K041493

AUG 1 9 2004

Cementek®
510(k) Summary
May 28, 2004

Submitter: Teknimed, S.A.
11 rue Apollo
31240 L'Union
FRANCE

Contact person: J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade Name: Cementek®

Common name: Bone void filler

Classification name: Class II per 21 CFR section 888.3045

Product Code: MQV

Equivalent Device: Cem-Ostetic™ (Berkley Advanced Biomaterials - K022622)
α-BSM (DePuy - K011048).

Device Description
As a malleable bone substitute, Cementek® is packaged as a solid phase and a liquid phase. The liquid and solid phases are mixed in the operating room, then introduced as a paste into the osseous cavity and allowed to set. This reaction is an athermic reaction resulting in a apatitic calcium phosphate cement. Cementek is marketed in two different dosages; Cementek® 20 produces 8cc of paste and Cementek® 40 produces 16cc.

Intended Use
Cementek® is intended for use only as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be molded to specific shapes and placed into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

Summary of Technological Characteristics Compared to Predicate Device
Cementek® is equivalent to α-BSM and Cem-Ostetic™ in terms of physical form, how supplied, compressive strength, porosity, average pore size, composition of final product and indications. In an animal model is performed similar to α-BSM.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 9 2004

Teknimed SA
c/o Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd.
Round Rock, TX 78681

Re: K041493
Trade Name: Cementek
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: May 28, 2004
Received: June 4, 2004

Dear Mr. Webb:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041493

Device Name: Cementek®

Indications for Use:

Cementek® is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be molded to specific shapes and placed into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, Cementek® resorbs and is replaced with bone during the healing process.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041493

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 9 2004

Teknimed SA
c/o Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd.
Round Rock, TX 78681

Re: K041493
Trade Name: Cementek
Regulation Number: 21 CFR 888.3045
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Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041493

Device Name: Cementek®

Indications for Use:

Cementek® is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be molded to specific shapes and placed into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, Cementek® resorbs and is replaced with bone during the healing process.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041493

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

June 04, 2004

TEKNIMED SA
C/O THE ORTHOMEDIX GROUP, INC.
1001 OAKWOOD BLVD
ROUND ROCK, TX 78681
ATTN: J.D. WEBB

510(k) Number: K041493
Received: 04-JUN-2004
Product: CEMENTEK

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

14

K041493

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)

Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

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

TEKNIMED SA
11 RUE APOLLO
L? UNION, 31240
FR

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
JD WEBB

2.1 E-MAIL ADDRESS
ortho.medix@sbcglobal.net

2.2 TELEPHONE NUMBER (Include Area Code)
512-388-0199

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
512-388-0199

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/oc/mdufma

Select an application type:

- Premarket notification (510(k)); except for third party
- Biologic License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

3.1 Select one of the types below:

- Original Application

Supplement Types:

- Efficacy (BLA, PMR)
- 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

NO, I am not a small business

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

5. 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, parents, and partner firms
- This biologic 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 distributed commercially

6. 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 THE USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS APPLICATION

(b) (4)

Sk 26
PM
II 15

THE ORTHOMEDIX GROUP, INC.

May 28, 2004

Document Mail Center (HFZ401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Premarket Notification – Cementek® Bone Void Filler

Dear Sir/Madam,

This Premarket Notification is being submitted in compliance with 21 CFR section 807.81 of the Federal Food, Drug and Cosmetic Act.

Applicant	Teknimed, S.A.
Address	11 rue Apollo 31240 L'Union FRANCE
Contact Person	J.D. Webb
Address	1001 Oakwood Blvd Round Rock, TX 78681
Telephone Number	512-388-0199
Fax Number	512-388-0199
E-mail Address	ortho.medix@sbcglobal.net

We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market this device.

Respectfully,

J D Webb

J.D. Webb
Authorized Contact Person

Table of Contents

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as <*M.LEONARD Alain* > of <TEKNIMED S.A.> 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.

(Signature)

A LEONARD

(Typed name)

12/05/2004

(Dated)

*(Premarket Notification [510(k)] Number)

* For a new submission, leave the space for the 510(k) number blank.

18

Indications for Use

510(k) Number (if known): K041493

Device Name: Cementek®

Indications for Use:

Cementek® is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be molded to specific shapes and placed into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, Cementek® resorbs and is replaced with bone during the healing process.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

X9

Cementek®
510(k) Summary
May 28, 2004

Submitter: Teknimed, S.A.
11 rue Apollo
31240 L'Union
FRANCE

Contact person: J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade Name: Cementek®

Common name: Bone void filler

Classification name: Class II per 21 CFR section 888.3045

Product Code: MQV

Equivalent Device: Cem-Ostetic™ (Berkley Advanced Biomaterials - K022622)
α-BSM (DePuy - K011048).

Device Description

As a malleable bone substitute, Cementek® is packaged as a solid phase and a liquid phase. The liquid and solid phases are mixed in the operating room, then introduced as a paste into the osseous cavity and allowed to set. This reaction is an athermic reaction resulting in a apatitic calcium phosphate cement. Cementek is marketed in two different dosages; Cementek® 20 produces 8cc of paste and Cementek® 40 produces 16cc.

Intended Use

Cementek® is intended for use only as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be molded to specific shapes and placed into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

Summary of Technological Characteristics Compared to Predicate Device

Cementek® is equivalent to α-BSM and Cem-Ostetic™ in terms of physical form, how supplied, compressive strength, porosity, average pore size, composition of final product and indications. In an animal model is performed similar to α-BSM.

1. Device Name

1.1. Trade Name
Cementek®

1.2. Common Name
Bone void filler

1.3. Classification Name
Filler, calcium sulfate, preformed pellets

2. Registration Number
9615788

3. Classification

3.1. Class
Class II per 21 CFR Sec. 888.3045

3.2. Panel
Orthopedic

3.3. Product Code
MQV

4. Performance Standards
There are no performance standards for calcium phosphate cement.

5. Labeling (Exhibit I)
Draft labels and Instructions for Use can be found in Exhibit I.

6. Substantial Equivalence Comparison (Exhibit II)
Cementek® is similar to Cem-Ostetic™ (Berkley Advanced Biomaterials - K022622) and α-BSM (DePuy - K011048). A table comparing the various properties is shown below.

Cementek®	*Property*	α-BSM	Cem-Ostetic™
(b)(4)			

21

Cementek®	*Property*	α-BSM	Cem-Ostetic™
(b) (4)			

7. Device Description (Exhibit III)

As a malleable bone substitute, Cementek® is packaged as a solid phase and a liquid phase. The liquid and solid phases are mixed in the operating room, then introduced as a paste into the osseous cavity and allowed to set.

7.1. Indications for Use

Cementek® is intended for use only as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be molded to specific shapes and placed into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

7.2. Chemical Composition

Cementek® is manufactured by processing and mixing calcium carbonate and calcium dihydrogenophosphate, creating tetracalcium phosphate(TTCP). In parallel, amorphous tricalcium phosphate(TCP) is processed creating α-tricalcium phosphate. These two components are mixed with sodium glycerophosphate to produce the solid phase of the product.

Calcium hydroxide, orthophosphoric acid and water are mixed and processed to create the liquid phase of Cementek®.

The solid and liquid phases are packaged separately in a pouch and flask then boxed together as a kit.

A schematic of the manufacturing process can be found in Exhibit III.

7.2.1. Raw materials

(b) (4)

7.3. Physical Properties

(b) (4)

7.4. Device Performance Characteristics

(b) (4)

8. Performance (Exhibit IV)

(b) (4)

[redacted]

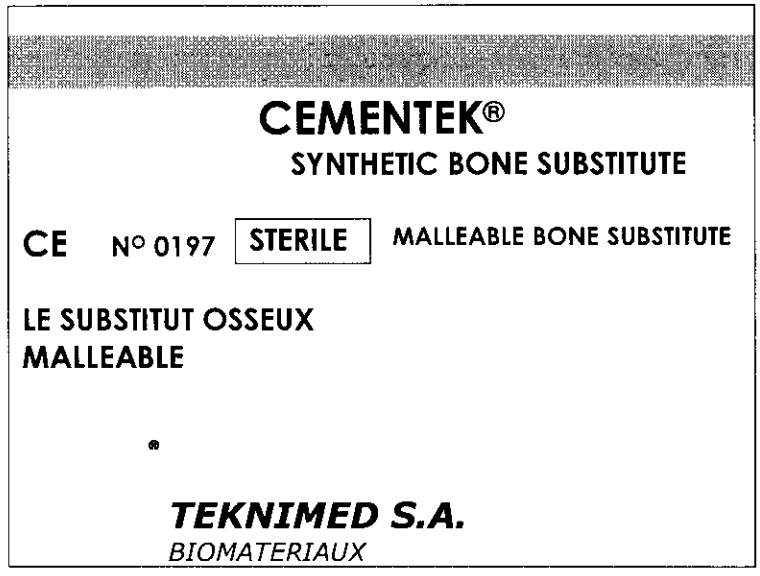
(b) (4)

9. Sterility

(b) (4)

(b) (4)

Sample Label



CEMENTEK®
Synthetic Bone Substitute

The malleable bone substitute

CE0197
Instructions leaflet
Manufactured in France by:
TEKNIMED S.A.
B.P. 60
65502 VIC-EN-BIGORRE Cedex
Tél. 33 (0)5 62 96 88 38
Fax 33 (0)5 62 96 28 72

Caution: U.S. Federal law restricts this device to sale by or on the order of the physician (or properly licensed practitioner)

Before using Teknimed products, the operating surgeon should study thoroughly the safety information specified in these instructions as well as the product-specific information (product description, surgical procedures, brochures etc.). The related documentation is obtainable from the respective national representative. At the same time the operating surgeon must be aware of the residual risks associated with the use of the intended products.

GENERAL INSTRUCTIONS

The implantation of Teknimed products may only be carried out by surgical staff who possess a thorough knowledge of and experience in the area of joint replacement and, in particular, have mastered the product specific surgical techniques relating to Teknimed products. The particular surgical techniques required for Teknimed bone substitute can be learned at Teknimed distributors.
Cementek ® bone substitute is in the form of an apatitic paste designed for the regenerative replacement of bone.

COMPOSITION

This product of synthesis is controlled during all its manufacture, from raw material to the final product.
Composition:

Powder:	
tetracalcium phosphate	49%
α tricalcium phosphate	38%
NaGP	13%
Liquid:	
calcium hydroxide	3,4%
phosphoric acid	13,8%
water	82,8%

PREPARATION FOR USE

Mix in a cup the whole of the powder and liquid to achieve a homogeneous mixture. The paste obtained will become less and less malleable, until becoming hard after 10 min.
Full hardening follows in-situ within 48 to 72 hours.
Match the quantity of Cementek® to the site of bone defect to obtain the fullest contact with the lost bone.

INSTRUCTIONS FOR USE

1. Open the sachet and pour the powder in a mortar.
2. Pour the liquid on the powder.
3. Mix energetically by crushing the powder and the liquid during 1 to 2 min.
4. Use the spatula to collect the paste and to homogenize the mixture. If possible, materialize the form of bone defect.
5. Let harden in the air 5 to 10 min.
6. After having dried the cavity, put the paste in the bone defect. A lot of manipulations of the paste will change the mechanical properties. It is possible to clean and to dry the cavity with STERILE hydrogen peroxide, unless otherwise exceptions.

PRECAUTIONS FOR USE

The cavity must be carefully irrigated and dried before application of Cementek®.
Cementek® has stability of shape after 10 minutes. It is recommended to limit the load applied during the first 48 hours, on large bone defects. In areas of weak regeneration an osteosynthetic support is recommended.

INDICATIONS

Cementek® is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be molded to specific shapes and placed into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, Cementek® resorbs and is replaced with bone during the healing process

CONTRAINDICATIONS

The same as applying to all bone grafts
- metabolic conditions.
- use in an infected area (osteomyelitis, tuberculosis).
- in an area having no possibility of regeneration or infected bone (risk of sequestration).

POSSIBLE ADVERSE EFFECTS

~~No secondary effect has been found to date~~. Use during pregnancy and breast-feeding no contraindications.

Possible adverse effects include, but are not limited to:

29

- Wound complications including hematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery
- Fracture or extrusion of Cementek® with or without generation of particulate debris
- Deformity of the bone at the site
- Incomplete, or lack of, osseous ingrowth into bone void, as is possible with any bone void filler.

STERILIZATION

Cementek ® is sterilized with 25 to 40 kGy (2,5 to 4,0 Mrad) gamma radiation. All sterile implants are to be kept unopened in the original packaging until the time of implantation. Before using the implant, the protective packaging should be checked for damage as this could be detrimental to the sterility. Aseptic procedures should be observed when removing the implant from the protective package.
Cementek® is delivered sterile under double wrapping, ready for use in an operating room.
Remarks:
Verify the integrity of the packaging before use, the guarantee of sterilization is 5 years from the date of sterilization.
Use after the peremptory date is not allowed. All re-sterilization of the product is forbidden use only once.

PATIENT INFORMATION

The doctor must draw the patient's attention to the contents of the indications and contraindications paragraph, as well as factors which can impair the results of the operation and to possible complications which can arise as a result of an indication. The patient must also be informed about the measures which the doctor will use to minimize the possible effects of these factors.

PACKAGING AND STORAGE

Individually wrapped in quantities.

Designation	Reference	Volume cm^3
Cementek 20	T815020	8 cm^3
Cementek 40	T815040	16 cm^3

Store at room temperature.

K011048

NOV 1 3 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581-0988
USA
Tel: +1 (219) 267 8143
Fax: +1 (219) 267 7196

NAME OF FIRM: DePuy, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(k) CONTACT: Lynnette Whitaker
Manager, Regulatory Affairs

TRADE NAME: α-BSM® Bone Substitute Material

COMMON NAME: Bone Substitute Material, Bone Void Filler, Bone Graft Material

CLASSIFICATION: Not classified

DEVICE PRODUCT CODE: MQV

SUBSTANTIALLY EQUIVALENT DEVICES:

- α-BSM – Bone Substitute Material (K983009)
- Pro Osteon Implant 500R Resorbable Bone Graft Substitute (K990131)
- Osteoplast, Model POP200 (K991854)

DEVICE DESCRIPTION :

α-BSM, Bone Substitute Material is a synthetic, biocompatible, calcium phosphate implantable paste that hardens endothermically at body temperature and converts to an apatitic calcium phosphate. It is provided in single use packages containing either 1.0, 2.5, 5.0, or 10 grams of α-BSM powder in a mixing bulb, sterile mixing solution, an appropriately sized syringe, and a 16 gauge needle.

INTENDED USE:

α-BSM Bone Substitute Material is indicated for filling bone voids or defects of the skeletal system (such as the extremities, spine, and the pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. α-BSM is a bone graft substitute that resorbs and is replaced with bone during the healing process.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject α-BSM Bone Substitute Material is identical in material, design, and method of use to the currently cleared and marketed α-BSM Bone Substitute Material for cranioplasty indications, and is identical in indications to the cleared ProOsteon 500R and Osteoplast devices. The safe and effective use of the device has been demonstrated through extensive testing, including a representative animal model. These facts provide all necessary information for a finding of substantial equivalency of the subject α-BSM Bone Substitute Material to the currently marketed predicate devices.

510(k) Number (if known) K011048

Device Name: α-BSM® Bone Substitute Material

NOV 1 3 2001

Indications for Use:

α-BSM® Bone Substitute Material is indicated for filling bone voids or defects of the skeletal system (such as the extremities, spine, and the pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. α-BSM is a bone graft substitute that resorbs and is replaced with bone during the healing process.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR (Per 21 CFR 801.109) Over-The Counter Use

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011048

000011

JAN 0 9 2003 K022622

BERKELEY ADVANCED BIOMATERIALS, INC.
1933 Davis Street, Suite 307, San Leandro, CA 94577, USA
Tel: 510) 883 1644; Fax: (510) 883 1315
Email: info@hydroxyapatite.com
http://www.hydroxyapatite.com

ISO9001 - ISO13485

510(K) Summary

In accordance with the Food and Drug Admisnistration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the Cem-Ostetic™ Bone Void Filler.

Submitted By:	Berkeley Advanced Biomaterials, Inc.
Date:	5 January 2003
Contact Person:	François Génin, Ph.D.
Position:	President and CEO
Contact Information:	Phone: 510-883-1644; Fax: 510-883-1315
Proprietary Name:	Cem-Ostetic™
Common Name:	Bone Void Filler
Classification Name and Reference:	Unclassified
Device Product Code and Panel Code:	Orthopedics/87/MQV

DEVICE INFORMATION

A. INTENDED USES/INDICATIONS

Cem-Ostetic™ is an osteoconductive putty that is intended to be used to fill voids and gaps that are not intrinsic to the stability of the bone structure. These gaps or voids may be located in the extremities, spine, pelvis, or cranium.

The putty may be shaped and pressed into the void by hand or inserted into a syringe and injected into the surgical site. The Cem-Ostetic™ paste set *in situ* or *ex situ* provides a void filler that can augment hardware to support bone fragments during the surgical procedure. The set putty acts as a temporary support medium and is not intended to provide structural support during the healing process. The implant is radio-opaque. Cem-Ostetic™ is biocompatible and resorbs in the body as bone ingrowth occurs.

B. DEVICE DESCRIPTION

Cem-Ostetic™ consists of a pre-measured formulation of distilled water and calcium-based compounds in a container that can be used to prepare a putty. Cem-Ostetic™ forms a paste when mixed with sterile distilled water. When 4 centimeter cubes (cc) of water are mixed with 10 cc of powder, the paste becomes hard after 5 minutes. Both powder and water are supplied pre-measured in separate containers. To prepare the putty, the water is first poured into the jar containing the powder and mixed with it for 60 seconds. For the next two minutes, the putty can be shaped into an implant or inserted into a syringe and injected into the surgical site (i.e., bony voids or gaps of skeletal system). The putty will harden on average within 5 minutes of contact between powder and water. The Cem-Ostetic™ powder and the water are supplied sterile for single patient use only.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

Cem-Ostetic™ is substantially equivalent to legally marketed, predicate devices OsteoSet BVF Kit and Osteoplast. The products have identical indications-for-use and identical contraindications. They also have the same warnings, precautions and potential adverse events. The technical characteristics of Cem-Ostetic™ are very similar to that of the predicate devices. The safety and effectiveness of Cem-Ostetic™ are adequately supported by the substantial equivalence information, materials data, and test results provided in the full document submitted within the scope of this Premarket Notification.

33

510(k) Number (if known): K022622

Device Name: **Cem-Ostetic™ bone void filler**

Indications for Use:

Cem-Ostetic™ is an osteoconductive putty that is intended to be used to fill voids and gaps that are not intrinsic to the stability of the bone structure. These gaps or voids may be located in the extremities, spine, pelvis, or cranium.
The putty may be shaped and pressed into the void by hand or inserted into a syringe and injected into the surgical site. The Cem-Ostetic™ paste set *in situ* or *ex situ* provides a void filler that can augment hardware to support bone fragments during the surgical procedure. The set putty acts as a temporary support medium and is not intended to provide structural support during the healing process. The implant is radio-opaque. Cem-Ostetic™ is biocompatible and resorbs in the body as bone ingrowth occurs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

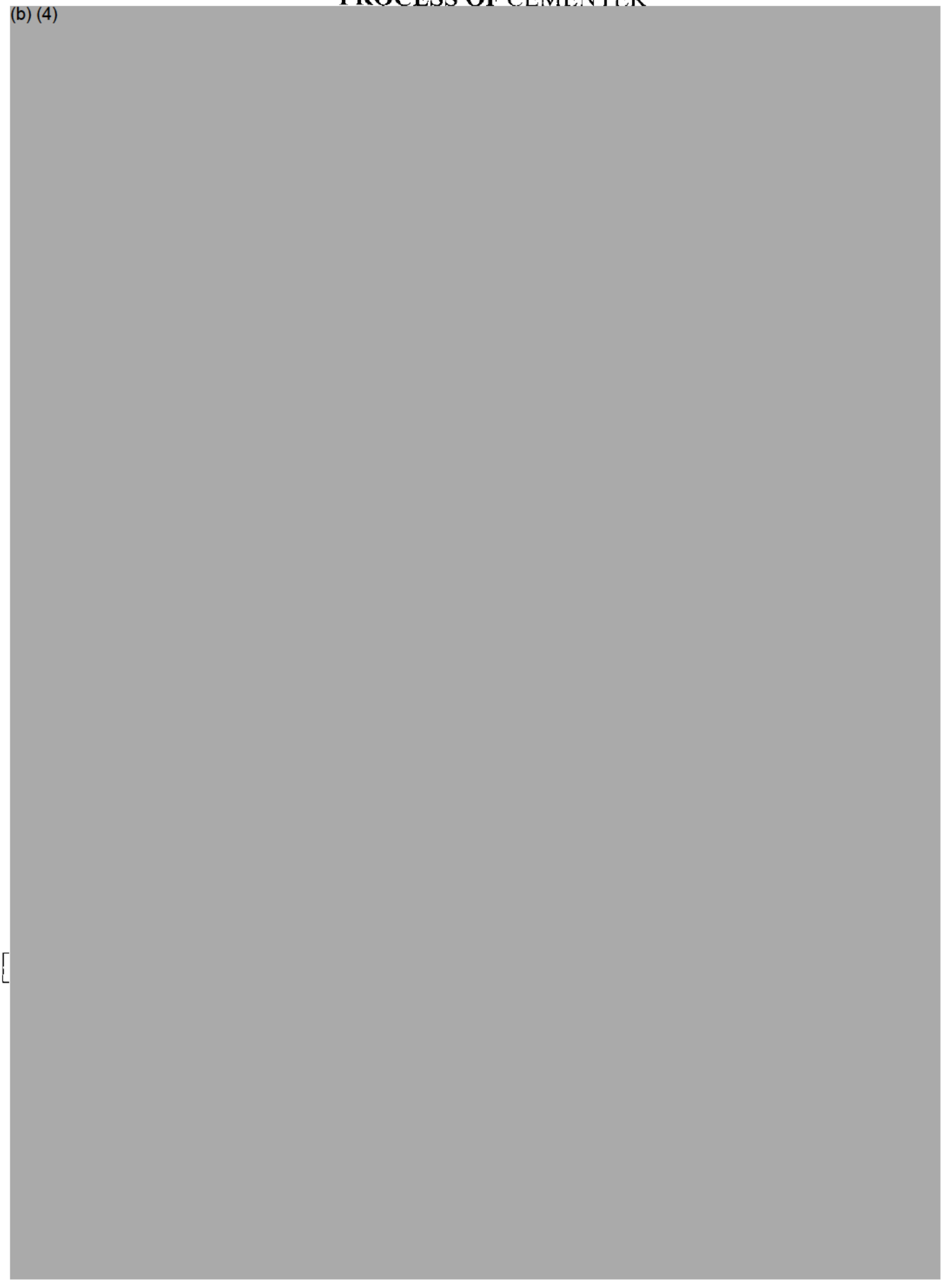
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022622

134

PROCESS OF CEMENTEK

(b) (4)



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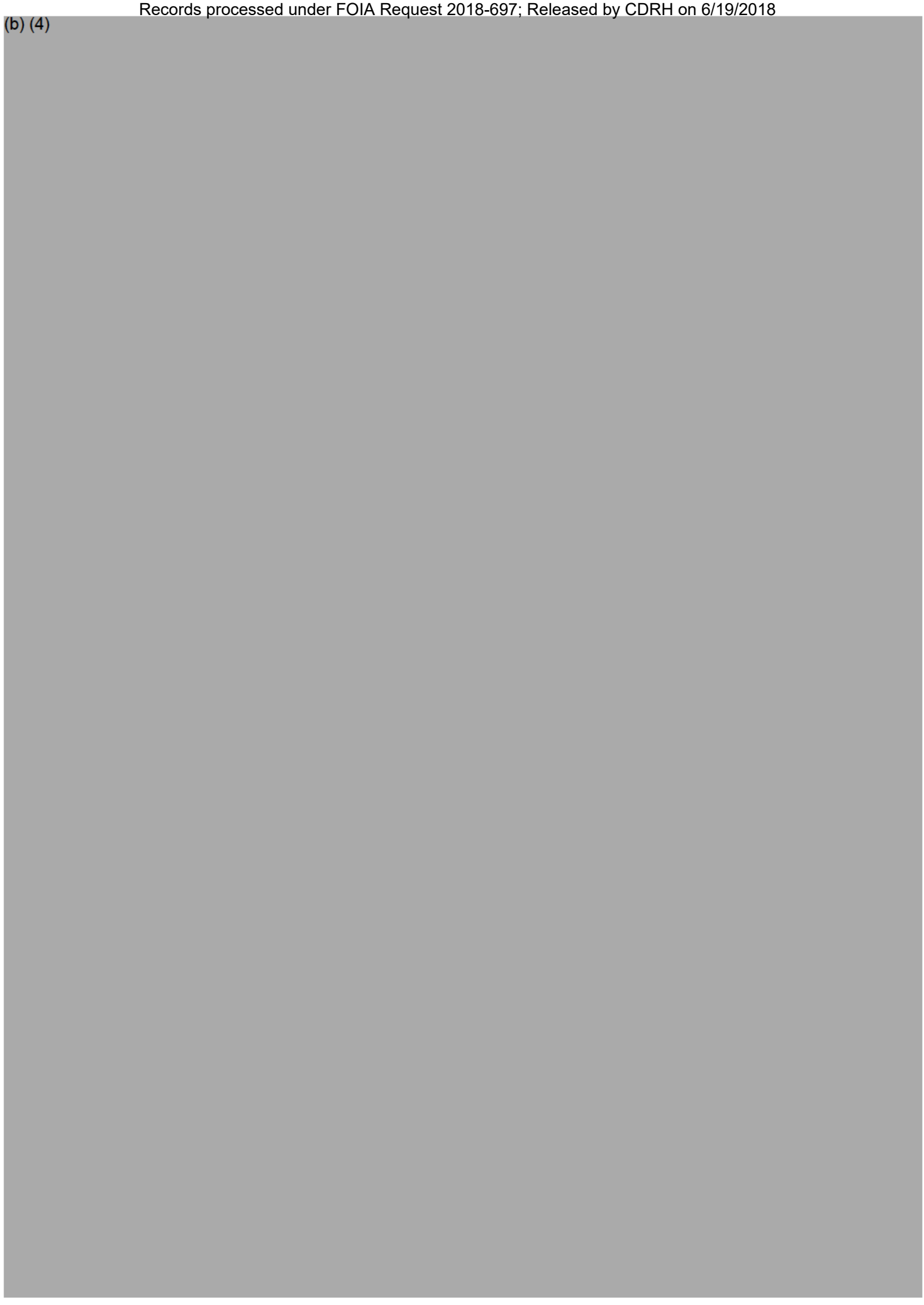

title page of whole thesis not what claiming

SPINAL FRACTURES:

TREATMENT OPTIONS AND DEVELOPMENT OF A VERTEBRAL REPLACEMENT IMPLANT

Paul VANDERSCHOOT

Click here to continue

Thesis submitted in fulfillment of the requirements for the degree of
Doctor in de Medische Wetenschappen, 2002

37

Chapter 8

Biocompatibility of Ca/P-Cements in critically sized bone defects: an animal study.

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38

8.2. Materials and methods

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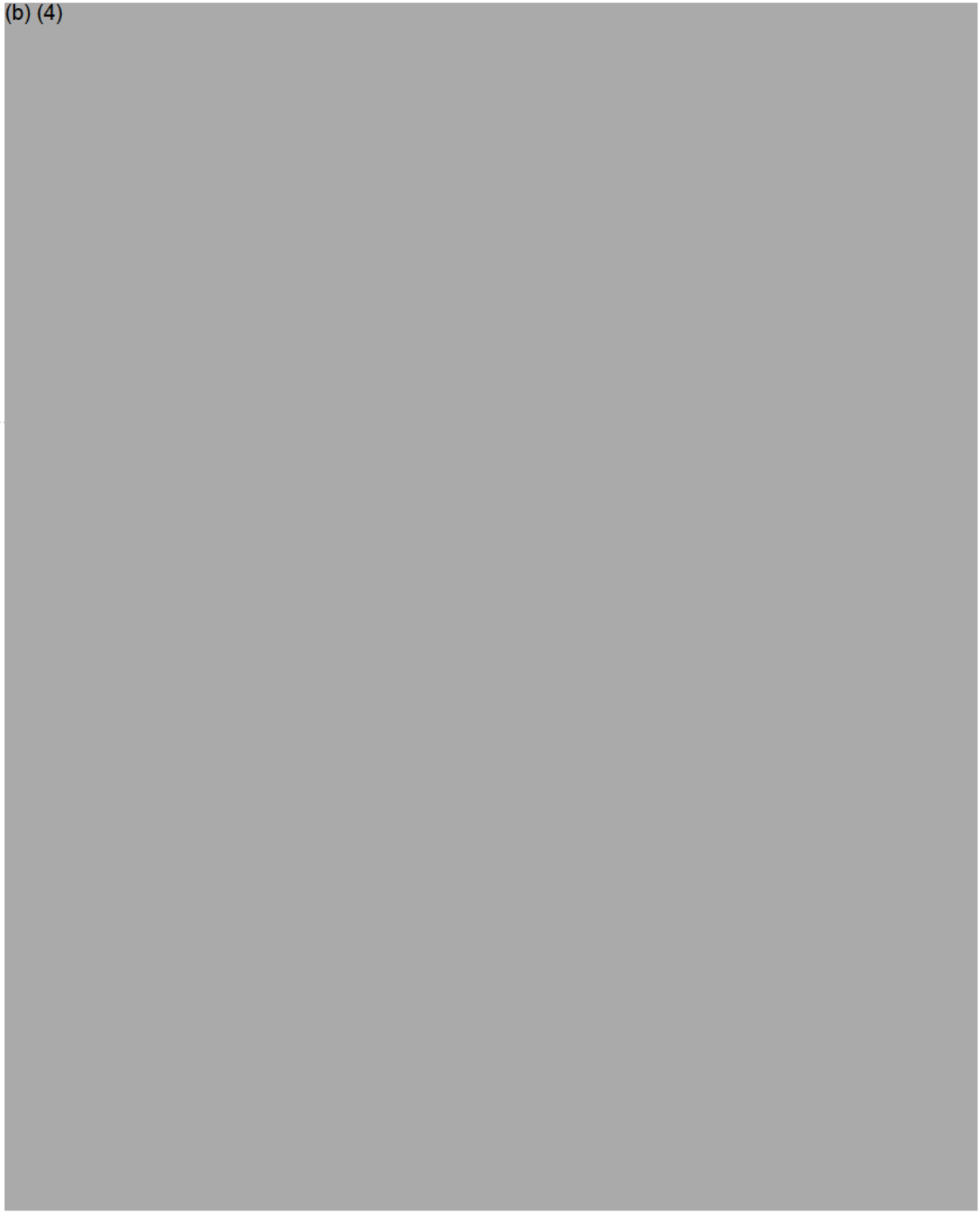

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8.2.2. Animals

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8.2.3. Surgical procedure

(b) (4)

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8.2.4. Histometric assessments.

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8.3. Results

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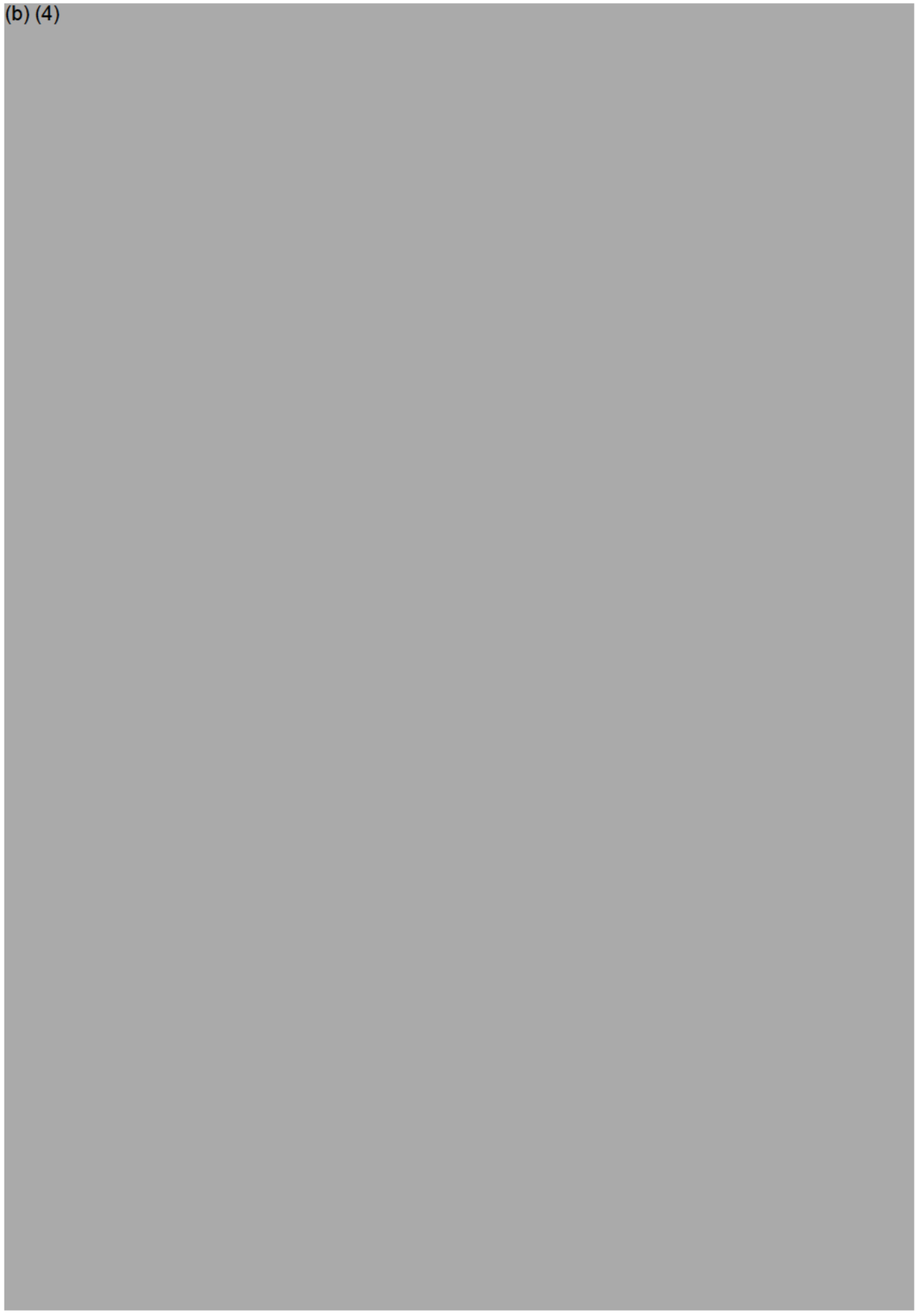

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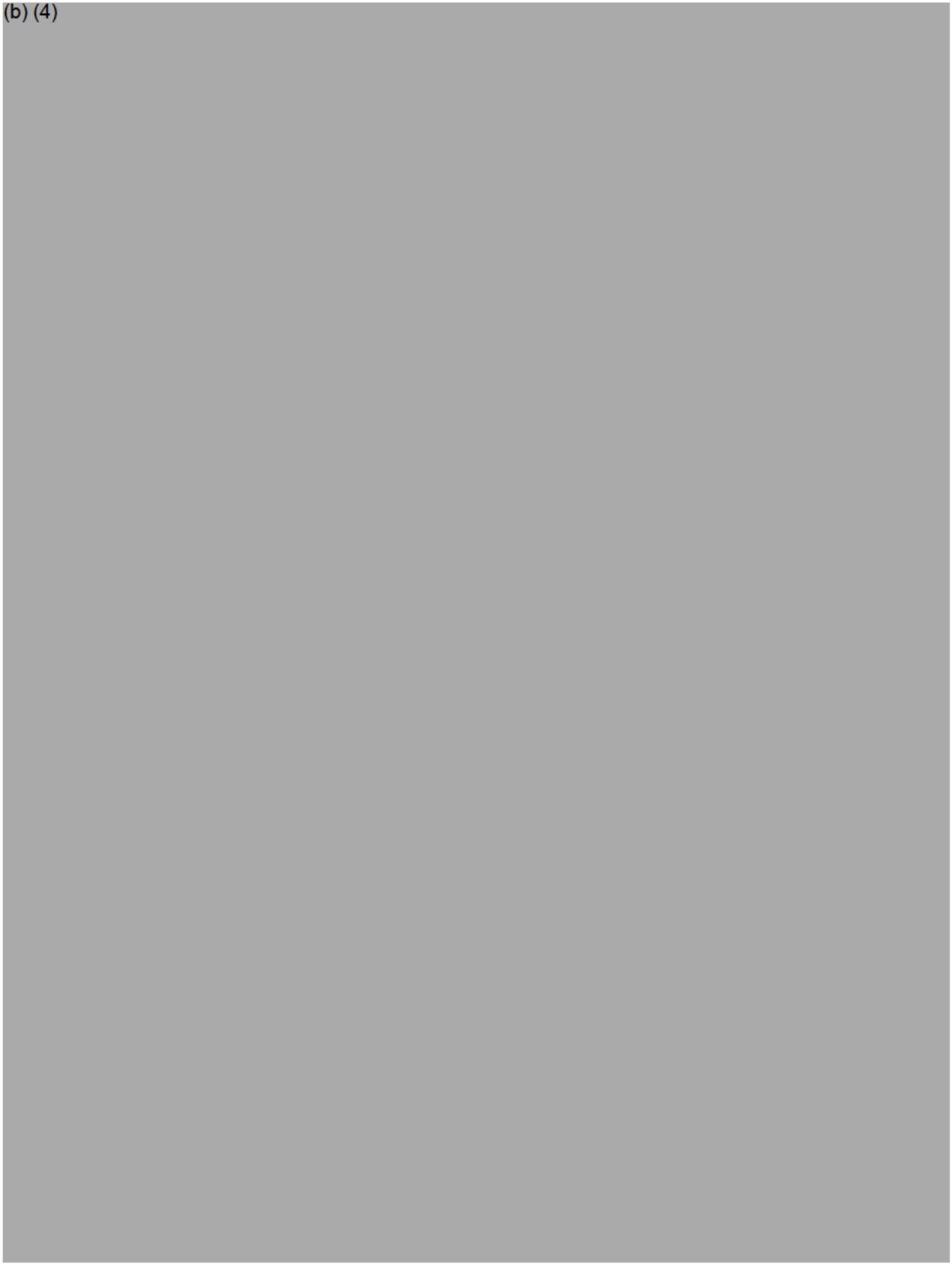

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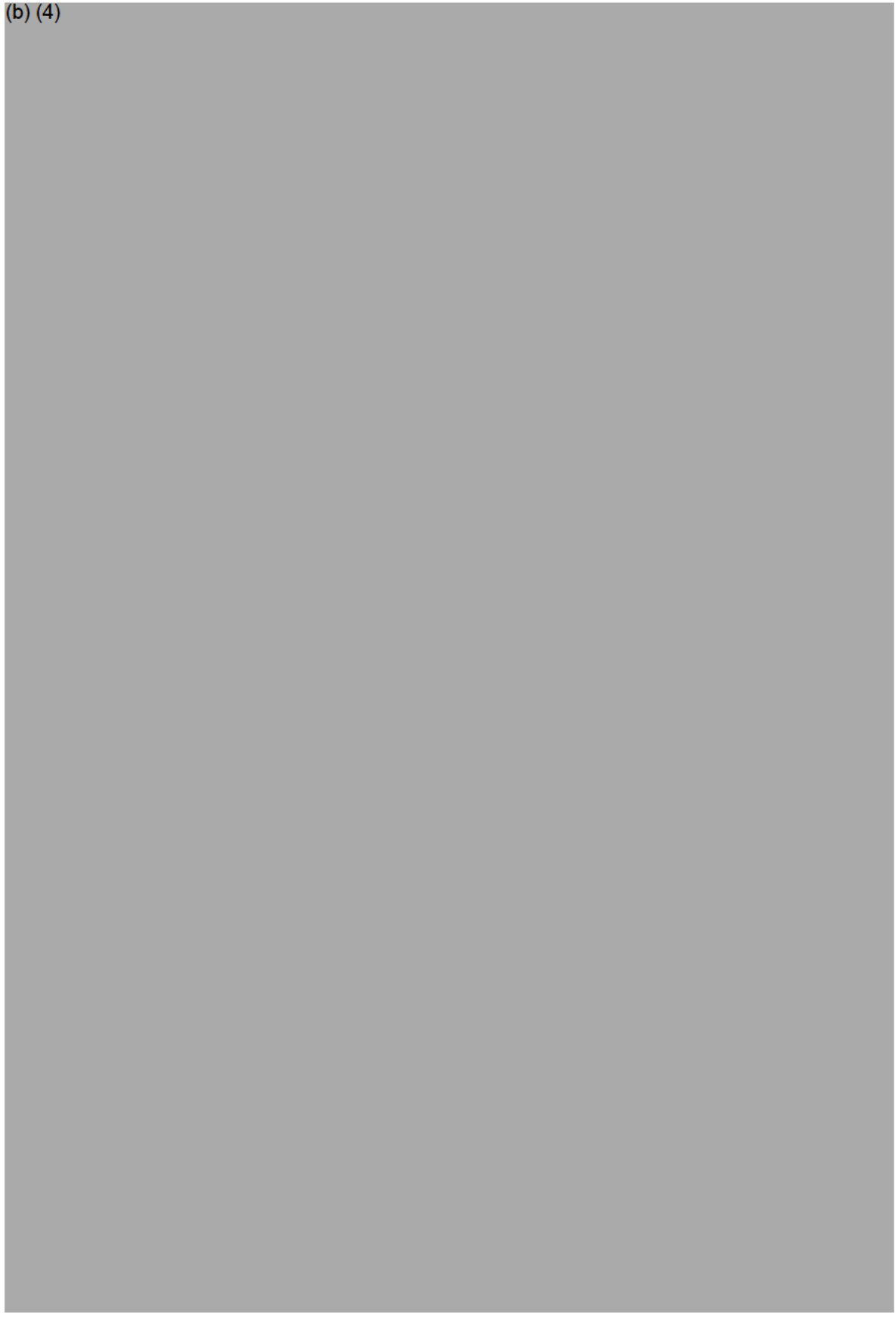

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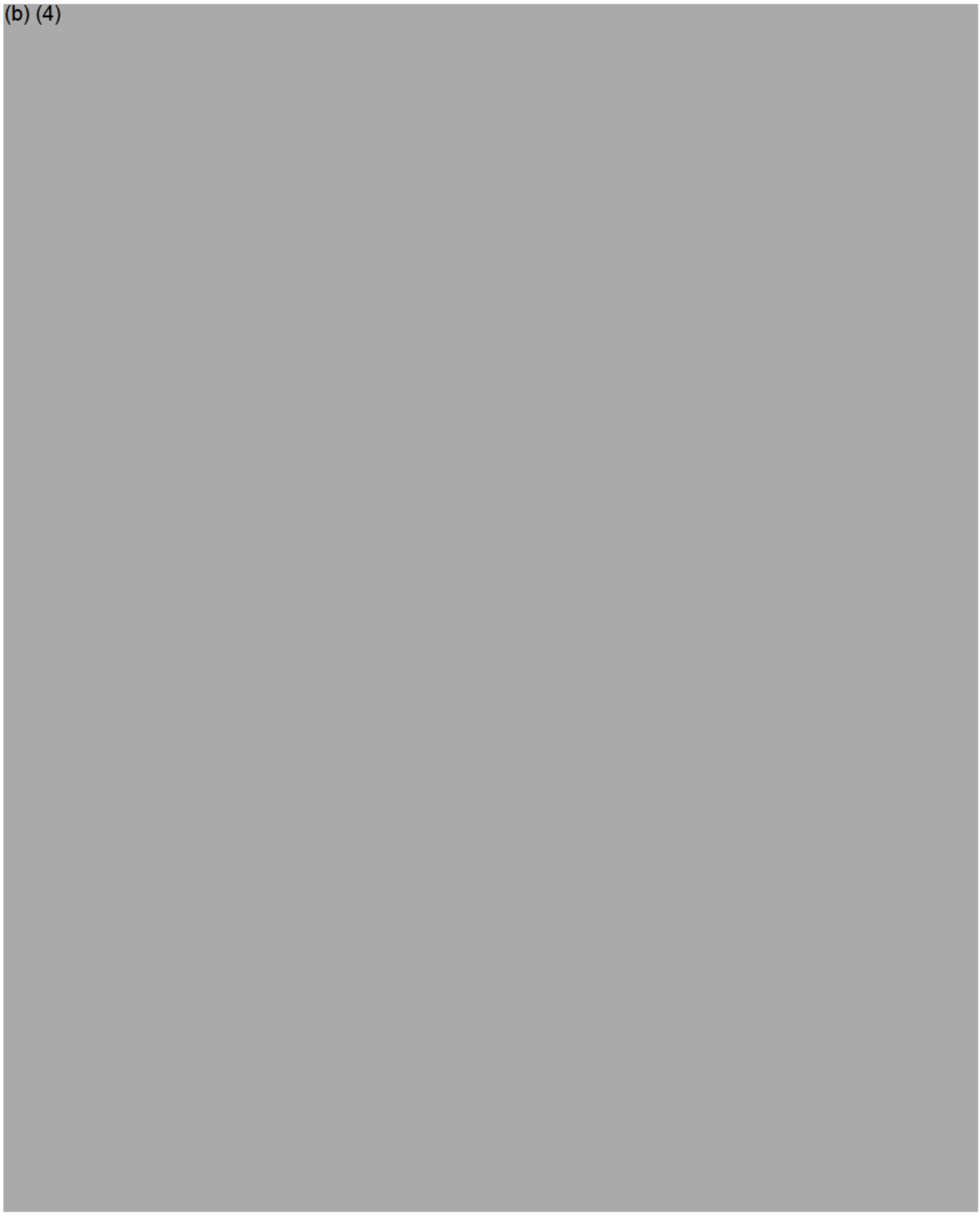

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8.4. Discussion

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8.5. Conclusions

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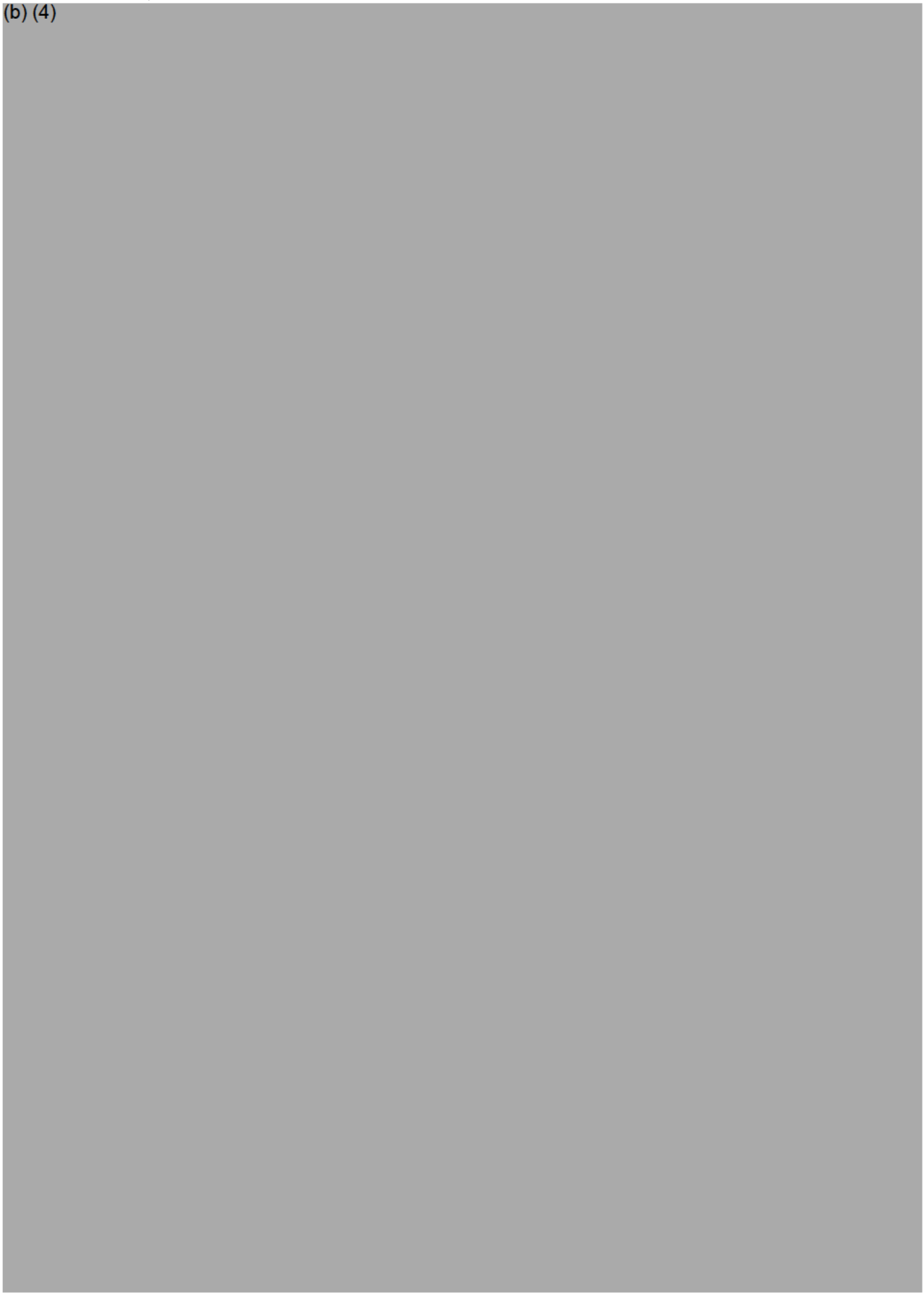

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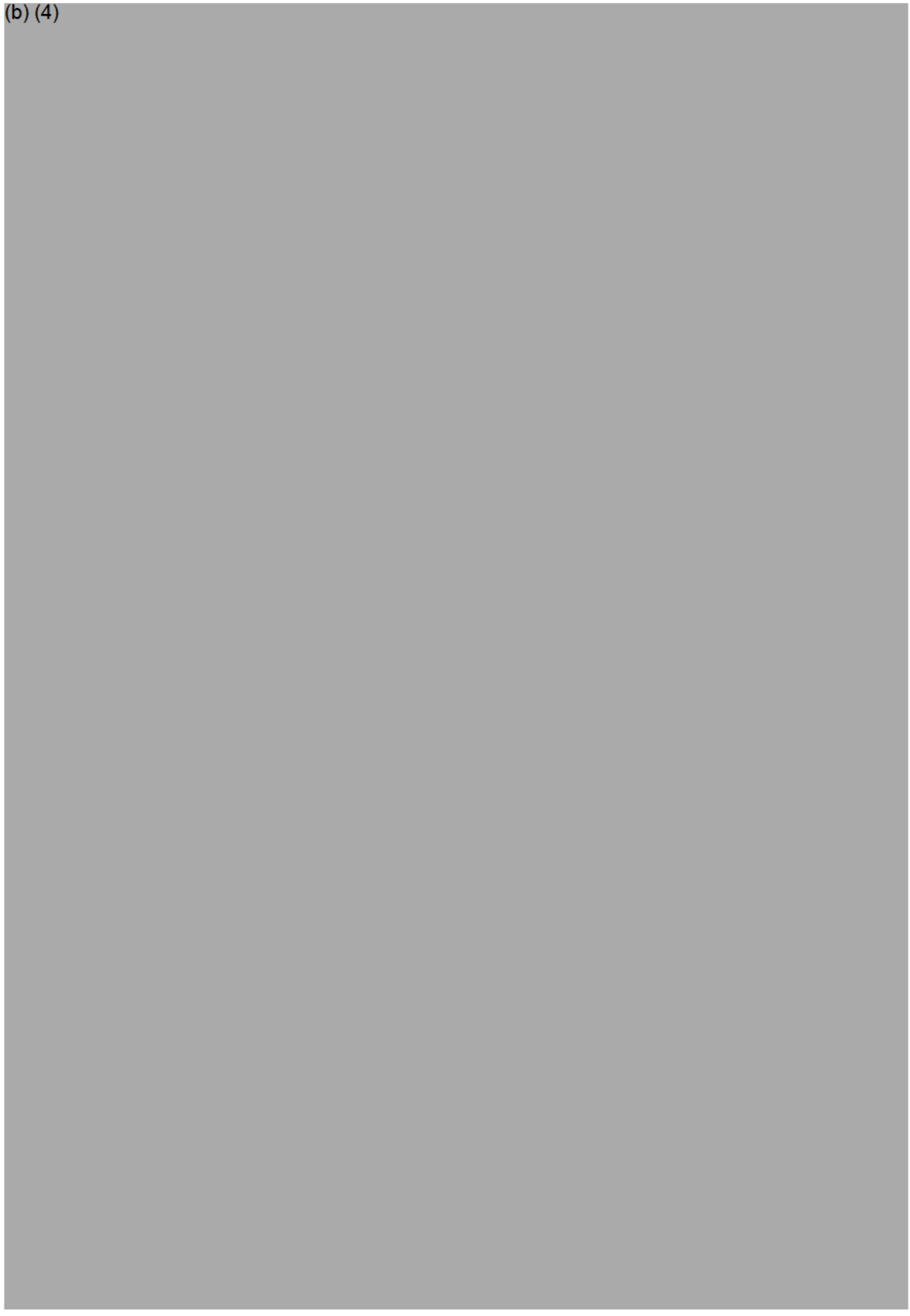

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TEKNIMED S.A.
BIOMATERIAUX - IMPLANTS ORTHOPEDIQUES

CEMENTEK®

The malléable bone substitute

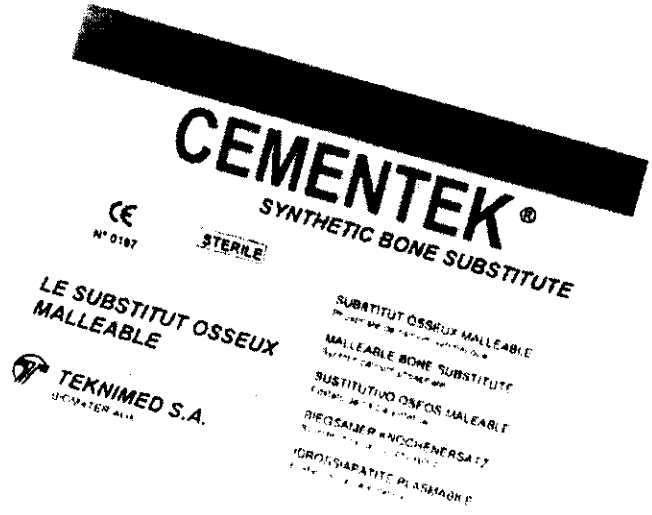
Evaluation of CEMENTEK.

Moldeable bone substitute

Clinical experience of 60 operations at two years

Prof JL LACOUT

Dr M Malissard



Siège social, administration et gestion des commandes
8, rue du Corps Franc-Pommiès F 65 502 VIC en BIGORRE Cedex
Tél (33) 5 62 96 88 38 - Fax (33) 5 62 96 28 72
E-mail teknimed@teknimed.com

Services commerciaux et techniques
ZI de Montredon F- 31 240 L'UNION

EN ISO 9001 - EN 46001 snch Certified

Professeur J.L. LACOUT

INP, ENSCT, UPRESA CNRS 5071

118 route de Narbonne

31077 Toulouse cedex 4

tèl: 05 61 17 56 74

Docteur M. MALISSARD

Polyclinique - Service d'Orthopédie

17110 Saint-Georges de Didonne

tèl: 05 46 05 88 89

fax: 05 46 05 88 88

1. Clinical and radiologic study ((b) (4)))

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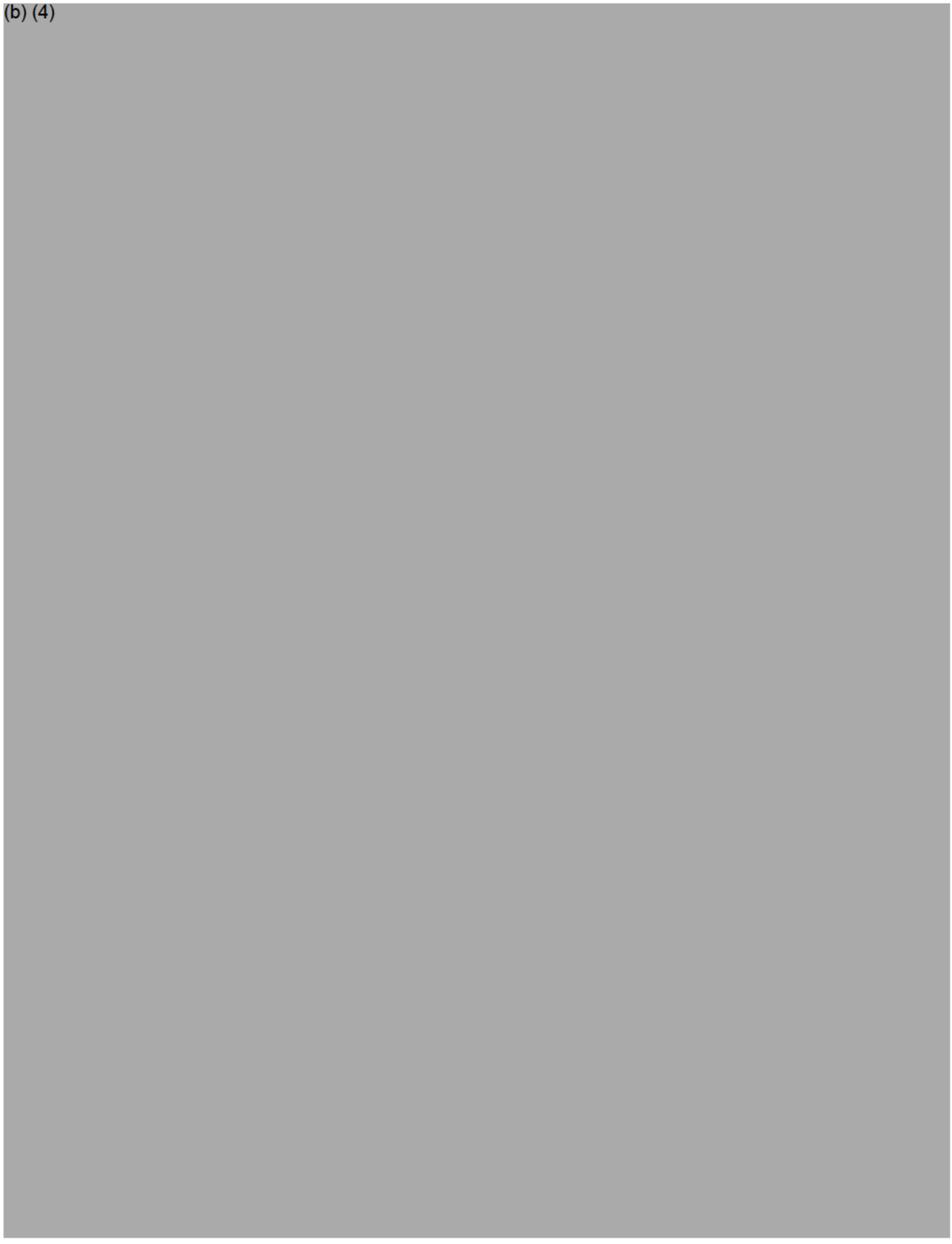

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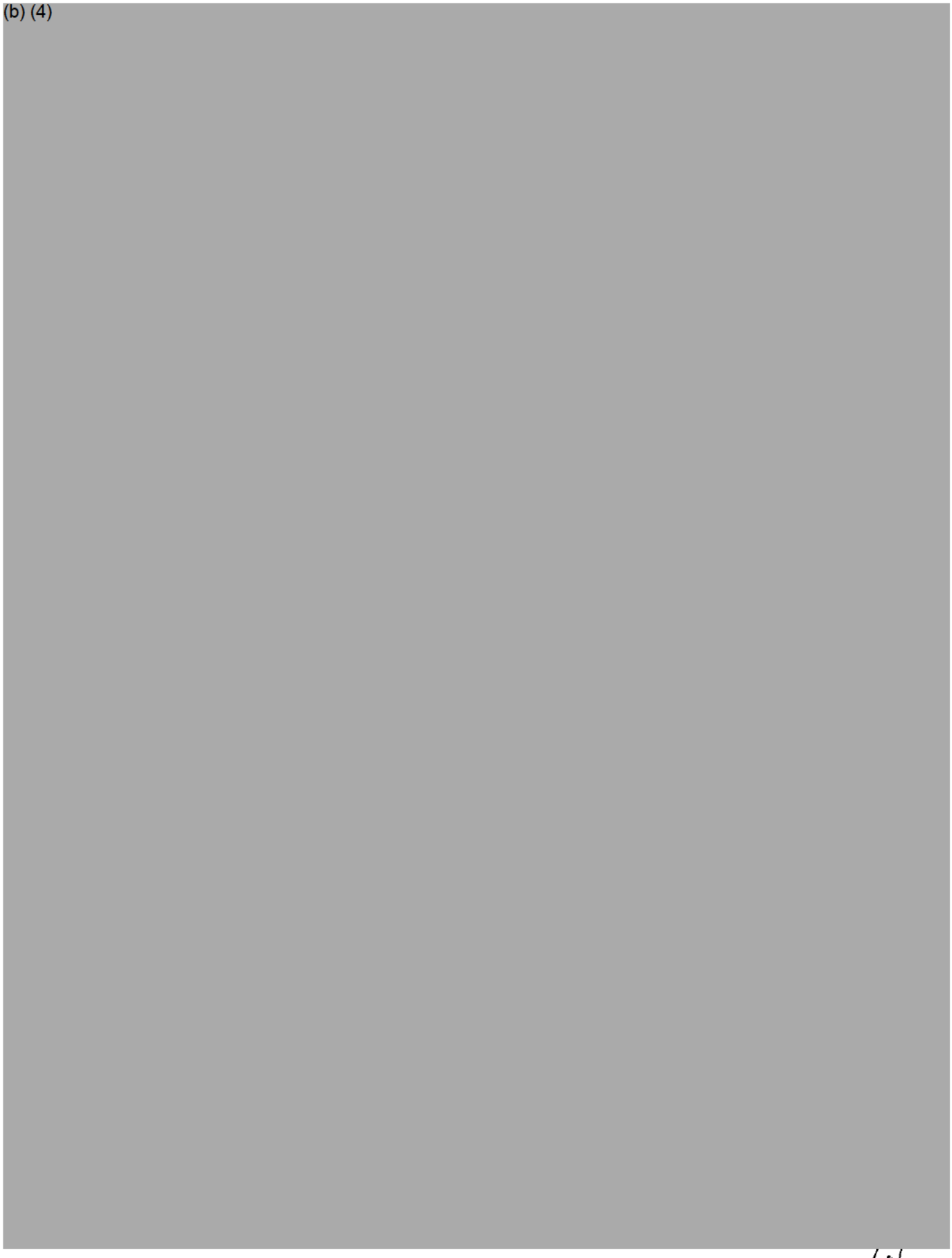

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5. ***Histological results***

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CEMENTEK®

Clinical Evaluation

Results synthesis

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Surgeons
Center
box
Resistance
Blister
IFU
Technical paper
Sterility protection
Precautions for use
Powder packaging
Liquid packaging
Volume
Implementation
Filling of tumours
Implants coating

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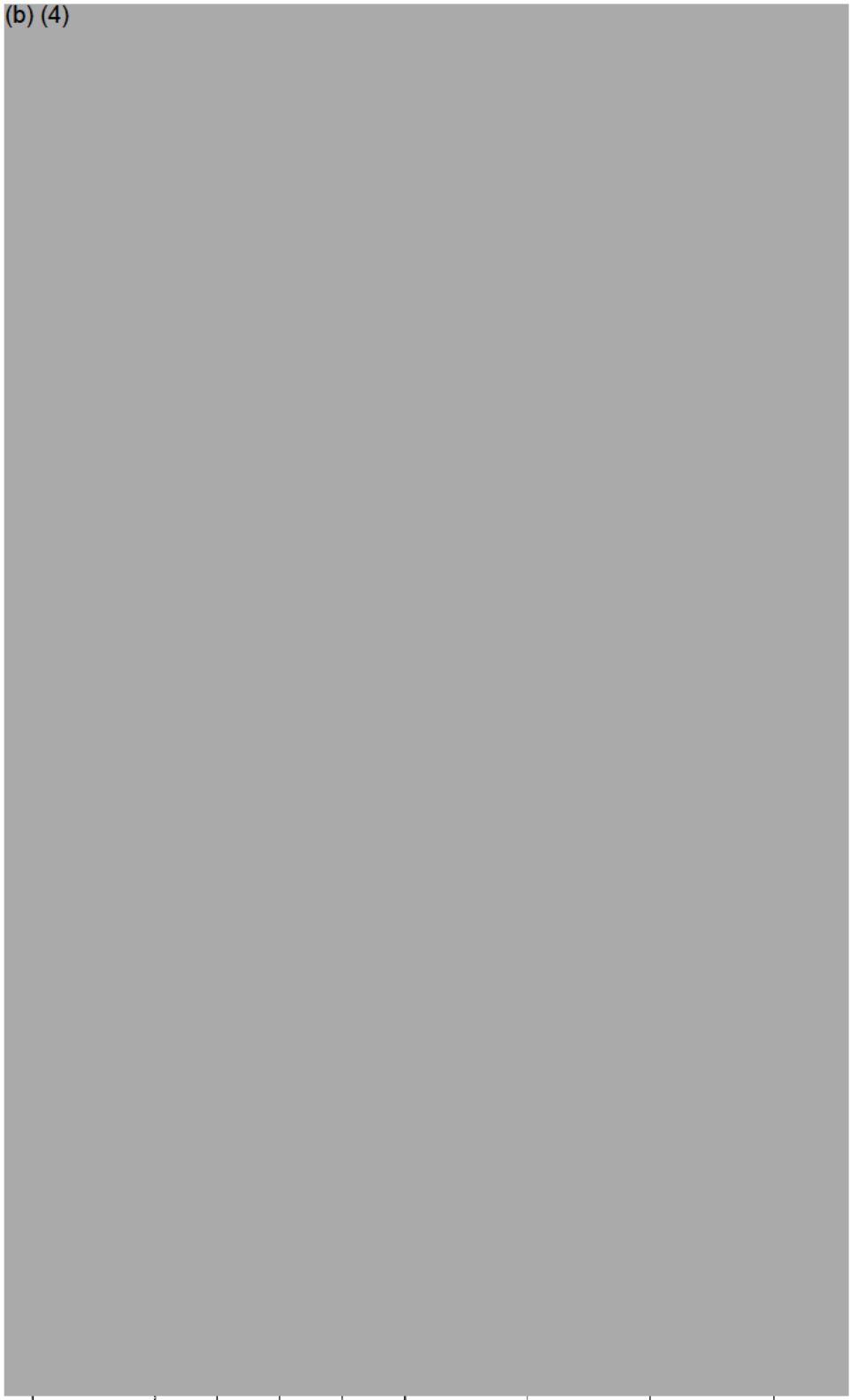

Filling in traumatology
Arthrodesis
Defects filling
Toxic effect
Intolerance
Pseudarthrosis phenomenon
Phenomenon of dye stick osseous
CLINICAL APPRECIATION

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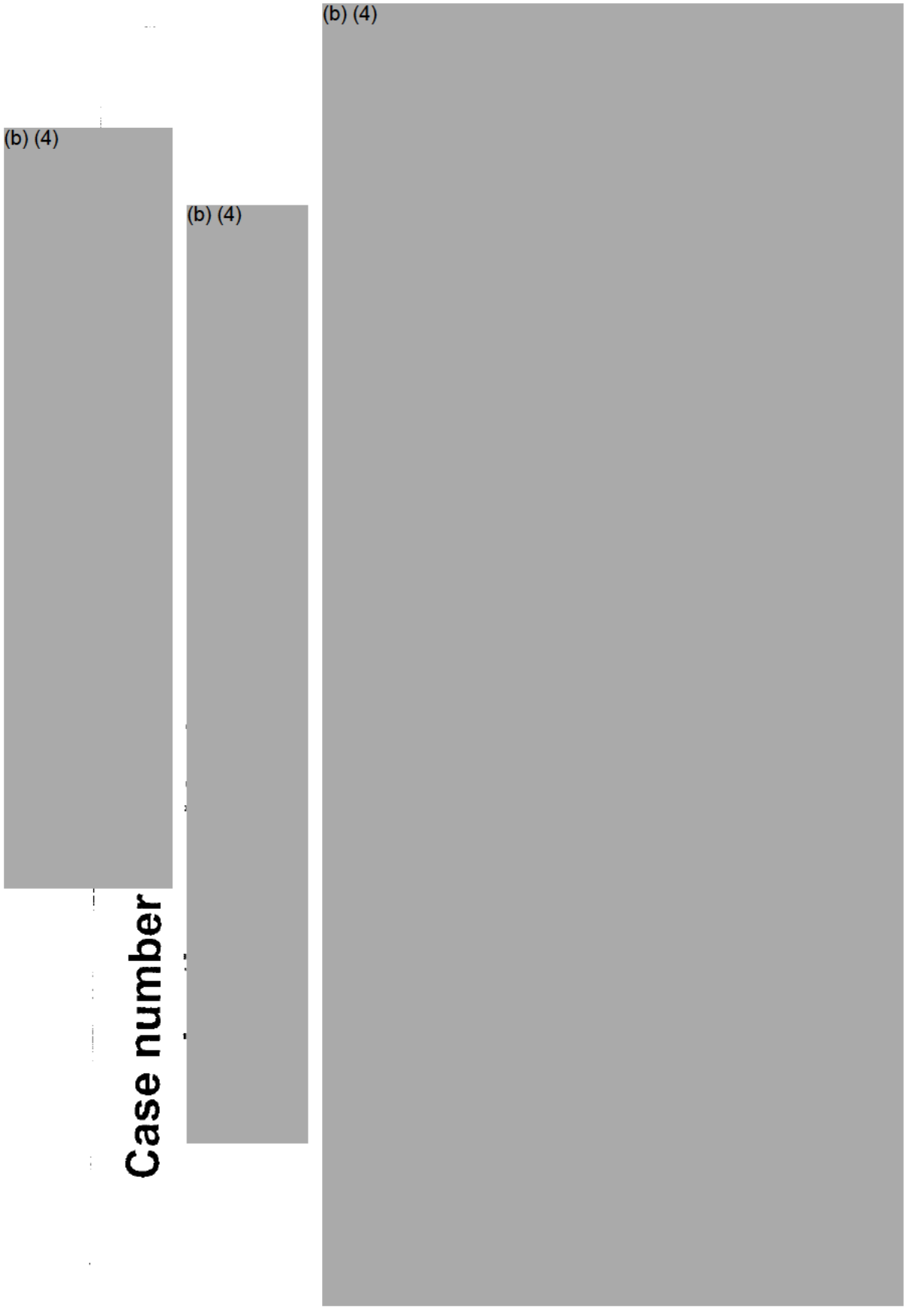
Case number



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Case number

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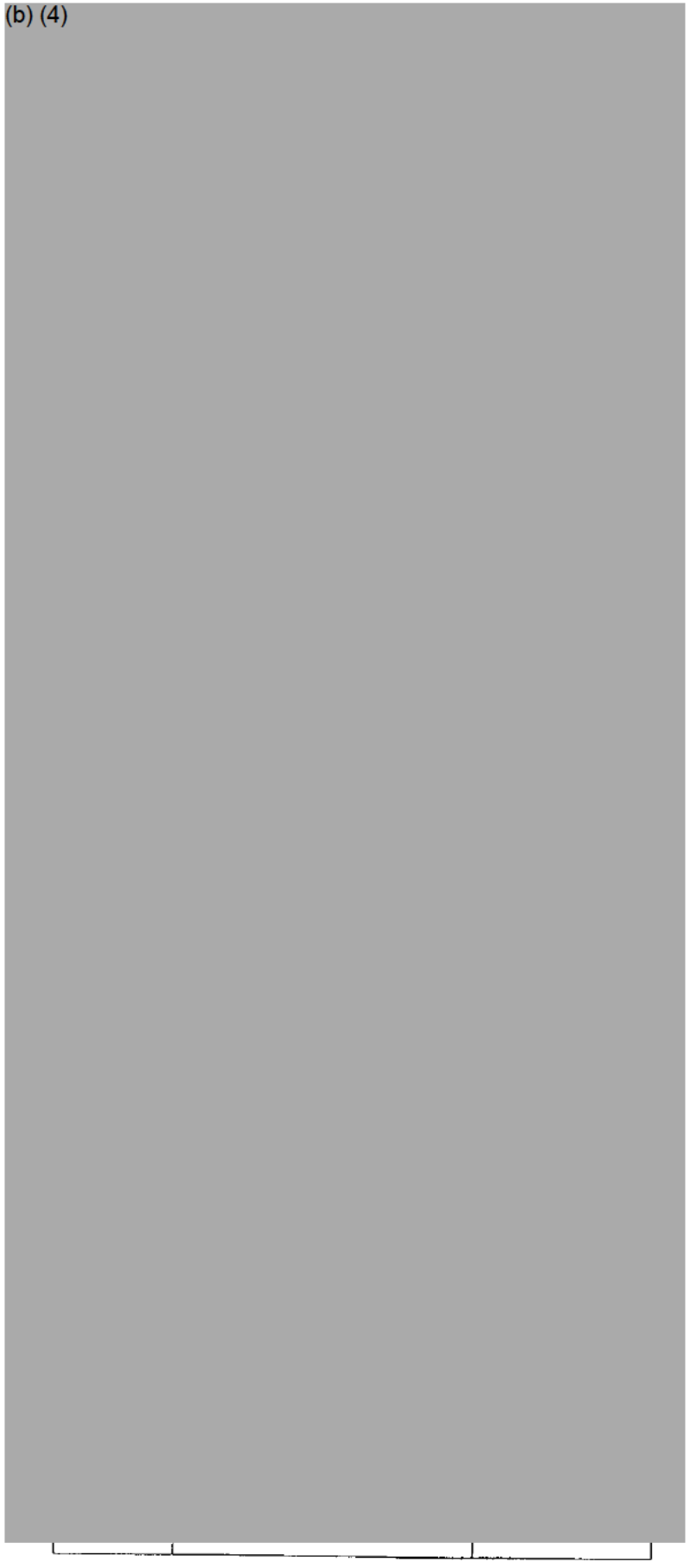

Revue de chirurgie orthopédique
2003, 89, 532-536

Article: Utilisation d'un ciment phospho-calcique dans le traitement de la dysplasie fibreuse

A propos d'un cas

Title: Treatment of bony fibrous dysplasia with calcium-phosphate cement: a case report

P.Liverneaux

Service de chirurgie orthopédique, centre hospitalier , BP9 , 17 301 Rochefort-sur-Mer Cedex

Abstract:
We report successful use of calcium-phosphate cement for the treatment of begnin polyostotic fibrous dysplasia in a patient who had undergone several unsuccessful surgical procedures. As no autologous bone was available for further grafting, we used a bone substitute to fill two defects, one in the upper part of the humerus and the other in the radial shaft. The curretage cavity was filled with calcium-phosphate hydroxyapatite cement. The type of bone substitute was chosen for its specific properties: mineral structure similar to bone, microporosity, resistance of compression between cancellous and cortical bone, composition favourable to exchange between the crystals and the interstitial medium. Outcome was favourable early for the shoulder and later for the forearm after surgery for recurrence.
Due to progress in the development of diphosphonates, indications for surgery for fibrous dysplasia have been reduced. There remains a risk of recurrence and incomplete results but bone substitute filling can be a useful alternative to autografts and complementary fixation. Calcium-phosphate cement is an easy-to-use paste like product with interesting physico-chemical and biological properties making it a leading choice for bone substitution.

Key words: Fibrous dysplasia, bone substitute, hydroxyapatite, calcium phosphate cement, bone density, peripheral quantitative computer tomography.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Vadim Y. Steen

Subject: 510(k) Number K041493

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices NA

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90

Predicate Product Code with class: MQV Class II

Additional Product Code(s) with panel (optional):

Review: _____ (Branch Chief) KEOB (Branch Code) 8/17/04 (Date)

Final Review: for Mark N. Melkerson (Division Director) 8/19/04 (Date)

Revised:4/2/03

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K041493

Reviewer: Nadine Y. Sloan – Biomedical Engineer

Date: 08/11/04

Division/Branch: DGRND/REDB

Device Name: Teknimed Cementek

Product To Which Compared (510(K) Number If Known): Depuy α-BSM (K011048), Berkley Advanced Biomaterials -CemOstetic (K022622): MQV class II

		YES	NO	
1.	Is Product A Device	✓		If **NO** = Stop
2.	Is Device Subject To 510(k)?	✓		If **NO** = Stop
3.	Same Indication Statement?	✓		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues Safety Or Effectiveness?			If **YES** = Stop **NE**
5.	Same Technological Characteristics?	✓		If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?		✓	If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10.	Performance Data Available?			If **NO** = Request Data
11.	Data Demonstrate Equivalence?			Final Decision: **SE**

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

6

1. **Intended Use:**

Cementek is intended for use only as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be molded to specific shapes and placed into the bony voids or gaps in the skeletal system (i.e., extremities, spine and pelvis). Following placement in the bony voids or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement.

Is the device life supporting or life sustaining? *No.*
Is the device implanted (short-term or long-term)? *The device is resorbed over a period of 3 months.*
Does the device design use software? *No.*
Is the device sterile? *Yes.*
Is the device for single use? *Yes.*
Is the device for home use or prescription use? *Prescription use.*
Does the device contain drug or biological product as a component? *No.*
Is this device a kit? *No.*

Provide a summary about the devices design, materials, physical properties and toxicology profile if important:

(b) (4)

[redacted]

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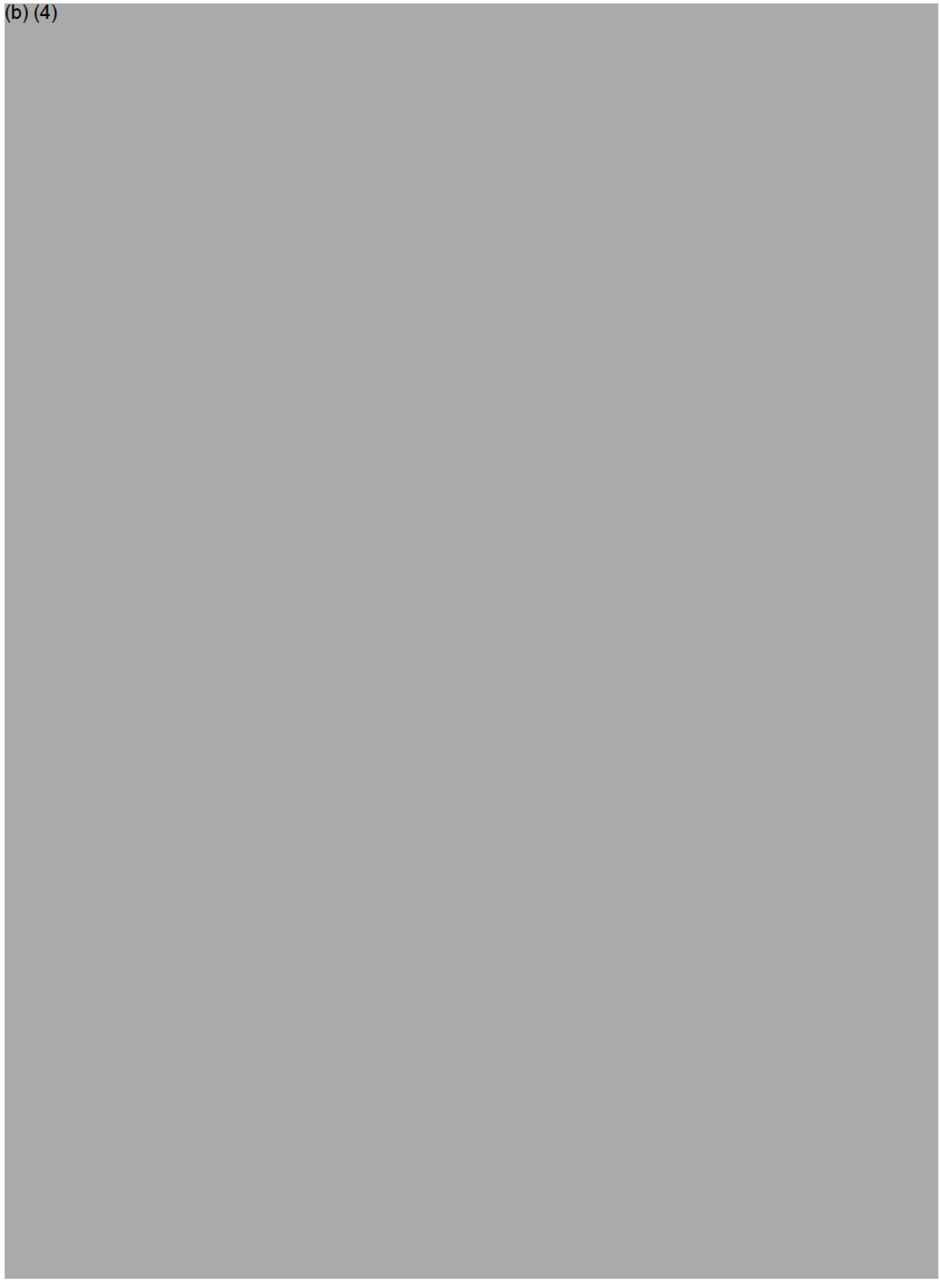


(b) (4)

Nadine Y. Sloan
Teknimed.Cementek.SE.dec

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?	NA	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Sloan, Nadine Y.

Nadine,

Attached is supplement 1 and a revised package insert.

Thanks
****

J.D. Webb
President
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199 Tele/Fax

11

8/13/2004

CEMENTEK®
Synthetic Bone Substitute

The malleable bone substitute

℞

CE0197
Instructions leaflet
Manufactured in France by:
TEKNIMED S.A.
B.P. 60
65502 VIC-EN-BIGORRE Cedex
Tél. 33 (0)5 62 96 88 38
Fax 33 (0)5 62 96 28 72

Caution: U.S. Federal law restricts this device to sale by or on the order of the physician (or properly licensed practitioner)

Before using Teknimed products, the operating surgeon should study thoroughly the safety information specified in these instructions as well as the product-specific information (product description, surgical procedures, brochures etc.). The related documentation is obtainable from the respective national representative. At the same time the operating surgeon must be aware of the residual risks associated with the use of the intended products.

GENERAL INSTRUCTIONS

The implantation of Teknimed products may only be carried out by surgical staff who possess a thorough knowledge of and experience in the area of joint replacement and, in particular, have mastered the product specific surgical techniques relating to Teknimed products. The particular surgical techniques required for Teknimed bone substitute can be learned at Teknimed distributors.
Cementek ® bone substitute is in the form of an apatitic paste designed for the ~~regenerative~~ osteoconductive replacement of bone.

COMPOSITION

This product of synthesis is controlled during all its manufacture, from raw material to the final product.
Composition:

Powder:	
tetracalcium phosphate	49%
α tricalcium phosphate	38%
NaGP	13%
Liquid:	
calcium hydroxide	3,4%
phosphoric acid	13,8%
water	82,8%

PREPARATION FOR USE

Mix in a cup the whole of the powder and liquid to achieve a homogeneous mixture. The paste obtained will become less and less malleable, until becoming hard after 10 min.
Full hardening follows in-situ within 48 to 72 hours.
Match the quantity of Cementek® to the site of bone defect to obtain the fullest contact with the lost bone.

INSTRUCTIONS FOR USE

1. Open the sachet and pour the powder in a mortar.
2. Pour the liquid on the powder.
3. Mix energetically by crushing the powder and the liquid during 1 to 2 min.
4. Use the spatula to collect the paste and to homogenize the mixture. If possible, materialize the form of bone defect.
5. Let harden in the air 5 to 10 min.
6. After having dried the cavity, put the paste in the bone defect. ~~A lot of manipulations of the paste will change the mechanical properties.~~ It is possible to clean and to dry the cavity with STERILE hydrogen peroxide, unless otherwise exceptions.

PRECAUTIONS FOR USE

The cavity must be carefully irrigated and dried before application of Cementek®.
Cementek® has stability of shape after 10 minutes. It is recommended to limit the load applied during the first 48 hours, on large bone defects. ~~In areas of weak regeneration an osteosynthetic support is recommended.~~ Cementek® is not intended to provide load-bearing structural support during the healing process, therefore, Cementek® is contraindicated where the device is intended as load-bearing structural support in the skeletal system.
Manipulations of the paste should be avoided as it may change the mechanical properties.

INDICATIONS

Cementek® is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be molded to specific shapes and placed into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, Cementek® resorbs and is replaced with bone during the healing process

CONTRAINDICATIONS

The same as applying to all bone grafts
- metabolic conditions.
- use in an infected area (osteomyelitis, tuberculosis).
- in an area having no possibility of regeneration or infected bone (risk of sequestration).

POSSIBLE ADVERSE EFFECTS

~~No secondary effect has been found to date. Use during pregnancy and breast-feeding no contraindications~~.

Possible adverse effects include, but are not limited to:

- Wound complications including hematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery
- Fracture or extrusion of Cementek® with or without generation of particulate debris
- Deformity of the bone at the site
- Incomplete, or lack of, osseous ingrowth into bone void, as is possible with any bone void filler.

STERILIZATION

Cementek ® is sterilized with 25 to 40 kGy (2,5 to 4,0 Mrad) gamma radiation. All sterile implants are to be kept unopened in the original packaging until the time of implantation. Before using the implant, the protective packaging should be checked for damage as this could be detrimental to the sterility. Aseptic procedures should be observed when removing the implant from the protective package.
Cementek® is delivered sterile under double wrapping, ready for use in an operating room.
Remarks:

Verify the integrity of the packaging before use, the guarantee of sterilization is 5 years from the date of sterilization.
Use after the peremptory date is not allowed. All re-sterilization of the product is forbidden use only once.

PATIENT INFORMATION

The doctor must draw the patient's attention to the contents of the indications and contraindications paragraph, as well as factors which can impair the results of the operation and to possible complications which can arise as a result of an indication. The patient must also be informed about the measures which the doctor will use to minimize the possible effects of these factors.

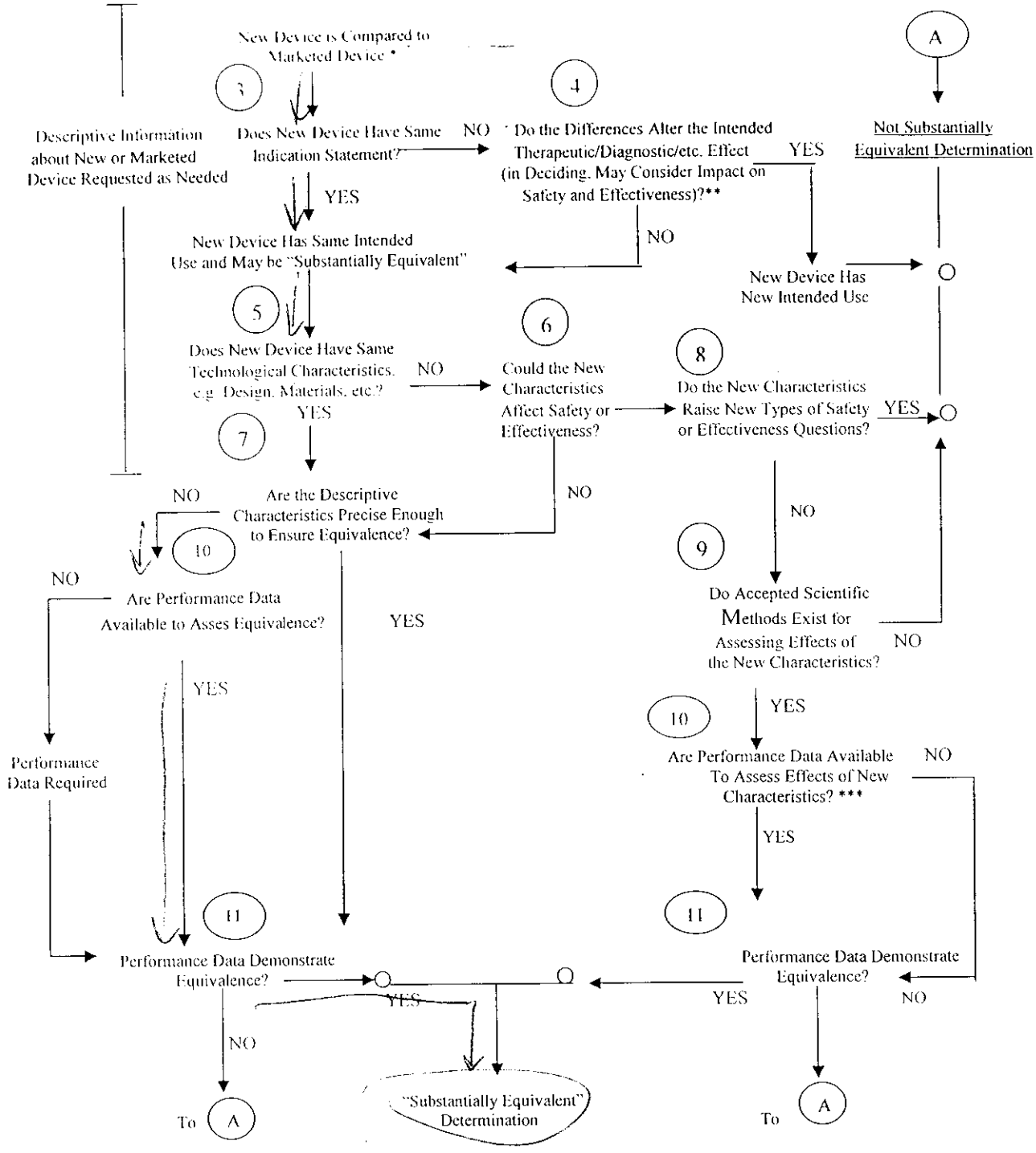
PACKAGING AND STORAGE

Individually wrapped in quantities.

Designation	Reference	Volume cm^3
Cementek 20	T815020	8 cm^3
Cementek 40	T815040	16 cm^3

Store at room temperature

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

5