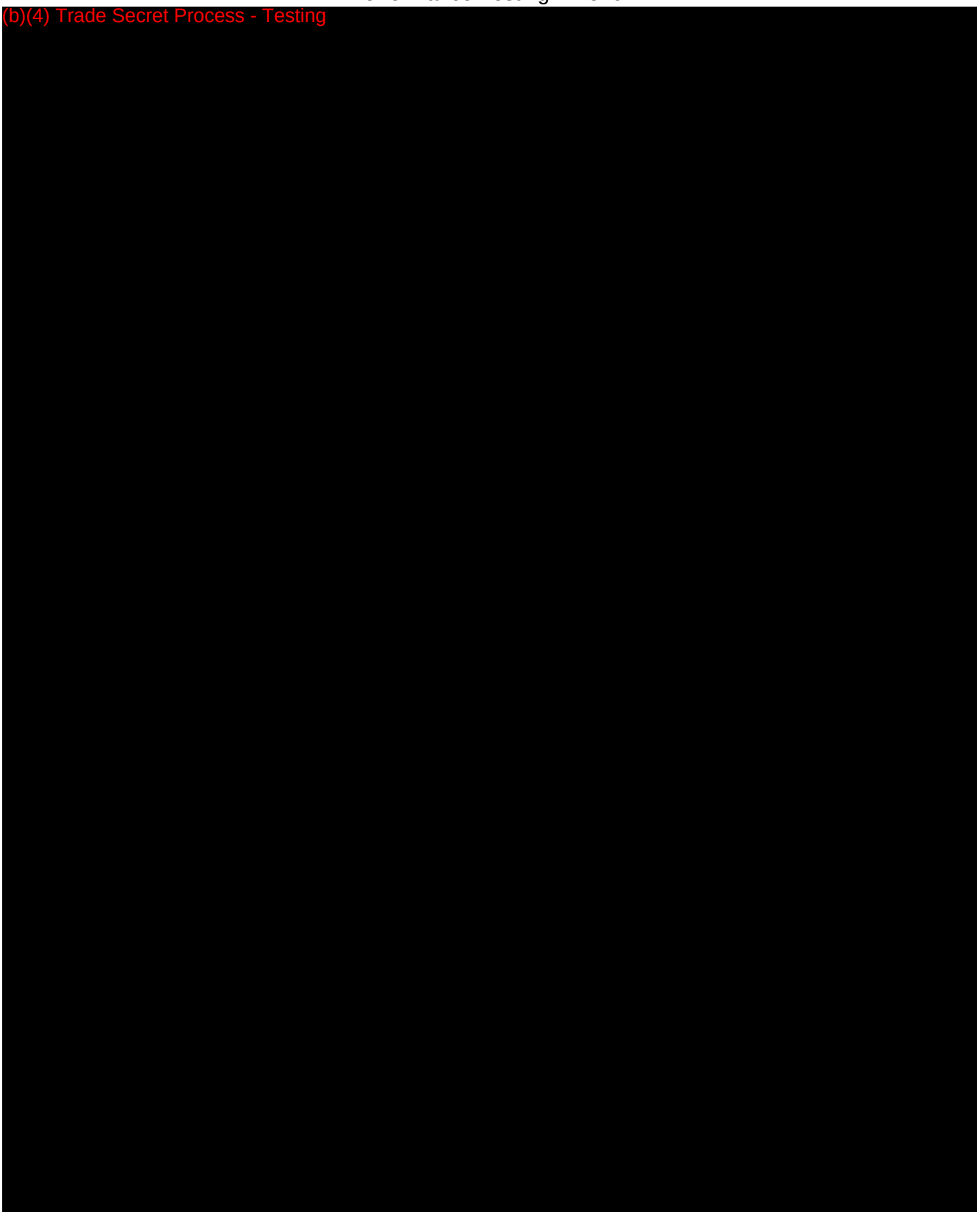
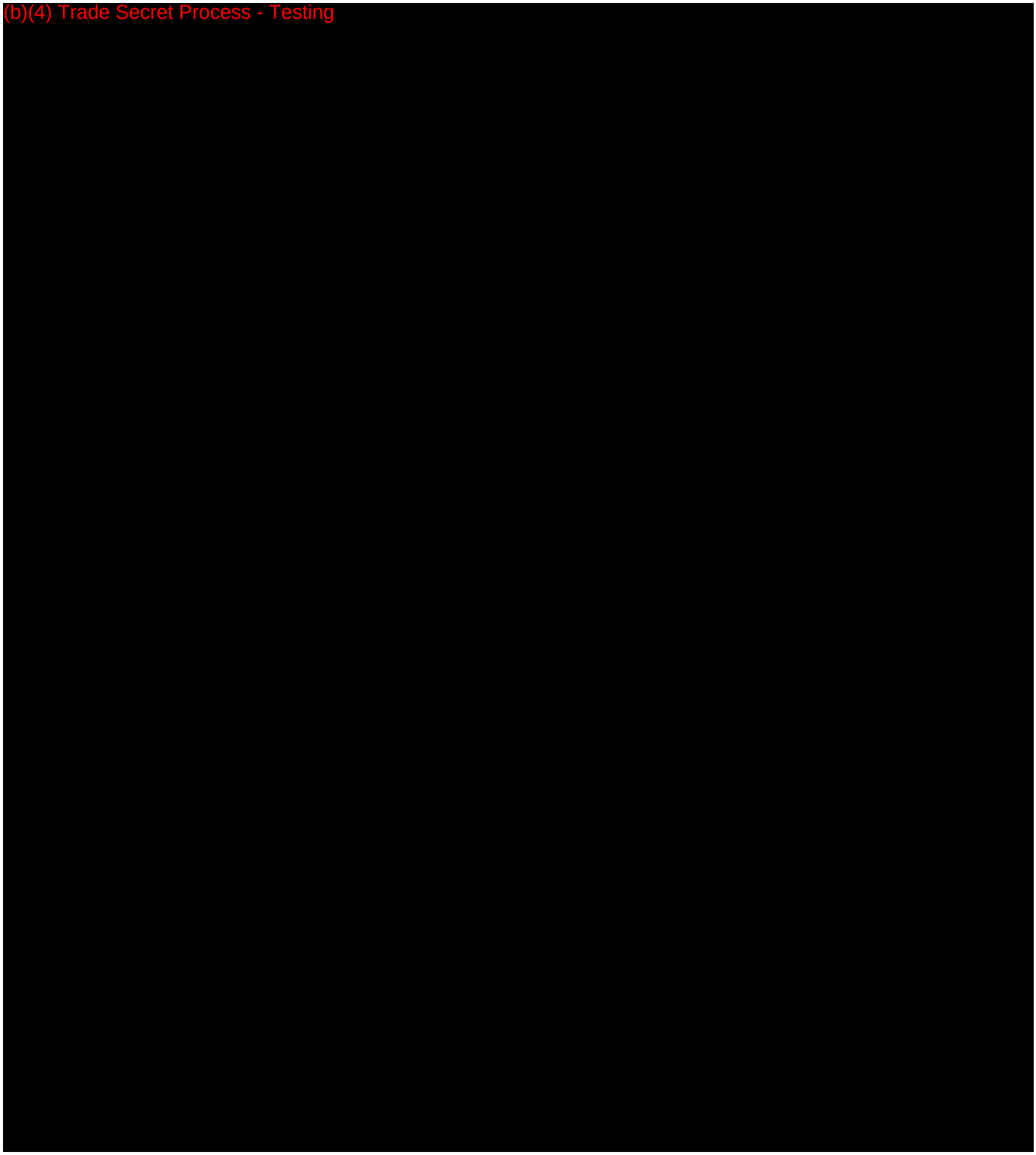


Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Performance Testing – Bench

(b)(4) Trade Secret Process - Testing



Performance Testing – Bench

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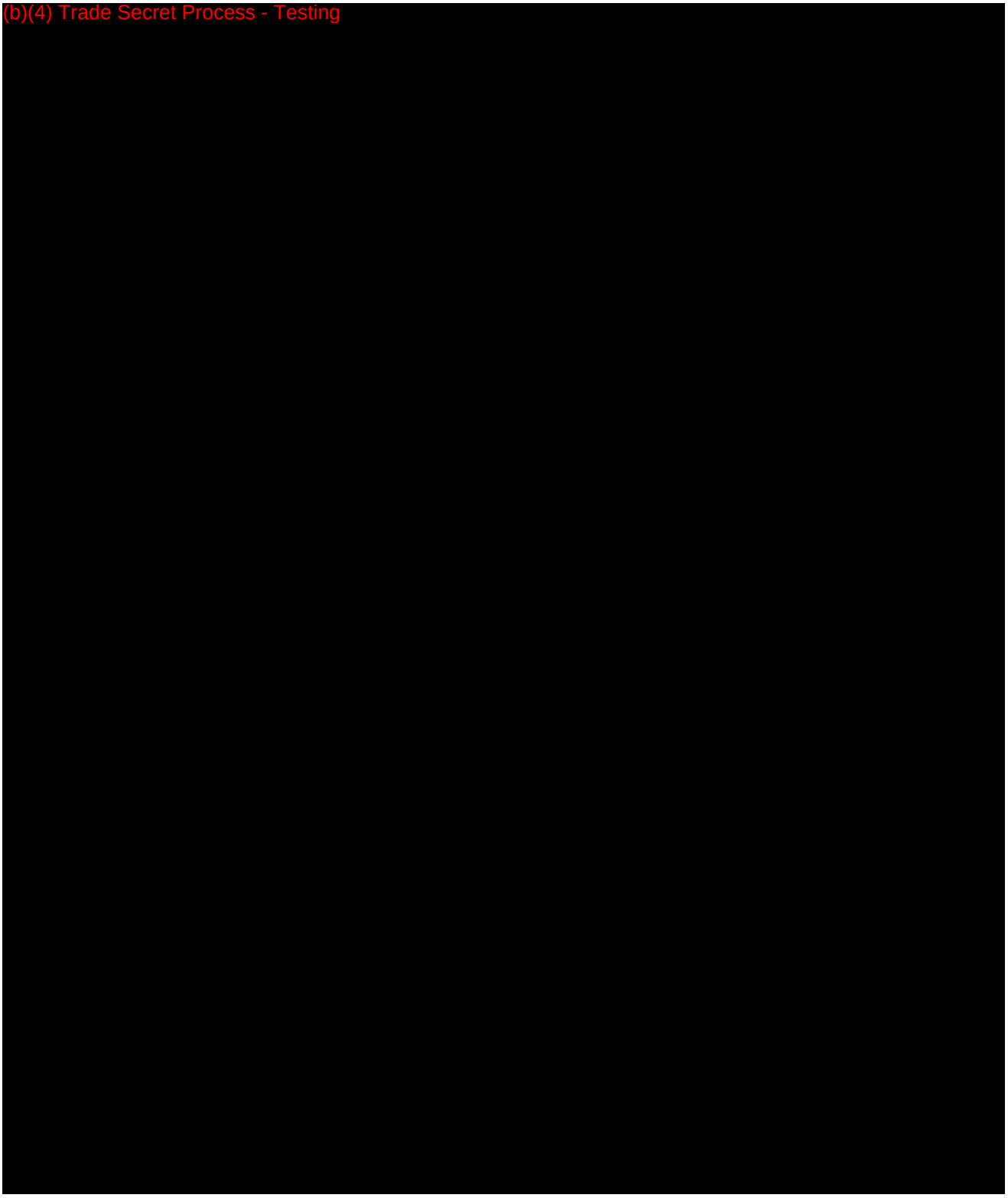
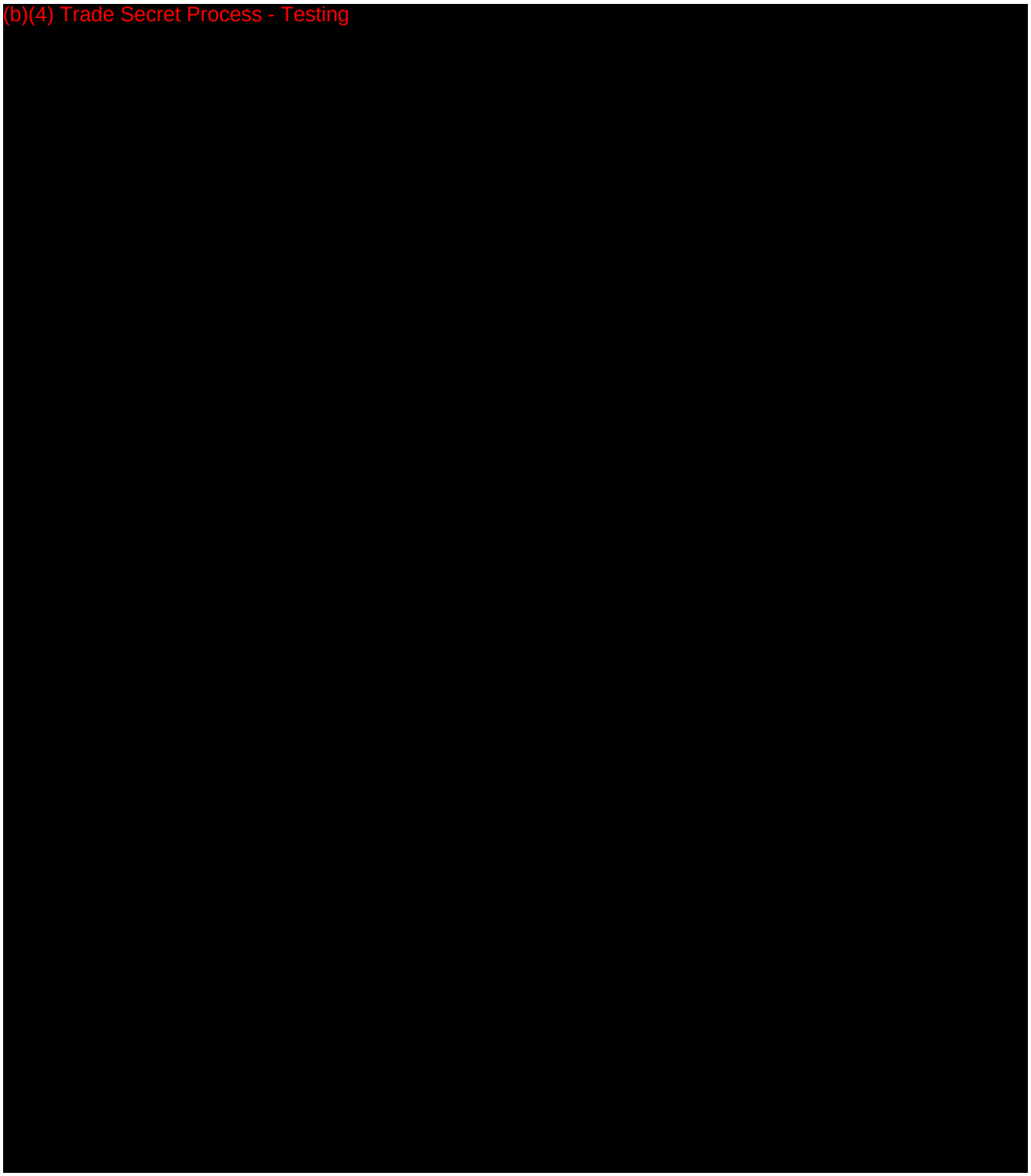


Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Performance Testing – Bench

(b)(4) Trade Secret Process - Testing

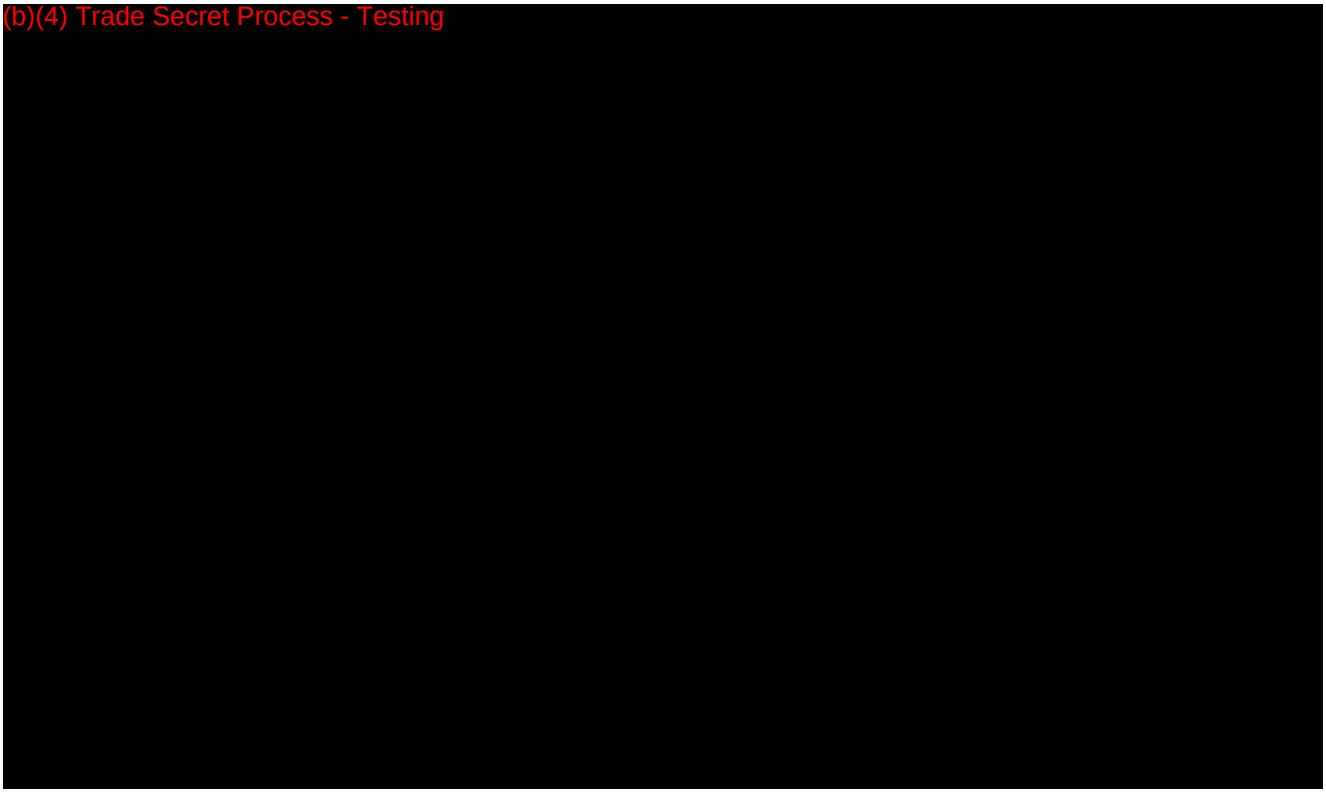


Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Performance Testing – Bench

(b)(4) Trade Secret Process - Testing



18 Performance Testing – Animal

This section is not applicable as no animal testing was performed in the development of the proposed devices.

19 Performance Testing – Clinical

This section is not applicable as clinical study results are not being submitted in this premarket notification.

Appendix 1 – Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Draft Product Specs

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(b)(4) Trade Secret Process - Draft Product Specs

(b)(4) Trade Secret Process - Draft Product Specs

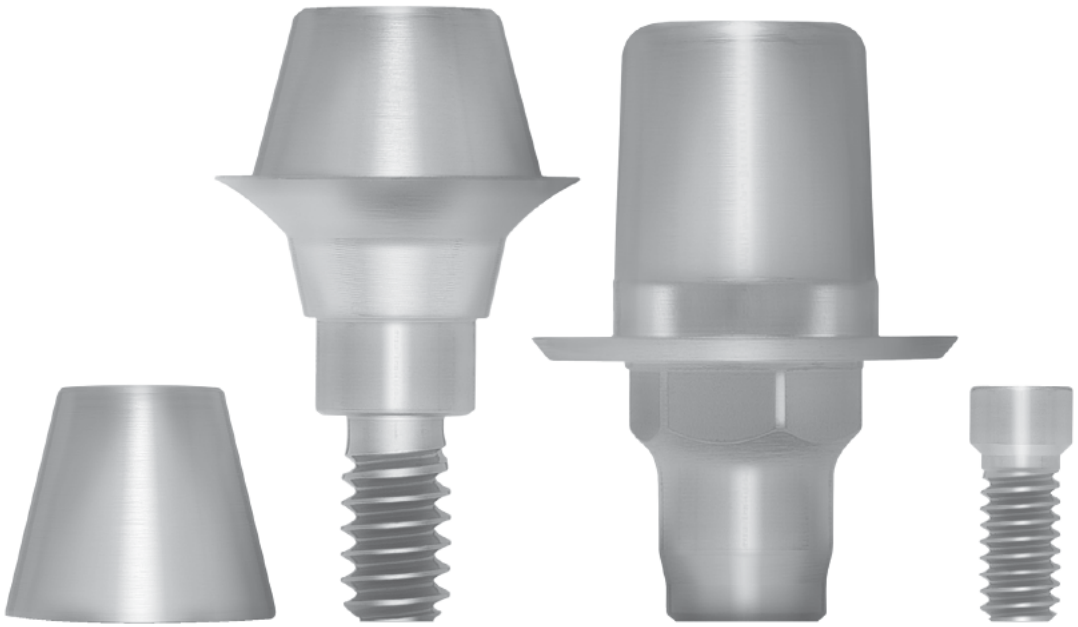
(b)(4) Trade Secret Process - Draft Product Specs

Appendix 3 – NT-Trading Product Catalog

nt-trading
www.nt-trading.com

MORE THAN ABUTMENT'S

CATALOGUE 2012/1



MORE THAN ABUTMENT

OPTIMIZED SAFETY AND QUALITY
CONSTANT LOAD ACCORDING TO DIN EN ISO 14801

To analyze the behavior of the material and the design of the implants on so many of these force effects and to determine the load limits, they will be reproduced in simulations. The international standard ISO 14801 describes the test setup and the implementation of such a test of fatigue limit endosseous dental implants.

We have had constant load tests for endosseous dental implants carried out for nt-trading abutments by the National Institute of Research and Development and Measurement Technique in accordance with standard DIN EN ISO 14801. The load corresponded to 30° angle to the implant axis. In addition, we have, in conformity with DIN EN ISO 14801 had a finite element analysis test carried out.

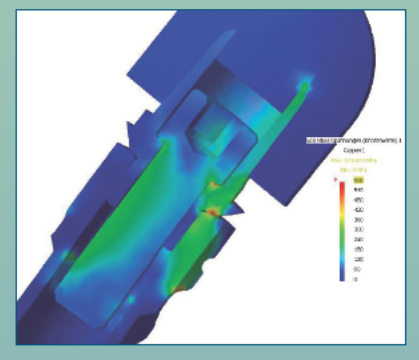
NATIONAL INSTITUTE OF RESEARCH
AND DEVELOPMENT FOR MECATRONICS AND
MEASUREMENT TECHNIQUE

INCDMTM

TESTING REPORT
No. 113 from 24.06.2010

F.POS – 8.2.4 – 2

APROVED,
GENERAL MANAGER
Univ.Prof.PhD.eng.Gh.Ion GHEORGHE



nt-trading GmbH & Co. KG meets the requirements of
ISO 13485:2007 and the EU Directive 93/42/EEC
Health Canada Recognized Registrar CMDCAS.

TÜV SÜD CE -0123

CONTENTS

IMPLANT SYSTEMS

E-SERIE

COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®

Platform 3,5 mm NP | Platform 4,3 mm RP | Platform 5,0 mm WP | Platform 6,0 mm

Titanium Base
for individual milled Zirconium Abutment
incl. screw
Titan Grade 5

E 800	E 810	E 820	E 830

Scan Body
for Titanium Base
PEEK

E 00 W	E 10 W	E 20 W	E 30 W

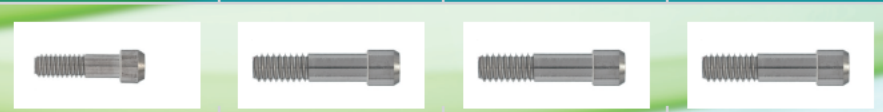
Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

E 9.3D3.500	E 9.3D4.300	E 9.3D5.000	E 9.3D6.000

Lab Analog
Stainless Steel

E 50	E 51	E 52	E 53

Abutment Screw
Titan Grade 5
Recommended tightening torques 35 Ncm



E 60	E 61	E 61	E 61

E-SERIE

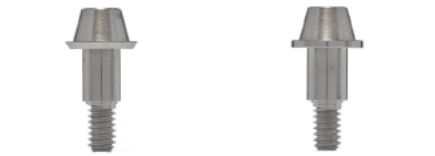
COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®

Platform 4,3 mm RP | Platform 5,0 mm WP

2-CONnect-Base Set
incl. 2-CONnect Cap and Cap-Screw
Titan Grade 5

E 810 S	E 820 S

2-CONnect-Base
Titan Grade 5
Recommended tightening torques 35 Ncm



E 810 M	E 820 M

2-CONnect Cap
Titan Grade 5

E 810 F	E 820 F

Cap-Screw
Titan Grade 5
Recommended tightening torques 30 Ncm

N 60	N 60

Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

E 9.3D4.300	E 9.3D5.000

Lab Analog
Stainless Steel

E 51	E 52

Notice: Products indicated with ® are registered brand names of the respective manufactures.

E-SERIE

COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®

Platform 3,5 mm NP | Platform 4,3 mm RP | Platform 5,0 mm WP

Straight Abutment

incl. Screw
GH 1,0 mm

E 100-1	E 110-1	E 120-1

Straight Abutment

incl. Screw
GH 2,5 mm

E 100	E 110	E 120

E-SERIE

COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®

Platform 3,5 mm NP | Platform 4,3 mm RP | Platform 5,0 mm WP

Angled Abutment 16°

angled over surface
GH 1,0 mm
incl. Screw

E 200-1-1	E 210-1-1	E 220-1-1

Angled Abutment 16°

angled over edge
GH 1,0 mm
incl. Screw

E 200-2-1	E 210-2-1	E 220-2-1

Angled Abutment 16°

angled over surface
GH 2,5 mm
incl. Screw

E 200-1	E 210-1	E 220-1

Angled Abutment 16°

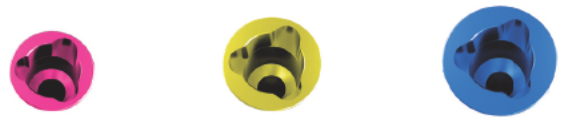
angled over edge
GH 2,5 mm
incl. Screw

E 200-2	E 210-2	E 220-2

Notice: Products indicated with ® are registered brand names of the respective manufactures.

E-SERIE

COMPATIBLE TO NOBEL BIOCARE REPLACE SELECT®



Platform 3,5 mm NP | Platform 4,3 mm RP | Platform 5,0 mm WP

HSL Abutment
rotation indexed
incl. Screw

E 11.CA3.500	E 11.CA4.300	E 11.CA5.000

Implant Pic-Up
incl. screw

E TR-NP013.5	E TR-RP024.3	E TR-WP035.0

F-SERIE

COMPATIBLE TO NOBEL BIOCARE™ NOBEL ACTIVE™

Platform 3,5 mm NP | Platform 4,3 mm / 5,0 mm RP

Titanium Base
for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5

F 800	F 810

Scan Body
for Titanium Base
PEEK

F 00 W	F 10 W

Scan Body 3D Guide
for Titanium Base +
2-CONnect
PEEK

F 9.3D3.500	F 9.3D4.350

Lab Analog
Stainless Steel

F 50	F 51

Abutment Screw
Titan Grade 5
Recommended tightening
torques 35 Ncm

F 60	F 61

Straumann USA, LLC
September 13, 2013
A3-6

F-SERIE

KOMPATIBEL ZU NOBEL BIOCARE™ NOBEL ACTIVE™

Platform 3,5 mm NP

Platform 4,3 mm / 5,0 mm RP

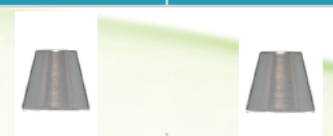
2-CONnect-Base Set
incl. 2-CONnect Cap and Cap-Screw
Titan Grade 5

F 800 S	F 810 S

2-CONnect-Base
Titan Grade 5
Recommended tightening torques 35 Ncm

F 800 M	F 810 M

2-CONnect Cap
Titan Grade 5



F 800 F	F 810 F

Cap-Screw
Titan Grade 5
Recommended tightening torques 30 Ncm

N 60	N 60

Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

F 9.3D3.500	F 9.3D4.350

Lab Analog
Stainless Steel

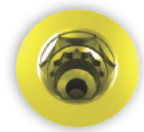
F 50	F 51

H-SERIE

KOMPATIBEL ZU BIOMET 3I CERTAIN®

Platform 3,4 mm

Platform 4,1 mm



Platform 5,0 mm

Titanium Base
for individual milled Zirconium Abutment
incl. screw
Titan Grade 5

H 800	H 810	H 820

Scan Body
for Titanium Base
PEEK

H 00 W	H 10 W	H 10 W

Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

H 9.3D3.400	H 9.3D4.150	H 9.3D4.150

Lab Analog
Stainless Steel

H 50	H 51	H 52

Abutment Screw
Titan Grade 5
Recommended tightening torques 20 Ncm

H 60	H 60	H 60

H-SERIE

COMPATIBLE TO BIOMET 3I CERTAIN®

Platform 3,4 mm | Platform 4,1 mm

2-CONnect-Base Set

incl. 2-CONnect Cap and Cap-Screw
Titan Grade 5

H 800 S	H 810 S

2-CONnect-Base

Titan Grade 5
Recommended tightening torques 20 Ncm

H 800 M	H 810 M

2-CONnect Cap

Titan Grade 5

H 800 F	H 810 F

Cap-Screw

Titan Grade 5
Recommended tightening torques 15 Ncm

KS 60	KS 60

Scan Body 3D Guide

for Titanium Base + 2-CONnect
PEEK

H 9.3D3.400	H 9.3D4.150

Lab Analog

Stainless Steel

H 50	H 51

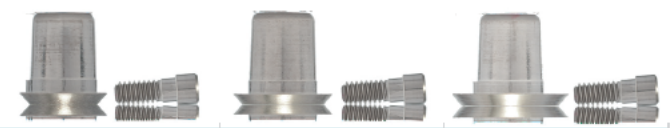
I-SERIE

COMPATIBLE TO BIOMET 3I OSSEOTITE®

Platform 3,4 mm | Platform 4,1 mm | Platform 5,0 mm

Titanium Base

for individual milled Zirconium Abutment
incl. screw
Titan Grade 5



I 800	I 810	I 820

Scan Body

for Titanium Base
PEEK

I 00 W	I 10 W	I 10 W

Scan Body 3D Guide

for Titanium Base + 2-CONnect
PEEK

I 9.3D3.400	I 9.3D4.150	I 9.3D4.150

Lab Analog

Stainless Steel

I 50	I 51	I 52

Straight Abutment

incl. Screw
GH 2,5 mm

	I 110	

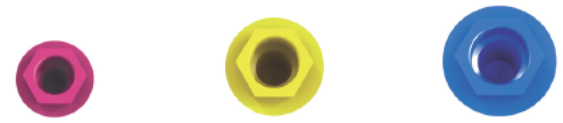
Abutment Screw

Titan Grade 5
Recommended tightening torques 35 Ncm

I 61	I 61	I 61

K-SERIE

COMPATIBLE TO NOBEL BIOCARE BRÅNEMARK®



Platform 3,5 mm	Platform 4,1 mm	Platform 5,1 mm

Titanium Base
for individual milled Zirconium Abutment
incl. screw
Titan Grade 5

K 800	K 810	K 820

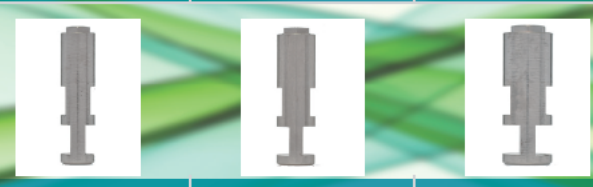
Scan Body
for Titanium Base
PEEK

K 00 W	K 10 W	K 20 W

Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

K 9.3D3.500	K 9.3D4.100	K 9.3D5.100

Lab Analog
Stainless Steel



K 50	K 51	K 52

Straight Abutment
incl. Screw
GH 2,5 mm

	K 110	

Abutment Screw
Titan Grade 5
Recommended tightening torques 35 Ncm

K 60	K 61	K62

L-SERIE

COMPATIBLE TO STRAUMANN BONE LEVEL®

Platform 3,3 mm NC	Platform 4,1 mm / 4,8 mm RC

Titanium Base
for individual milled Zirconium Abutment
incl. screw
Titan Grade 5

L 800	L 810

Scan Body
for Titanium Base
PEEK

L 00 W	L 10 W

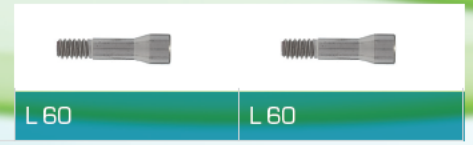
Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

L 9.3D3.300	L 9.3D4.148

Lab Analog
Stainless Steel

L 50	L 51

Abutment Screw
Titan Grade 5
Recommended tightening torques 35 Ncm



L 60	L 60

L-SERIE

COMPATIBLE TO STRAUMANN BONE LEVEL®

Platform
3,3 mm NC

Platform
4,1 mm / 4,8 mm RC

2-CONnect-Base Set

incl. 2-CONnect Cap and
Cap-Screw
Titan Grade 5

L 800 S	L 810 S

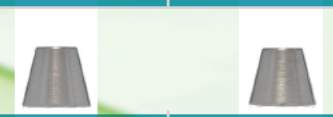
2-CONnect-Base

Titan Grade 5
Recommended tightening
torques 35 Ncm

L 800 M	L 810 M

2-CONnect Cap

Titan Grade 5



L 800 F	L 810 F

Cap-Screw

Titan Grade 5
Recommended tightening
torques 30 Ncm

N 60	N 60

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

L 9.3D3.300	L 9.3D4.148

Lab Analog

Stainless Steel

L 50	L 51

L-SERIE

COMPATIBLE TO STRAUMANN BONE LEVEL®

Platform
3,3 mm NC

Platform
4,1 mm / 4,8 mm RC

Straight Abutment

incl. Screw
GH 2,5 mm

L 100	L 110

Straight Abutment

incl. Screw
GH 3,0 mm

L 100-3	L 110-3

Angled Abutment 18°

angled over surface
GH 1,5 mm
incl. Screw

L 200-1	L 210-1

Angled Abutment 18°

angled over edge
GH 1,5 mm
incl. Screw

L 200-2	L 210-2

Notice: Products indicated with ® are registered brand names of the respective manufactures.

L-SERIE

COMPATIBLE TO STRAUMANN BONE LEVEL®

Platform
3,3 mm NC

Platform
4,1 mm / 4,8 mm RC

Angled Abutment 18°

angled over surface
GH 3,0 mm
incl. Screw

L 200-1-3

L 210-1-3

Angled Abutment 18°

angled over edge
GH 3,0 mm
incl. Screw

L 200-2-3

L 210-2-3

HSL Abutment

rotation indexed
incl. Screw

L 11.CA3.300

L 11.CA4.148

Implant Pic-Up

incl. screw

L TR-NC013.3

L TR-RC024.1

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform
3,5 mm NN

Platform
4,8 mm RN

Platform
6,5 mm WN

Titanium Base

for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5

N 800 | N 810 | N 820

Scan Body

for Titanium Base
PEEK

N 00 W | N 10 W | N 20 W

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

N 9.3D3.500 | N 9.3D4.800 | N 9.3D6.500

Lab Analog

Stainless Steel

N 50 | N 51 | N 52

Abutment Screw

Titan Grade 5
Recommended tightening
torques 35 Ncm

N 60 | N 62 | N 62

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform 4,8 mm RN

Platform 6,5 mm WN

2-CONnect-Base Set
incl. 2-CONnect Cap and Cap-Screw
Titan Grade 5

N 820 S

2-CONnect-Base
Titan Grade 5
Recommended tightening torques 35 Ncm

N 810 M | N 820 M

2-CONnect Cap
Titan Grade 5

N 810 | N 820 F

Cap-Screw
Titan Grade 5
Recommended tightening torques 30 Ncm

N 60 | N 60

Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

N 9.3D4.800 | N 9.3D6.500

Lab Analog
Stainless Steel

N 51 | N 52

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform 4,8 mm RN

Platform 4,8 mm RN

Platform 6,5 mm WN

Straight Abutment
incl. Screw

N 110 | N 110 L | N 120

Angled Abutment 16°
angled over surface
incl. Screw

N 210-1 | N 210-1 | N 220-1

Angled Abutment 16°
angled over edge
incl. Screw

N 210-2 | N 210-2 | N 220-2

Abutment Screw
Titan Grade 5
Recom. tight. torques 35 Ncm

N 61 | N 61 | N 61

Platform 4,8 mm RN

Total height 4,0 mm | Total height 5,5 mm | Total height 7,0 mm

RN-Massiv Abutment
only for Dentist

N 110-40 | N 110-55 | N 110-70

Platform 6,5 mm WN

Total height 5,5 mm

WN-Massiv Abutment
only for Dentist

N 120-55

Notice: Products indicated with ® are registered brand names of the respective manufactures.

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform 3,5 mm NN | Platform 4,8 mm RN | Platform 6,5 mm WN

Straight Abutment
incl. Screw

N 100

Angled Abutment 16°
incl. Screw

N 200

Abutment Screw

N 60

HSL Abutment
rotation indexed
incl. Screw

N 300	N 310	N 320

HSL Abutment
rotating
incl. Screw

N 300 R	N 310 R	N 320 R

Abutment Screw
Titan Grade 5
Recommended tightening torques 35 Ncm

N 60	N 62	N 62

N-SERIE

COMPATIBLE TO STRAUMANN SYNOCTA®

Platform 3,5 mm NN | Platform 4,8 mm RN | Platform 6,5 mm WN

Angled Abutment 21°
angled over surface
incl. Screw

N 210-1-21

Angled Abutment 21°
angled over edge
incl. Screw

N 210-2-21

WN-Massiv Abutment
Height 4,0 mm

N 120-40	N 120-40

Implant Pic-Up
incl. screw

N TR-NN013.5	N TR-RN024.8	N TR-WN036.5

Notice: Products indicated with ® are registered brand names of the respective manufactures.

R-SERIE

COMPATIBLE TO ZIMMER TAPERED SCREW-VENT®

Platform 3,5 mm | Platform 4,5 mm | Platform 5,7 mm

Titanium Base
for individual milled Zirconium Abutment
incl. screw
Titan Grade 5

R 800	R 810	R 820

Scan Body
for Titanium Base
PEEK

R 00 W	R 10 W	R 20 W

Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

R 9.3D3.500	R 9.3D4.500	R 9.3D5.700

Lab Analog
Stainless Steel

R 50	R 51	R 52

Abutment Screw
Hex 0,50" (1,26 mm)
Recommended tightening torques 30 Ncm

R 60	R 60	R 60

R-SERIE

COMPATIBLE TO ZIMMER TAPERED SCREW-VENT®

Platform 3,5 mm | Platform 4,5 mm

2-CONnect-Base Set
incl. 2-CONnect Cap and Cap-Screw
Titan Grade 5

R 800 S	R 810 S

2-CONnect-Base
Titan Grade 5
Recommended tightening torques 30 Ncm

R 800 M	R 810 M

2-CONnect Cap
Titan Grade 5

R 800 F	R 810 F

Cap-Screw
Titan Grade 5
Recommended tightening torques 25 Ncm

KS 60	KS 60

Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

R 9.3D3.500	R 9.3D4.500

Lab Analog
Stainless Steel

R 50	R 51

Notice: Products indicated with ® are registered brand names of the respective manufactures.

R-SERIE

COMPATIBLE TO ZIMMER TAPERED SCREW-VENT®

Platform 3,5 mm | Platform 4,5 mm | Platform 5,7 mm

Straight Abutment
incl. Screw
GH 2,5 mm

R 100	R 110	R 120

Angled Abutment 16°
angled over surface
incl. Screw
GH 2,5 mm

R 200-1	R 210-1	R 220-1

Angled Abutment 16°
angled over surface
incl. Screw
GH 2,5 mm

R 200-2	R 210-2	R 220-2

Massiv Abutment
Titan Grade 5

R 400	R 410	R 420

HSL Abutment
rotation indexed
incl. Screw

R 300	R 310	R 320

Abutment Screw
Hex 0,50" (1,26 mm)
Recommended tightening
torques 30 Ncm

R 60	R 60	R 60

R-SERIE

COMPATIBLE TO ZIMMER TAPERED SCREW-VENT®

Platform 3,5 mm | Platform 4,5 mm

Implant Pic-Up
incl. screw

R TR-00013.5	R TR-00024.5

S-SERIE

COMPATIBLE TO ASTRA TECH OSSEOSPEED®

Platform
3,5 mm / 4,0 mm

Platform
4,5 mm / 5,0 mm

Titanium Base

for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5

S 800	S 820

Scan Body

for Titanium Base
PEEK

S 00 W	S 20 W

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

S 9.3D3.540	S 9.3D4.550

Lab Analog

Stainless Steel

S 50	S 52

Straight Abutment

incl. Screw
GH 1,5 mm

S 100

Abutment Screw

Titan Grade 5
Recommended tightening
torques 25 Ncm

S 60	S 61

S-SERIE

COMPATIBLE TO ASTRA TECH OSSEOSPEED®

Platform
3,5 mm / 4,0 mm

Platform
4,5 mm / 5,0 mm

2-CONnect-Base Set

incl. 2-CONnect Cap and
Cap-Screw
Titan Grade 5

S 800 S	S 820 S

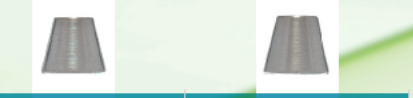
2-CONnect-Base

Titan Grade 5
Recommended tightening
torques 25 Ncm

S 800 M	S 820 M

2-CONnect Cap

Titan Grade 5



S 800 F	S 820 F

Cap-Screw

Titan Grade 5
Recommended tightening
torques 20 Ncm

N 60	N 60

Scan Body 3D Guide

for Titanium Base +
2-CONnect
PEEK

S 9.3D3.540	S 9.3D4.550

Lab Analog

Stainless Steel

S 50	S 52

S-SERIE

COMPATIBLE TO ASTRA TECH OSSEOSPEED®

Platform 3,5 mm / 4,0 mm	Platform 3,5 mm / 4,0 mm	Platform 4,5 mm / 5,0 mm

Straight Abutment
incl. Screw
GH 1,5 mm

	S 110	S 120

Angled Abutment 16°
incl. Screw
GH 1,5 mm

S 200	S 210	S 220

HSL Abutment
rotation indexed
incl. Screw

S 11.CA3.540		S 11.CA4.550

Implant Pic-Up
incl. screw

S TR-00013.5		S TR-00024.5

T-SERIE

COMPATIBLE TO DENTSPLY-FRIADENT FRIALIT/XIVE®

Platform 3,4 mm	Platform 3,8 mm	Platform 4,5 mm	Platform 5,5 mm

Titanium Base
for individual milled
Zirconium Abutment
incl. screw
Titan Grade 5

T 800	T 805	T 810	T 820

Scan Body
for Titanium Base
PEEK

T 00 W	T 05 W	T 10 W	T 10 W

Scan Body 3D Guide
for Titanium Base +
2-CONnect
PEEK

T 9.3D3.400	T 9.3D3.800	T 9.3D4.555	T 9.3D4.555

Lab Analog
Stainless Steel

T 50	T 55	T 51	T 52

Abutment Screw
Titan Grade 5
Recommended tightening
torques 25 Ncm

T 60	T 60	T 60	T 60

T-SERIE

COMPATIBLE TO DENTSPLY-FRIADENT FRIALIT/XIVE®

Platform 3,4 mm | Platform 3,8 mm | Platform 4,5 mm

2-CONnect-Base Set
incl. 2-CONnect Cap and Cap-Screw
Titan Grade 5

T 800 S | T 805 S | T 810 S

2-CONnect-Base
Titan Grade 5
Recommended tightening torques 25 Ncm

T 800 M | T 805 M | T 810 M

2-CONnect Cap
Titan Grade 5

T 800 F | T 805 F | T 810 F

Cap-Screw
Titan Grade 5
Recommended tightening torques 15 Ncm

KS 60 | N 60 | N 60

Scan Body 3D Guide
for Titanium Base + 2-CONnect
PEEK

T 9.3D3.400 | T 9.3D3.800 | T 9.3D4.555

Lab Analog
Stainless Steel

T 50 | T 55 | T 51

T-SERIE

COMPATIBLE TO DENTSPLY-FRIADENT FRIALIT/XIVE®

Platform 3,8 mm | Platform 4,5 mm

Angled Abutment 16°
angled over edge
GH 1,0 mm

T 205-2-1

Angled Abutment 16°
angled over surface
GH 1,0 mm

T 205-1-1

Angled Abutment 16°
angled over surface
GH 2,5 mm

T 205-1

Straight Abutment
incl. Screw
GH 1,0 mm

T 105-1 | T 110-1

Straight Abutment
incl. Screw
GH 2,5 mm

T 105 | T 110

Abutment Screw
Hex 0,50" (1,26 mm)
Recommended tightening torques 25 Ncm

T 60 | T 60

Notice: Products indicated with ® are registered brand names of the respective manufactures.

T-SERIE

COMPATIBLE TO DENTSPLY-FRIADENT FRIALIT/XIVE®

	Platform 3,4 mm	Platform 3,8 mm	Platform 4,5 mm
Implant Pic-Up incl. screw	T TR-00013.4	T TR-00023.8	T TR-00034.5

	T 11.CA3.400	T 11.CA3.800	T 11.CA4.500
HSL Abutment rotation indexed incl. Screw			

PROSTHETIC TOOLS

Torque Ratchet
continuously adjustable
to max. 40 Ncm
ISO-Shaft Connection

W 11.000.000

Laboratory
Screwdriver
for changeable inserts
(without ISO-Shaft)
ISO-Shaft Connection

W 11.100.000

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for S-, I- and R-Series
Hex 0,50" (1,26 mm)

W 11.IRS.G10

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for T- and H-Series
Hex 1,20 mm

W 11.THO.G20

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for Ankylos®
Hex 1,00 mm

W 11.YOO.G30

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for L- and N-Series
Torx T6

W 11.LNO.G40

Insert
for Laboratory Screwdriver
and Torque Ratchet
ISO-Shaft for E-, F- and
K-Serie UG

W 11.EFK.G50

Insert
for Laboratory Screwdriver
and Torque Ratchet ISO-Shaft
for 2-CONnect-Base-Primary

W 11.005.G60

DENTOKEEP PEEK DISC

Dentokeep

nt-trading Dentokeep Disc PEEK are blanks for technical milling manufacture of permanent dentures and prosthetic brace in the CAM process. The derived prosthetic designs are available on the remaining teeth, - can be attached to stumps and / or implant abutment and provide a basic functional and aesthetic care.

1. PEEK Disc 98.5 mm, pearl white, 14 mm and 18 mm thick
2. For CAD / CAM Technology for CAD/CAM Technology
3. Clip in prosthetics CAD/CAM
4. Class II product for permanent prosthetic restorations

Dentokeep
PEEK Disc
Size 14 mm

12.000.P14

Dentokeep
PEEK Disc
Size 18 mm

12.000.P18

SCAN EQUIPMENT

nt-OptiScan™ Spray

nt-OptiScan™ Spray a new product development of nt-trading GmbH & Co. KG.

nt-OptiScan™ Spray

Advantages:

- Optimize composition
- Perfect dosage with proven applicator
- Optimize preparation of your working model for optical scanning with modern dental scanner
- Economical application
- Water soluble
- Handy size: Volume 75 ml brutto
- Superior scanning results
- Special attractive price

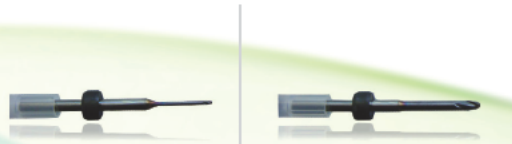
Straumann USA, LLC
September 13, 2013
A3-20

NT-MILLING AND GRINDING TOOLS

nt-trading tools are specially developed for dental CAD/CAM systems. They are up to the high mark to process dental materials and are constant liable to quality checks.
Tools coated with tax are especially qualified for process of dental high-capacity plastics, as well as for process of milling wax.
Tools coated with diamand are especially qualified for process of abrasive materials like zirconium dioxide.

nt-Diaburr			
Ø	0,6 mm	1,0 mm	2,5 mm
Art.-Nr.	11100	11101	11102

The milling tool coated with diamonds nt-Diaburr offers you a lifetime of at least 350 units while process of ZrO2 with the milling machine.



nt-Uburr		
Ø	1,0 mm	2,5 mm
Art.-Nr.	11201	11202

Universal milling tools are qualified for process of plastics, waxes and ZrO2 with the milling machine. Depending on choice of material the lifetime is at least 175 unites.

nt-PEEKburr		
Ø	1,0 mm	2,5 mm
Art.-Nr.	11301	11302

Special milling tools are qualified for process of PEEK materials like Dentokeep, plastics and waxes.

SINTER COMPONENTS

nt-pearls

Sinterization of Zr-oxide substructures.

Sinter pearls for dental CAD/CAM technology

Advantages:
Sinterization of Zr-oxide substructures. Full ceramics are the answer to patients demands for highly esthetic, metal-free and durable restaurations Zr-oxide became a common substructure for dental restaurations already quite a while ago. This material features outstanding biocompatibility and mechanical properties Zr-oxide is mechanically machined in its greenstage, taking into consideration the specific shrinkage of this material. The sinterization is optimized for the specific material and its overzised milling relative to the material properties, thus assuring the best possible fit.
Another important factor contributing to a perfect fit is the right choice of support for this to be sintered substructure. Every manufacturer has his own recommendations concerning these supports. Some suggest to sinter on special „pearls“, unfortunately particle size and quality are not always right to by example avoid getiing pinched between the interproximals and thus distorting the bridge.
Other solutions favour the use of „drops“, resting on very expensive and fragile support discs. The necessary preparations for this type of support are always time consuming, sometimes even cumbersome and allways generating additional costs.
A viable alternative are special hi- density and quality sinterization pearls from nt-trading, optimized for crowns and bridges and therefore avoiding the common „pinching“ and distortion problems especially known to bridges.

INSTRUCTION FOR USE

Indication:

For manufacturing of individual abutments on dental implants. The individual abutments can be combined with copings, crowns or suprastructures made of dental ceramics.

Contraindication:

The Ti-Bases of each Series can only be combined with the matching implant, e.g. the E-Series shall be combined exclusively with Replace Select® Implants. They cannot be combined with implants of a different implant type or manufacturer. The diameter of the Ti-base must correspond in size to the used implant in order to prevent a peri-implant tissue irritation.
The Ti-Bases are indicated for single use only. If they are use multiple times, they might damage the implants.
For fixation of the Ti-Bases on the implant, the correct torque force, recommended by the implant manufacturer, has to be considered carefully to avoid the damage of the implant-bone connection.

Ncm	Abutment				
20	H-Serie				
25	S-Serie	T-Serie	F-Serie		
30	R-Serie				
35	I-Serie	K-Serie	N-Serie	E-Serie	L-Serie

Mechanical treatment of the connection part of the Ti-Base will damage the correct fitting of the Ti-Base on the implant.

Handling method:

Ceramic abutments:
Milling with CAD/CAM-machines of zirconium oxide- or aluminum oxide- ceramics according to the anatomic form of a crown or coping. The ceramic copings or crowns shall be milled or polished with diamond instruments and with minimal pressure and watercooling. The minimal thickness shall be 0.5 mm Sharpe edges must be avoided.

Veneering:
Copings shall be veneered with appropriate ceramics before cementing onto the Ti-Base. The instructions for use of the ceramic manufacturers have to be considered. Treatment of the Ti-Base and the ceramic abutment before cementing: Sandblasting of the contact surfaces with Al2O3, 50 µm, 2 bar and intensive cleaning of dust and grease. It is recommended to protect the connection part of the Ti-Base with an implant analog during handling.

Cementing:
It is recommended to cement the ceramic abutment onto the Ti-Base with Panavia® F2.0 (Kuraray) with RelayXUnicem® (3M Espe) ore other equivalent cements. The instructions for use of the cements shall be followed carefully. The Ti-Base shall be fixed onto an implant analog with the abutments screw. The head of the screw has to be covered with wax or resin. The mixed cement is applied onto the contact part of the Ti-Base. The abutment is pressed onto the Ti-Base. The final position is evaluated by slight rotation. The gap between abutment and the Ti-Base must be as small as possible. Remaining cement shall be removed immediately.

Polishing:
After hardening the remaining cement shall be removed with rotating silicon instruments. The cement inside the screw channel has to be removed carefully.

Scan Body:

Indication:

Scan Body:
For the CAD/CAM scanning of the model, the Scan Body is used to indicate the position of the implant. The size of the Scan Body shall be corresponding to the original Implant system, implant diameter and Ti-Base Series.
The chamfer of the Scan Body prevents the rotation of the ceramic abutment. The Scan Body is fixed on the implant analogue with the abutment screw. After correct positioning, there is no gap visible between implant and Scan Body. Rotation of the Scan Body is impossible

Tightening torques

Ncm	2-CONnect-M-Abutment			
20	H-Serie			
25	S-Serie	T-Serie		
30	R-Serie			
35	E-Serie	F-Serie	L-Serie	N-Serie

Ncm	2-CONnect Cap-Screw N 60			
20	S-Serie	T 805, T 810		
30	E-Serie	F-Serie	L-Serie	N-Serie

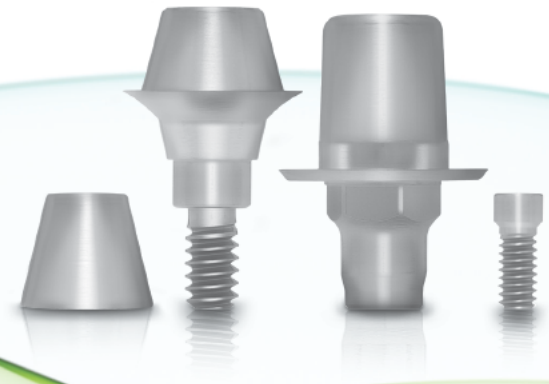
Ncm	2-CONnect Cap-Screw KS 60			
15	H 800, H 810	T 800	R 800	R 810

Conditions of warranty

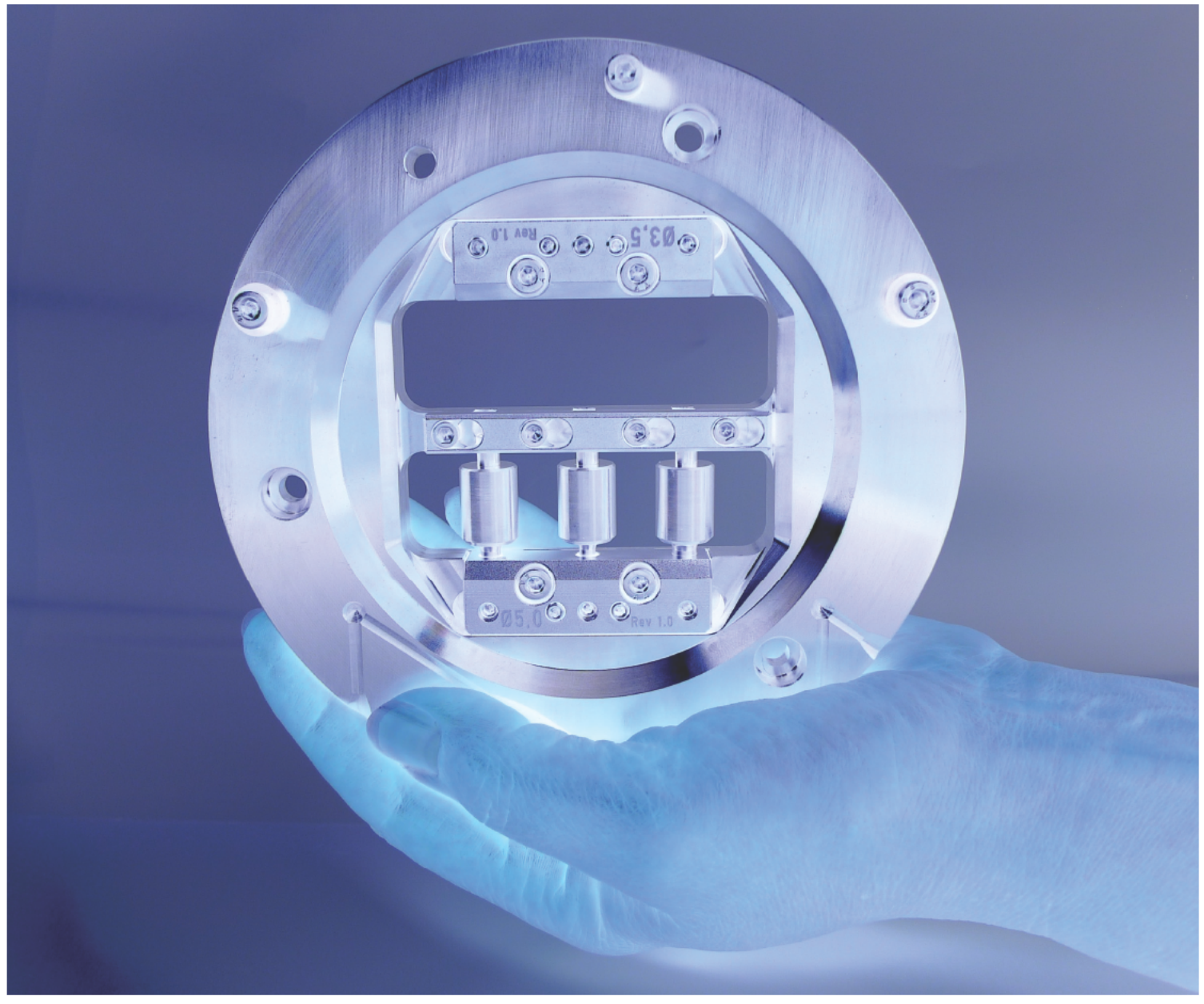
Within our general terms of sale and warranty we ensure the perfect quality of our products. Due to our high production standards can offer you a 10-years' warranty on our prosthetic components.
We offer you a warranty on our nt-trading components according to the conditions of warranty.
The warranty includes all material and manufacturing defects which may occur within the 10-years' time of warranty. We only give warranty for our contracting/purchasing partners (dentists, dental hospitals, laboratory). Any other persons besides those mentioned cannot lay claims to the warranty. It is not possible to assign the warranty claims.

Straumann USA, LLC
September 13, 2013
A3-22

NOTES



NT-PREFORM



The new address from February 2013:

nt-trading GmbH & Co. KG
Nördliche Uferstraße 8
76189 Karlsruhe
Germany

PCE/D-2012-12

nt-trading GmbH & Co. KG | Esso-Straße 16 | 76187 Karlsruhe | Germany
Phone: +49 (0)721 / 91 54 71 - 60 | info@nt-trading.com | www.nt-trading.com

Appendix 4 – NT-Trading Ti-Base Package Insert

Instruction for use

Ti- Base-, for Individual Abutments, Scan Base and Scan Body E-, I-, K-, N-, R-, S-, T-, H-, L-, and F- Series

CE 0123

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INDICATION:
The Ti-Base, is intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The Ti-Base are for manufacturing of individual abutments on dental implants. The individual abutments can be combined with restorations such as, crowns or superstructures made of dental ceramics.

The Ti-Bases of the E-Series are indicated for Replace select® implants, manufactured by Nobel Biocare®.

The Ti-Base of the I-Series are indicated for Osseotite® implants manufactured by Biomet 3i®.

The Ti-Bases of the K-Series are indicated for Brånemark® implants, manufactured by Nobel Biocare®.

The Ti-Bases of the N-Series are indicated for synOcta® implants, manufactured by Straumann®.

The Ti-Bases of the R-Series are indicated for Tapered Screw-vent® implants, manufactured by Zimmer®.

The Ti-Bases of the S-Series are indicated for OsseoSpeed® implants, manufactured by Astra Tech®.

The Ti-Bases of the T-Series are indicated for Frialit® implants, manufactured by Dentsply-Friadent®.

The Ti-Bases of the H-Series are indicated for Biomet 3i Certain® implants, manufactured by Biomet 3i®.

The Ti-Bases of the L-Series are indicated for Bone Level implants, manufactured by Straumann®.

The Ti-Bases of the F-Series are indicated for NobelActive™ implants, manufactured by Nobel Biocare®.

ARTICLE NO. OF TI-BASES AND ABUTMENT SCREWS

The Abutments Ti-Base E-Series is compatible with Nobel Biocare Replace Select® Implant.

Nobel Replace Select®	3.5 mm	4.3 mm	5.0 mm	6.0 mm
Ti-Base E-Series	E 800	E 810	E 820	E 830
Abutment screw	E 60	E 61	E 61	E 61

The Abutment Ti-Base I-Series is compatible with Biomet 3i Osseotite®.

Biomet 3i Osseotite®	3.4 mm	4.1 mm	5.0 mm
Ti-Base I-Series	I 800	I 810	I 820
Abutment screw	I 61	I 61	I 61

The Abutment Ti-Base K-Series is compatible with Nobel Biocare Brånemark® Implant.

Brånemark®	3.5 mm	4.1 mm	5.1 mm
Ti-Base K-Series	K 800	K 810	K 820
Abutment screw	K 60	K 61	K 62

The Abutment Ti-Base N-Series is compatible with Straumann SynOcta® Implant.

Straumann SynOcta®	3.5 mm	4.8 mm	6.5 mm
Ti-Base N-Series	N 800	N 810	N 820
Abutment screw	N 60	N 62	N 62

The Abutment Ti-Base R-Series is compatible with Zimmer Tapered Screw-vent® (Sulzer) Implant.

Zimmer (Sulzer) Tapered Screw-vent®	3.5 mm	4.5 mm	5.7 mm
Ti-Base R-Series	R 800	R 810	R 820
Abutment screw	R 60	R 60	R 60

The Abutment Ti-Base S-Series is compatible with Astra Tech OsseoSpeed® Implant.

Astra Tech Osseo-Speed®	3.5 / 4.0 mm	4.5 / 5.0 mm
Ti-Base S-Series	S 800 / 810	S 820
Abutment screw	S 60	S 61

The Abutment Ti-Base T-Series is compatible with Dentsply-Friadent Frialit® Implant.

Dentsply-Friadent Frialit®	3.4 mm	3.8 mm	4.5 mm	5.5 mm
Ti-Base T-Series	T 800	T 805	T 810	T 820
Abutment screw	T 60	T 60	T 60	T 60

The Abutment Ti-Base H-Series is compatible with Biomet 3i Osseotite® Certain®.

Biomet 3i Osseotite®Certain®	3.4 mm	4.1 mm	5.0 mm
Ti-Base H-Series	H800	H810	H 820
Abutment screw	H 60	H 60	H 60

The Abutment Ti-Base L-Series is compatible with Straumann® Bone Level Implant.

Straumann® BoneLevel	3.3 mm	4.1 / 4.8 mm
Ti-Base L-Series	L 800	L 810
Abutment screw	L 60	L 61

The Abutment Ti-Base F-Series is compatible with Nobel Biocare NobelActive™ Implant.

NobelActive™	3.5 mm	4.3 / 5.0 mm
Ti-Base F-Series	F 800	F 810
Abutment screw	F 60	F 61

Each Ti-Base is delivered with an abutment screw for fixation on the implant. The article number is the order number.

COMPOSITION:
Ti-Base and Abutment Screw: Ti6Al4V, medical grade 5, ASTM 136
Scan Body: Polyether-ether-ketone, PEEK

CONTRAINDICATION:
The Ti-Bases of each Series can only be combined with the matching implant, e.g. the E-Series shall be combined exclusively with Replace select® implants. They cannot be combined with implants of a different implant type or manufacturer. The diameter of the Ti-base must correspond in size to the used implant in order to prevent a peri-implant tissue irritation.
The Ti-Bases are indicated for single use only. If they are used multiple times, they might damage the implants.
For fixation of the Ti-Bases on the implant, the correct torque force, recommended by the implant manufacturer, has to be considered carefully to avoid the damage of the implant-bone connection.
Mechanical treatment of the connection part of the Ti-Base will damage the correct fitting of the Ti-Base on the implant.

Ncm	Abutment				
20	H-Series				
25	S-Series	T-Series	F-Series		
30	R-Series				
35	I-Series	K-Series	N-Series	E-Series	L-Series

Mechanical treatment of the connection part of the Ti-Base will damage the correct fitting of the Ti-Base on the implant.

HANDLING METHOD FOR FURTHER PROCESSING:
The following instruction describes possible steps in the Laboratory for further processing to design the prosthetic components. The ceramic crown is an example for a possible aid prosthetic.

Ceramic crown: Milled with CAD/CAM-machines for zirconium oxide- or aluminum oxide- ceramic according to the anatomic form of a crown.
The ceramic crown shall be grinded or polished with diamond instruments and with minimal pressure and water-cooling. The minimal thickness shall be 0.5 mm. Sharpe edges must be avoided.

VENEERING:
Crowns shall be veneered with appropriate ceramics before cementing onto the Ti-Base. The instructions for use of the ceramic manufacturers have to be considered.
Before cementing the Ti-Base and the ceramic crown: Sandblasting the contact surfaces with Al_2O_3, 50 µm, 2 bar and ensure intensive cleaning of dust and grease.
It is recommended to protect the connection part of the Ti-Base with an implant analog during handling.

CEMENTING:
It is recommended to cement the ceramic abutment onto the Ti-Base with Panavia® F2.0 (Kuraray) with RelayXUnicem® (3M Espe) are other equivalent cements. The instructions for use of the cements shall be followed carefully.
The Ti-Base shall be fixed onto an implant analog with the abutments screw. The head of the screw has to be covered with wax or resin. The mixed cement is applied onto the contact part of the Ti-Base. The abutment is pressed onto the Ti-Base. The final position is evaluated by slight rotation. The gap between abutment and the Ti-Base must be as small as possible. Remaining cement shall be removed immediately.

POLISHING:
After hardening the remaining cement shall be removed with rotating silicon instruments. The cement inside the screw channel has to be removed carefully.

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SCAN BODY INDICATIONS:
The Scan Body can be used as auxiliary component, to determine the exact position and insertion angle of the implant. This is helpful for the further process to design the prosthetics.

SCAN BODY:
For the CAD/CAM scanning of the model, the Scan Body is used to indicate the position of the implant. The size of the Scan Body shall be corresponding to the original Implant system, implant diameter and Ti-Base Series.
The chamfer of the Scan Body prevents the rotation of the ceramic abutment.
The Scan Body is fixed on the implant analogue with the abutment screw. After correct positioning, there is no gap visible between implant and Scan Body. Rotation of the Scan Body is impossible.

ARTICLE NO.:
The article number of Scan Body and Titanium Base is a combination of the code for the Series: E, I, K, N, R, S, T, H, L and F (→ X) with the code W for Scan Body and for Titanium Base.

Titanium-Base	X 800	X 805	X 810	X 820	X 830
Scan-Body	X 00W	X 05W	X 10W	X 20W	X 30W

WARNING:
Safety hint: metal dust is harmful to your health. When milling and sandblasting use a suction extraction system and a breathing mask.

SECONDARY EFFECTS:
Allergies to the alloy or contents of the alloy or electrochemically based reactions may very rarely occur.

REACTIONS:
In case of occlusal or approximal contact of different alloys electrochemically based reactions may very rarely occur.

WARRANTY:
10 Years on the mechanical stability of the Ti-Base, if it was processed according to the Instruction for use. Whether given verbally, in writing or by practical instructions, our recommendation for use is based upon own experience and trials and can only be con sidered as standard values. Our products are subject to a constant further development. Therefore alternations in construction and composition are reserved.

CLEANING, DISINFECTION AND STERILIZATION:
The nt-trading abutments and screws of the series E, I, K, N, R, S and T are supplied in non-sterile condition. The components should be cleaned, disinfected and in specific clinical procedures and cases be sterilized, prior to use after they are received from the dental laboratory (no liability on disregard). Effective cleaning and disinfection is an indispensable requirement for effective sterilization of the abutments. Prior to sterilization, please keep implants and screws clean when handling in the laboratory and operatory.
Additionally, please pay attention to legal regulations valid for your local areas as well as to the hygienic instructions of your dental practice. This applies particularly to the different guidelines regarding the inactivation of prions.

1. Pre-disinfection (avoidance of cross contaminations)
Place the abutments and screws in a germicidal bath* immediately after use. Remove all residues and disassemble demountable products.

2. Cleaning
Please use distilled water and neutral cleaning agents* only. The internal irrigation tube has to be cleaned with a Miller needle and must be rinsed with distilled water at the beginning and end of the exposure time using a disposable syringe (min. 10 ml). The products must be cleaned with a plastic instrument cleaning brush and then rinsed with distilled water. Please control all products after cleaning in order to avoid either damaging or corrosion. Damaged products must be replaced.

3. Rinsing and Drying
After removal of the products from the germicidal bath, all components must be rinsed 3 times with distilled water /e.g. Aqua purificata). Please dry all components thoroughly with a lint-free disposable cloth. For the cleaning of the internal irrigation tube oil-free compressed air is mandatory. Please re-check all parts for damage or corrosion afterwards.

4. Disinfection
We recommend a high level disinfectant such as, Cidex OPA (Johnson & Johnson) for disinfection of the abutments and screws.

a) Soak the abutments and screws in the disinfectant solution for the required amount of time. See instructions for use of Cidex OPA.
b) Remove the abutments and screws from the disinfectant solution.
c) Rinse at least three times with highly purified water.
d) Air dry and package the abutments and screws immediately.

5. Sterilization:
If no sterilization device is available in the laboratory, this information should be forwarded to the dentist so proper sterilization can occur. Please use only validated sterilization procedures for the sterilization of the abutments and screws. Other sterilization procedures must not be used.

Reusability:
You may only sterilize the abutments one time. In case of inadvertent contamination, you may re-sterilize one time after cleaning and disinfection.

Steam sterilization:
- fractionated vacuum procedure or gravity procedure (with sufficient product drying)
- steam sterilizer according to ISO 17665: 2006 or EN 13060 and EN 285 respectively or equivalent national standards
- validated according to EN ISO/ANSI AAMI 17665 (in past: EN 554/ANSI AAMI ISO 11134) (valid IQ/OQ) (commissioning and product specific performance qualification)
- sterilization time 20 minutes at 121 °C (250 °F) (listed exposure times are at sterilization temperature)

7. Storage
Store the sterilized parts dry and dust-free at room temperature.

* Please observe all manufacturers guidelines for disinfection and cleaning agents with special regard to the concentration, exposure time and temperature. Only neutral disinfection solutions without chlorine, ammoniac and aldehydes and with a proven effectiveness against HBV, HCV, and HIV must be used. The products have to meet the respective national regulations for disinfectants. If disinfectants containing aldehydes are used, this might lead to a possible fixation of proteins. Please use only freshly prepared solutions.

Rev. A/ 2012-03-20

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E-mail: info@nt-trading.com

Appendix 5 – NT-Trading Ti-Base 510(k) Summary

510(k) Summary K111935 FEB 17 2012

Submitter Name: Submitter Address:	**NT-Trading GmbH & Co. KG** Essostrasse 16 76187 Karlsruhe Germany
Phone Number: Fax Number:	+49-721-915471 60 +49-721-915471 61
Contact Person:	Dirk Jahn
Date Prepared:	June 29, 2011
Device Trade Name:	Ti-Base Abutment 2-CONnect Abutment
Common Name:	Dental Abutments
Classification Name, Number & Product Code:	Abutment, Implant, Dental, Endosseous 872.3630 NHA
Predicate Devices:	**(K100152)** Sirona Dental Systems Sirona Dental CAD/CAM System, **(K083871)** Atlantis™ Straumann Bone Level Abutment, **(K093483)** Atlantis™ Abutment for Nobel Active Implant, **(K072642)** Biomet 3I Dental Abutments And Restorative Components, **(K990342)** synOcta® Prosthetics, **(K080239)** P.004 Abutments, **(K072570)** NobelActive™Multi Unit Abutment
Device Description and Statement of Intended Use	The Ti-Base Abutment is a premanufactured prosthetic component supplied in two parts, the abutment and screw, for fixation onto dedicated endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. The 2-CONnect Abutment consists of 1 Abutment with screw (for fixation of abutment to the implant) and 1 titanium cap with 1 tiny screw (fixed into the hollow Abutment screw). The cap on top fits exactly to the abutment-geometry and does not have a rotation fixation, so it is easier to work with (not indicated for single crowns but strictly for bridges). The 2-CONnect is intended for use as an aid in prosthetic rehabilitation. The NT-Trading Ti-Base and 2-CONnect is compatible,with commercially available dental CAD/CAM systems, such as 3Shape, Exocad, Dental Wings. Such systems must be validated by the user. Indication for use: **Ti-Base Abutments**: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Nobel Biocare NobelActive™
- Biomet 3i® Osseotite®
- Biomet 3i® Osseotite® Certain®
- Nobel Biocare Branemark®
- Straumann® synOcta®
- Straumann® Bone Level®
- Zimmer® Tapered Screw-vent®
- Astra Tech OsseoSpeed®
- Dentsply-Friadent® Frialit®

2-CONnect Abutments: 2-CONnect abutment is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction.
The 2-CONnect abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Straumann® synOcta®
- Straumann® BoneLevel®

Summary of Technological Characteristics

The proposed Ti-Base abutments and 2-CONnect abutments are substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each individual diameter and connection type. Comparison Demonstrating Substantial Equivalence follows at the end of this section.

Testing Summary
In order to demonstrate compatibility of Ti-Base and 2-CONnect abutments to each implant system, fatigue testing was performed according to ISO 14801 Dentistry-Implants-Dynamic fatigue test for endosseous implants. Testing was performed on the abutments in this submission with the implants that they are intended to fit. See section 18.

Conclusion

The information discussed above demonstrates that the NT-Trading Ti-Base Dental Abutments and 2-CONnect Abutments are substantially equivalent to the predicate devices.

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Ti-Base and 2-CONnect	Sirona Dental Systems Sirona Dental CAD/CAM System	Atlantis™ Straumann Bone Level Abutment	Atlantis™ Abutment for Nobel Active Implant	Biomet 3I Dental Abutments And Restorative Components	synOcta® Prosthetics	P.004 Abutments	NobelActive™ Multi Unit Abutment
510(k) Number		K100152	K083871	K093483	K072642	K990342	K080239	K072570
Manufacturer	Nt-Trading GmbH & Co. KG	Sirona Dental Systems GmbH	Astra Tech Inc.	Astra Tech Inc.	Biomet 3I, Inc.	Straumann® USA	Straumann® Manufacturing, Inc	Nobel Biocare® AB
Classification # & Product Code	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA	872.3630 NHA
Intended Use	Ti-Base Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function	The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic reconstruction. The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement	The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	BIOMET 3i Dental Abutments and Overdenture Bars are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient. These are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.	ITI Dental implants are intended to be placed in the maxillary and/or mandibular arch to support crowns, bridges or overdentures in edentulous or partially edentulous patients. The prosthetic accessories to dental implants are used either in the process of fabricating the prosthetic restoration for the implant or as part of the prosthetic restoration.	Abutments are placed into dental implants to provide support for prosthetic restorations such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations. The subject abutments are for permanent screw-retained bridges and bar-retained implant-borne dentures. Permanent copings are intended to	Nobel Biocare's Multi-Unit is a premanufactured prosthetic component directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.

	intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Nobel Biocare NobelActive™ • Biomet 3i® Osseotite® • Biomet 3i® Osseotite® Certain® • Nobel Biocare Branemark® • Straumann® synOcta® • Straumann® Bone Level® • Zimmer® Tapered Screw-vent® • Astra Tech OsseoSpeed® • Dentsply-Friadent® Frialit® **2-CONnect Abutments**: 2-CONnect abutment is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be	and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems: • Nobel Biocare Replace • Nobel Biocare Branemark • Friadent Xive • Biomet 3i Osseotite • Astra Tech Osseospeed • Zimmer Tapered Screw-Vent • Straumann SynOcta	retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.				serve as a base for multi-unit bar or bridge restorations. Temporary Copings are intended to serve as a base for temporary restorations for up to 6 month. Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.	

	used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction. The 2-CONnect abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Straumann® synOcta® • Straumann® BoneLevel®							
Abutment Diameter min. Diameter max.	3.5 mm 6.5 mm	Same	Same	Same	Same	Same	Same	Same
Abutment Height	Ti-Base: 4 mm 2-CONnect: 2.3 / 4.3 mm	Same	4 / 5.5 mm	6.6 mm	7.0	1.5 / 6.0	1.5 / 6.0	1.0 / 5.5 mm
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw retained	Screw retained	Screw retained
Reusable	No	No	No	No	No	No	No	No
Material	Ti-6Al-4V	Ti-6Al-4V	Ti-6A1-4V ELI	Ti-6A1- 4V ELI	Ti-6Al-4V	Titanium, Titanium alloy	Ti-6Al-4V	Titanium Alloy

For the reasons stated above, we believe a determination of substantial equivalence between the Ti-Base and 2-CONnect and these predicate devices is appropriate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NT-Trading GmbH & Company AG
C/O Mr. William Greenrose
President
Qserve America, Inc.
220 River Road
Claremont, New Hampshire 03743

FEB 17 2012

Re: K111935
Trade/Device Name: Ti-Base for Individual milled Zirconium Abutment, 2-CONnect Abutment for Bridges and Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 28, 2011
Received: February 14, 2012

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111935

Device Name: Ti-Base for individual milled Zirconium Abutment, 2-CONnect Abutment for Bridges and Bars

Indications For Use:

Ti-Base for individual Zirconium Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration.

The Ti-Base for individual Zirconium Abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The Ti-Base abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Nobel Biocare NobelActive™
- Biomet 3i® Osseotite®
- Biomet 3i® Osseotite® Certain®
- Nobel Biocare Branemark®
- Straumann® synOcta®
- Straumann® Bone Level®
- Zimmer® Tapered Screw-vent®
- Astra Tech OsseoSpeed®
- Dentsply-Friadent® Frialit®

2-CONnect Abutment for Bridges and Bars: 2-CONnect Abutment for Bridges and Bars is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction.
The 2-CONnect abutments are indicated for use with the following implant systems:

- Nobel Biocare® Replace Select®
- Straumann® synOcta®
- Straumann® BoneLevel®

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K111935

(b)(4) Trade Secret Process - Testing

Attachment 3
02.11.2002

K014174

510(k) SUMMARY

FEB 2 2 2002

A. Submitter's Name and Address
Barnstead/Thermolyne Corp.
P.O. Box 797
Dubuque, IA 52004

B. Contact Person
Mia M. Ware
Regulatory Affairs Specialist
563-556-2241 Ext. 485
Fax: 563-557-0612

C. Establishment Registration Number of Submitter

1950043

D. Contract Manufacturing Facility

Not Applicable

E. Device Name

Proprietary Name: Harvey® PV Dry
Common Name: Steam Sterilizer
Classification Name: Steam Sterilizer

F. Device Classification

Class II §880.6880

G. Action Taken to Comply with Section 514 of the Act

The Agency has recognized the ANSI/AAMI ST55, Tabletop Steam Sterilizers, and the FDA Guidance on Premarket Notification Submissions for Sterilizers Intended for Use in Health Care Facilities, March 1993, and its addendum, dated September, 1995. Conformance or variance with these standards is described on the following pages.

H. Reason for 510(k) Submission

- ☒ Initial Product Introduction
- ☐ New Model for Product-line Extension
- ☐ Initial Import into the USA
- ☐ Other (Include in Part IV an explanation referenced to Part I. H.)

I. Predicate Device: Harvey® MC10 Steam Sterilizer, K924955

Attachment 3
02, 11, 2002

Description of the Device: The Harvey® PV Dry is a pre/post-vacuum table top steam sterilizer. Its enclosure is made of painted metal and door cover is made of plastic. The outside dimensions are 15.5"Hx19"Wx23"D, it weighs 115lbs and the chamber is 10" in diameter. The chamber is made from stainless steel rated at 45 psig to comply with the American Society of Mechanical Engineers (ASME) Pressure Vessel Code.

Intended Use of the Device: The Harvey® PV Dry is a pre/post-vacuum table top steam sterilizer that is designed for use in medical and dental offices, hospitals, clinics, and other facilities where a variety of materials require sterilization. Intended for sterilization of wrapped or unwrapped instruments, dental handpieces, and linen packs.

Technological Characteristics: The Harvey® PV Dry has very similar technological characteristics as the predicate device, Harvey® MC10 Steam Sterilizer. The Harvey® PV Dry is a table-top autoclave steam sterilizer with pre-vacuum air removal and sterile post-vacuum drying, similar to larger hospital type units.

The Harvey® PV Dry provides superior performance for dental handpieces and difficult to penetrate fabric packs and superior and rapid drying for all loads. With sterile vacuum drying, the Harvey® PV Dry is recommended for medical and dental offices where packs, bagged instruments, and wrapped instrument sets, such as surgical kits are stored for later usage. The integral sterile drying in a 30-40 minute cycle, gives assurance of sterile conditions of the instruments at the time of delivery to the operatory. Sterile vacuum drying eliminates the need for extended drying cycles using non-sterile air.

Some features unique to the Harvey® PV Dry also demonstrate safety as well as the efficiency of the unit. The interlocking device on the door prevents manual opening until the chamber pressure decreases to near atmospheric pressure. Other technologies which help in the convenience and ease of operation of the Harvey® PV Dry include indicator lights to tell the user when the waste tank needs to be emptied, and controls preventing the running of a cycle until it is drained, indicator lights telling the user when the water supply needs to be replenished, and cycle parameter display. In the predicate device comparison matrix in Section II, there are detailed differences and similarities between the Harvey® PV Dry and its predicate device, Harvey® MC10 Steam Sterilizer.

Non-clinical Testing: Validation studies were conducted by SPS Medical Supply Corporation located at 6789 West Henrietta Road, Rush, NY 14543. Validation testing is in accordance with ANSI/AAMI ST55, ANSI/AAMI ST37. Since neither standard specifically addresses handpiece cycle validation, additional handpiece cycle validation testing was performed with the protocol being written in accordance with FDA Draft Guidance Document on Dental Handpieces, 1995, and the Guidance on Premarket Notification Submissions for Sterilizers Intended for Use in Health Care Facilities, 1993. Successful sterilization was achieved in all three validations and the declarations of conformity to the consensus standards are located in Section III. Testing results and raw data are contained in the product's device master record.

Conclusion: It is Barnstead/Thermolyne's conclusion that the Harvey® PV Dry is substantially equivalent to its predicate device, the Harvey® MC10 Steam Sterilizer. Based on the validation results and information submitted, the Harvey® PV Dry provides effective sterilization of the indicated medical and dental materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

Barnstead/Thermolyne Corporation
C/O Mr. Reiner Krumme
Responsible Third Party
TUV Rheinland of North America, Inc
12 Commerce Road
Newton, Connecticut 06470

Re: K014174
Trade/Device Name: Harvey PV Dry Sterilizer, Model # ST127325; ST127320
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: February 12, 2002
Received: February 13, 2002

Dear Ms. Krumme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 4
02.11.2002

INDICATIONS FOR USE STATEMENT

510(k) Number : 014174

Device Name: Harvey® PV Dry

Indications for Use:

The Harvey® PV Dry is a prevacuum and post vacuum drying sterilizer intended to provide sterilization of medical and dental instruments. It is intended to provide sterilization of wrapped or unwrapped metal instruments, surgical devices and other heat stable devices in pouches, surgical packs, dental handpieces, and linen packs. Deionized or distilled water is required for operation of the Harvey® PV Dry.

The sterilizer has four standard cycles: Unwrapped Instruments (135C for 3 minutes); Wrapped Instruments (135C for five minutes); Packs (121C for 30 minute); Special, for dental handpieces (5 minutes at 134C). There is also an accessible Bowie-Dick test cycle for routine testing of the steam penetration capability into packs. The parameters are fixed for each cycle.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optonal Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K014174

Appendix 7 – (b)(4) TS/CCI Test Report (b)(4) TS/CCI

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process - Testing

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Appendix 10

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Testing

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Appendix 11

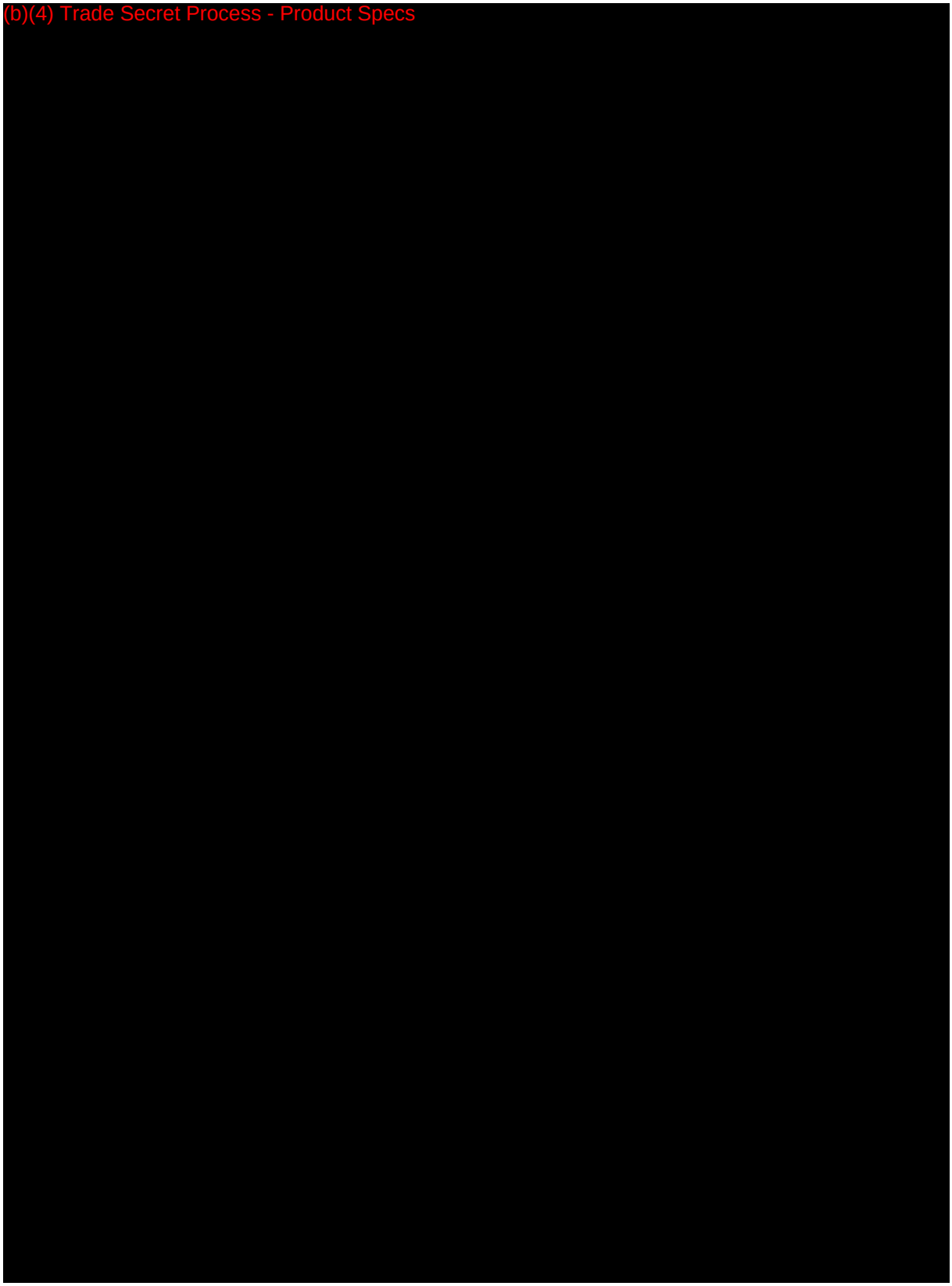
(b)(4) Trade Secret Process - Product Specs

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Appendix 11

(b)(4) Trade Secret Process - Product Specs



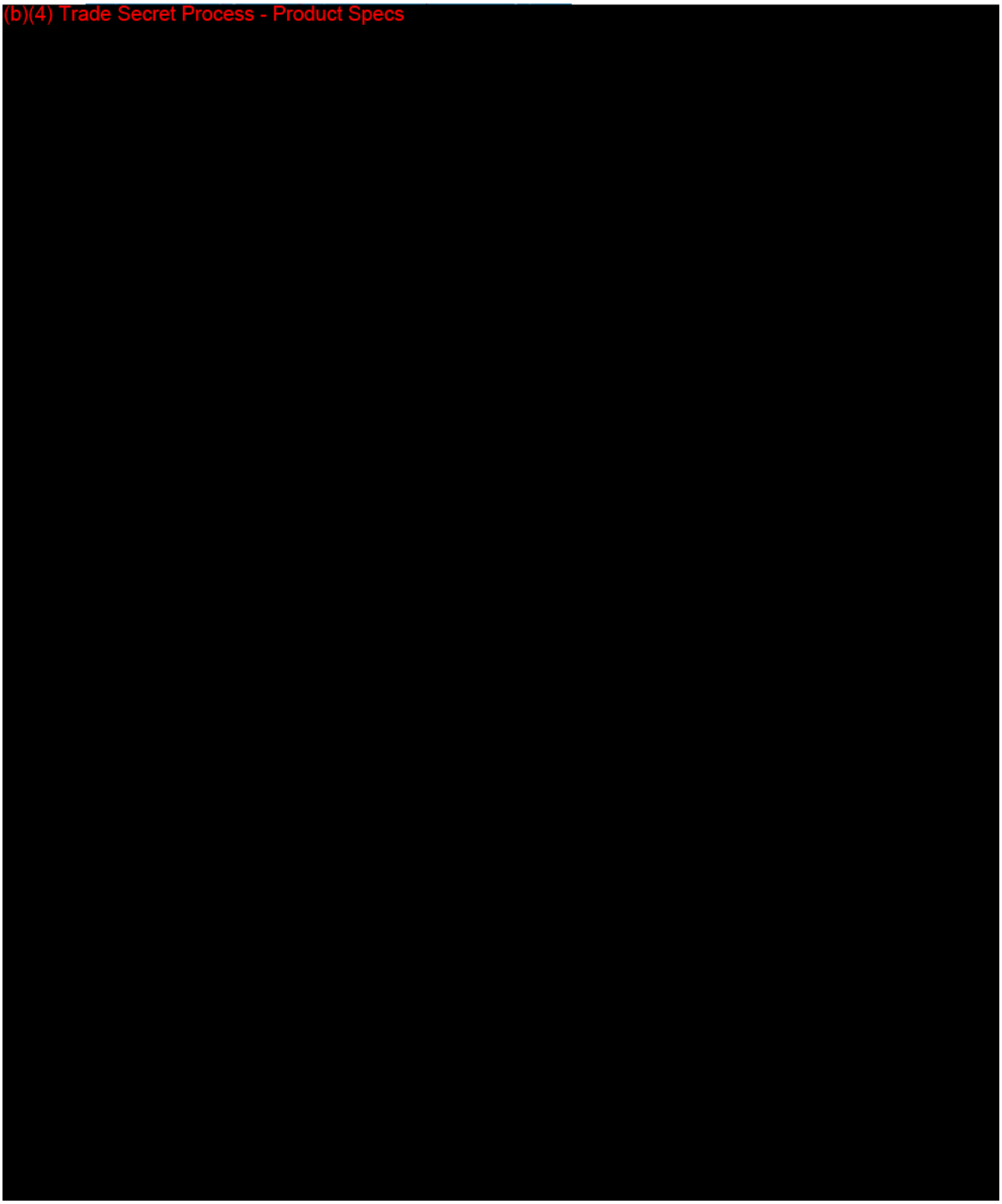
Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Appendix 12

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs



Traditional 510(k) Submission

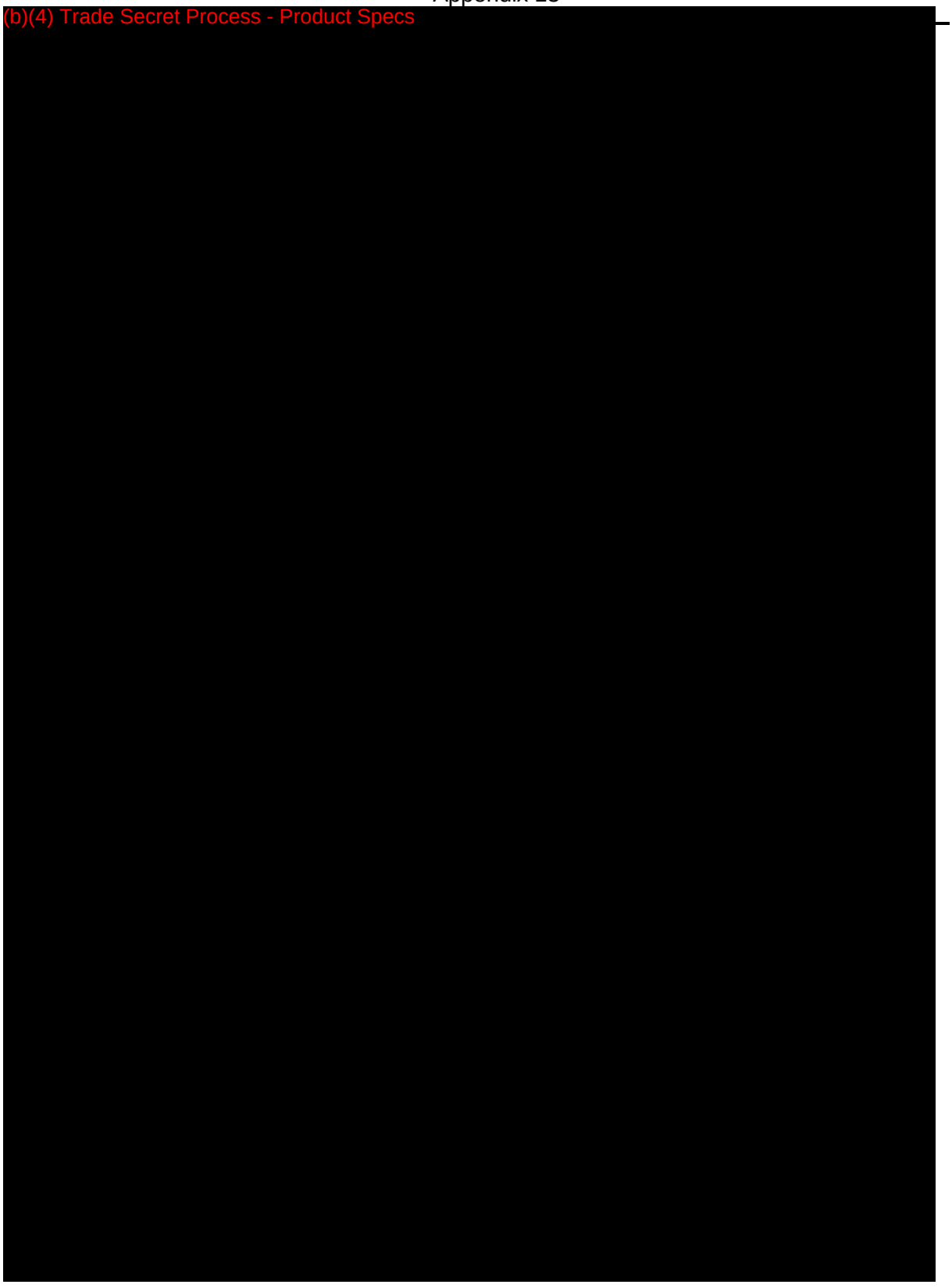
Straumann® Variobase™ Abutments

Appendix 13

(b)(4) Trade Secret Process - Product Specs

Appendix 13

(b)(4) Trade Secret Process - Product Specs



Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Appendix 14

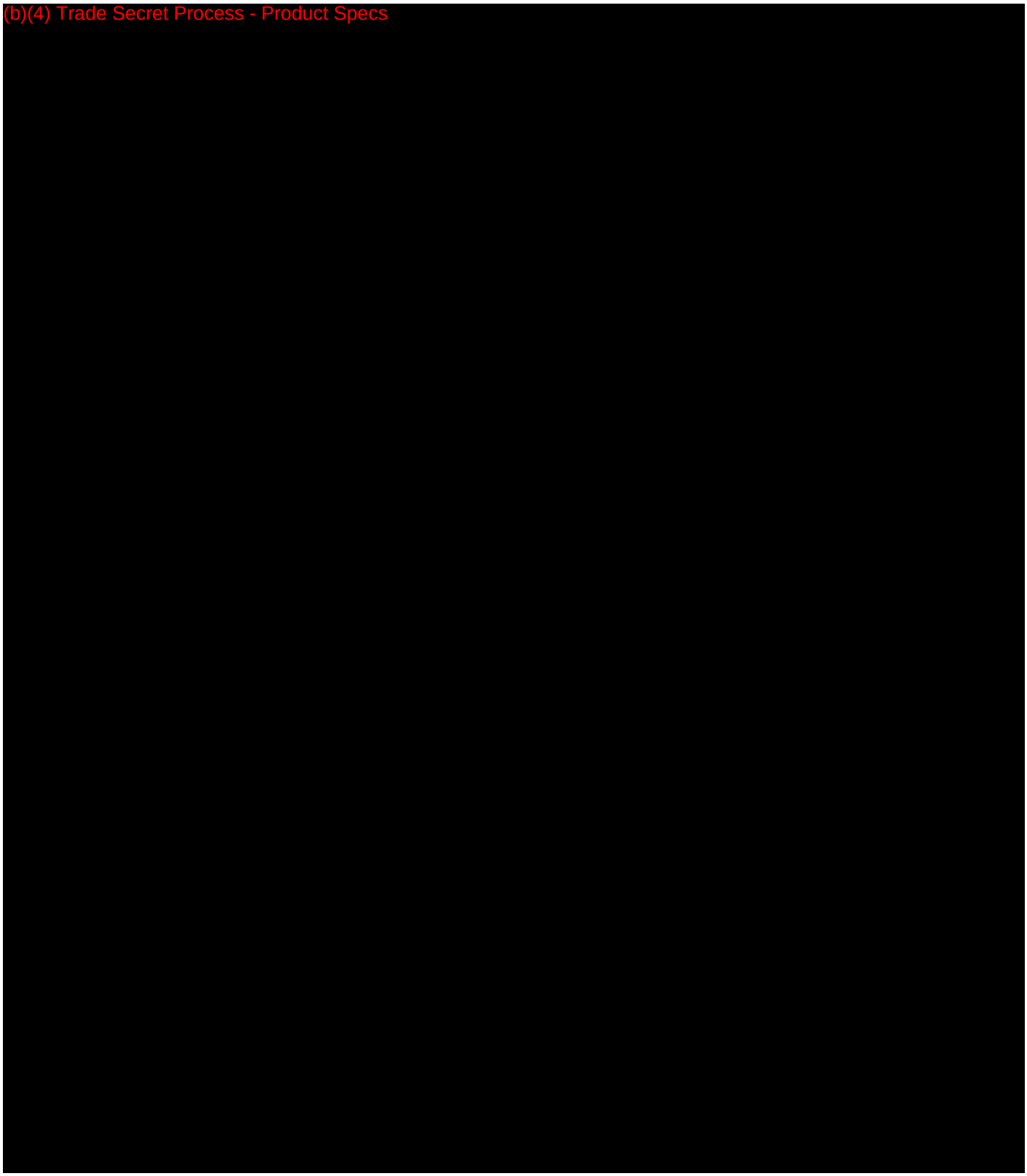
(b)(4) Trade Secret Process - Product Specs

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Appendix 14

(b)(4) Trade Secret Process - Product Specs

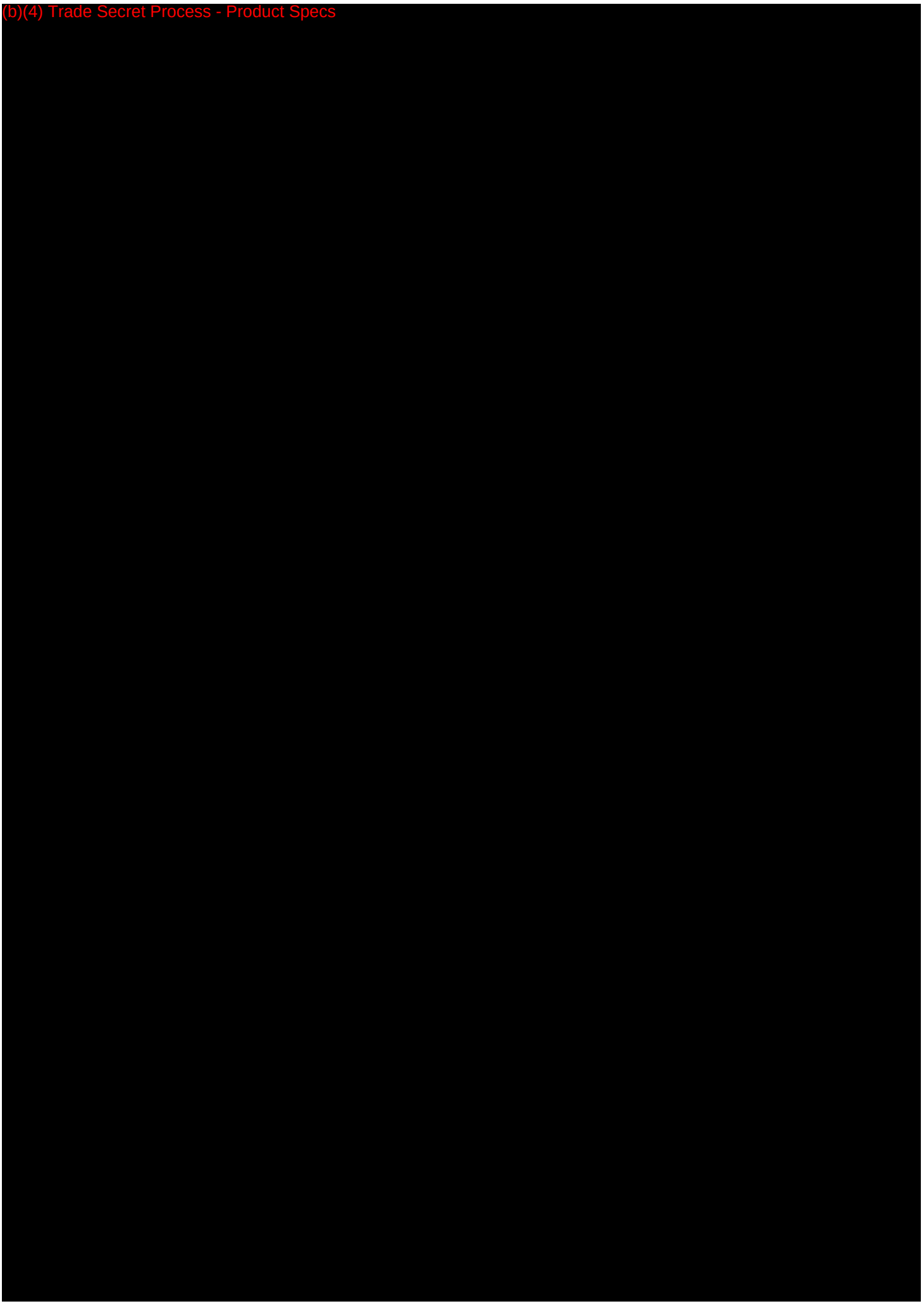


Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Appendix 15

(b)(4) Trade Secret Process - Product Specs [redacted]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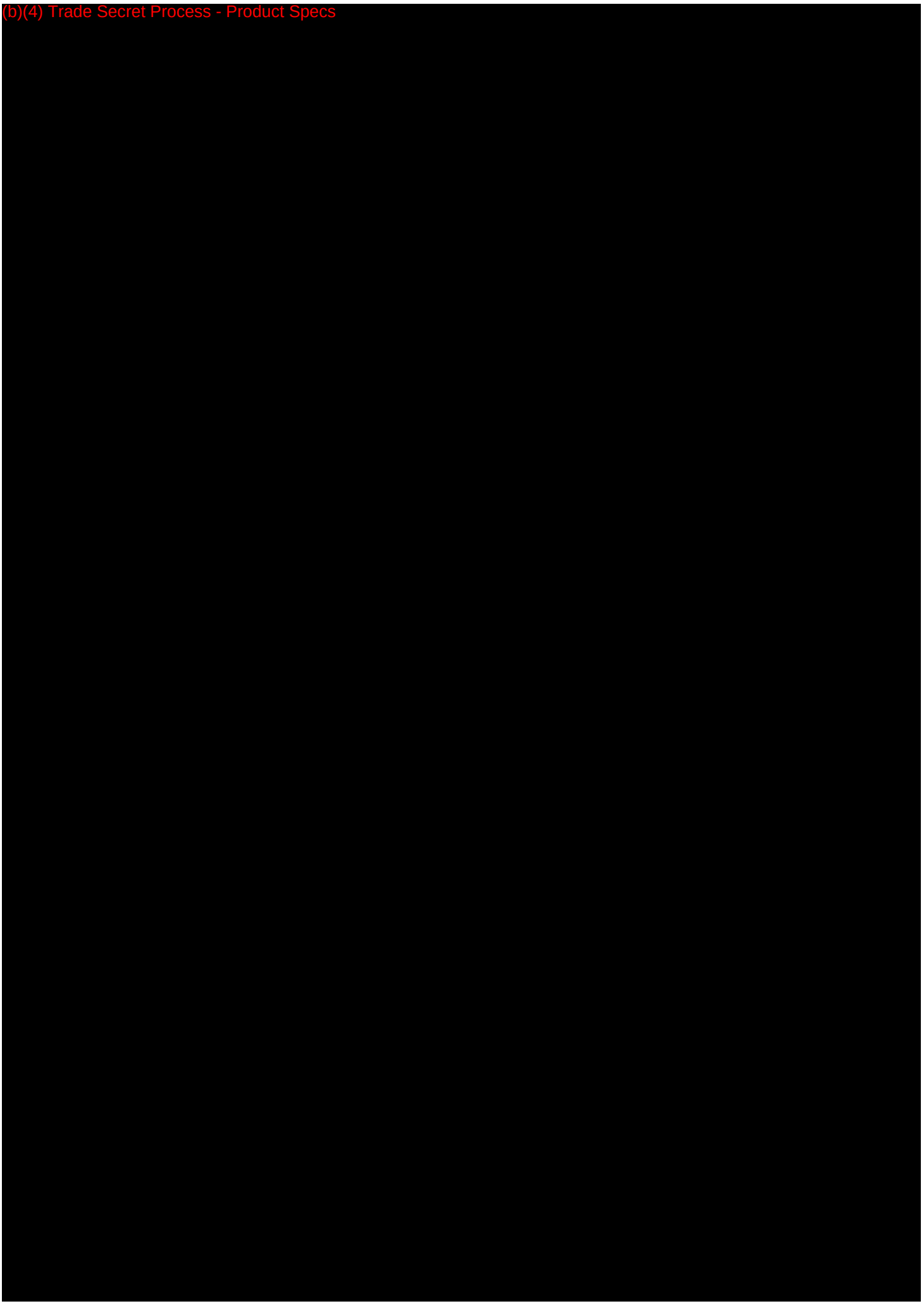
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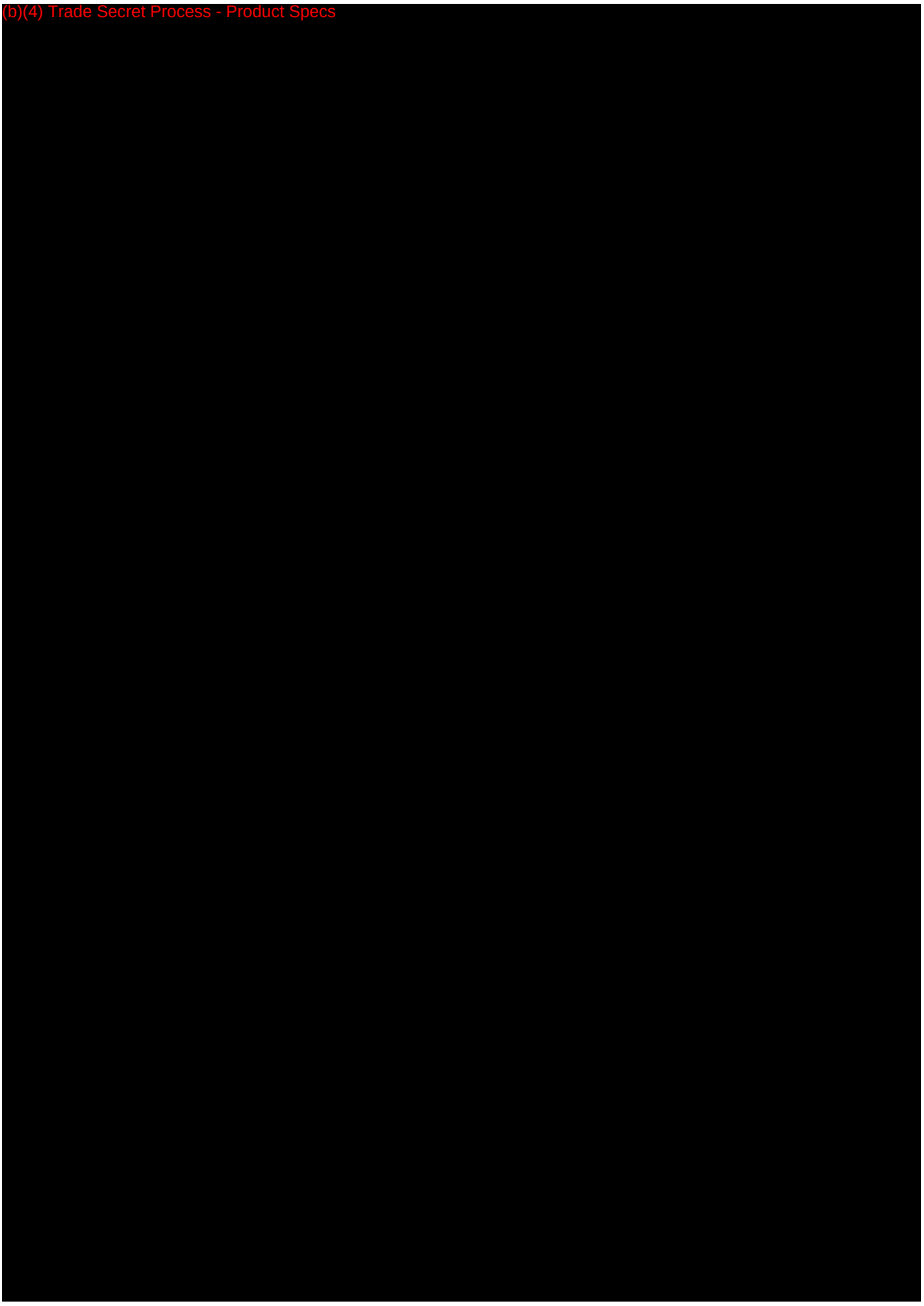
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(b)(4) Trade Secret Process - Product Specs

straumann®

January 23, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

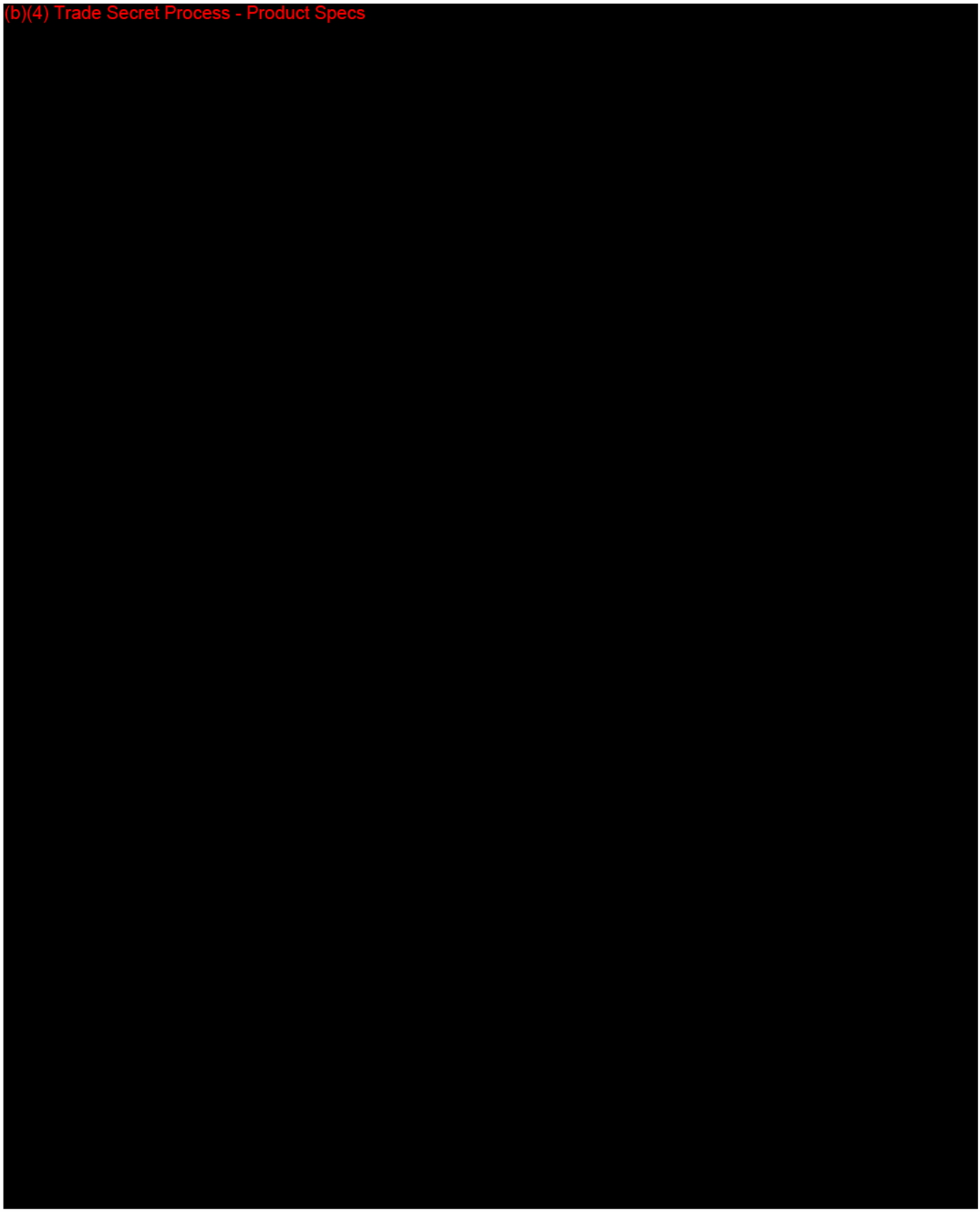
Subject: Response to Telephone Holds for K132219 Dated November 14, 2013 and November 19, 2013

Dear Sir or Madam:

(b)(4) Trade Secret Process - Product Specs

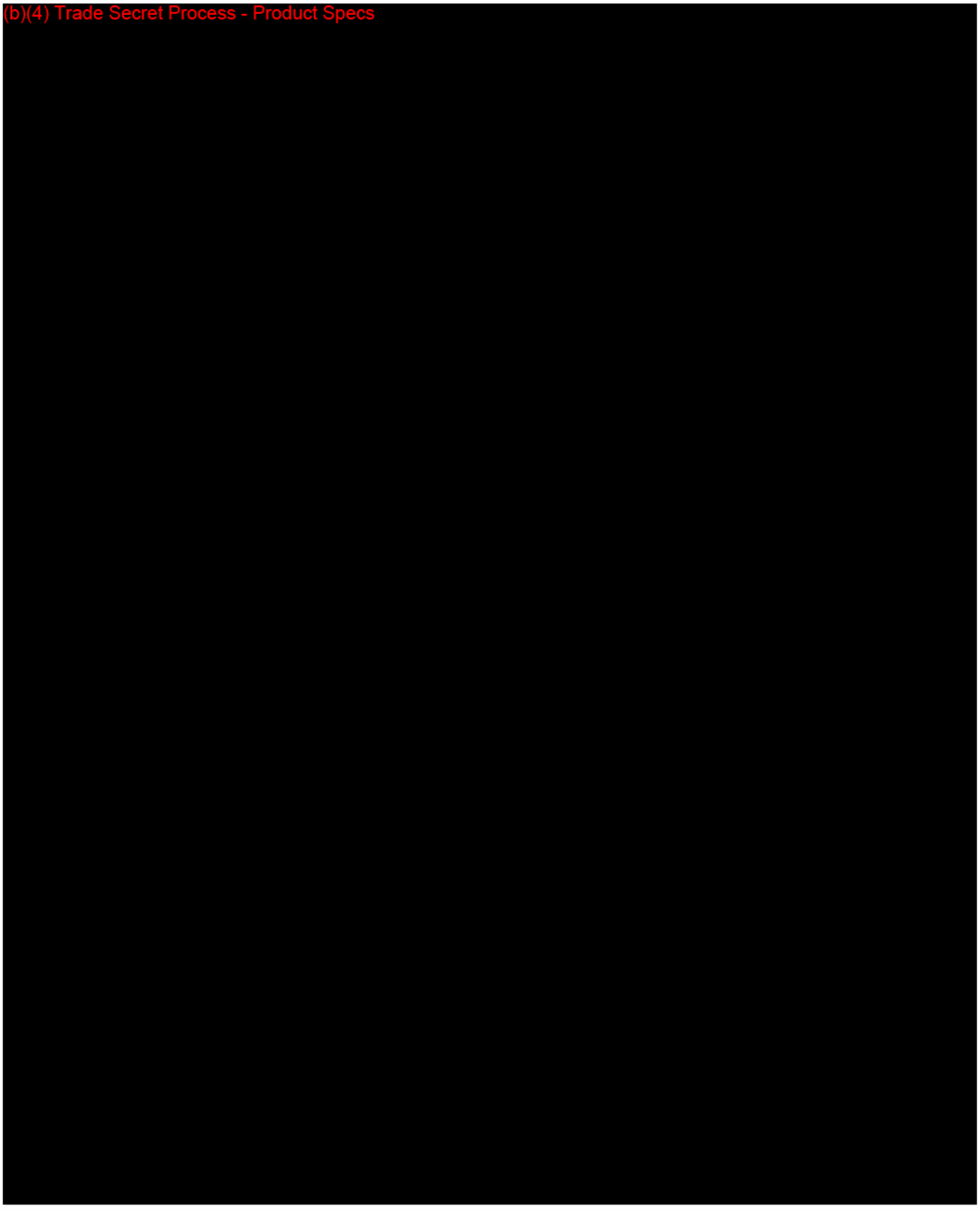
[redacted]

Straumann USA • 60 Minuteman Road • Andover, MA 01810
Phone 800/448 8168 • 978/747 2500 • Fax 978/747 2490 • www.straumannusa.com


(b)(4) Trade Secret Process - Product Specs

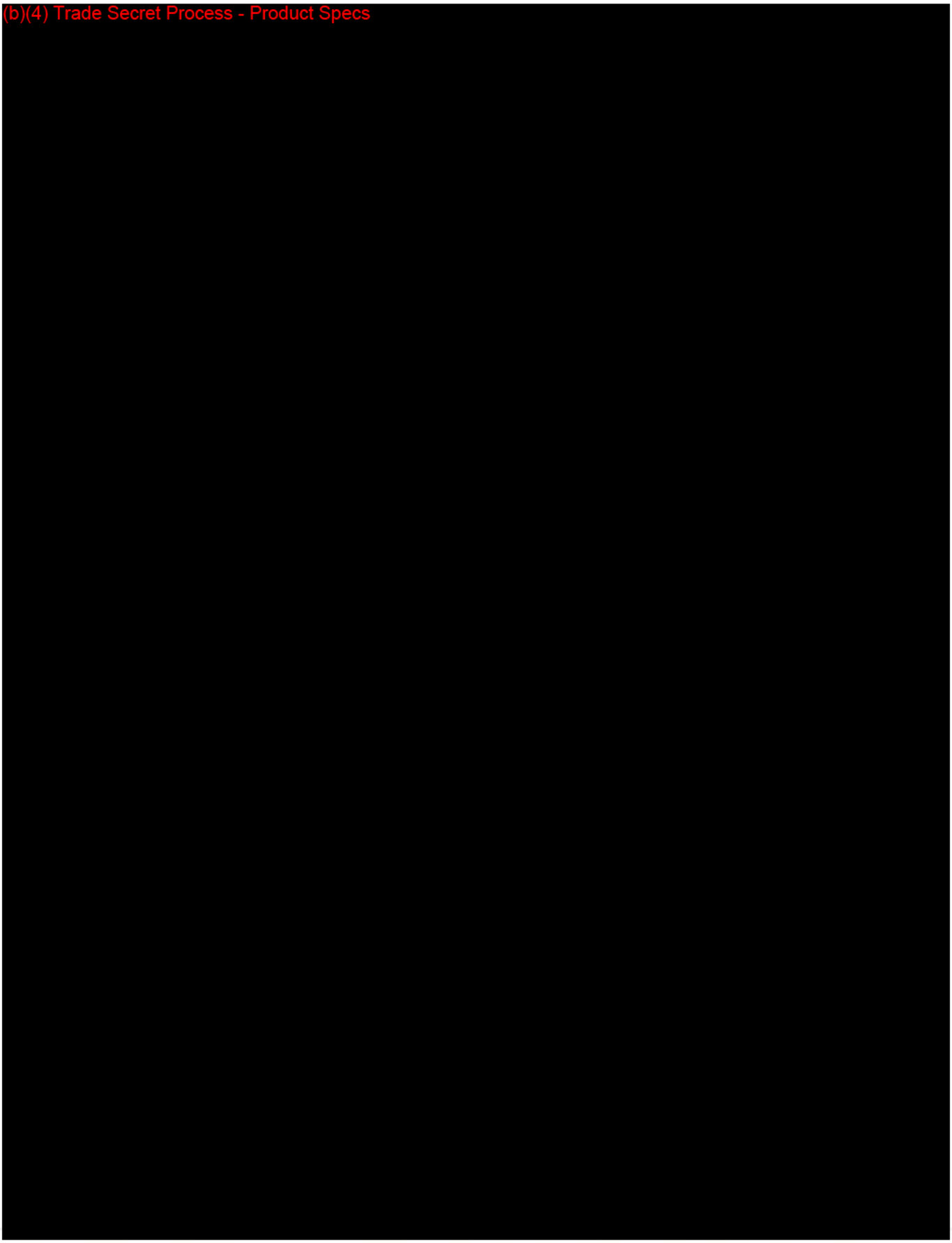
straumann

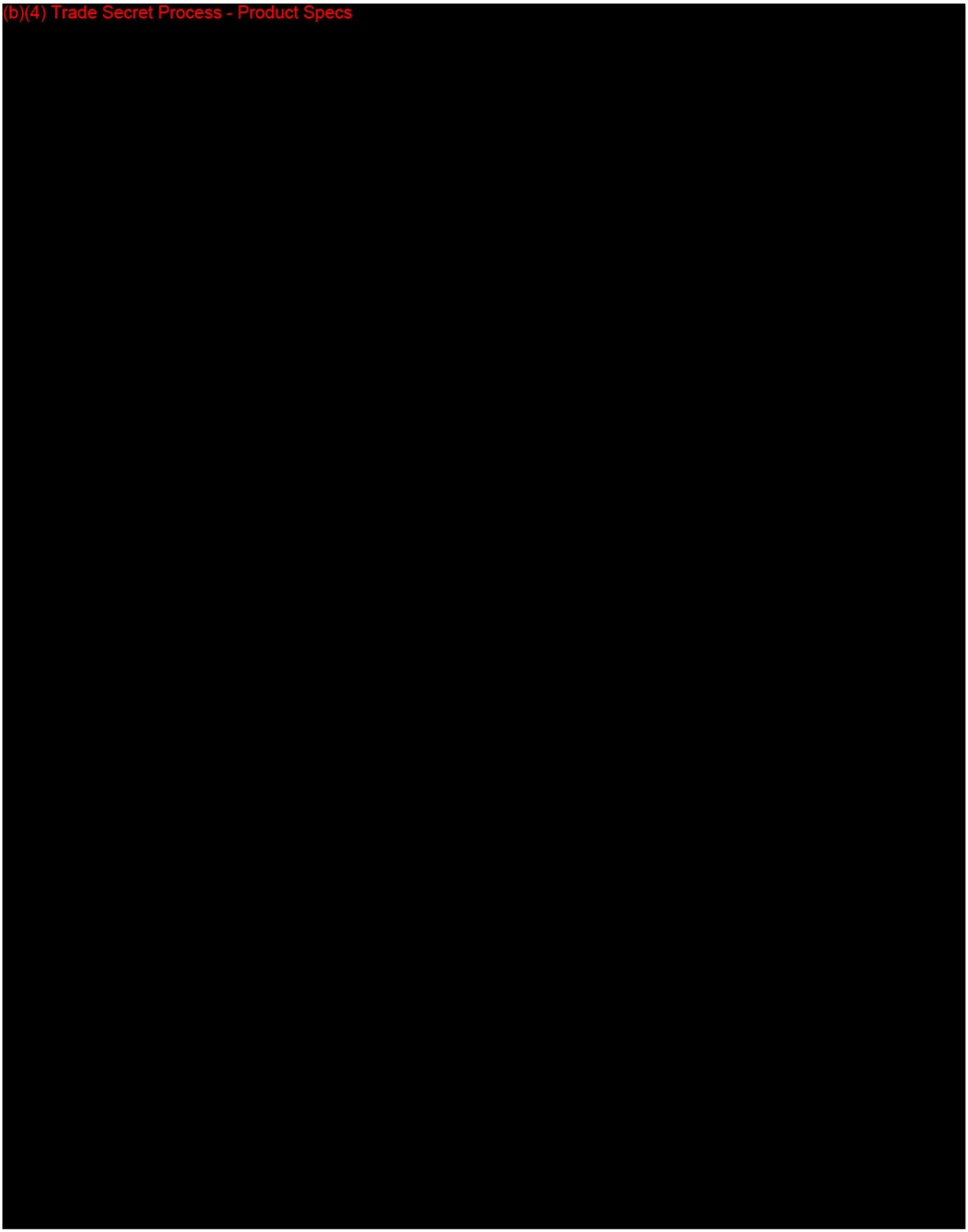
(b)(4) Trade Secret Process - Product Specs



straumann

(b)(4) Trade Secret Process - Product Specs




(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

[redacted]

Sincerely,

Jennifer M. Jackson

Jennifer M. Jackson, MS

Senior Regulatory Affairs Project Manager

Enclosures

2 CDRH Premarket Review Submission Cover Sheet

The CDRH Premarket Review Submission Cover Sheet begins on the next page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01-23-2014	(b)(4) Trade	K132219

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Straumann USA, LLC	1222315		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	978-747-2509		
Street Address	**FAX Number *(including area code)***		
60 Minuteman Road	978-747-0023		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Andover	MA	01810	USA
Contact Name			
Jennifer M. Jackson, MS			
Contact Title	**Contact E-mail Address**		
Senior Regulatory Affairs Project Manager	jennifer.jackson@straumann.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NHA	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K120822	1	Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC	1	Institut Straumann AG
2	K111935	2	Ti-Base Abutment	2	NT-Trading GmbH & Co. KG
3	K072055	3	Lava Frame, Lava Frame Shade	3	3M ESPE AG
4	K072071	4	P.004 RC Cementable Abutments	4	Institut Straumann AG
5	K111421	5	Sirona Dental CAD/CAM-System	5	Sirona Dental Systems GmbH
6	K120053	6	IPS e.max Press - Abutment Solutions	6	Ivoclar Vivadent AG

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Endosseous dental implant abutment

(b)(4) Trade Secret Process - Testing

[redacted]

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 None	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NHA	21 CFR 872.3630	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Dental		

Indications *(from labeling)*

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth restorations.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1		2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached

☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K132209	1	IPS e.max CAD Abutment Solutions	1	Ivoclar Vivadent AG
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device		Model Number
1		1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
		☐ Class I ☐ Class II ☐ Class III ☐ Unclassified
Classification Panel		

Indications *(from labeling)*

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Institut Straumann AG		Establishment Registration Number: 9613348
Division Name *(if applicable)*		Phone Number *(including area code)*: 978-747-2509
Street Address: Peter Merian-Weg 12		FAX Number *(including area code)*: 978-747-0023
City: Basel	State / Province	ZIP Code: CH-4052 / Country: Switzerland
Contact Name: Jennifer M. Jackson, MS	Contact Title: Senior Regulatory Affairs Project Manager	Contact E-mail Address: jennifer.jackson@straumann com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

SECTION I	UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

(b)(4) Trade Secret Process - Testing

[redacted]

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No. ISO 17664:2004	Standards Organization ISO	Standards Title Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices	Version 2004	Date 10-12-2012
2	Standards No. ISO 14801:2007	Standards Organization ISO	Standards Title Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants	Version 2007	Date 04-25-2012
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

4 Indications for Use Statement

The Indications for Use Statement associated with this 510(k) is located on the following page in the required format.

Indications for Use

510(k) Number (if known):

Device Name: Straumann® Variobase™ Abutments

Indications for Use:

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth restorations.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5 510(k) Summary

5.1 Submitter's Contact Information

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Contact Person: Jennifer M. Jackson, MS

Date of Submission: 23-Jan-2014

5.2 Name of the Device

Trade Name: Straumann® Variobase™ Abutments

Common Name: Dental Implant Abutment

Classification Name: Abutment, Implant, Dental, Endosseous

Regulation Number: §872.3630

5.3 Predicate Device(s)

- K120822, Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC (Institut Straumann AG)
- K111935, Ti-Base Abutment (NT-Trading GmbH & Co. KG)
- K072055, Lava™ Frame, Lava™ Frame Shade (3M ESPE AG)
- K072071, P.004 RC Cementable Abutments (Institut Straumann AG)
- K111421, Sirona Dental CAD/CAM-System (Sirona Dental Systems GmbH)
- K120053, IPS e.max® Press – Abutment Solutions (Ivoclar Vivadent AG)
- K132209, IPS e.max® CAD Abutment Solutions (Ivoclar Vivadent AG)

5.4 Device Description

The Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments, sometimes referred to as "Ti-bases". Straumann® Variobase™ Abutments are available

to fit Straumann® dental implant platforms NNC (Narrow Neck CrossFit®), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit®), and RC (Regular CrossFit®). A dental laboratory technician would design the corresponding coping and/or crown (the second component of the Variobase two-piece abutment) and/or prosthetic restoration in the dental laboratory via their preferred workflow for pressing, casting, or milling using either a burnout coping or STL model for open CAD software. The coping and/or crown would be manufactured via traditional laboratory methods for pressing or casting, or via validated Straumann milling.

5.5 Intended Use

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments intended to be placed onto Straumann dental implants to provide support for customized prosthetic restorations such as crowns. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth restorations.

5.6 Technological Characteristics

Straumann® Variobase™ Abutments are two-piece abutments consisting of a pre-manufactured (stock) abutment made from a titanium-aluminum-niobium alloy and a coping and/or crown which is designed in the dental laboratory by a dental technician and manufactured via traditional in-lab methods of pressing or casting, or via validated Straumann milling.

The Ti-base components of the Straumann® Variobase™ Abutments are identical to the Ti-base components of the Straumann predicate (K120822). The Ti-base components are also equivalent to the Ti-base components identified in K111935, K072055, K120053, and K132209.

The materials which may be used to manufacture the coping/crown component of the Straumann Variobase Abutments are identical to the identified predicate devices and include:

Casting: Type 4 metals (ISO 22674)

Pressing: IPS e.max® Press Ceramic (K120053)

Milling: Polycon® ae (temporary restorations – K120822)

Zerion® (K120822)

IPS e.max® CAD Ceramic (K132209)

Lava™ Frame, Lava™ Frame Shade (K072055)

5.7 Performance Testing

The material used in the manufacture of Straumann® Variobase™ Abutments is a titanium-aluminum-niobium alloy which meets the requirements of ISO 5832-11. Bench testing was performed with Polycon® ae and Zerion® to evaluate the fatigue load limits of the proposed Straumann® Variobase™ Abutments. Dynamic fatigue tests were conducted in according to the FDA guidance document *"Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments"*.

5.8 Conclusion

The documentation submitted in this premarket notification demonstrates that the Straumann® Variobase™ Abutments are substantially equivalent to the predicate devices and do not pose new issues of safety and effectiveness when used as labeled.

10 Device Description

(b)(4) Trade Secret Process - Testing

10.1 Straumann® Variobase™ Abutments

(b)(4) Trade Secret Process - Testing

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Device Description

(b)(4) Trade Secret Process - Testing

Table 3 outlines the Straumann® Variobase™ Abutments and their corresponding article numbers:

(b)(4) Trade Secret Process - Testing

[redacted]

10.2 Basal Screws

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

10.3 Accessories

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

10.4 Procedure

(b)(4) Trade Secret Process - Testing

10.4.1 Restoration Design and Manufacturing

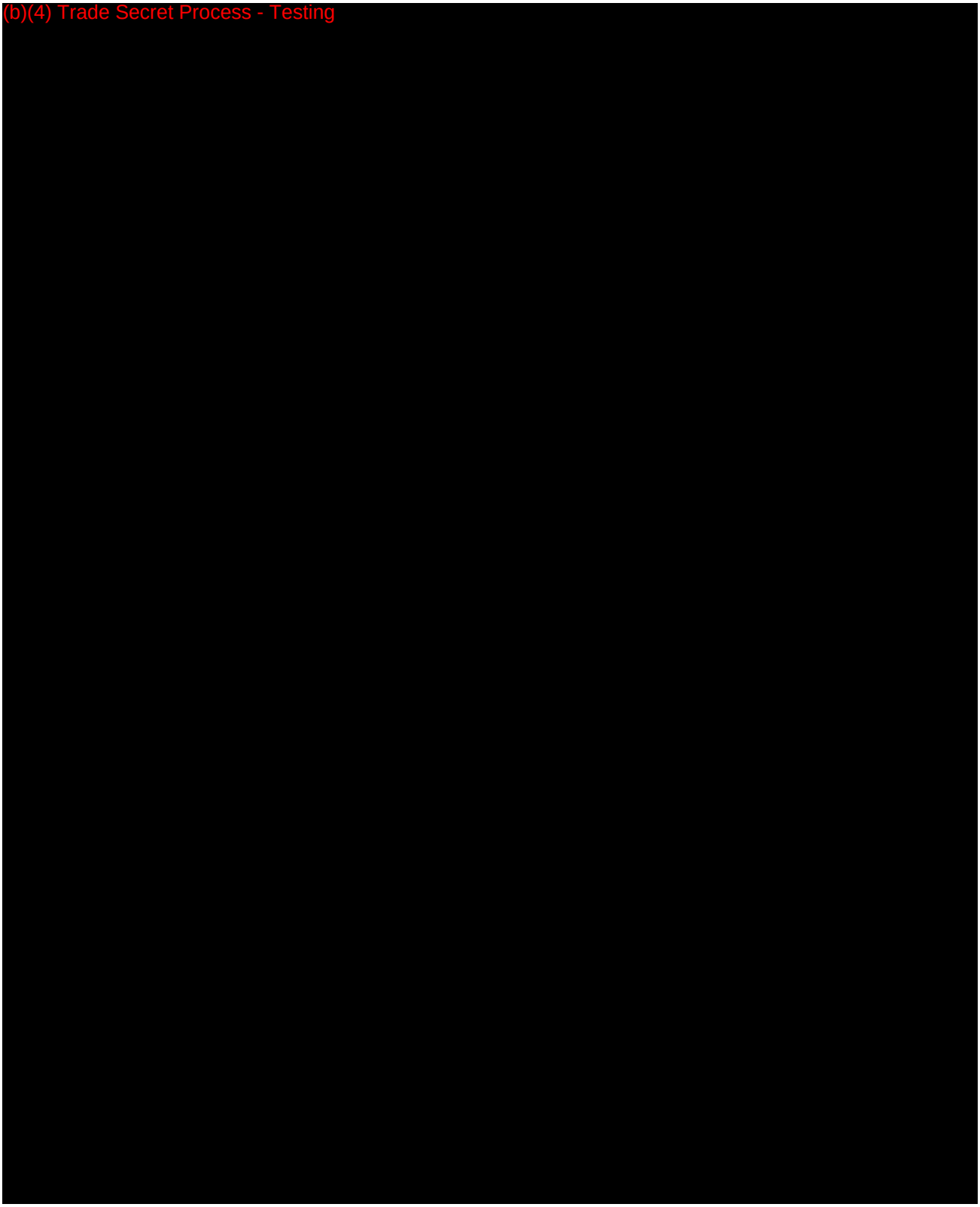
(b)(4) Trade Secret Process - Testing

10.4.1.1 In-lab Casting

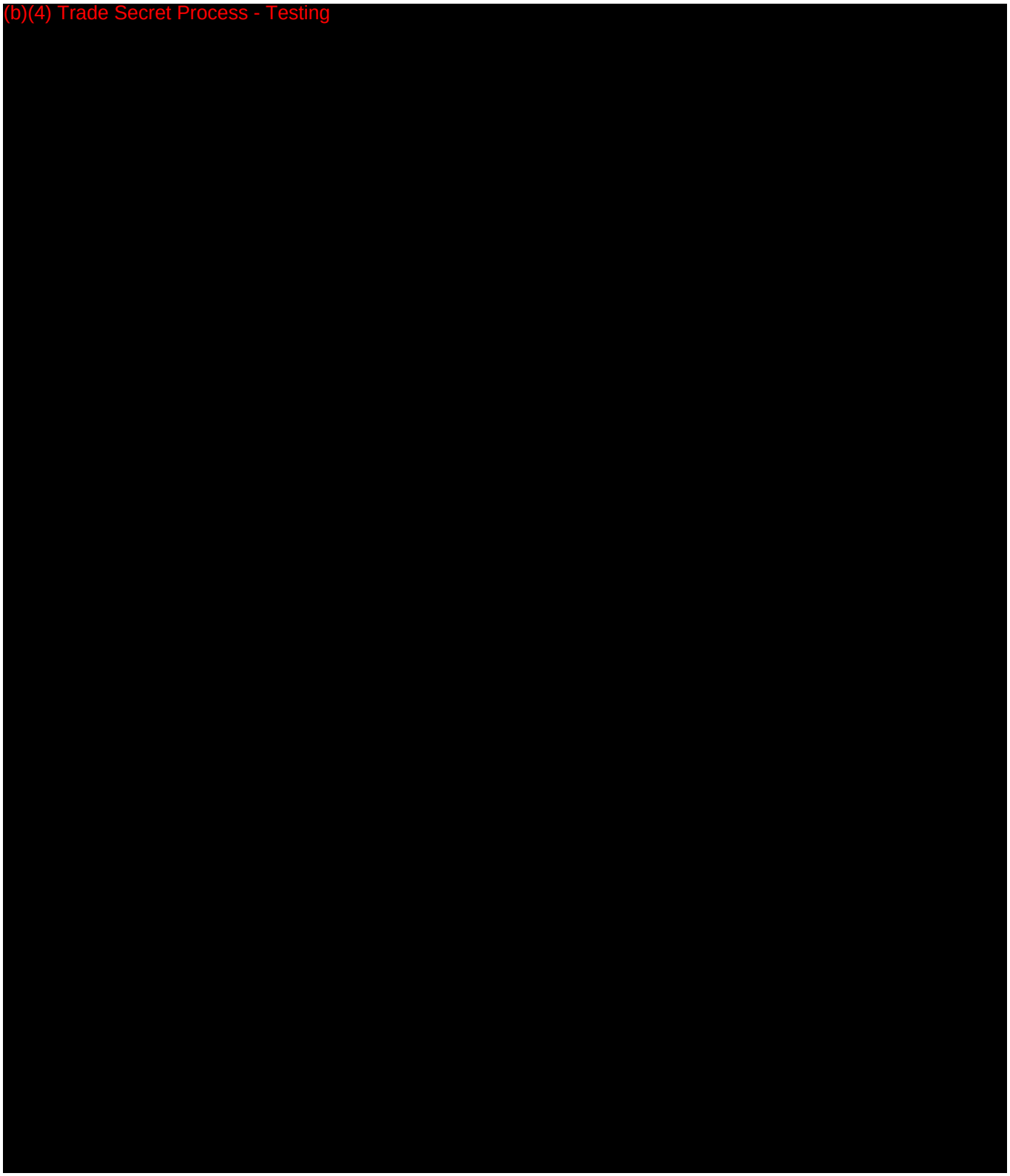
(b)(4) Trade Secret Process - Testing

Device Description

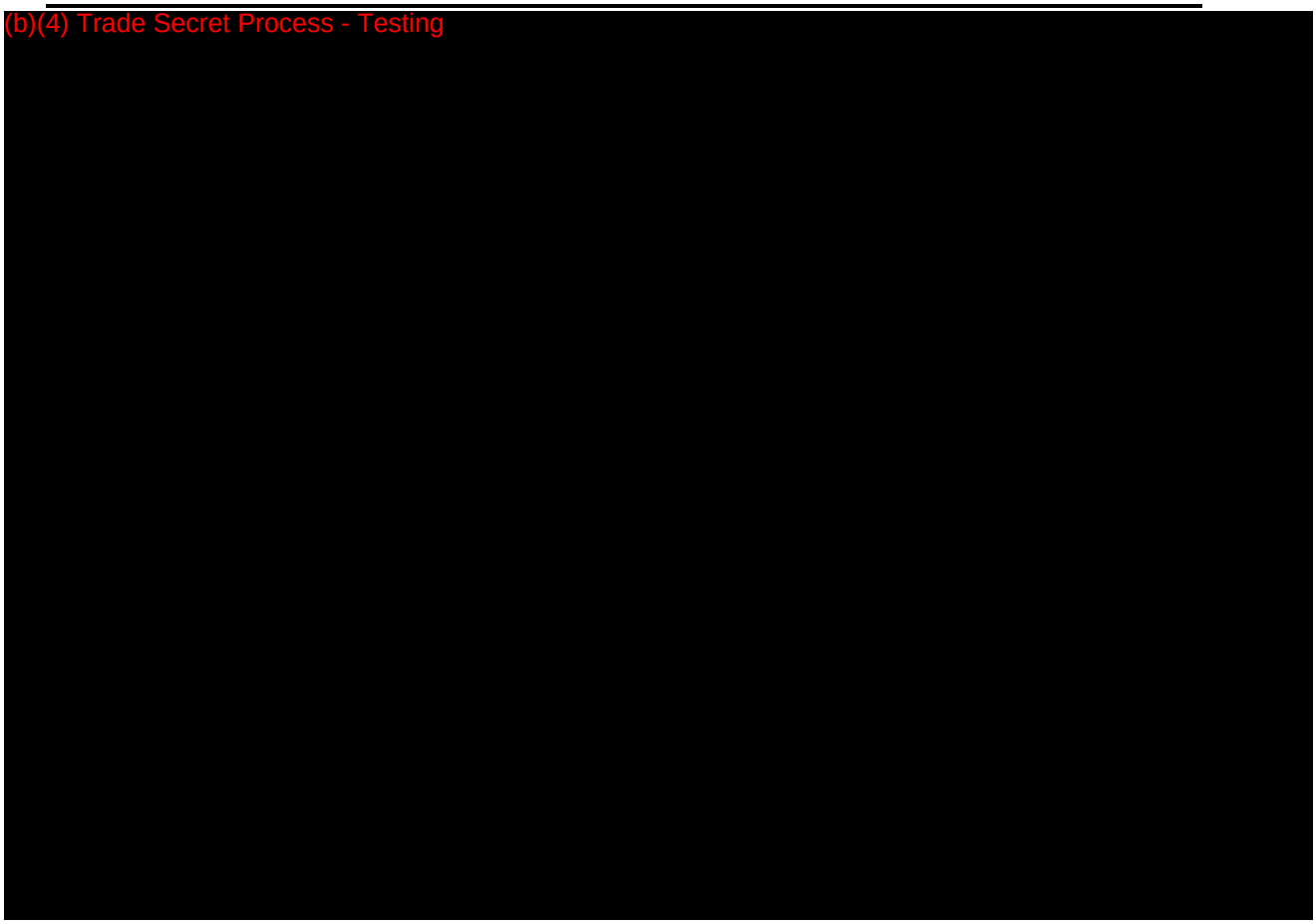
(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



11 Substantial Equivalence Discussion

Within the meaning of the Medical Device Amendments Act of 1976, the proposed change to the Indications for Use for the Straumann® Variobase™ Abutments in this 510(k) premarket notification are substantially equivalent to the medical devices currently in commercial distribution listed below:

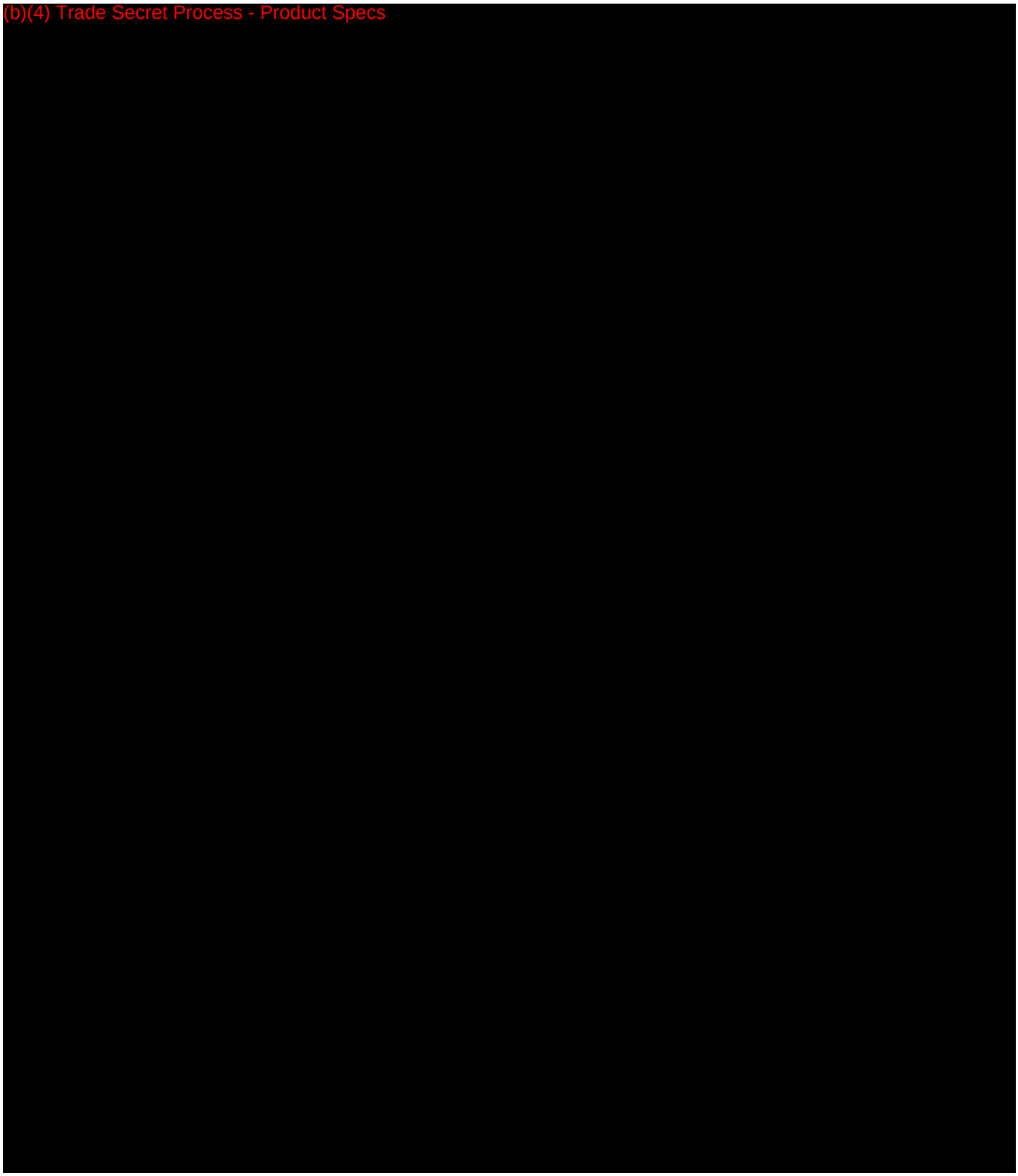
- K120822, Straumann CARES Variobase Abutment NNC, RN, WN, NC, RC (Institut Straumann AG)
- K111935, Ti-Base Abutment (NT-Trading GmbH & Co. KG)
- K072055, Lava™ Frame, Lava™ Frame Shade (3M ESPE AG)
- K072071, P.004 RC Cementable Abutments (Institut Straumann AG)
- K111421, Sirona Dental CAD/CAM-System (Sirona Dental Systems GmbH)
- K120053, IPS e.max® Press – Abutment Solutions (Ivoclar Vivadent AG)
- K132209, IPS e.max® CAD Abutment Solutions (Ivoclar Vivadent AG)

Straumann® Variobase™ Abutments are pre-manufactured (stock) abutments intended to be placed onto Straumann dental implants to provide support for customized prosthetic reconstructions such as crowns. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth restorations.

The NT-Trading Ti-Base Abutment is a pre-manufactured abutment supplied in two parts, the abutment and screw, for fixation onto dedicated endosseous dental implants and is intended for use as an aid in prosthetic restoration. As with the subject device, the coping/restoration is provided by the dental laboratory. The 510(k) Summary for the NT-Trading Ti-Base Abutment (Appendix 5) states “The Ti-Base is compatible with commercially available dental CAD/CAM systems, such as 3Shape, Exocad, and Dental Wings. Such systems must be validated by the user”.

The NT-Trading catalog and package insert are included in this submission in Appendices 3 and 4, respectively. The products that were cleared in premarket notification K111935 are outlined in Table 7 (the 510(k) Summary is included in Appendix 5). Specifically, the L-Series and N-Series abutments are compatible with implants of the Straumann Dental Implant System as shown in Table 7.

(b)(4) Trade Secret Process - Product Specs



Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

(b)(4) Trade Secret Process - Product Specs

[redacted]

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

The table below provides a comparison matrix of the proposed and predicate devices (K120822):

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Straumann® CARES® Variobase™ Abutments (K120822)**	
Indications for Use	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth restorations.	The Straumann® CARES® Variobase™ Abutment is a two-piece dental abutment consisting of the Straumann® Variobase™ Abutment and the Straumann® CARES® Variobase™ Coping which is intended to be placed onto Straumann dental implants to provide support for prosthetic reconstruction such as crown and bridges. Straumann® CARES® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. The Straumann® CARES® Variobase™ Coping polycon® ae in combination with the Straumann® CARES® Variobase™ Abutment is indicated for temporary (up to 180 days) dental restoration of a Straumann dental implant.	The indications for use are being modified to allow Straumann to market the Straumann® Variobase™ Abutment as a stand-alone component. The dental laboratory would then manufacture the respective coping and/or prosthetic restoration using a burnout coping or STL model for open CAD software.
Ti-base Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Identical
Abutment Diameter	(b)(4) Trade Secret Process - Product Specs		Identical
Abutment Height			Identical

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Straumann® CARES® Variobase™ Abutments (K120822)**	
Bonding Surface Area	(b)(4) Trade Secret Process - Product Specs		Identical
Coping/ Crow Material	(b)(4) Trade Secret Process - Product Specs		
Design Workflow	Wax-up or Open CAD	CARES® Visual	Equivalent
Manufacturing Workflow	(b)(4) Trade Secret Process - Product Specs		
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Identical
Reusable	No	No	Identical

Table 8 - Comparison Matrix: Proposed Device versus Predicate Devices (K120822)

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

The table below provides a comparison matrix of the proposed and predicate devices (K111935):

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Ti-Base Abutment (K111935)**	
Indications for Use	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth restorations.	Ti-Base for individual Zirconium Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base for individual Zirconium Abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems: • Nobel Biocare® Replace Select® • Nobel Biocare NobelActive™ • Biomet 3i® Osseotite® • Biomet 3i® Osseotite® Certain® • Nobel Biocare Branemark® • Straumann® synOcta® • Straumann® Bone Level® • Zimmer® Tapered Screw-vent® • Astra Tech OsseoSpeed® • Dentsply-Friadent® Frialit®	Equivalent – Both the subject and predicate devices are designed to interface with the Straumann Bone Level or the Straumann Tissue Level implants.

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Ti-Base Abutment (K111935)**	
Ti-base Material	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V)	Equivalent
Abutment Diameter	(b)(4) Trade Secret Process - Product Specs		Equivalent
Abutment Height			Equivalent
Bonding Surface Area	(b)(4) Trade Secret Process - Product Specs	Unknown	Unknown
Coping/ Cro Material		Not specified	The predicate device does not specify coping/crown material so a comparison cannot be made in this case.
Design Workflow	(b)(4) Trade Secret Process - Product Specs		

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Ti-Base Abutment (K111935)**	
Manufacturing Workflow	(b)(4) Trade Secret Process - Product Specs [redacted]		
Mode of Action	Screw-retained or cement retained	Screw-retained or cement retained	Identical
Reusable	No	No	Identical

Table 9 - Comparison Matrix: Proposed Device versus Predicate Devices (K111935)

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

The table below provides a comparison matrix of the proposed and predicate devices (K120053/K072071 and K132209/K111421):

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**IPS e.max® Press – Abutment Solutions (K120053) including P.004 RC Cementable Abutments (K072071)**	**IPS e.max CAD Abutment Solutions (K132209) including Sirona Dental CAD/CAM System (K111421)**	
Indications for Use	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth restorations.	IPS e.max® Press Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. IPS e.max Press Abutment Solutions is recommended for the fabrication of: - Hybrid abutments for single-tooth restorations - Hybrid abutment crowns for restorations The following Ti bases are intended to be used with IPS e.max Press Abutment Solutions: Straumann® Bone Level RC Ø4.1 mm or Ø4.8 mm (K062129) RC Cementable Abutment D 5.0 – 6.5 mm, GH 1.0 – 3.0 mm, HTi 4.0 – 5.5 mm (K072071)	IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. The system comprises three parts: IPS e.max CAD mesostructure Ti base and CAD/CAM software The IPS e.max CAD mesostructure cemented to the Ti base is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants. The compatible Implant systems, Ti bases and CAD/CAM systems are shown below: Implant systems: … Straumann Bone Level (K053088, K062129,	Equivalent

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**IPS e.max® Press – Abutment Solutions (K120053) including P.004 RC Cementable Abutments (K072071)**	**IPS e.max CAD Abutment Solutions (K132209) including Sirona Dental CAD/CAM System (K111421)**	
			K060958) … CAD/CAM Systems: Sirona inLab and Cerec SW 4.2 and above … Straumann, Bone Level NC, Ø3.3 mm, S BL 3.3, 6308154, L Straumann, Bone Level RC, Ø4.1 mm, S BL 4.1, 6308337, L … For the titanium base Straumann Bone Level 3.3 L the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible.	
Ti-base Material	Titanium-Aluminum-Niobium alloy	Grade 4 Titanium	Titanium-Aluminum-Vanadium alloy (Ti-6Al-4V), medical grade 5, ASTM 136	Equivalent
Abutment Diameter	(b)(4) Trade Secret Process - Product Specs [redacted]			Equivalent
Abutment Height				Equivalent

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**IPS e.max® Press – Abutment Solutions (K120053) including P.004 RC Cementable Abutments (K072071)**	**IPS e.max CAD Abutment Solutions (K132209) including Sirona Dental CAD/CAM System (K111421)**	
Bonding Surface Area	(b)(4) Trade Secret Process - Product Specs	43 mm^2 (RC)	53.5 mm^2 (RC)	Equivalent
Coping/ Crown Material	(b)(4) Trade Secret Process - Product Specs	IPS e.max® Press Ceramic	IPS e.max® CAD Ceramic	Identical for the IPS e.max® Press Ceramic and the IPS e.max® CAD Ceramic
Design Workflow	(b)(4) Trade Secret Process - Product Specs			
Manufacturing Workflow				
Mode of Action				
Reusable	No	No	No	Identical

Table 10 - Comparison Matrix: Proposed Device versus Predicate Devices (K120053/K072071 and K132209/K111421)

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

The table below provides a comparison matrix of the proposed and predicate devices (K072055):

FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Lava™ Frame, Lava™ Frame Shade (K072055)**	
Indications for Use	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth restorations.	The Lava™ system is intended for CAD/CAM fabrication of all-ceramic dental restorations. The system is used for the manufacturing of inlays, onlays, veneers, crowns and bridges. Lava™ Frame and Lava™ Frame Shade are intended for the manufacturing of abutments. The titanium connection for the abutment must meet the following dimensions: - Overall cementation surface >30 mm^2 - Height of the head of the titanium interface from the shoulder >2.8 mm The following systems fulfill the above described specifications: …	Equivalent
Ti-base Material	Titanium-Aluminum-Niobium alloy	Titanium	Equivalent
Abutment Diameter	(b)(4) Trade Secret Process - Product Specs		Equivalent
Abutment Height			Equivalent

Traditional 510(k) Submission

Straumann® Variobase™ Abutments

Substantial Equivalence Discussion

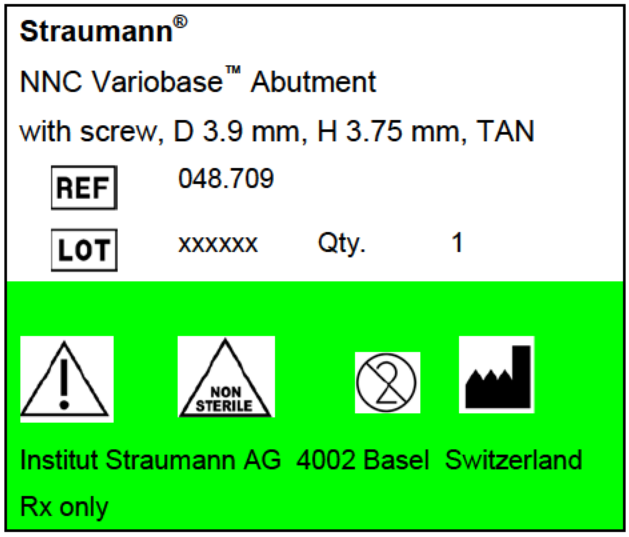
FEATURE	PROPOSED DEVICE	PREDICATE DEVICE	EQUIVALENCE DISCUSSION
K Number	**Straumann® Variobase™ Abutments Subject Submission**	**Lava™ Frame, Lava™ Frame Shade (K072055)**	
Bonding Surface Area	(b)(4) Trade Secret Process - Product Specs	≥33 mm^2	Equivalent
Coping/ Crown Material		Lava™ Frame and Lava™ Frame Shade	Identical for the Lava™ Frame and Lava™ Frame Shade
Design Workflow	(b)(4) Trade Secret Process - Product Specs		
Manufacturin Workflow			
Mode of Action	Screw-retained or cement retained	Cement retained	Equivalent
Reusable	No	No	Identical

Table 11 - Comparison Matrix: Proposed Device versus Predicate Devices (K072055)

12 Proposed Labeling

12.1 Package Label

There are no changes to the package label as a result of the proposed change in this premarket notification. To aid in the review of the submission, an example of the label is shown in Figure 1.



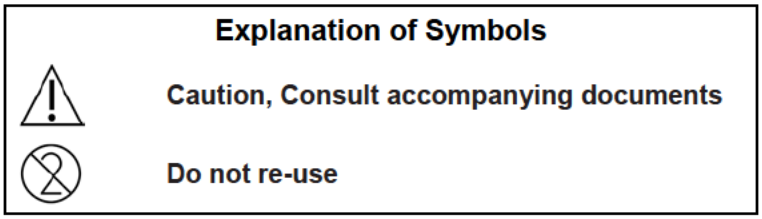


Figure 1 - Example label for Straumann® Variobase™ Abutment

12.2 Proposed Package Insert/Instructions for Use for Straumann® Variobase™ Abutments

Instructions for use: Straumann® Variobase™ Abutments

Institut Straumann AG, Peter-Merian-Weg 12, CH-4002 Basel/Switzerland, www.straumann.com

English

CAUTION: Federal law restricts this device to sale by or on the order of a dental professional.

Straumann® Variobase™ Abutments				
				
NNC	RN	WN	NC	RC

1. Product Description

Abutments

Abutments are placed into dental implants to provide support for prosthetic reconstructions such as crowns.

Basal Screws

Basal screws are used for the fixation of the abutment to the dental implant.

2. Intended use

Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations.

3. Indications

The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are indicated for screw-retained single tooth or cement-retained single tooth restorations.

4. Contraindications

Allergies or hypersensitivity to materials used, which are indicated in the following table:

Straumann Variobase™ Abutments, Screws	Titanium alloy, Ti-6Al-7Nb (titanium-aluminum-niobium or TAN).

5. Warnings and Precaution

Our products must be secured against aspiration when used intraorally. Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications:

- Aspiration or swallowing of a component
- Breakage
- Infection

The Straumann® Variobase™ Abutments are single use devices.

Place implant-borne restorations only in occlusion when the implant is completely osseointegrated.

Angled abutments should not be used in areas of high mechanical loads on small diameter implants.

Dental cement or any other material used for the attachment of prosthetic components should be processed as specified by the manufacturer.

Implants are only to be restored with the corresponding original abutment compatible with that specific implant.

The Straumann® Variobase™ Abutments have not been evaluated for safety and compatibility in the magnetic resonance environment. The Straumann® Variobase™ Abutments have not been tested for heating or migration in the magnetic resonance environment.

6. Compatibility information

Straumann® implants and the prosthetic components are available in a variety of configurations to meet your clinical needs. The label on each product uses abbreviations to help you identify whether a particular abutment or coping is compatible with the implant that you are restoring. The implant as well as the prosthetic component contains an identifier for the connection type, summarized in the table below.

Implant connection type	Compatible prostheses
NC (Narrow CrossFit®)	parts labeled NC
RC (Regular CrossFit®)	parts labeled RC
NNC (Narrow Neck CrossFit®)	parts labeled NNC
RN (Regular Neck)	parts labeled RN
WN (Wide Neck)	parts labeled WN

7. Cleaning and Disinfection

Straumann® Variobase™ Abutments and components are non-sterile when delivered. Before placing the restoration in the patient's mouth, the product must be cleaned, disinfected and sterilized. Straumann recommends the following procedure for cleaning, disinfection and sterilization of abutments prior to use.

1) Clean rinsing under flowing water while brushing outer and inner side with adequate brushes.

2) The pre-treated product is to be cleaned/disinfected in an automated washer disinfector. Select the appropriate program according to the manufacturer’s instructions.

8. Sterilization

The restoration may be sterilized unwrapped or can be placed in an accessory cassette and packaged twice in common sterilization wraps (paper/film bags). Steam sterilize according to the parameters below:

Material	Method	Conditions
Variobase™ Abutment, TAN Screw, TAN	Autoclave (moist heat) Displacement: gravity or fractionated vacuum	134 °C (273 °F) 5 minutes

Please note: User should ensure the use of the appropriate biological indicator for the sterilizer and parameters used.

Please note: User should consult the coping/restoration material manufacturer's recommendations regarding sterilization.

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

9. Procedure

Use and handling of the Straumann® Variobase™ Abutments for the Dental Technician

Restoration design

When using pressing or casting techniques via wax-up, use the burn-out coping for Straumann® Variobase™ Abutments which supports a clean and sharp-edged finish of the screw channel and a good fit to the Straumann® Variobase™ Abutment. When using a digital workflow, use the Straumann Variobase Implant Kit with any CAD software platform, to facilitate the precise design of the interface between the Straumann® Variobase™ Abutment and the coping. The kit consists of an STL file containing the required milling template for the inner coping geometry. Once the coping is designed using the CAD software, send to Straumann for milling.

Please note: For in-lab casting, Straumann recommends using materials Type 4 dental metals (ISO 22674). The $R_{p0.2}$ must be ≥360 MPa and have a minimum of 2% elongation after fracture. The manufacturing of the coping and/or crown must follow the standard procedure according to the material manufacturer's instructions for use.

Please note: For in-lab pressing, Straumann recommends using the IPS e.max® Press Abutment Solutions ceramic material according to the material manufacturer's instructions for use.

Please note: For milling, the following framework guidelines must be followed when designing in CAD software:

	Ceramic Material	Polymer Material
Minimum Wall Thickness	0.4 mm	0.5 mm
Minimum Angulation	0°	0°
Maximum Angulation	30°	30°

Please note: The milled restorations may be manufactured using polycon® ae, Zerion®, IPS e.max® CAD Abutment Solutions ceramic material, or Lava™ Frame. The design of the coping and/or crown must follow the standard procedure according to the material manufacturer's instructions for use.

Processing

Process the manufactured coping or crown following standard procedure according to the material manufacturer's instructions. Always finalize the crown or coping prior to bonding to the Straumann® Variobase™ Abutments.

Bonding

Please note: It is not necessary to sandblast the Straumann® Variobase™ Abutment.

1) Fix the abutment to the implant analog with a screw (hand-tight).

2) Seal the screw channel with wax.

3) Apply self-adhesive dental cement on the abutment. Only suitable self-adhesive cementation systems for the material used shall be used. Follow the instructions for use of both the dental material and cement/bonding material manufacturer. (Straumann® recommends Panavia™ F2.0 resin cement by Kuraray)

4) Bond the coping to the abutment.

5) Immediately remove excess cement from the abutment and polish the lower margin of the coping after the cement is set.

6) Optional: For cement retained-restorations: Make a crown following standard procedure according to the material manufacturer's instructions and finalize it.

7) Clean the restoration prior to sending it to the dentist.

8) Include this instruction for use when sending the restoration to the dentist.

Use and handling of the Straumann® Variobase™ Abutments for the Dentist

Remove the restoration from the master cast or the analog.

Clean, disinfect and sterilize the device as described in sections 7 and 8 of this Instructions for Use document.

Placing the restoration

a) Remove the healing cap or temporary restoration.

b) Clean and dry the interior of the implant and the abutment thoroughly.

c) Place the sterilized restoration into the patient's mouth.

d) Make sure that the retentive elements of the implant abutment connection are properly aligned.

e) Use the screw delivered with the abutment to screw the abutment into the dental implant.

Please note: Always ensure that the surfaces of threads and screw heads are clean and that a new screw is used for the restoration.

f) Straumann® abutments are fixed to the implant using the Straumann® SCS screwdriver, ratchet and torque control device. Use the respective torque according to the table below:

Device type	Tightening torque	Special considerations
Abutments (permanent)	35 Ncm	n/a
Temporary abutments	15 – 35 Ncm	Tighten only to 35 Ncm if the implant is fully osseointegrated
Components on implant analogs	Hand-tight	n/a

For cement-retained restorations (optional):

g) Close the screw channel with cotton and sealing compound (i.e., gutta-percha)

h) Apply self-adhesive dental cement on the two-piece abutment. Only suitable self-adhesive cementation systems for the used materials shall be used. Follow the instructions for use of the cement/bonding material manufacturer (Straumann recommends Panavia™ F2.0 resin cement by Kuraray).

i) Bond the crown to the two-piece abutment.

j) Immediately remove excess cement from the two-piece abutment.

Warning

Torques greater than 35 Ncm may result in failure of the abutment and/or implant. Torque values less than the recommended values may result in loosening of the abutment, which may lead to abutment and/or implant failure.

Please note

Once the Straumann® abutment has been secured to the implant using the indicated torque, it should not be removed.

10. Further Information

For additional information about the use of Straumann® products, call Straumann's customer service department or visit www.straumann.com.

For additional information, consult:

Basic information on the Straumann® Variobase™ Abutment

11. Please note

Practitioners must have appropriate knowledge and instruction in the handling of the Straumann product described herein ("Straumann Product") for using the Straumann Product safely and properly in accordance with these instructions for use.

The Straumann Product must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine, if the device fits to the individual patient situation.

The Straumann Product is part of an overall concept and must be used only in conjunction with the corresponding original components and instruments distributed by Institut Straumann AG, its ultimate parent company and all affiliates or subsidiaries of such parent company ("Straumann"), except if stated otherwise in these instructions for use. If use of products made by third parties is not recommended by Straumann in these instructions for use, any such use will void any warranty or other obligation, express or implied, of Straumann.

12. Validity

Upon publication of these instructions for use, all previous versions are superseded.

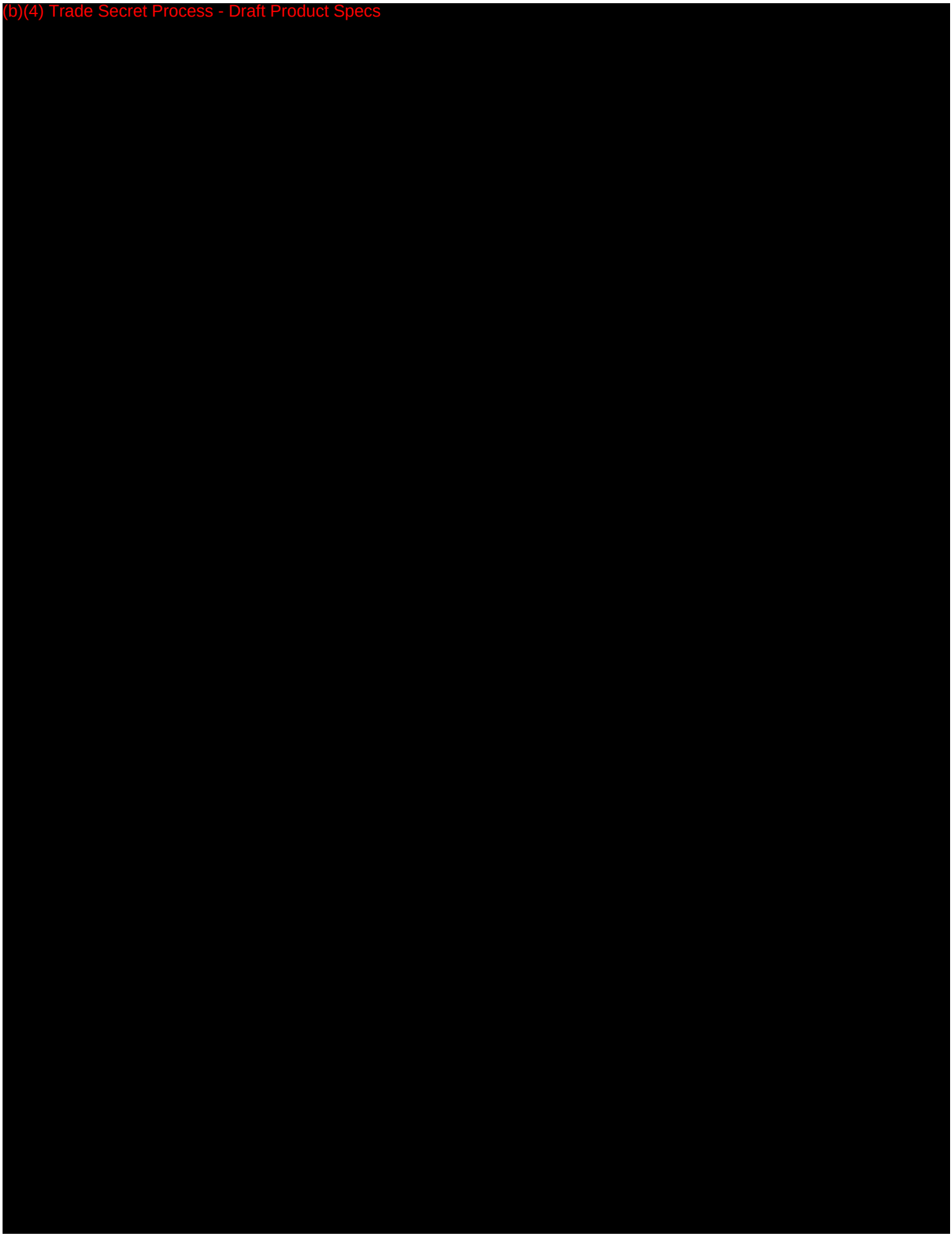
Availability

Some items of the Straumann® Dental Implant System are not available in all countries.

CE 0123	Straumann Products with the CE mark fulfill the requirements of the Medical Devices Directive 93/42 EEC /
	Refer to package insert
	Manufacturer
	Article number
	Lot Number
	Do not re-use
	Non-sterile
Rx only	Federal law restricts this device to sale by or on the order of a dental professional.

Appendix 2 – Basic Information on the Straumann® Variobase™ Abutment

(b)(4) Trade Secret Process - Draft Product Specs



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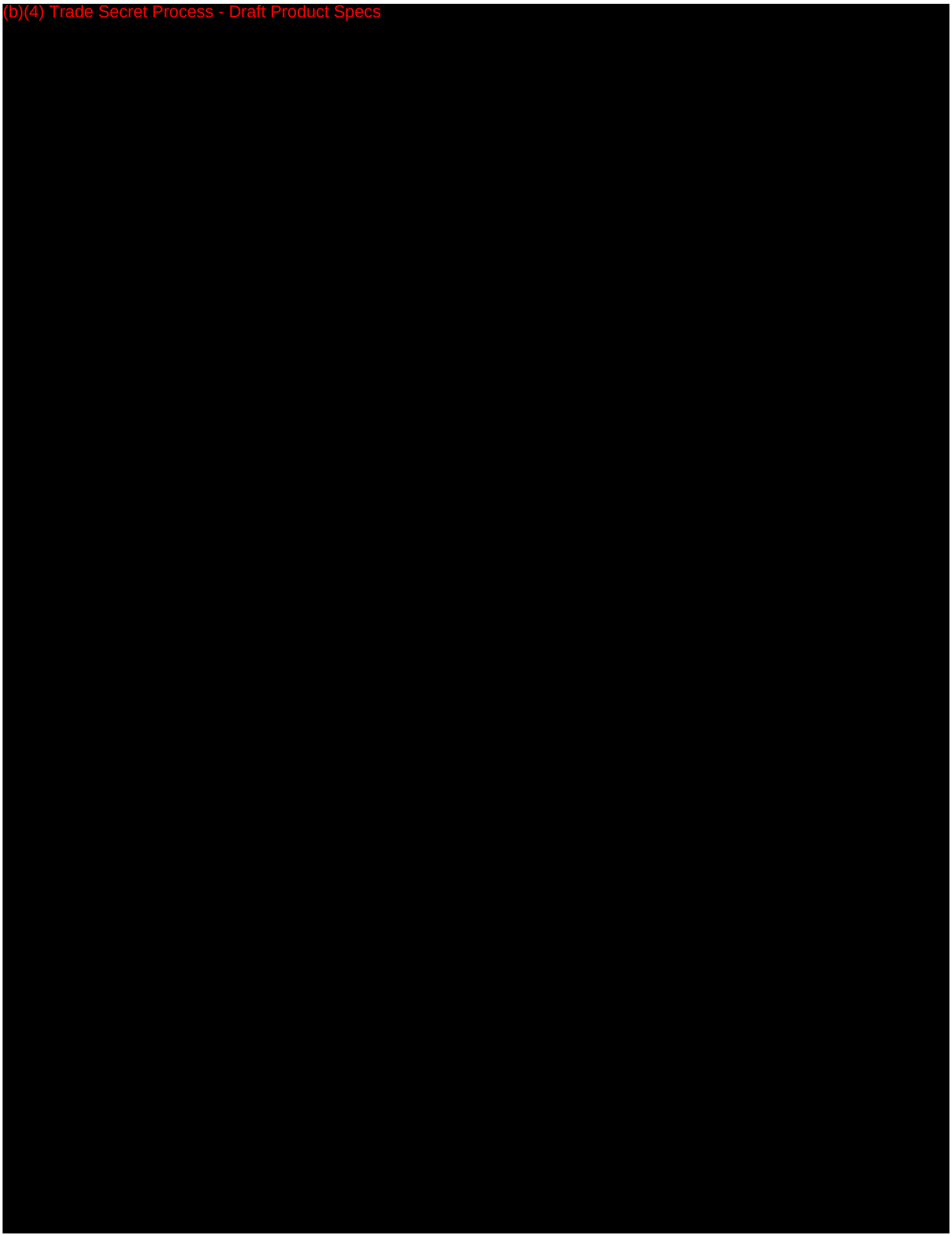

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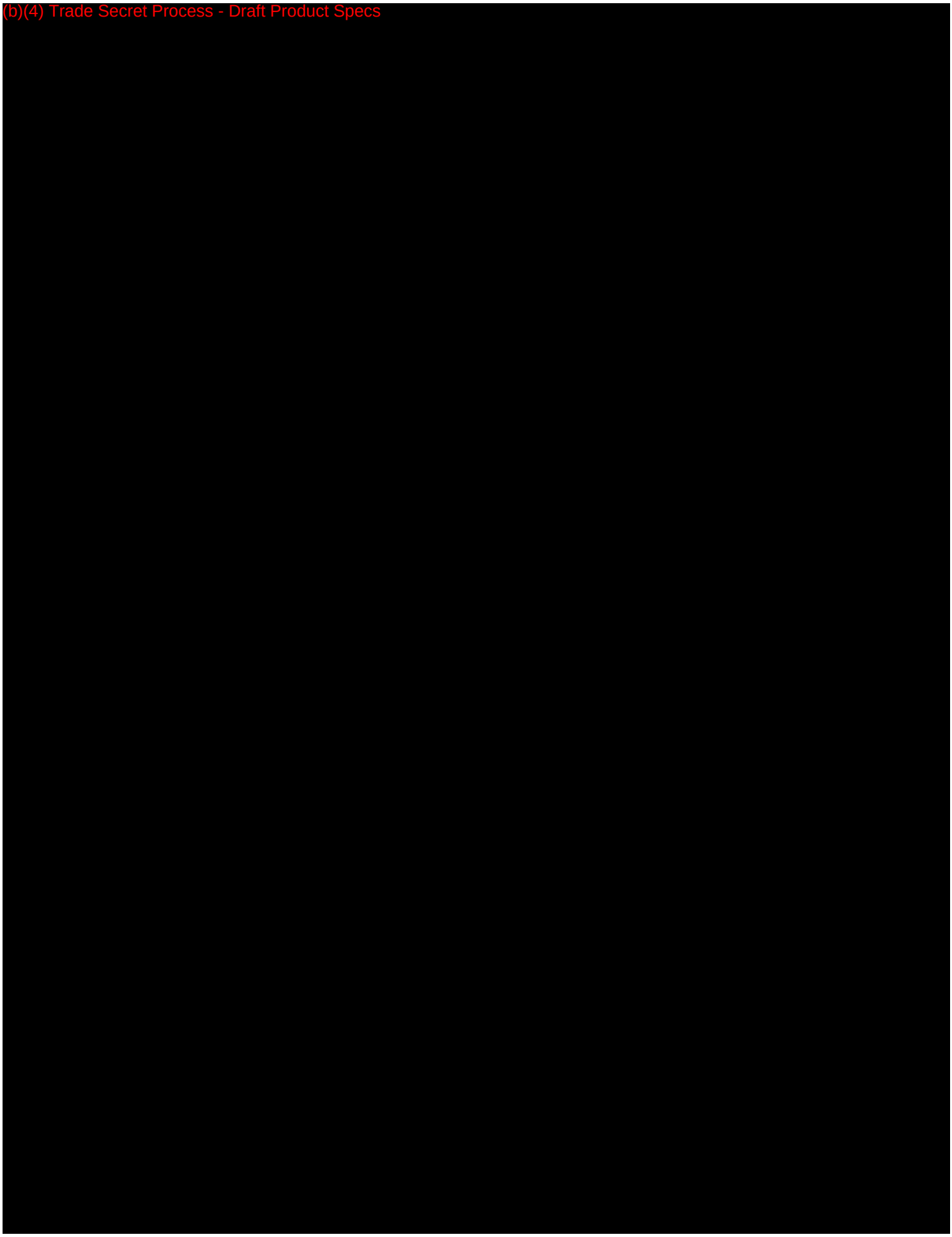

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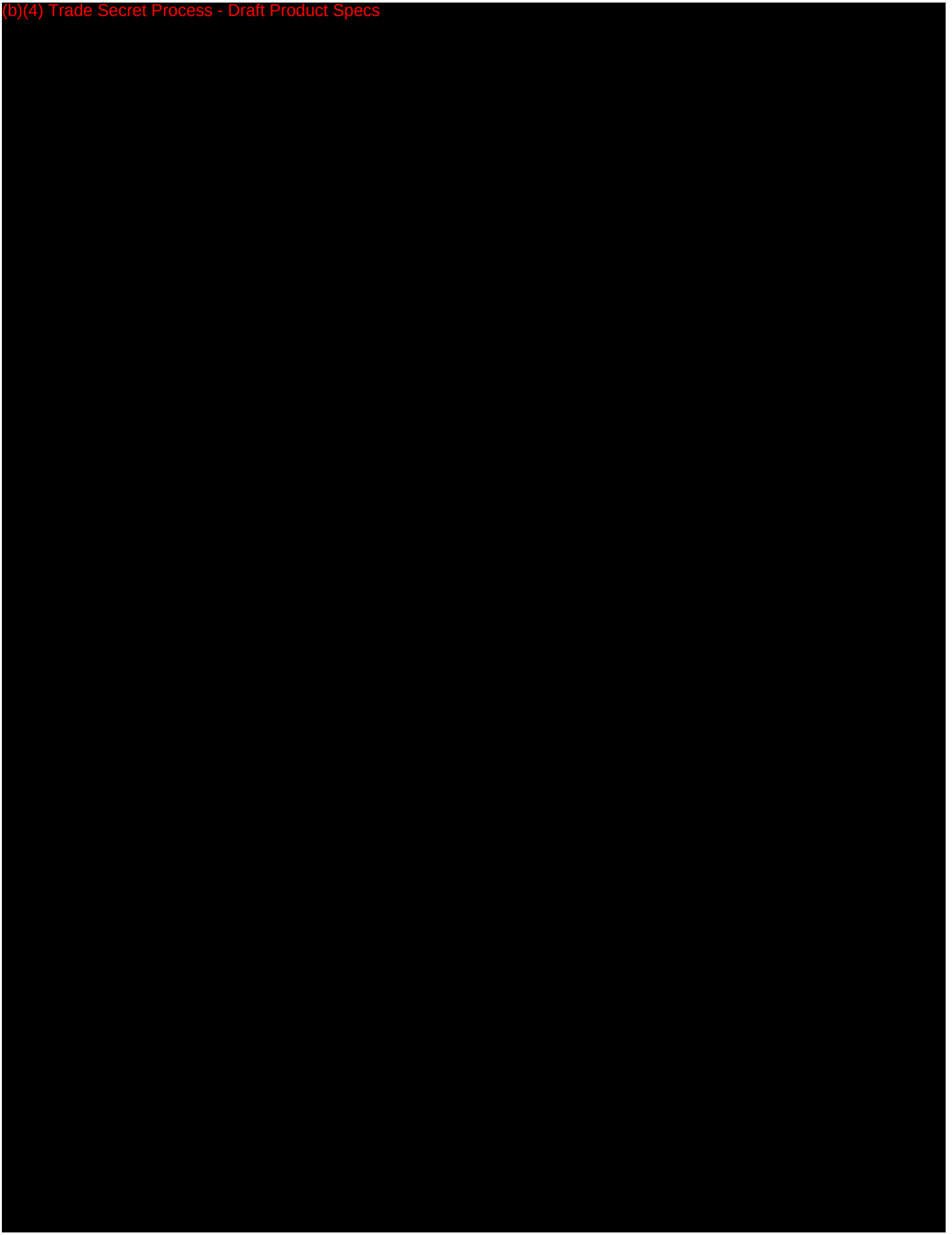

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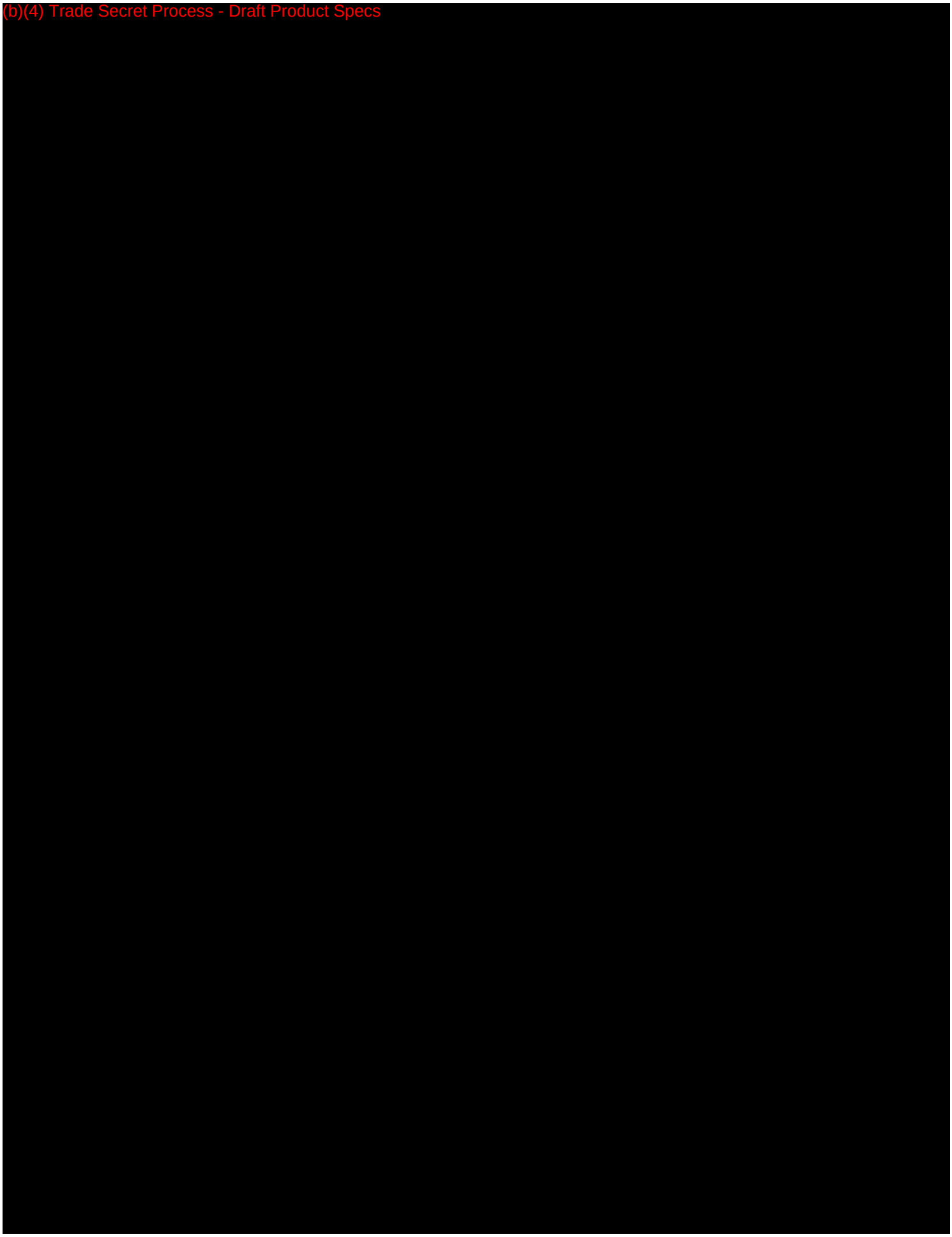

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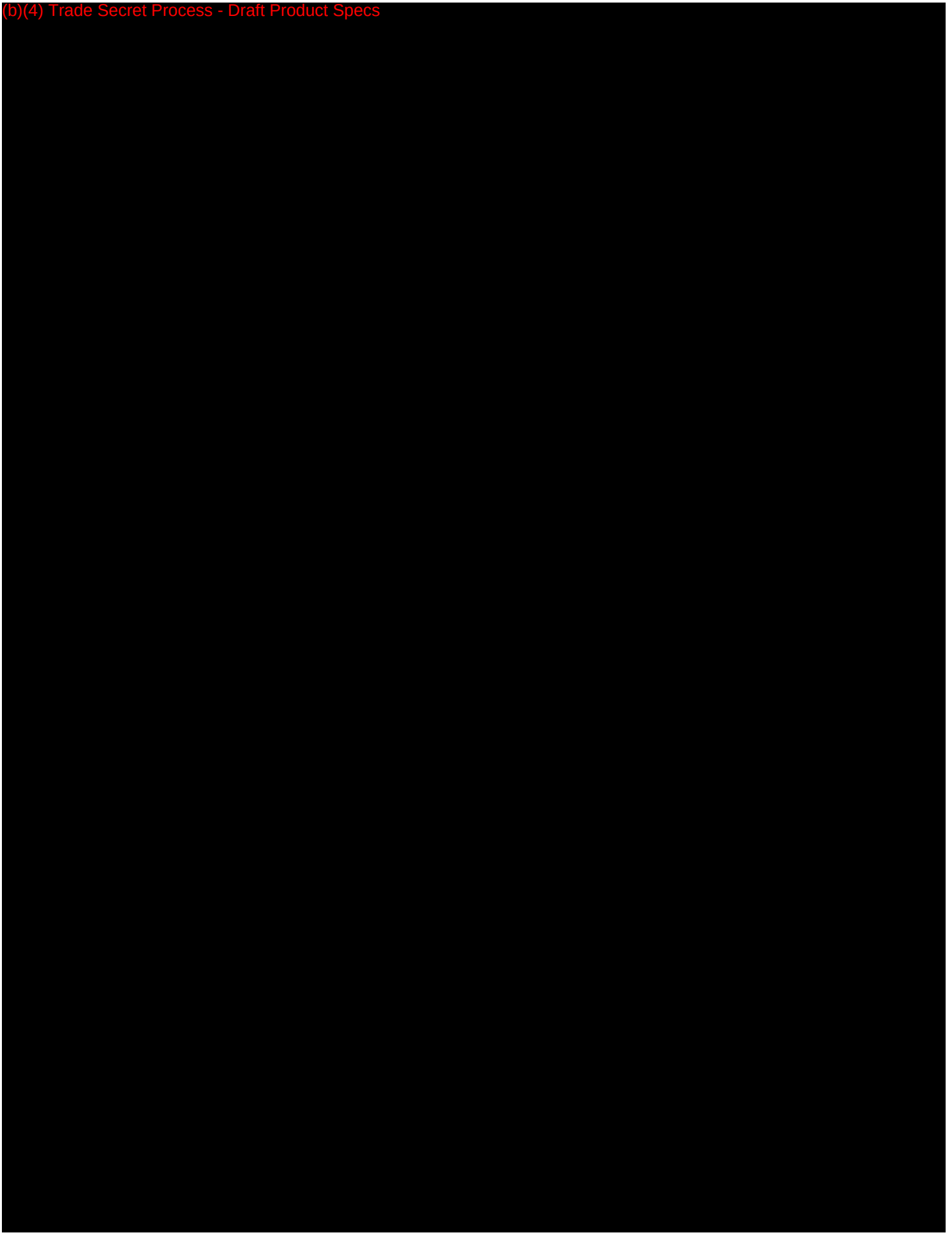

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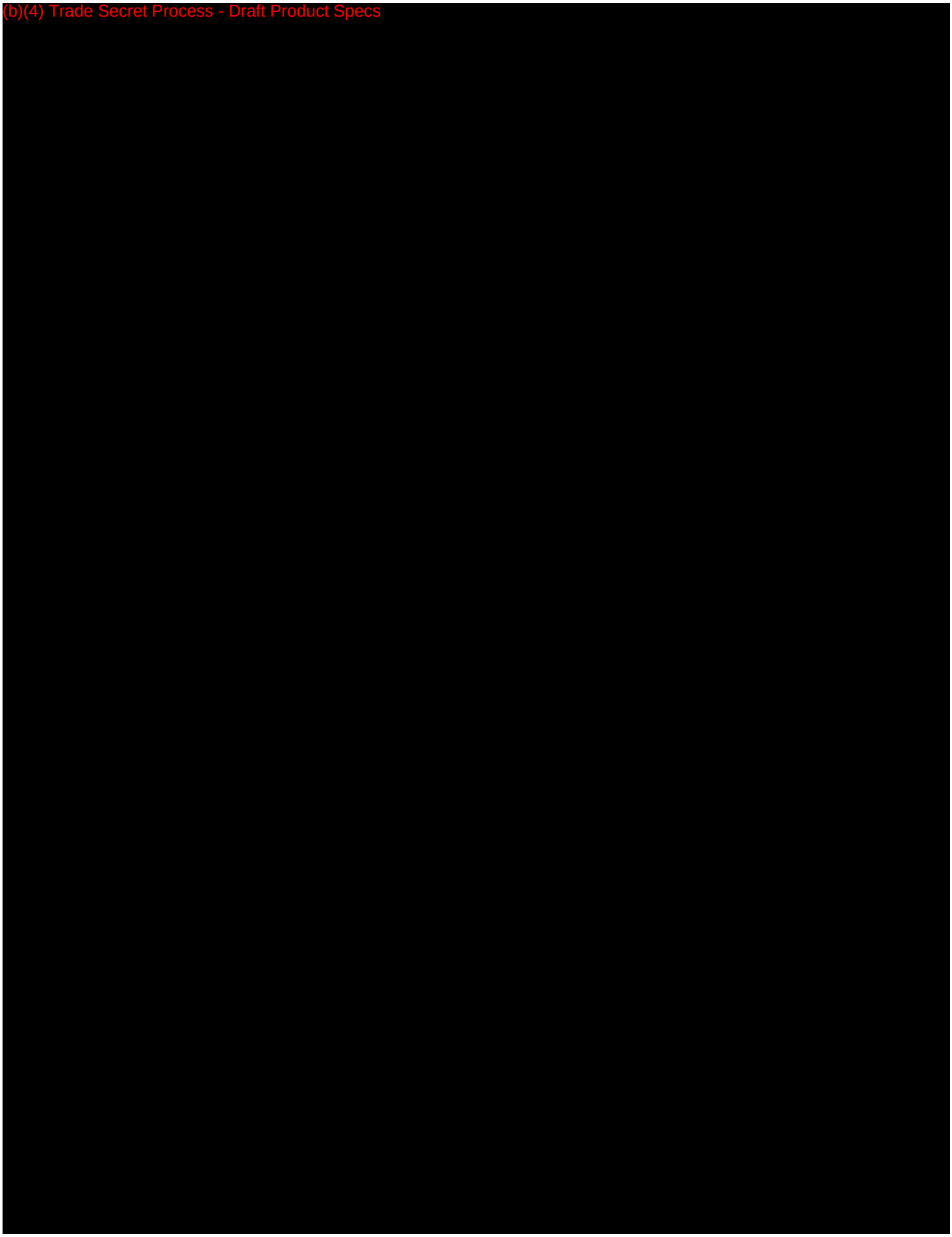

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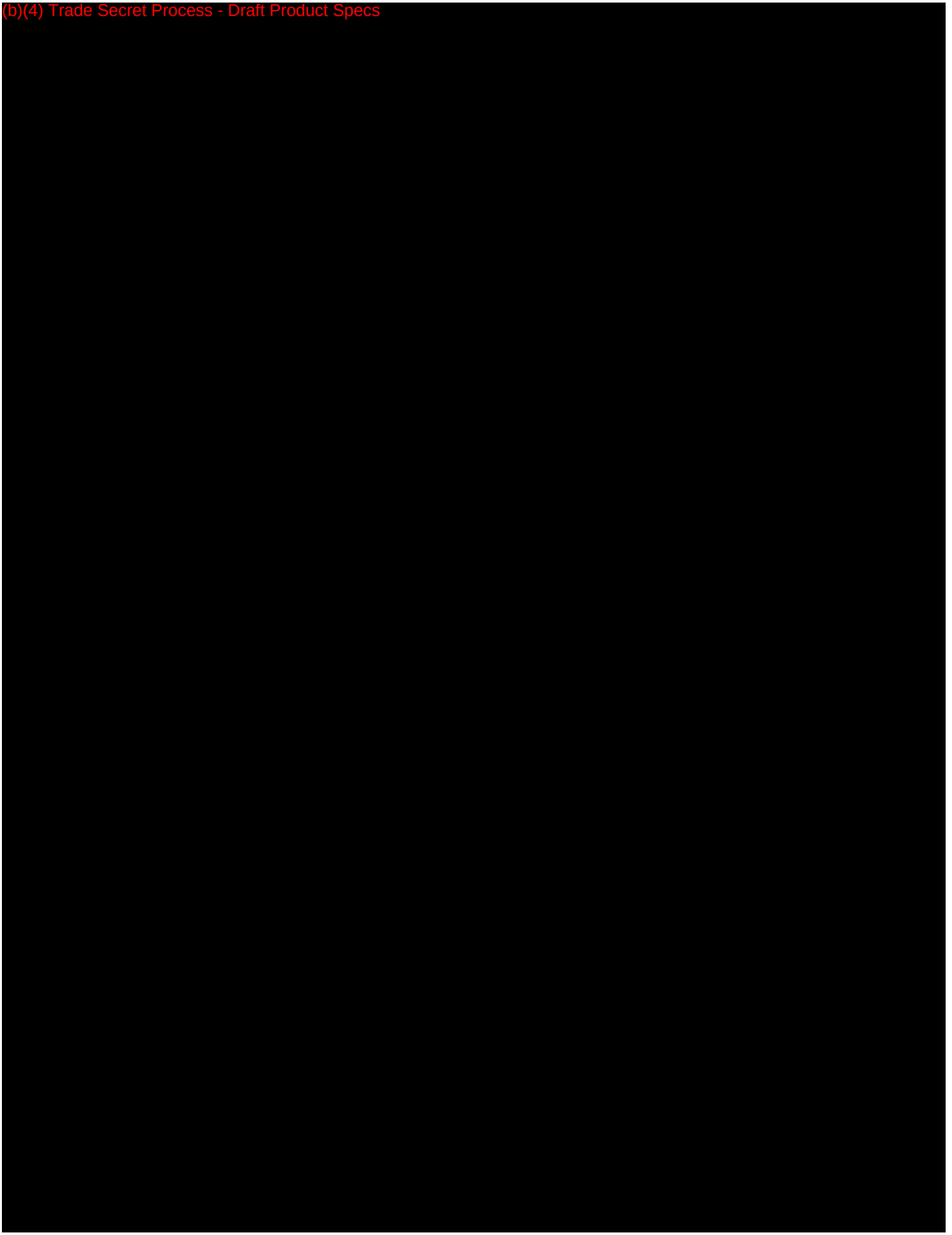

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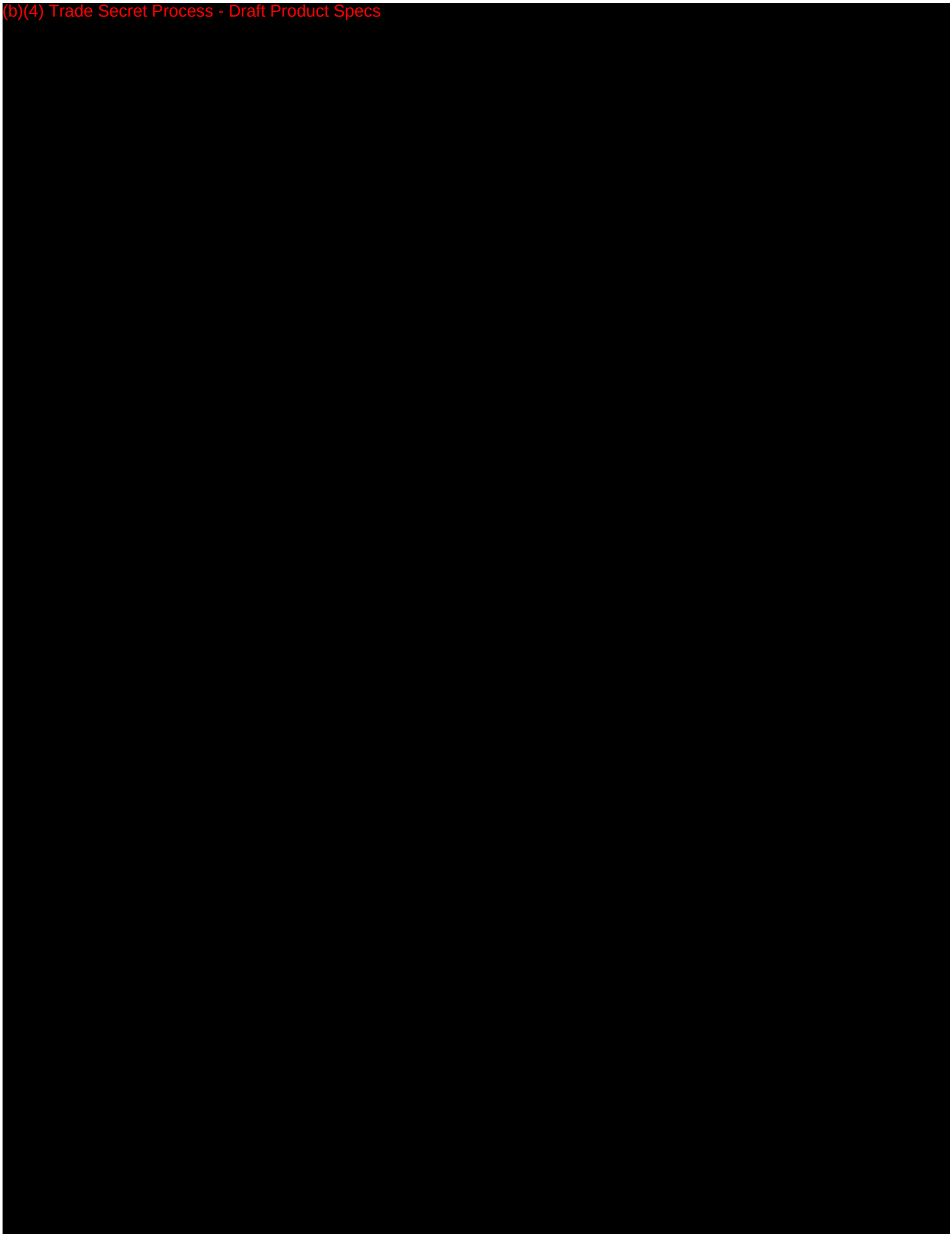

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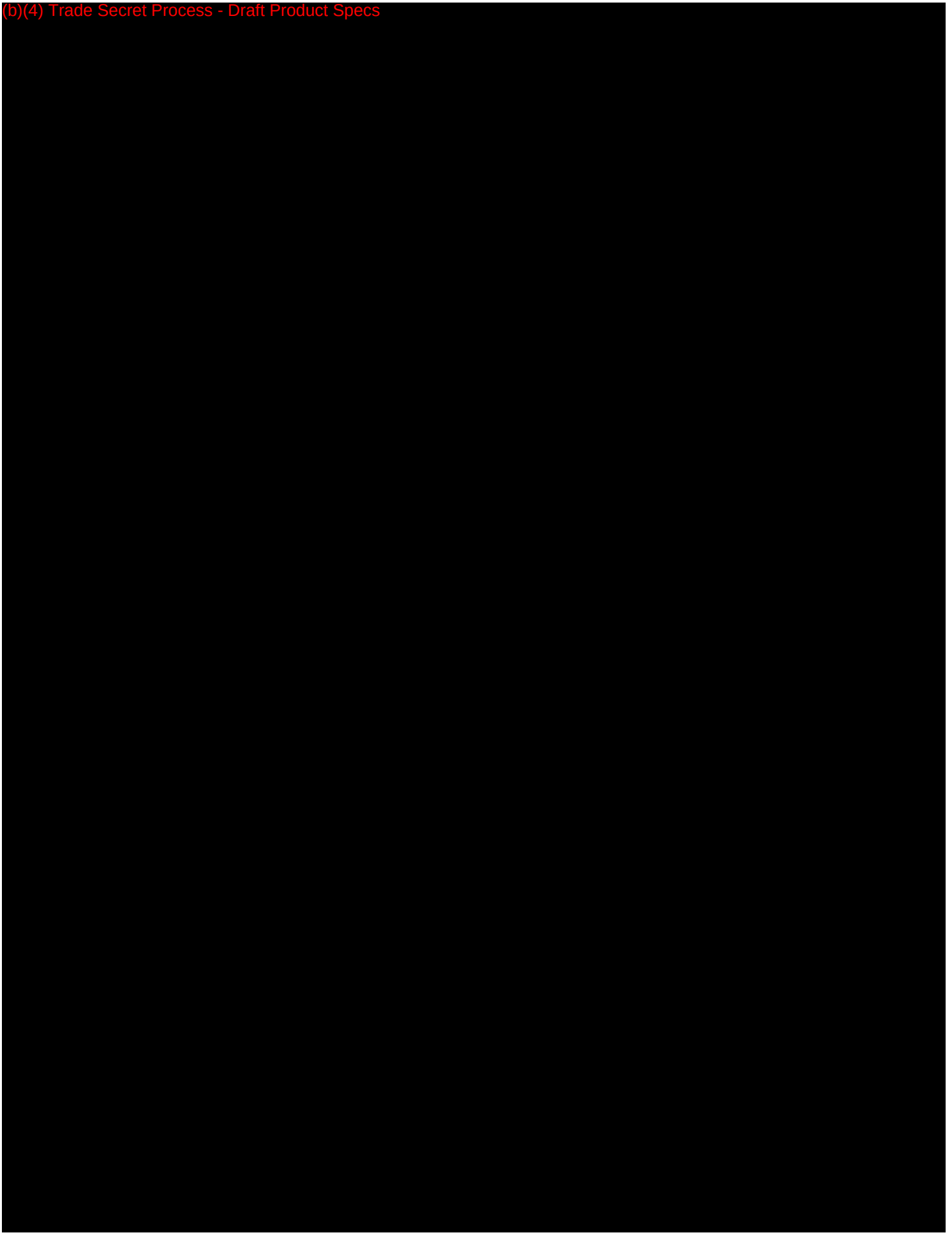

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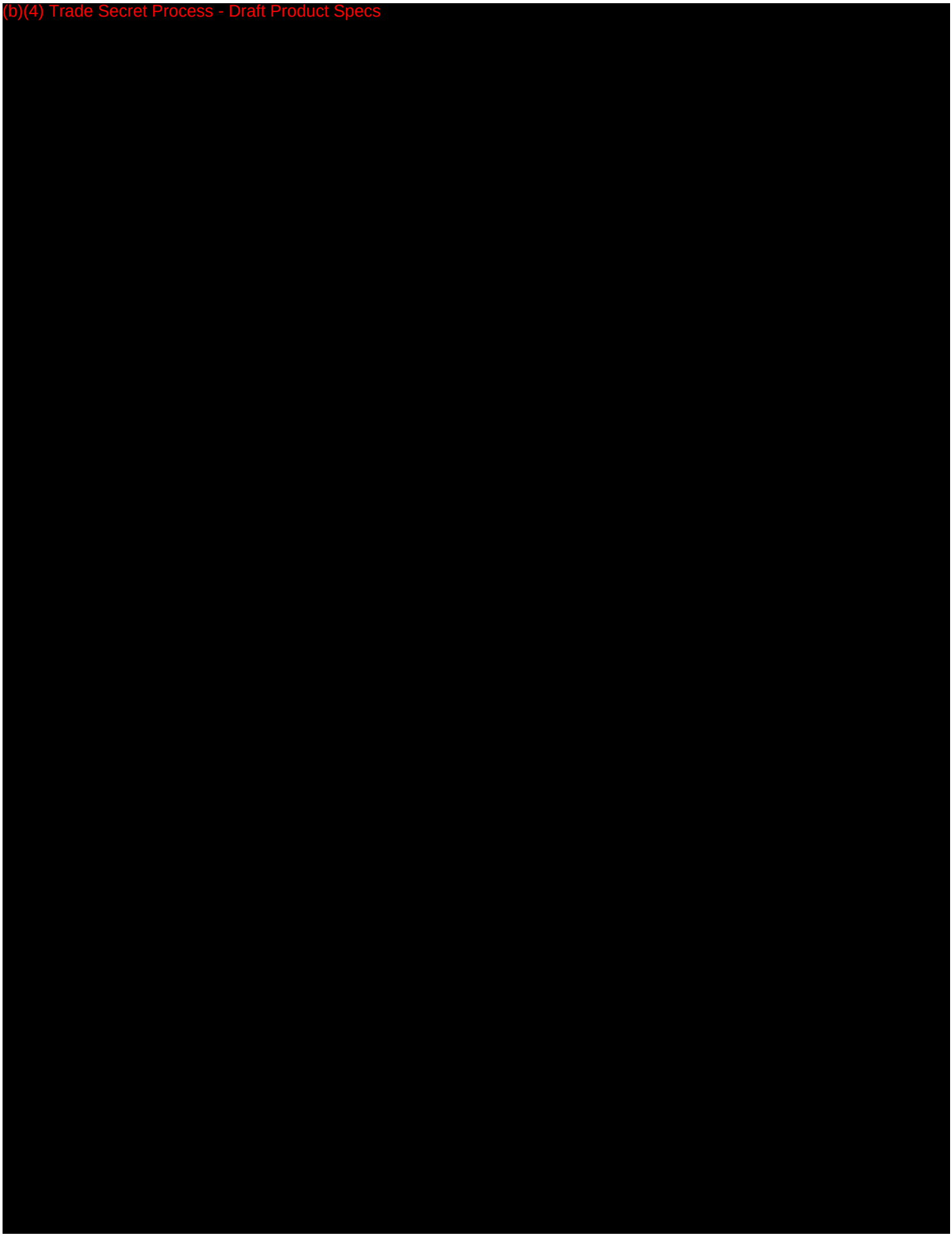

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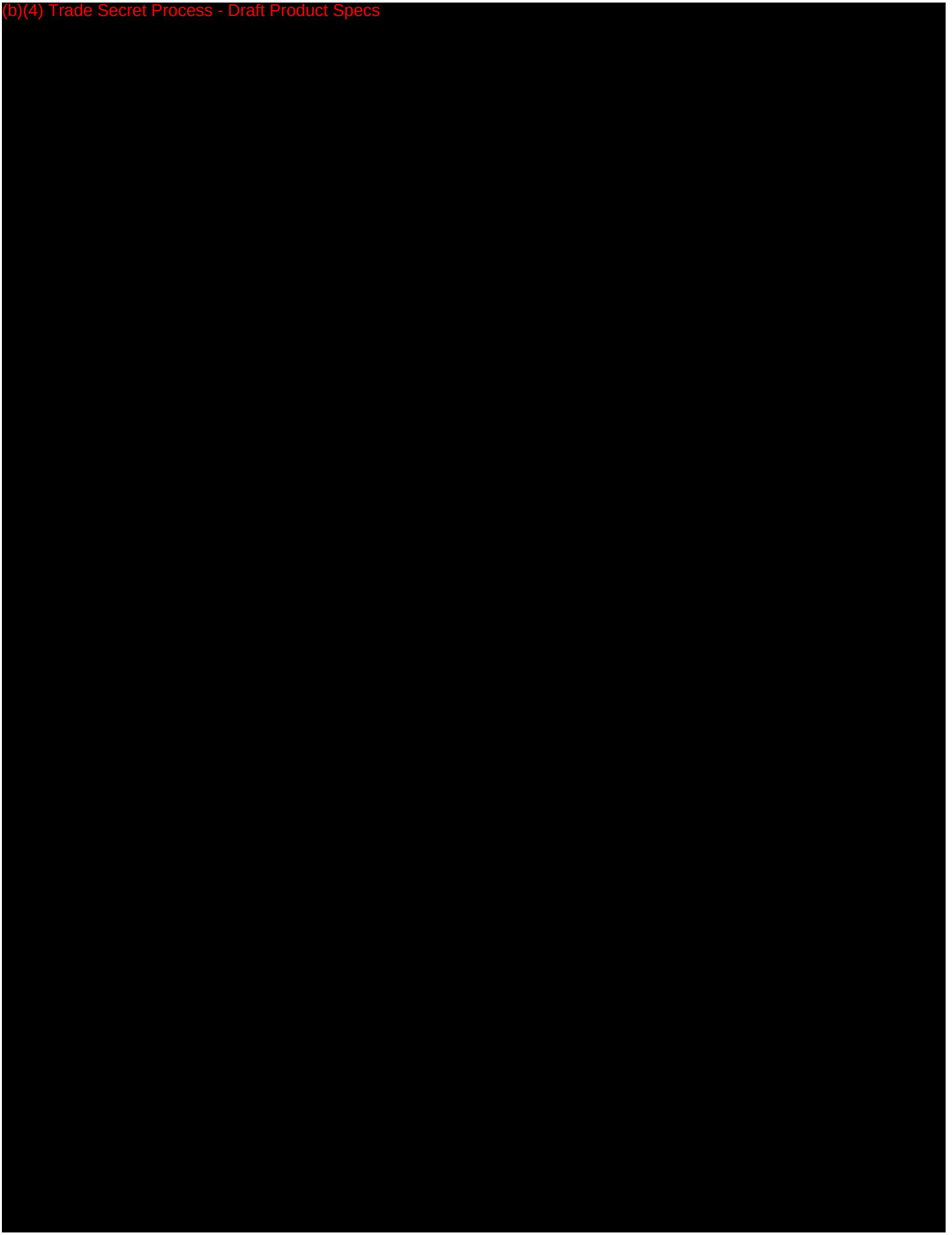

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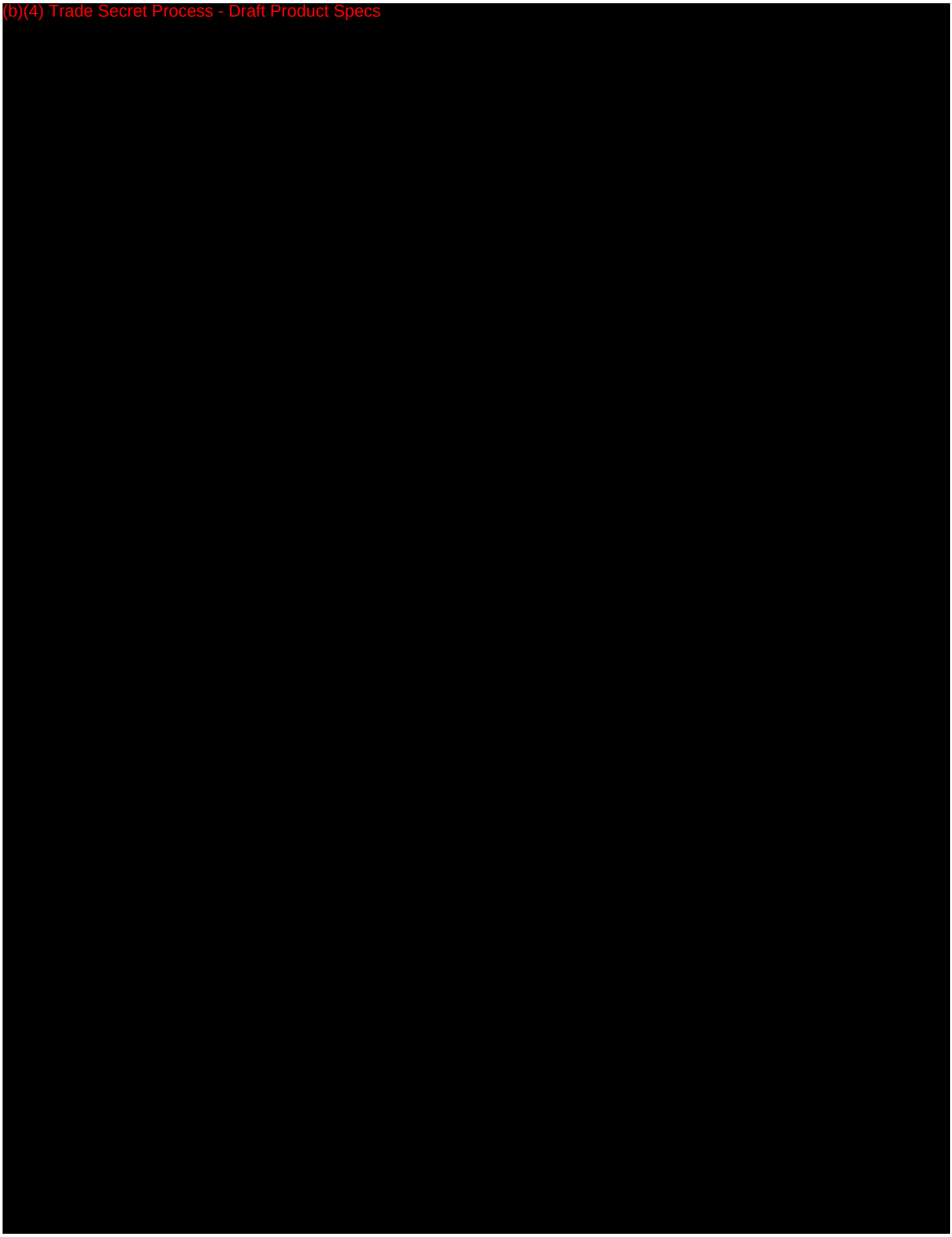
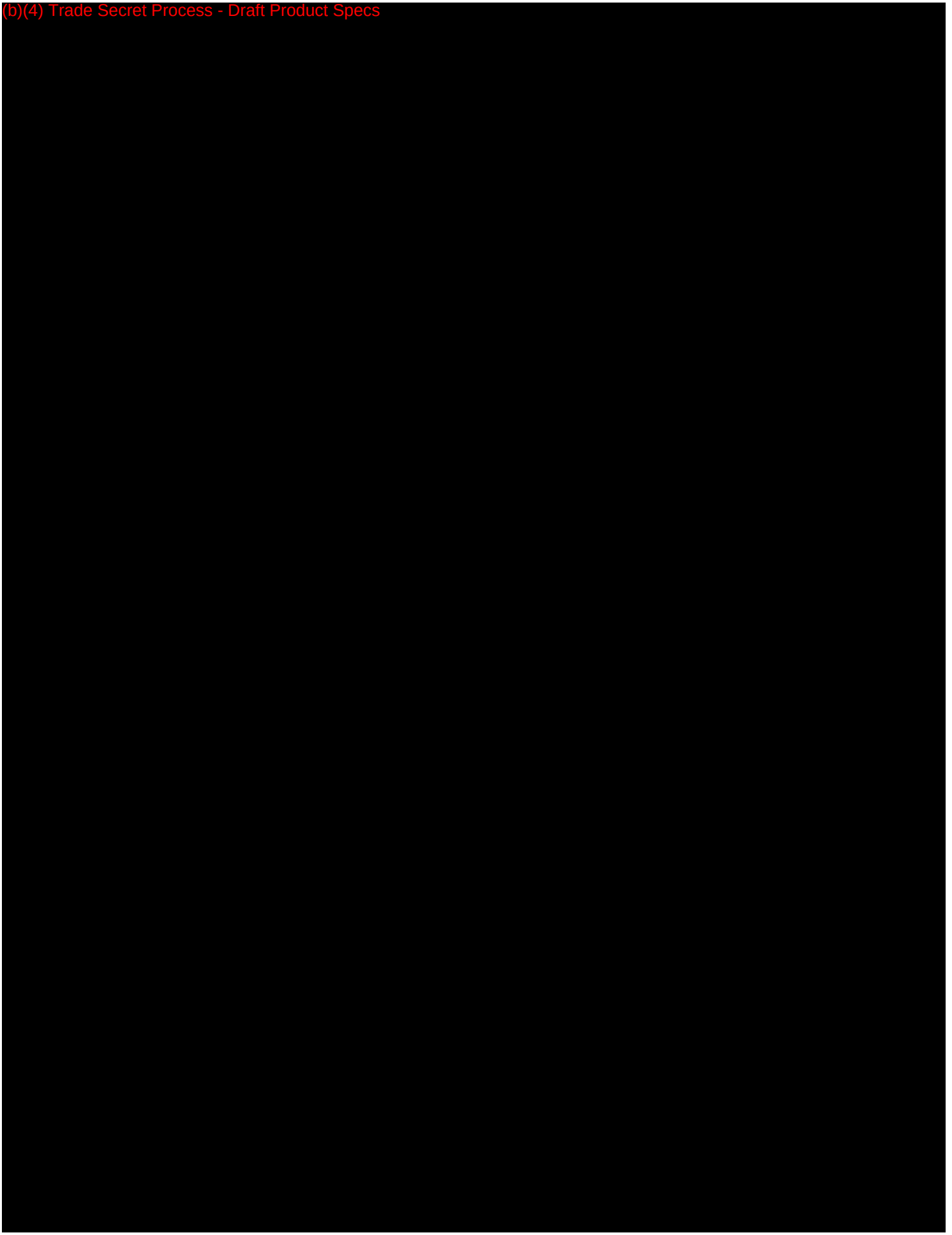


(b)(4) Trade Secret Process - Draft Product Specs



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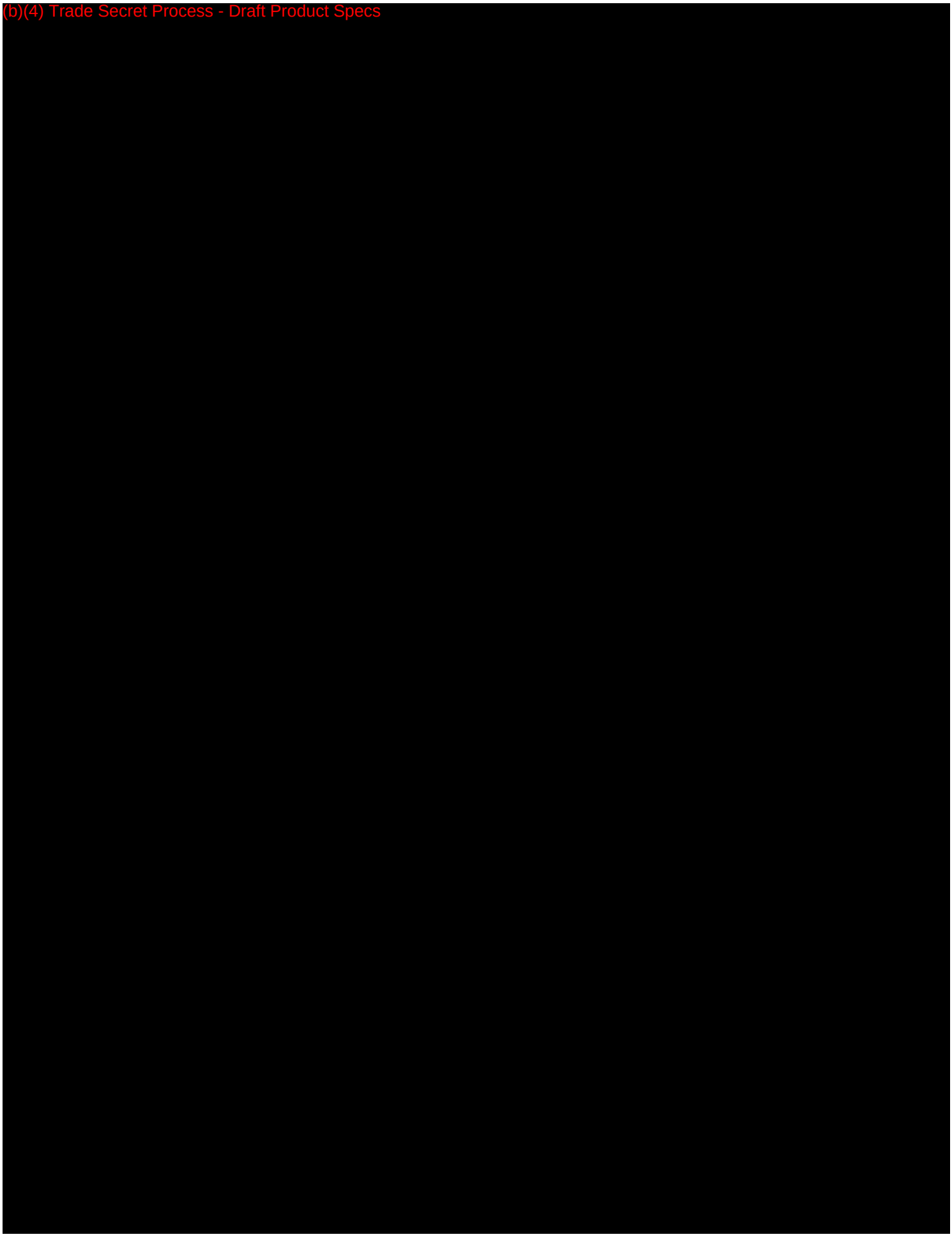

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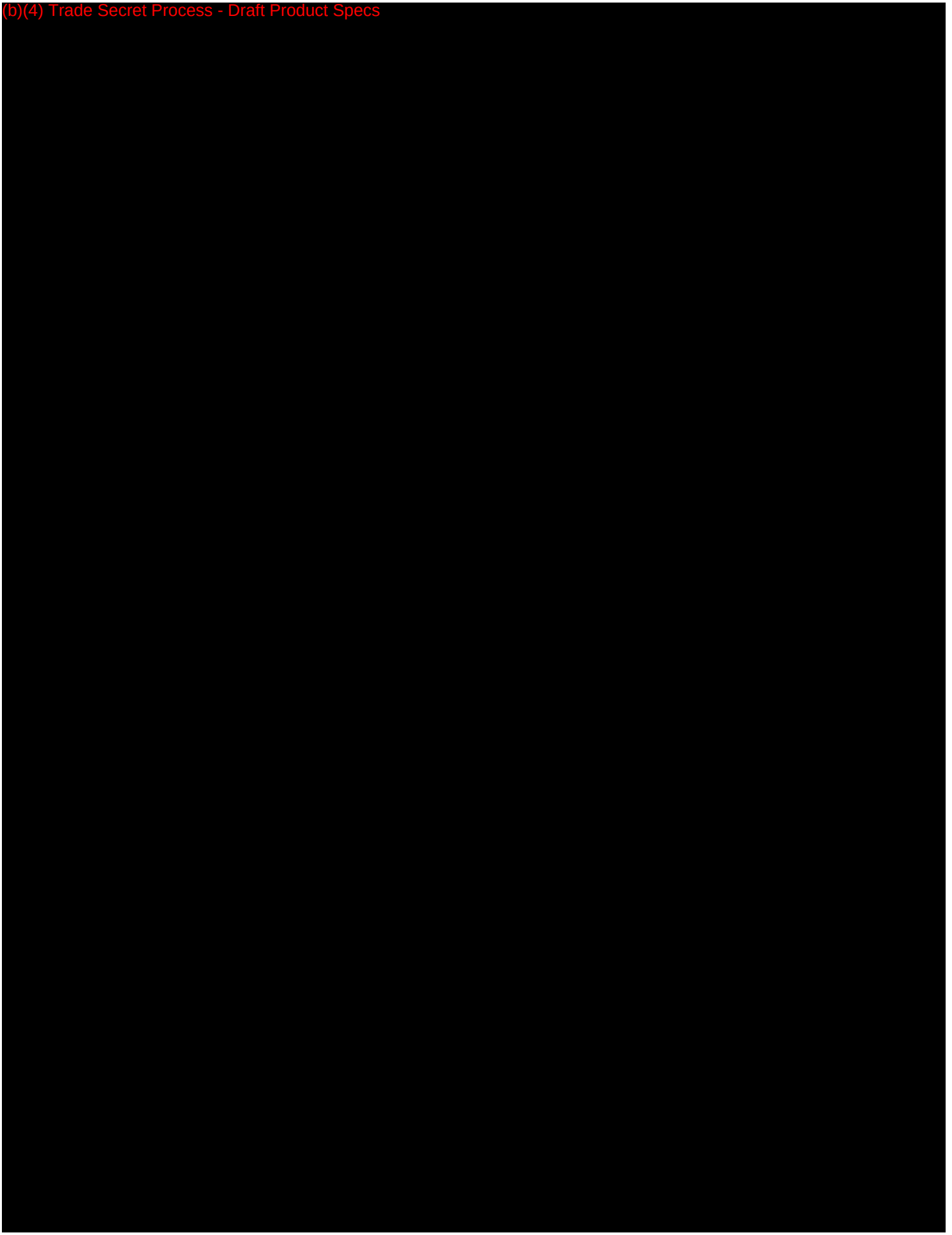

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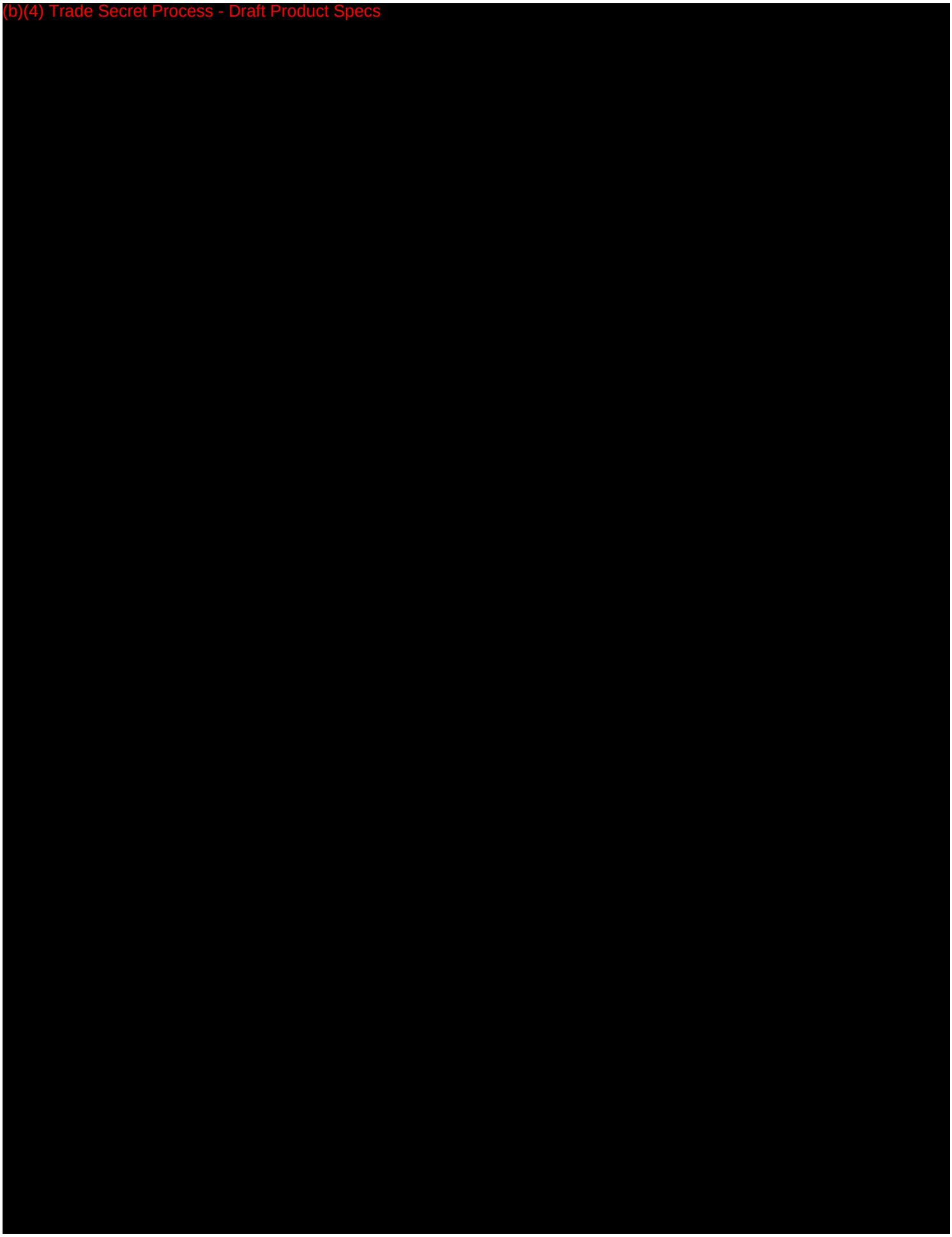

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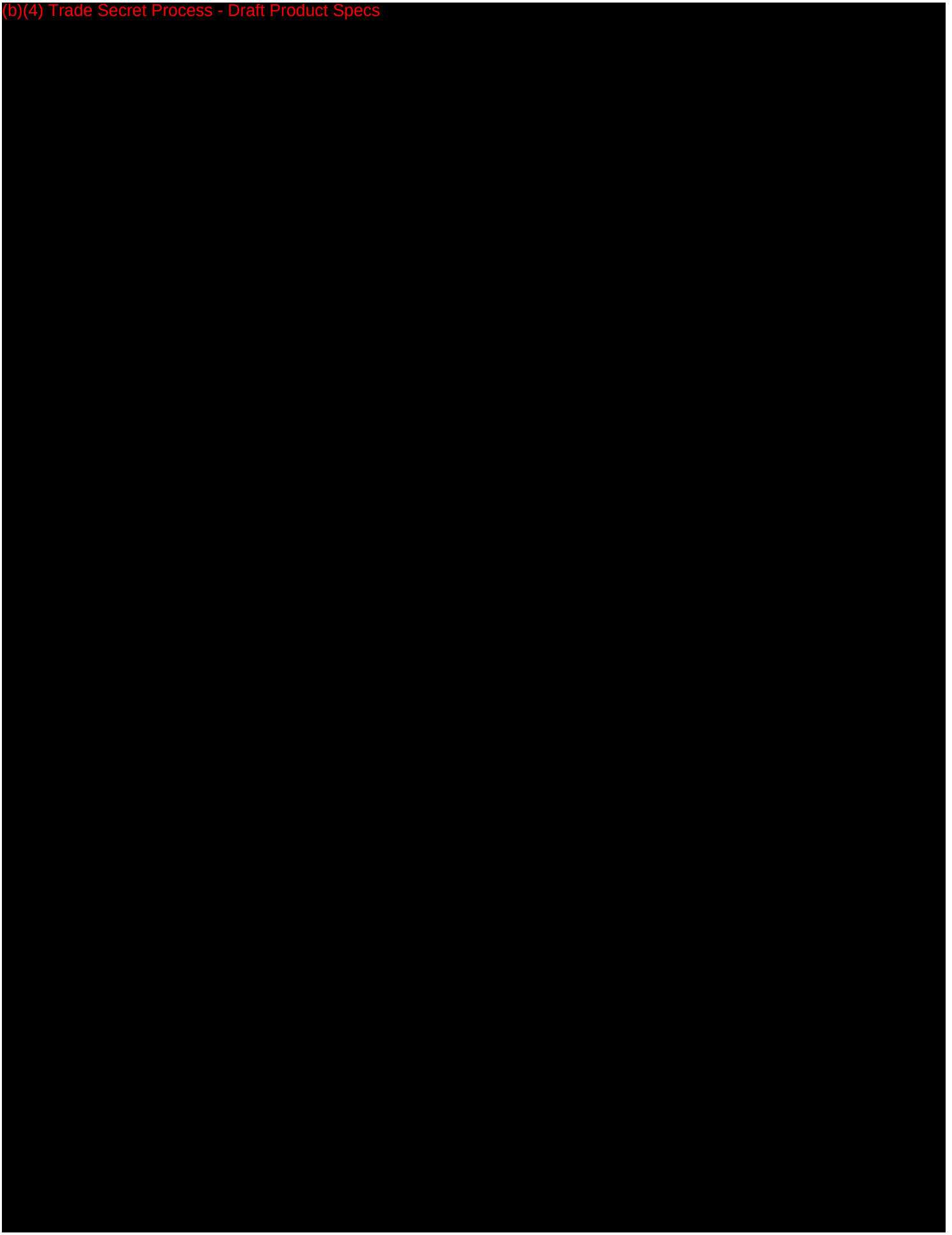

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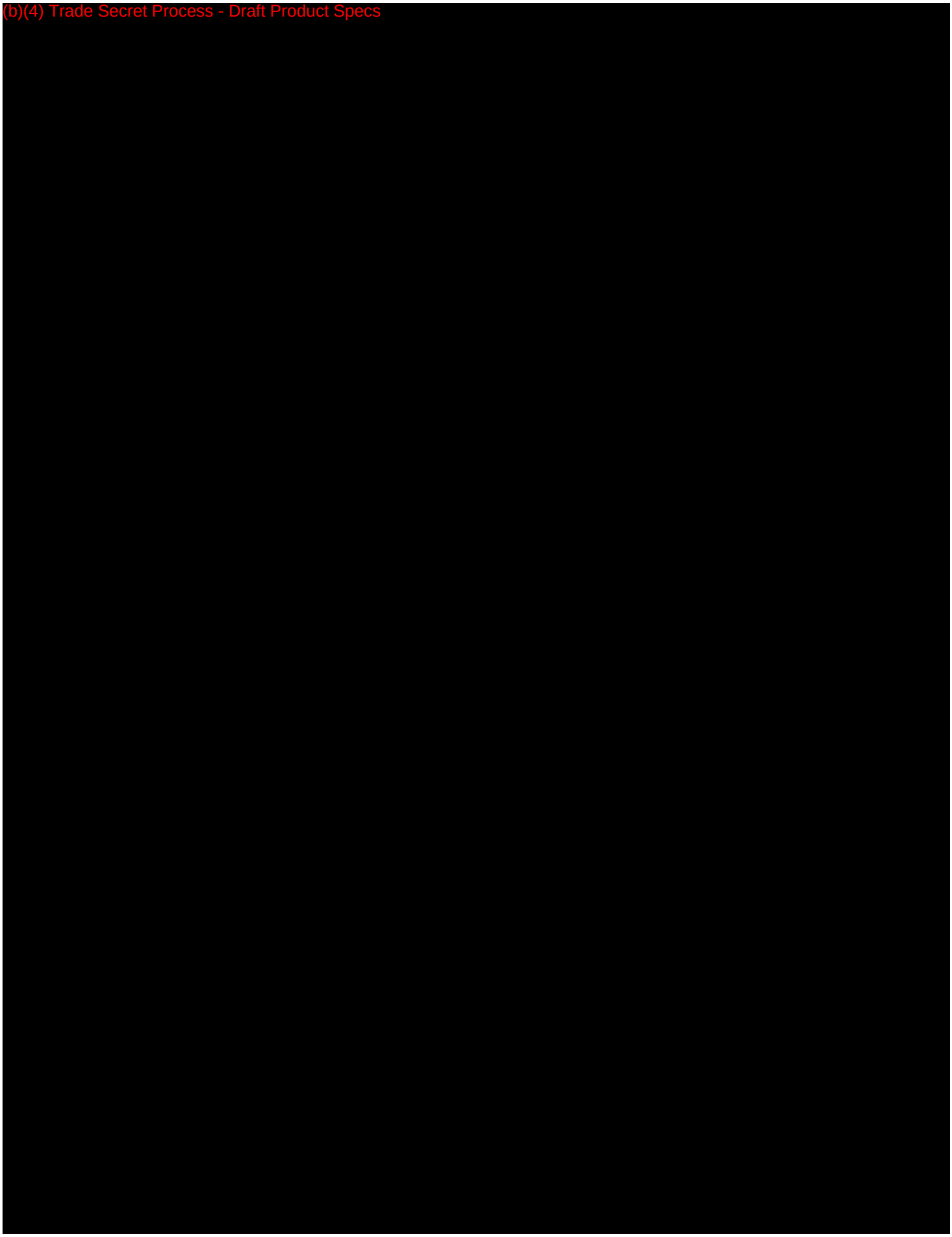

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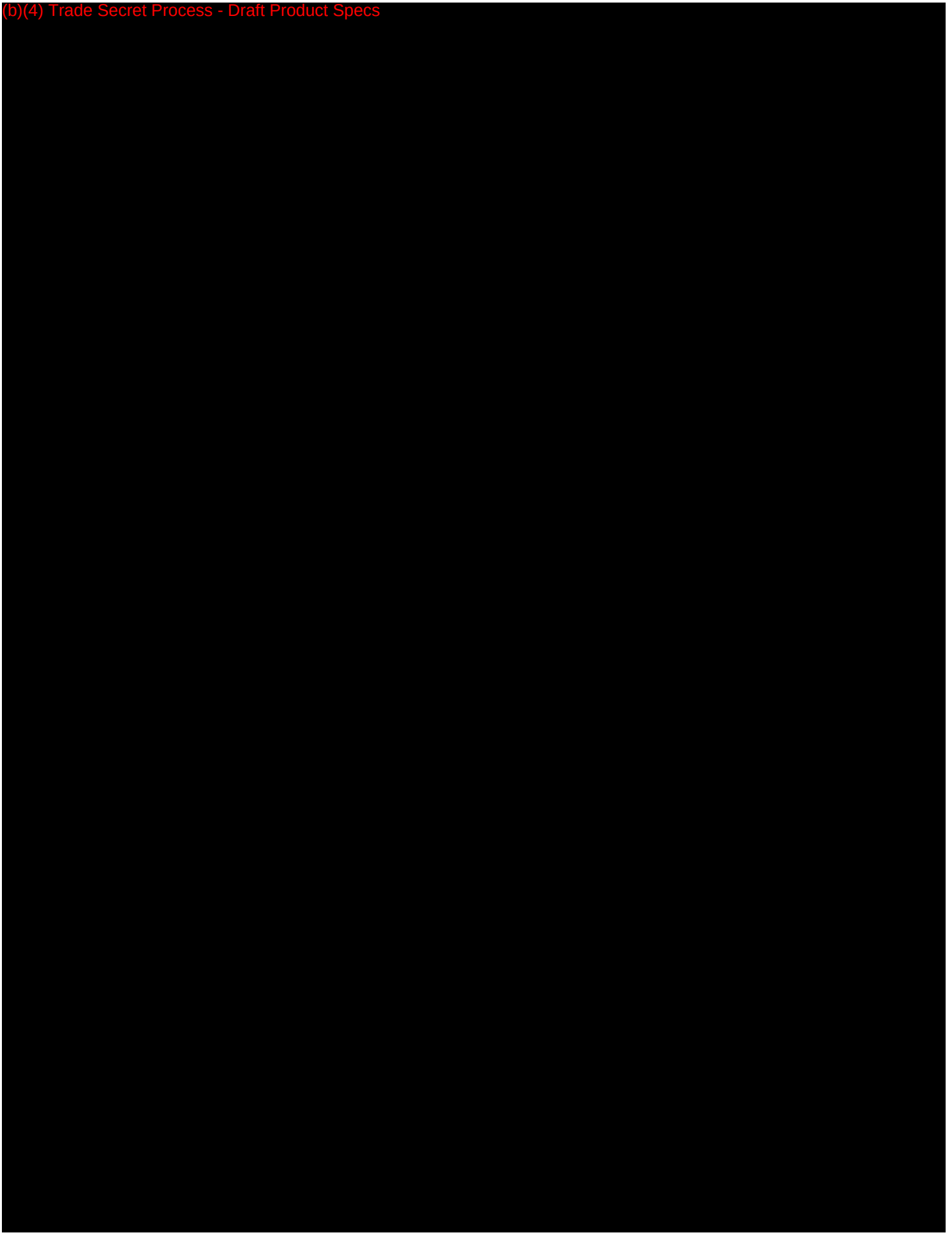
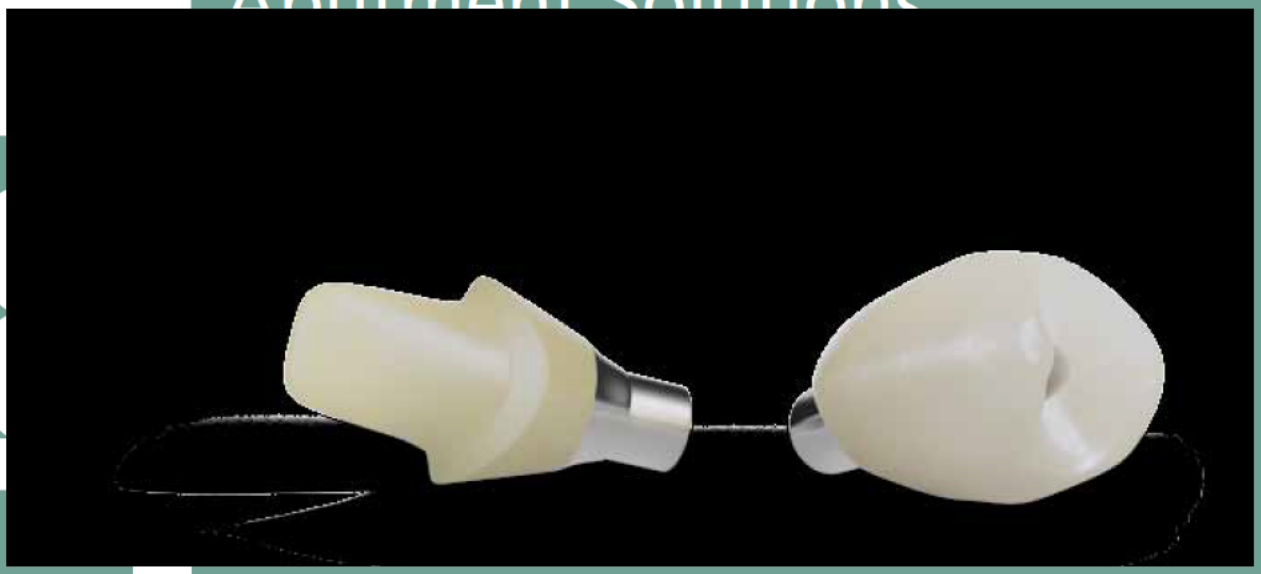


Appendix 16 – IPS e.max® Press Abutment Solutions Instructions for Use

IPS e.max® Press

Abutment Solutions



all ceramic
all you need

INSTRUCTIONS FOR USE

CE 0123

ivoclar vivadent technical

Traditional 510(k)
Straumann® Variobase™ Abutments

Straumann USA, LLC
January 23, 2014

A16-2

Table of Contents

IPS e.max® Press Abutment Solutions
Product Information

Press ceramics have been synonymous with esthetics, accuracy of fit, shape and function for decades. The IPS e.max Press lithium disilicate (LS_2) glass-ceramic additionally offers an outstanding strength of 400 MPa. The already extensive indication range from thin veneers (0.3 mm) and monolithic molar crowns to anterior and premolar bridges is now expanded to include hybrid abutment restorations.

With IPS e.max Press, you can fabricate such restorations in combination with a titanium base (Ti base). Two different approaches are available:
– Hybrid abutment and separate crown
– Hybrid abutment crown
Both solutions show outstanding function, efficiency and esthetics. The durable bond to the Ti base is achieved by means of the self-curing Multilink Implant luting composite.

Hybrid abutment

The hybrid abutment is an individually pressed LS_2 abutment which is luted to the Ti base. The shape, emergence profile and esthetic properties of this abutment can be ideally adjusted to the clinical situation.

Individual esthetics
Given the lifelike appearance of LS_2 glass-ceramics, the esthetic possibilities are virtually limitless, particularly in the anterior region. Due to the individual characterization, a lifelike appearance is achieved near the root and the transition area to the crown. With the preparation margin of the crown located on the gingival level, the geometry of the hybrid abutments allows for an easy integration of the restoration. Excess cementation material is therefore easily removed.

Flexibility due to laboratory fabrication
The pressed LS_2 abutment is extraorally luted to a Ti base with Multilink Implant, then screwed into place in the oral cavity and finally provided with a permanent IPS e.max crown. As the hybrid abutment is conveniently fabricated in the lab, the process is time-saving and flexible.

Hybrid abutment crown

Hybrid abutment crowns are characterized by combining abutment and monolithic crown in one piece. This is an efficient two-in-one solution made of lithium disilicate (LS_2), which is directly luted to a Ti base.

Efficient fabrication due to two-in-one approach
LS_2 glass-ceramics provide for strength, durability and efficiency, particularly in the posterior area. Moreover, the material offers well-known esthetic properties allowing restorations to be simply characterized with IPS e.max Ceram stains.

Luted extraorally, screwed in intraorally – for improved flexibility
The monolithically pressed hybrid abutment crown is reliably luted to the Ti base by means of Multilink Implant. Then, the restoration is screwed onto the implant – in one piece. Thus, the bothersome task of excess cement removal is a thing of the past. Subsequently, the screw access channel is sealed with a composite material (e.g. Tetric EvoCeram®). If required, the screw can be accessed at any time, which affords the dental team clincial flexibility.

New possibilities for economically efficient restorations
IPS e.max Press hybrid abutment crowns are a new, economically attractive alternative to conventional implant-supported restorations, particularly for the posterior area, where strength, durability and convenient clinical handling matter.

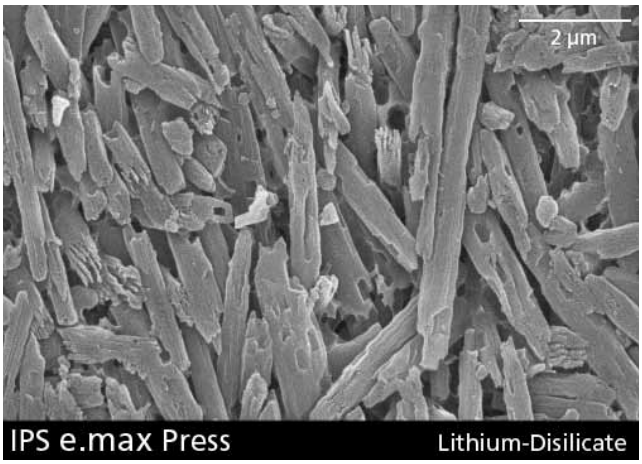
Note regarding the Instructions for Use:

The present Instructions for Use deal only with IPS e.max Press Abutment Solutions and represent a supplement to the existing IPS e.max Press Instructions for Use. The IPS e.max Press Instructions for Use contain more detailed descriptions of the material (e.g. ingot concept) and the entire indication range. In case you do not have the IPS e.max Press Instructions for Use, you can order them from your sales representative or simply download it from **www.ivoclarvivadent.com**.

Material

Press ceramic

IPS e.max Press are lithium disilicate glass-ceramic (LS_2) ingots for the press technology. The industrial production process creates absolutely homogeneous ingots in different translucency levels. For IPS e.max Press Abutment Solutions, ingots from the exisitng range of products are used.
The ingots feature a strength of 400 MPa and are thus the pressed ceramic ingots with the highest strength. They are pressed in Ivoclar Vivadent press furnaces to produce objects with outstanding accuracy of fit. The pressed, tooth-coloured, highly esthetic restorations are completed with IPS e.max Ceram.



CTE (100–400°C) [10^{-6}/K]	10.2
CTE (100-500°C) [10^{-6}/K]	10.5
Flexural strength (biaxial) [MPa]*	400
Fracture toughness [MPa $m^{0.5}$]	2.75
Modulus of elasticity [GPa]	95
Vickers hardness [MPa]	5800
Chem. solubility [µg/cm^2]*	40
Pressing temperature [°C]	915–920

*according to ISO 6872

Ti base

For IPS e.max Press Abutment Solutions, customary Ti bases made of titanium or titanium alloys are used.
Please observe the instructions for use and processing of the manufacturer of the Ti bases used.

Uses

Indications

- Hybrid abutments for anterior and posterior single-tooth restorations
- Hybrid abutment crowns for anterior and posterior restorations

Contraindications

- Use of Ti bases which do not fulfil the geometry requirements.
- Failure to observe the requirements stipulated by the implant manufacturer for using the selected implant type (diameter and length of the implant must be approved for the respective position in the jaw by the implant manufacturer).
- Bruxism
- Failure to observe the permissible maximum and minimum ceramic wall thicknesses.
- All uses not stated as indications are contraindicated.

Important processing restrictions

Failure to observe the following restrictions may compromise the results achieved with IPS e.max Press:

- If hybrid abutment crowns are fabricated, the opening of the screw channel must not be located in the area of contact points and areas with masticatory function. If this is not possible, a hybrid abutment with a separate crown would be preferred.
- No extension units; only single-tooth restorations
- Layering with a veneering ceramic other than IPS e.max Ceram
- Pressing of two or more IPS e.max Press ingots in one investment ring
- Pressing of IPS e.max Press in the IPS Investment System 300 g
- Use of a luting composite other than Multilink® Implant to lute IPS e.max Press to the Ti base
- Temporary cementation of the crown on the hybrid abutment.
- Failure to observe the manufacturer's instructions regarding the processing of the Ti base.

Side effects

If the patient is known to be allergic to any of the components, IPS e.max Press Abutment Solutions should not be used.

Composition

IPS e.max Press ingots and accessories required in conjunction with IPS e.max Press Abutment Solutions consist of the following main components:

- **IPS e.max Press ingots**
  Components: SiO_2
  Additional components: Li_2O, K_2O, MgO, ZnO, Al_2O_3, P_2O_5 and other oxides

- **IPS Alox Plunger**
  Components: Al_2O_3

- **IPS Alox Plunger Separator**
  Components: Boron nitride

- **IPS e.max Press Invex Liquid**
  Components: Hydrofluoric acid and sulphuric acid in water

- **IPS PressVEST Powder**
  Components: SiO_2, MgO and $NH_4H_2PO_4$

- **IPS PressVEST Liquid**
  Components: Colloidal silicic acid in water

- **IPS PressVEST Speed Powder**
  Components: SiO_2, MgO and $NH_4H_2PO_4$

- **IPS PressVEST Speed Liquid**
  Components: Colloidal silicic acid in water

- **IPS Object Fix Flow**
  Components: Oxides, water, thickening agent

- **IPS Ceramic Etching Gel**
  Components: Hydrofluoric acid (approx. 5%)

- **Virtual Extra Light Body Fast Set**
  Components: Addition-reaction silicone, vinyl polysiloxane, methylhydrogensiloxane, organoplatinic complex, silica

- **Monobond Plus**
  Components: Alcohol solution of silane methacrylate, phosphoric acid methacrylate and sulphide methacrylate

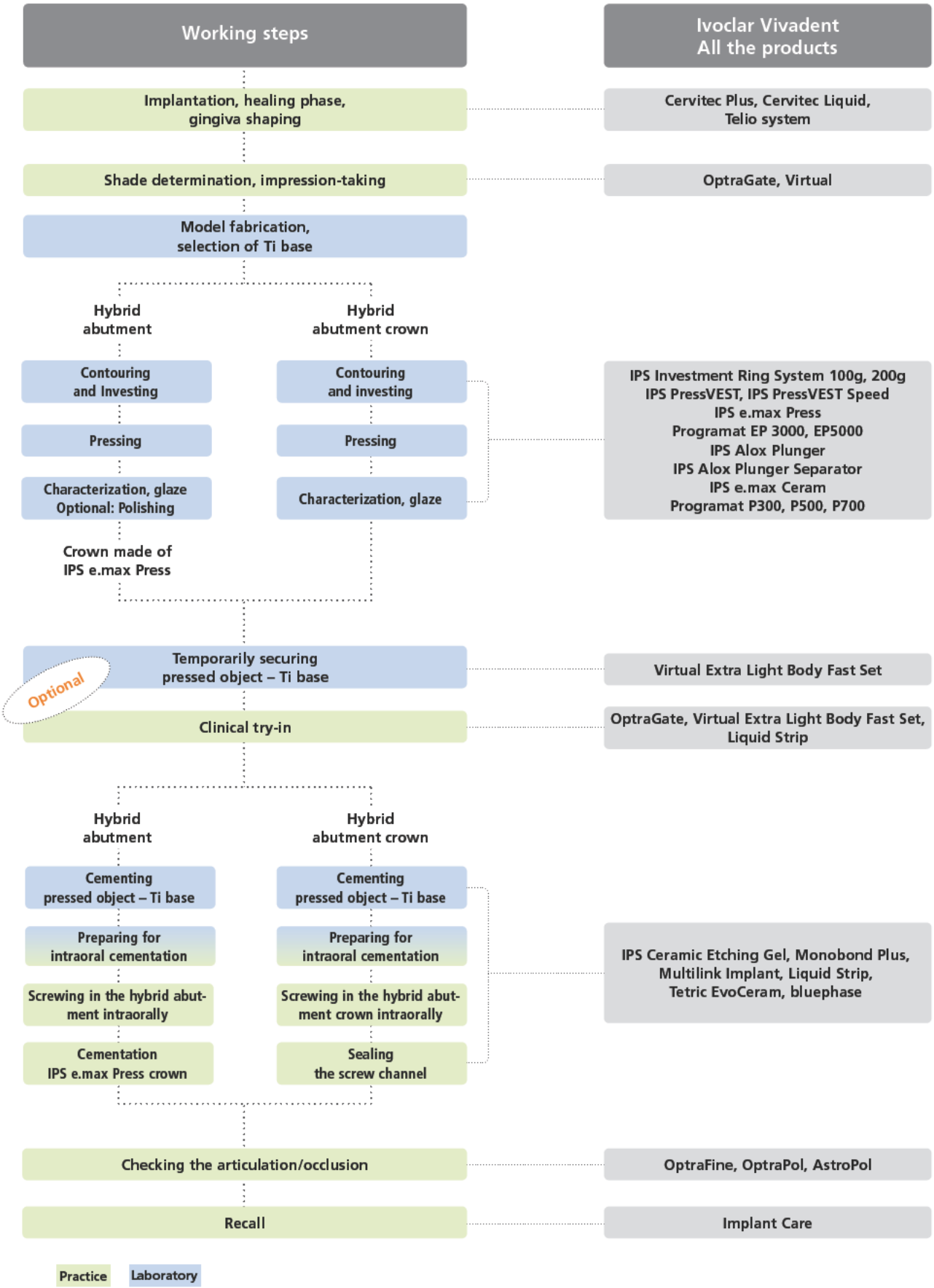
- **Multilink Implant**
  Components: Dimethacrylate, HEMA, barium glass, ytterbium trifluoride, spheroid mixed oxide

Warning

- Do not inhale ceramic dust during finishing – use exhaust air discharge and mouth protection.
- IPS Ceramic Etching Gel contains hydrofluoric acid. Contact with skin, eyes and clothing must be prevented at all costs, since the material is extremely toxic and corrosive. The etching gel is intended for professional use only and must not be applied intraorally (inside the mouth).

IPS e.max® Press Abutment Solutions

Treatment/Fabrication Process



The range of available products may vary from country to country.

Shade – tooth shade, preparation shade/abutment shade

Optimum integration in the oral cavity of the patient is the prerequisite for a true-to-nature all-ceramic restoration. To achieve this, the following guidelines and notes must be observed by both the dentist and the laboratory.

With IPS e.max Press Abutment Solutions, you can imitate not only the clinical crown of a natural tooth, but also a part of the "root". By defining/determining the "root shade" you can adjust the shade of the IPS e.max Press Abutment Solution restoration accordingly. This allows you to achieve a highly esthetic implant-supported restoration which retains its lifelike appearance also in the case of gingiva recession.

Hybrid abutment and separate crown

Restoration shade (pressed ceramic LS_2, characterization)	**Shade luting material** (crown on hybrid abutment)	**Shade hybrid abutment** (Ti base, luting material, pressed ceramic LS_2)
		

Hybrid abutment crown

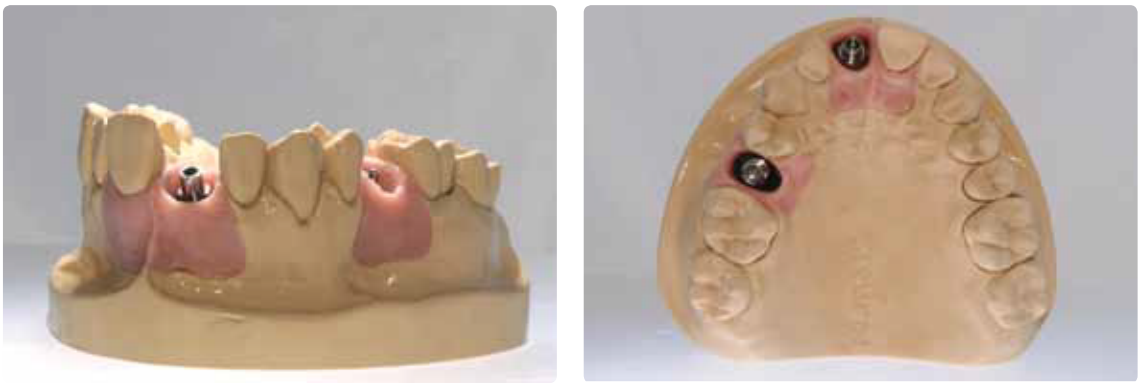
Shade hybrid abumtent crown
(Ti base, luting material, pressed ceramic LS_2, characterizations)

Please refer to the table on page 52 for the selection of the suitable IPS e.max Press ingot.

Model preparation

For the fabrication of an IPS e.max Press Abutment Solutions restoration, a model with gingiva mask is fabricated.

– Select the suitable model analog according to the implant system used.
– Fabricate a model with gingiva mask.



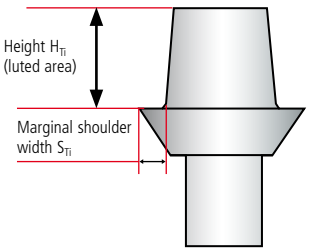
Prepared model with gingiva mask

Selecting a Ti base

The following paragraphs outline the selection criteria for a suitable Ti base. As a general rule, the instructions of the respective manufacturer regarding the use of the Ti base have to be observed.

– Only bases consisting of Ti or Ti alloys must be used.
– Select a Ti base with a size that matches the clinical situation and the chosen implant system. The geometry requirements must be observed.
– The rotation lock must be designed in such a way that stress concentrations on the pressed object are avoided.
– Ti bases with undercuts, e.g. retention grooves, are suitable to some extent.
– Check the available space for the pressed object taking the geometry of the Ti base into account on the model (e.g. silicone key).
– Observe the instructions of the manufacturer when modifying the Ti base.

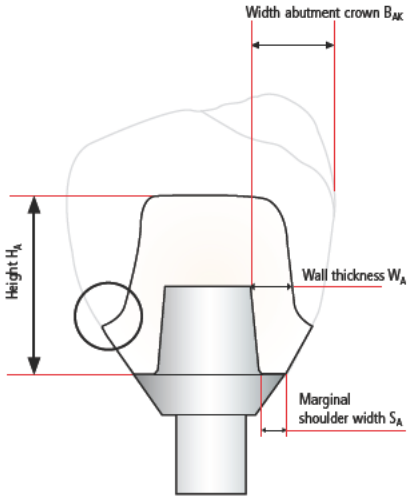
	Minimum dimensions	
	Height H_{Ti} (bonding surface)	**Shoulder width S_{Ti}**
Ti base	**H_{Ti} min. 4.0 mm**	**S_{Ti} min. 0.6 mm**



Layer thicknesses of the ceramic components

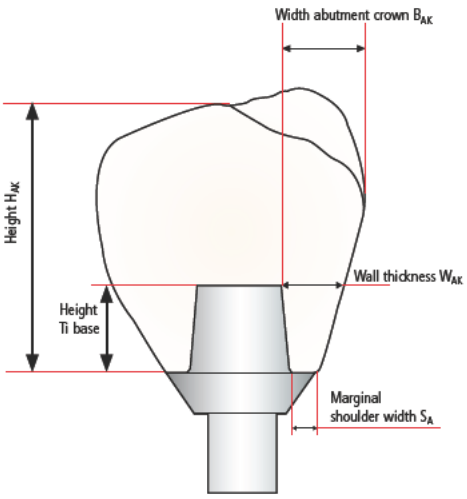
Observing the geometry requirements of the pressed objects made of IPS e.max Press material is the key to success for a durable restoration. The more attention given to the design, the better the final results and the clinical success will turn out to be. The following basic guidelines have to be observed:

Hybrid abutment



- The marginal shoulder width S_A must be at least 0.6 mm.
- Create an emergence profile with a right angle at the transition to the crown (see picture).
- The wall thickness W_A must be at least 0.5 mm.
- The height H_A must not exceed twice the height of the Ti base H_{Ti}.
- The hybrid abutment should be designed in a similar way as a prepared natural tooth:
  - Circular epi-/supragingival shoulder with rounded inner edges or a chamfer.
  - In order for the crown to be cemented to the hybrid abutment using a conventional/self-adhesive cementation protocol, retentive surfaces and a sufficient "preparation height" must be observed.
- The width B_{AK} of the crown is limited to 6.0 mm from the axial height of contour to the screw channel of the hybrid abutment.

Hybrid abutment crown



- The marginal shoulder width S_A must be at least 0.6 mm.
- The wall thickness W_{AK} must be larger than 1.5 mm for the entire circumference.
- The opening of the screw channel must not be located in the contact point areas or areas with a masticatory function. If this is not possible, a hybrid abutment with a separate crown should be preferred.
- The width of the hybrid abutment crown B_{AK} is limited to 6.0 mm from the axial height of contour to the screw channel.
- The height H_{AK} must not exceed twice the height of the Ti base by more than 2 mm.

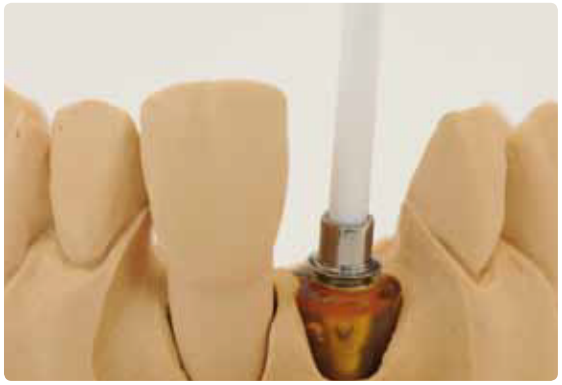
Modeling

Fabrication of a resin coping

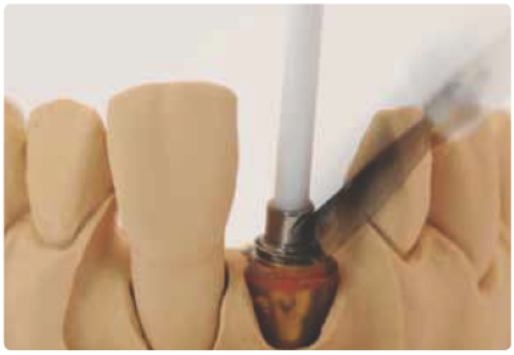
To prepare the wax-up, a resin coping is prepared if both hybrid abutments and hybrid abutment crowns are fabricated. Please observe the following procedure:

– Check the implant position and inclination with regard to the position of the screw channel.
– Screw the Ti base onto the model analog with the corresponding screw.
– **Tip**: Make sure that an additional model analog is available as this will facilitate some steps.
– Clean the Ti base with a steam cleaner.
– Insert a pin with the same diameter as the screw channel to "seal" and "extend" the screw channel.
– Do not apply die spacer.
– Isolate the Ti base and the pin with a thin application of separator. If too much separator is used, this might result in uneven areas on the inner aspect of the pressed object.
– In order to achieve a sound fit and to facilitate the subsequent wax-up, a coping is first fabricated on the Ti base with modelling resin. Design the coping in such a way that it can subsequently be completely covered with modelling wax. Please observe the instructions of the manufacturer regarding the processing of modelling resin.
– Remove the Ti base from the model.
– Eliminate possible over-contoured areas of the resin coping at the transition area to the Ti base by means of rubber polishers. Do not damage the Ti base.
– Remove the resin coping together with the pin from the Ti base.
– Loosen and remove the pin by rotating the resin coping.
– Screw the Ti base onto the model analog again.
– Place the resin coping back on the Ti base and check the fit and dimension (e.g. silicone key). If necessary, adjust the coping by means of rotary instruments.

Screw the Ti base onto the model analog with the corresponding screw.

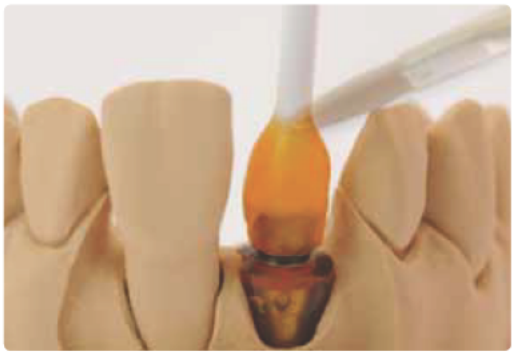


– Insert a pin with the same diameter as the screw channel to "seal" and "extend" the screw channel.



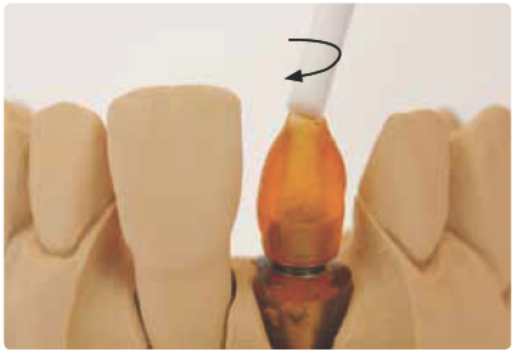
Isolate the Ti base and the pin with a thin application of separator.

Apply the modelling resin to the Ti base in increments.

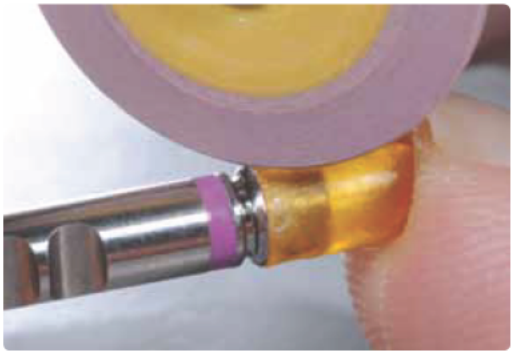


Design the resin coping on the entire Ti base.

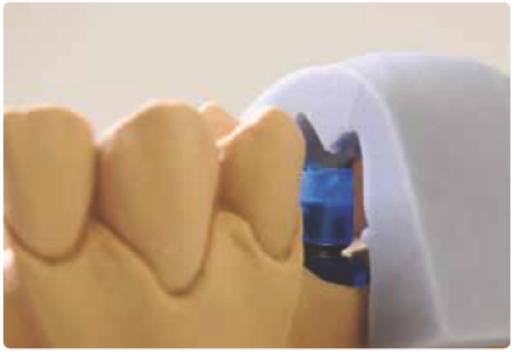
Remove the resin coping together with the pin from the Ti base.



Loosen and remove the pin by rotating the resin coping.



Eliminate possible over-contoured areas of the resin coping at the transition area to the Ti base by means of rubber polishers.



Place the resin coping back on the Ti base and check the fit and dimension (e.g. silicone key). If necessary, adjust the coping by means of rotary instruments. Design the coping in such a way that it can subsequently be covered with modelling wax.

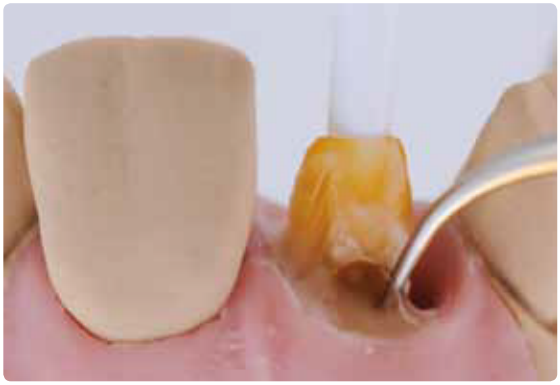
Wax-up

Please observe the following notes with regard to modelling:

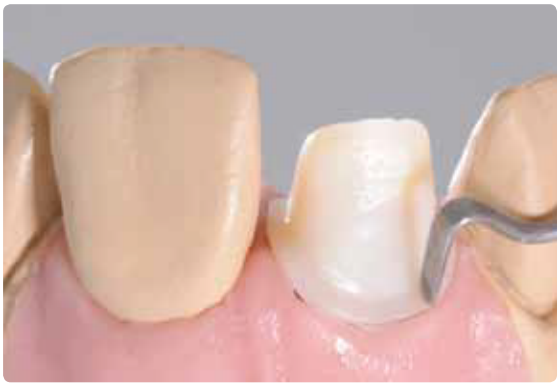
– Observe the stipulated layer thicknesses.
– Create an accurate model of the restoration, particularly at the transition area to the Ti base.
– Do not over-contour the margins, since this would require time-consuming and risky fitting procedures after pressing.
– Use an organic wax for modelling to ensure that it burns out without leaving residue in the investment ring.

Procedure for hybrid abutments

– Before creating the wax object, re-insert the isolated pin into the screw channel.
– Design the emergence profile by flooding the area between the gingiva mask and the resin coping with wax.
– Contour the hybrid abutment to a reduced tooth shape. The hybrid abutment should be designed in such a way that the required layer thicknesses are met in the crown that is fabricated. Check by means of the silicone key and in relation to the opposing dentition.
– Determine the crown margins in relation to the gingiva level.
– Design a chamfer on which the crown is subsequently seated.
– Remove the object together with the Ti base from the model and check the emergence profile. If necessary, make adjustments.
– Check the transition to the Ti base and remove excess wax.
– Check the required minimum thicknesses (page 9) prior to attaching the sprue.



Design the emergence profile by flooding the area between the gingiva mask and the resin coping with wax.



Design the hybrid abutment with a reduced tooth shape and determine the crown margin in relation to the gingiva level.

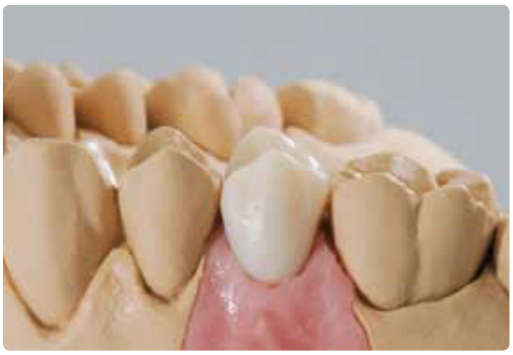
Check the dimensions by means of the silicone key and in relation to the opposing dentition.

Remove the object together with the Ti base from the model and check the emergence profile. If necessary, make adjustments. Check the transition to the Ti base and thoroughly remove excess wax.

Procedure for hybrid abutment crowns:

- If required, re-insert the isolated pin into the screw channel before creating the wax object.
- Design the emergence profile by flooding the area between the gingiva mask and the resin coping with wax.
- Design the abutment crown to full contour according to functional and esthetic criteria. Check in relation to the opposing dentition.
- Make sure to take a slightly reduced occlusal relief into consideration during the wax-up, since the application of the Stains and Glaze results in a slight increase in vertical dimensions.
- Remove the object together with the Ti base from the model and check the emergence profile. If necessary, make adjustments.
- Check the transition to the Ti base and remove possible excess wax.
- Check the required thicknesses (page 9) prior to attaching the sprues.

Design the emergence profile by flooding the area between the gingiva mask and the resin coping with wax. If necessary, re-insert the pin prior to modelling.

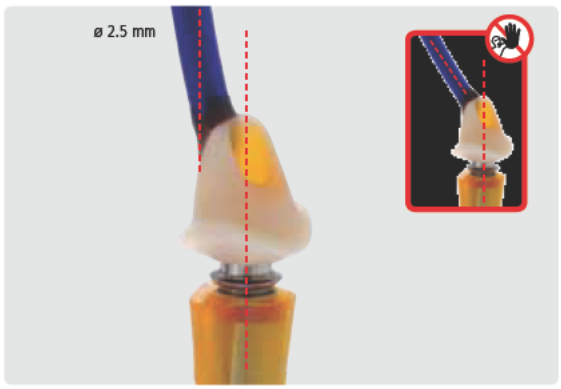


Design the abutment crown to full contour according to functional and esthetic criteria. Check the object in relation to the opposing dentition.

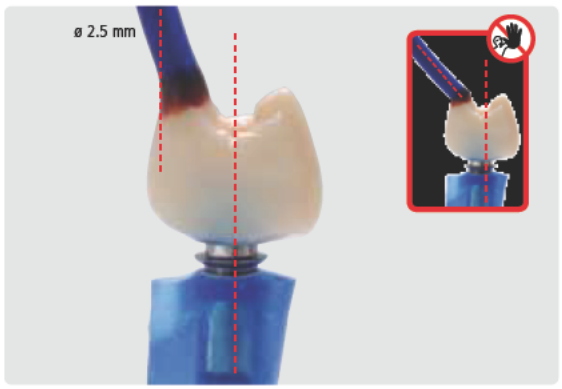
Sprueing

Please observe the following notes when attaching the sprues to the abutment or the abutment crown:

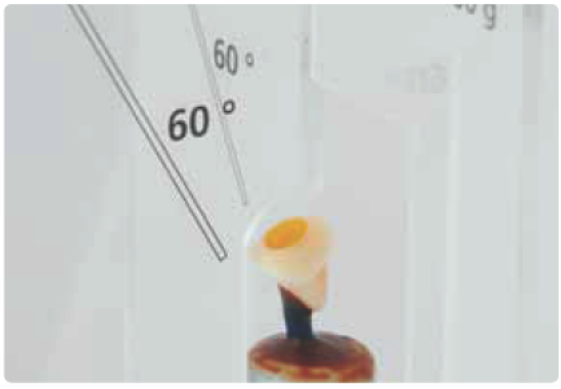
- Depending on the number and size of the objects to be invested, either the 100 g or 200 g IPS Investment Ring System is selected. Before sprueing, weigh the ring base and record the weight (seal the opening of the ring base with wax). Please note that the mixing ratio of the investment material is different for the various restoration types (e.g. inlays, crowns, abutments).
- Use a **2.5 mm wax wire** for sprueing.
- For abutments, the sprue is attached to an axial surface.
- For abutment crowns, the sprue is attached to a cusp.
- **Align the wax wire as parallel as possible to the screw channel in order to prevent the investment material from fracturing in the screw channel.**
- The maximum length (object + sprue) of 16 mm must not be exceeded.
- Place the object on the investment ring base in such a way that the screw channel is parallel to the outer wall of the investment ring. As a result, the investment material can subsequently be filled evenly and in a controlled manner. The objects could be placed in a tilted position on the investment ring base, but this may lead to difficulties during investing (e.g. bubbles in the screw channel).
- Observe a distance of at least 10 mm between the object and the silicone ring.
- If only one object is invested and pressed in an EP500 furnace, a second short (blind) sprue must be placed. This ensures that the switch-off function of the furnace works properly at the end of the pressing procedure.

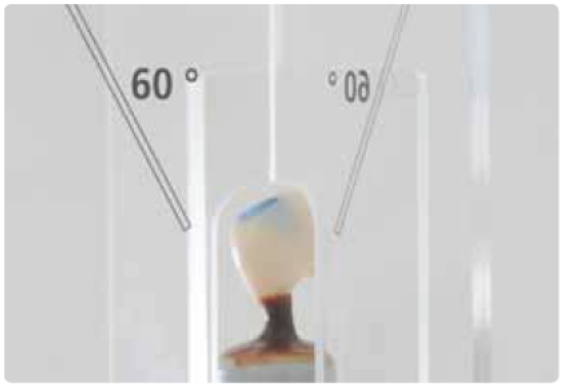


Attach the sprue to a circular area of the abutment model and as parallel as possible to the screw channel. Use a 2.5 mm wax wire.



Attach the sprue to an oral cusp of the abutment crown and as parallel as possible to the screw channel. Use a 2.5 mm wax wire.





Place the object on the investment ring base in such a way that the screw channel is parallel to the outer wall of the investment ring.
As a result, the investment material can subsequently be filled evenly and in a controlled manner.
Furthermore, this reduces the risk of the investment material breaking in the screw channel while the ceramic material is pressed.

Investing

Investing is carried out with either IPS PressVEST or IPS PressVEST Speed. The corresponding IPS Silicone Ring with the matching ring gauge is used for investment.
Determine the weight of the object before investing.
– Position the wax objects on the ring base and attach them with wax and weigh.
– The difference between the empty and the loaded ring base is the definitive wax weight.

	Small Ingot	Large Ingot (L)
Wax weight	up to max. 0.75 g	up to max. 2 g
Investment Ring System	100 g and 200 g	only 200 g

Please refer to the Instructions for Use of the corresponding investment material regarding the detailed processing parameters. The following basic procedure is recommended:
– Do not use a debubblizer on the wax objects.
– Carefully place the IPS Silicone Ring on the ring base without damaging the objects. The silicone ring must sit flush on the ring base.
– The processing temperature of the investment material is 18– max. 23 °C / 64 °F – max. 73 °F. Higher or lower processing temperatures substantially affect the setting behaviour.
– Mix the investment material. Note: The investment material contains quartz powder. Therefore, avoid the inhalation of dust.
– **Important: Pour the investment material slowly into the investment ring, so that the material continuously fills the screw channel. If the material does not sufficiently fill the screw channel, use an instrument to carefully apply additional investment material to the screw channel from the top.**
– Carefully fill the investment ring with investment material up to the marking on the silicone ring and position the ring gauge with a hinged movement.
– Allow the investment ring to set without manipulating it.
– To prevent crystallization of the IPS PressVEST investment material, the invested ring must be processed within 24 hours.
– If IPS PressVest Speed is used, make sure that the investment ring is placed in the preheating furnace after a setting time of at least 30 and maximum 45 minutes.

Investment material: Liquid concentration and quantity

Indication	IPS PressVEST		IPS PressVEST Speed	
	100 g Investment Ring Liquid : dist. water	200 g Investment Ring Liquid : dist. water	100 g Investment Ring Liquid : dist. water	200 g Investment Ring Liquid : dist. water
IPS e.max Press				
Hybrid abutment Hybrid abutment crown	16 ml : 6 ml	32 ml : 12 ml	20 ml : 7 ml	40 ml : 14 ml
Mixing time (under vacuum at approx. 350 rpm)	60 seconds		2.5 minutes If a high-speed mixer is used, the mixing time under vacuum has to be reduced.	

Liquid concentration: The data contained in the table are approximative values. Depending on the geometry of the Ti base and the materials used for the wax-up, these values may be individually changed. However, the concentrated Liquid content must not be lower than 50% in relation to distilled water.
Important: The total quantity of liquid (Liquid + dist. water) must not be altered.

Correctly sprued abutment (left) and abutment crown (right). The screw channel is in a vertical position and parallel with the wall of the investment ring.

Pour the investment material slowly into the investment ring, so that the material can continuously fill the screw channel.

Continue to carefully fill the investment ring up to the marking and position the ring gauge with a hinged movement.

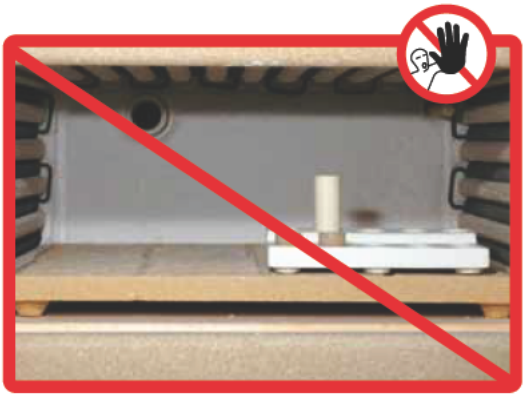
Preheating

After the stipulated setting time of the respective investment material (IPS PressVEST or IPS PressVEST Speed), the investment ring is prepared for preheating as follows:

- Remove the ring gauge with a turning movement.
- Carefully push the investment ring out of the IPS Silicone Ring.
- Remove the ring base with a turning movement.
- Remove rough spots on the bottom surface of the investment ring with a plaster knife. Check the 90° angle. Investment material residue must not enter the sprues. Blow into the sprues if necessary.
- If several investment rings are preheated together, mark them accordingly.

	IPS PressVEST	IPS PressVEST Speed
Setting time	min. 60 min, max. 24 hrs	min. 30 min, max. 45 min
Temperature of the preheating furnace when placing the investment ring	Room temperature	850 °C / 1562 °F; switch on the preheating furnace in time.
Position of the investment ring in the preheating furnace	Towards the rear wall, tipped with the opening facing down	Towards the rear wall, tipped with the opening facing down
Final temperature for preheating the investment ring	850 °C / 1562 °F	850 °C / 1562 °F
Holding time of the investment ring at final temperature	min. 60 min	100 g investment ring – min. 45 min 200 g investment ring – min. 60 min
IPS e.max Press ingots	**no preheating**	**no preheating**
IPS Alox Plunger	**no preheating**	**no preheating**
Important		If several Speed investments are to be conducted, they should be invested consecutively and placed into the preheating furnace at an interval of approx. 20 minutes. Make sure that the furnace temperature does not drop too much when placing the investment rings into the preheating furnace. The stipulated holding time counts from the point when the preheating temperature has been reached again.

Towards the rear wall, tipped with the opening facing down



Do not preheat the IPS e.max Press ingot and Alox Plunger.

In order to ensure smooth working procedures in the laboratory on a daily basis, impeccable functioning of the infrastructure, particularly the preheating furnaces, is essential. This includes their maintenance, cleaning with a vacuum cleaner in a cool state as well as regular checks of the temperature controls and heating elements, etc., by the manufacturer.

Pressing

Carry out the following preparatory steps for pressing before the preheating cycle for the investment ring has been completed:
- Provide a **cold** IPS Alox Plunger and a **cold** IPS e.max Press ingot in the desired shade (please refer to the material selection table on page 52).
- Dip the **cold** IPS Alox Plunger into the opening of the IPS Alox Plunger Separator and keep it ready for use.
- Turn on the press furnace (e.g. Programat EP 5000) in time so that the self-test and preheating phase are completed.
- Select the press program for IPS e.max Press and the desired investment ring size.

Remove the investment ring from the preheating furnace immediately after completion of the preheating cycle. This step may take max. 30 seconds to prevent the investment ring from cooling down too much.
- Place the **cold** IPS e.max Press ingot into the **hot** investment ring.
- Insert the ingots in the investment ring with the non-imprinted side facing down. The imprinted side faces up to check the ingot shade.
- Place the side of the **cold** IPS Alox Plunger which has been coated with Separator into the **hot** investment ring.
- Use the investment ring tongs to place the loaded investment ring in the centre of the **hot** press furnace.
- The selected press program is started by pressing START.

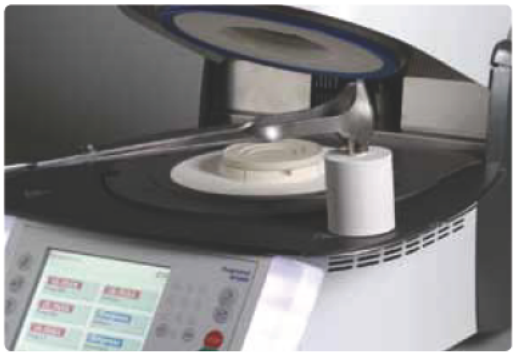
After the end of the press cycle (optical and/or acoustic signal) proceed as follows:
- Remove the investment ring from the press furnace using the investment ring tongs immediately after pressing.
- Place the investment ring on a cooling grid to cool in a place protected from draft.
- Do not speed up cooling, e.g. by blasting with compressed air.

	100 g Investment Ring	200 g Investment Ring
	1 small ingot	1 small ingot or 1 large ingot
IPS e.max Press ingots	**cold ingot**	**cold ingot**
IPS Alox Plunger	**cold plunger**	**cold plunger**
IPS Alox Plunger Separator	✓	✓

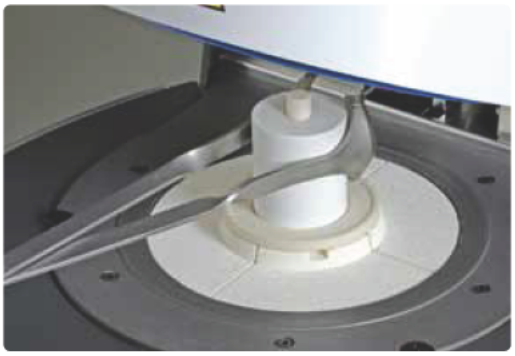
Ingots: select one large or one small ingot according to the determined wax weight!

Provide a **cold** isolated IPS Alox Plunger and a **cold** IPS e.max Press ingot in the desired shade.

Place the **cold** IPS e.max Press ingot into the **hot** investment ring with the imprinted side facing up.



Then, place the side of the IPS Alox Plunger which has been coated with Separator into the hot investment ring.



Place the hot and loaded investment ring in the centre of the hot press furnace using the IPS Investment Ring Tongs.

Press START to start the selected program.

Once the press program is completed, place the hot investment ring on the cooling grid using the Investment Ring Tongs and allow it to cool to room temperature.

Press parameters for IPS e.max Press

Programat EP 3000

Select the press program in accordance with the selected ingot to be pressed and the investment ring size used.

The press parameters for HO, MO, LT and HT are integrated starting with software V 6.1.

Programat EP 5000

Select the press program in accordance with the selected ingot to be pressed and the investment ring size used.

The press parameters for HO, MO, LT and HT are integrated starting with software V 6.1.

The press parameters for older-generation Ivoclar Vivadent press furnaces are listed on page 53 under Press Parameters.

Divesting

After cooling to room temperature (approximately 60 minutes), the investment ring may show cracks, which developed during the cooling phase (immediately around the Alox plunger). This is the result of the different CTEs of the various materials (Alox Plunger, investment material and press ingot) and does not compromise the press results.

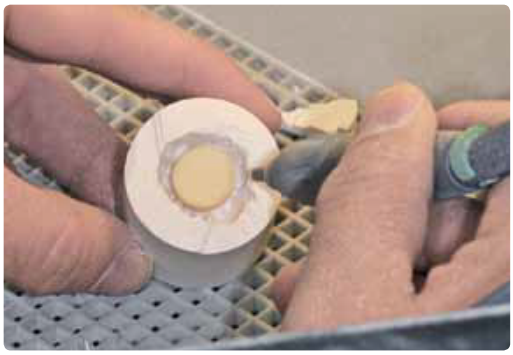
Divest the investment ring as follows:
- Mark the length of the Alox Plunger on the cooled investment ring.
- Separate the investment ring using a separating disc. This predetermined breaking point enables reliable separation of the Alox Plunger and the ceramic material.
- Break the investment ring at the predetermined breaking point using a plaster knife.
- Always use polishing beads to divest the pressed objects (rough and fine divestment). Do not use Al_2O_3.
- Rough divestment is carried out with polishing beads at 4 bar (58 psi) pressure.
- Fine divestment is carried out with polishing beads at 2 bar (29 psi) pressure.
- Observe the blasting direction and distance to prevent damage to the object margins during divestment.
- Same as the outer surfaces, thoroughly blast the screw channel with polishing beads at 2 bar (29 psi) pressure.
- Remove possible ceramic residue from the Alox Plunger with type 100 Al_2O_3.

Mark the length of the Alox Plunger.

Separate the investment ring using a separating disc and break it at the predetermined breaking point.

Tip

Pull out the plunger with pliers from the separated segment using a rotating movement. This also removes any possible ceramic residue from the Alox plunger.



Rough divesting with polishing beads at 4 bar (58 psi) pressure until the object becomes visible.

Fine divestment of the abutment is carried out with polishing beads at 2 bar (29 psi) pressure.

Fine divestment of the abutment crown is carried out with polishing beads at 2 bar (29 psi) pressure.

Completely divested IPS e.max Press objects.

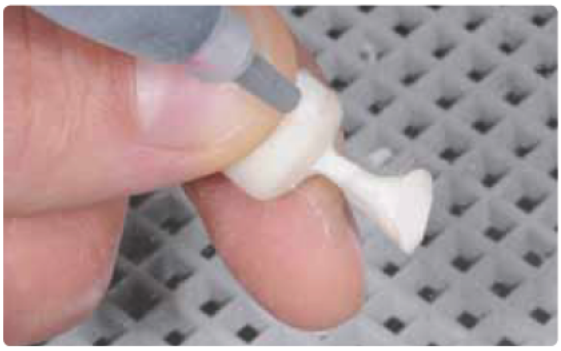
Removing the reaction layer

After fine divestment, the reaction layer formed during the press procedure is removed using IPS e.max Press Invex Liquid. The procedure is carried out as follows:

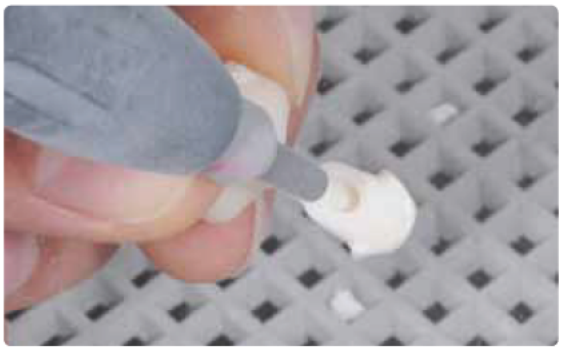
- Pour the Invex Liquid into a plastic cup.
- Immerse the pressed object in the Invex Liquid and clean in an ultrasonic cleaner for at least 10 min and at most 30 min. Make sure that the objects are completely covered with Invex Liquid.
- Use the sieve insert to remove the restoration from the Invex Liquid and clean the object under running water and blow dry.
- Carefully remove the white reaction layer with type 100 Al_2O_3 at max. 1–2 bar (15–29 psi) pressure.
- Make sure that the reaction layer is completely removed, both from the screw channel and the outer side of the object (repeat the procedure, if necessary).
- If the reaction layer is not completely removed, problems may occur in the further course of the fabrication process.
- Replace the IPS e.max Invex Liquid after 20 applications or after sedimentation of the Liquid.

To remove the reaction layer, immerse the pressed objects in IPS e.max Press Invex ...

... and place in an ultrasonic cleaner for at least 10 and at most 30 minutes.



Using Al_2O_3 and a pressure of at most 1–2 bar (15–29 psi) pressure, carefully remove the reaction layer from the outer side ...



... and the screw channel.

Warning

- The Invex Liquid contains < 1% hydrofluoric acid.
- It is harmful when inhaled, swallowed and when it comes into contact with the skin. Furthermore, it is corrosive.
- Keep the container tightly sealed and store it in a well-ventilated place (acid cabinet).
- If the material comes into contact with the eyes, immediately rinse with copious amounts of water and see an ophthalmologist immediately.
- In case of accidental contact with skin, immediately wash with plenty of water.
- Use suitable protective clothing, gloves and goggles when working.
- In case of an accident or physical discomfort, see a physician immediately, and take the Invex label with you, if possible.

Disposal

- Neutralize the Invex Liquid before disposal!
- Use the IPS Ceramic Neutralization Powder to neutralize the Invex Liquid.
- For 50 ml Invex Liquid, approx. 3–4 g of IPS Ceramic Neutralization Powder are required.
- Note: strong foam development during neutralization.
- Carefully add the neutralization powder to the Invex Liquid in small portions until foam is no longer formed; then allow a reaction time of 5 minutes.
- If larger quantities are disposed of, check the liquid with litmus paper (must show an alkaline reaction).
- After the reaction time, pour the neutralized solution into the sink, flushing it with running water.

Finishing

It is of critical importance to use the correct grinding instruments for finishing and adjusting high-strength glass-ceramics (please refer to the Ivoclar Vivadent Flow Chart "Recommended grinding instruments for glass-ceramics"). If unsuitable grinding instruments are used, chipping of the edges and local overheating may occur.

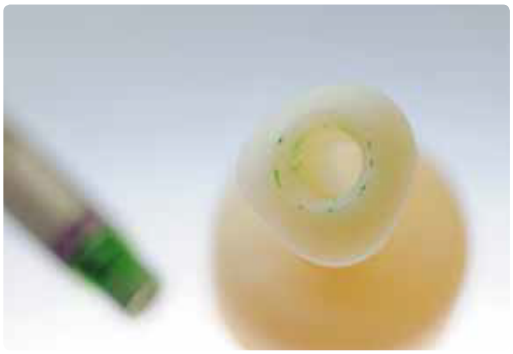
Observe the following procedure for finishing IPS e.max Press restorations:
- Adjustment by grinding of pressed IPS e.max Press restorations should be kept to a minimum.
- Overheating of the ceramic must be avoided. Low speed and light pressure is recommended.
- Make sure that the minimum thicknesses are maintained even after the minor adjustments.

Fitting to the Ti base

The fit of the abutment or abutment crown is checked on the Ti base before the sprue is separated.
- Before the object is fitted, the inner aspect of the object (screw channel) is checked for bubbles in the ceramic. If required, the bubbles are removed with suitable instruments.
- Carefully position the abutment or abutment crown on the Ti base. **Note**: Apply only light pressure to secure the pressed object on the Ti base in order to prevent chipping of the ceramic. Observe the position of the rotation lock.
- Possible rough spots interfering with the fit of the pressed object on the Ti base cause greyish-black markings on the screw channel. Carefully remove such markings with suitable grinding instruments. The diameter of the grinding instrument must be smaller than that of the screw channel. As an alternative to marking the rough spots, an occlusion spray can also be used.
- Carefully remove possible rough spots until an optimum fit between the Ti base and the pressed object is achieved. Repeat the procedure, if required.

Check the screw channel for bubbles ...

Carefully position the abutment or abutment crown on the Ti base.



Possible rough spots interfering with the fit on the Ti Base cause stains on the screw channel of the pressed object, ...

... which can be carefully removed by means suitable grinding tools.

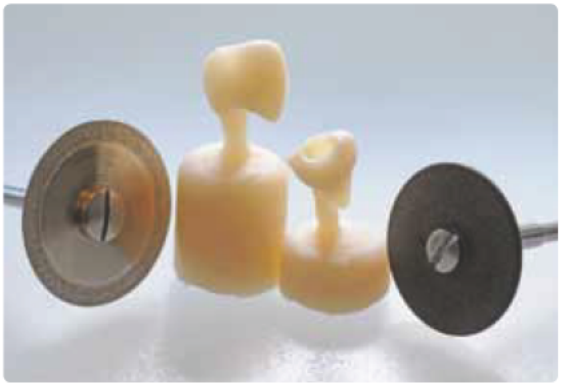
After possible rough spots have been removed, an optimum fit between the hybrid abutment ...

... or the abutment crown and the Ti base is achieved.

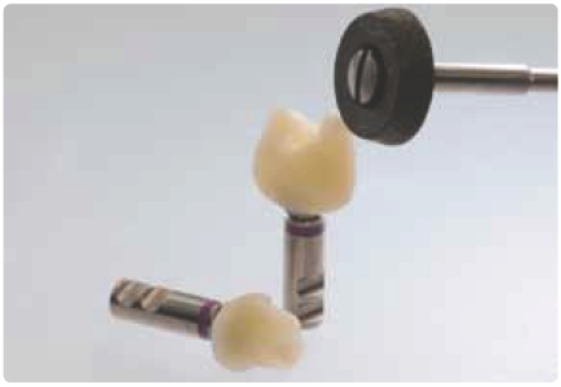
Finishing

Once an optimum fit between the abutment or the abutment crown and the Ti base has been achieved, please proceed as follows for the finishing steps:

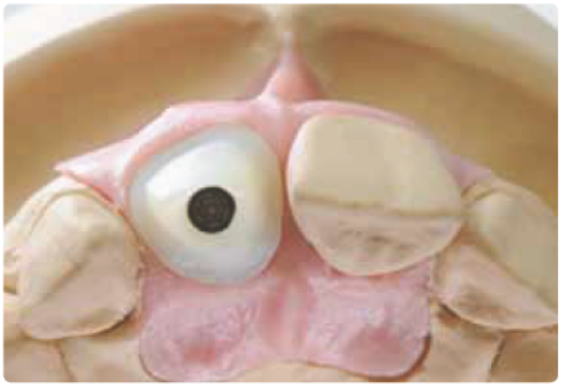
- Separate the sprue using a separating disc. Avoid overheating.
- Smooth out the attachment point of the sprue. Make sure that the minimum thicknesses are maintained.
- Check the emergence profile and the fit on the model.
- In the case of abutment crowns, additionally check the occlusion and articulation. Adjust by grinding, if necessary, and create surface textures.
- To clean the abutment crown, briefly blast the outer side with Al_2O_3 at 1 bar (15 psi) pressure and clean with the steam cleaner. Some blasting devices may require different pressure settings to accomplish this procedure.

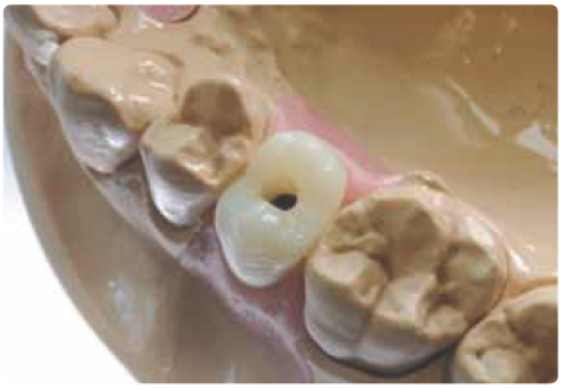


Separate the sprues using a separating disc. Avoid overheating.



Smooth out the attachment point of the sprue.





Check the emergence profile and the fit on the model.

Stain and Characterization firing

The following paragraphs will explain the steps of optional staining and characterizing with IPS e.max Ceram Shades and Essences. On abutments, only the emergence profile is characterized for the individual patient. This characterization may also take place at a later stage, i.e. when the crown is characterized.

If abutments are fabricated, only the area of the emergence profile is characterized with IPS e.max Ceram Shades and Essences.

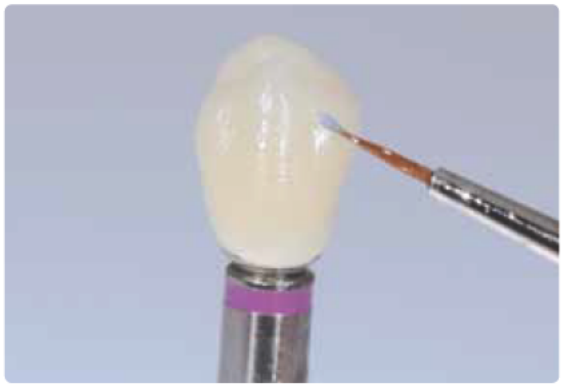
If abutment crowns are fabricated, the entire outer surface may be individually characterized.

The Stains and Characterization firing is conducted with IPS e.max Ceram Shades and Essences. For further information, please refer to the IPS e.max Ceram Instructions for Use.

- IPS e.max Ceram Shades are ready-to-use stains in syringes.
- IPS e.max Ceram Essences are intensively shaded powdered stains, which are mixed with IPS e.max Ceram Glaze and Stain Liquid.

The following steps must be observed:

- Clean the pressed object with a steam cleaner to remove any contaminations and grease residue. Any contamination after cleaning must be prevented.
- **Tip**: For the characterization, place the abutment or the abutment crown on the Ti base using a little IPS e.max Ceram Glaze and Stain Liquid. This allows you to assess the effect of the Ti base on the shade.
- For better wetting of the stains, a small quantity of IPS e.max Ceram Glaze and Stain Liquid may be slightly rubbed into the area that needs to be characterized.
- Mix the pastes or powders with the IPS e.max Ceram Glaze and Stain Liquids (allround or longlife) until the desired consistency is achieved.
- More intensive shades are achieved by several staining procedures and repeated firing, not by applying thicker layers.
- To imitate the incisal area and translucency of the abutment crown in the incisal and occlusal third, IPS e.max Ceram Shade Incisal may be used.
- The cusps and fissures can be individualized using Essences.
- If abutments are fabricated, only the area of the emergence profile is characterized with IPS e.max Ceram Shades and Essences. Do not apply materials to the bonding surface to the crown, as this might compromise the fit and the bond.
- **Important**: Make sure that absolutely no materials are applied to the screw channel and the interface to the Ti base in order not to compromise the fit and bond.
- Conduct the Stain and Characterization firing on a honey-comb firing tray using the stipulated firing parameters. Please observe the special firing parameters.
- Remove restoration from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).
- Allow the objects to cool to room temperature in a place protected from draft.
- Do not touch the hot objects with metal tongs.



Apply IPS e.max Ceram Shade Incisal to imitate the incisal area.

Enhance the chroma of the buccal surface.

Individual characterization of the emergence profile with IPS e.max Ceram Essences.

Conduct the Stain and Characterization firing on a honey-comb firing tray.

Firing parameters for the Stain and Characterization firing

IPS e.max Ceram on IPS e.max Press *Abutment Solutions*	B °C	S min	t↗ °C/min	T °C	H min	V_1 °C	V_2 °C	L °C
Stain and Characterization firing	403	6:00	60	770	01:00	450	769	500

Additional Stain and Characterization firing cycles can be conducted with the same firing parameters.

Note:
If the layer thickness is less than 2 mm on the entire pressed object, long-term cooling (L) is not required to produce a tension-free condition.

Glaze firing

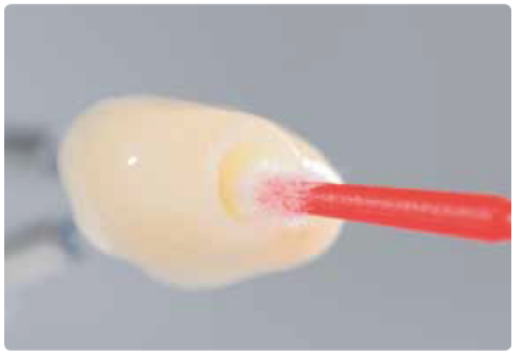
Glaze firing is conducted with powder or paste glaze. On abutments, only the emergence profile is glazed. Glaze firing may also take place at a later stage, i.e. when the crown is glazed. On abutment crowns, glaze is applied to the entire outer surface.

The following procedure is recommended:

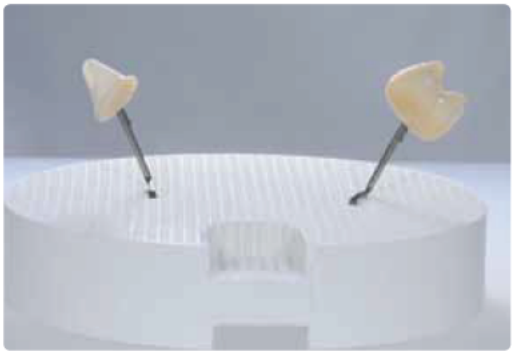
- Mix the glazing material (IPS e.max Ceram Glaze Paste or Powder) with the IPS e.max Ceram Glaze and Stain Liquids allround or longlife to the desired consistency.
- Apply an even layer of glazing material covering all areas that are to be glazed.
- If required, the fluorescence may be increased by applying a fluorescing glazing materal (paste or powder).
- **Important**: Make sure that absolutely no materials are applied to the screw channel and the interface to the Ti base in order not to compromise the fit.
- Make sure that no glaze material is present on the interface of abutments and abutment crowns prior to the firing cycle. If necessary, carefully remove the glaze material.
- Conduct the Glaze firing on a honey-comb firing tray using the stipulated firing parameters. Please observe the special firing parameters.
- Remove restoration from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).
- Allow the objects to cool to room temperature in a place protected from draft.
- Do not touch the hot objects with metal tongs.
- If adjustments are required after Glaze firing (e.g. contact points), they may be applied using IPS e.max Ceram Add-on (see page 28).

Apply an even layer of glaze material to the emergence profile of the abutment. Make sure that no glaze material enters the screw channel.

Apply the glazing material evenly on the outer surface of the abutment crown. Make sure that no glaze material enters the screw channel.



Make sure that no glaze material is present on the interface of abutments and abutment crowns prior to the firing cycle. If necessary, carefully remove the glaze material.



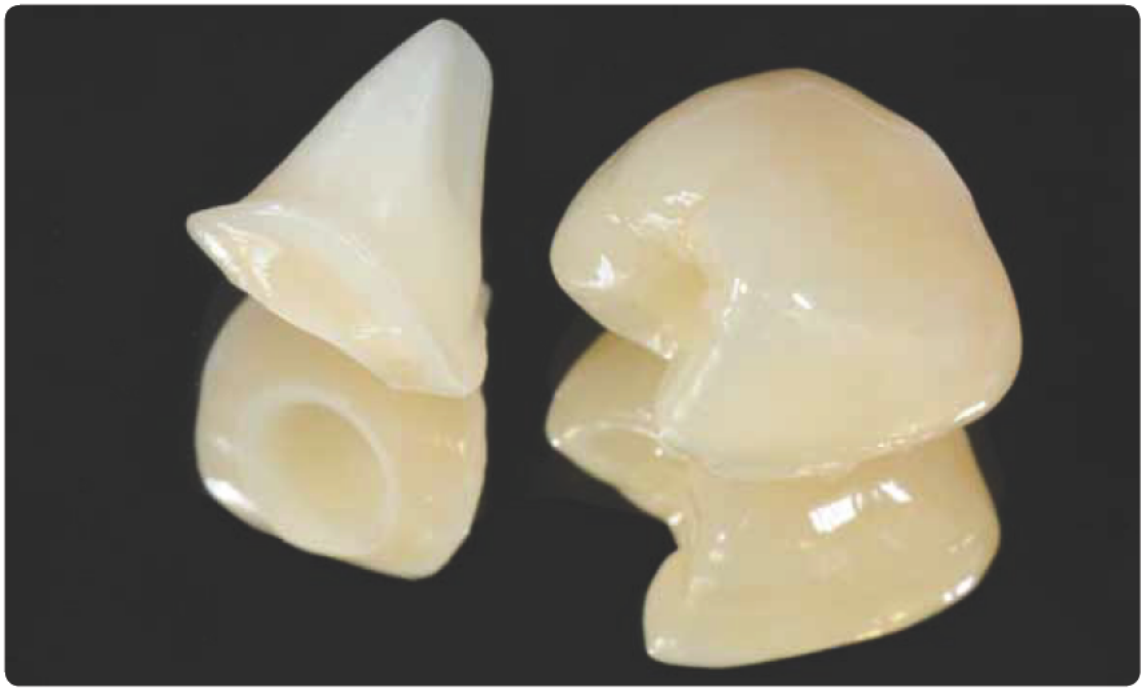
Conduct the Glaze firing on a honey-comb firing tray with the corresponding parameters.

Firing parameters for the Glaze firing

IPS e.max Ceram on IPS e.max Press *Abutment Solutions*	B °C	S min	t↗ °C/min	T °C	H min	V_1 °C	V_2 °C	L °C
Glaze firing	403	6:00	60	770	1:00–2:00	450	769	500

If the gloss is unsatisfactory after the first Glaze firing, further Glaze firing procedures may be conducted using the same firing parameters.

Note:
If the layer thickness is less than 2 mm on the entire pressed object, long-term cooling (L) is not required to produce a tension-free condition.



Completely glazed and characterized abutment and abutment crown

Adjustments with IPS e.max Ceram Add-On

Use IPS e.max Ceram Add-On Dentin and/or Incisal to make adjustments to the abutment or abutment crown after Glaze firing. Please observe the following procedure for processing:

- Mix IPS e.max Ceram Add-On Dentin or Incisal with IPS e.max Ceram Build-Up Liquid soft or allround and apply on the corresponding areas.
- Fire with the stipulated parameters for the "Add-On after Glaze firing". Observe long-term cooling! If necessary, polish the adjusted areas to a high gloss after firing.

Firing parameters IPS e.max Ceram Add-On after Glaze firing.

IPS e.max Ceram on IPS e.max Press	B °C	S min.	t↗ °C/min	T °C	H min	V_1 °C	V_2 °C	L °C
Glaze firing	403	6:00	50	700	01:00	450	699	500

Optional: Polishing the emergence profile of the abutment

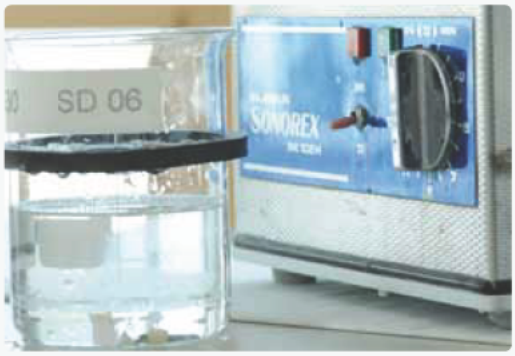
If no characterizations and no glaze firing of the abutment are required, the emergence profile may be manually polished. Please remember that polishing results in a slight reduction of the emergence profile, which might influence the fit to the gingiva in certain situations.

Please observe the following procedure for polishing:

- Clean the pressed object with a steam cleaner to remove any contaminations.
- Place the pressed object onto the Ti base for processing.
- Overheating of the glass-ceramic must be avoided. Observe the recommendations of the manufacturer of the grinding tool.
- Pre-polish the emergence profile with a diamond-coated rubber polisher. **Note**: The Ti base should not be modified.
- Fine polishing of the emergence profile with a high-gloss rubber polisher.
- High-gloss polishing with brushes and polishing paste.
- Clean the abutment with an ultrasonic or steam cleaner.

Pre-polish the emergence profile with a diamond-coated rubber polisher.

High-gloss polishing with brushes and polishing paste.



Then clean the abutment with ultrasonic ...

... or with steam.

Crown on hybrid abutment

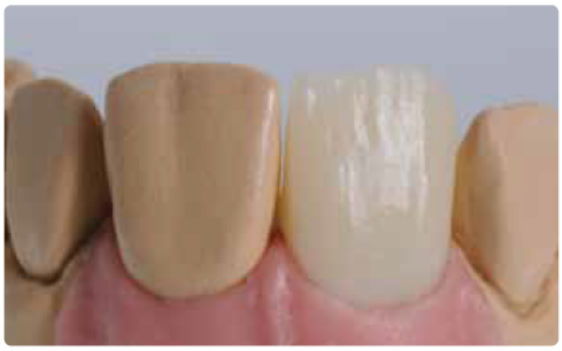
Preferably, a crown made of IPS e.max Press is seated on an IPS e.max Press hybrid abutment. Depending on your preference, the staining, cut-back or layering technique may be applied for this. For a detailed description of the fabrication, please refer to the IPS e.max Press Instructions for Use.

The following paragraphs describe the working steps which deviate from the procedure applied for the fabrication of restorations on prepared teeth. In this example, an IPS e.max Press crown is fabricated in the cut-back technique.

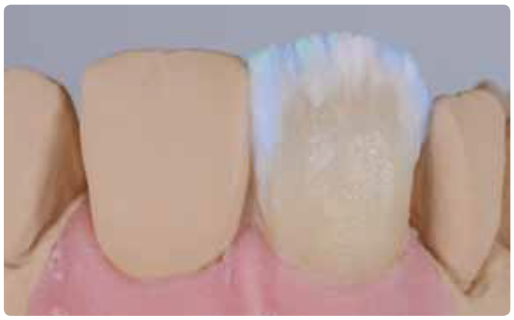
Screw the Ti base onto the model analog with the corresponding screw. If required, the abutment can be secured on the Ti base by means of Virtual Extra Light Body Fast Set.
Seal the screw channel (e.g. with silicone).

Before contouring the crown, apply a spacer up to approx. 1 mm from the cervical crown margin.

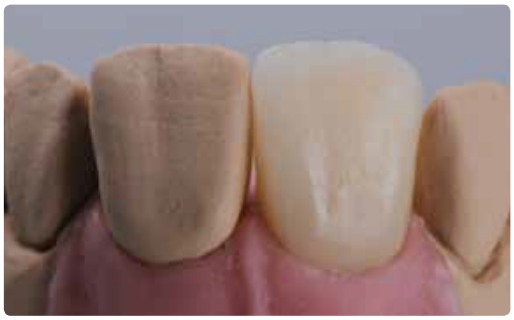
Isolate the abutment and then contour the crown with wax.
Finally, the restoration is pressed with IPS e.max Press material.



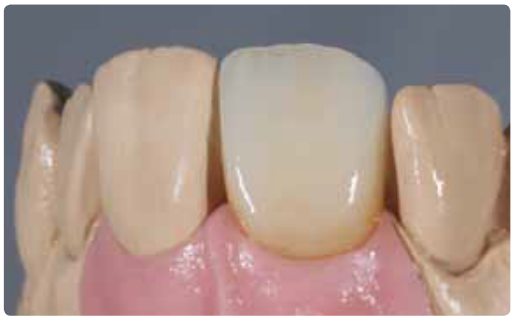
Pressed IPS e.max Press crown with cut-back after divesting and finishing.



Complete the anatomical shape of the reduced areas using IPS e.max Ceram layering materials, such as Incisal and Opal.



Finish the restoration with diamonds and give it a true-to-nature shape and surface structure.



Finally, conduct the Stain and Glaze firing with IPS e.max Ceram Shades, Essences and Glaze.

Abutment and matching crown after Characterization and Glaze firing.

IPS e.max® Press Abutment Solutions

Optional: Clinical Try-in

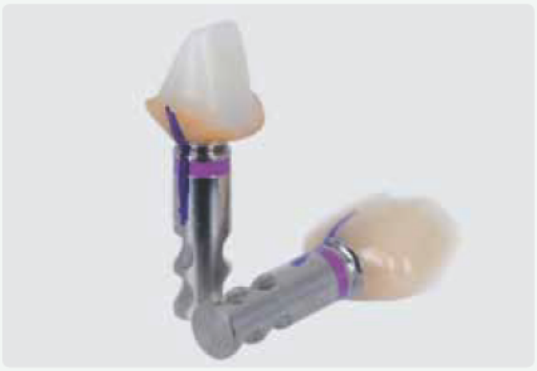
Temporarily securing the pressed object on the Ti base

Before the abutment or abutment crown is permanently luted to the Ti base, a clinical try-in may be performed. To facilitate the intraoral handling, the components are temporarily arttached to one another with silicone material, e.g. Virtual® Extra Light Body Fast Set.

Please observe the following procedure to temporarily secure the components in place:

- Clean the non-pre-treated Ti base and the pressed object (abutment or abutment crown) with steam and blow dry.
- Place the pressed object on the Ti base (which is screwed to the model analog) and mark the relative position of the components. This facilitates the achievement of the correct position when the parts are subsequently temporarily assembled.
- Seal the screw channel with a foam pellet.
- Insert the Virtual cartridge into the dispenser and remove the protective cap.
- Screw on the mixing tip and attach the Oral Tip to the mixing tip.
- Apply Virtual Extra Light Body Fast Set both to the Ti base and directly into the pressed object.
- Insert the Ti base into the pressed object. Observe the relative position of the objects (rotation lock/marking).
- Hold the parts in the correct relative position for 2:30 minutes until the Virtual Extra Light Body Fast Set has set.
- Carefully remove protruding excess material with a suitable instrument, e.g. a scalpel.

Cleaned, non-pre-treated pressed objects (abutment or abutment crown)

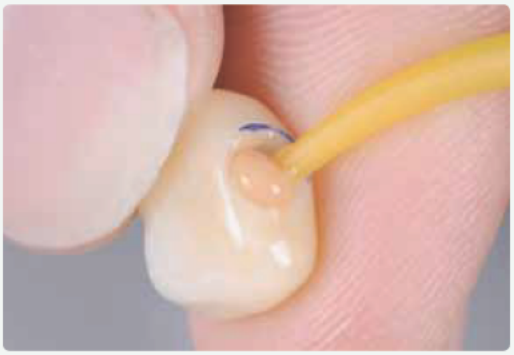


Place the abutment or abutment crown onto the Ti base and mark the relative position.

Seal the screw channel with a foam pellet.

Insert the Virtual cartridge into the dispenser, screw on the mixing tip and attach the Oral Tip.

Apply Virtual Extra Light Body Fast Set both to the Ti base ...



... and directly into the pressed object (abutment/abutment crown).

Insert the Ti base into the pressed object. In doing so, observe the relative position of the two components (rotation lock/marking). Hold the components in place for approx. 2:30 minutes until the Virtual Extra Light Body Fast Set material has set.

Carefully remove protruding excess material with a suitable instrument, e.g. a scalpel.

Remove excess Virtual Extra Light Body Fast Set material from the screw channel with an instrument.

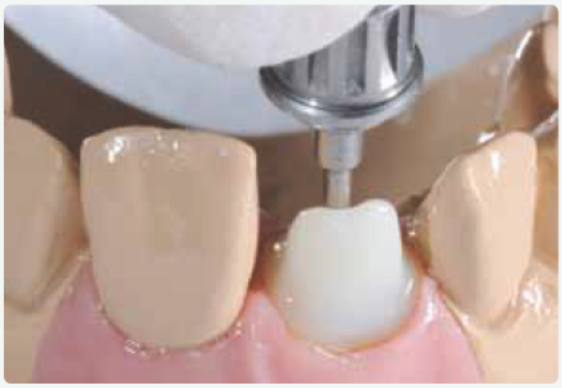
Clinical try-in

Hybrid abutment

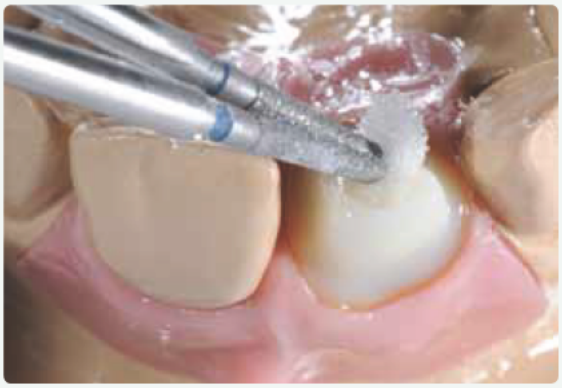
Important note: Any intraoral checking of the occlusion/articulation and possible adjustments by grinding may only be performed if the objects have been attached to one another by means of Virtual Extra Light Body Fast Set. During try-in, the Virtual material acts as a buffer, particularly if grinding is necessary, and prevents chipping in the transition area between the hybrid abutment and the crown.

Please observe the following procedure for the clinical try-in:

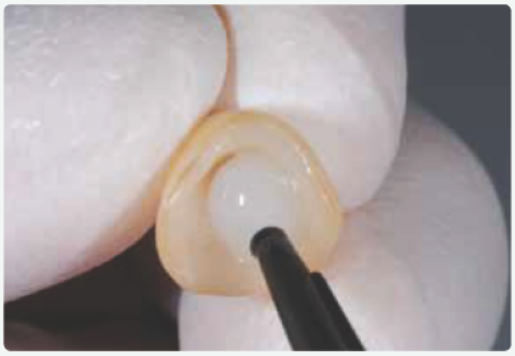
- Have the clean prepared hybrid abutment (temporarily secured) and the matching clean crown ready at hand.
- Remove the temporary restoration.
- Manually screw in the hybrid abutment with the matching screw.
- Check the geometry of the hybrid abutment (e.g. fit, gingival anaemia) with regard to the gingival margin.
- If required, seal the screw channel on the hybrid abutment with a foam pellet.
- **Tip**: Isolate the inner aspect of the crown with glycerin gel, e.g. Try-in paste, Liquid Strip
- **Place the crown intraorally onto the hybrid abutment to check and adjust the proximal contacts, if necessary. Note: No occlusal functional checks must be performed at this stage.**
- **For the functional check, the crown has to be secured on the hybrid abutment with Virtual Extra Light Body Fast Set. Do not use Try-in paste for this purpose, as this material is not sufficiently resistant against the compressive forces.**
- Insert the Virtual cartridge into the dispenser and remove the protective cap.
- Screw on the mixing tip and attach the Oral Tip to the mixing tip.
- Apply Virtual Extra Light Body Fast Set to the inner aspect of the crown.
- Use your finger to press the crown to the hybrid abutment until the final position has been achieved. Hold the crown in the final position until the Virtual material has set.
- Remove excess Virtual material.
- Check the occlusion/articulation and make required adjustments with suitable grinding instruments (see separate IPS e.max Recommended grinding instruments for ceramics – use in the dental practice). If adjustments have been made by grinding, conduct another polishing cycle or glaze firing.
- Carefully remove the crown from the hybrid abutment and the hybrid abutment (including Ti base).
- Insert the temporary restoration.



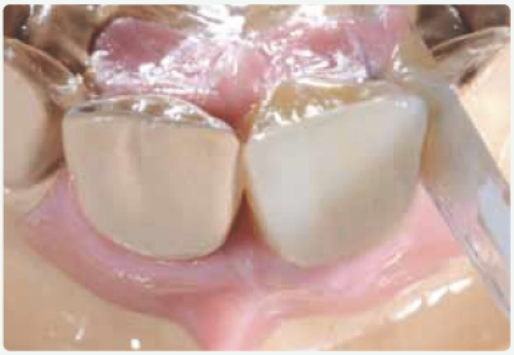
Manually screw in the hybrid abutment with the matching screw. Check the geometry of the hybrid abutment (e.g. fit, gingival anaemia) with regard to the gingival margin.



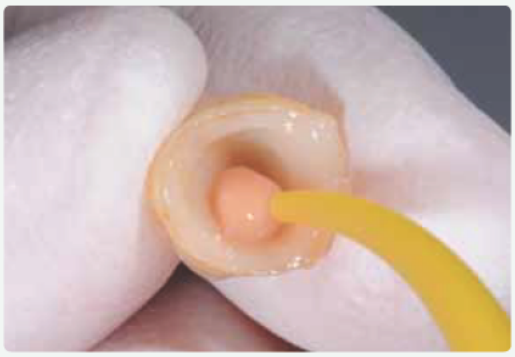
If required, seal the screw channel of the hybrid abutment with a foam pellet.



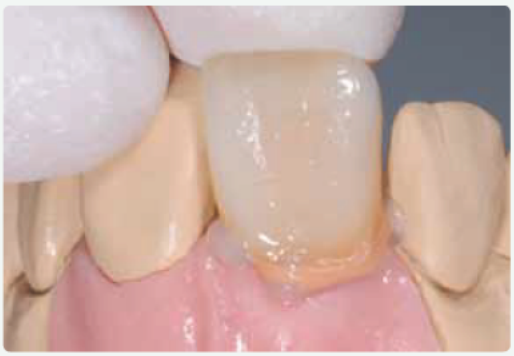
Tip: Isolate the inner aspect of the crown with glycerine gel.



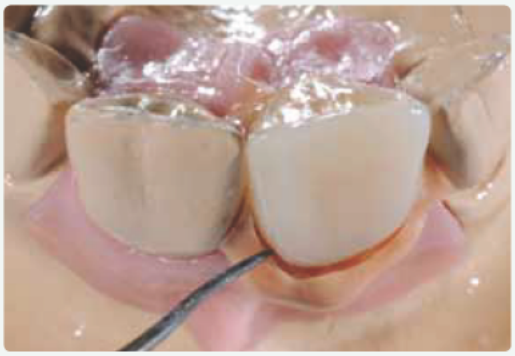
Place the crown intraorally onto the hybrid abutment to check and adjust the proximal contacts, if necessary. **Note: No occlusal functional checks must be performed at this stage.**



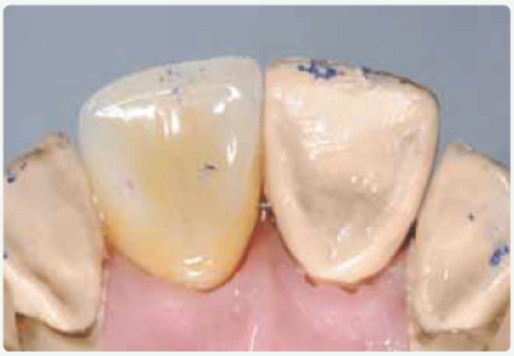
Apply Virtual Extra Light Body Fast Set to the inner aspect of the crown.



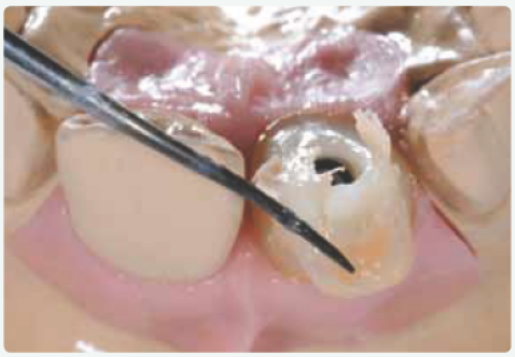
Use your finger to press the crown to the hybrid abutment until the final position has been achieved. Hold the crown in the final position until the Virtual material has set.



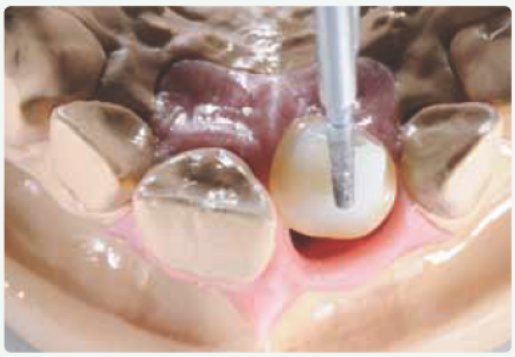
Remove excess Virtual material.



Check the occlusion/articulation and use suitable grinding instruments to make possibly required adjustments.



Carefully remove the crown from the hybrid abutment and remove the Virtual Extra Light Body Fast Set material.

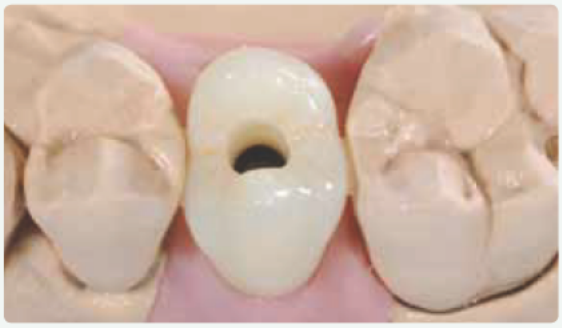


Unscrew the hybrid abutment.

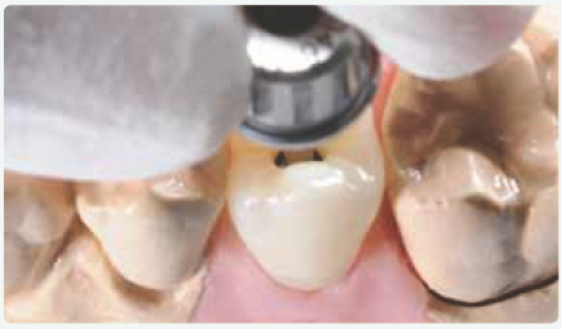
Hybrid abutment crown

Please observe the following procedure for the clinical try-in:

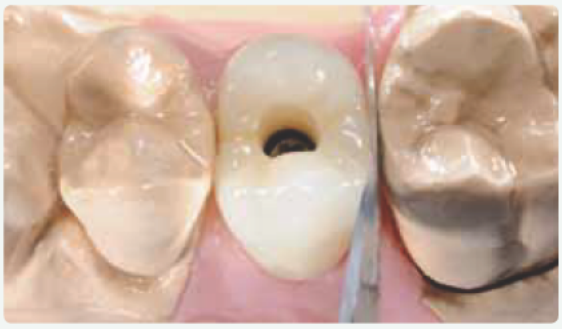
- Have the cleaned hybrid abutment crown (temporarily secured with Virtual Extra Light Body Fast Set) at hand.
- Remove the temporary restoration.
- **Place the hybrid abutment crown intraorally onto the implant to check and possibly adjust the proximal contacts. Note: No occlusal functional checks must be performed at this stage.**
- Manually screw in the hybrid abutment crown with the matching screw.
- Check the geometry of the hybrid abutment crown (e.g. fit, gingival anaemia) with regard to the gingiva.
- Check the occlusion/articulation and make possibly required adjustments with suitable grinding instruments (see separate IPS e.max Recommended grinding instruments for ceramics – use in the dental practice). If adjustments have been made by grinding, conduct another polishing cycle or glaze firing.
- Carefully remove the hybrid abutment crown (including Ti base).
- Rinse the implant site e.g. with Cervitec Liquid (antibacterial mouth wash with chlorhexidine) to clean and disinfect it.
- Insert the temporary restoration.



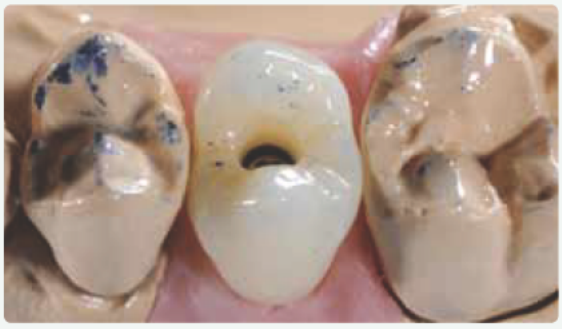
Place the hybrid abutment crown intraorally onto the implant to check and possibly adjust the proximal contacts. **Note: No occlusal functional checks must be performed at this stage.**



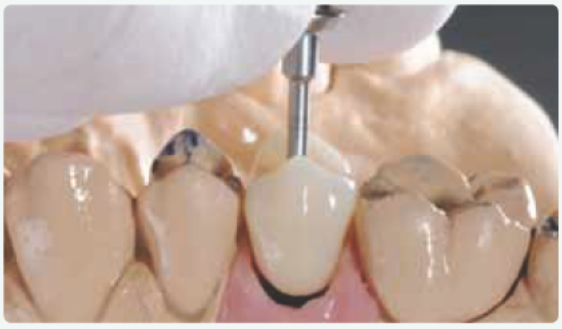
Manually screw in the hybrid abutment crown with the matching screw.



Check the geometry of the hybrid abutment crown (e.g. fit, gingival anaemia) with regard to the gingiva.



Check the occlusion/articulation and use suitable grinding instruments to make possibly required adjustments.



Carefully remove the hybrid abutment crown (including Ti base).

IPS e.max® Press Abutment Solutions

Permanent Cementation

Careful preparation of the bonding surface is a prerequisite for an optimum adhesive cementation of the Ti base and the pressed object. The following paragraphs outline the required procedures. The procedure is the same for hybrid abutments and hybrid abutment crowns.

	IPS e.max Press Abutment Solutions	
	Abutment, abutment crown	**Ti base**
Blasting	–	The bonding area with Al_2O_3 at low pressure
Etching	The bonding area with IPS® Ceramic Etching Gel for 20 s	–
Conditioning/silanating	The bonding area with Monobond® Plus for 60 s	
Adhesive cementation	Multilink® Implant MO 0	
Covering the cementation joint	Glycerine gel, e.g. Liquid Strip	
Curing	7-minute curing (optionally in a light-curing device)	
Polishing the cementation joint	Customary polishers for ceramic/resin materials	

All the materials that are required for permanent cementation and for clinical try-in are contained both in the **IPS e.max Press Abutment Solutions Basic Kit A–D*** and the **IPS e.max Abutment Solutions Cem Kit***.

* The range of available products may vary from country to country.

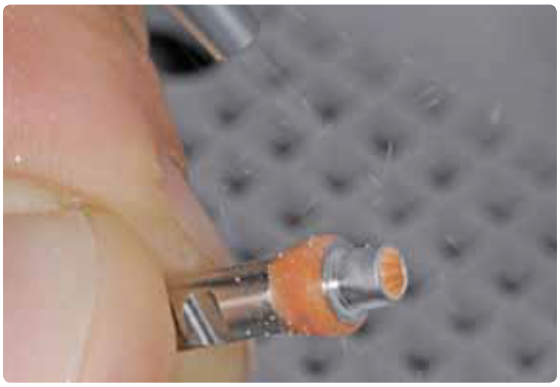
Pre-treatment of the Ti base

To prepare the Ti base for cementation with the pressed object, please observe the following procedure:

– Observe processing instructions of the manufacturer of the Ti base.
– Clean the Ti base in an ultrasonic cleaner and blow dry or use a steam cleaner.
– Screw Ti base onto a model analog.
– Place the pressed object on the Ti base and mark the relative position of the components. This facilitates locating the correct position when the parts are assembled at a later stage.
– The emergence profile of the Ti base must not be blasted or modified in any way. To protect the emergence profile, hard modelling wax is applied, as this material can be easily removed later on.
– Seal the screw channel with wax.
– Carefully blast the bonding area with Al_2O_3 (50–100 µm) at low pressure until an even mat surface has been achieved.
– Clean with an instrument and steam cleaner. Make sure that any wax residue is carefully removed.
– After cleaning, any contamination of the bonding surface must be prevented, since contaminations negatively influence the bond.
– Apply Monobond Plus on the cleaned bonding surface and allow to react for 60 seconds. After the reaction time, dry the remaining residue with water- and oil-free air.
– Seal the screw channel with a foam pellet or wax. Make sure that the bonding surface is not contaminated.

Screw Ti base onto a model analog. Mark the relative position to the pressed object.

Apply wax to protect the emergence profile. In addition, seal also the screw channel with wax.



Carefully blast the bonding area with Al_2O_3 (50–100 µm) at low pressure until an even mat surface has been achieved.

Clean with an instrument and steam cleaner. Make sure that any wax residue is carefully removed.

Apply Monobond Plus on the cleaned bonding surface and allow to react for 60 seconds. After the reaction time, dry the remaining residue with water- and oil-free air.

Seal the screw channel with a foam pellet or wax. Make sure that the bonding surface is not contaminated.

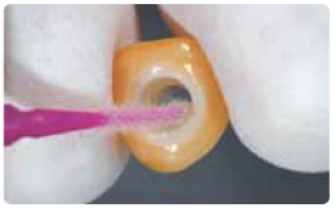
Preparing the pressed object

To prepare the pressed object for cementation onto the Ti base, please observe the following procedure:

- Do **not** blast the IPS e.max Press object to prepare it for cementation.
- Clean the pressed object in an ultrasonic cleaner and blow dry or use a steam cleaner.
- After cleaning, any contamination of the bonding surface must be prevented, since contaminations negatively influence the bond.
- To protect the outer surfaces or the glazed areas, wax may be applied.
- Etch the bonding surface with 5% hydrofluoric acid gel (IPS Ceramic Etching Gel) for 20 seconds.
- Subsequently, thoroughly rinse the bonding surface under running water and dry with oil-free air.
- Apply Monobond Plus on the cleaned bonding surface and allow to react for 60 seconds. After the reaction time, dry the remaining residue with water and oil-free air.

Do **not** blast IPS e.max Press object

Etch with IPS Ceramic Etching Gel for 20 seconds.



Allow Monobond Plus to react for 60 seconds and dry with air.

Cementation with Multilink® Implant

For an optimum bond between the IPS e.max Press object and the Ti base, use the self-curing luting composite Multilink® Implant with light-curing option. Read the respective Instructions for Use for more detailed information.

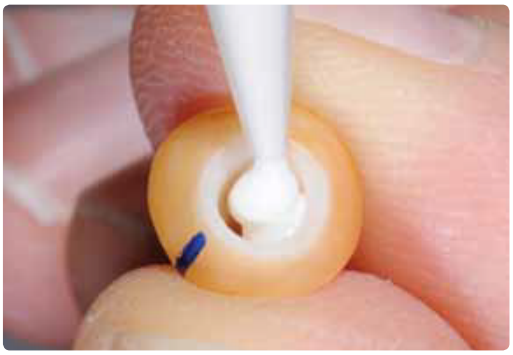
Please observe the following procedure for cementation:

- Keep the cleaned and conditioned components that are to be luted (pressed objects, Ti base) at hand.
- **The subsequent cementation procedure must be carried out quickly and without interruption. The working time of Multilink Implant is 90 (± 15) seconds at 23 °C (± 1 °C) or 73 °F (± 1.8 °F).**
- As a general rule, attach a new mixing tip to the Multilink Implant syringe prior to each use.
- Apply Multilink Implant directly from the mixing tip in a thin layer on the bonding surface of the **Ti base and the bonding surface of the pressed object**.
- Leave the mixing tip attached to the Multilink Implant syringe until the next application. As the material will cure in the mixing tip, it will serve as a seal.
- Position the pressed object above the Ti base in such a way that the position markings are aligned.
- Use even and low pressure to join the parts and check the correct relative position of the components when they are in their final position (transition Ti base/pressed object).
- Subsequently, tightly press the components together for 5 seconds.
- Carefully remove excess in the screw cavity, e.g. with Microbrush or brush, using a rotary movement.
- Remove excess at the transition to the Ti base carefully in its ductile state, e.g. with a foam pellet, while applying slight pressure to hold the components in place.
- Apply a glycerine gel (e.g. Liquid Strip) to the cementation joint to prevent the formation of a inhibition layer.
- After that, completely polymerize the luting composite for 7 minutes in a light-polymerization device.
- **Important: Do not move the objects until the Multilink Implant material has completely cured and hold them in place without allowing for any motion, e.g. with diamond-coated tweezers.**
- After completion of the polymerization, rinse off the glycerine gel with water.
- **Smooth out and polish the cementation joint with rubber polishers.**
- If there are any cement residues in the screw channel, remove them using suitable rotary instruments.
- Clean with a steam cleaner.

Keep the cleaned and conditioned components that are to be luted at hand.

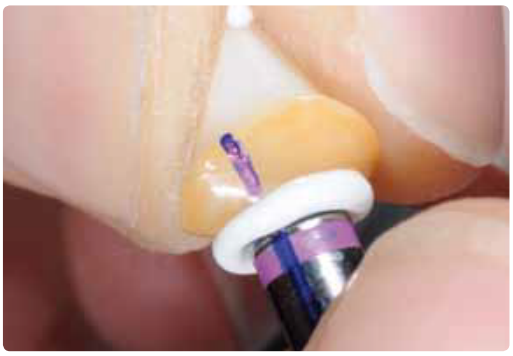
Attach a new mixing tip to the Multilink Implant syringe prior to each use.

Apply Multilink Implant directly from the mixing tip in a thin layer on the bonding surface of the Ti base.

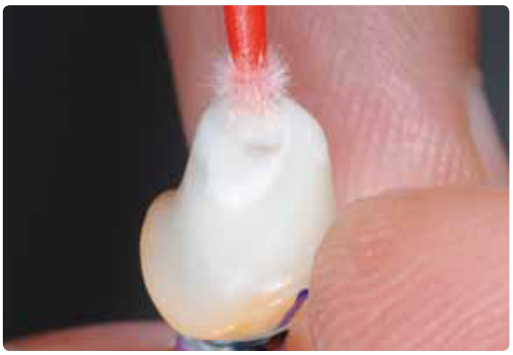


Apply Multilink Implant directly from the mixing tip in a thin layer on the bonding surface of the pressed object.

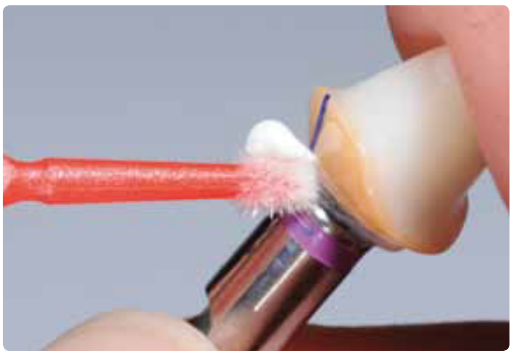
Position the pressed object above the Ti base in such a way that the position markings are aligned.



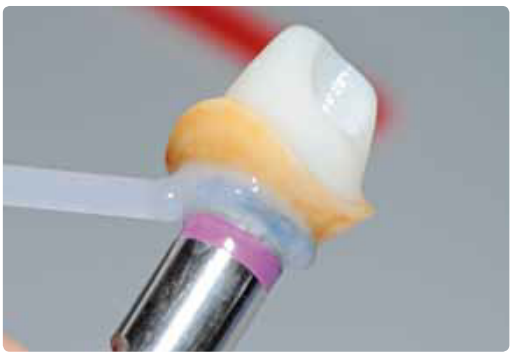
Join the components using even and light pressure. Subsequently, tightly press the components together for 5 seconds.



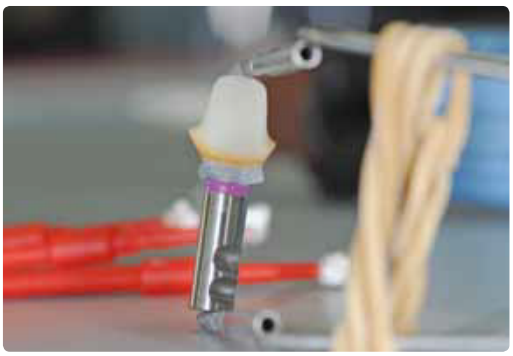
Carefully remove excess in the screw cavity, e.g. with a Microbrush or a brush, using a rotary movement.



Remove excess carefully in its ductile state, e.g. with a foam pellet, while applying slight pressure to hold the components in place.



Apply a glycerine gel (e.g. Liquid Strip) to the cementation joint to prevent the formation of a inhibition layer.

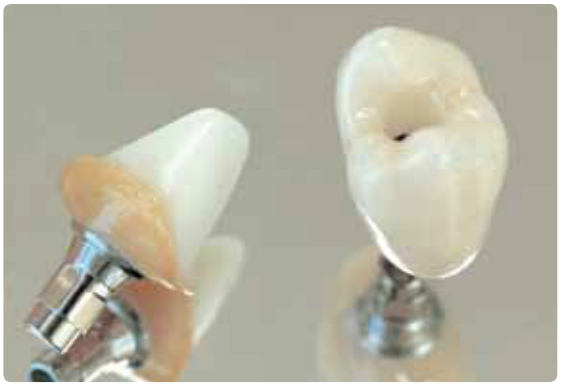


Polymerize the luting composite for 7 minutes (optionally in a light-curing unit).
Important: Do not move the objects until the material has completely cured and hold them in place without allowing for any motion.

After completion of the polymerization, rinse off the glycerine gel with water.

Smooth out and polish the cementation joint with rubber polishers.

If there is any cement residue in the screw channel, remove using suitable rotary instruments. Do not damage the Ti base.



Completed hybrid abutment and hybrid abutment crown after cementation.

IPS e.max® Press Abutment Solutions
Seating and Aftercare

Sterilization

We recommend sterilizing hybrid abutments or hybrid abutment crowns before seating them in the patient's mouth.
- The sterilization time is 15 minutes at 121 °C / 250 °F.
- Only devices which comply with the standards EN 13060 and EN 285 should be used for sterilization. The sterilization processes are validated according to EN ISO-17664:2004.

Intraoral preparation

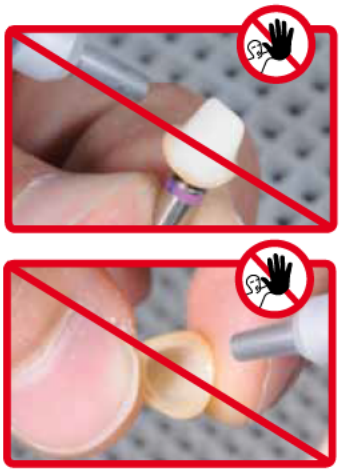
Please observe the following procedure to prepare for the permanent cementation of the implant-supported restoration:
- Remove the temporary restoration.
- Clean the implant site.
- Check the periimplant tissue (emergence profile).

Seating the hybrid abutment and crown

Preparing/conditioning the hybrid abutment and crown

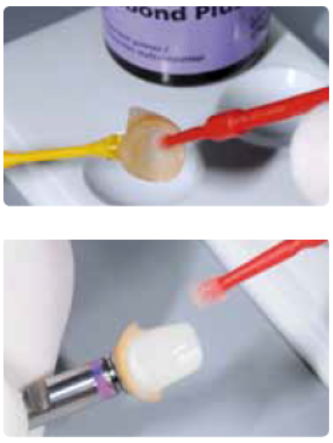
Conditioning of the ceramic surface, i.e. the bonding surface, in preparation for cementation is critical for generating a sound bond between the cementation material and the all-ceramic material.

The following steps must be observed:
- Do not blast the IPS e.max Press hybrid abutment or the IPS e.max Press crown with Al_2O_3 or glass polishing beads prior to seating.
- Ideally, conduct the clinical try-in before etching in order not to contaminate the bonding surface.
- Thoroughly clean the hybrid abutment and the crown with water and blow dry.
- Etch the bonding surfaces with 5% hydrofluoric acid gel (IPS Ceramic Etching Gel) for 20 seconds. Make sure that no etching gel comes into contact with the emergence profile or the outer side of the crown. **Important: Do not use the IPS Ceramic Etching Gel intraorally.**
- Thoroughly rinse off the etching gel with water and dry with oil- and water-free air.
- If an adhesive or self-adhesive cementation protocol is used, apply Monobond Plus to the bonding surfaces, allow to react for 60 seconds and then dry with oil- and water-free air.



Do **not** blast IPS e.max Press objects.

Etch the bonding surfaces with IPS Ceramic Etching Gel for 20 seconds.

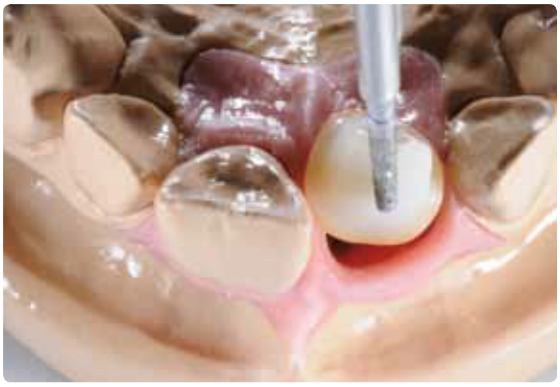


Apply Monobond Plus to the bonding areas, allow to react for 60 s and blow dry.

Seating the hybrid abutment and crown

For the permanent seating of the hybrid abutment and the crown, please observe the following working steps. Please also observe the Instructions for Use of the selected luting material.

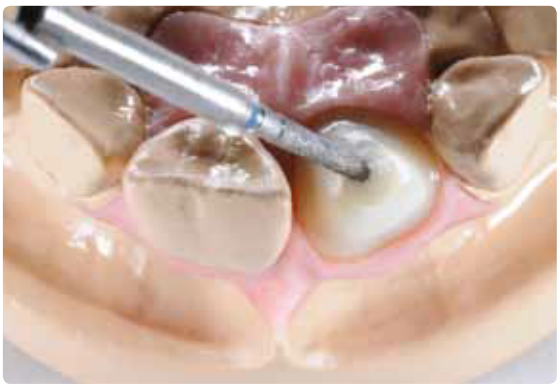
– Do not use phenolic mouth washes, as such products negatively influence the bond between the ceramic and the composite.
– Insert the hybrid abutment intraorally into the implant.
– Manually screw in the matching implant screw.
– Tighten the implant screw with a torque wrench (observe the instructions of the manufacturer).
– Insert a cotton or foam pellet into the screw channel.
– Seal the screw channel with a temporary composite (e.g. Telio® CS Inlay). This serves to ensure access to the screw at a later stage.
– Check the bonding area for contamination/moisture and clean or dry with an air syringe, if necessary.
– Apply the luting material, e.g. SpeedCEM®, into the conditioned crown.
– Place the crown onto the hybrid abutment and secure in place in the final position.
– Conduct the pre-polymerization using the four-quarter technique.
– Remove excess luting material.
– Cover the cementation joint with glycerine gel (e.g. Liquid Strip).
– Polymerize with an LED curing light (e.g. bluephase®).
– Rinse off the glycerine gel with water.
– Check the occlusion and articulation and make adjustments, if necessary. If adjustments are made to the restoration by grinding, these areas must subsequently be polished to a high gloss, e.g. using OptraFine.
– Polish restoration margins and the cementation joint with silicone polishers (e.g. Astropol®, OptraFine).
– Apply Cervitec Plus in the area of the gingival margin.



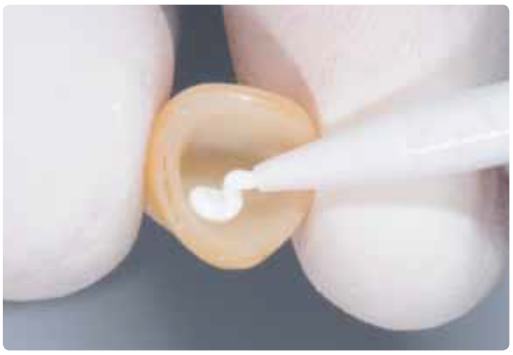
Insert the hybrid abutment intraorally into the implant.

Manually screw in the matching implant screw.

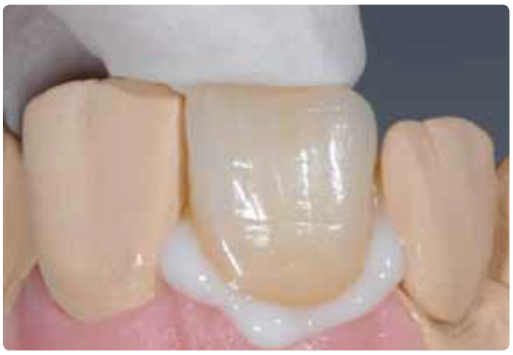
Tighten the implant screw with a torque wrench (observe the instructions of the manufacturer).



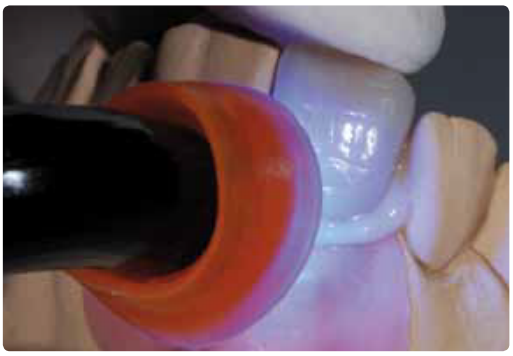
Seal the screw channel, for instance with a cotton or foam pellet and a temporary composite material.



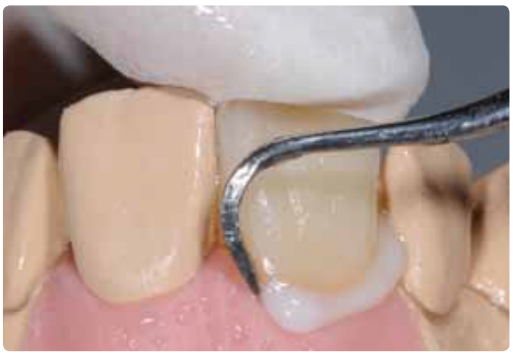
Apply the luting material, e.g. SpeedCEM, into the conditioned crown.



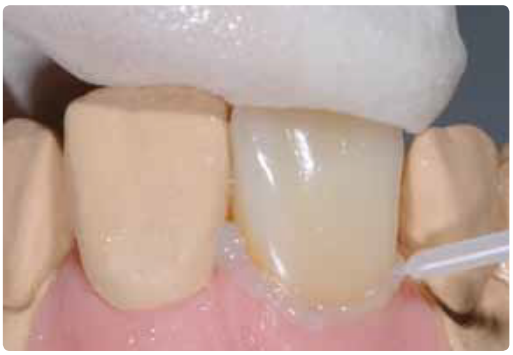
Place the crown onto the hybrid abutment and secure in place.



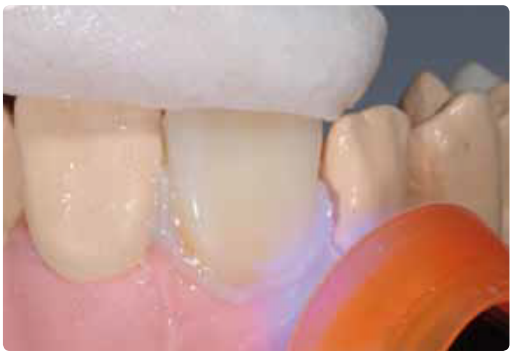
Conduct the pre-polymerization using the four-quarter technique.



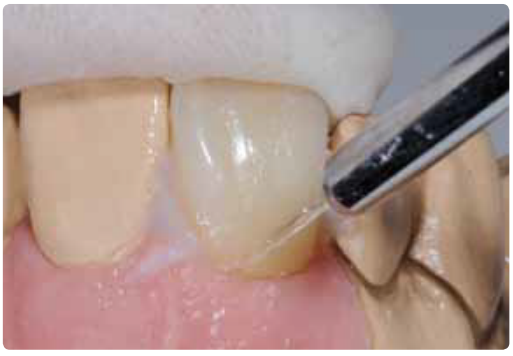
Remove excess luting material.



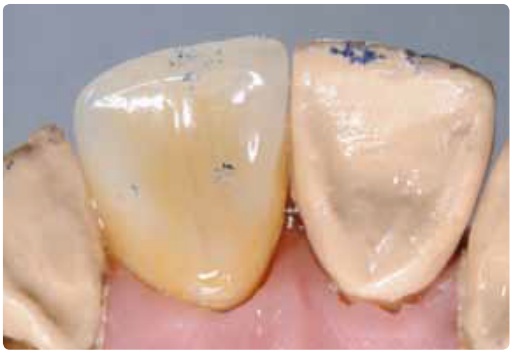
Cover the restoration margin with glycerine gel (e.g. Liquid Strip).



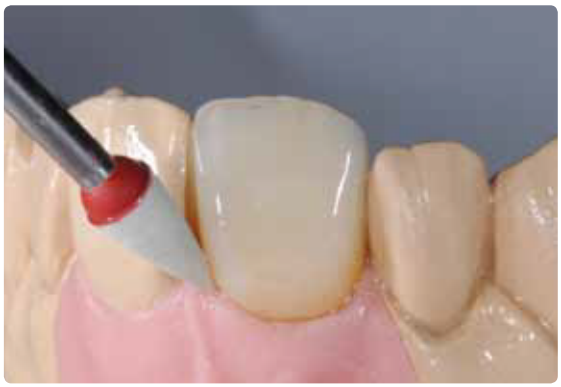
Polymerize with an LED curing light (e.g. bluephase).



Rinse off the glycerine gel with water.



Check the occlusion and articulation and make adjustments, if necessary.



Polish restoration margins and the cementation joint with polishers (e.g. Astropol, OptraFine).

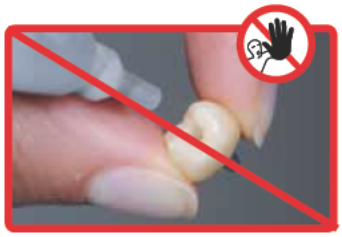
Completed IPS e.max Press hybrid abutment and crown.

Seating the hybrid abutment crown.

Preparing/conditioning the hybrid abutment crown

Please observe the following notes to prepare for the intraoral sealing of the screw channel:

- As a general rule, do **not** blast IPS e.max Press hybrid abutment crowns with Al_2O_3 or glass polishing beads.
- Thoroughly clean the the hybrid abutment crown with water and blow dry.
- Etch the screw channel from the occlusal side with 5% hydrofluoric acid gel (IPS Ceramic Etching Gel) for 20 seconds. Make sure that no etching gel comes into contact with the occlusal surface. **Important: Do not use the IPS Ceramic Etching Gel intraorally.**
- **Thoroughly rinse off the etching gel with water and dry with oil- and water-free air.**
- Apply Monobond Plus to the etched and cleaned surface in the screw channel, allow to react for 60 seconds and then blow dry with oil- and water-free air.



Do **not** blast IPS e.max Press object

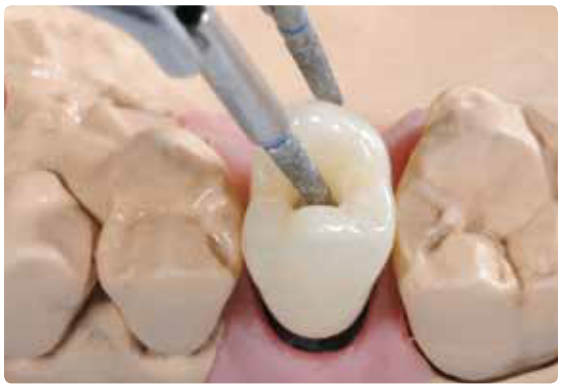
Etch with IPS Ceramic Etching Gel for 20 seconds.

Apply Monobond Plus and allow to react for 60 seconds and blow dry with air.

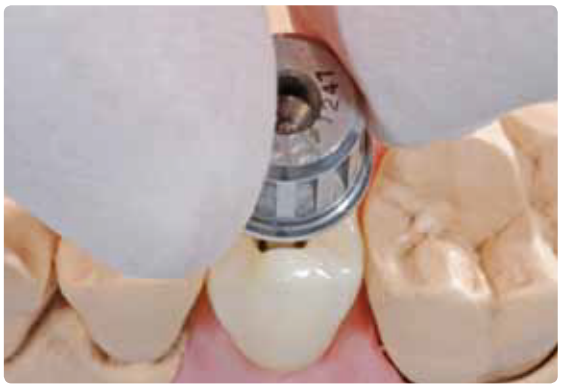
Seating the hybrid abutment crown.

For the permanent seating of the hybrid abutment crown, please observe the following working steps.

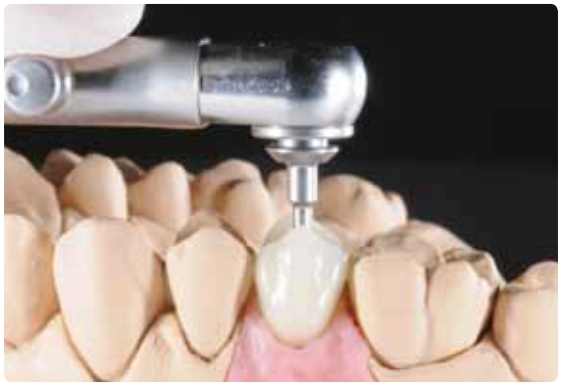
- Do not use phenolic mouth washes, as such products negatively influence the bond between the ceramic and the composite.
- Insert the hybrid abutment crown intraorally into the implant.
- Manually screw in the matching implant screw.
- Tighten the implant screw with a torque wrench (observe the instructions of the manufacturer).
- Check the screw channel for contamination/moisture and clean with Total Etch (phosporic acid gel), if necessary.
- Insert a cotton or foam pellet into the screw channel.
- Apply the bonding agent.
- Seal the screw channel with a composite material (e.g. Tetric EvoCeram) in the appropriate shade.
- Polymerize with an LED curing light (e.g. bluephase).
- Check the occlusion/articulation after polymerization and correct possible rough spots with suitable fine-grain diamonds.
- Polish to a high gloss with silicone polishers (e.g. OptraFine).



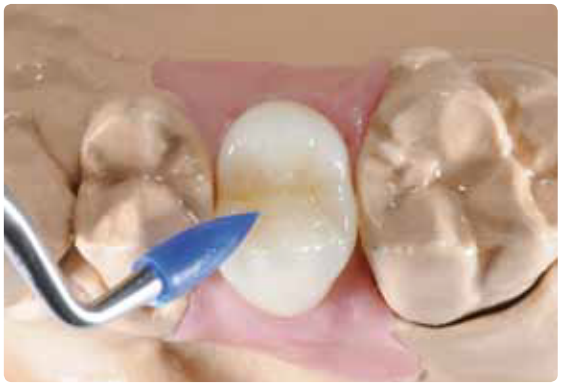
Insert the hybrid abutment crown intraorally into the implant.



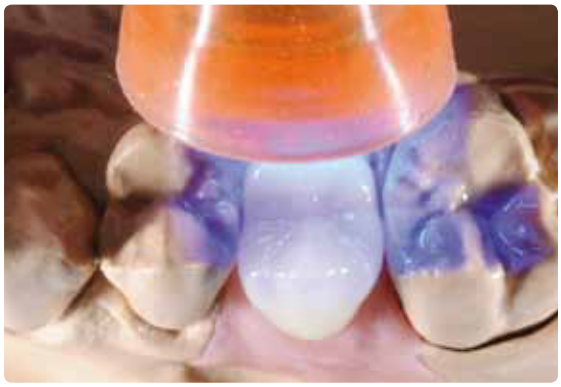
Manually screw in the matching implant screw.



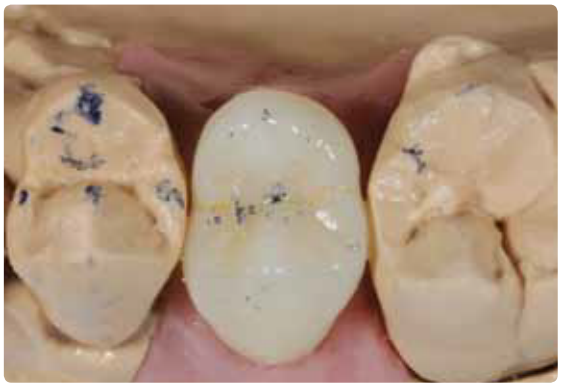
Tighten the implant screw with a torque wrench (observe the instructions of the manufacturer).



Seal the screw channel with a composite material (e.g. Tetric EvoCeram) in the appropriate shade.

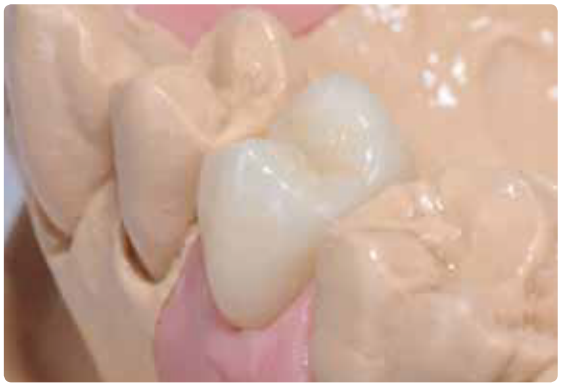


Polymerize with an LED curing light (e.g. bluephase).



After polymerization, check the occlusion/articulation and correct possible rough spots with suitable finishers (e.g. Astropol F) or fine diamonds.

Polish to a high gloss using silicone polishers (e.g. Astropol P, Astropol HP or Astrobrush).



Completed IPS e.max Press hybrid abutment crown

Care Notes – Implant Care

Implant Care comprises a range of coordinated products for the professional care of patients during the various phases of implant treatment and lifelong aftercare. Products for professional tooth cleaning and bacterial control contribute to the long-term quality assurance of implant-supported restorations. Structural elements, peri-implant tissue, natural teeth, dental restorations, gingiva and the mucosa are treated in an optimum way with regard to function and esthetics.

IPS e.max® Press Abutment Solutions
General Information

Frequently Asked Questions

In addition to the desired tooth shade, why should the root shade also be defined/ determined upon shade determination?
IPS e.max Press Abutment Solutions allow you to fabricate restorations with a lifelike appearance both in the visible area and the area below the gingiva (root). By defining the root shade, a highly esthetic outcome can be achieved especially receding gingiva.

Is it possible to fabricate an abutment or an abutment crown with IPS e.max Press (LS_2) without using a Ti base?
No! For this indication, IPS e.max Press needs the support provided by the Ti base. In addition, the Ti base allows an optimum (industrially fabricated) fit to the implant to be achieved.

Is it possible to use any commercially available Ti base in conjunction with IPS e.max Press Abutment Solutions?
When selecting a suitable Ti base, the requirements in terms of minimum dimensions (height, shoulder width, no undercuts) must be taken into account. In addition, the Ti base must be equipped with a rotation lock which does not entail a reduction of the ceramic layer thickness.

Is it permissible to modify the selected Ti base?
The instructions of the manufacturer with regard to modifying the Ti base must be observed. Prior to permanent cementation, the bonding surface of the Ti base must be blasted with Al_2O_3.

Is a hybrid abutment crown indicated in the anterior region?
This indication depends on the position and inclination of the implant. If the opening of the screw channel is located on the lingual/palatinal surface, a hybrid abutment crown may be fabricated in the anterior region.

Is it possible to use an IPS e.max Press hybrid abutment as an abutment for a bridge restoration?
No. Only single-tooth restorations may be fabricated.

What do I need to take into consideration when designing a hybrid abutment or hybrid abutment crown in order to fabricate a durable restoration?
The stipulated minimum and maximum layer thicknesses for IPS e.max Press need to be observed. In addition, the ratio between the height of the Ti base and the height of the entire restoration must be observed.

What do I need to take into consideration when attaching sprues and investing the wax-up?
The screw channel of the sprued wax-up must be parallel to the outer wall of the investment ring. As a result, the investment material can be filled evenly and in a controlled manner. In addition, the risk that the flowing ceramic material could break off the investment material in the screw channel is reduced. The objects could be placed in a tilted position on the investment ring base, but this may lead to difficulties during investing (e.g. bubbles in the screw channel).
If the screw channel is very long, the investment material in the screw channel can be stabilized with a pin (e.g. high-grade steel, ZrO_2) during investing. For this purpose, pour investment material into the investment ring up to the restoration margin, insert the pin into the screw channel and fill up the investment ring up to the marking without vibrating it.

When is the sprue of the pressed object separated?
We recommend that the pressed objects should be fitted to the Ti base first, as this facilitates the handling. Subsequently, the pressed objects are separated from the sprue.

How should the emergence profile of the hybrid abutment be finished?
Preferably, a Characterization and Glaze firing is conducted on the emergence profile prior to the cementation procedure. In this way, you may adjust the esthetic appearance of the abutment to the clinical situation ("root shade"). If no characterization is required, the emergence profile may be polished to a high gloss with polishers as well as brushes and paste.

Is it possible to use IPS e.max Ceram Glaze Spray to glaze the abutment or the abutment crown?
We do not recommend using the Glaze Spray in this indication, as the bonding surface and the screw channel may be contaminated with glaze material.

An optional clinical try-in may be performed. How are the objects prepared for this?
The Ti base and the pressed abutment or abutment crown are temporarily joined in the laboratory by means of a silicone material, e.g. Virtual Extra Light Body Fast Set. This facilitates the intraoral handling.

What must be observed for the clinical try-in of a crown on a hybrid abutment?
To check the occlusion/articulation and to make possible adjustments, the crown must be temporarily secured on the hybrid abutment with a silicone material, e.g. Virtual Extra Light Body Fast Set. The silicone material acts as a buffer and prevents chipping in the marginal area of the crown. Try-in pastes or Vaseline must not be used for functional checks.

What material is used to permanently cement the abutment or the abutment crown made of IPS e.max Press with the Ti base?
Only Multilink Implant is to be used for the permanent cementation. Other luting materials have not been tested for this purpose.

How is the Ti base prepared for the permanent cementation with Multilink Implant?
Carefully blast the bonding area with Al_2O_3 at low pressure until an even mat surface has been achieved. After cleaning, the area is conditioned with Monobond Plus.

How is the screw channel of a hybrid abutment crown sealed intraorally?
After the hybrid abutment crown has been screwed into place and the screw has been tightened with a torque wrench, the screw channel is sealed with a composite restorative material.

Hybrid abutment and separate crown

The material is selected on the basis of the desired tooth shade (Bleach BL or A–D). Depending on the Ti base selected and the design of the hybrid abutment or crown, characterizations with IPS e.max Ceram Shades and Essences may be necessary to achieve the desired shade.

The desired tooth shade is achieved after the restoration has been seated and is made up of the shade of the hybrid abutment and the shade of the crown that is cemented onto it. The ingot recommendations for the hybrid abutment have been selected in such a way that the desired tooth shade is achieved in combination with the crown. In the "cervical area", it may be necessary to characterize the hybrid abutment according to the clinical situation.

		Desired tooth shade: Bleach BL and A-D Shade Guide																			
		BL1	**BL2**	**BL3**	**BL4**	**A1**	**A2**	**A3**	**A3,5**	**A4**	**B1**	**B2**	**B3**	**B4**	**C1**	**C2**	**C3**	**C4**	**D2**	**D3**	**D4**
		Ti base																			
Cementation in the laboratory		Multilink Implant MO 0																			
Ingot* for the hybrid abutment	**MO**	–	MO 0						MO 1	MO 2	MO 0			MO 2	MO 0			MO 2		MO 0	MO 1
	HO	HO 0				HO 1	HO 2				HO 1	HO 2							HO 1	HO 2	
Cementation (intraoral)		adhesive, self-adhesive or conventional cementation e.g. Multilink Implant, SpeedCEM, etc.																			
IPS e.max Press crown		LT BL1	LT BL2	LT BL3	LT BL4	LT A1	LT A2	LT A3	LT A3.5	LT A4	LT B1	LT B2	LT B3	LT B4	LT C1	LT C2	LT C3	LT C4	LT D2	LT D3	LT D4

* Given the high opacity, HO ingots are better suited to cover the (grey) titanium bases. These ingots may also be used for thinner hybrid abutment designs.

Hybrid abutment crown

The material is selected on the basis of the desired tooth shade (Bleach BL or A–D). Depending on the Ti base selected and the design of the hybrid abutment crown, characterization with IPS e.max Ceram Shades and Essences may be necessary to achieve the desired shade.

	Desired tooth shade: Bleach BL and A-D Shade Guide																			
	BL1	**BL2**	**BL3**	**BL4**	**A1**	**A2**	**A3**	**A3,5**	**A4**	**B1**	**B2**	**B3**	**B4**	**C1**	**C2**	**C3**	**C4**	**D2**	**D3**	**D4**
	Ti base																			
Cementation in the laboratory	Multilink Implant MO 0																			
Abutment crown IPS e.max Press	LT BL1	LT BL2	LT BL3	LT BL4	LT A1	LT A2	LT A3	LT A3.5	LT A4	LT B1	LT B2	LT B3	LT B4	LT C1	LT C2	LT C3	LT C4	LT D2	LT D3	LT D4

Press and Firing Parameters

Press parameters for IPS e.max Press

The press furnace, investment ring size and the selected IPS e.max Press ingot must be considered:

Press furnace	IPS e.max Press ingots	IPS Investment Ring System	B °C	t↗ °C/min	T °C	H min	V¹ °C	V² °C	
EP 500	 HO, MO, LT	100 g	700	60	925	15	500	925	Program 11-20 Software 2.9
		200 g	700	60	930	25	500	930	Program 11-20 Software 2.9
	 HT	100 g	700	60	920	15	500	920	Program 11-20 Software 2.9
		200 g	700	60	925	25	500	925	Program 11-20 Software 2.9

Press furnace	IPS e.max Press ingots	IPS Investment Ring System	B °C	t↗ °C/min	T °C	H min	A
EP 600 Combi	 HO, MO, LT	100 g	700	60	915	15	300 µm/min
		200 g	700	60	920	25	300 µm/min
	 HT	100 g	700	60	910	15	300 µm/min
		200 g	700	60	915	25	300 µm/min

Programat EP 3000

Select the press program in accordance with the selected ingot to be pressed and the investment ring size used.

The press parameters for HO, MO, LT and HT are integrated starting with software V 6.1.

Programat EP 5000

Select the press program in accordance with the selected ingot to be pressed and the investment ring size used.

The press parameters for HO, MO, LT and HT are integrated starting with software V 6.1.

- The firing parameters listed represent standard values and apply to the Ivoclar Vivadent furnaces P300, P500, P700, EP 3000 and EP 5000. The temperatures indicated also apply to furnaces of older generations. However, the temperature in the firing chamber may deviate by approx. ± 10 °C/18 °F, depending on the age of the heating muffle.
- If a non-Ivoclar Vivadent furnace is used, temperature corrections may be necessary.
- Regional differences in the power supply or the operation of several electronic devices by means of the same circuit may also render adjustments of the temperatures necessary.

Firing parameters for IPS e.max Press Abutment Solutions

- Use a honey-comb tray and the corresponding pins for firing.
- Do not use ceramic pins.
- The stipulated parameters are coordinated with Ivoclar Vivadent furnaces (tolerance range +/- 10 °C/18 °F).
- If furnaces other than those from Ivoclar Vivadent are used, temperature adjustments may be necessary.
- Remove IPS e.max Press objects from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).
- Allow the objects to cool to room temperature in a place protected from draft.
- Do not touch the hot objects with metal tongs.
- Do not blast or quench the objects.

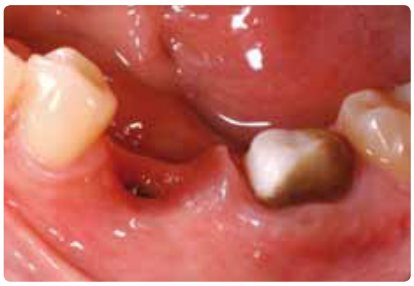
Note regarding the firing parameters for IPS e.max Press Abutment Solutions:
Given the geometry of hybrid abutments and hybrid abutment crowns, the layer thicknesses of the pressed object may vary considerably. When the objects cool after the firing cycle, the different cooling speeds in the areas with different thicknesses may result in internal tensions. In the worst case, these tensions may result in fractures in the pressed ceramic objects. By using slow cooling (long-term cooling (L)), these tensile stresses can be minimized.

Note:
Please read the notes of the manufacturer of the ceramic furnace for more details on the programming of the long-term cooling (L). If the layer thickness is less than 2 mm on the entire pressed object, long-term cooling (L) is not required.

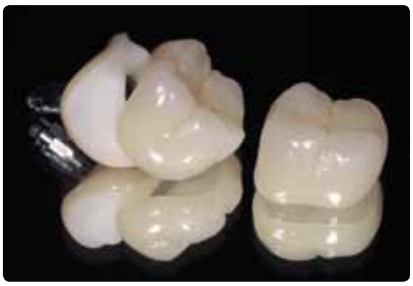
IPS e.max Ceram on IPS e.max Press ***Abutment Solutions***	**B** °C	**S** min	**t↗** °C/min	**T** °C	**H** min	**V_1** °C	**V_2** °C	**L** °C
Stain and Characterization firing	403	6:00	60	770	01:00	450	769	500
Glaze firing	403	6:00	60	770	1:00 – 2:00	450	769	500
Add-On after Glaze firing	403	6:00	50	700	01:00	450	699	500

Clinical cases (R. Watzke, Liechtenstein)

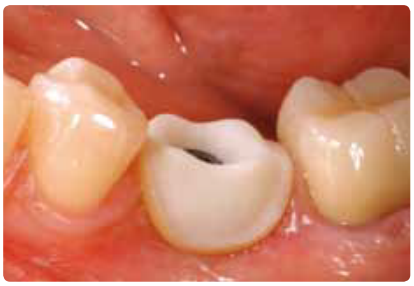
IPS e.max Press hybrid abutment / IPS e.max Press crown (area 36), IPS e.max Press crown (area 37).



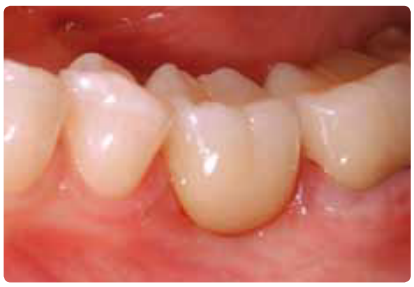
Clinical situation after implantation and gingiva shaping



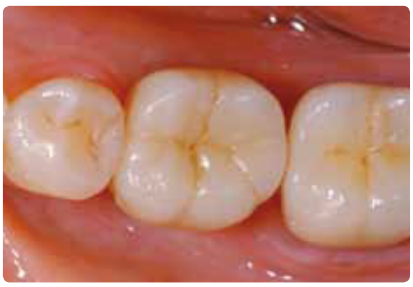
IPS e.max Press hybrid abutment (36) and IPS e.max Press crown, IPS e.max Press single crown



IPS e.max Press hybrid abutment, screwed in, cemented IPS e.max Press crown

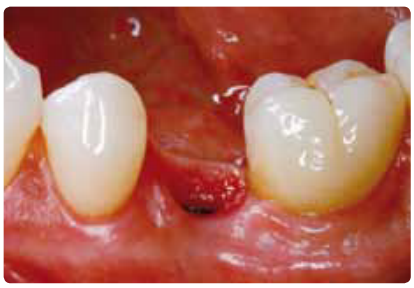


Final image, buccal view: IPS e.max Press crown cemented onto an IPS e.max Press hybrid abutment

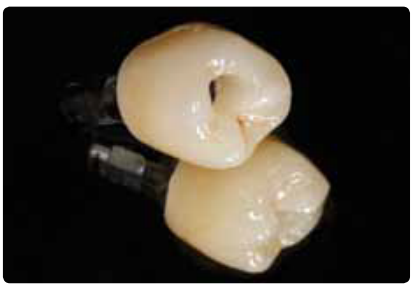


Final image, occlusal view: IPS e.max Press crown cemented onto an IPS e.max Press hybrid abutment

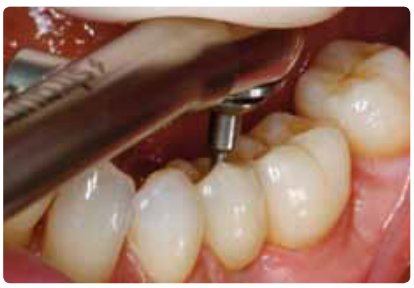
IPS e.max Press hybrid abutment crown (area 35)



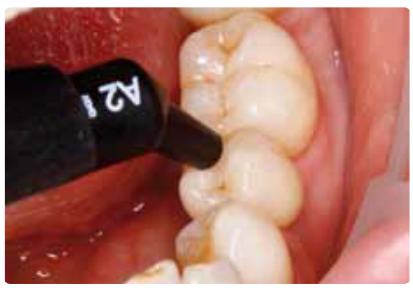
Clinical situation after implantation and gingiva shaping



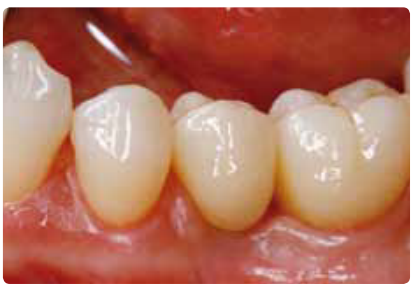
IPS e.max Press hybrid abutment crown



Screwing in the hybrid abutment crown



Sealing the screw channel with composite material (e.g. Tetric EvoCeram)



Final image of an IPS e.max Press hybrid abutment crown

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ivoclar vivadent® technical

Appendix 17 – IPS e.max® CAD Abutment Solutions Instructions for Use

IPS e.max® CAD

Abutment Solutions

Instructions for Use

CE 0123

ivoclar vivadent technical

A17-2

Traditional 510(k)
Straumann® Variobase™ Abutments

Straumann USA, LLC
January 23, 2014

Table of Contents

IPS e.max System

IPS e.max is an innovative all-ceramic system which covers the entire all-ceramic indication range – from thin veneers to 14-unit bridges.

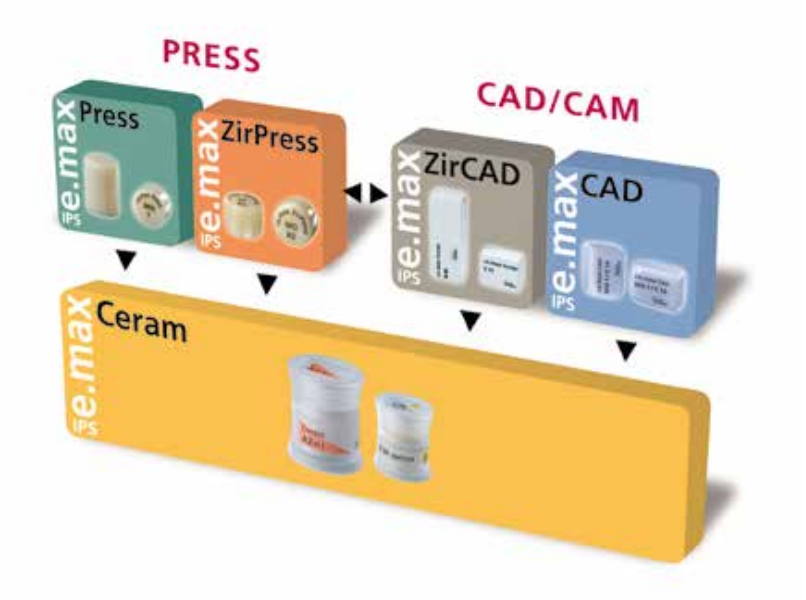
IPS e.max delivers high-strength and highly esthetic materials for the Press and the CAD/CAM technologies. The system consists of innovative lithium disilicate glass-ceramics for smaller restorations and high-strength zirconium oxide for large-span bridges.

The requirements and aims of every case differ. IPS e.max meets these requirements, because due to the system components, you obtain exactly what you need.

– In the field of the **Press technology,** the highly esthetic **IPS e.max Press lithium disilicate glass-ceramic is available** and with **IPS e.max ZirPress** a **fluor apaptite glass-ceramic ingot** for the quick and efficient press-on technique on zirconium oxide.

– For the **CAD/CAM technology,** depending on the case requirements, the innovative **lithium disilicate block IPS e.max CAD** is used or the high-strength **zirconium oxide IPS e.max ZirCAD**.

– The **nano-fluorapatite layering ceramic IPS e.max Ceram**, which is used to characterize and/or veneer all IPS e.max components – glass or oxide ceramics –, completes the IPS e.max System.



IPS e.max CAD Solutions

IPS e.max CAD stands for individuality. Depending on the indication, users may select from three approaches: This ensures maximum flexibility in the digital work process.

IPS e.max CAD
Monolithic Solutions

Efficient fabrication of full-contour restorations with high strength (≥360 MPa) ranging from thin veneers to three-unit bridges.

IPS e.max CAD
Veneering Solutions

Digitally fabricated high-strength veneering structures for zirconium oxide frameworks (ZrO_2) – for tooth- and implant-retained crowns and long-span bridges (CAD-on).

NEW

IPS e.max CAD
Abutment Solutions

Individual CAD/CAM-fabricated hybrid restorations for implants – for single-tooth restorations in the anterior and posterior region.

IPS e.max CAD Abutment Solutions

Product Information

Description

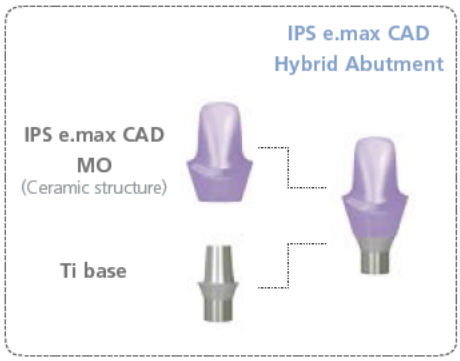
IPS e.max® CAD Abutment Solutions are CAD/CAM-fabricated, implant-supported hybrid restorations for single teeth. These hybrid restorations are individually fabricated of lithium disilicate glass-ceramics (LS_2) and cemented onto a titanium base (Ti base).

Two different approaches are available:
– IPS e.max CAD hybrid abutment and separate IPS e.max CAD crown
– IPS e.max CAD hybrid abutment crown

Both solutions show outstanding function, efficiency and esthetics. The durable bond to the Ti base is achieved by means of the self-curing Multilink® Hybrid Abutment luting composite.

Hybrid abutment

The hybrid abutment is an individually milled LS_2 abutment which is luted to the Ti base. The shape, emergence profile and esthetic properties of this abutment can be ideally adjusted to the clinical situation.

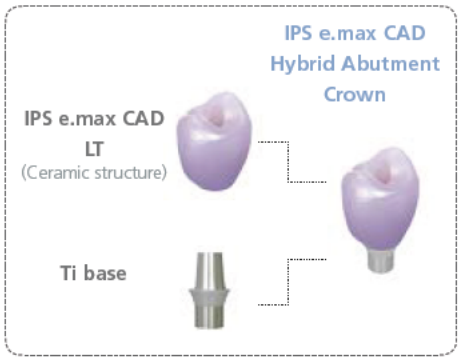


Given the lifelike appearance of LS_2 glass-ceramics, the esthetic possibilities are virtually limitless, particularly in the anterior region. Due to the individual characterization, a lifelike appearance is achieved near the root and the transition area to the crown. With the preparation margin of the crown located on the gingival level, the geometry of the hybrid abutments allows for an easy integration of the restoration. Excess cementation material is therefore easily removed.

The milled and crystallized LS_2 ceramic structure is extraorally luted to a Ti base with Multilink Hybrid Abutment, then screwed into place in the oral cavity and finally provided with a permanent IPS e.max CAD crown. Given the convenient fabrication of the hybrid abutment, the process is time-saving and flexible.

Hybrid abutment crown

Hybrid abutment crowns are characterized by combining abutment and monolithic crown in one piece. This is an efficient two-in-one solution made of lithium disilicate (LS_2), which is directly luted to a Ti base.



LS_2 glass-ceramics provide for strength, durability and efficiency, particularly in the posterior region. Moreover, the material offers well-known esthetic properties, allowing restorations to be simply characterized with IPS e.max Ceram stains.

The monolithically milled hybrid abutment crown is reliably and extraorally luted to the Ti base by means of Multilink Hyrid Abutment. Then, the restoration is screwed onto the implant – in one piece. Subsequently, the screw access channel is sealed with a composite material (e.g. Tetric EvoCeram®). If required, the screw can be accessed at any time, which affords the dental team clinical flexibility.

IPS e.max CAD hybrid abutment crowns are a new, economically attractive alternative to conventional implant-supported restorations, particularly for the posterior region, where strength, durability and convenient clinical handling matter.

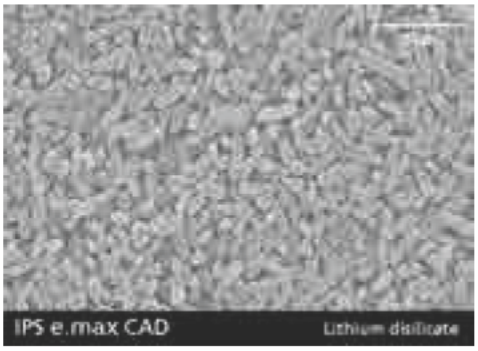
Ideally coordinated – Multilink® Hybrid Abutment

The self-curing luting composite Multilink Hybrid Abutment in conjunction with Monobond® Plus is used for the permanent cementation of ceramic structures made of lithium disilicate glass-ceramic (LS_2) or zirconium oxide (ZrO_2) onto bases (e.g. abutment or adhesive base) of titanium/titanium alloy.
This allows
– reliable adhesion due to high bonding values
– optimum esthetics due to two available degrees of opacity
– easy handling due to the convenient Automix syringe

Material

IPS e.max CAD

IPS e.max CAD is a lithium disilicate glass-ceramic block for the CAD/CAM technology. It is fabricated using an innovative process which provides an impressive homogeneity of the material. The block can be processed very easily in a CAD/CAM unit in this crystalline intermediate stage. The typical and striking colour of IPS e.max CAD ranges from whitish to blue and bluish-grey. This shade is a result of the composition and the microstructure of the glass-ceramic. The strength of the material in this processable intermediate phase is ≥130 MPa. After the IPS e.max CAD blocks are milled, the restoration is crystallized in an Ivoclar Vivadent ceramic furnace (e.g. Programat® P500). Unlike with some other CAD/CAM ceramics, the easy-to-conduct crystallization process neither causes any major shrinkage, nor are any complicated infiltration processes required. The crystallization process leads to a change in the microstructure in the IPS e.max CAD material, during which lithium disilicate crystals grow. The densification of 0.2% is accounted for in the CAD software and taken into account upon milling. The final physical properties, such as the strength of ≥ 360 MPa and the corresponding optical properties, are achieved through the transformation of the microstructure.



CTE (100–500°C) [10^{-6}/K]	10.5 ± 0.5
Flexural strength (biaxial) [MPa]	≥ 360 according to ISO 6872
Fracture toughness [MPa $m^{0.5}$]	≥ 2.0 according to ISO 6872
Chem. solubility [µg/cm^2]	≤ 50 according to ISO 6872

Ti base

Ti bases are used for the fabrication of IPS e.max CAD Abutment Solutions. The suitable Ti bases are selected in accordance with the CAD/CAM system used. Please observe the instructions for use and processing of the manufacturer of the Ti bases used.

More information about the authorized CAD/CAM systems is available on the Internet from www.ivoclarvivadent.com.

Uses

Indications

- Hybrid abutments for anterior and posterior single-tooth restorations
- Hybrid abutment crowns for anterior and posterior restorations

Contraindications

- Failure to observe the requirements stipulated by the implant manufacturer for using the selected implant type (diameter and length of the implant must be approved for the respective position in the jaw by the implant manufacturer)
- Failure to observe the permissible maximum and minimum ceramic wall thicknesses
- Parafunctions (e.g. bruxism)
- Use of a luting composite other than Multilink® Hybrid Abutment to lute IPS e.max CAD to the Ti base
- Intraoral adhesion of the ceramic structures to the Ti base
- Temporary cementation of the crown on the hybrid abutment
- All uses not stated as indications are contraindicated.

Important processing restrictions

- Do not mill the blocks with non-compatible CAD/CAM systems.
- If hybrid abutment crowns are fabricated, the opening of the screw channel must not be located in the area of contact points. If this is not possible, a hybrid abutment with a separate crown should be preferred.
- Combination with materials other than IPS e.max Ceram or IPS e.max CAD Crystall./ materials
- Crystallization in a non-recommended ceramic furnace
- Crystallization in a non-calibrated ceramic furnace
- Crystallization in a high-temperature furnace (e.g. Programat® S1)
- Crystallization with deviating firing parameters
- Failure to observe the manufacturer's instructions regarding the processing of the Ti base.

Side effects

If the patient is known to be allergic to any of the components, IPS e.max CAD and the other materials necessary for the fabrication should not be used.

Composition

- **IPS e.max CAD blocks**
  Components: SiO_2, Li_2O, K_2O, MgO, Al_2O_3, P_2O_5 and other oxides
- **IPS e.max CAD Crystall./Glaze, Shades and Stains**
  Components: Oxide, glycols
- **IPS e.max CAD Crystall./Glaze Liquid**
  Components: Butandiol
- **IPS e.max CAD Crystall./Add-On**
  Components: Oxides
- **IPS e.max CAD Crystall./Add-On Liquid**
  Components: Water, propylene glycol, butandiol and chloride
- **IPS Object Fix Putty/Flow**
  Components: Oxides, water, thickening agent
- **IPS Natural Die Material**
  Components: Polymethacrylate, paraffin oil, SiO_2 and copolymer
- **IPS Natural Die Material Separator**
  Components: Wax dissolved in hexane
- **Virtual Extra Light Body Fast Set**
  Components: Vinyl polysiloxane, methyl hydrogen polysiloxane, organic platinum complex, silicate and food colouring
- **Multilink Hybrid Abutment**
  Components: Dimethacrylate, HEMA, as well as fillers (barium glass, ytterbium trifluoride, spheroid mixed oxide and titanium dioxide).
- **Monobond Plus**
  Components: Alcohol solution of silane methacrylate, phosphoric acid methacrylate and sulphide methacrylate
- **IPS Ceramic Etching Gel**
  Components: Hydrofluoric acid (approx. 5%)

Warning

- Do not inhale ceramic dust during finishing. Use exhaust air discharge and mouth protection.
- IPS Ceramic Etching Gel contains hydrofluoric acid. Contact with skin, eyes and clothing must be prevented at all costs, since the material is extremely toxic and corrosive. The etching gel is intended for extraoral use only and must not be applied intraorally (inside the mouth).

Scientific data

Further scientific data (i.e. strength, wear, biocompatibility) are contained in the **Scientific Documentation IPS e.max CAD**.

The **IPS e.max Scientific Report** contains all studies (in vitro, in vivo) on IPS e.max CAD and the IPS e.max system.

For further information about all-ceramics in general, please refer to the **Ivoclar Vivadent Report No. 16**.

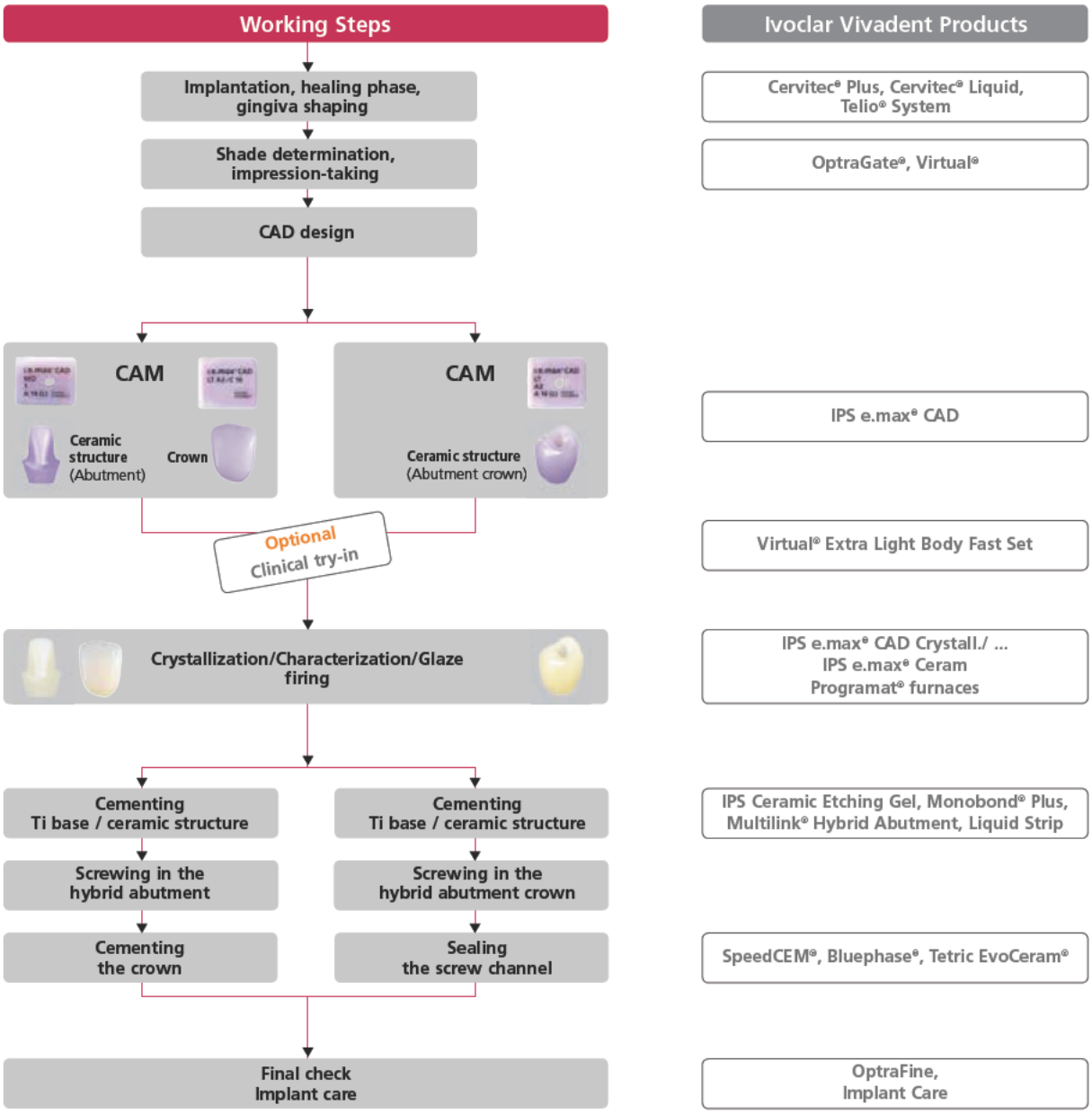
CAD/CAM partners

IPS e.max CAD has to be processed with an authorized CAD/CAM system. For questions regarding the different systems, please contact the respective cooperation partners.

More information is available on the Internet from **www.ivoclarvivadent.com.**

IPS e.max CAD Abutment Solutions

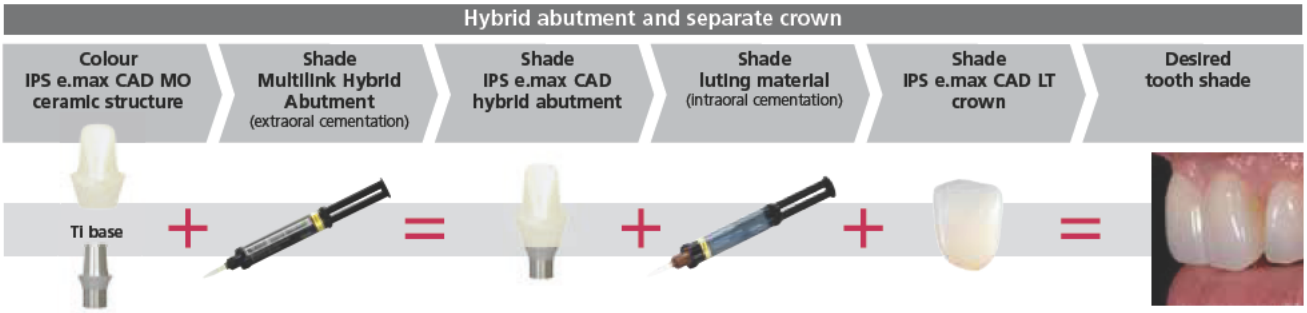
Fabrication of IPS e.max CAD hybrid abutment and hybrid abutment crown



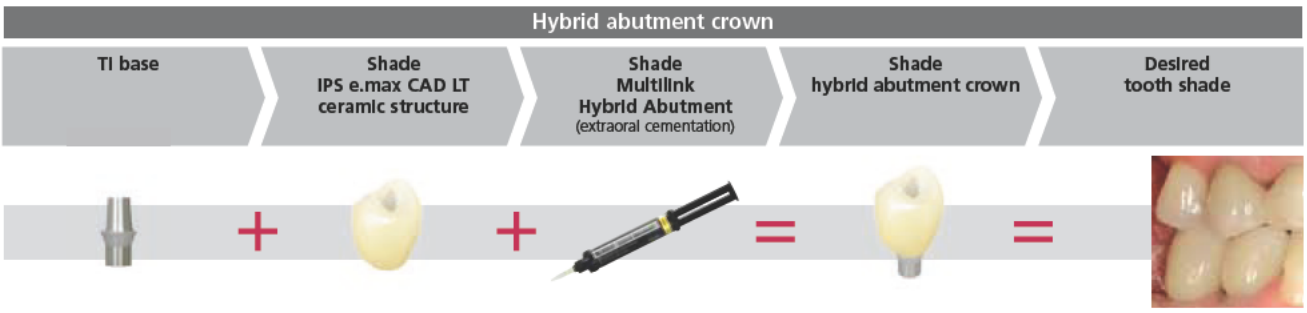
Shade – tooth shade and abutment shade

Optimum integration in the oral cavity of the patient is the prerequisite for a true-to-nature all-ceramic restoration. To achieve this, the following guidelines and notes must be observed.
With IPS e.max CAD Abutment Solutions, you can imitate not only the clinical crown of a natural tooth, but also a part of the root. This allows you to achieve highly esthetic implant-supported restorations which retain their lifelike appearance also in the case of gingiva recession.

For IPS e.max CAD **hybrid abutment and the separate crown**, the desired tooth shade results from
- the shade of the IPS e.max CAD hybrid abutment (IPS e.max CAD MO ceramic structure, Multilink Hybrid Abutment)
- the shade of the luting material for intraoral cementation of the crown on the IPS e.max CAD hybrid abutment (e.g. SpeedCEM)
- the shade of the IPS e.max CAD LT crown.



For the IPS e.max CAD **hybrid abutment crown**, the desired tooth shade results from
- the shade of the IPS e.max CAD LT ceramic structure
- the shade of Multilink Hybrid Abutment.



Preparation for the CAD/CAM process

Scanning

For the fabrication of IPS e.max CAD Abutment Solutions and depending on the CAD/CAM system used, the clinical situation is digitalized either by a direct intraoral scan or an indirect model scan. For notes regarding the scan, please observe the manufacturer's instructions for use of the CAD/CAM system.

Selecting a Ti base

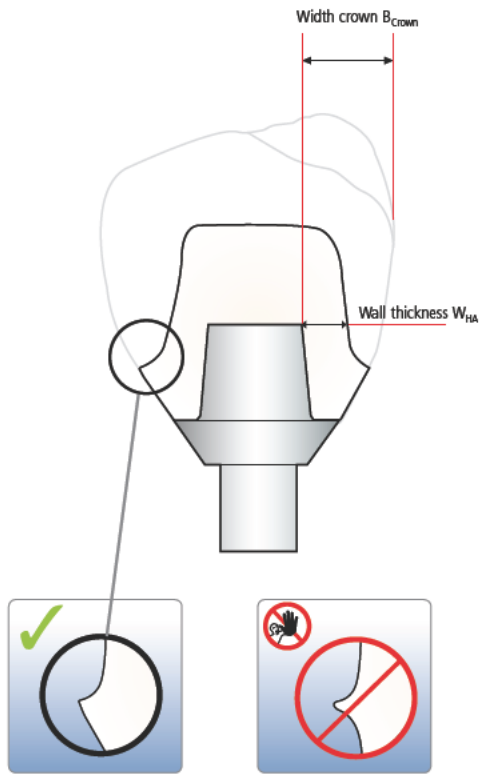
The required Ti base is selected depending on the inserted implant and the CAD/CAM system used.

Layer thicknesses of the ceramic components

Observing the geometry requirements of the IPS e.max CAD ceramic structures is the key to success for a durable restoration. The more attention is given to the design, the better the final results and the clinical success will turn out to be.

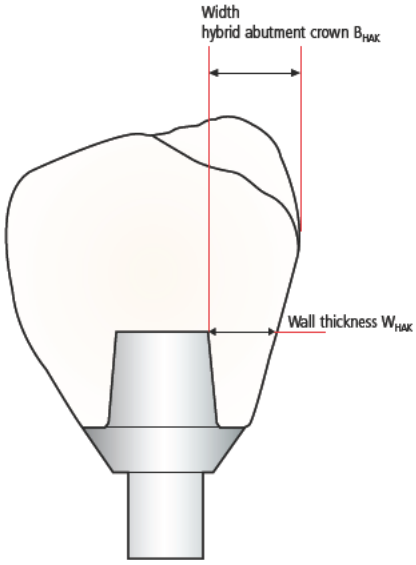
The following basic guidelines have to be observed:

Hybrid abutment



- The **wall thickness W_{HA}**, must be at least 0.5 mm.
- The hybrid abutment should be designed in a similar way as a prepared natural tooth:
  - Circular epi-/supragingival shoulder with rounded inner edges or a chamfer.
  - In order for the crown to be cemented to the hybrid abutment using a conventional/self-adhesive cementation protocol, retentive surfaces and a sufficient "preparation height" must be observed.
  - Create an emergence profile with a right angle at the transition to the crown (see picture).
- The **crown width B_{Crown}** is limited to 6.0 mm from the axial height of contour to the screw channel of the hybrid abutment.
- The notes of the implant manufacturer must be observed regarding the maximum height of the hybrid abutment and separate crown.

Hybrid abutment crown



- The wall thickness of **hybrid abutment crown W_{HAK}** must be larger than 1.5 mm for the entire circumference.
- The opening of the screw channel must not be located in the area of contact points. If this is not possible, a hybrid abutment with a separate crown would be preferred.
- The width of the **hybrid abutment crown B_{HAK}** is limited to 6.0 mm from the axial height of contour to the screw channel.
- The notes of the implant manufacturer must be observed regarding the maximum height of the hybrid abutment crown.

Block selection

An IPS e.max CAD MO or LT block is selected depending on the indication.
When using a Ti base from Sirona, the dimensions of the interface to the Ti Base (S or L) have to be observed.

IPS e.max CAD hybrid abutment	 IPS e.max CAD **MO** (Medium Opacity)	Please refer to the table on **page 62** for the **selection of the block shade** for the desired tooth shade.
IPS e.max CAD crown (on IPS e.max CAD hybrid abutment)	 IPS e.max CAD **LT** (Low Translucency)	
IPS e.max CAD hybrid abutment crown	 IPS e.max CAD **LT** (Low Translucency)	

CAD/CAM processing

As densification of about 0.2% occurs in IPS e.max CAD during crystallization, this factor has been taken into account in the respective software of the tested CAD/CAM system. Consequently, the milled IPS e.max CAD restorations demonstrate a high accuracy of fit after crystallization. The fabrication steps are described in the directions for use and user manuals of the different CAD/CAM systems. The instructions of the manufacturers must be followed.

Finishing

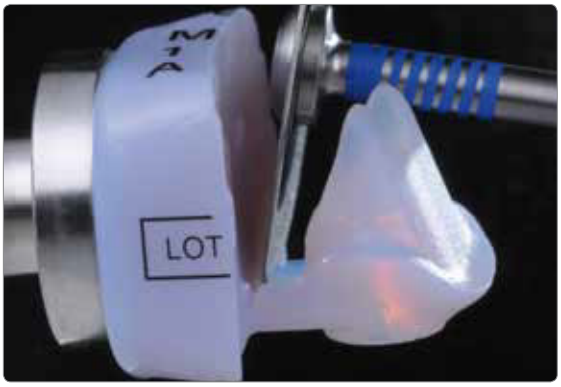
It is of critical importance to use the correct grinding instruments for finishing and adjusting the IPS e.max CAD ceramic structure. If unsuitable grinding instruments are used, chipping of the edges and local overheating may occur (please observe the Ivoclar Vivadent Flow Chart "Recommended grinding tools for PS e.max glass-ceramics").

Basic notes regarding the finishing of IPS e.max CAD

- Carry out adjustments by grinding of IPS e.max CAD restorations while they are still in their pre-crystallized (blue) state, if possible.
- Only use suitable grinding instruments, low speed and light pressure to prevent delamination and chipping at the margins in particular. **Overheating of the glass-ceramic must be avoided.**
- During finishing, make sure that the minimum layer thicknesses are observed.
- Cut the ceramic structure from the block using a diamond separating disc. Slightly scratch the attachment area at the incisal side of the abutment and separate the attachment point from the basal.

Checking the fit of the ceramic structure on the Ti base

- Carefully place the ceramic structure on the Ti base and check the fit. Observe the position of the rotation lock.



The incisal side of the attachment point is scratched with a diamond separating disc.


The attachment is cut from the basal using a diamond separating disc.


The ceramic structure is carefully placed on the Ti base to check the fit.


Optimum fit of the ceramic structure on the Ti base

Finishing

Important!

- **Do not finish the shoulder of the ceramic structure to prevent negatively affecting the Ti base.**
- **Finish the emergence profile if required taking the fit to the gingiva and the minimum thickness (0.5mm) into account.**

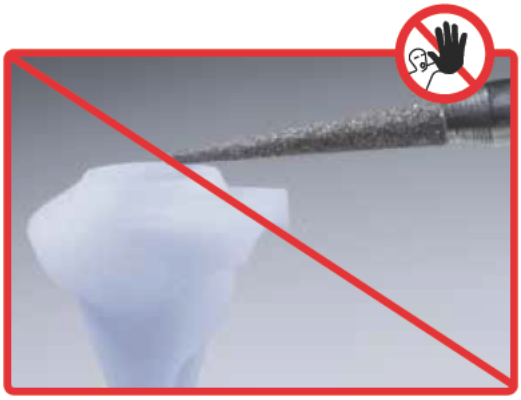
Finishing the outer surface of the ceramic structure (hybrid abutment)

- Smooth out the attachment point to the block with fine diamond grinding instruments taking the shape of the emergence profile and the crown margin into account.
- Do not perform any individual shape adjustments, as this will negatively affect the fit of the crown on the hybrid abutment. **Note regarding the crown**: If there are any inaccuracies of fit to the hybrid abutment, adjust the crown by grinding.

Finishing the outer surface of the ceramic structure (hybrid abutment crown)

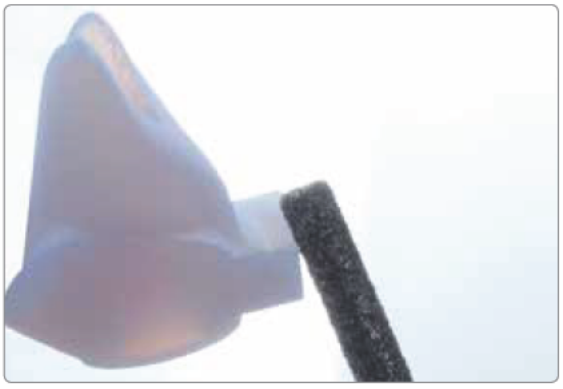
- Smooth out the attachment point to the block with fine diamond grinding instruments taking the shape of the emergence profile and the proximal contacts into account.
- Surface-grind the entire occlusal surface with a fine diamond to smooth out the surface structure created by the CAD/CAM procedure.
- Check the proximal and occlusal contacts.
- Design surface textures.

- Clean the ceramic structures with ultrasound in a water bath or blast with the steam jet before further processing.
- Make sure to thoroughly remove any residue of the milling additive of the CAD/CAM milling unit. Residue of the milling additive remaining on the surface may result in bonding problems and discolouration.
- Do **not** blast ceramic structures with Al_2O_3 or glass polishing beads!

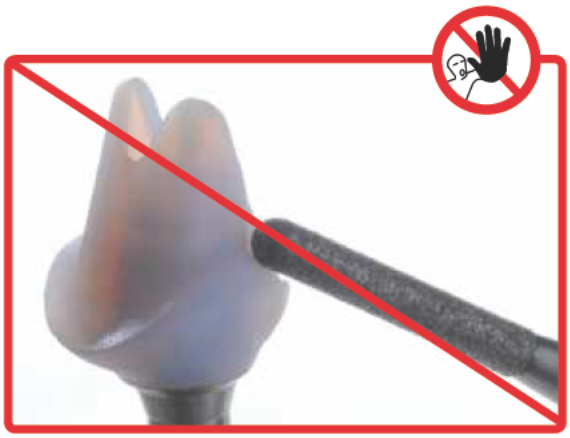


The shoulder of the ceramic structure must not be finished to prevent negatively affecting the Ti base.

Care should be taken when finishing the emergence profile to prevent affecting the fit to the gingiva.



The attachment point to the block is smoothed out taking the shape of the emergence profile and the crown margin into account.



Individual shape adjustments must not be performed, as this negatively affects the fit of the crown on the hybrid abutment.

The attachment point to the block is smoothed out taking the shape of the emergence profile and the crown margin into account.

The surface of the ceramic structure is ground with a fine diamond to smooth out the surface structure created by the CAD/CAM procedure.

Tip

Place the crown on the ceramic structure to finish the crown margins. In this way, a smooth transition between the crown and hybrid abutment can be achieved.

next working step ...

Optional: Clinical try-in page 17

Completing the IPS e.max CAD ceramic structure page 22

IPS e.max CAD Abutment Solutions

Optional: Clinical try-in

A clinical try-in to check the accuracy of fit can be conducted prior to further processing. Clinical try-in may also take place at a later stage, i.e. with the crystallized, tooth-coloured IPS e.max CAD ceramic structure.

Provisional securing of the ceramic structure on the Ti base

To facilitate the intraoral handling, the components are temporarily attached to one another with silicone material, e.g. Virtual Extra Light Body Fast Set.

The following procedure should be observed in the temporary attachment of the components:

- Clean the untreated Ti base and the ceramic structure with steam and subsequently dry with blown air.
- Place the ceramic structure on the Ti base (which is screwed on the model analog) and mark the relative position of the components with a waterproof pen. This step makes it easier to attain the correct position when the parts are temporarily assembled.
- Seal the screw channel with a foam pellet.
- Insert the Virtual cartridge in the dispenser and remove the protective cap.
- Screw on the mixing tip and attach the Oral Tip to the mixing tip.
- Apply Virtual Extra Light Body Fast Set to the Ti base and directly into the ceramic structure.
- Introduce the Ti base into the ceramic structure. The alignment of the two component must be checked (rotation lock/marking).
- Hold the components firmly in the correct position for 2:30 minutes until Virtual Extra Light Body Fast Set has set.
- Carefully remove any excess that has been displaced with a suitable instrument, e.g. a scalpel.

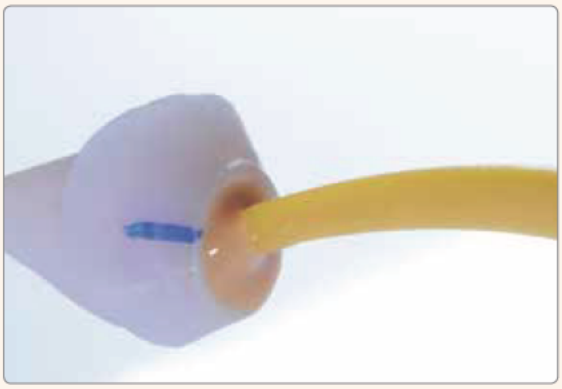
Cleaned, untreated ceramic structures

The ceramic structure is placed on the Ti base and the relative position is marked.

The screw channel is sealed with a foam pellet.

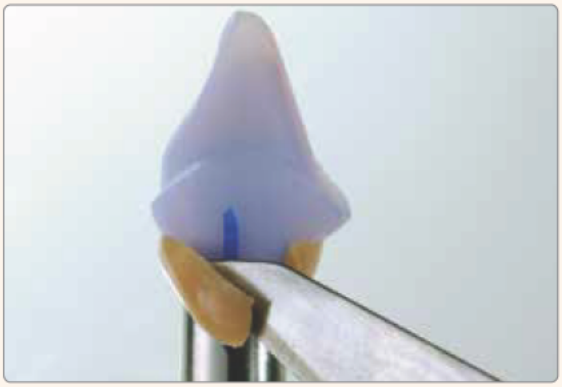
The Virtual cartridge is inserted in the dispenser. The mixing tip is screwed on and the Oral Tip is attached.

Virtual Extra Light Body Fast Set is applied to the Ti base ...



... and directly on the ceramic structure.

The Ti base is introduced into the ceramic structure. In doing so, the alignment of the two components is checked (rotation lock/marking). The components are firmly held in place for approx. 2:30 minutes until the Virtual Extra Light Body Fast Set has set.



Excess Virtual Extra Light Body Fast Set is removed from the screw channel with an instrument, e.g. a scalpel.

Excess Virtual Extra Light Body Fast Set material is removed from the screw channel with an instrument.

Prepared hybrid abutment or hybrid abutment crown

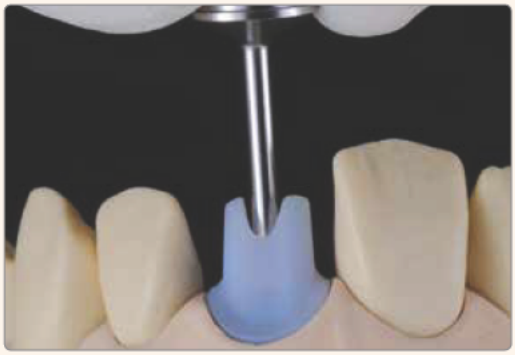
Clinical try-in

Hybrid abutment and dedicated crown

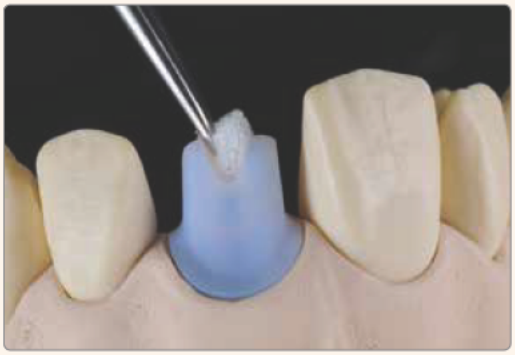
Important note: Any intraoral inspection of the occlusion/articulation and necessary grinding adjustments may only be carried out if the components have been attached to one another with Virtual Extra Light Body Fast Set. Virtual has a cushioning effect during the try-in procedure, in particular, if any grinding adjustments have to be made. Therefore, it prevents chipping in the transition area between the hybrid abutment and the crown.

The following procedure should be observed during the clinical try-in:

- The prepared hybrid abutment (provisionally secured in place) and the clean corresponding crown are laid out.
- Remove the provisional restoration.
- Screw the hybrid abutment in manually with the dedicated screw.
- Check the geometry of the hybrid abutment (e.g. fit gingival anaemia) in relation to the gingival margin.
- If desired, the screw channel on the hybrid abutment can be sealed with a foam pellet.
- **Tip**: Isolate the inner aspect of the crown with glycerine gel, e.g. Try-in paste, Liquid Strip
- Place the crown on the hybrid abutment intraorally to check and adjust the proximal contacts, if necessary.
  Note: No occlusal functional inspection must be performed at this stage.
- For the functional inspection, the crown has to be secured on the hybrid abutment with Virtual Extra Light Body Fast Set. Try-in paste must not be used for this purpose, as this material is not sufficiently resistant to compressive force.
- Insert the Virtual cartridge in the dispenser and remove the protective cap.
- Screw on the mixing tip and attach the Oral Tip to the mixing tip.
- Apply Virtual Extra Light Body Fast Set to the inner aspect of the crown.
- Press the crown onto the hybrid abutment using the fingers until it has reached the final position. Hold the crown in the final position until the Virtual material has set.
- Remove excess Virtual material.
- Check the occlusion/articulation and make adjustments with suitable grinding instruments, if necessary (see separate IPS e.max recommended grinding instruments for ceramics – use in the dental practice).
- Carefully remove the crown from the hybrid abutment and the hybrid abutment from the implant (including the Ti base).
- Rinse the implant site e.g. with Cervitec Liquid (antibacterial mouth wash with chlorhexidine) to clean and disinfect it.
- Place the temporary restoration.

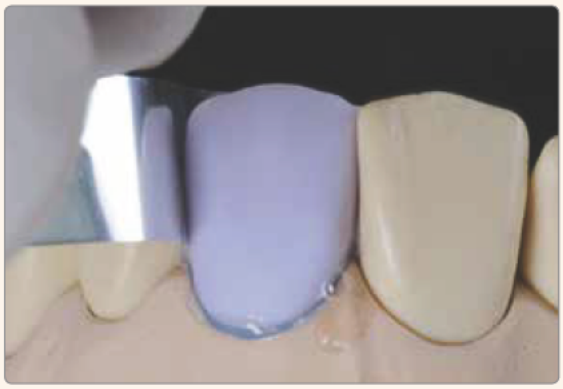


The hybrid abutment is manually screwed in place with the dedicated screw. The geometry of the hybrid abutment (e.g. fit, gingival anaemia) is checked in relation to the gingival margin.



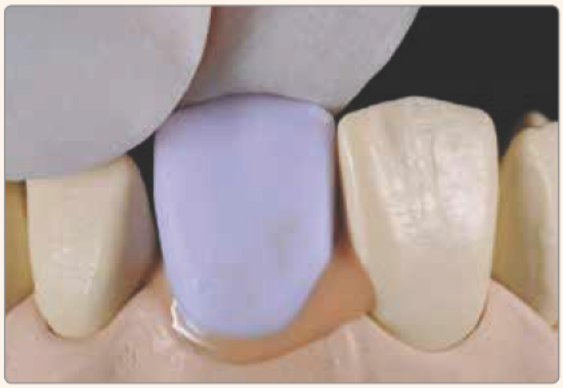
If desired, the screw channel of the hybrid abutment can be sealed with a foam pellet.

Tip: The inner aspect of the crown can be isolated with glycerine gel.

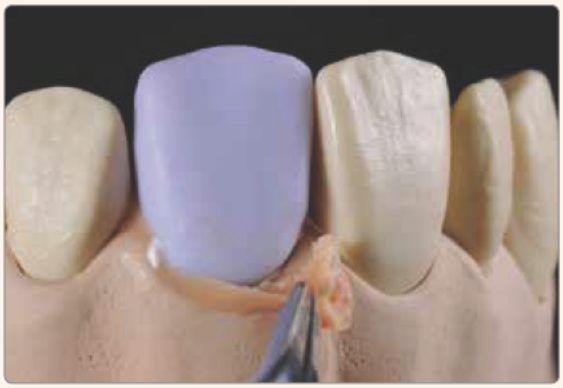


The crown is placed on the hybrid abutment intraorally to check and if necessary adjust the proximal contacts. **Note: No occlusal functional inspection must be performed at this stage.**

Virtual Extra Light Body Fast Set is applied to the inner aspect of the crown.

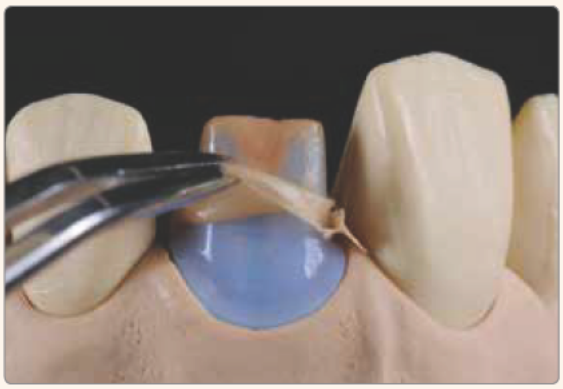


The crown is pressed onto the hybrid abutment using the fingers until the final position is reached. The crown is held in the final position until the Virtual material has set.

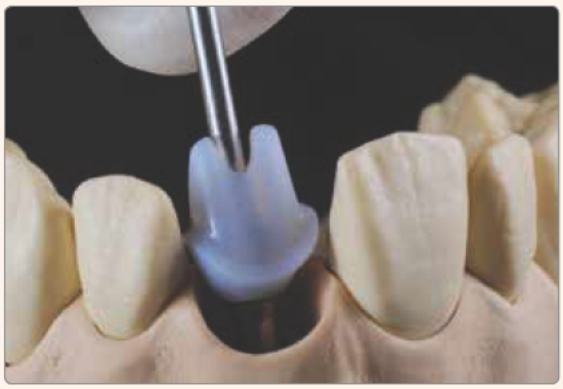


Excess Virtual material is removed.

The occlusion/articulation is checked and adjustments are made with suitable grinding instruments, if necessary.



The crown is carefully lifted from the hybrid abutment and the Virtual Extra Light Body Fast Set material is removed.

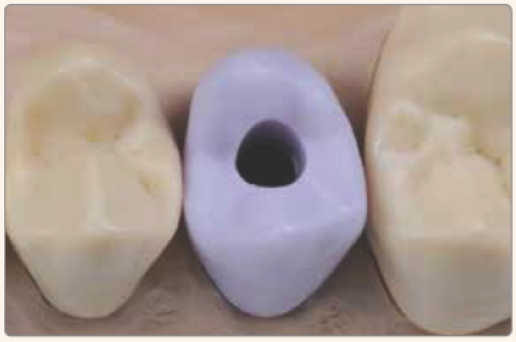


The hybrid abutment is unscrewed.

Hybrid abutment crown

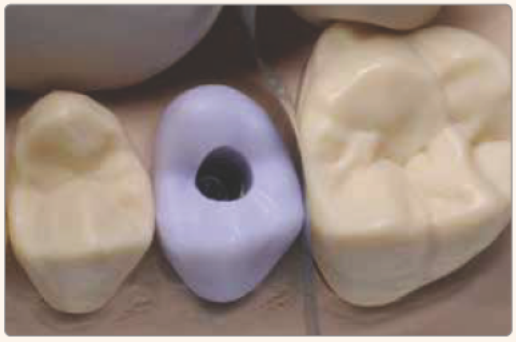
The following procedure should be observed during the clinical try-in:

- The prepared and cleaned hybrid abutment crown (provisionally secured with in place with Virtual Extra Light Body Fast Set) is laid out.
- Remove the provisional restoration.
- Place the hybrid abutment crown on the implant intraorally in order to check and adjust the proximal contacts, if necessary. **Note: No occlusal functional inspection must be performed at this stage.**
- Screw the hybrid abutment crown in manually with the dedicated screw.
- Check the geometry of the hybrid abutment crown (e.g. fit, gingival anaemia) in relation to the gingiva.
- Check the occlusion/articulation and make adjustments with suitable grinding instruments, if necessary (see separate IPS e.max recommended grinding instruments for ceramics – use in the dental practice).
- Carefully remove the hybrid abutment crown.
- Rinse the implant site, e.g. with Cervitec Liquid (antibacterial mouth rinse containing chlorhexidine), to clean and disinfect it.
- Place the temporary restoration.

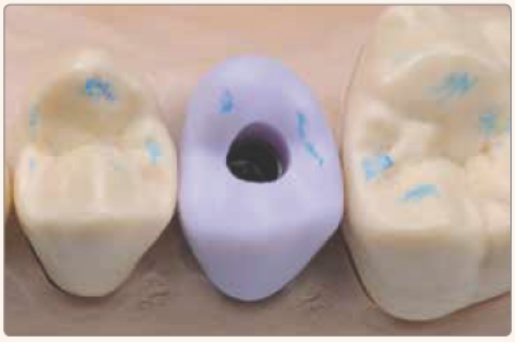


The hybrid abutment crown is placed on the implant intraorally in order to check and if necessary adjust the proximal contacts. **Note: No occlusal functional inspection must be performed at this stage.**

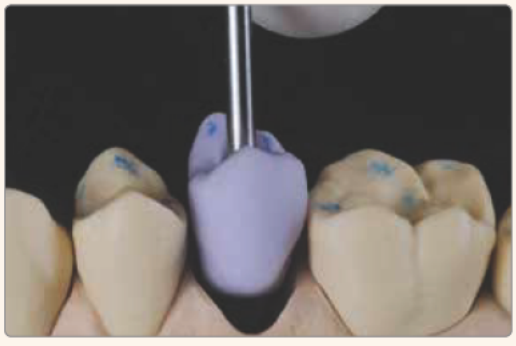
The hybrid abutment crown is screwed in with the dedicated screw.



The geometry of the hybrid abutment crown is checked (e.g. fit, gingival anaemia) in relation to the gingiva.



The occlusion/articulation is checked and if necessary adjustments are made with suitable grinding instruments.



The hybrid abutment crown (including base) is carefully removed.

IPS e.max CAD Abutment Solutions

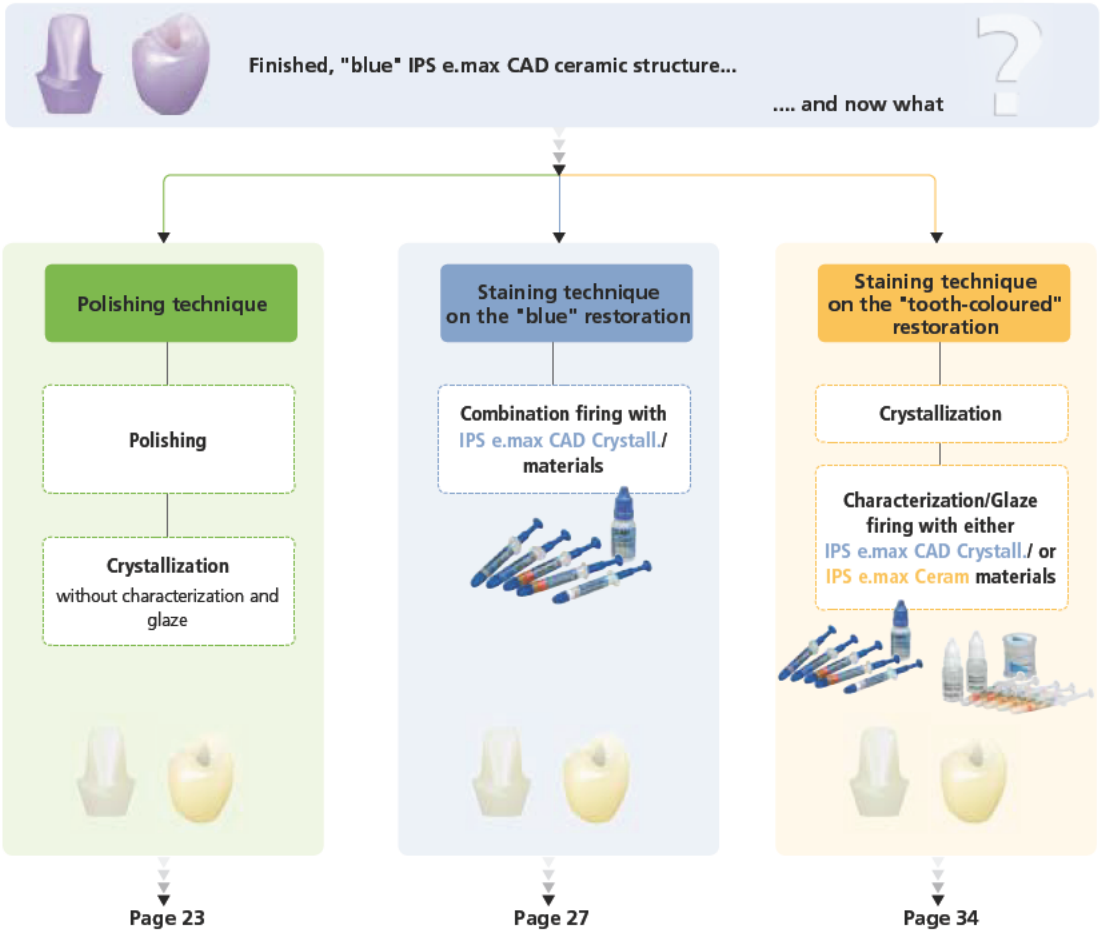
Completing the IPS e.max CAD ceramic structure

Depending on the desired processing technique and materials, the way to complete the ceramic structure is selected. Basically, two ways to complete the ceramic structure can be distinguished.

- **Polishing technique**
  Polishing of the "blue" restoration, followed by crystallization without individual characterization and glaze.

- **Staining technique on the "blue" restoration**
  Characterization and glaze with IPS e.max CAD Crystall./ materials on the blue restoration, followed by Combination firing (Crystallization and Characterization/Glaze firing in one step).

- **Staining technique on the tooth-coloured restoration**
  Crystallization without the application of materials. Characterization/Glaze firing of the tooth-coloured restorations with either IPS e.max CAD Crystall./ or IPS e.max Ceram materials.



Page 23 Page 27 Page 34

Polishing technique

Polishing of the "blue" restoration, followed by crystallization without individual characterization and glaze

If **no characterizations** and **no Glaze firing** are desired, it is possible to polish the ceramic structure manually, followed by crystallization. Please note that polishing causes slight abrasion.

The polishing technique is preferably used for the emergence profile of the hybrid abutment. For the hybrid abutment crown, the application of glaze is recommended.

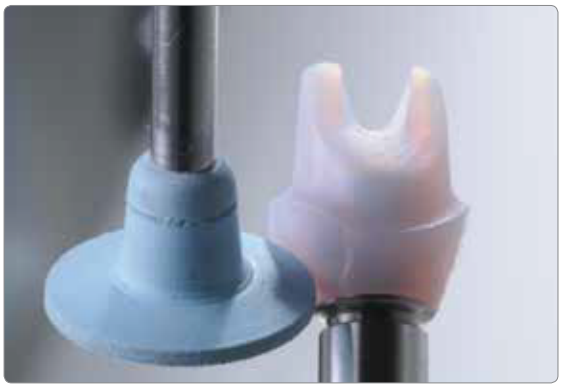
On hybrid abutments, only the emergence profile is polished.

On hybrid abutment crowns, the entire outer aspect is polished.

Polishing

Please observe the following procedure for polishing the pre-crystallized (blue) ceramic structure:

- Clean the ceramic structure with ultrasound in a water bath or a steam cleaner to remove any contaminations and grease residue.
- Screw Ti base onto a model analog for easier handling.
- Secure the ceramic structure on the Ti base. **Note**: Do **not** finish the Ti base.
- **Overheating of the glass-ceramic must be avoided during polishing.** Observe the recommendations of the manufacturer of the grinding tools.
- Pre-polishing with a diamond rubber polisher (e.g. OptraFine F).
- Fine polishing with a high-gloss rubber polisher (e.g. OptraFine P)
- High-gloss polishing with brushes and polishing paste (e.g. OptaFine HP)
- Clean the ceramic structure with ultrasound in a water bath or the steam jet.



Pre-polishing by means of diamond rubber polishers

Fine polishing by means of high-gloss rubber polishers

High-gloss polishing with brushes and polishing paste

Residue is removed with ultrasound in a water bath…

...or with the steam jet.

Crystallization

The following steps must be observed:

– Clean the ceramic structure to remove any contaminations and grease residue. Any contamination after cleaning must be prevented.
– Slightly overfill the interface of the ceramic structure with IPS Object Fix Putty or Flow.
Immediately reseal the IPS Object Fix Putty/Flow syringe after extruding the material.
– Place the ceramic structure in the centre of the IPS e.max CAD Crystallization Tray.

Important

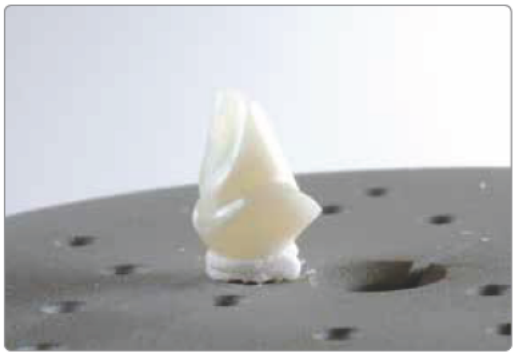
– Conduct the **crystallization** on the IPS e.max CAD Crystallization Tray using the stipulated firing parameters.

Observe the firing parameters for IPS e.max CAD MO and IPS e.max CAD LT. Firing parameters see page 64

– **Note:**
If a restoration made of IPS e.max CAD MO and one made of IPS e.max CAD LT are to be crystallized in the same firing, the firing parameters for IPS e.max CAD MO must be used.

– Remove ceramic structure from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).
– Allow the objects to cool to room temperature in a place protected from draft.
– Do not touch the hot objects with metal tongs.
– Remove the ceramic structure from the IPS e.max CAD Crystallization Tray.
– Remove any residue with ultrasound in a water bath and/or with steam.
– Do **not** remove residue with Al_2O_3 or glass polishing beads.
– Place the ceramic structure on the Ti base and check the fit.
– **If adjustments by grinding of the restoration are required, make sure that no overheating of the ceramic occurs.**

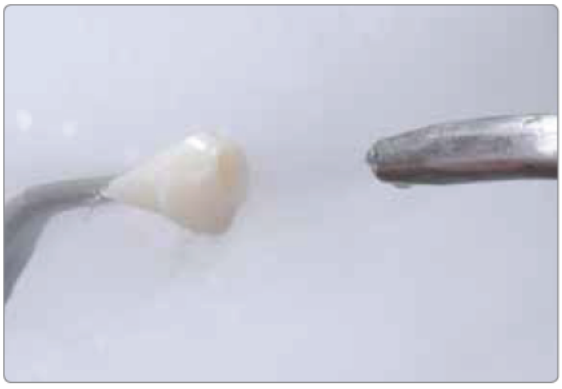
The interface of the ceramic structure is slightly overfilled with IPS Object Fix Putty or Flow. Then the ceramic structure is placed in the centre on the IPS e.max CAD Crystallization Tray.



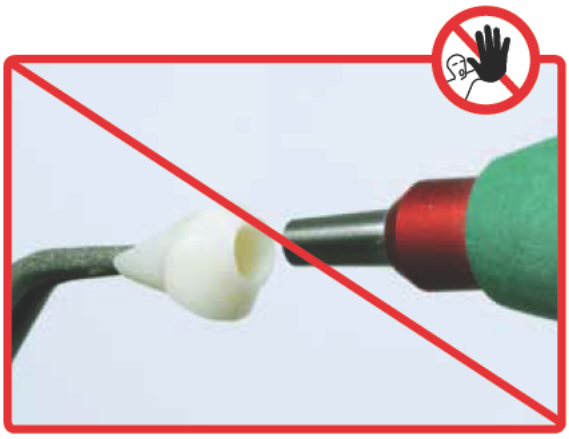
The crystallization tray is removed from the furnace once the crystallization program has been completed and the object is allowed to cool

The ceramic structure is removed from the IPS e.max CAD Crystallization Tray.

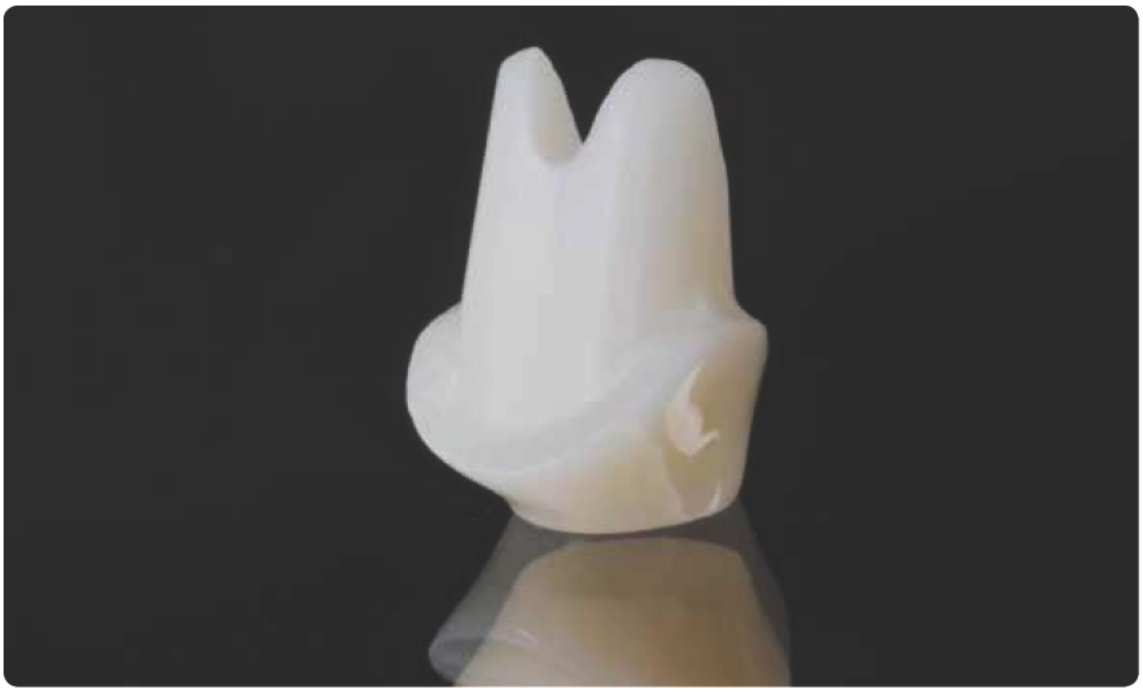
Residue is removed with ultrasound in a water bath....



… or with the steam jet.



Residue **must not** be removed with Al_2O_3 or glass polishing beads.



Polished, crystallized ceramic structure

next working step … Permanent cementation Ti base / ceramic structure page 46

Staining technique on the "blue restoration"

Characterization and glaze with IPS e.max CAD Crystall./ materials on the "blue" restoration, followed by Combination firing

The following paragraphs will explain the steps of glazing and characterizing with IPS e.max CAD Crystall./Shades, Stains and Glaze. In this processing technique, Crystallization and Glaze firing are performed in one step. Characterizations are applied using IPS e.max CAD Crystall./Shades and Stains.

If hybrid abutments are fabricated, only the area of the emergence profile is characterized with IPS e.max CAD Crystall./Shades, Stains and Glaze.

If hybrid abutment crowns are fabricated, the entire outer surface may be individually characterized.

Required materials

– IPS e.max CAD Crystall./Shades are ready-to-use "Dentin" stains in syringes.

– IPS e.max CAD Crystall./Stains are ready-to-use intensive stains in syringes.

– IPS e.max CAD Crystall./Glaze Paste is a ready-to-use glazing paste.
– IPS e.max CAD Crystall./Glaze Liquid is a special liquid for mixing with Shades, Stains and Glaze.

Note:
The IPS e.max CAD Crystall./**Glaze Spray** is **not** recommended for glazing IPS e.max CAD Abutment Solutions, as it requires very targeted application. The glazing material must neither reach the bonding surface to the Ti base nor the screw channel, as this may compromise the accuracy of fit.

Preparing for Combination firing (Crystallization and Stain/Glaze firing in one step)

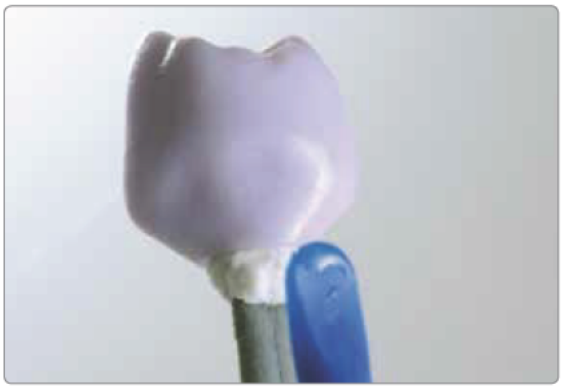
- Clean the ceramic structure with the steam jet to remove any contaminations and grease residue. Any contamination after cleaning must be prevented.
- Use the **IPS e.max CAD Crystallization Pin XS** for the crystallization of the ceramic structure.
- Fill the interface of the ceramic structure with either IPS Object Fix Putty or Flow auxiliary firing paste. **Immediately reseal the IPS Object Fix Putty/Flow syringe after extruding the material.**
- Press the **IPS e.max CAD Crystallization Pin XS only slightly** into the IPS Object Fix Putty/Flow. **Important: Do not press the pin in too deep to make sure that it does not touch the walls. This may lead to cracks in the ceramic structure**.
- Smooth out displaced auxiliary firing paste using a plastic spatula so that the pin is securely in place.
- Prevent contamination of the outer surface / occlusal surface of the ceramic structure.
- Clean off any possible contamination with a brush dampened with water and dry.

The IPS e.max CAD Crystallization Pin XS is used for the crystallization of the ceramic structure.

The interface of the ceramic structure is filled with either IPS Object Fix Putty or Flow auxiliary firing paste.

Important: – The IPS e.max CAD Crystallization Pin XS should be pressed only slightly into the IPS Object Fix Putty/Flow so that it does not touch the walls of the ceramic structure.

Incorrect: Pin pressed in too deep. Pin touches the ceramic structure, which may lead to cracks.



Displaced auxiliary firing paste is smoothed out with a plastic spatula from the margin towards the support pin so that the pin is secured in the paste.

Any possible residue adhering to the outer surface/occlusal surface is cleaned off with a brush dampened with water and dried.

Combination firing (Crystallization and Stain/Glaze firing in one step)

Please observe the following procedure for the combination firing:
- Extrude the ready-to-use IPS e.max CAD Crystall./Glaze Paste from the syringe and mix.
- If a slight thinning is desired, the ready-to-use glaze may be mixed with a small amount of IPS e.max CAD Crystall./Glaze Liquid.

Important:
- The glazing material must neither reach the bonding surface to the Ti base nor the screw channel, as this may compromise the accuracy of fit. Check the interface before firing and carefully remove any contamination.
- On the abutment, do not apply any materials to the bonding surface to the crown, as this might compromise the fit of the crown.

- Apply IPS e.max CAD Crystall./Glaze Paste evenly on the areas to be glazed using a small brush. Avoid to apply too thick a glaze layer. Avoid "pooling", especially on the occlusal surface of the abutment crown.
- Too thin a glaze layer may lead to an unsatisfactory gloss.
- Apply characterizations with IPS e.max CAD Crystall./Shades and/or IPS e.max CAD Crystall./Stains. For that purpose, extrude the Shades and Stains from the syringe and mix. If necessary, slightly thin them using IPS e.max CAD Crystall./Glaze Liquid. However, the consistency should still remain pasty.
- Apply mixed Shades and Stains directly into the unfired glaze layer using a fine brush. More intensive shades are achieved by several staining procedures and repeated firing, not by applying thicker layers.
- To imitate the incisal area and translucency of the hybrid abutment crown in the incisal and occlusal third, IPS e.max CAD Crystall./Shades Incisal may be used. The cusps and fissures can be individualized using Stains.

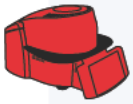
Optional:

For minor shape adjustments (e.g. proximal or occlusal contact points), IPS e.max CAD Crystall./Add-On is available. The detailed procedure is described on page 33.

After glazing and staining, the Combination firing is conducted in a compatible ceramic furnace (e.g. Programat® CS or Programat P500). When placing the objects into the furnace and setting the firing parameters, observe the following points:
- Place the restoration in the centre of the IPS e.max CAD Crystallization Tray.
- A maximum of 6 units can be positioned on the firing tray and crystallized in the Combination firing with IPS e.max CAD Crystall./Glaze Paste.

Important

- Conduct the **Combination firing** on the IPS e.max CAD Crystallization Tray using the stipulated firing parameters.



Observe the firing parameters for IPS e.max CAD MO and IPS e.max CAD LT. Firing parameters see page 64

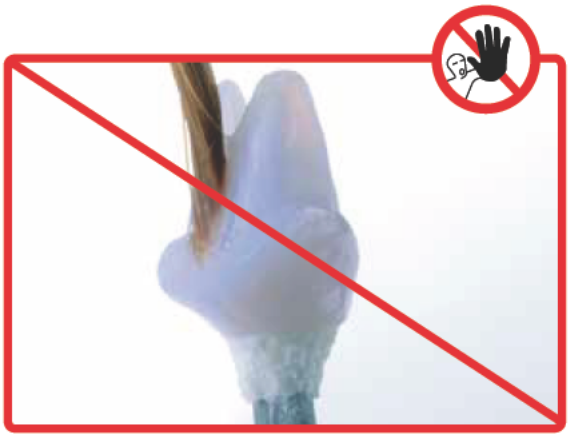
- **Note:**
  If a restoration made of IPS e.max CAD MO and one made of IPS e.max CAD LT are to be crystallized in the same firing, the firing parameters for IPS e.max CAD MO must be used!

- Remove restoration from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).
- Allow the objects to cool to room temperature in a place protected from draft.
- Do not touch the hot objects with metal tongs.

IPS e.max CAD Crystall./Glaze Paste is extruded from the syringe and mixed.
If required, the paste can be thinned with IPS e.max CADCrystall./Glaze Liquid.

IPS e.max CAD Crystall./Glaze Paste is applied evenly on the emergence profile of the hybrid abutment or the outer surface of the hybrid abutment crown.

Important: The glazing material must reach neither the bonding surface to the Ti base nor the screw channel, as this may compromise the accuracy of fit.

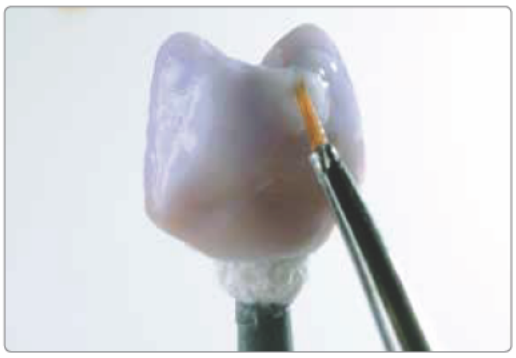


Important: The materials must not be applied to the bonding surface to the crown, as this might compromise the fit of the crown.

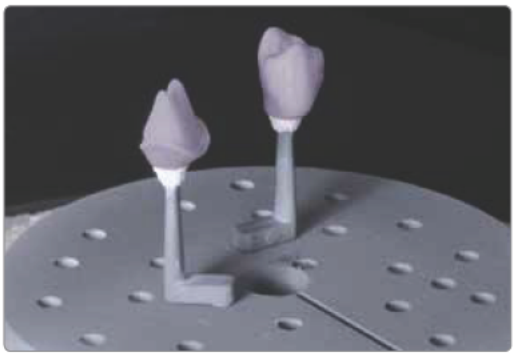
Individual characterizations of the emergence profile are applied using IPS e.max CAD Crystall./Shades.

Enhancing the chroma on the buccal surface with IPS e.max CAD Crystall./Shades

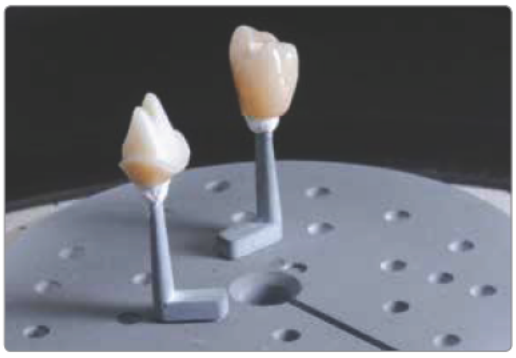
IPS e.max CAD Crystall./Shade Incisal is applied to imitate the incisal area.



Optional: For minor shape adjustments (e.g. proximal contact points), IPS e.max CAD Crystall./Add-On is available.



The ceramic structure is placed in the centre of the IPS e.max CAD Crystallization Tray. The **Combination firing** is conducted using the stipulated **firing parameters**. The firing parameters for **IPS e.max CAD MO** and **IPS e.max CAD LT** must be observed.



The ceramic structure is removed from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).

Optional

Corrective firing

If characterizations or adjustments are required after crystallization, a corrective firing using IPS e.max CAD Crystall./Shades and Stains and Glaze can be conducted. Conduct the corrective firing also on the IPS e.max CAD Crystallization Tray.
For minor shape adjustments (e.g. proximal or occlusal contact points), IPS e.max CAD Crystall./Add-On is available.
The detailed procedure is described on page 33.

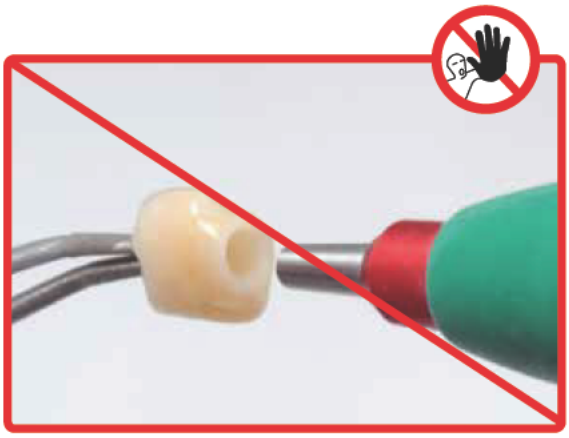
Once the IPS e.max CAD ceramic structure has cooled to room temperature, proceed with the following steps:

- Remove the ceramic structure from the IPS e.max CAD Crystallization Pin XS.
- Remove any residue with ultrasound in a water bath and/or with the steam jet.
- Do **not** remove residue with Al_2O_3 or glass polishing beads.
- Place the ceramic structure on the Ti base and check the fit.
- **If adjustments by grinding are required, make sure that no overheating of the ceramic occurs.**

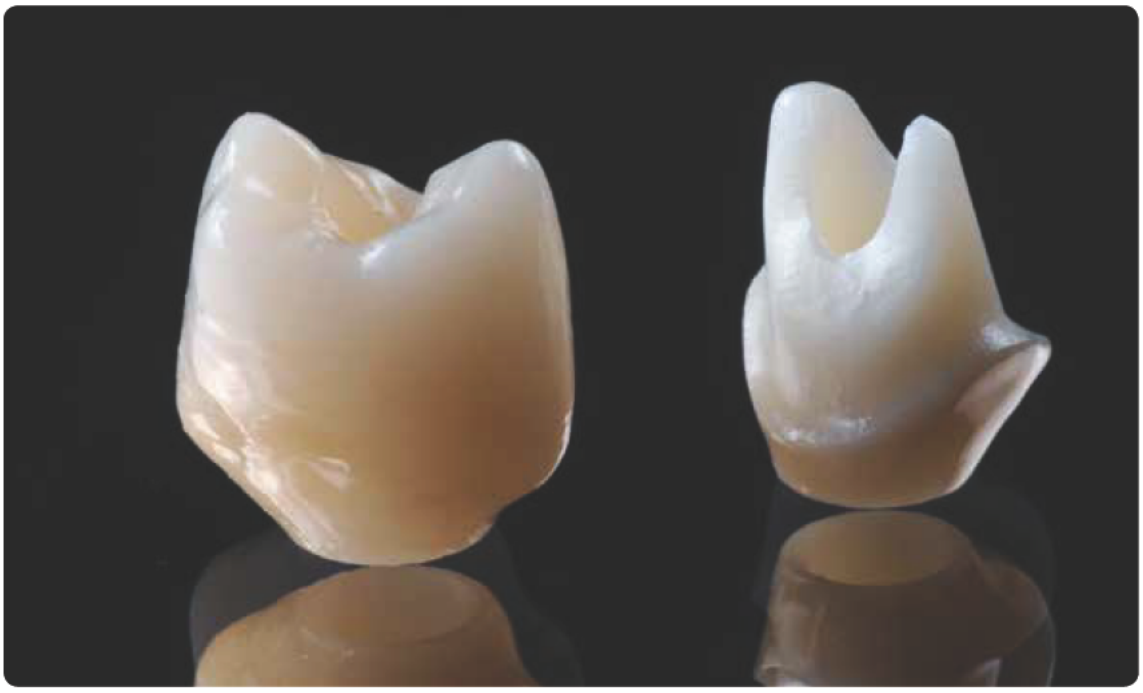
The ceramic structure is removed from the IPS e.max CAD Crystallization Pin XS.

Residue is removed with ultrasound in a water bath....

... or with the steam jet.



Residue **must not** be removed with Al_2O_3 or glass polishing beads.



Glazed and characterized ceramic structures (hybrid abutment crown and hybrid abutment)

Optional

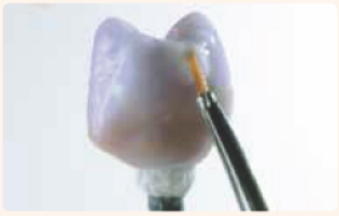
Shape adjustments with IPS e.max CAD Crystall./Add-On

For minor shape adjustments (e.g. proximal contact points), IPS e.max CAD Crystall./Add-On is available. The adjustments may be made with both the Combination firing or a separate Corrective firing.

Processing

- Mix IPS e.max CAD Crystall/Add-On with IPS e.max CAD Crystall/Add-On Liquid to an easy-to-contour consistency.
- Ensure even mixing of the add-on material and the liquid in order to achieve an optimum firing result.
- Apply the mixed add-on material directly on the unfired Glaze Paste and/or Shades and Stains in the areas to be adjusted and fire.
- Conduct the Combination firing if Add-On is applied on the "blue" partially crystallized restoration.
- Conduct the Corrective firing if Add-On is applied on an already crystallized restoration.

Mixing IPS e.max CAD Crystall/Add-On with IPS e.max CAD Crystall/Add-On Liquid to an easy-to-contour consistency

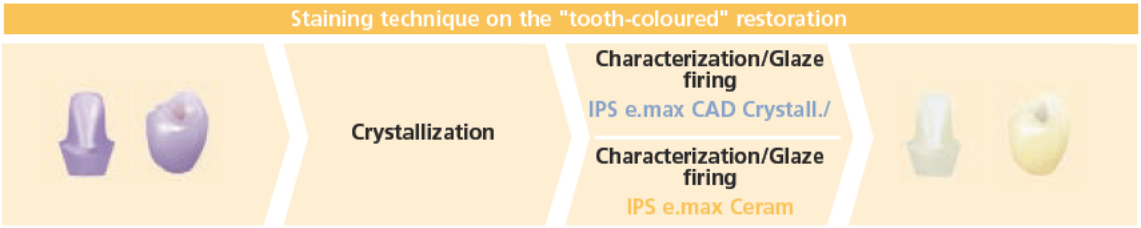


Application of the mixed Add-On on the blue restoration before crystallization or on the crystallized restoration

Firing parameters see page 64

next working step ... **Permanent cementation Ti base / ceramic structure page 46**

Staining technique on the "tooth-coloured" restoration



Crystallization without application of any materials; separate Characterization/Glaze firing with either IPS e.max CAD Crystall./ or IPS e.max Ceram materials.

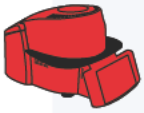
Crystallization

The following steps must be observed:

- Use the **IPS e.max CAD Crystallization Pin XS** for the crystallization of the ceramic structure.
- Fill the interface of the ceramic structure with either IPS Object Fix Putty or Flow auxiliary firing paste. **Immediately reseal the IPS Object Fix Putty/Flow syringe after extruding the material.**
- Slightly press the **IPS e.max CAD Crystallization Pin XS** into the IPS Object Fix Putty/Flow. **Important: Do not press the pin in too deep to make sure that it does not touch the walls. This may lead to cracks in the ceramic structure**.
- Smooth out displaced auxiliary firing paste using a plastic spatula so that the pin is securely in place.
- Prevent contamination of the outer restoration surface. Clean off contamination with a brush dampened with water and dry.
- Place the ceramic structure in the centre of the IPS e.max CAD Crystallization Tray.

Important

- Conduct the **crystallization** on the IPS e.max CAD Crystallization Tray using the stipulated firing parameters.



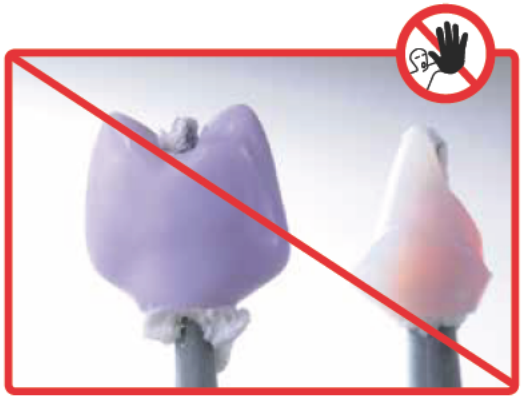
Observe the firing parameters for IPS e.max CAD MO and IPS e.max CAD LT. Firing parameters see page 64

- **Note:**
  If a restoration made of IPS e.max CAD MO and one made of IPS e.max CAD LT are to be crystallized in the same firing, the firing parameters for IPS e.max CAD MO must be used!

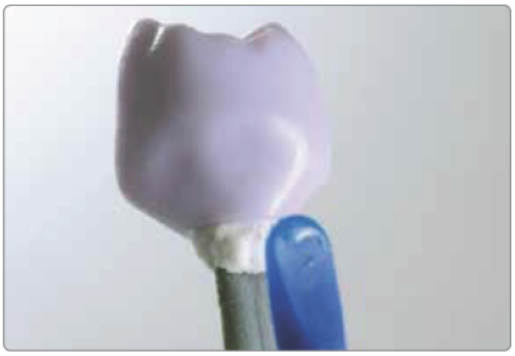
The IPS e.max CAD Crystallization Pin XS should be used for the crystallization of the ceramic structure.

The interface of the ceramic structure is filled with either IPS Object Fix Putty or Flow auxiliary firing paste.

Important: – The IPS e.max CAD Crystallization Pin XS is only slightly pressed into the IPS Object Fix Putty/Flow so that it **does not** touch **the walls** of the ceramic structure.

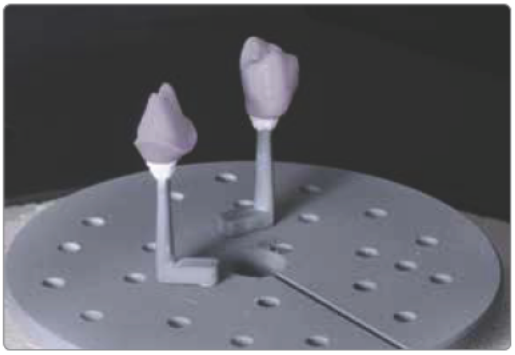


Incorrect: Pin pressed in too deep. Pin touches the ceramic structure. This may lead to cracks in the ceramic structure.

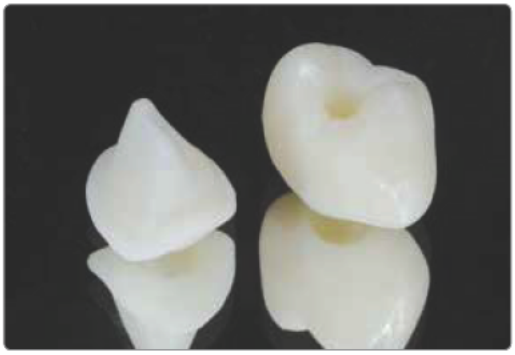


Displaced auxiliary firing paste is smoothed out with a plastic spatula from the margin towards the support pin so that the pin is secured in the paste.

Any possible residue adhering to the outer surface is cleaned off with a brush dampened with water and dred.



Conduct the crystallization using the stipulated firing parameters. The **firing parameters** for **IPS e.max CAD MO** and **IPS e.max CAD LT** must be observed.



Crystallized ceramic structures

- Remove ceramic structures from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).
- Allow the objects to cool to room temperature in a place protected from draft.
- Do not touch the hot objects with metal tongs.
- Remove the ceramic structure from the IPS e.max CAD Crystallization Pin.
- Remove any residue with ultrasound in a water bath and/or with the steam jet.
- Do **not** remove residue with Al_2O_3 or glass polishing beads.
- Place the ceramic structure on the Ti base and check the fit.
- **If adjustments by grinding of the restoration are required, make sure that no overheating of the ceramic occurs.**

next working step, either...

Stain / Glaze firing with IPS e.max CAD Crystall./; page 36
Stain / Glaze firing with IPS e.max CAD Ceram; page 40

Characterization/Glaze firing with IPS e.max CAD Crystall./...

The following paragraphs will explain the steps of characterizing and glazing with IPS e.max CAD Crystall./Shades, Stains and Glaze.

If hybrid abutments are fabricated, only the area of the emergence profile is characterized with IPS e.max CAD Crystall./Shades, Stains and Glaze.

If hybrid abutment crowns are fabricated, the entire outer surface may be individually characterized.

Required materials

– IPS e.max CAD Crystall./Shades are ready-to-use "Dentin" stains in syringes.

– IPS e.max CAD Crystall./Stains are ready-to-use intensive stains in syringes.

– IPS e.max CAD Crystall./Glaze Paste is a ready-to-use glazing paste.
– IPS e.max CAD Crystall./Glaze Liquid is a special liquid for mixing with Shades, Stains and Glaze.

Note:

The IPS e.max CAD Crystall./**Glaze Spray** is **not** recommended for glazing IPS e.max CAD Abutment Solutions, as is requires very targeted application. The glazing material must neither reach the bonding surface to the Ti base nor the screw channel, as this may compromise the accuracy of fit.

Please observe the following procedure for the Characterization/Glaze firing:
– Extrude the ready-to-use IPS e.max CAD Crystall./Glaze Paste from the syringe and mix.
– If a slight thinning is desired, the ready-to-use glaze may be mixed with a small amount of IPS e.max CAD Crystall./ Glaze Liquid.

Important:
– The glazing material must neither reach the bonding surface to the Ti base nor the screw channel, as this may compromise the accuracy of fit. Check the interface before firing and carefully remove any contamination.
– On the hybrid abutment, do not apply any materials to the bonding surface to the crown, as this might compromise the fit of the crown.

– Apply IPS e.max CAD Crystall./Glaze Paste evenly on the areas to be glazed using a small brush. Avoid to apply too thick a glaze layer. Avoid "pooling", especially on the occlusal surface of the hybrid abutment crown.
– Too thin a glaze layer may lead to an unsatisfactory gloss.
– Apply characterizations with IPS e.max CAD Crystall./Shades and/or IPS e.max CAD Crystall./Stains. For that purpose, extrude the Shades and Stains from the syringe and mix. If necessary, slightly thin them using IPS e.max CAD Crystall./ Glaze Liquid. However, the consistency should still remain pasty.
– Apply mixed Shades and Stains directly into the unfired glaze layer using a fine brush. More intensive shades are achieved by several staining procedures and repeated firing, not by applying thicker layers.
– To imitate the incisal area and translucency of the abutment crown in the incisal and occlusal third, IPS e.max CAD Crystall./Shades Incisal may be used. The cusps and fissures can be individualized using Stains.

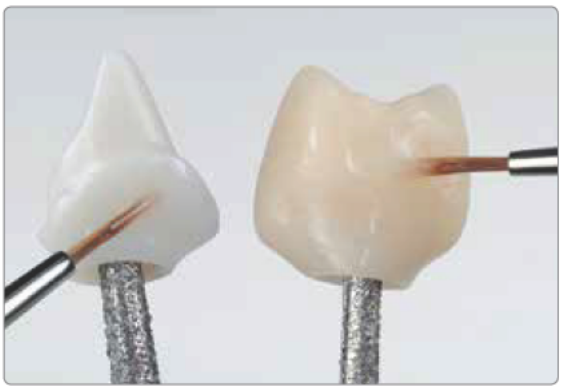
After glazing and staining, the Characterization/Glaze firing (Corrective firing) is conducted in a compatible ceramic furnace (e.g. Programat® CS or Programat P500). When placing the objects into the furnace and setting the firing parameters, observe the following points:

– Place the restoration in the centre of the IPS e.max CAD Crystallization Tray.
– A maximum of 6 units can be positioned on the firing tray for the firing with IPS e.max CAD Crystall./Glaze Paste.

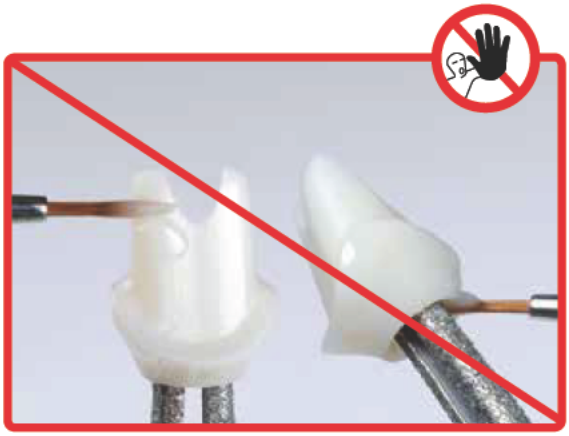
Important
– Conduct the **Corrective firing** on the IPS e.max CAD Crystallization Tray using the stipulated firing parameters.

Firing parameters see page 64

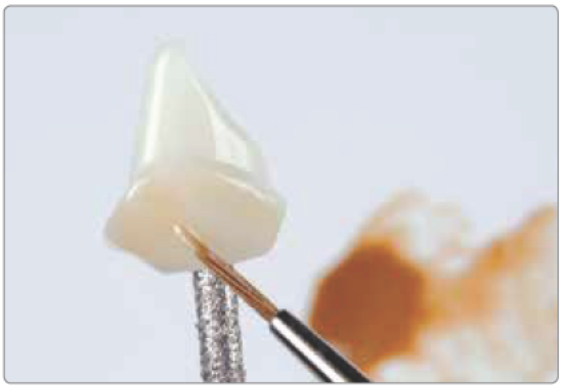
IPS e.max CAD Crystall./Glaze Paste is extruded from the syringe and mixed. If required, the paste is thinned with IPS e.max CADCrystall./Glaze Liquid.



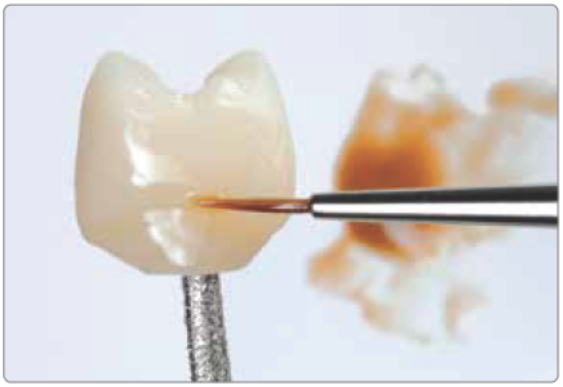
IPS e.max CAD Crystall./Glaze Paste is applied evenly on the emergence profile of the hybrid abutment or the outer surface of the hybrid abutment crown.



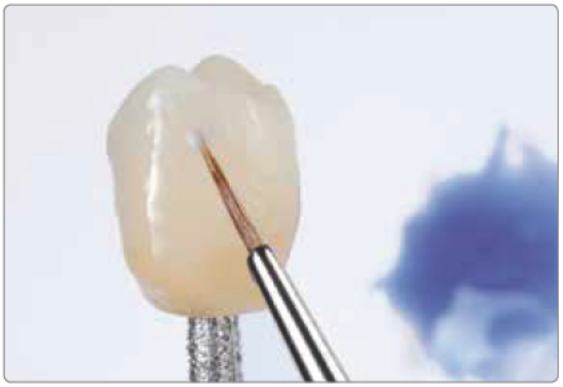
Important: The glazing material must reach neither the bonding surface to the Ti base nor the screw channel or the bonding surface to the crown, as this may compromise the accuracy of fit.



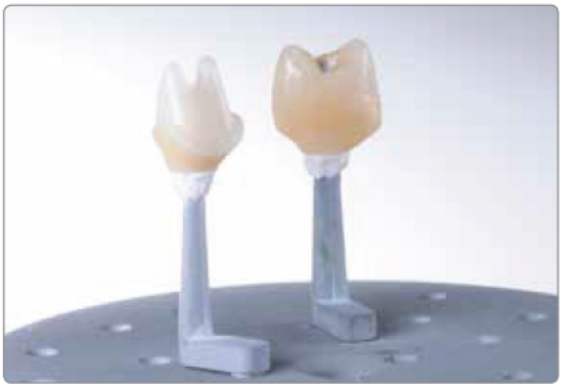
Characterizing the emergence profile with Shades



Enhancing the chroma of the buccal surface



IPS e.max CAD Crystall./Shade Incisal is applied to imitate the incisal area.



The Corrective firing is conducted on the IPS e.max CAD Crystallization Tray using the stipulated firing parameters.

Optional

Corrective firing

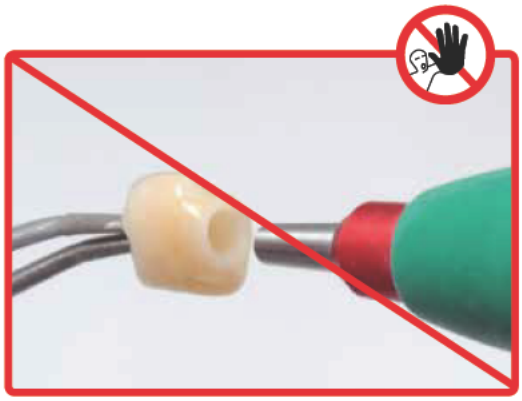
- If adjustments are required, another Corrective firing using IPS e.max CAD Crystall./Shades and Stains and Glaze can be conducted. Conduct the Corrective firing also on the IPS e.max CAD Crystallization Tray.
- For minor shape adjustments (e.g. proximal contact points), IPS e.max CAD Crystall./Add-On is available. The adjustments may be made with both Crystallization/Glaze and Corrective firing.
- The detailed procedure is described on page 33.

Once the IPS e.max CAD ceramic structure has cooled to room temperature, proceed with the following steps:

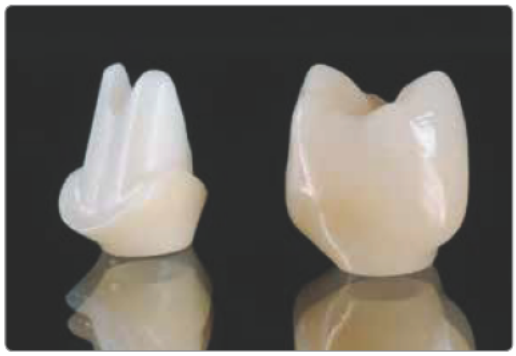
- Remove the ceramic structure from the IPS e.max CAD Crystallization Pin XS.
- Remove any residue with ultrasound in a water bath and/or with the steam jet.
- Do **not** remove residue with Al_2O_3 or glass polishing beads.
- Place the ceramic structure on the Ti base and check the fit.
- If adjustments by grinding are required, make sure that no overheating of the ceramic occurs.
- If the restoration is ground, manually polish the corresponding areas to a high gloss after grinding.

The ceramic structure is removed from the IPS e.max CAD Crystallization Pin XS.

Any residue is removed with ultrasound in a water bath or with the steam jet.



Residue **must not** be removed with Al_2O_3 or glass polishing beads.



Glazed and characterized ceramic structures (hybrid abutment and/or hybrid abutment crown)

next working step … **Permanent cementation Ti base / ceramic structure page 46**

Characterization/Glaze firing with IPS e.max Ceram

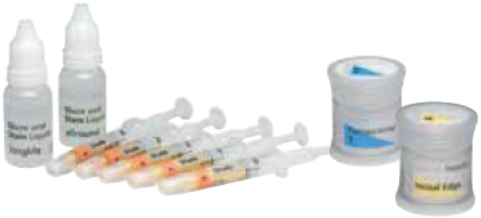
The following paragraphs will explain the steps of characterizing and glazing with **IPS e.max Ceram**.

If hybrid abutments are fabricated, only the area of the emergence profile is characterized with IPS e.max Ceram Shades, Essences and Glaze.

If hybrid abutment crowns are fabricated, the entire outer surface may be individually characterized with IPS e.max Ceram Shades, Essences, and Glaze.

Required materials

- **IPS e.max Ceram Essences** are intensively shaded stains in powder form.
- **IPS e.max Ceram Shades** are ready-to-use stains in syringes.
- **IPS e.max Ceram Glaze and Stain Liquid (allround, longlife) to mix** the materials in powder form (Essences, Glaze), as well as to thin paste materials (Shades, Glaze).

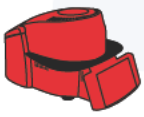


IPS e.max CAD Crystall./Shades, Stains, Glaze and IPS e.max Ceram Shades, Essence, Glaze must not be mixed with each other!

The following steps must be observed:

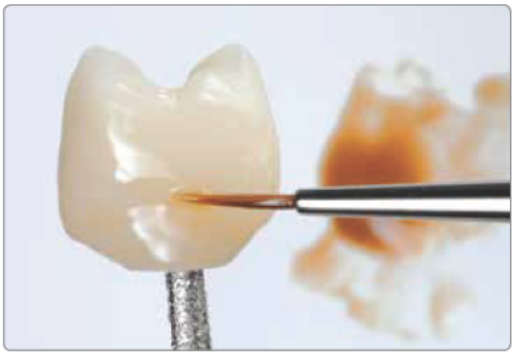
- Clean the finished ceramic structure with the steam jet to remove any contaminations and grease residue. Any contamination after cleaning must be prevented.
- For better wetting of the stains, a small quantity of IPS e.max Ceram Glaze and Stain Liquid may be slightly rubbed into the area that needs to be characterized.
- Mix the pastes or powders with the IPS e.max Ceram Glaze and Stain Liquid allround or longlife to the desired consistency.
- More intensive shades are achieved by several staining procedures and repeated firing, not by applying thicker layers.
- To imitate the incisal area and translucency of the hybrid abutment crown in the incisal and occlusal third, IPS e.max Ceram Shade Incisal may be used. The cusps and fissures can be individualized using Essences.
- If hybrid abutments are fabricated, only the area of the emergence profile is characterized with IPS e.max Ceram Shades and Essences.
- Secure the ceramic structure on the firing pin of the honey-comb tray with a little IPS Object Fix Putty or Flow for firing.

Important:
The characterization must neither reach the bonding surface to the Ti base nor the screw channel, as this may compromise the accuracy of fit. Check the interface before firing and carefully remove any contamination.
On the hybrid abutment, do not apply any materials to the bonding surface to the crown, as this may compromise the fit of the crown.

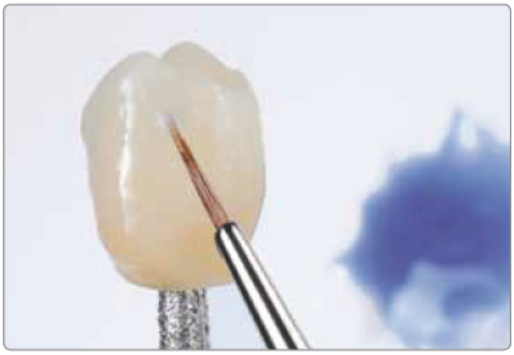


Conduct the Characterization/Glaze firing for IPS e.max Ceram on a honey-comb firing tray using the stipulated firing parameters. Firing parameters see page 64

IPS e.max Ceram Shade Incisal is applied to imitate the incisal area.



Enhancing the chroma of the buccal surface



Individual characterization of the emergence profile with IPS e.max Ceram Essences

The Stain and Characterization firing is conducted on a honey-comb firing tray.

– Remove restoration from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).
– Allow the objects to cool to room temperature in a place protected from draft.
– Do not touch the hot objects with metal tongs.

Additional Characterization firings can be conducted with the same firing parameters.

Glaze firing

Glaze firing is conducted with powder or paste glaze. On abutments, only the emergence profile is glazed. On hybrid abutment crowns, glaze is applied to the entire outer surface.

Required materials

– **IPS e.max Ceram Glaze Paste, Glaze Powder** are glazing materials in paste and powder forms.
– **IPS e.max Ceram Glaze and Stain Liquid (allround, longlife) to mix** the materials in powder form (Essences, Glaze), as well as to thin paste materials (Shades, Glaze)

IPS e.max CAD Crystall./Shades, Stains, Glaze and IPS e.max Ceram Shades, Essence, Glaze must not be mixed with each other!

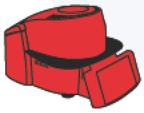
The following procedure is recommended:

- For easier handling, the ceramic structure can be positioned on the Ti base for glazing. For that purpose, secure Ti base on a model analog.
- Mix the glazing material (IPS e.max Ceram Glaze Paste or Powder) with the IPS e.max Ceram Glaze and Stain Liquid allround or longlife to the desired consistency.
- Apply an even layer of glazing material covering all areas that are to be glazed.
- If required, the fluorescence may be increased by applying a fluorescing glazing material (paste or powder).

Important:

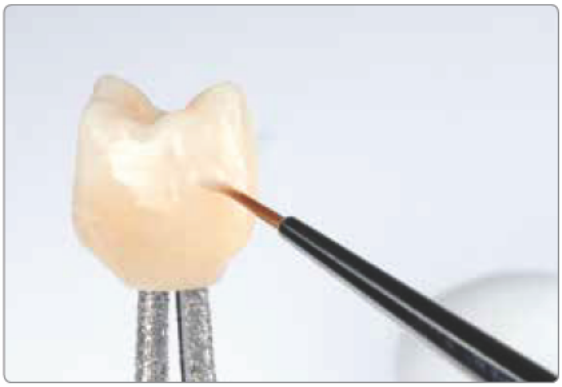
The glazing material **must neither reach the bonding surface** to the Ti base nor the screw channel, as this may compromise the accuracy of fit. Check the interface before firing and carefully remove any contamination. On the abutment, do not apply any glaze to the bonding surface to the crown, as this might compromise the fit of the crown.

The **IPS e.max CAD Crystall./Glaze Spray** is not recommended for glazing IPS e.max CAD Abutment Solutions, as is requires very targeted application. The glazing material must neither reach the bonding surface to the Ti base nor the screw channel, as this may compromise the accuracy of fit.

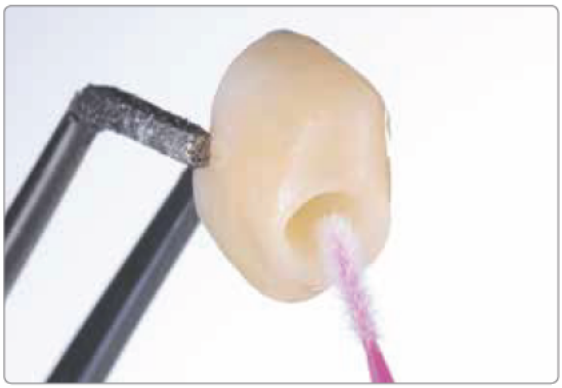


Conduct the Characterization/Glaze firing for IPS e.max Ceram on a honey-comb firing tray using the stipulated firing parameters. Firing parameters see page 64

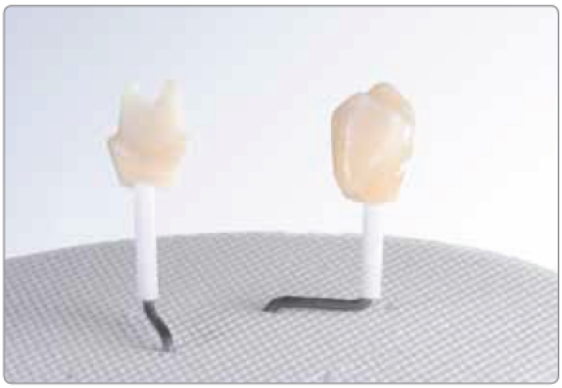
An even layer of glaze material is applied to the emergence profile of the hybrid abutment. Care has to be taken that no glaze material enters the screw channel.



The glazing material is applied evenly on the outer surface of the hybrid abutment crown. Care has to be taken that no glaze material enters the screw channel.



Care has to be taken that no glaze material is present on the interface of the hybrid abutment and hybrid abutment crown prior to the firing cycle. The glaze material is carefully removed, if necessary.



The Characterization/Glaze firing is conducted on a honey-comb firing tray with the corresponding parameters.

– Remove restoration from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).
– Allow the objects to cool to room temperature in a place protected from draft.
– Do not touch the hot objects with metal tongs.

Optional

Shape adjustments of IPS e.max Ceram Add-On

Use IPS e.max Ceram Add-On Dentin and/or Incisal for shape adjustments after Glaze firing. Please observe the following procedure for processing:

– Mix IPS e.max Ceram Add-On Dentin or Incisal with IPS e.max Ceram Build-Up Liquid soft or allround and apply on the corresponding areas.
– Fire with the stipulated parameters for the "Add-On after Glaze firing". Observe long-term cooling!
– If necessary, polish the adjusted areas to a high gloss after firing.

Firing parameters see page 64

next working step ... **Permanent cementation Ti base / ceramic structure page 46**

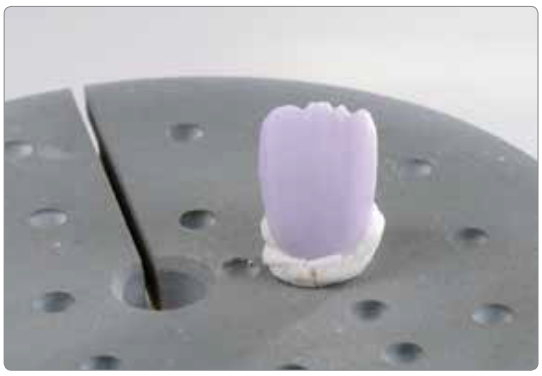
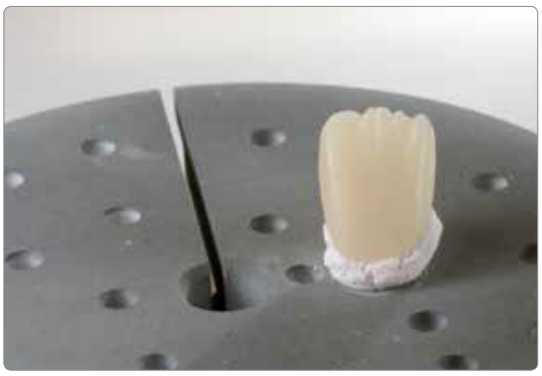
IPS e.max® CAD Abutment Solutions

Crown on IPS e.max CAD hybrid abutment

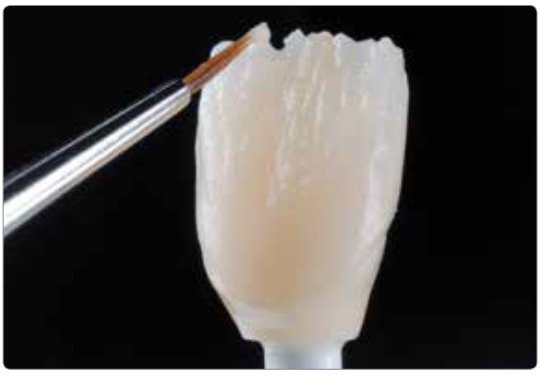
The crown on the IPS e.max Hybrid Abutment can be completed using either the staining technique or the cut-back technique. To characterize and glaze, either the PS e.max CAD Crystall./ materials or the IPS e.max Ceram materials are used.

Basically, the procedure for completing a crown is the same as that for a crown on a prepared tooth. For detailed information about the procedure, please refer to the IPS e.max CAD Instructions for Use.
Example: IPS e.max CAD crown – Cut-back technique – IPS e.max Ceram

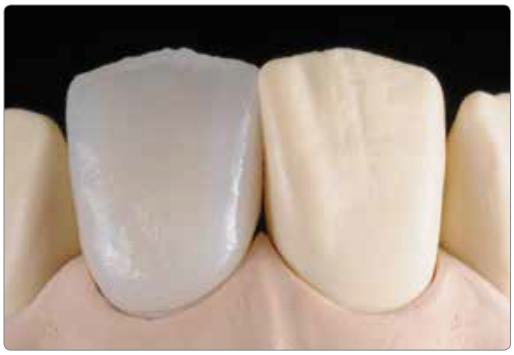

Partially reduced IPS e.max CAD restorations fitted on the model. Always observe minimum thicknesses!

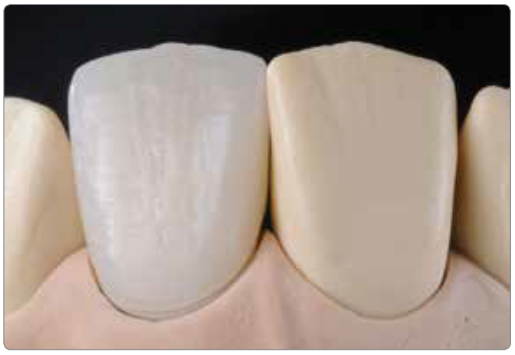
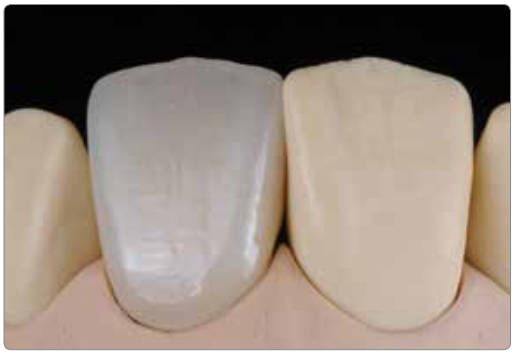
For crystallization, the partially reduced IPS e.max CAD restorations are placed directly on the IPS e.max CAD Crystallization Tray using IPS Object Fix Putty or Flow.



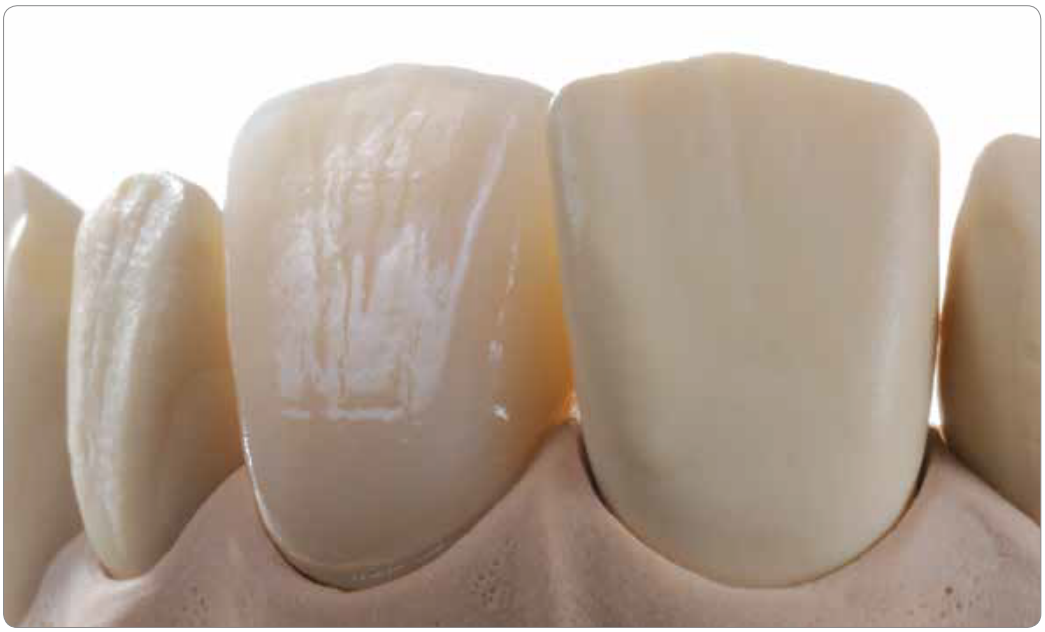

The wash firing is conducted using e.g. IPS e.max Ceram Glaze, Shades and Essences.

Completion of the anatomical shape of the reduced areas using IPS e.max Ceram Incisal and Opal materials

Finishing with diamond burs and design of a true-to-nature shape and surface structure Finally, glaze firing is conducted using IPS e.max Ceram Glaze.



IPS e.max CAD crown after glaze firing (partially reduced and veneered with IPS e.max Ceram) on a IPS e.max CAD hybrid abutment

IPS e.max CAD Abutment Solutions

Permanent cementation of base / ceramic structure

Careful preparation of the bonding surface is a prerequisite for the successful adhesive cementation of the base and the ceramic structure. The following paragraphs outline the required procedure. The procedure is the same for hybrid abutments and hybrid abutment crowns.

Required materials
- IPS Ceramic Etching Gel
- Monobond® Plus
- Multilink® Hybrid Abutment
- Glyceringel (z.B. Liquid Strip)

	IPS e.max CAD ceramic structure (LS_2)	Base
Blasting	–	According to the instructions of the manufacturer
Etching	Bonding area to the base with IPS® Ceramic Etching Gel for 20 s	–
Conditioning	The bonding area with Monobond® Plus for 60 s	
Adhesive cementation	Multilink® Hybrid Abutment	
Covering the cementation joint	Glycerine gel, e.g. Liquid Strip	
Curing	7 minutes auto-polymerization	
Polishing the cementation joint	Conventional polishers for ceramic/composite resin	

Preparation of the Ti base

The following procedure should be observed in the preparation of the Ti base for the cementation with the ceramic structure:
- The Ti base should be prepared according to the instructions of the manufacturer.
- Clean the Ti base with an ultrasonic bath or with a steam cleaner and then dry it with blown air.
- Screw the Ti base on the model analog.
- Place the ceramic structure on the Ti base and mark the relative position of the components with a waterproof pen. This facilitates locating the correct position when the parts are assembled at a later stage.
- The emergence profile of the base must not be blasted or modified in any way.
- **If the manufacturer recommends that the bonding surface of the Ti base be blasted, the following procedure should be observed**:
  - Apply silicone (Virtual Extra Light Body Fast Set) to protect the emergence profile and the screw channel .
  - Carefully blast the bonding area according to the instructions of the manufacturer.
  - Remove silicone.
  - Clean the Ti base with ultrasound in a water bath or with the steam jet.
  - After cleaning, the bonding surface must not be contaminated under any circumstances, as this would impair the bond.
- Apply Monobond Plus on the clean bonding surface and allow it to react for 60 s. After the reaction time, disperse any residue with air that is free of water and oil.
- Seal the screw channel with a foam pellet or wax. The bonding surface must not be contaminated in the process.

The Ti base is screwed on the model analog. The relative position to the ceramic structure is marked with a waterproof pen.

E.g. silicone (Virtual Extra Light Body Fast Set) is applied in order to protect the emergence profile and the screw channel.

The bonding surface can be carefully blasted **according to the instructions of the manufacturer.**

Removal of the silicone and subsequently cleaning with ultrasound in a water bath or with the steam jet.

Monobond Plus is applied to the clean bonding surface and allowed to react for 60 s. After the reaction time, any remaining residue is dried with blown air that is free of water and oil.

The screw channel is sealed with a foam pellet or wax. The bonding surface must not be contaminated in the process.

Preparing the ceramic structure

The following procedure must be observed in the preparation of the ceramic structure for cementation on the Ti base:

- Do **not** blast the ceramic structure in preparation for the cementation.
- Clean the ceramic structure in an ultrasonic bath or with a steam cleaner and subsequently blow dry.
- After cleaning, the bonding surface must not be contaminated under any circumstances, as this would impair the bond.
- Wax can be applied to protect the outer surfaces or the glazed areas.
- Etch the bonding surface with 5% hydrofluoric acid gel (IPS Ceramic Etching Gel) for 20 s.
- Subsequently, thoroughly rinse the bonding surface under running water and dry with air that is free of water and oil.
- Apply Monobond Plus on the clean bonding surface and allow it to react for 60 s. After the reaction time, dry any remaining residue with blown air that is free of water and oil.

The ceramic structure **must not** be blasted.

Etching with IPS Ceramic Etching Gel for 20 seconds. Subsequently, the restoration is rinsed with water and blown dry.

Monobond Plus is allowed to react for 60 s, and excess is blown dry.

Cementation with Multilink® Hybrid Abutment

The following instructions must be observed in the cementation procedure:

- The cleaned and conditioned components (ceramic structure, Ti base) are laid out ready for cementation.
- **The subsequent cementation procedure must be carried out quickly and without interruption. The working time of Multilink Hybrid Abutment is approximately 2 min at 23 °C (± 1 °C) or 73 °F (± 1.8 °F).**
- As a general rule, a new mixing tip is attached to the Multilink Hybrid Abutment syringe prior to each use.
- Apply a thin layer of Multilink Hybrid Abutment directly from the mixing syringe to the bonding surface of the Ti base and **the bonding surface of the ceramic structure**.
- The mixing tip is left on the Multilink Hybrid Abutment syringe until the next use. The remaining cement polymerizes in the tip and functions as a seal.
- Place the ceramic structure on the Ti base in such a way that the position markings are aligned.
- Press the parts lightly and evenly together and check the correct relative position of the components (transition Ti base/ ceramic structure).
- Subsequently, press the parts tightly together for 5 s.
- Carefully remove excess in the screw channel, e.g. with a Microbrush or brush, using rotary movements.

Important:

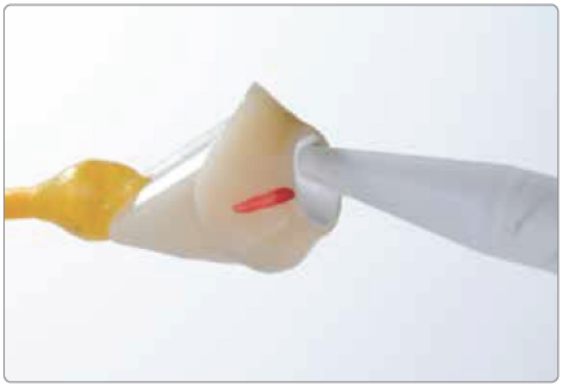
- **Important: Excess must not be removed before curing has started, i.e. 2-3 minutes after mixing. For the purpose, a suitable dental lab instrument (e.g. Le Cron) is used. The components are held in place with light pressure in the process**.

- Glycerine gel is applied (e.g. Liquid Strip) on the cementation joint to prevent the formation of an inhibition layer. The glycerine gel must be applied cautiously to avoid blending it with or displacing the composite. Make sure to leave the gel on the cementation joint until polymerization is complete.
- Next, the luting composite is completely auto-polymerized within 7 min.
- **Important: Do not move the components until Multilink Hybrid Abutment has completely cured. They can be held immobile with e.g. diamond-coated tweezers.**
- After the completion of auto-polymerization, rinse off the glycerine gel with water.
- **Make sure to cautiously polish the cementation joint with rubber polishers at a low speed (< 5,000 rpm) to avoid overheating**.
- Remove any cement residue left in the screw channel with suitable rotating instruments.
- Clean the restoration with ultrasound in a water bath or with the steam jet.

The cleaned and conditioned components are laid out ready for cementation.

A new mixing tips is attached to the Multilink Hybrid Abutment prior to each use. The Multilink Hybrid Abutment mixing syringe is attached.

A thin layer of Multilink Hybrid Abutment is directly applied from the mixing tip to the bonding surface of the Ti base.



A thin layer of Multilink Hybrid Abutment is directly applied from the mixing tip on the bonding surface of the ceramic structure.

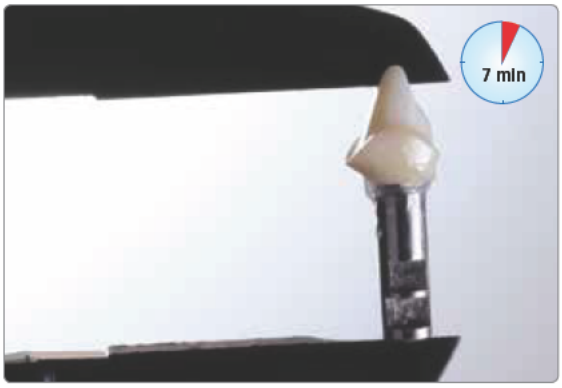
The ceramic structure is placed on the Ti base in such a way that the position markings are aligned. The components are joined using even and light pressure and the relative position of the components is checked (transition base/ceramic structure).

Subsequently, the components are tightly pressed together for 5 s.

Excess in the screw channel is carefully removed, e.g. with a Microbrush or brush, using rotary movements.

Important: Excess must not be removed before **curing has started, i.e. 2–3 minutes after mixing.** The components are held in place with light pressure in the process.

Glycerine gel (e.g. Liquid Strip) is applied on the cementation joint to prevent the formation of an inhibition layer.

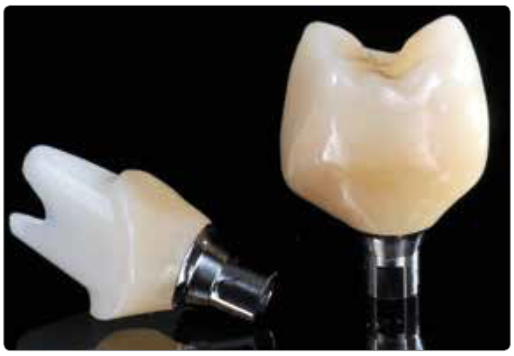


The luting composite auto-polymerizes within 7 min.
Important: The components must not be moved until auto-polymerization is completed. The components must be immobilized during this time.

After the completion of auto-polymerization, the glycerine gel is rinsed off with water.

The cementation joint is cautiously polished with rubber polishers at low speed (< 5,000 rpm), to avoid overheating.

Any remaining cement residue in the screw channel is removed with suitable rotating instruments. The Ti base must no be damaged.



Completed hybrid abutment and hybrid abutment crown after cementation

IPS e.max CAD Abutment Solutions

Seating and Aftercare

Sterilization

The hybrid abutments or hybrid abutment crowns must be sterilized prior to insertion. Furthermore, the locally applicable legal regulations and the hygiene standards applicable for a dental practice must be observed.

Steam sterilization can be performed with the 3 x fractionated pre-vacuum with the following parameters: Sterilization time 3 min; steam temperature 132 °C/270 °F; resulting in a half-cycle exposure time of 1.5 min. The abutment is for immediate use. No storage after sterilization!

The responsibility for the sterility of the hybrid abutment or hybrid abutment crown lies with the user. It must be ensured that only suitable devices, materials and product-specifically validated methods are used to perform sterilization.
The equipment and devices must be properly maintained and serviced at regular intervals. The fabricator (dental technician) of the IPS e.max CAD Abutment Solution must inform the dentist of the need to sterilize the abutment before inserting it in the patient's mouth!

Intraoral preparation

Please observe the following procedure to prepare for the permanent cementation of the implant-supported restoration:
- Remove the temporary restoration.
- Clean the implant site.
- Check the periimplant tissue (emergence profile).

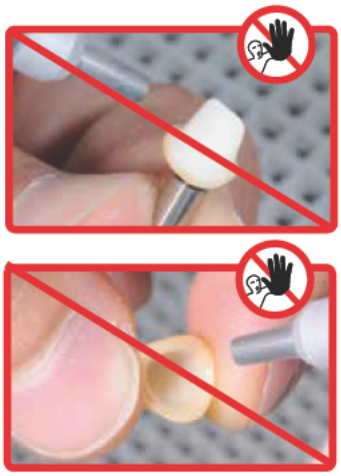
Seating the hybrid abutment and crown

Preparing/conditioning the hybrid abutment with dedicated crown

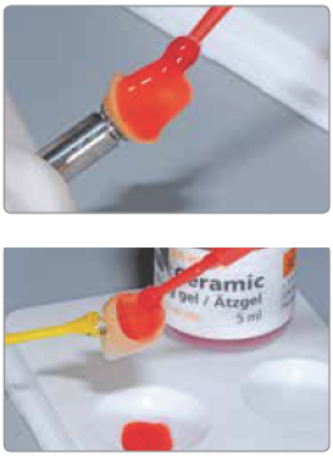
Conditioning of the ceramic surface, i.e. the bonding surface, in preparation for cementation is critical for generating a sound bond between the cementation material and the all-ceramic material.

The following procedure must be observed in the preparation of the ceramic structure for cementation on the Ti base:

- Do **not** blast IPS e.max CAD hybrid abutment or IPS e.max CAD crown with Al_2O_3 or glass polishing beads.
- Ideally, the clinical try-in is conducted before etching to prevent contamination of the bonding surface.
- Thoroughly clean the hybrid abutment and crown with water and subsequently blow dry.
- Etch the bonding surface with 5% hydrofluoric acid gel (IPS Ceramic Etching Gel) for 20 s. The etching gel must not come into contact with the emergence profile or the outer side of the crown. **Important: No intraoral application of the IPS Ceramic Etching Gel**.
- Subsequently, thoroughly rinse the bonding surface under running water and dry it with air that is free or water and oil.
- If an adhesive or self-adhesive cementation protocol is used, apply Monobond Plus to the clean bonding surface and allow it to react for 60 s. After this reaction time, disperse any residue with air that is free of water and oil.



The IPS e.max CAD ceramic structures **must not** be blasted in preparation for cementation.



The bonding surfaces are etched with IPS Ceramic Etching Gel and subsequently cleaned.

Monbond Plus is applied to the bonding surfaces, and allowed to react for 60 s. Excess is dispersed with air.

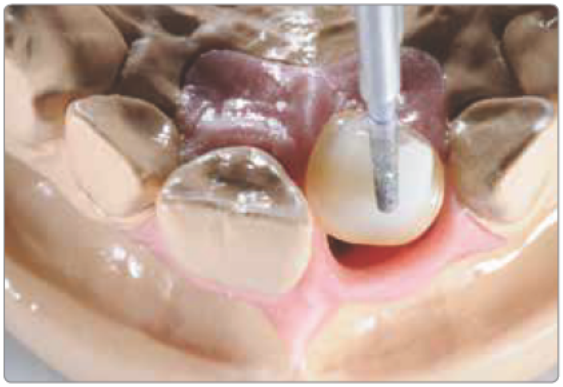
Seating the hybrid abutment and dedicated crown

Note:
Temporary insertion of the IPS e.max CAD crown on the IPS e.max CAD hybrid abutment is contraindicated!

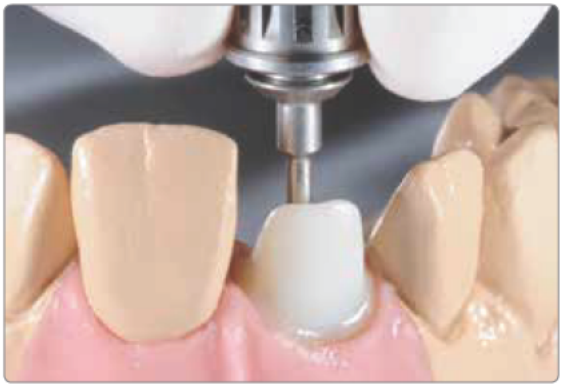
For the permanent seating of the hybrid abutment and the crown, please observe the following working steps. Please also observe the Instructions for Use of the selected luting material.

SpeedCEM® is recommended for the seating of IPS e.max CAD crowns on IPS e.max hybrid abutments.

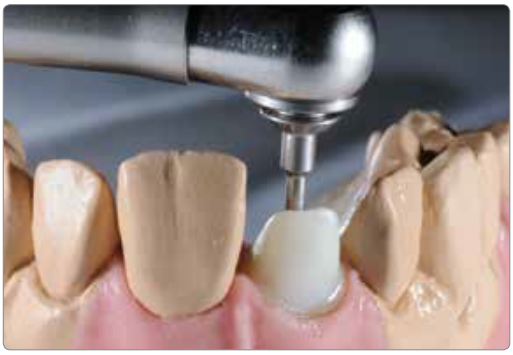
- Do not use phenolic mouth washes, as such products negatively influence the bond between the ceramic and the composite.
- Insert the hybrid abutment intraorally into the implant.
- Manually screw in the matching implant screw.
- Tighten the implant screw with a torque wrench (observe the instructions of the manufacturer).
- Insert a cotton or foam pellet into the screw channel.
- Seal the screw channel with a temporary composite (e.g. Telio® CS Inlay). This serves to ensure access to the screw at a later stage.
- Check the bonding area for contamination/moisture and clean or dry with an air syringe, if necessary.
- Apply the luting material, **e.g. SpeedCEM**, into the conditioned crown.
- Place the crown onto the hybrid abutment and secure in place in the final position.
- Conduct the pre-polymerization using the four-quarter technique.
- Remove excess luting material.
- Cover the cementation joint with glycerine gel (e.g. Liquid Strip).
- Polymerize with an LED curing light (e.g. Bluephase®).
- Rinse off the glycerine gel with water.
- Check the occlusion and articulation and make adjustments, if necessary. If adjustments are made to the restoration by grinding, these areas must subsequently be polished to a high gloss, e.g. using OptraFine.
- Polish restoration margins and the cementation joint with silicone polishers (e.g. Astropol®, OptraFine).
- Apply Cervitec Plus in the area of the gingival margin.



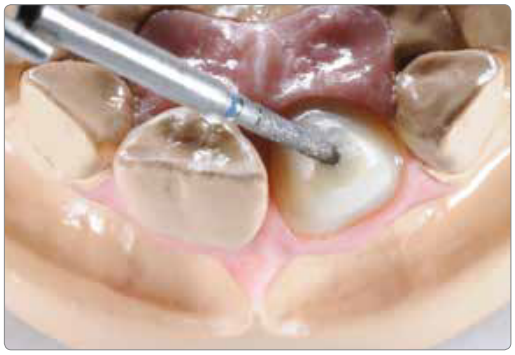
The hybrid abutment is inserted into the implant intraorally.



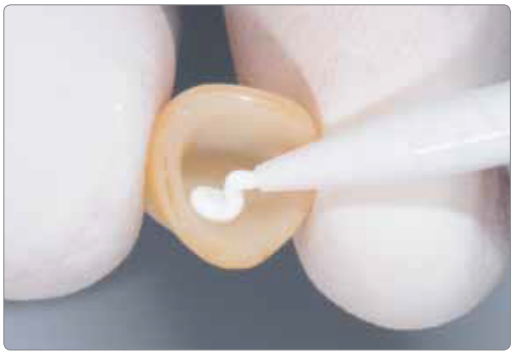
The matching implant screw is screwed in manually.



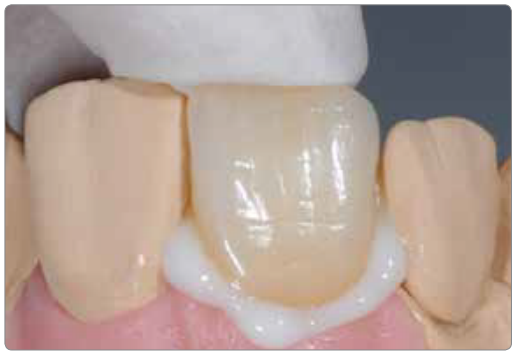
The implant screw is tightened with a torque wrench (the instructions of the manufacturer must be observed).



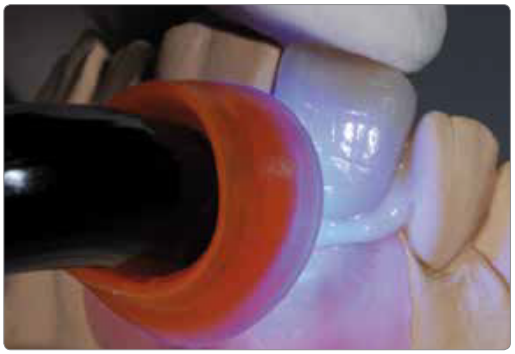
The screw channel is sealed, for instance with a cotton or foam pellet and a temporary composite material.



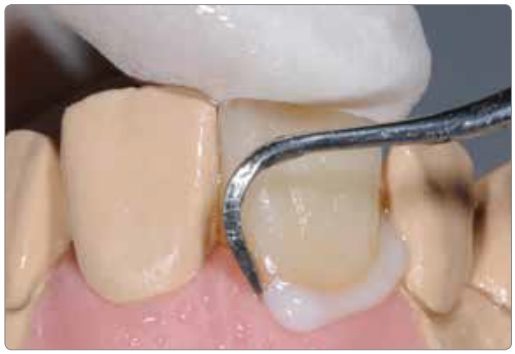
The luting material, e.g. SpeedCEM, is applied into the conditioned crown.



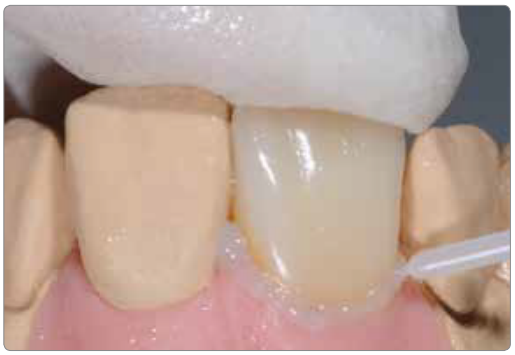
The crown is placed on the hybrid abutment and secured in place.



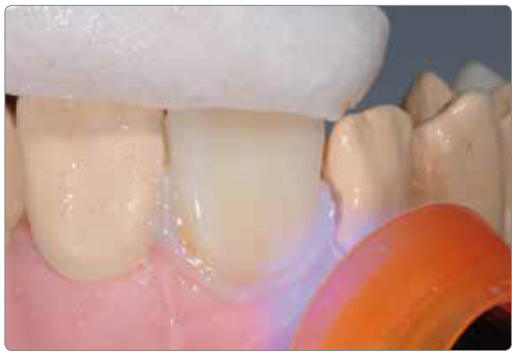
Pre-polymerization using the four-quarter technique



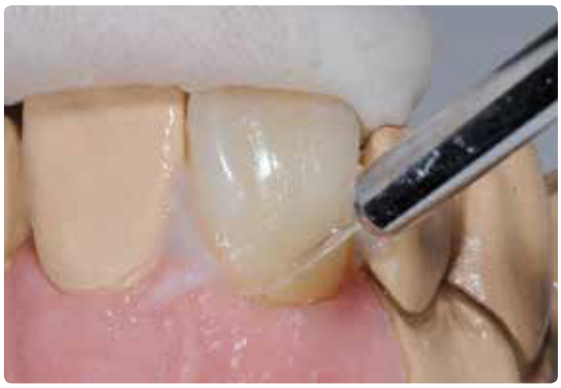
Excess luting material is removed.



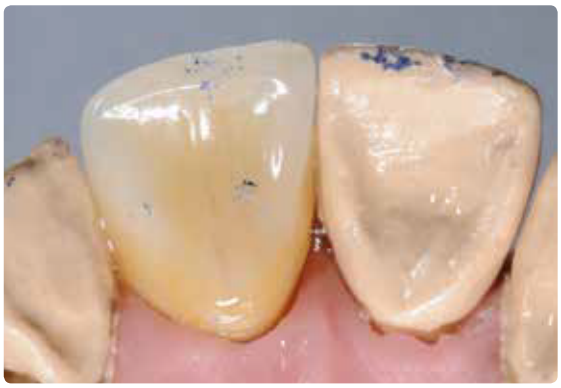
The restoration margin is covered with glycerine gel (e.g. Liquid Strip).



The luting material is cured with an LED curing light (e.g. Bluephase).



The glycerine gel is rinsed off with water.



The occlusion and articulation is checked and adjustments are made, if necessary.

The restoration margins and the cementation joint are polished (e.g. OptraPol, OptraFine).

Completed IPS e.max CAD hybrid abutment and crown

Seating the hybrid abutment crown

Preparing/Conditioning the Hybrid Abutment Crown

Please observe the following notes to prepare for the intraoral sealing of the screw channel:

- As a general rule, do **not** blast IPS e.max CAD hybrid abutment crowns with Al_2O_3 or glass polishing beads.
- Thoroughly clean the the hybrid abutment crown with water and blow dry.
- Etch the screw channel from the occlusal side with 5% hydrofluoric acid gel (IPS Ceramic Etching Gel) for 20 seconds. Make sure that no etching gel comes into contact with the occlusal surface. **Important: Do not use the IPS Ceramic Etching Gel intraorally**.
- Thoroughly rinse off the etching gel with water and dry with oil- and water-free air.
- Apply Monobond Plus to the etched and cleaned surface in the screw channel, allow to react for 60 seconds and then disperse excess with oil- and water-free air.

IPS e.max CAD ceramic structures **must not** be blasted.

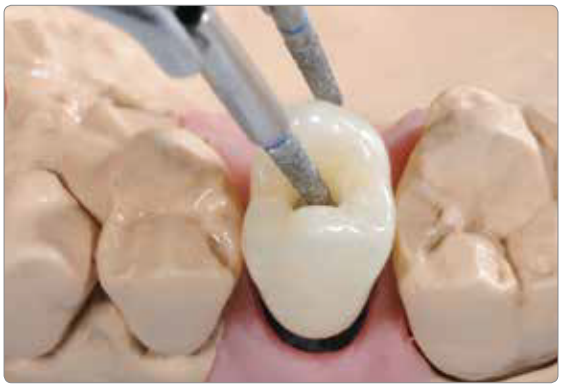
The screw channel is etched with IPS Ceramic Etching Gel for 20 s and subsequently cleaned.

Monobond Plus is applied, allowed to react for 60 s and excess is dispersed.

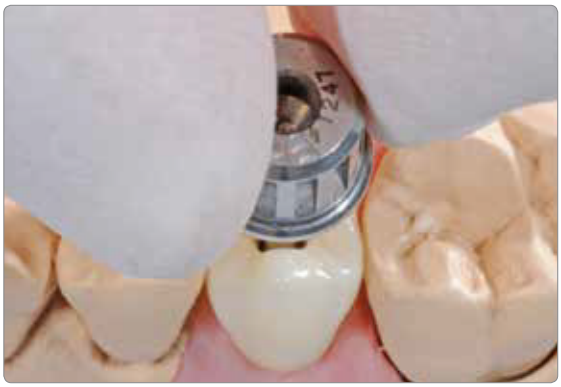
Seating the hybrid abutment crown

For the permanent seating of the hybrid abutment crown, please observe the following working steps:

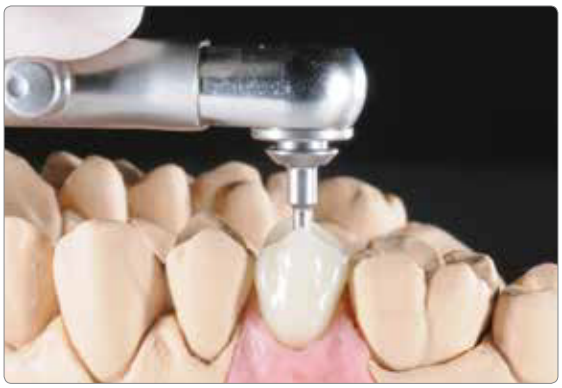
- Do not use phenolic mouth washes, as such products negatively influence the bond between the ceramic and the composite.
- Insert the hybrid abutment crown intraorally into the implant.
- Manually screw in the matching implant screw.
- Tighten the implant screw with a torque wrench (observe the instructions of the manufacturer).
- Check the screw channel for contamination/moisture and clean with Total Etch (phosphoric acid gel), if necessary.
- Insert a cotton or foam pellet into the screw channel.
- Apply the bonding agent, followed by polymerization.
- Seal the screw channel with a composite material (e.g. Tetric EvoCeram) in the appropriate shade.
- Polymerize with an LED curing light (e.g. Bluephase).
- Check the occlusion/articulation after polymerization and correct possible rough spots with suitable fine-grit diamonds.
- Polish to a high gloss with silicone polishers (e.g. OptraPol/OptraFine).



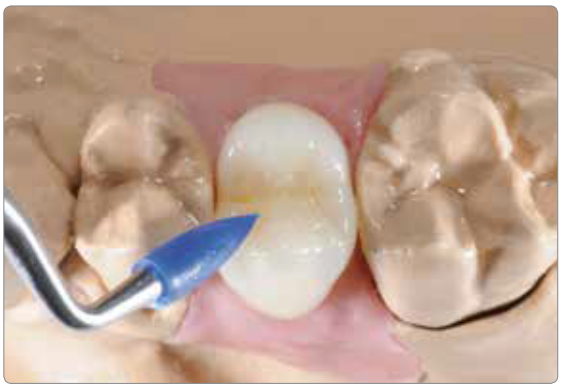
The hybrid abutment crown is inserted into the implant intraorally.



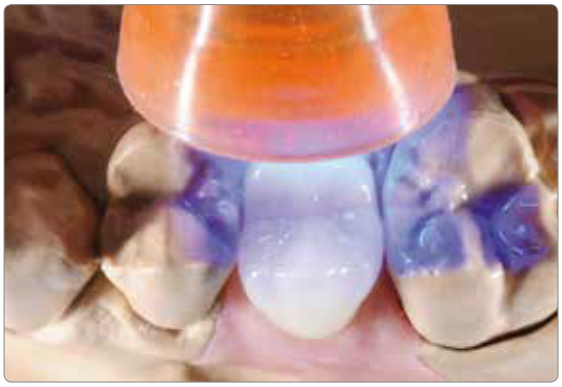
The matching implant screw is screwed in manually.



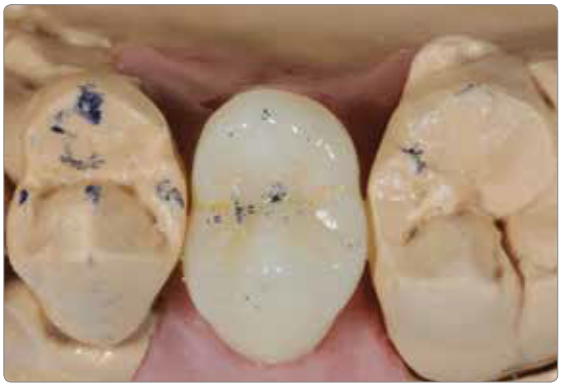
The implant screw is tightened with a torque wrench (the instructions of the manufacturer must be observed).



The screw channel is sealed with a composite material (e.g. Tetric EvoCeram) in the appropriate shade.

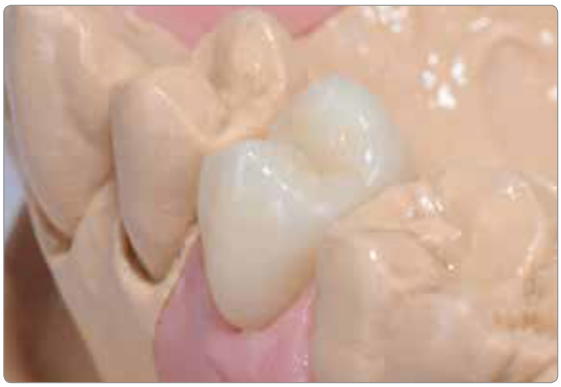


Polymerization with an LED curing light (e.g. Bluephase)



After polymerization, the occlusion/articulation is checked and possible rough spots are adjusted with suitable finishers or fine diamonds.

High-gloss polishing is performed using silicone polishers (e.g. Astropol P, Astropol HP or Astrobrush).



Completed IPS e.max CAD hybrid abutment crown

Care notes – Implant Care

Implant Care comprises a range of coordinated products for the professional care of patients during the various phases of implant treatment and lifelong aftercare. Products for professional tooth cleaning and bacterial control contribute to the long-term quality assurance of implant-supported restorations. Structural elements peri-implant tissue, natural teeth, dental restorations, gingiva and the mucosa are treated in an optimum way with regard to function and esthetics.

IPS e.max CAD Abutment Solutions

General Information

Frequently Asked Questions

In addition to the desired tooth shade, why should the root shade also be defined/determined upon shade determination?

IPS e.max CAD Abuttment Solutions allow you to fabricate restorations with a lifelike appearance both in the visible area and the area below the gingiva (root). By defining the root shade, a highly esthetic outcome can be achieved especially in the case of receding gingiva.

Is it possible to fabricate an abutment or an abutment crown with IPS e.max CAD (LS_2) without using a Ti base?

No! *For this indication, IPS e.max CAD needs the support provided by the Ti base. In addition, the Ti base allows an optimum (industrially fabricated) fit to the implant to be achieved.*

Which Ti bases can be used for the fabrication of IPS e.max CAD Abutment Solutions?

Only Ti bases of authorized CAD/CAM systems may be used. More information about the CAD/CAM cooperation systems is available on the Internet from www.ivoclarvivadent.com.

Is it permissible to modify the selected Ti base?

The Ti base must not be adjusted by grinding, as this would compromise the fit of the IPS e.max CAD ceramic structure.
The instructions of the manufacturer regarding the preparation for permanent cementation must be observed.

Is a hybrid abutment crown indicated in the anterior region?

This indication depends on the position and inclination of the implant. If the opening of the screw channel is located on the oral surface, a hybrid abutment crown may be fabricated in the anterior region.

May a hybrid abutment crown be cut-back and subsequently supplemented with IPS e.max Ceram layering materials.?

No. For implant-supported restorations, it is recommended to fabricate monolithic restorations (without veneer). In this way, chipping of the layering ceramic is prevented.

Do IPS e.max CAD ceramic structures have to be glazed in all cases?

No. High gloss can also be achieved by a corresponding polishing procedure. The polishing technique (before crystallization) is preferably used for the emergence profile of the hybrid abutment. For the hybrid abutment crown, the application of glaze is recommended.

Is it possible to use an IPS e.max CAD hybrid abutment as an abutment for a bridge restoration?

No. Only single-tooth restorations may be fabricated.

Can different CAM units be used for milling the IPS e.max CAD ceramic structure (abutment) and the dedicated IPS e.max CAD crown?

If different CAM units are used, inaccuracies of fit may occur in unfavourable cases. Therefore, both IPS e.max CAD objects (abutment, crown) should be ideally milled in the same CAM unit.

Can a clinical try-in be conducted with the IPS e.max CAD Abutment Solutions? How are the ceramic structures prepared for this?

Yes. Clinical try-in may be performed either before or after crystallization of the IPS e.max CAD ceramic structures. The Ti base and IPS e.max CAD ceramic structure are temporarily joined in the laboratory by means of a silicone material, e.g. Virtual Extra Light Body Fast Set. This facilitates the intraoral handling during clinical try-in with the patient.

What must be observed for the clinical try-in of a crown on a hybrid abutment?

To check the occlusion/articulation and to make possible adjustments, the crown must be temporarily secured on the hybrid abutment with a silicone material, e.g. Virtual Extra Light Body Fast Set. The silicone material acts as a buffer and prevents chipping in the marginal area of the crown. Try-in pastes or Vaseline must not be used for functional checks.

Can a glaze spray be used for glazing IPS e.max CAD ceramic structures (e.g. IPS e.max CAD Crystall./Glaze Spray)?

We do not recommend using the Glaze Spray for the indications hybrid abutment or hybrid abutment crown, as there is a risk that the bonding surface to the Ti base or the scew channel are contamination with glaze.

What material is used to permanently cement the IPS e.max CAD ceramic structures to the Ti base?

Only Multilink Hybrid Abutment is to be used for permanent cementation. This ensures a high-quality bond. Given the high opacity of the luting composite, complete optical masking of the Ti base is achieved and thus an excellent esthetic appearance ensured.

How is the Ti base prepared for the permanent cementation with Multilink Hybrid Abutment?

Provided it has been approved by the manufacturer, carefully blast the bonding area with Al_2O_3 at low pressure until an even mat surface has been achieved. After cleaning, the area is conditioned with Monobond Plus.

How is the screw channel of a hybrid abutment crown sealed after seating?

The screw channel is extraorally conditioned (etching, silanating). After the restoration has been intraorally screwed down on the implant, the screw channel is sealed with a restorative composite.

IPS e.max CAD hybrid abutment and IPS e.max CAD dedicated crown

The material is selected on the basis of the desired tooth shade (Bleach BL or A–D). Depending on the geometry of the hybrid abutment and the crown, shade adjustment by means of characterization with IPS e.max CAD Crystall./Shades, Stains, or IPS e.mx Ceram Shades and Essences may be necessary to achieve the desired shade.
The block recommendations for the hybrid abutment have been selected in such a way that the desired tooth shade is achieved in combination with the crown. In the "cervical area", it may be necessary to characterize the hybrid abutment according to the clinical situation.

	Desired tooth shade	Bleach BL and A-D Shade Guide																			
		BL1	BL2	BL3	BL4	A1	A2	A3	A3.5	A4	B1	B2	B3	B4	C1	C2	C3	C4	D2	D3	D4
Material combination to achieve the tooth shade		Ti base																			
	Extraoral cementation IPS e.max CAD abutment / Ti base	Multilink Hybrid Abutment HO 0*																			
	IPS e.max CAD ceramic structure	M0 0				M0 1		M0 2		M0 3	M0 1		M0 3		M0 1		M0 4			M0 3	
	Intraoral cementation Crown on hybrid abutment	Adhesive, self-adhesive or conventional cementation, e.g. SpeedCEM																			
	IPS e.max CAD crown	LT BL1	LT BL2	LT BL3	LT BL4	LT A1	LT A2	LT A3	LT A3.5	LT A4	LT B1	LT B2	LT B3	LT B4	LT C1	LT C2	LT C3	LT C4	LT D2	LT D3	LT D4

* The range of products may vary from country to country.

IPS e.max CAD hybrid abutment crown

The material is selected on the basis of the desired tooth shade (Bleach BL or A–D). Depending on the geometry of the hybrid abutment crown, shade adjustment by means of characterization with IPS e.max CAD Crystall./Shades, Stains, or IPS e.mx Ceram Shades and Essences may be necessary to achieve the desired shade. In the "cervical area", it may be necessary to characterize the hybrid abutment crown according to the clinical situation.

	Desired tooth shade	Bleach BL and A-D Shade Guide																			
		BL1	BL2	BL3	BL4	A1	A2	A3	A3.5	A4	B1	B2	B3	B4	C1	C2	C3	C4	D2	D3	D4
Material combination to achieve the tooth shade		Ti base																			
	Extraoral cementation IPS e.max CAD abutment crown / Ti base	Multilink Hybrid Abutment HO 0*																			
	IPS e.max CAD ceramic structure	LT BL1[1]	LT BL2	LT BL3[1]	LT BL4[1]	LT A1	LT A2	LT A3	LT A3.5	LT A4[1]	LT B1	LT B2	LT B3[1]	LT B4[1]	LT C1	LT C2	LT C3[1]	LT C4[1]	LT D2	LT D3[1]	LT D4[1]

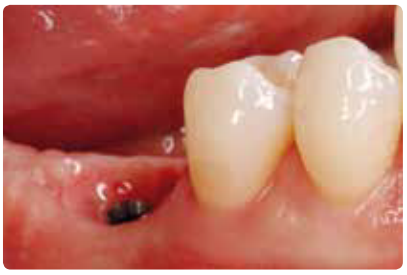
* The range of products may vary from country to country.

[1] IPS e.max CAD LT Blocks are available in 10 shades. To create the desired tooth shade, select the closest block shade in the respective shade group and determine the restoration shade by means of Stains.

Clinical Cases

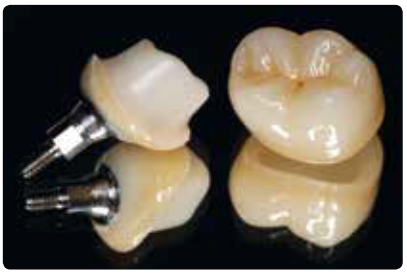
IPS e.max CAD hybrid abutment / IPS e.max CAD-crown

Dr. R. Watzke / F. Perkon, Ivoclar Vivadent, Liechtenstein

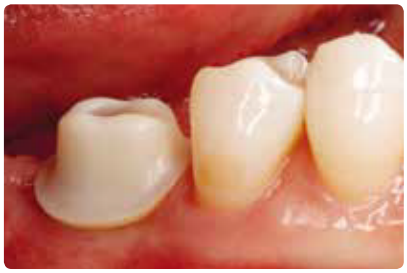


Starting situation with shaped emergence profile

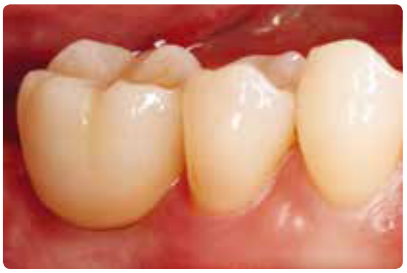
IPS e.max CAD ceramic structure (abutment) / IPS e.max CAD crown, milled



IPS e.max CAD hybrid abutment / IPS e.max CAD crown, completed



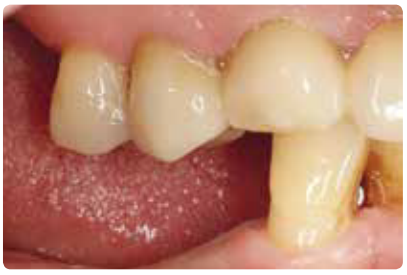
Screwed in IPS e.max CAD hybrid abutment



IPS e.max CAD crown on IPS e.max CAD hybrid abutment, cemented

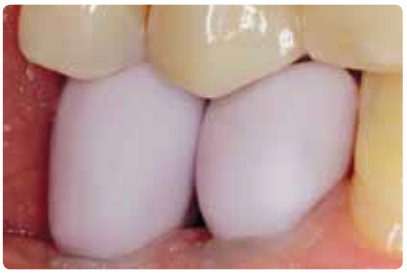
IPS e.max CAD hybrid abutment crown

Dr. L. Enggist / P. Scherrer, Ivoclar Vivadent, Liechtenstein

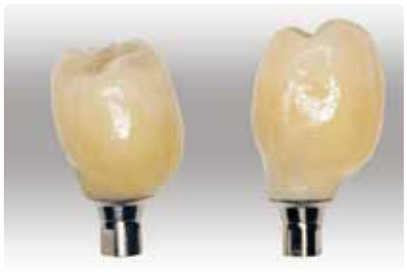


Starting situation

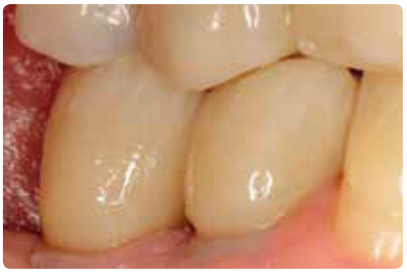
IPS e.max CAD hybrid abutment crowns (prepared for clinical try-in)



Try-in of the IPS e.max CAD hybrid abutment crowns



Completed IPS e.max CAD hybrid abutment crowns



Seated IPS e.max CAD hybrid abutment crowns

Crystallization and Firing Parameters

Crystallization/Combination firing: IPS e.max CAD MO – optional for LT

with or *without* application of IPS e.max CAD Crystall./ materials

Furnaces	Stand-by temperature B [°C/°F]	Closing time S [min]	Heating rate t_1 [°C/°F/min]	Firing temperature T_1 [°C/°F]	Holding time H_1 [min]	Heating rate t_2 [°C/°F/min]	Firing temperature T_2 [°C/°F]	Holding time H_2 [min]	Vacuum 1 1_1 [°C/°F] 1_2 [°C/°F]	Vacuum 2 2_1 [°C/°F] 2_2 [°C/°F]	Long-term cooling L [°C/°F]	Cooling rate t_L [°C/°F/min]
Programat P300 P500 P700	403/757	06:00	60/108	770/1418	00:10	30/54	850/1562	10:00	550/770 1022/1418	770/850 1418/1562	700/1292	0
Programat CS Program 7	403/757	06:00	60/108	770/1418	00:10	30/54	850/1562	10:00	550/770 1022/1418	770/850 1418/1562	700/1292	0

Crystallization/Combination firing: IPS e.max CAD LT – not suitable for MO

with or *without* application of IPS e.max CAD Crystall./ materials

Furnaces	Stand-by temperature B [°C/°F]	Closing time S [min]	Heating rate t_1 [°C/°F/min]	Firing temperature T_1 [°C/°F]	Holding time H_1 [min]	Heating rate t_2 [°C/°F/min]	Firing temperature T_2 [°C/°F]	Holding time H_2 [min]	Vacuum 1 1_1 [°C/°F] 1_2 [°C/°F]	Vacuum 2 2_1 [°C/°F] 2_2 [°C/°F]	Long-term cooling L [°C/°F]	Cooling rate t_L [°C/°F/min]
Programat P300 P500 P700	403/757	06:00	90/162	820/1508	00:10	30/54	840/1544	07:00	550/820 1022/1508	820/840 1508/1544	700/1292	0
Programat CS Program 1	403/757	06:00	90/162	820/1508	00:10	30/54	840/1544	07:00	550/820 1022/1508	820/840 1508/1544	700/1292	0

Corrective firing – Characterization/Glaze firing IPS e.max CAD MO, LT

with IPS e.max CAD Crystall./ materials

Furnaces	Stand-by temperature B [°C/°F]	Closing time S [min]	Heating rate t_1 [°C/°F/min]	Firing temperature T_1 [°C/°F]	Holding time H_1 [min]	Heating rate t_2 [°C/°F/min]	Firing temperature T_2 [°C/°F]	Holding time H_2 [min]	Vacuum 1 1_1 [°C/°F] 1_2 [°C/°F]	Vacuum 2 2_1 [°C/°F] 2_2 [°C/°F]	Long-term cooling L [°C/°F]	Cooling rate t_L [°C/°F/min]
Programat P300 P500 P700	403/757	06:00	90/162	820/1508	00:10	30/54	840/1544	03:00	550/820 1022/1508	820/840 1508/1544	700/1292	0
Programat CS Program 3	403/757	06:00	90/162	820/1508	00:10	30/54	840/1544	03:00	550/820 1022/1508	820/840 1508/1544	700/1292	0

Characterization/Glaze firing

with IPS e.max Ceram Shades, Essences, Glaze

Furnaces	Stand-by temperature B [°C/°F]	Closing time S [min]	Heating rate t [°C/°F/min]	Firing temperature T_1 [°C/°F]	Holding time H [min]	Vacuum 1 V_1 [°C/°F]	Vacuum 2 V_2 [°C/°F]	Long-term cooling L [°C/°F]
Programat P300 P500 P700	403/757	06:00	60/108	770/1418	1:00 – 2:00	450/842	769/1416	500/932

Note:
If the layer thickness is less than 2 mm on the IPS e.max CAD object, long-term cooling (L) is not required.

Corrective firing

with IPS e.max Ceram Add-On

Furnaces	Stand-by temperature B [°C/°F]	Closing time S [min]	Heating rate t [°C/°F/min]	Firing temperature T_1 [°C/°F]	Holding time H [min]	Vacuum 1 V_1 [°C/°F]	Vacuum 2 V_2 [°C/°F]	Long-term cooling L [°C/°F]
Programat P300 P500 P700	403/757	06:00	50/90	700/1292	01:00	450/842	699/1290	500/932

Crystallization and Firing Parameters

The following points should be observed for ceramic furnaces used for the crystallization of IPS e.max CAD:

- Crystallization should be carried out in an Ivoclar Vivadent ceramic furnace (e.g. Programat CS, Programat P300, P500, or P700).
- If you use other, untested ceramic furnaces, please consult Ivoclar Vivadent about their compatibility with IPS e.max CAD.

Basically, the following applies:

Ceramic furnaces without
- function for controlled (long-term) cooling
- vacuum function

cannot be used.

- Before the first crystallization and every six months after that, the ceramic furnace must be calibrated.
- Depending on the mode of operation, more frequent calibrations may be required. Observe the instructions of the manufacturer.

The following aspects should be observed for conducting the **crystallization**:

- Use only IPS Object Fix Putty or Flow as an auxiliary firing paste to place the restoration directly on the IPS e.max CAD Crystallization Tray.
- IPS e.max CAD restorations must not be directly placed on the IPS e.max CAD Crystallization Tray and the Pins, i.e. without auxiliary firing paste, for crystallization.
- Use only the IPS e.max CAD Crystallization Tray and the corresponding Pins, since they store the heat necessary for slow and above all tension-free cooling of the glass-ceramic.
- Always conduct the crystallization under vacuum.
- Remove IPS e.max CAD objects from the furnace after completion of the firing cycle (wait for the acoustic signal of the furnace).
- Allow the objects to cool to room temperature in a place protected from draft.
- Do not touch the hot objects with metal tongs.
- Do not blast or quench the objects.

crystallization and firing p arameters ☞ **please fold out the page**

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Date information prepared: 2013-04/Rev. 0

ivoclar vivadent® technical

A17-67

Appendix 18 – Lava™ Frame Instructions for Use

3M ESPE

Lava™ Frame

- (en) Zirconia Crown/Bridge Mill Blanks
- (de) Zirkonoxid-Kronen-/Brückenrohlinge
- (fr) Barreaux à fraiser pour couronnes/bridges en zircone
- (it) Blocchi grezzi per corone/ponti in ossido di zirconio
- (es) Bloques de fresado de óxido de zirconio para la fabricación de coronas y puentes
- (pt) Peças em bruto de zircónia para a confecção de coroas e de pontes
- (nl) Zirkoniumoxide kronen/bruggen freesblanks
- (el) Προπλάσματα οξειδίου του ζιρκονίου για στεφάνες/γέφυρες
- (sv) Ämnen för zirkoniumdioxidkronor/-broar
- (fi) Zirkoniumoksidikruunu-/siltarungot
- (da) Zirkonia krone-/broemner
- (no) Zirkoniumoksid-krone-/broemner

Instructions for Use
Gebrauchsinformation
Mode d'emploi
Informazioni per l'uso
Instrucciones de uso
Instruções de uso
Gebruiksinformatie
Οδηγίες χρήσης
Bruksanvisning
Käyttöohje
Brugsanvisning
Bruksinformasjon

3M Deutschland GmbH
Dental Products
Carl-Schurz-Str. 1
41453 Neuss – Germany

3M ESPE Customer Care/MSDS Information:
U.S.A. 1-800-634-2249 and Canada 1-888-363-3685.

CE 0123

44000183051/02

(en) ENGLISH

Product Description
Lava™ Frame Zirconia Mill Blanks are used for the fabrication of Zirconia frameworks and all-Zirconia restorations and are available in various sizes.
The frameworks/restorations are designed using a dental CAD software and the data are subsequently converted into tool paths. The mill blanks are milled in a milling machine suitable for processing Lava Zirconia.
After milling, the frameworks/restorations are dyed to the desired color using Lava Frame Shade Dyeing Liquid.
The frameworks/restorations are sintered in a sintering furnace suitable for processing Lava Zirconia controlled by the program intended for Lava Frame.
Lava Frame Zirconia Mill Blanks conform with ISO 6872:2008, Type II, Class 6. TEC (25–500° C): $10.5 \pm 0.2 \; 10^{-6} \cdot K^{-1}$.

☞ These Instructions for Use should not be discarded for the duration of product use. For details on all mentioned products, please refer to the respective Instructions for Use.

Indications
Preparation of Zirconia frameworks and all-Zirconia restorations for anterior and posterior teeth in consideration of the prescribed wall thicknesses and connector cross-sections, see chapter "Designing Frameworks/Restorations":
- Single crowns
- Bridges up to 42 mm in length with a maximum of two pontics next to one another in the posterior area and a maximum of four pontics next to one another in the anterior area. A maximum of four dies is approved for 5-unit and 6-unit bridges.
- Crowns on implants and 3-unit bridges on two implants
  - Lava Frame restorations on implants are contraindicated for patients with bruxism.
  - Lava Frame restorations on implants should have a passive (tension-free) fit.
- Splinted crowns (maximum 4 splinted crowns)
- Cantilever bridges with a maximum of 1 pendant at the position of a premolar or incisor
  - Cantilever bridges are contraindicated for patients with bruxism.
- 3-unit inlay/onlay and 2-unit or 3-unit Maryland bridges
  - Inlay/onlay and Maryland bridges are contraindicated for patients with bruxism.
- Primary crowns
- Zirconia build-up for two-piece abutments

Notes on Preparation Guidelines
Perfectly fitting restorations can be manufactured only in compliance with the preparation guidelines, see also the brochure "Clinical Handling Guidelines".
The guidelines set forth by the relevant national health care supervisory agencies must also be observed for the respective indications.

Notes on Cantilever, Inlay/Onlay, Maryland, and Long-Span Bridges
Tests have proven that Lava Frame Zirconia Mill Blanks show sufficient strength for inlay/onlay and Maryland bridges. Nevertheless, restorations for these indications can, regardless of the manufacturer of the material, show a greater failure risk from decementation and secondary caries.
In general, the risk of fracture is greater for cantilever bridges, inlay/onlay bridges, and Maryland bridges. Consequently, these indications should be used only on vital abutment teeth without increased mobility and in patients with good oral hygiene. They are contraindicated for patients with parafunctions (e.g., bruxist patients). When inlay and Maryland bridges are used, do not set a strong occlusal contact point on the restoration. The occlusal surface of a cantilever bridge should be out of occlusion. The guidelines of the relevant national professional associations must also be observed for cantilever bridges, inlay/onlay bridges, and Maryland bridges. Many educational books recommend as a minimum the same number of abutments and bridge units for long-span bridges to secure the stability of the restoration.

Precautionary Measures
3M Deutschland MSDSs can be obtained at www.mmm.com or from your local subsidiary.

Model Preparation
- ▶ A light-colored super-hard plaster ISO 6873 Type 4 without using any plastics additives must be used for model preparation. The model must not have any silicon oil residue (e.g., from doublication or bite registration).
- ▶ All segments of the saw cut model have to be removable and secured against rotation (double pin).
- ▶ The model base should have a smooth bottom. We recommend the use of the universal model holder to fix the models in the scanner.
- ▶ The die must have a sharp undercut underneath the preparation margin; the preparation margin must not be marked, and the die must not be varnished or hardened.
- ▶ Block out defects and undercuts (as necessary, after consultation with the dentist) with a light wax or by using a dental CAD software.
- ▶ Reflecting areas on the die are detrimental for the scanning procedure; if necessary, dull these areas with a suitable scan spray.
- ▶ Caution: In cases of distinct bifurcation, there may, in rare cases, be insufficient detection, inherent to the system, of the preparation margin. We recommend blocking out these areas as a preventive measure and using a diamond tool to fit the framework/restoration afterwards.

Designing Frameworks/Restorations
The wall thicknesses and connector cross-sections are decisive for the strength of the later restoration. Perfect milling results depend, among other factors, on the correct positioning of the holding pins and the ideal milling direction. The designing of frameworks or restorations, the positioning of the holding pins, and the orientation in the blank are carried out after digitalization in the dental CAD or CAM software. During data capture, follow the pertinent design guidelines in the scanner operating instructions.
All restorations created using wax modeling must also meet the wall thicknesses and connector cross-sections shown here.

For Lava Frame restorations, the following design specifications must be observed:

Wall Thicknesses

Wall thickness	generally ≥ 0.5 mm (see below for exceptions)
Anterior crowns	≥ 0.3 mm, but not in cases of bruxism
Primary crowns	≥ 0.3 mm, but not in cases of bruxism
Abutment tooth crowns to the cantilever bridge unit for posterior teeth	≥ 0.7 mm
Abutment tooth crowns to the cantilever bridge unit for anterior teeth	≥ 0.6 mm
Abutment tooth crowns to the anterior tooth bridges with 3 or 4 bridge units	≥ 0.7 mm
Zirconia build-up for two-piece abutment	≥ 0.8 mm ≥ 1.0 mm in case of angulation and milling over 3 axes

Margin Reinforcement

Margin reinforcement	0.20 mm

Connector Cross-Sections

Anterior tooth bridge unit – bridge unit	7 mm² (up to 2 bridge units) 10 mm² (more than 2 bridge units)
Anterior tooth die – bridge unit	7 mm² (up to 2 bridge units) 10 mm² (more than 2 bridge units)
Anterior tooth die – die	7 mm²
Anterior tooth die – cantilever bridge unit	8 mm²
Anterior tooth Maryland wing – bridge unit	7 mm²
Posterior tooth bridge unit – bridge unit	12 mm²
Posterior tooth die – bridge unit	9 mm²
Posterior tooth die – die	9 mm²
Posterior tooth die – cantilever bridge unit	12 mm²
Posterior inlay – bridge unit	9 mm²

Maryland bridges

2-unit and 3-unit Maryland bridges	Bridge unit at the position of an incisor. Bridge unit with one wing on one or both sides.
3-unit inlay/onlay bridges	The bridge unit is mesially and distally anchored to the natural tooth by an inlay/onlay.

Prosthetic Height of Posterior Tooth Zirconia Build-Up for Two-Piece Abutments: 12.0 mm
Caution: Failure to observe the prescribed minimum wall thickness or connector cross-section may cause fracture of the later restoration. In extreme cases, the patient may swallow or even breathe in parts, resulting in risks to his/her health. Surgical intervention may be required under certain circumstances. Users are themselves responsible for the use of Lava Frame only for the approved indications, for observing the prescribed minimum wall thicknesses and connector cross-sections, and for the correct positioning of the holding pins.

Design of the Zirconia Build-Up for Two-Piece Abutments
The cementation of the Zirconia build-up for two-piece abutments on metal abutments has been approved. A direct connection of the Zirconia build-up to the implant without using a metal interface is not permissible. The fit of the Zirconia build-up on the metal abutment must be as precise as possible.
In order to warrant a safe and secure cementation of the Zirconia build-up to the corresponding titanium abutment, the following specifications of the titanium abutment must be fulfilled:
- Cylindrical interface made of titanium or a titanium alloy approved for dental applications
- Inner cylinder diameter: ≥ 2.9 mm
- Outer diameter: ≥ 4.5 mm
- Cylinder height of the metal abutment shoulder: 2.6 to 6.0 mm
- Overall cementation surface area (abutment shoulder + flange): ≥ 33 mm²

Preparation of the Milling Unit
Prior to processing Lava Frame frameworks/restorations, clean the milling chamber of the milling unit. Depending on the type of case and the blank being used, the following tools are required for processing on the milling units:

Milling unit	Lava Frame blanks: 20, 40, 60, Multi	Lava Frame blanks: 20 XL
Lava Form/Lava CNC 500/ Lava CNC 240 (three-axis processing)	Milling tool types 4, 5, 6, 9*	Milling tool types 1, 2, 3, 4*, 5*, 6*, 9*
Lava CNC 500 (five-axis processing)	Milling tool types 1, 2, 3, 4*, 5*, 6*, 9*	Milling tool types 1, 2, 3, 4*, 5*, 6*, 9*

* From Lava Design Software 7.x on

Processing After Milling
Caution, ceramic dust: Aspirate all dust and air with a fine dust filter commonly used in the dental lab. Use protective goggles in all framework/restoration processing work.
In order to prevent contamination, the blank must not be exposed to water or any other liquids, fats (hand lotion), or oils during processing.

Removal of the Milled Blank from the Holding Device
We recommend the use of a turbine handpiece to remove the milled blank. If no turbine is available, fine cross-cut tungsten carbide cutters can also be used – rotary speed ≤ 20,000 rpm.
- ▶ First, notch all holding pins on their top as closely as possible to the crown from the occlusal side and then carefully extend the notches from the opposite side to separate the blank.
  - Use as little pressure as possible in removing the blank and let it gently slip into the hand or onto a soft pad.

Finishing of the Milled Surface (Frameworks/Restorations)
Shape correction and smoothing of the surface is easier and safer when done on the green body (framework/restoration before sintering) in comparison with working with sintered objects. Grinding sintered frameworks/restorations may cause damage invisible to the naked eye. For this reason, corners, edges, joints of the holding pins, and all other uneven surfaces should be smoothed prior to sintering so that it is necessary only to fit the framework/restoration once it has been sintered.
Caution: The presence of notches and sharp edges or damage on the bottom side of the interdental connectors may substantially reduce the stability of the sintered framework/restoration. Smooth these surfaces in the green state.
Make sure that the workpiece is in compliance with the required minimum wall thicknesses and connector cross-sections after finishing.
- ▶ White Universal Polishers, for example, can be used for processing, rotational speed 10,000–20,000 rpm.
- ▶ Finish the holding pin joints, then all of the edges outside the crown margin.
- ▶ When finishing the outer contour in the vicinity of the crown margin, make sure that the crown margin is not damaged.
- ▶ When preparing all-Zirconia restorations, smooth the restoration with fine-grain sandpaper (2500 grain) or similar material and trim the occlusal surface with the tools normally used for processing ceramics after removing and grinding the holding pins.

Cleaning of Frameworks/Restorations
To ensure even coloring, the framework/restoration must be clean, free of oils, and completely dry prior to dyeing.
- ▶ Touch the framework/restoration only with clean, non-oily hands.
- ▶ Remove any milling dust completely from the entire framework/restoration, including the inner surfaces of the crown, e.g., using a soft brush for layered ceramic, Size 6.

Dyeing of the Frameworks/Restorations
Both the Lava Frame Shade mixing ratio and the recommendations for custom dyeing serve merely as guidelines because the wall thickness of the restoration has an effect on the color intensity and there are many and varied color-design possibilities. Lava Frame frameworks/restorations can be dyed either as a unit (monochrome) or in specific areas (custom).

1. Monochrome Dyeing in Tooth Color
Color classifications for frameworks:

Lava Frame Shade Dyeing Liquid	FS1	FS2	FS3	FS4	FS5	FS6	FS7
Coordinates with VITA Classic Colors	A1 B1	B2 C1	A2 A3	A3.5 A4	B3 B4	C2 C3 C4	D2 D3 D4

Color classifications for all-Zirconia restorations:

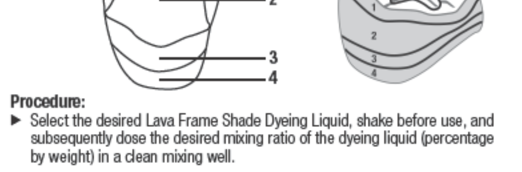
Tooth color	Mixing ratio of the dyeing liquids in weight percent				Framework color (information for the Lava Design Software, menu "Case information")
W1	10%	FS1	90%	H_2O	FS1
W2	30%	FS1	70%	H_2O	FS1
W3	50%	FS1	50%	H_2O	FS1
A1	70%	FS1	30%	FS2	FS1
A2	50%	FS2	50%	FS3	FS3
A3	100%	FS3	–	–	FS3
A3.5	30%	FS4	70%	FS6	FS4
A4	60%	FS4	40%	FS6	FS4
B1	100%	FS1	–	–	FS1
B2	70%	FS1	30%	FS7	FS7
B3	60%	FS3	40%	FS7	FS3
B4	50%	FS5	50%	FS7	FS5
C1	70%	FS1	30%	FS6	FS6
C2	30%	FS1	70%	FS6	FS6
C3	100%	FS6	–	–	FS6
C4	50%	FS6	50%	FS7	FS6
D2	100%	FS7	–	–	FS7
D3	50%	FS3	50%	FS6	FS3
D4	30%	FS3	70%	FS6	FS6

- ▶ Select the appropriate size of the immersion container. The container must be large enough to allow easy insertion and removal of the framework/restoration without the risk of jamming. The immersion container must be dry, clean, and free of any residual dyeing liquid to ensure that the desired color results are obtained.
- ▶ Select the Lava Frame Shade Dyeing Liquid corresponding to the tooth color, shake before use, and subsequently fill the immersion container.
  - Reseal the bottle immediately after use so that the concentration of the dyeing liquid does not change.
- ▶ Use plastic forceps to place the framework/restoration in the immersion container; the workpiece must be completely covered by the dyeing liquid.
- ▶ Carefully tilt the immersion container to allow any air bubbles trapped inside a coping to escape.
- ▶ Leave the framework/restoration in the dyeing liquid for 2 minutes, then use plastic forceps to remove it. Dye each framework/restoration only once.
- ▶ Remove the excess dyeing liquid from the coping and from around the interdental connectors, e.g., using a cotton swab or an absorbent paper towel, to ensure even coloring. Make sure that no lint from the paper towel remains on the framework or restoration.

2. Custom Dyeing in Tooth Color
A brush or disposable applicator can be used to apply the dyeing liquid in specific areas to achieve (to a certain degree) a customized differentiation in the tooth color.

Application Diagram for Lava Frame Shade Dyeing Liquids
The table below shows the mixing ratios of the dyeing liquids, the areas where the mixture is applied, and how often.

Tooth color	Incisal (1)	Dentin (2)	Dentin (3)	Cervical (4)	Framework color (information for the Lava Design Software, menu "Case information")
W1	None	None	FS1 – 50% H_2O – 50%	FS1 – 50% H_2O – 50%	FS1
Number of applications	1	1	1	1	
W2	FS1 – 50% H_2O – 50%	FS1 – 50% H_2O – 50%	FS1 – 100%	FS1 – 100%	FS1
Number of applications	1	1	2	2	
W3	FS1 – 100%	FS1 – 100%	FS2 – 100%	FS2 – 100%	FS1
Number of applications	2	2	1	1	
A1	FS1 – 100%	FS1 – 100%	FS1 – 80% FS2 – 20%	FS1 – 80% FS2 – 20%	FS1
Number of applications	2	2	2	4	
A2	FS2 – 100%	FS2 – 100%	FS3 – 100%	FS3 – 100%	FS3
Number of applications	1	2	4	5	
A3	FS1 – 70% FS7 – 30%	FS3 – 80% FS4 – 20%	FS3 – 80% FS4 – 20%	FS4 – 50% FS6 – 50%	FS4
Number of applications	2	3	3	3	
A3.5	FS1 – 100%	FS4 – 70% FS7 – 30%	FS4 – 70% FS7 – 30%	FS4 – 60% FS6 – 40%	FS4
Number of applications	2	4	4	4	
A4	FS3 – 100%	FS4 – 70% FS7 – 30%	FS4 – 70% FS7 – 30%	FS4 – 70% FS7 – 30%	FS4
Number of applications	3	5	5	7	
B1	FS7 – 50% H_2O – 50%	FS7 – 100%	FS7 – 100%	FS7 – 100%	FS7
Number of applications	1	1	1	1	
B2	FS1 – 100%	FS2 – 80% FS4 – 20%	FS2 – 80% FS4 – 20%	FS4 – 50% FS6 – 50%	FS4
Number of applications	3	3	3	5	
B3	FS1 – 20% FS2 – 80%	FS4 – 30% FS5 – 70%	FS4 – 30% FS5 – 70%	FS5 – 100%	FS5
Number of applications	3	4	4	4	
B4	FS2 – 100%	FS4 – 50% FS5 – 50%	FS4 – 50% FS5 – 50%	FS4 – 100%	FS4
Number of applications	3	5	5	5	
C1	FS2 – 100%	FS2 – 100%	FS6 – 100%	FS6 – 100%	FS6
Number of applications	3	3	4	4	
C2	FS6 – 100%	FS7 – 100%	FS7 – 100%	FS7 – 100%	FS7
Number of applications	3	8	8	8	
C3	FS2 – 100%	FS6 – 100%	FS6 – 100%	FS6 – 100%	FS6
Number of applications	3	8	8	8	
C4	FS6 – 100%	FS7 – 100%	FS7 – 100%	FS7 – 100%	FS7
Number of applications	4	8	8	8	
D2	FS7 – 60% FS1 – 40%	FS7 – 60% FS1 – 40%	FS7 – 60% FS1 – 40%	FS4 – 100%	FS4
Number of applications	4	4	4	3	
D3	FS7 – 100%	FS7 – 100%	FS4 – 50% FS7 – 50%	FS4 – 50% FS7 – 50%	FS4
Number of applications	1	1	4	4	
D4	FS7 – 30% FS3 – 70%	FS6 – 60% FS3 – 40%	FS6 – 60% FS3 – 40%	FS6 – 100%	FS6
Number of applications	3	6	6	6	



Procedure:
- ▶ Select the desired Lava Frame Shade Dyeing Liquid, shake before use, and subsequently dose the desired mixing ratio of the dyeing liquid (percentage by weight) in a clean mixing well.
- ▶ Use a clean, metal-free brush or disposable applicator to apply the dyeing liquid; see "Application Diagram for Lava Frame Shade Dyeing Liquids" for the procedure. Allow each layer to be absorbed before applying the next one.
  - The brush must not have a metal shaft. There must not be any ceramic particles on the brush, and it must not be used to layer ceramics.
  - Use a separate brush/disposable applicator for each color mixture, or wash out and dry the brush/disposable applicator before each change of color.
- ▶ To achieve a greater color intensity of the all-Zirconia restoration, apply the darkest mixture of the dyeing liquid once to the inner surface of each crown.

Reuse of Lava Frame Shade Dyeing Liquid
- ▶ The dyeing liquid can be used for up to 24 hours if it is covered immediately after use and stored in a cool, dry place. Failure to observe the above precautions may have the following effects on the framework/restoration:
  - Discoloration
  - Changes in sintering behavior, e.g., distortion due to sintering
  - Reduction in durability
- ▶ Dilute used dyeing liquid with large quantities of water and pour down the drain.

Positioning for Sintering
The framework/restoration must be ideally positioned to allow linear shrinkage during sintering while at the same time retaining the precision of the fit. For that purpose, the following aids are available: sintering pegs (25 and 33 mm long), sintering wires, sintering swings, soft wires, and honeycomb sintering carriers. The Lava Furnace 200 Crown Sintering Tray can also be used for single restorations.

Specifications for Positioning for Sintering

Framework Type	Positioning for Sintering
Single crown, anterior tooth	1 peg per coping or Lava Crown Sintering Tray
Single crown, premolar	2–3 pegs per coping or Lava Crown Sintering Tray
Single crown, molar	3–4 pegs per coping or Lava Crown Sintering Tray
Abutment	1 peg or Lava Crown Sintering Tray
Two blocked anterior teeth	1 peg per coping
Two blocked premolars	2 pegs per coping
Two blocked molars	2–3 pegs per coping
Anterior tooth bridges with two outer copings	1 peg per coping or 2 swings
Posterior tooth bridges with two outer copings	2 wires or 2 swings
Cantilever bridges, up to 5 units	2 swings
Bridges with 3–4 units and more than two copings	2 swings
Straight 5-unit bridges	2 swings
Bent 5-unit bridges	2 swings or 3 soft wires
6-unit bridges (including cantilever bridges)	3 soft wires
Inlay, onlay, Maryland bridges	2 swings

- ▶ All of the sintering wires and pegs must be placed free of tension in the honeycomb sintering carrier so that they can follow the shrinkage of the framework.
- ▶ Place no more than one wire or peg in each honeycomb opening of the sintering carrier.
- ▶ The frameworks must be secured so that they cannot tip over and will be hanging freely during sintering, without touching the neighboring frameworks or the sintering carrier, so that they do not become deformed.

Exception: When abutments with screw canal are peg positioned, they lie occlusally or basally on the honeycomb sintering carrier. The sintering peg is used to fix the abutment mainly as an aid for tipping or transport. Deformation in this case is improbable due to the massiveness of abutments.

If the center of gravity of the bridges is in an awkward position, use a combination of pegs and wires.
- ▶ Position the bridges perpendicularly to the direction of insertion into the furnace on the sintering tray (only valid for Lava Therm).
- ▶ The honeycomb sintering carrier used for sintering bridges must not be deformed. Check every 2 weeks to see that it is still straight by laying both sides on a flat surface.

Observe the following instructions, depending on indication and method:

Peg Positioning:
- ▶ Place the restoration, hanging freely, on the 25 mm-long pegs.
- ▶ Position the pegs in a V-shape for bridges.
- ▶ The restoration edges and the bridge framework must not touch the sintering carrier (see Exception Abutment); if necessary, use longer pegs. Note that the use of 33 mm-long pegs can cause an instable position; the framework may tip over.

Wire Positioning:
- ▶ Position the sintering wires in a slight V-shape in the honeycomb sintering carrier.
- ▶ Position the bridge framework with the basal side of the outer connectors on two sintering wires.

Swing Positioning:
- ▶ Position the sintering swings in a slight V-shape in the honeycomb sintering carrier.
- ▶ Position the bridge framework with the buccal side of the outer connectors on two sintering swings.

Soft Wire Positioning:
- ▶ Position the bridge frameworks with the outer and one of the middle connectors on three soft wires. To do this, place the soft wires in the honeycomb sintering carrier in a bow form, i.e., following the bend of the bridge.
- ▶ Make sure that the connectors of the bridge framework are in contact with all three soft wires. If they are not, bend the soft wires to make contact. The soft wires can be bent back into their original shape after sintering.

Positioning of Single Restorations on Lava Crown Sintering Tray:
- ▶ Place the single restorations on the occlusal side or side surfaces in the depressions of the wave-shaped honeycomb.
  - Make sure that the restorations do not touch one another. Avoid placement on the edge of the preparation or on the fitting surface.

Sintering
- ▶ After it has been dyed, position the framework/restoration on a sintering tray and allow it to dry for a minimum of 2 hours under ambient conditions or in the cold sintering furnace (room temperature). The drying periods must be observed strictly.
  - The drying period must be extended by about 30 minutes for solid bridge units and long-span restorations.
- ▶ Lava Frame frameworks/restorations are sintered exclusively in furnaces suitable for Lava Zirconia at 1500° C/2732° F.
  - Please see the pertinent operating instructions for information about the firing program or operation of the sintering furnace.

Finishing of Sintered Frameworks/Restorations
- ▶ Finish sintered frameworks/restorations using a turbine at 30,000 to 120,000 rpm or with a fast-running handpiece at up to 30,000 rpm. The use of any water cooling which is available can always be recommended, but is not necessary for selective adjustments.
- ▶ Finish primary crowns with the appropriate abrasive tools while cooling with water; at this time, check the wall thickness (minimum 0.3 mm) and optionally polish with a felt wheel and diamond polishing paste (avoid overheating).
- ▶ Use only fine-grain diamonds with grain sizes between fine 30 µm (red) and extra-fine 15 µm (yellow). Whether the diamonds are bonded galvanically or ceramically is of importance only for the endurance of the diamond cutter.
- ▶ To avoid overheating the framework or restoration, apply only light pressure and smooth a particular place for only a short time.
- ▶ If there is cervical smoothing, whether intentionally or accidentally, on a connector, the position must be polished again. Diamond-equipped rubber polishers, discs or cones, are suitable for this, coarse = blue, medium = pink, fine = gray (high polish).
- ▶ The minimum values for wall thicknesses and connectors must be maintained after finishing, see chapter "Designing Frameworks/Restorations".

Veneering
- ▶ For veneering, use a veneer ceramic approved for Zirconia, e.g., VITA™ VM™9, manufactured by VITA™ Zahnfabrik H. Rauter GmbH & Co. KG, or Jensen Willi Geller Creation, manufactured by Jensen Dental Incorporated. Observe the instructions for use issued by the specific veneering ceramic manufacturer for the processing.
- ▶ Never remove veneers with hydrofluoric acid since this substance damages the Lava Frame restoration.

Finishing the Sintered All-Zirconia Restoration
The restoration must either be polished or coated with a glaze approved for Zirconia and fired. More naturally appearing aesthetics can be achieved by finishing with a glaze. The manual high-shine polishing of the restoration will cause it to appear more opalescent.

Polishing
- ▶ Crown margins, fissures, and cusps can be processed using the rubber polishers normally used for ceramics.
- ▶ Use diamond polishing paste and a suitable polishing brush for the final polishing.

Glaze Firing
All-Zirconia restorations require higher temperatures for glaze firing, hence the firing temperature for glaze firing needs to be increased depending on the wall thickness of the restoration.
- ▶ After completion of the sintering process, the restoration is customized with stains, glaze, and glaze firing; please observe the appropriate Instructions for Use.

Temporary Cementation
- ▶ Clean the Lava Frame restoration thoroughly.
- ▶ If the restoration will later be permanently seated using a composite or resin-modified glass-ionomer cement, use a eugenol-free cement (e.g., RelyX™ Temp NE) for temporary cementation.
  - Residuals of products containing eugenol inhibit the setting of composite cement during the permanent cementation process!
- ▶ If the restoration will later be permanently seated using a cement without any composite elements, use a eugenol-containing or eugenol-free cement (e.g., RelyX Temp NE or RelyX™ Temp E) for temporary cementation.

Permanent Cementation
Please see the appropriate Instructions for Use for detailed information about the products mentioned below.

Conventional Cementation
- ▶ Blast the interior surfaces of the crown with aluminum oxide ≤ 50 µm and blasting pressure of 2 bar and clean thoroughly with alcohol.
- ▶ Use a conventional glass ionomer cement (e.g., from the Ketac™ Cem product group) or a resin-modified glass ionomer cement (e.g., RelyX™ Luting Plus Automix or Ketac Cem Plus Automix) for the cementation. The use of phosphate cements will not lead to the desired esthetic results.

Adhesive Cementation
Lava Frame restorations are so strong that adhesive cementation does not offer any additional mechanical advantages in comparison with conventional cementation for most indications. Inlay/onlay and Maryland bridges are exceptions to this (see chapter "Adhesive Cementation of Inlay/Onlay and Maryland Bridges").

Self-Adhesive Cementation Using a Composite Cement from 3M ESPE (e.g., RelyX™ Unicem 2 Automix or RelyX™ U200):
- ▶ Blast the surfaces to be cemented with aluminum oxide ≤ 50 µm and blasting pressure of 2 bar and clean thoroughly with alcohol.
- ▶ Observe the relevant instructions for use for processing the self-adhesive composite attachment cement RelyX Unicem.

Notes on cementing a Zirconia build-up on a metal base:
- ▶ Before sandblasting the metal base, cover the connection to the implant (e.g., using Erkoskin from Erkodent or with a laboratory implant).
- ▶ Blast the surfaces of the Zirconia build-up and metal base to be cemented with aluminum oxide ≤ 50 µm and blasting pressure of 2 bar and clean thoroughly with alcohol.
- ▶ The screw channel of the metal base should be closed (e.g., with wax) before cementing.
- ▶ Apply the self-adhesive composite attachment cement according to the relevant instructions for use to the pre-treated surfaces of both parts, press the parts together, and maintain the pressure during the curing of the parts.
- ▶ Curing of the cement:
  - Either pre-polymerize, using a tabletop light-curing device (e.g., 3M ESPE Visio™ Alfa), and subsequently cure thoroughly for 15 minutes in a vacuum in the light-curing device (e.g., 3M ESPE Visio™ Beta Vario, Cycle 1),
  - or use a hand-held light-curing device with a light intensity of at least 1000 mW/cm² (e.g., 3M ESPE Elipar™ S10) to expose to light from all four sides for 20 seconds a side when in the final position. The cemented joint must be light-cured for 80 seconds in total.
- ▶ Remove excess cement and polish the cemented seam with a silicon polisher.

Adhesive Cementation with Composite Cements:
- ▶ Lava Frame restorations cannot be etched or silanized by direct application of a silane coupling agent. For adhesive cementation with composite cements, the adhesive surfaces can therefore be silicatized for 15 seconds with Rocatec™ Soft or CoJet™ Sand and silanized with ESPE™ Sil. See the Instructions for Use for Rocatec System or CoJet Sand for details about processing.
  - If the restoration is to be tried in, it must be done before the silicatization/silanization.
  - Place the restoration in the mouth with a composite cement as soon as possible after silanization.

Notes on Adhesive Cementation of Inlay/Onlay and Maryland Bridges:
Inlay/Onlay and Maryland bridges made of ceramic or Zirconia must be cemented adhesively using cements which have been expressly approved for these indications, e.g., RelyX™ Ultimate. For more information, see the RelyX Ultimate Instructions for Use. The guidelines of the relevant national professional associations must also be observed for such indications.

Occlusion Check for All-Zirconia Restorations
- Zirconia occlusal surfaces are not subject to any noteworthy abrasive wear. This must be considered when planning the therapy. Special attention must be paid to the design of the occlusal surface so that dynamic and static occlusion is correct. This should be checked regularly by a dentist, e.g., during preventive check-ups.
- If the finished restoration has been adapted after placement in the patient's mouth, the contact surfaces must finally be given a high-shine polish.

Removal of a Seated Lava Restoration
- ▶ Use conventional rotating tools and adequate water cooling to introduce a slit and lift the restoration and/or use common office instruments as an aid to pull off the restoration.

Errors

Error	Cause	Solution
Restoration breaks during removal from the holding structure.	Holding pin was separated too far from the object.	Separate closer to the object to reduce vibrations.
	Handpiece wobbles.	Check the handpiece. Use a turbine, if available.
	Cutter is blunt.	Use a new cutter.
Restoration does not fit.	Erroneous positioning of crowns and bridges during sintering.	Ensure proper positioning during sintering as described under "Positioning for Sintering".
	Die was not placed correctly on the model.	Prior to scanning, check the proper position of the die on the model.
	The preparation guidelines were not observed.	Contact dentist/customer, rework model as necessary.
	Inadequate model preparation.	Observe the model guidelines in the Lava Scan Operating Instructions. Rework the framework/restoration as necessary and contact the customer, or do the work again.
	Not all of the data for the die surface were captured during scanning (causing gaps in the data)	Use Scan Spray before scanning. Depending on the scale, rework the framework/restoration or create a new one.
Contamination on the restoration surface.	The dyeing liquid was used too often and is contaminated.	Do not use the dyeing liquid for more than 24 hours.
Whitish spots apparent on the restoration surface.	Milling dust was not removed.	Carefully remove all milling dust prior to dyeing.

Storage and Stability
Store Lava Frame Zirconia Mill Blanks and Lava Frame Shade Dyeing Liquids at 15–25° C/59–77° F. Avoid direct exposure to sunlight. Do not use after the expiration date.

Customer Information
No person is authorized to provide any information that deviates from the information provided in this instruction sheet.

Warranty
3M Deutschland warrants this product will be free from defects in material and manufacture. 3M Deutschland MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M Deutschland's sole obligation shall be repair or replacement of the 3M Deutschland product.

Limitation of Liability
Except where prohibited by law, 3M Deutschland will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Information valid as of December 2012

(de) DEUTSCH

Produktbeschreibung
Lava™ Frame Zirkonoxid-Rohlinge dienen zur Herstellung von Zirkonoxidgerüsten und Voll-Zirkonoxid-Restaurationen und sind in verschiedenen Größen erhältlich.
Die Gerüste/Restaurationen werden mit einer dentalen CAD-Software gestaltet und die Daten anschließend in Fräsbahnen umgewandelt. Das Fräsen der Rohlinge erfolgt in einer für Lava Zirkonoxid geeigneten Fräsmaschine.
Die gefrästen Gerüste/Restaurationen erhalten die gewünschte Farbe durch Färben mit der entsprechenden Lava Frame Shade-Färbelösung.
Die Sinterung der Gerüste/Restaurationen erfolgt in einem für Lava Zirkonoxid geeigneten Sinterofen mit der für Lava Frame vorgesehenen Programmführung.
Lava Frame Zirkonoxid-Rohlinge entsprechen ISO 6872:2008 Typ II, Klasse 6. WAK (25–500 °C): $10{,}5 \pm 0{,}2 \; 10^{-6} \cdot K^{-1}$.

☞ Die Gebrauchsinformation dieses Produktes ist für die Dauer der Verwendung aufzubewahren. Details zu allen erwähnten Produkten bitte den jeweiligen Gebrauchsinformationen entnehmen.

Anwendungsgebiete
Herstellung von Zirkonoxidgerüsten und Voll-Zirkonoxid-Restaurationen für den Front- und Seitenzahnbereich unter Berücksichtigung der vorgeschriebenen Wandstärken und Konnektorquerschnitte, siehe Abschnitt „Gerüst/Restauration gestalten":
- Einzelkronen
- Brücken bis zu einer Länge von 42 mm mit maximal zwei nebeneinander liegenden Brückengliedern im Seitenzahnbereich und maximal vier nebeneinander liegenden Brückengliedern im Frontzahnbereich. Bei 5- und 6-gliedrigen Brücken ist eine maxi ale Anzahl von vier Stümpfen freigegeben.
- Kronen auf Implantaten und 3-gliedrige Brücken auf zwei Implantaten
  - Lava Frame Restaurationen auf Implantaten sind für Patienten mit Bruxismus kontraindiziert.
  - Lava Frame Restaurationen auf Implantaten sollten eine passive (spannungsfreie) Passung aufweisen.
- Verblockungen (maximal 4 verblockte Kronen)
- Freiendbrücken mit maximal 1 Anhänger an Position eines Prämolaren oder Schneidezahnes
  - Freiendbrücken sind für Patienten mit Bruxismus kontraindiziert.
- 3-gliedrige Inlay-/Onlay- und 2- oder 3-gliedrige Marylandbrücken
  - Inlay-/Onlay- und Marylandbrücken sind für Patienten mit Bruxismus kontraindiziert
- Primärkronen
- Zirkonoxidaufbau für zweiteilige Abutments

Hinweis zu Präparationsrichtlinien
Passgenaue Restaurationen können nur gefertigt werden, wenn die vorgegebenen Präparationsrichtlinien eingehalten werden, siehe auch Broschüre „Lava Kronen und Brücken Präparations- und Verarbeitungsgrundlagen".
Die Richtlinien der relevanten nationalen Gesundheitsbehörden sind ebenfalls für die jeweiligen Indikationen zu beachten.

Hinweise zu Freiend-, Inlay-/Onlay-, Maryland- und langspannigen Brücken
Tests haben für Lava Frame Zirkonoxid-Rohlinge eine ausreichende Festigkeit für Inlay-/Onlay und Marylandbrücken belegt. Trotzdem können Restaurationen bei diesen Indikationen, unabhängig vom Hersteller des Materials, ein höheres Ausfallrisiko durch Dezementierung und Sekundärkaries aufweisen.
Bei Freiend-, Inlay-/Onlay- und Marylandbrücken besteht generell ein höheres Frakturrisiko. Daher sollten diese Indikationen nur auf vitalen Pfeilerzähnen ohne erhöhte Mobilität und bei guter Mundhygiene des Patienten eingesetzt werden. Sie sind kontraindiziert für Patienten mit Parafunktionen (z. B. Bruxisten). Bei Inlay- und Marylandbrücken sollte kein starker okklusaler Kontaktpunkt auf die Restauration gesetzt werden. Der Anhänger bei Freiendbrücken sollte aus der Okklusion genommen werden. Für Freiend-, Inlay-/Onlay- und Marylandbrücken sind auch die Richtlinien der entsprechenden nationalen und regionalen Fachverbände zu beachten. Bei langspannigen Brücken empfehlen viele Lehrbücher für die Stabilität der Restauration eine mindestens gleiche Anzahl an Pfeilern und Brückengliedern.

Vorsichtsmaßnahmen
3M Deutschland Sicherheitsdatenblätter sind unter www.mmm.com oder bei Ihrer lokalen Niederlassung erhältlich.

Modellherstellung
- ▶ Für die Modellherstellung muss ein heller Superhartgips (ISO 6873, Typ 4) ohne Kunststoffzusatz verwendet werden. Das Modell darf keine Silikonölreste aufweisen (z. B. von Dublierung oder Bissregistrat).
- ▶ Alle Segmente des Sägeschnittmodells müssen abnehmbar und gegen Verdrehen gesichert sein (z. B. mit Doppelpin).
- ▶ Der Modellsockel sollte e ne ebene Unterseite haben. Zur Befestigung der Modelle im Scanner wird die Verwendung der universalen Modellhalterung empfohlen.
- ▶ Der Stumpf muss an der Präparationsgrenze scharfkantig unterkehlt sein, die Präparationsgrenze darf nicht angezeichnet und der Stumpf nicht lackiert oder gehärtet werden.
- ▶ Defekte und unter sich gehende Bereiche (ggf. nach Rücksprache mit dem Zahnarzt) mit hellem Wachs bzw. über eine dentale CAD-Software ausblocken.
- ▶ Reflektierende Stellen am Stumpf beeinträchtigen den Scanvorgang, gegebenenfalls mit einem geeigneten Scanspray mattieren.
- ▶ Achtung: Bei starken Bifurkationen kann es in seltenen Fällen systembedingt zu einer unvollkommenen Darstellung des Präparationsrandes kommen. Es empfiehlt sich, solche Stellen präventiv auszublocken und das Gerüst/die Restauration später mit Diamantschleifern aufzupassen.

Gerüst/Restauration gestalten
Die Wandstärken und Konnektorquerschnitte sind ausschlaggebend für die Festigkeit der späteren Restauration. Ein einwandfreies Fräsergebnis hängt unter anderem von der richtigen Positionierung der Haltestifte und der optimalen Fräsrichtung ab. Die Gestaltung von Gerüst oder Restauration, die Positionierung der Haltestifte und die Ausrichtung im Rohling erfolgen nach der Digitalisierung in der dentalen CAD-, bzw. CAM-Software. Bei der Datenerfassung die entsprechenden Gestaltungsrichtlinien der Scanner Betriebsanleitung beachten.
Auch alle mittels Wachsmodellation erstellten Restaurationen müssen die genannten Wandstärken und Konnektorenquerschnitte erfüllen.

Für Lava Frame Restaurationen müssen folgende Gestaltungsvorgaben eingehalten werden:

Wandstärken

Wandstärke	generell ≥ 0,5 mm (Ausnahmen siehe unten)
Frontzahnkronen	≥ 0,3 mm, jedoch nicht bei Bruxismus
Primärkronen	≥ 0,3 mm, jedoch nicht bei Bruxismus
Pfeilerzahnkronen zu Freiendbrückenglied im Seitenzahnbereich	≥ 0,7 mm
Pfeilerzahnkronen zu Freiendbrückenglied im Frontzahnbereich	≥ 0,6 mm
Pfeilerzahnkronen zu Frontzahnbrücken mit 3 oder 4 Brückengliedern	≥ 0,7 mm
Zirkonoxidaufbau für zweiteilige Abutments	≥ 0,8 mm ≥ 1,0 mm im Falle von Angulation und Fräsung über 3 Achsen

Randverstärkung

Randverstärkung	0,20 mm

Konnektorquerschnitte

Frontzahn Brückenglied – Brückenglied	7 mm² (bis zu 2 Brückenglieder) 10 mm² (mehr als 2 Brückenglieder)
Frontzahn Stumpf – Brückenglied	7 mm² (bis zu 2 Brückenglieder) 10 mm² (mehr als 2 Brückenglieder)
Frontzahn Stumpf – Stumpf	7 mm²
Frontzahn Stumpf – Freiendbrückenglied	8 mm²
Frontzahn Marylandflügel – Brückenglied	7 mm²
Seitenzahn Brückenglied – Brückenglied	12 mm²
Seitenzahn Stumpf – Brückenglied	9 mm²
Seitenzahn Stumpf – Stumpf	9 mm²
Seitenzahn Stumpf – Freiendbrückenglied	12 mm²
Seitenzahn Inlay – Brückenglied	9 mm²

Marylandbrücken

2- und 3-gliedrige Marylandbrücken	Brückenglied an Position eines Schneidezahnes. Brückenglied mit einem Flügel an einer bzw. beiden Seiten.
3-gliedrige Inlay-/Onlay-Brücken	Brückenglied ist mesial und distal über ein Inlay/Onlay mit dem natürlichen Zahn verankert.

Prothetische Höhe des Zirkonoxidaufbaus für zweiteilige Abutments im Seitenzahnbereich: 12,0 mm
Achtung: Das Unterschreiten der vorgegebenen Mindestwandstärken oder Konnektorquerschnitte kann zur Fraktur des späteren Zahnersatzes führen. In ungünstigen Fällen kann es zu einem Verschlucken oder sogar Aspirieren von Teilen und den damit verbundenen gesundheitlichen Risiken kommen. Unter Umständen kann dadurch ein chirurgischer Eingriff erforderlich werden. Der Anwender ist selbst dafür verantwortlich, dass Lava Frame nur für die freigegebenen Indikationen eingesetzt wird, dass die vorgegebenen Mindestwandstärken und Konnektorquerschnitte eingehalten und die Haltestifte richtig positioniert werden.

Gestaltung des Zirkonoxidaufbaus für zweiteilige Abutments
Die Zementierung des Zirkonoxidaufbaus für zweiteilige Abutments auf Metallbasis ist freigegeben. Eine direkte Verbindung des Zirkonoxidaufbaus für zweiteilige Abutments mit dem Implantat ohne die Benutzung eines Metallzwischenstückes ist nicht zulässig. Die Passung des Zirkonoxidaufbaus auf der Metallbasis sollte so präzise wie möglich sein.
Um eine sichere Zementierung des Zirkonoxidaufbaus mit der entsprechenden Metallbasis zu gewährleisten, sind folgende Spezifikationen für die Metallbasis zu erfüllen:
- Zylindrisch geformtes Zwischenstück aus Titan oder einer Titanlegierung für dentale Anwendungen
- Innerer Durchmesser des Zylinders: ≥ 2,9 mm
- Äußerer Durchmesser: ≥ 4,5 mm
- Zylinderhöhe der Basisschulter: 2,6 mm bis 6,0 mm
- Gesamtzementierungsfläche (Schulter + Zylinderfläche): ≥ 33 mm²

Fräsmaschine vorbereiten
Vor der Bearbeitung von Lava Frame Gerüsten/Restaurationen den Fräsraum der Fräsmaschine reinigen. Für die Bearbeitung in den Fräsmaschinen sind je nach Art der Arbeit und verwendetem Rohling folgende Werkzeuge notwendig:

Fräsmaschine	Lava Frame Rohlinge: 20, 40, 60, Multi	Lava Frame Rohlinge: 20 XL
Lava Form/Lava CNC 500/ Lava CNC 240 (dreiachsige Bearbeitung)	Fräsertyp 4, 5, 6, 9*	Fräsertyp 1, 2, 3, 4*, 5*, 6*, 9*
Lava CNC 500 (fünfachsige Bearbeitung)	Fräsertyp 1, 2, 3, 4*, 5*, 6*, 9*	Fräsertyp 1, 2, 3, 4*, 5*, 6*, 9*

* Ab Lava Design Software 7.x

Ausarbeitung nach dem Fräsen
Achtung Keramikstaub: Bei der Ausarbeitung der Gerüste/Restaurationen eine Absaugung mit einem im Labor üblichen Feinststaubfilter verwenden und eine Schutzbrille tragen.
Um Verunreinigungen zu vermeiden, darf der Rohling während der Ausarbeitung nicht mit Wasser, sonstigen Flüssigkeiten oder Fetten (Handcreme) und Ölen in Kontakt kommen.

Heraustrennen des gefrästen Rohlings aus der Halterung
Zum Heraustrennen des gefrästen Rohlings ist die Verwendung eines Turbinenhandstücks zu empfehlen! Ist keine Turbine vorhanden, feine querverzahnte Hartmetallfräser verwenden – Drehzahl ≤ 20.000 1/min!
- ▶ Alle Haltestifte so nah wie möglich an der Krone zunächst von okklusal einkerben, dann von der gegenüberliegenden Seite her vorsichtig durchtrennen.
  - Beim Heraustrennen so wenig Druck wie möglich anwenden und den Rohling auf die Hand oder eine weiche Unterlage fallen lassen!

Nachbearbeitung der gefrästen Oberfläche (Gerüste/Restaurationen)
Die Formkorrektur und Oberflächenglättung am Grünkörper (Gerüst/Restauration im vorgesinterten Zustand) ist leichter und sicherer im Vergleich zur Bearbeitung im gesinterten Zustand. Während des Beschleifens gesinterter Gerüste/Restaurationen können Schäden entstehen, die mit bloßem Auge nicht sichtbar sind. Aus diesem Grund sollten Ecken, Kanten, die Ansätze der Haltestifte und alle sonstigen Unebenheiten bereits am Grünkörper glatt geschliffen werden.
Das Gerüst/die Restauration sollte im gesinterten Zustand nur noch aufgepasst werden müssen.
Achtung: Insbesondere Einkerbungen, scharfe Kanten oder Beschädigungen im Bereich der Unterseite der interdentalen Konnektoren können die Festigkeit von gesinterten Gerüsten/Restaurationen deutlich reduzieren. Diese Stellen im Grünzustand glätten!
Nach der Nachbearbeitung muss darauf geachtet werden, dass die erforderlichen Mindestwandstärken und Konnektorquerschnitte noch gegeben sind.
- ▶ Für die Bearbeitung zum Beispiel weiße Universal Polierer verwenden, Drehzahl 10.000–20.000 1/min!
- ▶ Ansatzpunkte der Haltestifte und anschließend alle Kanten, die nicht im Kronenrandbereich liegen, nacharbeiten.
- ▶ Bei Bearbeitung der Außenkontur im Bereich des Kronenrandes darauf achten, dass der Kronenrand nicht beschädigt wird.
- ▶ Bei Voll-Zirkonoxid-Restaurationen nach dem Heraustrennen und Verschleifen der Haltestifte, die Restauration z. B. mit feinkörnigem Schleifpapier (Körnung 2500) glätten, und die Okklusionsfläche mit den zur Bearbeitung von Keramik üblichen Werkzeugen ausarbeiten.

Reinigen von Gerüsten/Restaurationen
Um gleichmäßige Farbergebnisse zu erhalten, muss das Gerüst/die Restauration vor dem Färben sauber, fettfrei und vollkommen trocken sein!
- ▶ Das Gerüst/die Restauration nur mit sauberen, fettfreien Händen anfassen.
- ▶ Das gesamte Gerüst/die gesamte Restauration, auch die Kroneninnenflächen, zum Beispiel mit einem weichen Pinsel für Schichtkeramik Größe 6, gründlich von Frässtaub befreien.

Färben von Gerüsten/Restaurationen
Sowohl die angegebenen Mischverhältnisse von Lava Frame Shades, als auch die Empfehlungen für die individuelle Einfärbung können nur als Richtlinie dienen, da die Wandstärke der Restauration die Farbwirkung beeinflusst und die Farbgestaltungsmöglichkeiten vielfältig sind.
Lava Frame Gerüste/Restaurationen können sowohl monochrom als auch individuell eingefärbt werden.

1. Monochrome Färbung in Zahnfarbe
Farbzuordnungen für Gerüste:

Lava Frame Shade Färbelösung	FS1	FS2	FS3	FS4	FS5	FS6	FS7
Zuordnung zu VITA Classic Farben	A1 B1	B2 C1	A2 A3	A3,5 A4	B3 B4	C2 C3 C4	D2 D3 D4

Farbzuordnungen für Voll-Zirkonoxid-Restaurationen:

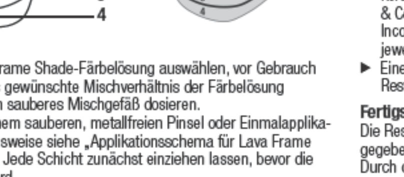
Zahnfarbe	Mischverhältnisse der Färbelösungen in Gewichtsprozent				Gerüstfarbe Angabe für die Lava Design Software, (Menü „Auftragsinformationen")
W1	10%	FS 1	90%	H_2O	FS 1
W2	30%	FS 1	70%	H_2O	FS 1
W3	50%	FS 1	50%	H_2O	FS 1
A1	70%	FS 1	30%	FS 2	FS 1
A2	50%	FS 2	50%	FS 3	FS 3
A3	100%	FS 3	–	–	FS 3
A3,5	30%	FS 4	70%	FS 6	FS 4
A4	60%	FS 4	40%	FS 6	FS 4
B1	100%	FS 1	–	–	FS 1
B2	70%	FS 1	30%	FS 7	FS 7
B3	60%	FS 3	40%	FS 7	FS 3
B4	50%	FS 5	50%	FS 7	FS 5
C1	70%	FS 1	30%	FS 6	FS 6
C2	30%	FS 1	70%	FS 6	FS 6
C3	100%	FS 6	–	–	FS 6
C4	50%	FS 6	50%	FS 7	FS 6
D2	100%	FS 7	–	–	FS 7
D3	50%	FS 3	50%	FS 6	FS 3
D4	30%	FS 3	70%	FS 6	FS 6

- ▶ Ein Tauchgefäß in passender Größe auswählen. Das Gerüst/die Restauration muss leicht einzulegen und zu entnehmen sein und darf sich nicht verkanten. Das Tauchgefäß muss trocken, sauber und frei von Färbelösungsresten sein, andernfalls wird nicht das gewünschte Farbergebnis erzielt.
- ▶ Je nach Zahnfarbe die passende Lava Frame Shade-Färbelösung auswählen, vor Gebrauch schütteln und dann und in das Tauchgefäß füllen.
  - Um die Konzentration der Färbelösung nicht zu verändern, die Flasche sofort wieder gut verschließen.
- ▶ Das Gerüst/die Restauration mit einer Kunststoffpinzette so in das Tauchgefäß legen, dass es vollständig mit der Färbelösung bedeckt ist!
- ▶ Das Tauchgefäß vorsichtig hin und her kippen, um evtl. vorhandene Luftblasen im Inneren eines Käppchens aufsteigen zu lassen.
- ▶ Das Gerüst/die Restauration 2 Minuten in der Färbelösung belassen und dann mit einer Kunststoffpinzette entnehmen. Jedes Gerüst/jede Restauration nur einmal färben!
- ▶ Die überschüssige Färbelösung z. B. mit einem Wattestäbchen oder einem saugfähigen Papiertuch aus dem Käppchen und im Bereich der interdentalen Konnektoren absaugen, um eine gleichmäßige Farbwirkung zu erhalten. Darauf achten, dass keine Fusseln an Gerüst oder Restauration haften bleiben.

2. Individuelle Einfärbung in Zahnfarbe
Durch gezielten Farbauftrag von Färbelösung mit einem Pinsel oder Einmalapplikator kann in einem gewissen Rahmen, eine individuelle Abstufung der Zahnfarbe erzielt werden.

Applikationsschema für Lava Frame Shade-Färbelösungen
Die nachfolgende Tabelle gibt das Mischverhältnis der Färbelösungen an, in welchem Bereich die jeweilige Mischung aufgetragen wird und wie oft.

Zahnfarbe	Inzisal (1)	Dentin (2)	Dentin (3)	Zahnhals (4)	Gerüstfarbe (Angabe für die Lava Design Software, Menü „Auftragsinformationen")
W1	Keine	Keine	FS1 – 50% H_2O – 50%	FS1 – 50% H_2O – 50%	FS1
Anzahl Applikationen	1	1	1	1	
W2	FS1 – 50% H_2O – 50%	FS1 – 50% H_2O – 50%	FS1 – 100%	FS1 – 100%	FS1
Anzahl Applikationen	1	1	2	2	
W3	FS1 – 100%	FS1 – 100%	FS2 – 100%	FS2 – 100%	FS1
Anzahl Applikationen	2	2	1	1	
A1	FS1 – 100%	FS1 – 100%	FS1 – 80% FS2 – 20%	FS1 – 80% FS2 – 20%	FS1
Anzahl Applikationen	2	2	2	4	
A2	FS2 – 100%	FS2 – 100%	FS3 – 100%	FS3 – 100%	FS3
Anzahl Applikationen	1	2	4	5	
A3	FS1 – 70% FS7 – 30%	FS3 – 80% FS4 – 20%	FS3 – 80% FS4 – 20%	FS4 – 50% FS6 – 50%	FS4
Anzahl Applikationen	2	3	3	3	
A3,5	FS1 – 100%	FS4 – 70% FS7 – 30%	FS4 – 70% FS7 – 30%	FS4 – 60% FS6 – 40%	FS4
Anzahl Applikationen	2	4	4	4	
A4	FS3 – 100%	FS4 – 70% FS7 – 30%	FS4 – 70% FS7 – 30%	FS4 – 70% FS7 – 30%	FS4
Anzahl Applikationen	3	5	5	7	
B1	FS7 – 50% H_2O – 50%	FS7 – 100%	FS7 – 100%	FS7 – 100%	FS7
Anzahl Applikationen	1	1	1	1	
B2	FS1 – 100%	FS2 – 80% FS4 – 20%	FS2 – 80% FS4 – 20%	FS4 – 50% FS6 – 50%	FS4
Anzahl Applikationen	3	3	3	5	
B3	FS1 – 20% FS2 – 80%	FS4 – 30% FS5 – 70%	FS4 – 30% FS5 – 70%	FS5 – 100%	FS5
Anzahl Applikationen	3	4	4	4	
B4	FS2 – 100%	FS4 – 50% FS5 – 50%	FS4 – 50% FS5 – 50%	FS4 – 100%	FS4
Anzahl Applikationen	3	5	5	5	
C1	FS2 – 100%	FS2 – 100%	FS6 – 100%	FS6 – 100%	FS6
Anzahl Applikationen	3	3	4	4	
C2	FS6 – 100%	FS7 – 100%	FS7 – 100%	FS7 – 100%	FS7
Anzahl Applikationen	3	8	8	8	
C3	FS2 – 100%	FS6 – 100%	FS6 – 100%	FS6 – 100%	FS6
Anzahl Applikationen	3	8	8	8	
C4	FS6 – 100%	FS7 – 100%	FS7 – 100%	FS7 – 100%	FS7
Anzahl Applikationen	4	8	8	8	
D2	FS7 – 60% FS1 – 40%	FS7 – 60% FS1 – 40%	FS7 – 60% FS1 – 40%	FS4 – 100%	FS4
Anzahl Applikationen	4	4	4	3	
D3	FS7 – 100%	FS7 – 100%	FS4 – 50% FS7 – 50%	FS4 – 50% FS7 – 50%	FS4
Anzahl Applikationen	1	1	4	4	
D4	FS7 – 30% FS3 – 70%	FS6 – 60% FS3 – 40%	FS6 – 60% FS3 – 40%	FS6 – 100%	FS6
Anzahl Applikationen	3	6	6	6	



Vorgehensweise:
- ▶ Die gewünschte Lava Frame Shade-Färbelösung auswählen, vor Gebrauch schütteln und dann das gewünschte Mischverhältnis der Färbelösung (Gewichtsprozent) in ein sauberes Mischgefäß dosieren.
- ▶ Die Färbelösung mit einem sauberen, metallfreien Pinsel oder Einmalapplikator auftragen, Vorgehensweise siehe „Applikationsschema für Lava Frame Shade-Färbelösungen". Jede Schicht zunächst einziehen lassen, bevor die nächste aufgetragen wird.
  - Der Pinsel darf keinen Metallschaft haben. Er muss frei von Keramikpartikeln sein und darf nicht zum Schichten von Keramik verwendet werden.
  - Für jede Farbmischung einen separaten Pinsel/Einmalapplikator verwenden oder vor jedem Farbwechsel den Pinsel/Einmalapplikator auswaschen und trocknen.
- ▶ Um eine intensivere Farbwirkung der Voll-Zirkonoxid-Restauration zu erreichen, die jeweils dunkelste Mischung der Färbelösung 1x auf die Kroneninnenfläche jeder Krone auftragen.

Wiederverwendung von Lava Frame Shade-Färbelösung
- ▶ Die Färbelösung kann 24 Stunden lang verwendet werden, wenn sie nach Gebrauch sofort abgedeckt und kühl und dunkel gelagert wird. Bei Nichtbeachten bestehen die folgenden Risiken für das Gerüst/die Restauration:
  - Farbveränderungen,
  - Änderungen im Sinterverhalten, z. B. Sinterverzug,
  - Beeinträchtigung der Lebensdauer.
- ▶ Gebrauchte Färbelösung mit reichlich Wasser verdünnt über das Abwasser entsorgen.

Sinterlagerung
Um lineare Schrumpfung beim Sintern zu ermöglichen und gleichzeitig die hohe Passgenauigkeit zu bewahren, muss das Gerüst/die Restauration optimal gelagert werden. Hierfür stehen folgende Hilfsmittel zur Verfügung: Sinterstifte (25 und 33 mm lang), Sinterdrähte, Sinterschaukeln, Softdrähte und Wabenträger. Für Einzelrestaurationen kann auch der Lava Furnace 200 Crown Sintering Tray verwendet werden.

Sinterlagerung im Einzelnen

Gerüst-Typ	Sinterlagerung
Einzelkrone Frontzahn	1 Stift pro Käppchen oder Lava Crown Sintering Tray
Einzelkrone Prämolar	2–3 Stifte pro Käppchen oder Lava Crown Sintering Tray
Einzelkrone Molar	3–4 Stifte pro Käppchen oder Lava Crown Sintering Tray
Abutment	1 Stift oder Lava Crown Sintering Tray
Zwei verblockte Frontzähne	1 Stift pro Käppchen
Zwei verblockte Prämolaren	2 Stifte pro Käppchen
Zwei verblockte Molaren	2–3 Stifte pro Käppchen
Frontzahnbrücken mit zwei außenstehenden Käppchen	1 Stift pro Käppchen oder 2 Schaukeln
Seitenzahnbrücken mit zwei außenstehenden Käppchen	2 Drähte oder 2 Schaukeln
Freiendbrücken bis 5-gliedrig	2 Schaukeln
3–4-gliedrige Brücken mit mehr als zwei Käppchen	2 Schaukeln
Gerade 5-gliedrige Brücken	2 Schaukeln
Gebogene 5-gliedrige Brücken	2 Schaukeln oder 3 Softdrähte
6-gliedrige Brücken (auch Freiendbrücken)	3 Softdrähte
Inlay-, Onlay-, Marylandbrücken	2 Schaukeln

- ▶ Alle Sinterdrähte und -stifte spannungsfrei in den Wabenträger stecken, sodass sie der Schrumpfrichtung des Gerüstes folgen können.
- ▶ Immer nur einen Draht oder Stift in eine Wabenöffnung des Sinterträgers stecken.
- ▶ Die Gerüste während des Sinterns kippsicher und frei hängend ohne Kontakt zu benachbarten Gerüsten oder zum Sinterträger lagern. Andernfalls kann es zu Verformungen kommen.

Ausnahme: bei der Stiftlagerung von Abutments mit Schraubkanal liegen diese okklusal bzw. basal auf dem Wabenträger auf. Die Fixierung durch den Sinterstift dient hier hauptsächlich als Kipp- bzw. Transporthilfe. Aufgrund der Massivität von Abutments ist hier eine Verformung unwahrscheinlich.

Bei Brücken mit ungünstigem Schwerpunkt eine Kombination aus Stiften und Drähten verwenden.
- ▶ Die Brücken quer zur Ofeneinschubrichtung auf dem Sinterträger positionieren (gilt nur bei Lava Therm).
- ▶ Der Wabenträger darf für das Sintern von Brücken nicht verzogen sein. Deshalb alle 2 Wochen durch beidseitiges Auflegen auf eine ebene Fläche prüfen, ob er noch gerade ist.

Je nach Indikation und Methode ist folgendes zu beachten:

Stiftlagerung:
- ▶ Die Restauration frei hängend auf die 25 mm langen Stifte setzen.
- ▶ Bei Brücken die Stifte V-förmig positionieren.
- ▶ Die Restaurationsränder und das Brückengerüst dürfen den Sinterträger nicht berühren (siehe Ausnahme Abutment), ggf. längere Stifte verwenden. Dabei beachten, dass die 33 mm langen Stifte zu einer instabilen Lagerung führen können, das Gerüst kann herunterfallen.

Drahtlagerung:
- ▶ Die Sinterdrähte leicht V-förmig im Wabenträger positionieren.
- ▶ Brückengerüste mit der basalen Seite der äußeren Verbinder auf zwei Sinterdrähte auflegen.

Schaukellagerung:
- ▶ Die Sinterschaukeln leicht V-förmig im Wabenträger positionieren.
- ▶ Brückengerüste mit der bukkalen Seite der äußeren Verbinder auf zwei Sinterschaukeln auflegen.

Softdrahtlagerung:
- ▶ Brückengerüste mit den äußeren und einem mittleren Verbinder auf drei Softdrähte auflegen. Hierfür die Softdrähte bogenförmig, d. h. der Biegung der Brücke folgend, in den Wabenträger stecken.
- ▶ Überprüfen, ob die Verbinder des Brückengerüstes zu allen drei Softdrähten Kontakt haben. Falls das nicht der Fall ist, die Softdrähte entsprechend verbiegen. Die Softdrähte können nach dem Sintern wieder in die Ausgangsform zurück gebogen werden.

Lagerung von Einzelrestaurationen auf Lava Crown Sintering Tray:
- ▶ Einzelrestaurationen auf der okklusalen Seite bzw. Seitenfläche in den Vertiefungen der wellenförmigen Wabe lagern.
  - Darauf achten, dass sich die Restaurationen dabei nicht berühren. Eine Lagerung auf dem Präparationsrand oder auf der Passungsfläche vermeiden.

Sintern
- ▶ Nach dem Färben das Gerüst/die Restauration auf einen Sinterträger positionieren und mindestens 2 Stunden unter Umgebungsbedingungen oder im kalten Sinterofen (Raumtemperatur) trocknen. Die Trockenzeiten müssen eingehalten werden.
  - Bei massiven Brückengliedern und langspannigen Restaurationen muss die Trockenzeit um ca. 30 min verlängert werden.
- ▶ Lava Frame Gerüste/Restaurationen werden bei 1500 °C/2732 °F und ausschließlich in für Lava Zirkonoxid geeigneten Sinteröfen endgesintert.
  - Informationen zu den Brennprogrammen oder zur Bedienung des Sinterofens bitte der jeweiligen Betriebsanleitung entnehmen.

Nacharbeitung von gesinterten Gerüsten/Restaurationen
- ▶ Gesinterte Gerüste/Restaurationen mit einer Turbine bei 30.000–120.000 1/min oder mit einem schnell laufenden Handstück bei bis zu 30.000 1/min bearbeiten. Der Einsatz einer eventuell vorhandenen Wasserkühlung ist grundsätzlich empfehlenswert aber bei punktuellen Korrekturen nicht notwendig.
- ▶ Primärkronen unter Wasserkühlung mit entsprechenden Schleifkörpern bearbeiten, dabei die Wandstärke (mindestens 0,3 mm) kontrollieren, und optional mit einem Filzrad und Diamantpolierpaste polieren (Überhitzung vermeiden).
- ▶ Nur feinkörnige Diamanten mit einer Körnung zwischen fein 30 µm (rot) und extrafein 15 µm (gelb) verwenden. Ob die Diamanten galvanisch oder keramisch gebunden sind, hat nur Einfluss auf die Standzeit des Diamantschleifers.
- ▶ Um eine zu starke Erhitzung von Gerüst oder Restauration zu vermeiden, generell nur mit geringem Anpressdruck und an einzelnen Stellen kurzzeitig schleifen.
- ▶ Falls zervikal am Konnektor bewusst oder versehentlich geschliffen wurde, muss die jeweilige Stelle wieder poliert werden. Hierfür eignen sich diamantierte Gummipolierer, scheiben- oder kegelförmig; grob = blau; mittel = rosa; fein = grau (Hochglanz).
- ▶ Die Mindestwerte für Wandstärke und Konnektoren dürfen auch nach der Bearbeitung nicht unterschritten werden, siehe Abschnitt „Gerüst/Restauration gestalten".

Verblendung
- ▶ Die Verblendung erfolgt mit einer für Zirkonoxid freigegebenen Verblendkeramik, z. B. VITA™ VM™9 hergestellt von VITA™ Zahnfabrik H. Rauter GmbH & Co. KG oder Jensen Willi Geller Creation hergestellt von Jensen Dental Incorporated. Für die Verarbeitung bitte die Gebrauchsinformation des jeweiligen Verblendkeramikherstellers beachten.
- ▶ Eine Verblendung keinesfalls mit Flussäure entfernen, da die Lava Frame Restauration dadurch beschädigt würde.

Fertigstellen der gesinterten Voll-Zirkonoxid-Restauration
Die Restauration muss entweder poliert oder mit einer für Zirkonoxid freigegebenen Glasurmasse und abschließendem Glanzbrand versehen werden. Durch die Fertigstellung mittels Glasurmasse kann eine natürlichere Ästhetik erzielt werden. Eine manuelle Hochglanzpolitur der Restauration lässt diese opaleszenter wirken.

Politur
- ▶ Kronenränder, Fissuren und Höcker können mit den für Keramik üblichen Gummipolierern ausgearbeitet werden.
- ▶ Die Endpolitur erfolgt z. B. mit Diamantpolierpaste und einer geeigneten Polierbürste.

Glanzbrand
Voll-Zirkonoxid-Restaurationen benötigen höhere Temperaturen beim Glanzbrand, daher muss die Brenntemperatur für den Glanzbrand, abhängig von der Wandstärke der Restauration, angehoben werden.
- ▶ Die Restauration wird nach dem Sinterprozess mit Malfarben individualisiert und mit Glasurmasse und Glanzbrand versehen, bitte dabei die jeweilige Gebrauchsinformation beachten.

Temporäre Befestigung
- ▶ Die Lava Frame Restauration gründlich säubern.
- ▶ Wenn die Restauration später mit einem Composite- oder kunststoffmodifizierten Glasionomerzement definitiv eingesetzt werden soll, für die temporäre Befestigung einen eugenolfreien Zement (z. B. RelyX™ Temp NE) verwenden,
  - Reste von eugenolhaltigen Produkten inhibieren die Abbindung des Befestigungs-Composites bei der definitiven Befestigung!
- ▶ Wenn die Restauration später mit einem Zement ohne Composite-Anteile definitiv eingesetzt werden soll, für die temporäre Befestigung einen eugenolhaltigen oder eugenolfreien Zement (z. B. RelyX Temp NE oder RelyX™ Temp E) verwenden.

Definitive Befestigung
Ausführliche Informationen zu den nachfolgend genannten Produkten bitte der entsprechenden Gebrauchsinformation entnehmen.

Konventionelle Zementierung
- ▶ Die Kroneninnenflächen mit Aluminiumoxid ≤ 50 µm und einem Strahldruck von 2 bar abstrahlen und gründlich mit Alkohol säubern.
- ▶ Für die Zementierung einen konventionellen Glasionomerzement, z. B. aus der Ketac™ Cem-Produktgruppe oder einen kunststoffmodifizierten Glasionomerzement, z. B. RelyX™ Luting Plus Automix oder Ketac Cem Plus Automix, verwenden. Bei Verwendung von Phosphatzementen werden nicht die gewünschten ästhetischen Ergebnisse erzielt.

Adhäsive Befestigung
Lava Frame Restaurationen haben eine so hohe Festigkeit, dass eine adhäsive Befestigung für die meisten Indikationen keine zusätzlichen mechanischen Vorteile gegenüber der konventionellen Zementierung bietet. Davon ausgenommen sind Inlay-/Onlay- und Marylandbrücken (siehe Abschnitt „Adhäsive Befestigung von Inlay-/Onlay- und Marylandbrücken").

Selbstadhäsive Befestigung mit einem Composite-Zement von 3M ESPE (z. B. RelyX™ Unicem 2 Automix bzw. RelyX™ U200):
- ▶ Die zu zementierenden Flächen mit Aluminiumoxid ≤ 50 µm und einem Strahldruck von 2 bar abstrahlen und gründlich mit Alkohol säubern.
- ▶ Für die Verarbeitung des selbstadhäsiven Composite-Befestigungszements, bitte die dazugehörige Gebrauchsinformation beachten.

Hinweise zur Befestigung eines Zirkonoxidaufbau auf eine Metallbasis:
- ▶ Vor dem Sandstrahlen der Metallbasis die Verbindungsstelle zum Implantat abdecken (z. B. mit Erkoskin Fa. Erkodent oder mit einem Laborimplantat).
- ▶ Die zu zementierenden Flächen des Zirkonoxidaufbaus und der Metallbasis mit Aluminiumoxid ≤ 50 µm und einem Strahldruck von 2 bar abstrahlen und gründlich mit Alkohol säubern.
- ▶ Der Schraubenkanal der Metallbasis sollte vor der Zementierung z. B. mit Wachs verschlossen werden.
- ▶ Den selbstadhäsiven Composite Befestigungszement gemäß der dazugehörigen Gebrauchsinformation auf die vorbehandelten Oberflächen beider Teile auftragen, die Teile zusammendrücken und während des Aushärtens zusammengedrückt halten.
- ▶ Aushärtung des Zementes:
  - Entweder mit einem Tischgerät zur Lichthärtung (z. B. 3M ESPE Visio™ Alfa) vorpolymerisieren und anschließend 15 min unter Vakuum im Lichtgerät (z. B. 3M ESPE Visio™ Beta Vario, Programm 1) durchhärten,
  - oder mit einem Handgerät zur Lichthärtung mit einer Lichtintensität von mindestens 1000 mW/cm² (z. B. 3M ESPE Elipar™ S10) in der fixierten Position von allen vier Seiten je 20 Sekunden belichten. Insgesamt muss die Klebestelle 80 Sekunden belichtet werden.
- ▶ Den Zementüberschuss entfernen und die Klebefuge mit einem Silikonpolierer polieren.

Adhäsive Befestigung mit Composite-Zementen:
- ▶ Lava Frame Restaurationen können weder angeätzt noch durch direktes Auftragen von Silanflüssigkeit silanisiert werden. Für die adhäsive Befestigung mit Composite-Zementen kann die Klebeflächen mit Rocatec™ Soft oder CoJet™ Sand für 15 Sekunden silikatisiert und mit ESPE™ Sil silanisiert werden. Details zur Verarbeitung entnehmen Sie bitte der Rocatec System bzw. CoJet Sand Gebrauchsinformation.
  - Soll die Restauration einprobiert werden, muss die Einprobe vor der Silikatisierung/Silanisierung erfolgen.
  - Die Restauration möglichst bald nach der Silanisierung mit einem Composite-Zement einsetzen.

Hinweise zu adhäsiver Befestigung von Inlay-/Onlay- und Marylandbrücken:
Inlay-/Onlay- und Marylandbrücken aus Keramik bzw. Zirkonoxid müssen adhäsiv mit Zementen eingesetzt werden, die ausdrücklich für diese Indikationen freigegeben sind, wie z. B. RelyX™ Ultimate. Für weitere Informationen siehe RelyX Ultimate Gebrauchsinformation. Für solche Indikationen sind auch die Richtlinien der entsprechenden nationalen Fachverbände zu beachten.

Okklusionskontrolle bei Voll-Zirkonoxid-Restaurationen
- Zirkonoxid Kauflächen unterliegen keinem nennenswertem Verschleiß. Dies muss bei der Therapieplanung berücksichtigt werden. Besonderes Augenmerk gilt der Kauflächengestaltung für eine korrekte dynamische und statische Okklusion. Diese sollte regelmäßig, z. B. im Rahmen der Vorsorgeuntersuchung, durch einen Zahnarzt überprüft werden.
- Wenn die fertige Restauration beim Patienten nach dem Einsetzen eingeschliffen wurde, müssen die Kontaktflächen abschließend hochglanzpoliert werden.

Entfernung einer festsitzenden Zirkonoxid-Restauration
- ▶ Mit üblichen rotierenden Werkzeugen und ausreichender Wasserkühlung einen Schlitz anbringen und die Restauration aufhebeln und/oder praxisübliche Instrumente als Abzugshilfe verwenden.

Fehler

Fehler	Ursache	Lösung
Restauration zerbricht beim Heraustrennen aus der Halterung.	Haltestift wurde zu weit vom Objekt entfernt abgetrennt.	Näher am Objekt abtrennen, so werden Schwingungen vermieden.
	Handstück läuft unrund.	Handstück kontrollieren. Falls vorhanden mit Turbine heraustrennen.
	Fräser ist stumpf.	Neuen Fräser verwenden.
Restauration passt nicht.	Falsche Sinterlagerung bei Kronen oder Brücken.	Korrekte Sinterlagerung einhalten, siehe unter „Sinterlagerung".
	Stumpf war nicht korrekt auf dem Modell platziert.	Vor dem Scanvorgang den korrekten Sitz der Stümpfe auf dem Modell überprüfen.
	Die Präparationsrichtlinien wurden nicht eingehalten.	Den Zahnarzt/Kunden kontaktieren, ggf. Modell nacharbeiten.
	Unzureichende Modellvorbereitung.	Die Modellrichtlinien in der Lava Scan Betriebsanleitung beachten. Das Gerüst/die Restauration ggf. nacharbeiten und den Kunden kontaktieren oder die Arbeit neu erstellen.
	Beim Scannen sind nicht alle Daten der Stumpfoberfläche erfasst worden (Datenlöcher sind entstanden).	Vor dem Scannen Scanspray verwenden. Je nach Ausmaß das Gerüst/die Restauration nacharbeiten oder ein neues herstellen.
Verunreinigungen auf Restaurationsoberfläche.	Die Färbelösung wurde zu oft benutzt und ist dadurch verschmutzt.	Die Färbelösung max. 24 Stunden verwenden!
Weißliche Stellen auf Restaurationsoberfläche.	Frässtaub wurde nicht genügend entfernt.	Frässtaub vor dem Färben gründlich entfernen.

Lagerung und Haltbarkeit
Lava Frame Zirkonoxid-Rohlinge und Lava Frame Shade-Färbelösungen bei 15–25 °C/59–77 °F lagern. Direkte Sonneneinstrahlung vermeiden. Nach Ablauf des Verfalldatums nicht mehr verwenden.

Kundeninformation
Niemand ist berechtigt, Informationen bekannt zu geben, die von den Angaben in diesen Anweisungen abweichen.

Garantie
3M Deutschland garantiert, dass dieses Produkt frei von Material- und Herstellungsfehlern ist. 3M Deutschland ÜBERNIMMT KEINE WEITERE HAFTUNG, AUCH KEINE IMPLIZITE GARANTIE BEZÜGLICH VERKÄUFLICHKEIT ODER EIGNUNG FÜR EINEN BESTIMMTEN ZWECK. Der Anwender ist verantwortlich für den Einsatz und die bestimmungsgemäße Verwendung des Produkts. Wenn innerhalb der Garantiefrist Schäden am Produkt auftreten, besteht Ihr einziger Anspruch und die einzige Verpflichtung von 3M Deutschland in der Reparatur oder dem Ersatz des 3M Deutschland Produkts.

Haftungsbeschränkung
Soweit ein Haftungsausschluss gesetzlich zulässig ist, besteht für 3M Deutschland keinerlei Haftung für Verluste oder Schäden durch dieses Produkt, gleichgültig ob es sich dabei um direkte, indirekte, besondere, Begleit- oder Folgeschäden, unabhängig von der Rechtsgrundlage, einschließlich Garantie, Vertrag, Fahrlässigkeit oder Vorsatz, handelt.

Stand der Information: Dezember 2012

(fr) FRANÇAIS

Description du produit
Les barreaux à fraiser en zircone Lava™ Frame sont utilisés pour la fabrication d'armatures en oxyde de zirconium et de prothèses tout-zircone. Ils sont disponibles en plusieurs tailles.
Les armatures/prothèses sont conçues à l'aide du logiciel CAD et les données sont ensuite converties en séquences de fraisage. Les barreaux sont fraisés dans une fraiseuse adaptée pour l'oxyde de zirconium Lava.
Après le fraisage, les armatures/prothèses sont teintées en fonction de la teinte désirée à l'aide d'un liquide colorant Lava Frame Shade.
Les armatures/prothèses sont frittées dans un four de frittage adapté pour l'oxyde de zirconium Lava et contrôlé par le programme prévu pour Lava Frame.
Les barreaux à fraiser en zircone Lava Frame sont conformes à la norme ISO 6872:2008, Type II, Classe 6. TEC (25 – 500 °C) : $10{,}5 \pm 0{,}2 \; 10^{-6} \cdot K^{-1}$.

☞ Ce mode d'emploi doit être conservé pendant toute la durée d'utilisation du produit. Pour des détails concernant les autres produits mentionnés, veuillez consulter leur mode d'emploi respectif.

Indications
Réalisation d'armatures en zircone et de prothèses tout-zircone pour les dents antérieures et postérieures en respectant les épaisseurs de paroi et les sections transversales des connecteurs prescrites, voir chapitre « Modélisation numérique de l'armature/la prothèse » :
- Couronnes unitaires
- Bridges d'une longueur maximale de 42 mm avec un maximum de deux éléments intermédiaires consécutifs dans le secteur postérieur et un maximum de quatre éléments intermédiaires consécutifs dans le secteur antérieur. Pour les bridges de 5 et 6 éléments, un nombre maximal de quatre piliers est indiqué.
- Couronnes sur implants et bridges à 3 éléments sur deux implants.
  - Les prothèses Lava Frame sur implants sont contre-indiquées pour des patients enclins au bruxisme.
  - Les prothèses Lava Frame sur implants doivent présenter un ajustement passif (sans tensions).
- Couronnes solidarisées (maximum 4 couronnes)
- Bridges cantilever avec au maximum une dent en extension prémolaire ou incisive.
  - L'utilisation de bridges cantilever est contre-indiquée pour des patients enclins au bruxisme.

Appendix 19 – IPS e.max® Press Abutment Solutions 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 18 2012

Ivoclar Vivadent AG
C/O Ms. Donna Marie Hartnett
Director of Quality Assurance / Regulatory Affairs
Ivoclar Vivadent, Incorporated
175 Pineview Drive
Amherst, New York 14228

Re: K120053
Trade/Device Name: IPS e.max® Press – Abutment Solutions
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA, EIH
Dated: September 28, 2012
Received: October 2, 2012

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120053

Indications for Use

510(k) Number (if known): K120053

Device Name: IPS e.max® Press – Abutment Solutions

Indications For Use:

IPS e.max® Press Abutment Solutions is intended for use in partially or fully endentuous mandibles and maxillae in support of single or multiple-unit cement retained restorations.

IPS e.max Press Abutment Solutions is recommended for the fabrication of:

- Hybrid abutments for single-tooth restorations
- Hybrid abutment crowns for restorations

The following Ti bases are intended to be used with IPS e.max Press Abutment Solutions.

Implant manufacture	**Implant system, diameter**	**Compatible Ti base (abutment), dimensions** diameter = D gingiva height = GH height = HTi
Straumann®	Bone Level RC Ø 4.1 mm or Ø 4.8 mm 510K K062129	RC Cementable abutment D 5.0–6.5 mm GH 1.0–3.0 mm HTi 4.0–5.5 mm 510K K072071

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120053

Appendix 20 – P.004 RC Cementable Abutments 510(k) Summary

K072071

1 of 3

Section H
510(k) SUMMARY

AUG 15 2007

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1. **Applicant's Name and Address**

Straumann US (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 978-747-2513
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Regulatory Affairs Specialist
Date of Submission: July 27, 2007

2. **Name of the Device**

Trade Name: P.004 RC Cementable Abutments
Common Name: Abutment, Dental, Endosseous implants
Classification Name: Abutment, Dental, Endosseous implants
Regulation Number: 21 CFR 872.3630

3. **Legally Marketed Device to which Equivalence is Claimed (Predicate Device)**

P.004 RC Anatomic Abutments, K062129
Temporary Copings, K041070
ITI Protective Healing Caps, K962023

4. **Description of the Device**

The Straumann P.004 Dental Implant System is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments and surgical and prosthetic parts and instruments.

Abutments are placed into dental implants to provide support for prosthetic restorations, temporary copings support a temporary restoration out of occlusion and protective caps protect the abutment during the healing phase.

5. **Intended Use of the Device**

Abutments are placed into dental implants to provide support for prosthetic restorations such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations. Temporary Copings are intended to serve as a base for temporary restorations for up to 28 days. Protective Caps are intended to protect the outer configuration of the abutment and to maintain and

condition the contours of the soft tissue during the healing phase for up to 6 months.

6. **Technological Characteristics**
The modified Anatomic Abutments, Temporary Copings and Protective Caps are substantially equivalent to the currently cleared devices. The intended use is **identical** to the predicate devices. The proposed devices have the same material composition, basic design and fundamental operating principles to the currently cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2007

Institut Straumann AG
C/O Ms. Elaine Alan
Regulatory Affairs Specialist
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

Re: K072071
Trade/Device Name: P.004 Cementable Abutments, Temporary Copings and Protective Caps
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 27, 2007
Received: July 30, 2007

Dear Ms. Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

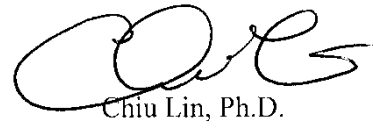
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 of 1

K072071

INDICATIONS FOR USE STATEMENT

Device Name: P.004 Cementable Abutments

Indications for Use:

Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures.

Device Name: P.004 Protective Caps

Indications for Use:

Protective Caps are intended to protect the outer configuration of the abutment and to maintain and condition the contours of the soft tissue during the healing phase for up to 6 months.

Device Name: P.004 Temporary Copings

Indications for Use:

Temporary Copings are intended to serve as a base for temporary restorations for up to 28 days.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K072071

Appendix 21 – IPS e.max® CAD Abutment Solutions 510(k) Summary

K132209

510(K) SUMMARY (revised)

IPS e.max® CAD Abutment Solutions

Contact:	Donna Marie Hartnett, Director QA/Regulatory Affairs
Company:	Ivoclar Vivadent. 175 Pineview Drive, Amherst, NY 14228 (716) 691-0010
Date Prepared:	October 18, 2013
Proprietary Name:	IPS e.max® CAD Abutment Solutions
Classification Name:	Abutment, Implant, Dental Endosseous (872.3630)
Predicate Devices:	Sirona Dental CAD/CAM System (K111421) IPS e.max CAD (K051705) IPS e.max Press Abutment Solutions (K120053 and K124008)

OCT 3 1 2013

Device Description: IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. Titanium bases are a premanufactured prosthetic component directly connected to dedicated endosseous dental implants. The Titanium base is used for adhesion to mesostructures to restore function and esthetics in the oral cavity. IPS e.max CAD Abutment Solutions are lithium disilicate blocks in various sizes. One side of the block is mounted to a mandrel that will be inserted into the spindle's clamping chuck of the grinding machine. The connection geometry to titanium bases is prefabricated, i.e. already include in the shipped block. Connection geometries fit select Titanium Bases marketed by Straumann, Nobel Biocare and Biomet 3i as identified in the Intended Use section. The mesostructure is individually designed and milled using CAD/CAM Technology into the shape of a hybrid abutment or hybrid abutment crown as designed by the trained professional using the Sirona inLab and Cerec SW 4.2 (or higher) software.. The device serves as the esthetic mesostructure which is extraorally cemented onto a Titanium Base. The two piece abutment is mounted onto the implant and fixed with a screw.

Predicate Device: The predicate device to which IPS e.max® CAD Abutment Solutions has been compared is Sirona Dental CAD/CAM System(K111421). For this application, IPS e.max® CAD Abutment Solutions has been compared to its predicate with regard to chemical composition, performance data and indications for use. The comparison shows that IPS e.max® CAD Abutment Solutions is substantially equivalent to the predicate device.

510(K) SUMMARY (revised)

IPS e.max® CAD Abutment Solutions

Intended Use:

IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. The system comprises three parts:

IPS e.max CAD ceramic structure,

Ti base and

CAD/CAM software

The IPS e.max CAD ceramic structure cemented to the Ti base is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants. The compatible Implant systems, Ti bases and CAD/CAM systems are shown below:

Implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Activem (K071370), Straumann Bone Level (K053088,), Biomet 3i Certain (K014235)

CAD/CAM Systems: Sirona inLab and Cerec SW 4.2 (or higher) software

Titanium bases:

Implant manufacturer	Implant System	Implant Diameter (mm)	TiBase	Sirona Ref.	Interface size
Nobel Biocare	Replace NP	3.5	NBRS 3.5	6282474	L
	Replace RP	4.3	NBRS 4.3	6282482	L
	Replace WP	5.0	NBRS 5.0	6282490	L
	Replace 6.0	6.0	NBRS 6.0	6282508	L
Nobel Biocare	Nobel Active NP	3.5	NB A 4.5	6208188	L
	Nobel Active RP	4.3 / 5.0	NB A 5.0	6208253	L
Straumann	Bone Level NC	3.3	S BL 3.3	6308154	L
	Bone Level RC	4.1 / 4.8	S BL 4.1	6308337	L
Biomet 3i	Certain	3.4	B C 3.4	6308048	S
	Certain	4.1	B C 4.1	6308097	L
	Certain	5.0	B C 5.0	6308121	L

For the titanium base Straumann Bone Level 3.3 L the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible.

Material Composition: The device is composed or proprietary lithium disilicate ($Li Si_{2}$) dental ceramic and is identical in composition to IPS e/max CAD (K051705).

510(K) SUMMARY (revised)

IPS e.max® CAD Abutment Solutions

Technological Characteristics: The device design, i.e. delivery form, and intended use of IPS e.max CAD Abutment Solutions and the predicate device are the same. The materials comply with ISO 6872:2008 for Dental Ceramics. The composition of the subject device has been modified from the predicate, however, there are no ingredients in the subject device which pose any new issues of safety and effectiveness.

Scientific Concept: The underlying scientific concept is the use of an already introduced technology of a titanium base abutment combined with individually CAD/CAM fabricated ceramic prosthetics made from lithium disilicate, a material proven to be suitable for safe and effective dental restoratives.

Testing Summary: According to FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" may 12, 2004, fatigue testing has been performed for angled abutments.

Physical properties of IPS e.max CAD:

- CTE (100°C – 500°C) $10.5 \pm 0.5\ 10^{-6}$/K
- Flexural strength (Biaxial) $\geq$ 360 MPa (Test Method ISO 6872)
- Fracture toughness ≥ 2.0 MPa $m^{0.5}$ (Test Method ISO 6872)
- Chemical solubility ≤ 50 □g/cm^2 (Test Method ISO 6872)
- Crystallization temperature 840 – 850°C

Conclusion: IPS e.max CAD Abutment Solutions is substantially equivalent to the predicate device.

510K Summary 5-3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 31, 2013

Ivoclar Vivadent AG
C/O Donna Hartnett
Director of Quality Affairs/Regulatory Affairs
Ivoclar Vivadent, Incorporation
175 Pineview Dr.
AMHERST NY, 14228

Re: K132209
Trade/Device Name: IPS e.max® CAD Abutment Solutions
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: II
Product Code: NHA
Dated: August 6, 2013
Received: August 7, 2013

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, MS
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132209

Device Name: IPS e.max® CAD Abutment Solutions

Indications For Use:

IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. The system comprises three parts:

IPS e.max CAD mesostructure,
Ti base and
CAD/CAM software.

The IPS e.max CAD mesostructure cemented to the Ti base is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants. The compatible Implant systems, Ti bases and CAD/CAM systems are shown below:

Implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Activem (K071370), Straumann Bone Level (K053088, K062129, K060958), Biomet 3i Osseotite (K980549)

CAD/CAM Systems: Sirona inLab and Cerec SW 4.2 and above

Titanium bases:

Implant manufacturer	Implant System	Implant Diameter (mm)	TiBase	Sirona Ref.	Interface size
Nobel Biocare	Replace NP	3.5	NBRS 3.5	6282474	L
	Replace RP	4.3	NBRS 4.3	6282482	L
	Replace WP	5.0	NBRS 5.0	6282490	L
	Replace 6.0	6.0	NBRS 6.0	6282508	L
Nobel Biocare	Nobel Active NP	3.5	NB A 4.5	6208188	L
	Nobel Active RP	4.3 / 5.0	NB A 5.0	6208253	L
Straumann	Bone Level NC	3.3	S BL 3.3	6308154	L
	Bone Level RC	4.1 / 4.8	S BL 4.1	6308337	L
Biomet 3i	Certain	3.4	B C 3.4	6308048	S
	Certain	4.1	B C 4.1	6308097	L
	Certain	5.0	B C 5.0	6308121	L

Concurrence of CDRH, Office of Device Evaluation (ODE)

For the titanium base Straumann Bone Level 3.3 L the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Andrew I. Steen -S
2013.10.30 13:55:24 -04'00'

Concurrence of CDRH, Office of Device Evaluation (ODE)

Appendix 22 – Sirona Dental CAD/CAM System 510(k) Summary

K111421

FEB 17 2012

510(k) Summary

for

Sirona Dental Systems

Sirona Dental CAD/CAM System

1 Sponsor

Sirona Dental Systems GmbH

Fabrikstrasse 31

D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 32 94

Date Prepared: May 06, 2011

2 Device Name

Proprietary Name:	Sirona Dental CAD/CAM-System
Common/Usual Name:	Abutment, implant, dental, endosseous
Classification Names:	Endosseous dental implant abutment

3 Predicate Devices

Replace® NP, K091756, Brånemark®, K091756, Tissue level NN, K081005, OsseoSpeed™, K081666, Frialit® / Xive®, K032158, Osseotite K072642, Tapered Screw-Vent®, K060880, Nobel Active NP, K102436, Bone Level NC, K062129, Certain®, K073345.

Sirona Dental CAD/CAM System (K100152)

4 Intended Use

The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the titanium bases SSO 3.5 L and SBL 3.3 L, the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems:

- Nobel Biocare Replace (K020646)
- Nobel Biocare Branemark (K022562)
- Friadent Xive (K013867)
- Biomet 3i Osseotite (K980549)
- Astra Tech Osseospeed (K091239)
- Zimmer Tapered Screw-Vent (K061410)
- Straumann SynOcta (K061176)
- Straumann Bone Level (K053088, K062129, K060958)
- Biomet 3i Certain (K014235, K061629)
- Nobel Biocare Active (K071370)

5 Device Description

The Sirona Dental CAD/CAM-System takes optical impressions and records the topographical characteristics of teeth, dental impressions, or stone models. Dental restorative prosthetic devices are manufactured using computer aided design and fabrication. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments.

The system that features the processing of mesostructures comprises

- Titanium bases TiBase and Camlog

- inCoris ZI meso blocks
- Sirona Dental CAD/CAM Design and fabricating devices

Titanium bases are used as an implant prosthetic titanium base for adhesion to mesostructures to restore function and aesthetics in the oral cavity.

inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.

Sirona Dental CAD/CAM design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. This component consists of the devices CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL.

5.1 TiBase

5.1.1 Device Function

The Sirona TiBase is a premanufactured prosthetic component directly connected to dedicated endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.

The Sirona offering consists of the titanium base TiBase, the abutment screw and the scanbody. The parts are marketed non-sterile and for single use only.

The Sirona TiBase is bonded to an individually designed mesostructure, a ceramic prosthetic/restoration, that supports the final restoration. The mesostructure is milled from an inCoris ZI meso block with Sirona CAD/CAM milling machines CEREC or inLab, and sintered afterwards.

The two piece abutment is mounted onto the implant and fixed with a screw.

The scope of delivery contains a scanbody (ABS plastic) which is mounted on a TiBase in order to acquire the topographical surface of the area where the endosseous dental implant abutment is located with Sirona Dental CAD/CAM fabricating devices. From the acquired data the position of the implant can be calculated. After an optical impression has been taken the scanbody is removed.

Sirona TiBase devices are compatible with following systems (Table 1):

Table 1: Sirona TiBase Devices Compatibility

Sirona TiBase	Compatible System		
	Manufacturer	System	Diameter
NBRS 3.5	Nobel Biocare	Replace® NP	3,5 mm
NBRS 4.3		Replace® RP	4.3 mm
NBRS 5.0		Replace® WP	5.0 mm
NBRS 6.0		Replace® 6.0	6.0 mm
NBB 3.4	Nobel Biocare	Brånemark®	3.4 mm
NBB 4.1		Brånemark®	4.1 mm
SSO 3.5	Straumann	Tissue level NN	3.5 mm
SSO 4.8		Tissue level RN	4.8 mm
SSO 6.5		Tissue level WN	6.5 mm
ATOS 3.5/4.0	Astra Tech	OsseoSpeed™	3.5 S / 4.0 S mm
ATOS 4.5/5.0		OsseoSpeed™	4.5 / 5.0 mm
FX 3.4	Friadent	Frialit® / Xive®	3.4 mm
FX 3.8		Frialit® / Xive®	3.8 mm
FX 4.5		Frialit® / Xive®	4.5 mm
FX 5.5		Frialit® / Xive®	5.5 mm
BO 3.4	Biomet 3i	Osseotite (Connec-tion type: Ex. Hex)	3.4 mm
BO 4.1		Osseotite (Connec-tion type: Ex. Hex)	4.1 mm

Sirona TiBase	Compatible System		
	Manufacturer	**System**	**Diameter**
BO 5.0		Osseotite (Connec-tion type: Ex. Hex)	5.0 mm
ZTSV 3.5	Zimmer	Tapered Screw-Vent®	3.5 mm
ZTSV 4.5		Tapered Screw-Vent®	4.5 mm
ZTSV 5.7		Tapered Screw-Vent®	5.7 mm
NB A 4.5	Nobel Biocare	Nobel Active NP	3.5mm
NB A 5.0		Nobel Active NP	4.3 / 5.0mm
S BL 3.3	Straumann®	Bone Level NC	3.3mm
S BL 4.1		Bone Level NC	4.1 / 4.8mm
B C 3.4	Biomet 3i	Certain®	3.4mm
B C 4.1		Certain®	4.1mm
B C 5.0		Certain®	5.0mm

5.1.2 Scientific Concept

The underlying scientific concept is the use of an already introduced technology of a titanium base abutment combined with individually CAD/CAM fabricated ceramic prosthetics.

5.1.3 Physical and Performance Characteristics

5.1.3.1 Design

The TiBase devices have various diameters, are compatible with dedicated implant systems, and fit to compatible implants as provided in Table 2.

Table 2: Implant Compatibility

TiBase	Implant-Manufacturer	Implant-System	510(k) Implant
NBRS	Nobel Biocare	Replace	K020646
NBB	Nobel Biocare	Branemark	K022562
FX	Friadent	Xive	K013867
BO	Biomet 3i	Osseotite	K980549
ATOS	Astra Tech	OsseoSpeed	K091239
ZTSV	Zimmer	Tapered Screw-Vent	K061410
SSO	Straumann	SynOcta	K061176
NB A	Nobel Biocare	Nobel Active	K071370
S BL	Straumann®	Bone Level	K053088
B C	Biomet 3i	Certain®	K014235

5.1.3.2 Material Used

TiBase and abutment screw are made of Ti6Al4V.

5.1.3.3 Physical Properties

TiBase material composition and mechanical properties comply with ISO 5832-3:1996, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

Sirona TiBase devices are compatible with systems listed in Table 1.

5.2 inCoris ZI meso

5.2.1 Device Description

The inCoris ZI meso offerings are blocks of various sizes from which individual dental mesostructures are grinded by milling machines (inLab MCXL, CEREC MCXL). The mesostructure is a part of a 2 part endosseous dental implant

abutment which comprises a titanium base and a zirconium oxide mesostructure. The connection geometries are prefabricated.

5.2.2 Scientific Concept

The underlying scientific concept is the use of an already introduced technology of a titanium base abutment combined with individually CAD/CAM fabricated ceramic prosthetics.

5.2.3 Physical and Performance Characteristics

5.2.3.1 Design

The inCoris ZI meso are blocks of various sizes. The marketed ceramic is pre-sintered. One side of a block is mounted to a mandrel that will be inserted in the spindle's clamping chuck of the grinding machine. The connection geometry to titanium bases is prefabricated, i.e. already included in the shipped block. Connection geometries fit on Camlog (type K2244.xxxx) and Sirona (Tibase) titanium bases (Table 3 and Table 4).

Table 3: Sirona inCoris ZI meso - TiBase Devices Compatibility

Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
NBRS 3.5	6282474	3,5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 4.3	6282482	4.3 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 5.0	6282490	5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 6.0	6282508	6.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBB 3.4	6282516	3.4 mm	inCoris ZI	62 31 810	F0.5

Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
			meso L	62 31 836	F2
NBB 4.1	6282524	4.1 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 3.5	6284231	3.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 4.8	6284249	4.8 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 6.5	6284256	6.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ATOS 3.5/4.0	6282532	3.5 S / 4.0 S mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ATOS 4.5/5.0	6282540	4.5 / 5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
FX 3.4	6282433	3.4 mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
FX 3.8	6282441	3.8 mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
FX 4.5	6282458	4.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
FX 5.5	6282466	5.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
BO 3.4	6282557	3.4 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
BO 4.1	6282565	4.1 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
BO 5.0	6282573	5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 3.5	6282581	3.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 4.5	6282599	4.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 5.7	6282607	5.7 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NB A 4.5	6308188	3.5mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NB A 5.0	6308253	4.3 / 5.0mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
S BL 3.3	6308154	3.3mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
S BL 4.1	6308337	4.1 / 4.8mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
B C 3.4	6308048	3.4mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
B C 4.1	6308097	4.1mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

Titanium Base			Ceramic Block		
TiBase (Sirona)	**REF**	**Diameter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
B C 5.0	6308121	5.0mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

Table 4: Sirona inCoris ZI meso - Camlog Devices Compatibility

Titanium Base			Ceramic Block		
Camlog	**REF**	**Dia-meter**	**inCoris ZI meso (Sirona)**	**REF**	**Color inCoris ZI meso (Sirona)**
K2244.3348	K2244.3348	3.3	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.3848	K2244.3848	3.8	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.4348	K2244.4348	4.3	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.5048	K2244.5048	5.0	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
K2244.6048	K2244.6048	6.0	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

5.2.3.2 Material Used

The inCoris ZI meso are pre-sintered zirconium oxide ceramic blocks. The metal block holder is made of aluminum. The material is composed of:

$ZrO_2+HfO_2+Y_2O_3$	> 99.0%
Al_2O_3	< 0.5%
Other oxides	< 0.5%

5.2.3.3 Physical Properties

The final technical data of inCoris ZI meso are (after final sintering):

Density:	6.06 g/cm^3
Coefficient of thermal expansion (CTE):	11.0*10-6 K^{-1}
Flexural strength:	> 900 MPa
Fracture toughness (KIC):	5.9 MPa·m$^{1/2}$

5.3 Sirona Dental CAD/CAM Design and fabrication Devices

5.3.1 Device Description

The Sirona Dental CAD/CAM Design and fabricating devices for processing mesostructures includes

- Optical acquisition or recording of the topographical characteristics of dental impressions, or stone models using the devices Acquisition unit CEREC 3, CEREC AC, and stationary scanning system inEos Blue
- Design of mesostructures and processing the acquired or recorded data for these purposes using Sirona Dental CAD/CAM Software which runs on a CEREC 3, CEREC AC or PC. Design is performed by a dentist or dental technician
- Milling of the mesostructure using CEREC MCXL or inLab MCXL milling machines from ceramic blocks intended for dental restorations and mesostructures

The Sirona Dental CAD/CAM Design and fabricating devices also processes other dental restorations like crowns, bridge-frameworks, inlays, onlays all regulated under 21 CFR 872.3661, Optical Impression Systems for CAD/CAM, for such intended use.

5.3.2 Scientific Concept

The underlying scientific concept is the use of CAD/CAM technology for the optical acquisition of the topographical characteristics of dental impressions, and models, the design of individual mesostructures using recorded data (CAD), and eventually fabricating (milling) these designed mesostructures (CAM).

5.3.3 Physical and Performance Characteristics

5.3.3.1 Design

Acquisition unit: the device consists of a camera for acquiring optical topographical characteristics of dental impressions. The recorded data are used for the design of individual mesostructures using CAD techniques specific to the dental field.

Fabricating devices: the devices mill the individual designed mesostructures from incoris ZI meso blocks. For this purpose the chucked block and the milling tools move according to prescribed trajectories to generate the shape which is intended to be milled.

5.3.3.2 Materials Used

Not applicable.

5.3.3.3 Physical Properties

Not applicable.

6 Summary of the technological characteristics

6.1 TiBase

All proposed and predicate titanium bases and screws are made of Ti6Al4V, medical grade 5. Connection interfaces to the implants are identical for each defined diameter and connection type. Connection interfaces to dental restorations differ in that proposed devices have an additional notch.

An extensive list is provided in Table 5.

6.2 inCoris ZI meso

Proposed and predicate (K100152) device are inCoris ZI meso.

There has been no modification to inCoris ZI meso from Premarket Notification K100152. Specifically, the following aspects remain identical:

- Composition
- Material properties
- Thickness / design restrictions
- Shape and bonding surface of connection interfaces to Camlog and Sirona Tibase for Sirona inCoris ZI meso blocks
- Bonding material

InCoris ZI meso is bonded to titanium bases for supporting further dental restorations.

InCoris ZI meso material is made of zirconium oxide. The composition of inCoris complies with ISO standard 13356:1997, "Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)". Such compositions are classified as biocompatible by this standard.

An extensive list is provided in Table 6.

6.3 Sirona Dental CAD/CAM Design and fabrication Devices

There has been no modification to the Sirona Dental CAD/CAM Design and fabricating devices from Premarket Notification K100152. Specifically, the following aspects remain identical:

- optical impressions record topographical characteristics of teeth, dental impressions, or stone models for use in the computer aided design and fabrication of dental restorative prosthetic devices in conjunction with endosseous dental implant abutments, i.e. it is an accessory
- features the transfer of data of the optical impression to a remote milling machine via internet or exportation/importation of milling data

The software database of titanium bases has been extended to cover new additional titanium bases.

An extensive list is provided in Table 7.

Table 5: Comparison of Sirona TiBase to Predicate Devices

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
NBRS 3.5	Nobel Biocare	Replace® NP	3,5 mm	Nobel Biocare product catalog page 14. Product-No. 32376	K091756	yes	yes	Internal 3 tenons	yes	same
NBRS 4.3	Nobel Biocare	Replace® RP	4.3 mm	Product-No. 32377	K091756	yes	yes	Internal 3 te-	yes	same

Proposed Device	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry	Connection geometry	Screw geometry
TiBase								Type	Anti-rotational features	
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
								nons		
NBRS 5.0	Nobel Biocare	Replace® WP	5.0 mm	Product-No. 32378	K091756	yes	yes	Internal 3 tenons	yes	same
NBRS 6.0	Nobel Biocare	Replace® 6.0	6.0 mm	Product-No. 32375	K091756	yes	yes	Internal 3 tenons	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
NBB 3.4	Nobel Biocare	Brånemark®	3.4 mm	Nobel Biocare product catalog page 14. Product-No. 32396	K091756	yes	yes	External Hexagonal	yes	same
NBB 4.1	Nobel Biocare	Brånemark®	4.1 mm	Product-No. 32397	K091756	yes	yes	External Hexagonal	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
SSO 3.5	Straumann	Tissue level NN	3.5 mm	Straumann product catalog page 51. Product-No. 048.505	K081005	yes	yes	external octagonal	yes	same
SSO 4.8	Straumann	Tissue level RN	4.8 mm	Product-No. 048.600 (p 55)	K081005	yes	yes	Internal Octagonal	yes	same
SSO 6.5	Straumann	Tissue level WN	6.5 mm	Product-No. 048.606	K081005	yes	yes	Inter-	yes	same

Proposed Device	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
TiBase	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
				(p 62)				nal Octagonal		
ATOS 3.5/4.0	Astra Tech	OsseoSpeed™	3.5 S / 4.0 S mm	Product-No. 24285	K081666	yes	yes	Internal Hexagonal	yes	same
ATOS 4.5/5.0	Astra Tech	OsseoSpeed™	4.5 / 5.0 mm	Product-No. 24235	K081666	yes	yes	Internal Hexa-	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
								gonal		
FX 3.4	Friadent	Frialit® / Xive®	3.4 mm	Friadent product catalog page 32. Product-No. 46-2132	K032158	yes	yes	Internal Hexagonal	yes	same
FX 3.8	Friadent	Frialit® / Xive®	3.8 mm	Product-No. 46-2142	K032158	yes	yes	Internal Hexagonal	yes	same

Proposed Device	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
TiBase	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
FX 4.5	Friadent	Frialit® / Xive®	4.5 mm	Product-No. 46-2152	K032158	yes	yes	Internal Hexagonal	yes	same
FX 5.5	Friadent	Frialit® / Xive®	5.5 mm	Product-No. 46-2162	K032158	yes	yes	Internal Hexagonal	yes	same
BO 3.4	Biomet 3i	Osseotite (Connec-tion	3.4 mm	3i Biomet product catalog page 25.	K072642	yes	yes	External	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
		type: Ex. Hex)		Product-No. MAP32G				Hexagonal External Hexagonal	yes	same
BO 4.1	Biomet 3i	Osseotite (Connec-tion type: Ex. Hex)	4.1 mm	Product-No. APP452G	K072642	yes	yes			
BO 5.0	Biomet 3i	Osseotite (Connec-tion type: Ex. Hex)	5.0 mm	Product-No. WPP552G	K072642	yes	yes	External Hexagonal	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
ZTSV 3.5	Zimmer	Tapered Screw-Vent®	3.5 mm	Zimmer product catalog page 9. Product-No. ZOA342S	K060880	yes	yes	Internal Hexagonal	yes	same
ZTSV 4.5	Zimmer	Tapered Screw-Vent®	4.5 mm	Product-No. ZOA442S	K060880	yes	yes	Internal Hexagonal	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
ZTSV 5.7	Zimmer	Tapered Screw-Vent®	5.7 mm	Product-No. ZOA562S	K060880	yes	yes	Internal Hexagonal	yes	same
NB A 4.5	Nobel Biocare	Nobel Active NP	3,5mm	Nobel Biocare product Catalog page 71. Product-No. 34194	K102436	yes	yes	Internal Hexagonal	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
NB A 5.0	Nobel Biocare	Nobel Active RP	4,3 / 5,0mm	Product-No. 34198	K102436	yes	yes	Internal Hexagonal	yes	same
S BL 3.3 ®	Straumann	Bone Level NC	3,3mm	Straumann product Catalog Product-No. 022.2102	K062129	yes	yes	Internal 4 slots	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
S BL 4.1	Straumann	Bone Level RC	4,1 / 4,8mm	Product-No. 022.4102	K062129	yes	yes	Internal 4 slots	yes	same
B C 3.4	Biomet 3i	Certain®	3,4mm	Biomet product Catalog page 5 Product-No. IMAP32G	K073345	yes	yes	Internal. Hexagonal	yes	same
B C 4.1	Biomet 3i	Certain®	4,1mm	Biomet product	K073345	yes	yes	Internal	yes	same

Proposed Device TiBase	Predicate Device					Abutment and Screw made of Ti6Al4V	Identical connection geometry to abutments	Connection geometry Type	Connection geometry Anti-rotational features	Screw geometry
	Manufacturer	System	Diameter	Titanium Base	Predicate Devices K-Number					
				Catalog page 5 Product-No. IAPP452G				Hexagonal		
B C 5.0	Biomet 3i	Certain®	5,0mm	Biomet product Catalog page 5 Product-No. IWPP562G	K073345	yes	yes	Internal Hexagonal	yes	same

Table 6: Comparison of InCoris ZI meso to Predicate Device

	InCoris ZI meso	InCoris ZI meso (K100152)
Intended use	inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.	inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.
Application	inCoris ZI mesostructures can only be used for the intended titanium bases or implants. Allocation of the connection size to the respective titanium base can be determined by the scanbody set of the respective implant system. Please observe the indications and contraindications of the implant.	inCoris ZI mesostructures can only be used for the intended titanium bases or implants. Allocation of the connection size to the respective titanium base can be determined by the scanbody set of the respective implant system. Please observe the indications and contraindications of the implant.
Contra-Indications	• Insufficient oral hygiene • Insufficient space available • Bruxism • For mesostructure-geometry with angulation correction greater than 20° to the implant axis • For mesostructure-geometry with angulation correction to the implant axis for Camlog only • For individual tooth restorations with free end saddle • For restorations with a length to implant length ratio of more than 1:1.25	• Insufficient oral hygiene • Insufficient space available • Bruxism • For restorations with angulation correction to the implant axis • For individual tooth restorations with free end saddle • For restorations with a length to implant length ratio of more than 1:1.25
Technical Data		
Block-Material Composition	• ZrO2+HfO2+Y2O3: > 99.0% • Y2O3: 5.2% • HfO2: 2%	• ZrO2+HfO2+Y2O3: > 99.0% • Y2O3: 5.2% • HfO2: 2%

	InCoris ZI meso	InCoris ZI meso (K100152)
	• Al2O3: ≤ 0.05% • Fe2O3: 0.3%	• Al2O3: ≤ 0.05% • Fe2O3: 0.3%
Density (sintered)	6.06 g/cm^3	6.06 g/cm^3
Coefficient of thermal expansion (CTE)	11.0*10^{-6} K^{-1} (20 °C - 500 °C)	11.0*10^{-6} K^{-1} (20 °C - 500 °C)
Flexural strength	> 900MPa	> 900MPa
Fracture toughness (K_{IC})	5.8 MPa·m$^{1/2}$	5.8 MPa·m$^{1/2}$
Grain Size	about 0.5 µm	about 0.5 µm
Bonding Material	Panavia F 2.0 (www.kuraray-dental.de)	Panavia F 2.0 (www.kuraray-dental.de)

Table 7: Comparison of Sirona Dental CAD/CAM Design and fabricating Devices to Predicate Devices

	Sirona Dental CAD/CAM Design and fabricating Devices	Sirona Dental CAD/CAM Design and fabricating Devices (K100152)
Used for	The Sirona Dental CAD/CAM-System is indicated for taking optical impressions to record the topographical characteristics of teeth, dental impressions, or stone models by computer aided design and fabrication in patients that require dental restorative prosthetic devices. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments. Sirona Dental CAD/CAM Design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. Devices which feature the processing of mesostructures comprises CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL	The Sirona Dental CAD/CAM-System is indicated for taking optical impressions to record the topographical characteristics of teeth, dental impressions, or stone models by computer aided design and fabrication in patients that require dental restorative prosthetic devices. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments. Sirona Dental CAD/CAM Design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. Devices which feature the processing of mesostructures comprises CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL
Used with	Sirona Dental CAI/CAM Hardware	Sirona Dental CAI/CAM Hardware
Controlling of recording process (CAI) (optical impression)	Yes	Yes
Processing the recorded	Yes	Yes

	Sirona Dental CAD/CAM Design and fabricating Devices	Sirona Dental CAD/CAM Design and fabricating Devices (K100152)
data (data of optical impression) (CAD)		
Export of milling data to milling machine	Yes	Yes
Administration of patient data	Yes	Yes
Further functions	Calibration of CAI/CAM hardware	Calibration of CAI/CAM hardware
Online capability	Option to upload/download the data from a web portal (Cerec Connect), to have CAI and CAM operating on two different locations connected via Internet	Option to upload/download the data from a web portal (Cerec Connect), to have CAI and CAM operating on two different locations connected via Internet
Scan Implant Interface/surface	Yes (or with mounted scanbody)	Yes (or with mounted scanbody)
Scan custom wax-up	Yes	Yes
Preparation of individual restoration ("meso-structure") to be mounted on the abutment	Yes	Yes
Bond of milled ziconia/ceramic individual meso-structure to metal abutment	Yes	Yes
Create of fitting crown to be mounted on top of meso-structure	Yes	Yes
Used with	Sirona Dental CAI/CAM Hardware	Sirona Dental CAI/CAM Hardware

	Sirona Dental CAD/CAM Design and fabricating Devices	Sirona Dental CAD/CAM Design and fabricating Devices (K100152)
Used for	CAD creation of dental restorations including inlays, onlay, venners, crowns, bridges and meso-structure to be mounted on top of abutments	CAD creation of dental restorations including inlays, onlay, venners, crowns, bridges and meso-structure to be mounted on top of abutments
Controlling of measurement process (CAI)	Yes	Yes
Processing the measurement data (CAD)	Yes	Yes
Export to milling machine	Yes	Yes
Administration of patient data	Yes	Yes
Further functions	Calibration of CAI/CAM hardware	Calibration of CAI/CAM hardware

7 Nonclinical Testing

According to FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", May 12, 2004, fatigue testing has been performed for angled abutments. A reverse-engineering analysis has demonstrated that the devices are identical with their predicates and compatible with their mating implants.

Software validation testing has been performed according to IEC 62304:2006. A warning has been added warning the user that abutments with an angle of greater than 20° are out of specification.

8 Clinical Testing

Clinical testing is not required and has not been performed.

9 Conclusion

Based on a comparison of intended use, indications, construction materials, principal of operations, features and technical data, the Sirona Dental CAD/CAM System which comprises of titanium bases TiBase, inCoris ZI meso blocks and Sirona Dental CAD/CAM Design and fabricating devices are safe and effective their intended use and perform as well as and are substantially equivalent to their Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Fritz Kolle
Sirona Dental Systems GmbH
Fabrikstrasse 31
Bensheim
Germany D-64625

FEB 17 2012

Re: K111421
Trade/Device Name: Sirona Dental CAD/CAM System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 14, 2012
Received: February 16, 2012

Dear Mr. Kolle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Sirona Dental CAD/CAM System

Indications for Use:

The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems:

- Nobel Biocare Replace (K020646)
- Nobel Biocare Branemark (K022562)
- Friadent Xive (K013867)
- Biomet 3i Osseotite (K980549)
- Astra Tech Osseospeed (K091239)
- Zimmer Tapered Screw-Vent (K061410)
- Straumann SynOcta (K061176)
- Straumann Bone Level (K053088)
- Biomet 3i Certain (K014235)
- Nobel Biocare Active (K071370)

for Dr S. Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111421

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Appendix 23 – Lava™ Frame, Lava™ Frame Shade 510(k) Summary

K072055 1/2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:.....3M ESPE AG

Strect:.....ESPE Platz

ZIP-Code, City:.....D-82229 Seefeld

Federal State: .....Bavaria

Country: .....Germany

Establishment Registration Number 9611385

Official Correspondent: .....Dr. Andreas Petermann,

.....Manager Regulatory Affairs

Phone: 011-49-8152-700 1395

Fax: 011-49-8152-700 1869

E-mail:.....Andreas.Petermann@mmm.com

Date:.....July 23, 2007

Name of Device

Proprietary Name:.....Lava™ Frame, Lava™ Frame Shade

Classification Name:.....Porcelain powder for clinical use

.....Endosseous dental implant abutment

Common Name: .....All-ceramic core material

.....All-ceramic stain solution

.....Abutment

Predicate Device

ALTATEC Camlog Implant System and

Abutments by Altatec Biotechnologies K032448

1562

K072055

Description for the Premarket Notification

Lava™ abutment made from Lava™ Frame zirconia mill blanks and dyed with Lava™ Frame Shade is classified as endosseous dental implant abutment (21 C.F.R. § 872.3630) because it is a prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Lava™ Frame and Lava™ Frame Shade are parts of the Lava™ system (K011394). Lava™ Frame Zirconia mill blanks are used for the fabrication of frameworks for all-ceramic restorations. The frameworks for onlays, inlays, veneers, crowns and bridges are designed and manufactured by CAD/CAM technology, whereas the CAM fabricated Lava™ Abutments made from Lava™ Frame Zirconia mill blanks will be designed by means of a traditional wax up technique. The wax up will be scanned (Lava™ Scan, K062493) and milled without any further design step in the CNC milling unit Lava™ Form. After milling, the abutments are dyed with one of the 7 Lava™ Frame Shade dyeing liquids as required to achieve the desired tooth color, then sintered. The dyed abutments are sintered using the specialized program of the Lava™ Therm sintering furnace.

The wax up designed abutment will be cemented to a titanium interface which will be subsequently screwed into the respective implant (e.g. Camlog, Altatec Biotechnologies).

The comparison for composition, performance data and indications for use shows that Lava™ abutment made from Lava™ Frame and dyed with Lava™ Frame Shade is substantially equivalent to the predicate device.

In summary, it can be concluded that safety and effectiveness requirements for Lava™ Frame and Lava™ Frame Shade for the fabrication of abutments are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Desi W. Soegiarto
Regulatory Affairs Specialist
3M ESPE AG Dental Products
ESPE Platz
Seefeld, Bavaria
GERMANY D-82229

MAR 29 2011

Re: K072055
Trade/Device Name: Lava™ Frame, Lava™ Frame Shade
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 18, 2008
Received: February 21, 2008

Dear Dr. Soegiarto:

This letter corrects our substantially equivalent letter of February 26, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072055

Device Name: Lava™ Frame, Lava™ Frame Shade

Indications For Use: The Lava™ system is intended for CAD/CAM fabrication of all-ceramic dental restorations.

The system is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

Lava™ Frame and Lava™ Frame Shade are intended for the manufacturing of abutments. The titanium connection for the abutment must meet the following dimensions:
- Overall cementation surface > 30 mm²
- Height of the head of the titanium interface from the shoulder > 2.8 mm

The following systems fulfill the above described specifications:
- Co. Alltec Dental GmbH: Camlog Titanium-base for Ceramic-abutment – Abutment ø ≥ 4.3 mm
- Co. Dentsply Friadent GmbH: Friadent Cera Base
- Co. Neoss GmbH: Neo Link Neoss Mono Abutment Titanium; Neo Link Neoss Multi Abutment Titanium; Neo Link Neoss Mono Aesthetic Abutment Titanium; Neo Link Neoss Multi Aesthetic Abutment Titanium; Matrix Abutment Hex – Regular Mono Titan; Matrix Abutment Hex – Regular Multi Titan; Matrix Abutment Hex – Narrow Mono Titan; Matrix Abutment Hex – Narrow Multi Titan; Matrix Abutment C-Lect – Regular Mono Titan; Matrix Abutment, C-Lect – Regular Multi Titan; Matrix Abutment C-Lect – Narrow Mono Titan; Matrix Abutment C-Lect – Narrow Mono Titan; Matrix Abutment ST – Mono Titan; Matrix Abutment ST – Mono Titan

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of _____

510(k) Number: K072055

92