K141081

3M ESPE

MAY 0 8 2014

3. 510(k) Summary

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

3M ESPE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

Contact person..... Scott Erickson, RAC
Senior Regulatory Affairs Specialist
Phone: (651) 736-9883
Fax: (651) 736-1599
sterickson@mmm.com

Date Summary was Prepared..... 15Apr2014

Trade Name..... Filtek™ Bulk Fill Posterior Restorative

Common Name(s)..... Tooth shade resin material
Restorative

Recommended Classification..... 21 CFR 872.3690
Tooth shade resin material
Product Code: EBF

Predicate Devices:
Filtek™ Supreme Ultra Universal Restorative (K083610)
Metamorphosis (K091023)
Trade name: SonicFill, Sonic-Activated Bulk Fill Composite
Tetric EvoCeram Bulk Fill (K111958)

Description of Device:
3M™ ESPE™ Filtek™ Bulk Fill Posterior Restorative material is a visible-light activated, restorative composite optimized to create posterior restorations simpler and faster. This bulk fill material provides excellent strength and low wear for durability. The shades are semi-translucent and low stress curing, enabling up to a 5 mm depth-of-cure. With excellent polish retention, Filtek™ Bulk Fill Posterior Restorative is also useful for anterior restorations that call for a semi-translucent shade. All shades are radiopaque. Filtek™ Bulk Fill Posterior Restorative is offered in A1, A2, A3, B1, and C2 shades. Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as manufactured by 3M™ ESPE™, which permanently bonds the restoration to the tooth structure.

Filtek™ Bulk Fill Posterior Restorative is packaged in traditional syringes, for dispensing restorative on a pad outside the mouth, and single-dose capsules for dispensing restorative intraorally. The capsules are dispensed using the 3M ESPE Restorative Dispenser.

Indications for Use:
- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

Technological Characteristics:
Filtek™ Bulk Fill Posterior Restorative is a modification of predicate device, Filtek™ Supreme Ultra Universal Restorative. The formulation was modified to create semi-translucent shades with low polymerization shrinkage stress to enable bulk placement and cure for ease of use.

The fillers used in Filtek™ Bulk Fill Posterior Restorative are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of agglomerated 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.4% by volume). The principal resins used in Filtek™ Bulk Fill Posterior Restorative are ERGP-DMA, diurethane-DMA and 1, 12-dodecane-DMA.

When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

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Substantial Equivalence:

Technological property	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Photoinitiator system	X	X	NA[1]	X[2]
Methacrylate-based resin matrix	X	X	X	X
Compatible with methacrylate-based dental adhesives	X	X	NA[1]	X
Inorganic fillers	X	X	X	X
Oxide fillers are silane treated so that they bond to the resin matrix when the restorative is cured	X	X	X[3]	NA[1]
Bulk fill (up to 4 mm depth of cure)	X	-	X	X
Bulk fill (5 mm depth of cure, Class II)	X[4]	-	X[4]	
When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.	X	X	X	X
Dispensing system: single-use capsule (intraoral)[5] reusable syringe (extraoral)[6]	 X X	 X X	 X -	 X X
Recommended for load-bearing occlusal surfaces	X	X	X	X
FDA-Recognized Standards followed	Risk Management: ISO 14971 Biocomp stds[7]: ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds[8]: ISO 4049 ISO 6874	Risk Management: ISO 14971 Biocomp stds[7]: ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds[8]: ISO 4049	NA[1]	NA[1]

1. Not available, details not disclosed by manufacturer.
2. Product also contains a second photoinitiator.

3. Based on disclosure that product contains 3-trimethoxysilylpropyl methacrylate.
4. Similarity: In order to obtain 5 mm depth of cure for Class II restorations, product is light-cured from the occlusal surface and, after the matrix band is removed, light-cured from the buccal and lingual surfaces.

   Difference: The predicate device techniques states up to a 5mm depth of cure for Class I restorations, as well, also using the multi-site light-curing process described above. For Filtek™ Bulk Fill Posterior Restorative, 4mm Depth of Cure is stated for Class I restorations, light-curing from the occlusal aspect only, as supported by ISO 4049 Depth of Cure test results. This difference does not affect the safety or efficacy of the device.
5. Restorative material is dispensed from a single-use capsule in the mouth.

   Difference: The predicate device SonicFill, Sonic-Activated Bulk Fill Composite (K091023) is dispensed from the capsule using the air-driven SonicFill Handpiece, which, per the Instructions for Use "offers sonically activated delivery."

   Similarity: Filtek™ Bulk Fill Posterior Restorative and predicates Filtek™ Supreme Ultra Universal Restorative (K083610) and Tetric EvoCeram Bulk Fill (K111958) all use a traditional manual restorative dispenser (not air-driven) for dispensing capsules. In light of this similarity, the difference mentioned above does not affect the safety or efficacy of the device.
6. Restorative material is dispensed from a reusable syringe outside the mouth (e.g., onto a pad).
7. Newer versions of several biocompatibility standards were applied to Filtek™ Bulk Fill Posterior Restorative, due to time elapsed since the predicate device was evaluated. This difference is not significant because for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610):

   a. A Diplomate of the American Board of Toxicology assessed the safety of the product.

   b. Standard risk assessment techniques and consideration of internationally recognized guidelines were used in the evaluation.

   c. The conclusion of the assessment is that the device is safe for its intended use.
8. ISO 4049 data in this submission for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610), was generated using the current version of the standard, ISO 4049:2009.

   Difference: ISO 6874:2005 was not used to evaluate the predicate device, Filtek™ Supreme Ultra Universal Restorative for the 510(k) submission K083610, because it does not have a sealant indication. The only test in ISO 6874 that is applicable for a light-cure material, like Filtek™ Bulk Fill Posterior

Restorative, is Depth of Cure. This submission includes data showing both Filtek™ Bulk Fill Posterior Restorative and predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610) readily pass the ISO 6874 Depth of Cure requirement. Therefore, this difference is not significant and does not affect the safety or efficacy of the device.

Test results for the following physical properties were included in this submission: Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Volumetric Shrinkage, Wear, Depth of Cure, Cusp Deflection and Polish Retention.

Conclusion:
Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the predicate devices, Filtek™ Supreme Ultra Universal Restorative, SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill in terms of intended use, indications for use, physical properties, and technological characteristics. Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the predicate device, Filtek™ Supreme Ultra Universal Restorative in terms of formulation.

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

May 8, 2014

3M ESPE Dental Products
Scott Erickson, RAC
Senior Regulatory Affairs Specialist
2510 Conway Avenue
St. Paul, MN 55144-1000

Re: K141081
Trade/Device Name: Filtek™ Bulk Fill Posterior Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 15, 2014
Received: April 25, 2014

Dear Mr. Erickson:

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,

Mary S. Runner -S

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

Enclosure

3M ESPE

4. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141081

Device Name
Filtek™ Bulk Fill Posterior Restorative

Indications for Use *(Describe)*
- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sheena A. Green -S
2014.05.08 11:23:43 -04'00'

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

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FORM FDA 3881 (1/14) Page 1 of 1

3M ESPE

2. 510(k) Cover Letter

K141081

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

3M ESPE

Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Subject: Traditional 510(k) Premarket Notification for Filtek™ Bulk Fill Posterior Restorative

Dear Mr. Job:

In compliance with the Federal Food, Drug, and Cosmetic Act (as amended) and as required in 21 CFR 807, Subpart E, 3M ESPE Dental Products submits this 510(k) Premarket Notification for Filtek™ Bulk Fill Posterior Restorative to Regulatory Technology Services, LLC, for 3rd party review.

Consistent with 21 CFR 807.90, FDA eCopy Guidance and the instructions provided by Regulatory Technology Services, LLC, in quote 20140221MJ01, please find enclosed three (3) complete copies (1 paper and 2 eCopy) of the 510(k) submission for Filtek™ Bulk Fill Posterior Restorative. Please note that each eCopy is an exact duplicate of the original paper submission. Also enclosed are two (2) additional copies of this cover letter.

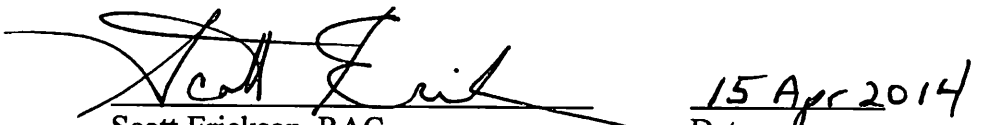
This is the first submission for this medical device (e.g., no pre-IDE was filed for this device). This 510(k) submission includes a signed Authorization Letter and a completed RTA checklist, as recommended in FDA Guidance Document, Refuse to Accept Policy for 510(k)s. This submission does not contain any master files.

3M ESPE Dental Products requests that all trade secret and confidential commercial information contained in this submission to be maintained as confidential by the Agency and not disclosed publicly, consistent with 21 CFR 20.61.

If there are any questions concerning this submission, please contact me as soon as possible. My contact information is provided below.

3M ESPE

Sincerely,



15 Apr 2014

Scott Erickson, RAC
Date
Senior Regulatory Affairs Specialist
3M ESPE Dental Products
3M Center, Building 275-2W-08
2510 Conway Avenue
St. Paul, MN 55144-1000
Phone: (651) 736-9883
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Enclosures

3M ESPE

510(k) Premarket Notification for

3M™ ESPE™

Filtek™ Bulk Fill Posterior Restorative

Table of Contents

ADMINISTRATIVE

Refuse to Accept Checklist

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
Organizational Elements				
1) Submission contains a Table of Contents	Yes			
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	Yes			
3) All pages of the submission are numbered.	Yes			
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	Yes			Traditional
Part "A" Administrative				
1) All content in English.	Yes			
2) a: Device Trade Name or proprietary name included. b: Device Common Name. c: Device Class and Panel or Statement the device has not been classified with rationale.	Yes Yes Yes			Section 11.2 Device Name Section 11.4 Classification Panel
3) Completed Indications for Use Statement.	Yes			Section 4 Indications Statement
4) 510(k) Summary or 510(k) Statement with Required Elements per 21 CFR807.92 or 21 CFR807.93.	Yes			Section 3 510k Summary
5) Truthful and Accuracy Statement per 21 CFR807.87(k) included.	Yes			Section 5 Truthful and Accuracy Statement

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
6) Class III Summary and Certificate Included.		No	N/A	Device is not a Class III device.
7) Clinical Data included a: if clinical data included, Financial Certificate (FDA Form 3454) or Disclosure 9FDA Form 3455) for each covered clinical study included in the submission. b: if clinical data included, Certification of Compliance with ClinicalTrials.gov Data Bank (FDA Form 3674) included in the submission.		No	N/A N/A	Section 20 Clinical Data Device type does not require submission of clinical data in general and proposed indications do not require submission of clinical data Section 10 FDA Form 3674
8) Standards Data Report (FDA Form 3654) completed for each national or international standard used to demonstrate substantial equivalence.	Yes			Section 8.2 FDA Form 3654
9) Prior submissions identified for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence. a : if prior submissions, it is identified in the current submission where any issues related to a determination of substantial equivalence outlined in prior communications are addressed.			N/A	There have been no prior submissions for this device (i.e., Filtek™ Bulk Fill Posterior Restorative).
Part "B" Device Description				

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
10) a: If there are requirements regarding device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			N/A	
b: If there is device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	Yes			Used the following FDA Guidance in preparation of this submission: "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions," issued October 26, 2005 Section 11.2 The Device Name Section 11.4 Regulation & ProCode Section 11.1.2 Mechanism of Action Section 11.6 Commercial Presentation Section 12.2.1 Indications for Use Comparison Section 12.2.2 Formulation Comparison Section 12.2.3 Physical Property Comparison Section 12.2.5 Technology Comparison

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
11) Descriptive information if present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:	Yes			Section 11.1.1 General Description Section 13.2 Instructions for Use
a: A description of the principle of operation and mechanism of action for achieving the intended effect.	Yes			Section 11.1.2 Mechanism of Action
b: A description of the proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	Yes			Section 13.2 Instructions for Use
c: A list and description of each device for which clearance is requested. ("device" may refer to models, part numbers or various sizes, etc.)	Yes			Section 11.2 Device Name Section 11.6 Commercial Presentation
12) Submission contains representative engineering drawings(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled and include dimensions.				Prior to being light-cured by the dentist, Filtek™ Bulk Fill Posterior Restorative is a paste-like material. Simple drawings of the dispensing devices that contain this restorative material are included in this submission. Section 11.5 Photos and Drawings
13) If device is intended to be marketed with multiple components, accessories, and/or as a part of a system.			N/A	

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
a: Submission includes a list of all components and accessories to be marketed with the subject device.			N/A	Section 11.6 Commercial Presentation
b: Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.			N/A	Section 11.1.1 See comments on Restorative Dispenser
c: A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			N/A	
Part "C" Substantial Equivalence Discussion				
14) Submitter has identified a predicate(s) device.	Yes			
a: Predicate's 510(k) number, trade name and model number (if applicable) provided. For predicates that are preamendment devices, information is provided to document preamendments status.	Yes			Section 12.1 Predicate Devices
b: The identified predicate(s) is consistent throughout the submission (i.e., the predicates identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	Yes			Section 7 FDA Form 3514 - Predicates (See SECTION E of form) Section 3 510(k) Summary - Predicates Section 12.2.4 Bench Test Data
15) Submission includes a comparison of the following for the predicate(s) and subject devices:				
a: Indications for use.	Yes			Section 12.2.1 Indications for Use Comparison
b: Technology, including				

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
features, materials and principles of operation.				Section 12.2.2 Formulation Comparison Section 12.2.3 Physical Property Comparison Section 12.2.5 Technology Comparison
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness.	Yes			Section 12.2.1 Differences Indications Section 12.2.2 Differences Formulation Section 12.2.4 Differences Bench Test Results Section 12.2.5 Differences Technological Properties Section 12.2.6 Differences IFU
Part "D" Proposed Labeling				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that included a description of the device, its intended use, and directions for use.	Yes			Section 13.2 Instructions for Use Section 13.3 Technical Product Profile Section 13.4 Labels
18) If indicated for prescription use, labeling includes the prescription use statement or "Rx only" symbol.	Yes			Section 13.2 IFU - Prescription Use Section 13.4 Labels - Prescription Use

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
				Section 13.4 Labels - Rx Only
19) General labeling provisions				
a: Labeling includes name and place of business of the manufacturer, packer, or distributor.	Yes			Section 13.4 Labels
b: Labeling includes device common or usual name.	Yes			
20) a: If there are requirements regarding labeling, such as special controls, in a device-specific regulation applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			N/A	
b: If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	Yes			Section 13.1 FDA Guidance - Composites Labeling Section 21.1 FDA Guidance - Mitigation Measures
c: if there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a			N/A	

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.				
21) If the device in an in-vitro diagnostic device, provided labeling includes all applicable information requirement per 21 CFR 809.10.			N/A	The device is not an in-vitro diagnostic device.
Part "E" Sterilization				
Submission states that the device and/or accessories are: • provided sterile. • provided non-sterile but sterilized by the end-user. • non-sterile when used.	Yes			The device is non-sterile when used. Section 14.1 Sterilization
22) Assessment of the need for sterilization information: a: Identification of the device, and/or accessories, and/or components that are provided sterile. b: Identification of the device, and/or accessories, and/or components that are end-user sterilized. c: Identification of the device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	Yes			The device is non-sterile when used. Filtek™ Bulk Fill Posterior Restorative capsule labeling indicates that the capsule is not reusable. Section 13.4 Capsule Bottle Label Like predicate device Filtek™ Supreme Ultra Universal Restorative (K083610), Filtek™ Bulk Fill Posterior Restorative is also packaged in a traditional syringe for dispensing restorative on a pad outside the mouth.
23) If the device and/or accessory, and or a component is provided sterile:			N/A	The device is non-sterile when used.
a: Sterilization method is stated for each component (including			N/A	The device is non-sterile when used.

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
parameters such as dry time for steam sterilization, radiation dose, etc.).				
b: A description of method to validate the sterilization parameters (e.g. half-cycle method and full citation of FDA-recognized standard including date) is provided for each proposed sterilization method.			N/A	The device is non-sterile when used.
c: For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device, and sterilant residual limits.			N/A	The device is non-sterile when used.
d: Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.).			N/A	The device is non-sterile when used.
e: Sterility Assurance Level (SAL) stated			N/A	The device is non-sterile when used.
24) If the device, and/or accessory, and/or component is end-user sterilized:			N/A	The device is non-sterile when used.
a: Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).			N/A	The device is non-sterile when used.
b: A description of method to validate the sterilization parameters (e.g. half-cycle method and full citation of FDA-recognized standard including date) is provided for each proposed sterilization method.			N/A	The device is non-sterile when used.
c: Submission includes			N/A	The device is non-sterile

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.).				when used.
d: Submission includes sterilization instructions for the end-user.			N/A	The device is non-sterile when used.
25) a: If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			N/A	The device is non-sterile when used.
b: If there is a device-specific guidance, other than a special-controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			N/A	The device is non-sterile when used.
c: If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has completed with particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will			N/A	The device is non-sterile when used.

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
provide at least an equivalent assurance of safety and effectiveness.				
Part "F" Shelf-Life				
26) Proposed shelf-life/expiration date stated.	Yes			Section 13.2 IFU - Shelf Life - Exp Section 14.2.1 Shelf Life Report
27) For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent of the predicate through the proposed shelf-life, or a rationale for why testing to predict shelf-life is not applicable.			N/A	The device is non-sterile when used.
28) Submission includes a summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	Yes			ISO test methods used. See Section 14.2.1 Shelf Life Report
Part "G" Biocompatibility				
Submission states that there: ☒ are or □ are not Direct or indirect (e.g., through fluid infusion) patient-contacting components.	Yes			Filtek™ Bulk Fill Posterior Restorative directly contacts the patient.
29) Submission includes a list of patient-contacting device	Yes			Section 11.13 Filtek™ Bulk Fill

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
components and associated materials of construction, including identification of color additives, if present.				Posterior Restorative Formulation
30) Submission identifies contact classification (e.g., surface contacting, less than 24 hour duration).	Yes			Section15.1 Biocompatibility Assessment Filtek™ Bulk Fill Posterior Restorative is and external communicating device that is intended to be in contact with the body for greater than 30 days (ISO 10993 and ISO 7405, G95)
31) Biocompatibility assessment of patient-contacting components: Submission includes: • Test protocol (including identification and description of test article, methods, pass/fail criteria, and results provided for each test, **OR** • A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	Yes			Section15.1 Biocompatibility Assessment
Part "H" Software				
Submission states that the device: □ does ☒ does not Contain software/firmware	Yes			Section 16 Software The device does not contain software/firmware.
32) Submission includes a			N/A	The device does not

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
statement of Software Level of Concern and rationale for the Software Level of Concern.				contain software/firmware.
33) All applicable software document provided based on Level of Concern identified by the submitted, as described in *FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., alternate approach with rationale).			N/A	The device does not contain software/firmware.
Part "I" EMC and Electrical Safety				
Submission states that the device: □ does ☒ does not Require EMC and Electrical Safety Evaluation.	Yes			Section 17 EMC & Electrical Safety The device is not an electrical device.
34) Submission includes evaluation of electrical safety (e.g., per IEC60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), **OR** submission includes electrical safety evaluation using methods or standards that are			N/A	The device is not an electrical device.

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).				
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC60601-1-2 or equivalent FDA-recognized standard and if applicable, device-specific standard) **OR** submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).			N/A	The device is not an electrical device.
Part "J" Performance Data-General				
36) A full test report is provided for each completed test. A full test report includes: objective of the	Yes			Section 12.2.4 Bench Test Data Report

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of the data generated from the test supports a finding of substantial equivalence.				Section 14.2.1 Shelf Life Report
37) a: If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish the submitter has followed the device- specific requirement.			N/A	
b: If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish the submitter has addressed the recommendations or otherwise met the applicable statutory or regulatory criteria through an alternative approach.	Yes			Section 12.2.4 FDA Guidance - Physical Properties
c: If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate those alternative measures identified by the firm will provide at least			N/A	

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
an equivalent assurance of safety and effectiveness.				
38) If literature is referenced in the submission, submission includes:				
a: Legible reprints or a summary of each article	Yes			Section 23 Literature
b: Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	Yes			Section 12.2.4 Depth of Cure Discussion Section 12.2.4 Cusp Deflection
39) For each non-clinical study (i.e., animal) study conducted,			N/A	Section 19 Animal Performance Testing No non-clinical (i.e., animal) studies conducted
a: Submission includes a study protocol which includes all elements as outline in 21 CFR 58.120			N/A	No non-clinical (i.e., animal) studies conducted
b: Submission includes a final study report which includes all elements outlined in 21 CFR 58.185			N/A	No non-clinical (i.e., animal) studies conducted
c: Submission contains statement that study was conducted in conformance with applicable requirements of GLP regulation (21 CFr Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the non-compliance would not impact the validity of the study data to support a SE determination.			N/A	No non-clinical (i.e., animal) studies conducted
Part "K" Performance Characteristics- In Vitro Diagnostic Devices (21 CFR 809.10(b)(12)				

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
Submission indicates that the device: □ is ☒ is not an in-vitro diagnostic device (IVD)	Yes			The device is not an in-vitro diagnostic device (IVD).
40) Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:			N/A	The device is not an in-vitro diagnostic device (IVD).
a: Precision/reproducibility			N/A	The device is not an in-vitro diagnostic device (IVD).
b: Accuracy (includes as appropriate, linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.			N/A	The device is not an in-vitro diagnostic device (IVD).
c: Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).			N/A	The device is not an in-vitro diagnostic device (IVD).
d: Analytical specificity.			N/A	The device is not an in-vitro diagnostic device (IVD).
41) a: If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			N/A	The device is not an in-vitro diagnostic device (IVD).
b: If there is a device-specific guidance, other than a special			N/A	The device is not an in-vitro diagnostic device (IVD).

510(k) Submission Elements				
	Yes	**No**	**N/A**	**Comment**
controls guidance document, applicable to the device, the submission includes performance data to established that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.				
c: If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			N/A	The device is not an in-vitro diagnostic device (IVD).

1. Letter of Authorization for 3rd Party Review

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

3M ESPE

Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Subject: Authorization for Accredited Person Review of 510(k) for Filtek™ Bulk Fill Posterior Restorative

To Whom it May Concern:

Enclosed is the Premarket Notification 510(k) for Filtek™ Bulk Fill Posterior Restorative, manufactured by 3M ESPE Dental Products.

We at 3M ESPE Dental Products hereby authorize Regulatory Technology Services, LLC, to submit the enclosed 510(k) to the Food and Drug Administration (FDA) on our behalf, discuss its contents with the FDA, and function as the Accredited Person to perform the third party review.

We certify that we have not contacted another Accredited Person to perform the review of this 510(k) submission.

We accept the quote for 510(k) review services including the Regulatory Technology Services LLC Terms and Conditions.

Sincerely,

Scott Erickson, RAC
Senior Regulatory Affairs Specialist
3M ESPE Dental Products

15 Apr 2014
Date

1.1 Medical Device User Fee 510(k) Cover Sheet

A Medical Device User Fee Cover Sheet is not required because this Premarket Notification for Filtek™ Bulk Fill Posterior Restorative is being submitted to an accredited person for third party review.

3M ESPE

2. 510(k) Cover Letter

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

3M ESPE

Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Subject: Traditional 510(k) Premarket Notification for Filtek™ Bulk Fill Posterior Restorative

Dear Mr. Job:

In compliance with the Federal Food, Drug, and Cosmetic Act (as amended) and as required in 21 CFR 807, Subpart E, 3M ESPE Dental Products submits this 510(k) Premarket Notification for Filtek™ Bulk Fill Posterior Restorative to Regulatory Technology Services, LLC, for 3rd party review.

Consistent with 21 CFR 807.90, FDA eCopy Guidance and the instructions provided by Regulatory Technology Services, LLC, in quote 20140221MJ01, please find enclosed three (3) complete copies (1 paper and 2 eCopy) of the 510(k) submission for Filtek™ Bulk Fill Posterior Restorative. Please note that each eCopy is an exact duplicate of the original paper submission. Also enclosed are two (2) additional copies of this cover letter.

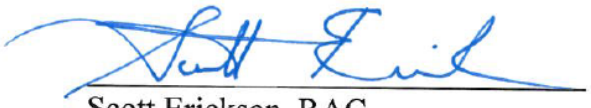
This is the first submission for this medical device (e.g., no pre-IDE was filed for this device). This 510(k) submission includes a signed Authorization Letter and a completed RTA checklist, as recommended in FDA Guidance Document, Refuse to Accept Policy for 510(k)s. This submission does not contain any master files.

3M ESPE Dental Products requests that all trade secret and confidential commercial information contained in this submission to be maintained as confidential by the Agency and not disclosed publicly, consistent with 21 CFR 20.61.

If there are any questions concerning this submission, please contact me as soon as possible. My contact information is provided below.

3M ESPE

Sincerely,



15 Apr 2014
Date

Scott Erickson, RAC
Senior Regulatory Affairs Specialist
3M ESPE Dental Products
3M Center, Building 275-2W-08
2510 Conway Avenue
St. Paul, MN 55144-1000
Phone: (651) 736-9883
Fax: (651) 736-1599
sterickson@mmm.com

Enclosures

3. 510(k) Summary

3M ESPE 2510 Conway Avenue
Dental Products St. Paul, MN 55144-1000

3M ESPE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter…… 3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

Contact person……..…. Scott Erickson, RAC
Senior Regulatory Affairs Specialist
Phone: (651) 736-9883
Fax: (651) 736-1599
sterickson@mmm.com

Date Summary was Prepared…… 15Apr2014

Trade Name…….... Filtek™ Bulk Fill Posterior Restorative

Common Name(s)…….…. Tooth shade resin material
Restorative

Recommended Classification…… 21 CFR 872.3690
Tooth shade resin material
Product Code: EBF

Predicate Devices:
Filtek™ Supreme Ultra Universal Restorative (K083610)
Metamorphosis (K091023)
Trade name: SonicFill, Sonic-Activated Bulk Fill Composite
Tetric EvoCeram Bulk Fill (K111958)

Description of Device:
3M™ ESPE™ Filtek™ Bulk Fill Posterior Restorative material is a visible-light activated, restorative composite optimized to create posterior restorations simpler and faster. This bulk fill material provides excellent strength and low wear for durability. The shades are semi-translucent and low stress curing, enabling up to a 5 mm depth-of-cure. With excellent polish retention, Filtek™ Bulk Fill Posterior Restorative is also useful for anterior restorations that call for a semi-translucent shade. All shades are radiopaque. Filtek™ Bulk Fill Posterior Restorative is offered in A1, A2, A3, B1, and C2 shades. Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as manufactured by 3M™ ESPE™, which permanently bonds the restoration to the tooth structure.

Filtek™ Bulk Fill Posterior Restorative is packaged in traditional syringes, for dispensing restorative on a pad outside the mouth, and single-dose capsules for dispensing restorative intraorally. The capsules are dispensed using the 3M ESPE Restorative Dispenser.

Indications for Use:
- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

Technological Characteristics:
Filtek™ Bulk Fill Posterior Restorative is a modification of predicate device, Filtek™ Supreme Ultra Universal Restorative. The formulation was modified to create semi-translucent shades with low polymerization shrinkage stress to enable bulk placement and cure for ease of use.

The fillers used in Filtek™ Bulk Fill Posterior Restorative are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of agglomerated 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.4% by volume). The principal resins used in Filtek™ Bulk Fill Posterior Restorative are ERGP-DMA, diurethane-DMA and 1, 12-dodecane-DMA.

When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

Substantial Equivalence:

Technological property	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Photoinitiator system	X	X	NA[1]	X[2]
Methacrylate-based resin matrix	X	X	X	X
Compatible with methacrylate-based dental adhesives	X	X	NA[1]	X
Inorganic fillers	X	X	X	X
Oxide fillers are silane treated so that they bond to the resin matrix when the restorative is cured	X	X	X[3]	NA[1]
Bulk fill (up to 4 mm depth of cure)	X	-	X	X
Bulk fill (5 mm depth of cure, Class II)	X[4]	-	X[4]	
When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.	X	X	X	X
Dispensing system: single-use capsule (intraoral)[5] reusable syringe (extraoral)[6]	 X X	 X X	 X -	 X X
Recommended for load-bearing occlusal surfaces	X	X	X	X
FDA-Recognized Standards followed	Risk Management: ISO 14971 Biocomp stds[7]: ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds[8]: ISO 4049 ISO 6874	Risk Management: ISO 14971 Biocomp stds[7]: ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds[8]: ISO 4049	NA[1]	NA[1]

1. Not available, details not disclosed by manufacturer.
2. Product also contains a second photoinitiator.

3. Based on disclosure that product contains 3-trimethoxysilylpropyl methacrylate.
4. Similarity: In order to obtain 5 mm depth of cure for Class II restorations, product is light-cured from the occlusal surface and, after the matrix band is removed, light-cured from the buccal and lingual surfaces.

   Difference: The predicate device techniques states up to a 5mm depth of cure for Class I restorations, as well, also using the multi-site light-curing process described above. For Filtek™ Bulk Fill Posterior Restorative, 4mm Depth of Cure is stated for Class I restorations, light-curing from the occlusal aspect only, as supported by ISO 4049 Depth of Cure test results. This difference does not affect the safety or efficacy of the device.
5. Restorative material is dispensed from a single-use capsule in the mouth.

   Difference: The predicate device SonicFill, Sonic-Activated Bulk Fill Composite (K091023) is dispensed from the capsule using the air-driven SonicFill Handpiece, which, per the Instructions for Use "offers sonically activated delivery."

   Similarity: Filtek™ Bulk Fill Posterior Restorative and predicates Filtek™ Supreme Ultra Universal Restorative (K083610) and Tetric EvoCeram Bulk Fill (K111958) all use a traditional manual restorative dispenser (not air-driven) for dispensing capsules. In light of this similarity, the difference mentioned above does not affect the safety or efficacy of the device.
6. Restorative material is dispensed from a reusable syringe outside the mouth (e.g., onto a pad).
7. Newer versions of several biocompatibility standards were applied to Filtek™ Bulk Fill Posterior Restorative, due to time elapsed since the predicate device was evaluated. This difference is not significant because for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610):
   a. A Diplomate of the American Board of Toxicology assessed the safety of the product.
   b. Standard risk assessment techniques and consideration of internationally recognized guidelines were used in the evaluation.
   c. The conclusion of the assessment is that the device is safe for its intended use.
8. ISO 4049 data in this submission for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610), was generated using the current version of the standard, ISO 4049:2009.

   Difference: ISO 6874:2005 was not used to evaluate the predicate device, Filtek™ Supreme Ultra Universal Restorative for the 510(k) submission K083610, because it does not have a sealant indication. The only test in ISO 6874 that is applicable for a light-cure material, like Filtek™ Bulk Fill Posterior

Restorative, is Depth of Cure. This submission includes data showing both Filtek™ Bulk Fill Posterior Restorative and predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610) readily pass the ISO 6874 Depth of Cure requirement. Therefore, this difference is not significant and does not affect the safety or efficacy of the device.

Test results for the following physical properties were included in this submission: Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Volumetric Shrinkage, Wear, Depth of Cure, Cusp Deflection and Polish Retention.

Conclusion:
Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the predicate devices, Filtek™ Supreme Ultra Universal Restorative, SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill in terms of intended use, indications for use, physical properties, and technological characteristics. Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the predicate device, Filtek™ Supreme Ultra Universal Restorative in terms of formulation.

4. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Filtek™ Bulk Fill Posterior Restorative

Indications for Use *(Describe)*

- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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

The burden time for this collection of information is estimated to average 79 hours 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
PRAStaff@fda.hhs.gov

"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 number."

FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

3M ESPE

5. Truthful and Accuracy Statement

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

3M ESPE

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Senior Regulatory Affairs Specialist of 3M ESPE Dental Products, 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)

Scott Erickson
(Typed Name)

15 Apr 2014
(Date)

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

*For a new submission, leave the 510(k) number blank.
Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

6. Class III Summary and Certification

Not applicable. Subject medical device is not a Class III device.

3M ESPE

7. Form FDA 3514 - CDRH Premarket Review Submission Cover Sheet

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)*
04/15/2014	Third Party Review	

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)*		
3M Company	3005174370		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
3M ESPE Dental Products	651-736-9883		
Street Address	**FAX Number *(including area code)***		
2510 Conway Avenue	651-736-1599		
City	**State / Province**	**ZIP/Postal Code**	**Country**
St. Paul	MN	55144-1000	USA
Contact Name			
Scott Erickson			
Contact Title	**Contact E-mail Address**		
Senior Regulatory Affairs Specialist	sterickson@mmm		

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**		

FORM FDA 3514 (1/13) Page 1 of 5 Pages

3M ESPE

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

- ☐ 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)*:

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	EBF	2	EBF, EBC	3	EBF	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	K083610	1	Filtek™ Supreme Ultra Universal Restorative	1	3M ESPE Dental Products
2	K091023	2	SonicFill, Sonic-Activated Bulk Fill Composite (Metamorphosis)	2	Kerr Corporation
3	K111958	3	Tetric EvoCeram Bulk Fill	3	Ivoclar Vivadent
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Tooth Shade Resin Material, 21 CFR 872.3690

	Trade or Proprietary or Model Name for This Device		Model Number
1	Filtek™ Bulk Fill Posterior Restorative	1	Not applicable
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: EBF

C.F.R. Section *(if applicable)*: 21 CFR 872.3690

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel: Dental 76

Indications *(from labeling)*

• Direct anterior and posterior restorations (including occlusal surfaces) • Base/liner under direct restorations • Core build-ups • Splinting • Indirect restorations including inlays, onlays and veneers • Restorations of deciduous teeth • Extended fissure sealing in molars and premolars • Repair of defects in porcelain restorations, enamel, and temporaries

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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: (b) (4)

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

Company / Institution Name: 3M Company	Establishment Registration Number: (b) (4)
Division Name *(if applicable)*: 3M ESPE Dental Products	Phone Number *(including area code)*: (b) (4)
Street Address: (b) (4)	FAX Number *(including area code)*: (b) (4)

City	State / Province	ZIP Code	Country
(b) (4)	(b) (4)	(b)	USA

Contact Name	Contact Title	Contact E-mail Address
(b) (4)	(b) (4)	(b) (4)

☐ 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

FORM FDA 3514 (1/13) Add Continuation Page Page 4 of 5 Pages

3M ESPE

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 14971	ISO	Medical Devices - Application of Risk Management to Medical Devices	2007	10/01/2007
2	ISO 10993-1	ISO	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process	2009	10/15/2009
3	ISO 10993-3	ISO	Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	2003	10/15/2003
4	ISO 10993-5	ISO	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity	2009	06/01/2009
5	ISO 10993-6	ISO	Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation	2007	04/15/2007
6	ISO 10993-10	ISO	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	2010	08/01/2010
7	ISO 10993-11	ISO	Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity	2006	08/15/2006

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.

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Rockville, MD 20850

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Additional Standards cited in this submission:

	Standards No.	Standards Organization	Standards Title	Version	Date
8	ISO 10993-12	ISO	Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials	2012	07/01/2012
	Standards No.	Standards Organization	Standards Title	Version	Date
9	ISO 7405	ISO	Dentistry - Evaluation of Biocompatibility of Medical Devices Used in Dentistry	2008	12/15/2008
	Standards No.	Standards Organization	Standards Title	Version	Date
10	ISO 4049	ISO	Dentistry - Polymer-based restorative materials	2009	10/01/2009
	Standards No.	Standards Organization	Standards Title	Version	Date
11	ISO 6874	ISO	Dentistry - Polymer-Based Pit and Fissure Sealants	2005	08/15/2005

8. Declaration of Conformity and FDA Form 3654

8.1 Declaration of Conformity

Not applicable. This is not an Abbreviated 510(k) submission.

8.2 FDA Form 3654 Standards Data Report

Please see Forms 3654 beginning on next page.

8.2.1 Form FDA 3654 for ISO 14971

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ⁺		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ⁺		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ⁺		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

⁺ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

8.2.2 Form FDA 3654 for ISO 10993-1

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 10993-1:2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-179	
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: FDA Memorandum G95-1 was also considered.

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-1:2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Paperwork Reduction Act (PRA) Staff
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8.2.3 Form FDA 3654 for ISO 10993-3

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 10993-3:2003 Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive To

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2/175	
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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-3:2003 Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive To

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2	Test Strategy	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Selected Option 2 (4.2.1.2)

DESCRIPTION
Performed OECD test methods 471 and 476 with colony number and size determination

JUSTIFICATION
Complies with 4.2.1.2

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3	Sample Preparation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Test article

DESCRIPTION
Saline and DMSO extracts prepared according to ISO 10993-12:2012

JUSTIFICATION
Complies with Section 4.3

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4.1	In vitro genotoxicity tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Performed OECD test methods 471 and 476

DESCRIPTION
Performed OECD test methods 471 and 476 with colony number and size determination

JUSTIFICATION
Complies with 4.4.1

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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8.2.4 Form FDA 3654 for ISO 10993-5

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity

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: ISO 10993-12:2007 and FDA Memorandum G95-1 were also considered.

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	General	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Extracted the Test Sample

DESCRIPTION
Extracted the test sample

JUSTIFICATION
Complies with 4.1(a)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.2	Extraction vehicle	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Used culture medium with serum

DESCRIPTION
Used culture medium with serum for extraction

JUSTIFICATION
Preferred extraction medium (4.2.2(a))

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.3	Extraction conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Selected 4.2.3.2 (a)

DESCRIPTION
Selected 24 hours at 37 °C

JUSTIFICATION
Higher temperature may degrade the extraction medium (4.2.3.2)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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3M ESPE

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex B.2.2.4.4	Preparation of sample extract	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Extraction ratio

DESCRIPTION
Extracted the cured material at 0.1 g/mL (Colony formation test) or 0.2 g/mL (MEM Elution Test)

JUSTIFICATION
Recommended extraction ratios per Annex B.2.2.4.4 and ISO 10993-12:2007

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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8.2.5 Form FDA 3654 for ISO 10993-6

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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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]

ISO 10993-6:2007 Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-120	
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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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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3M ESPE

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-6:2007 Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.1	Tissue and implantation site	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Choice of tissue and implantation site

DESCRIPTION
Paravertebral muscle was chosen as the tissue implantation site

JUSTIFICATION
Muscle is appropriate to evaluate potential local tissue effects. Preferred site in rabbits selected (Annex C.4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2	Animals	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Choice of animal

DESCRIPTION
Rabbits were the selected species

JUSTIFICATION
Rabbit is a preferred animal (5.2)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.3	Test periods	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Selection of exposure time

DESCRIPTION
Tissue was evaluated at 1-, 4-, and 12-weeks after implantation

JUSTIFICATION
Material has no or minimal degradation (5.3)

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3M ESPE

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-6:2007 Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex C.3	Test specimens	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Option: Size of the test specimen

DESCRIPTION
The test implants were 10 mm diameter x 2 mm thick discs

JUSTIFICATION
Acceptable size (Annex C.3).

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex C.5	Implantation procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Option: Implantation technique

DESCRIPTION
Appropriate surgical techniques were used to implant the larger implants

JUSTIFICATION
Provision for implanting larger implants (Annex C.5)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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8.2.6 Form FDA 3654 for ISO 10993-10

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-174	
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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation Tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Irritation test type

DESCRIPTION
Intracutaneous (intradermal) reactivity test (6.4)

JUSTIFICATION
More sensitive test than the animal irritation test (6.3)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.1	Choice of Test	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Selected the Guinea Pig Maximization Test

DESCRIPTION
Selected the Guinea Pig Maximization Test

JUSTIFICATION
Test is specified as the most sensitive method (7.1)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex A.3 and A.4	Solvents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Selected suitable non-irritant extraction solvents per ISO 10993-12

DESCRIPTION
Saline and sesame oil were selected as the extraction solvents

JUSTIFICATION
Complies with ISO 10993-12: 2012

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8.2.7 Form FDA 3654 for ISO 10993-11

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STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-11:2006 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-176	
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.	☒	☐
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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: ISO 10993-12:2007 and FDA Memorandum G95-1 were also considered.

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-11:2006 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.5.1	Size of groups	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Testing in a single sex

DESCRIPTION
Acute oral test was performed in females only. Females are more sensitive to toxic effects (OECD 423)

JUSTIFICATION
Testing in a single sex is acceptable per standard (Table 1, footnote A)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Acute systemic toxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Acute Systemic Toxicity Test conducted

DESCRIPTION
Single oral gavage dose of product extracts with 14-day observation period in rats

JUSTIFICATION
Evaluated potential health hazard associated with acute exposure to extractables by the clinically relevant route

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Repeated exposure systemic toxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Subacute (28-day) systemic toxicity study conducted

DESCRIPTION
28-day oral gavage study using product extract in the rat

JUSTIFICATION
Evaluated potential health hazards associated with prolonged exposure to product leachates by the intended clinical route

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3M ESPE

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-11:2006 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2.3.1	Dose levels	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Number of dose groups

DESCRIPTION
Dose groups received undiluted extract at either 100 or 800 ug residue/kg-day

JUSTIFICATION
Dose appropriately addressed worst-case scenario exposure

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex B.1	Dosage Volumes, General	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Dose Volume

DESCRIPTION
Dose volumes of 6 mL/kg-day (28-day study) and 10 mL/kg (acute study) were selected

JUSTIFICATION
Dose volumes were less than the maximum oral gavage dose (i.e., 50 mL/kg) which meets animal welfare requirements

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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8.2.8 Form FDA 3654 for ISO 10993-12

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-12:2012 Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-191	
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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: FDA Memorandum G95-1 was also considered.

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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3M ESPE

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-12:2012 Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.1	Test sample selection	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Test sample selection

DESCRIPTION
Tested extracts of the cured test sample (extract tests) or in situ cured material (pulp-dentin study)

JUSTIFICATION
Test sample prepared as required for each specific test

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10.3	Extraction conditions and methods	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Extraction Temperature and Time

DESCRIPTION
Extracted test sample at 37 °C for 24 hours for cytotoxicity tests and 37 °C for 72 hours for all other extract tests

JUSTIFICATION
Extraction conditions listed in standard (10.3.1)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10.3	Extraction conditions and methods	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Extraction ratio

DESCRIPTION
Selected 0.1 g/mL (colony assay) and 0.2 g/mL for all other tests

JUSTIFICATION
Ratios are appropriate for intended product application and specific test

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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

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FORM FDA 3654 (1/14) Page 2

3M ESPE

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-12:2012 Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10.3	Extraction conditions and methods	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Extraction solvents

DESCRIPTION
Test system compatible extraction solvents were selected

JUSTIFICATION
Choice of solvents as appropriate for each test

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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FORM FDA 3654 (1/14) Page 2

8.2.9 Form FDA 3654 for ISO 7405

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 7405:2008 Dentistry - Evaluation of Biocompatibility of Medical Devices Used in Dentistry

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#4-179	
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: FDA Memorandum G95-1 was also considered.

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

FORM FDA 3654 (1/14) Page 1 PSC Publishing Services (301) 443-6740 EF

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 7405:2008 Dentistry - Evaluation of Biocompatibility of Medical Devices Used in Dentistry

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.4.c	Group III	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Pulp and dentin usage test and pulp capping test

DESCRIPTION
Performed the pulp and dentin usage test (6.4) and pulp capping test (6.5)

JUSTIFICATION
Choice of tests appropriate for intended use

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.4.3.2.3	Treatment of teeth	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Species selection for pulp and dentin usage test

DESCRIPTION
Selected miniature pigs as the lowest order species with appropriate dentition

JUSTIFICATION
Species appropriate for evaluation of product

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.5.3.2.3	Treatment of teeth	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: Species selection for pulp capping test

DESCRIPTION
Selected miniature pigs as the lowest order species with appropriate dentition

JUSTIFICATION
Species appropriate for evaluation of product

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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FORM FDA 3654 (1/14) Page 2

8.2.10 Form FDA 3654 for ISO 4049

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 4049:2009 Dentistry - Polymer-based restorative materials

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#4-181	
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: 2005 Guidance for Industry & FDA Staff-Dental Composite Resin Devices-Premarket Notification 510(k)

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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3M ESPE

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 4049:2009 Dentistry - Polymer-based restorative materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.10	Depth of cure, Class 2 materials	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Deviation: alternate method used to verify 5mm depth of cure

DESCRIPTION
4mm depth of cure verified using ISO 4049 method. 5mm depth of cure using multi-site (occlusal, lingual, buccal) light-curing verified using alternate method developed at the Oregon Health Science University (Dr. Tom Hilton, Principal Investigator).

JUSTIFICATION
ISO 4049 depth of cure method can not accommodate multi-site light-curing.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.14	Radio-opacity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Option: This test can be conducted with analogue or digital X-ray apparatus at the discretion of the test laboratory.

DESCRIPTION
Digital X-ray apparatus used

JUSTIFICATION
Availability of apparatus

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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FORM FDA 3654 (1/14) Page 2

8.2.11 Form FDA 3654 for ISO 6874

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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]

ISO 6874:2005 Dentistry - Polymer-Based Pit and Fissure Sealants

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#4-132	
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: 2005 Guidance for Industry & FDA Staff-Dental Composite Resin Devices-Premarket Notification 510(k)

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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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FORM FDA 3654 (1/14) Page 1 PSC Publishing Services (301) 443-6740 EF

3M ESPE

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 6874:2005 Dentistry - Polymer-Based Pit and Fissure Sealants

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

3M ESPE

9. Financial Certification or Disclosure Statement

Not applicable. This submission does not contain information from clinical studies.

3M ESPE

10. Form FDA 3674 - Certification of Compliance\ClinicalTrials.gov

FDA Form 3674 - Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter: 3M ESPE Dental Products

2. Date of the Application/Submission Which This Certification Accompanies: 04/15/2014

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*: 2510 Conway Avenue

Address 2 *(Apartment, suite, unit, building, floor, etc.)*:

City: St. Paul

State/Province/Region: MN

Country: USA

ZIP or Postal Code: 55144-1000

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 651-736-9883

(Fax): 651-736-1599

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Filtek™ Bulk Fill Posterior Restorative
Tooth Shade Resin Material, 21 CFR 872.3690, Class II Medical Device

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

3M ESPE

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Scott Erickson	Senior Regulatory Affairs Specialist

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	3M Center, Building 275-2W-08
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	2510 Conway Avenue
City	St. Paul
State/Province/Region	MN
Country	USA
ZIP or Postal Code	55144-1000

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 651-736-9883

(Fax): 651-736-1599

14. Date of Certification

04/15/2014

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

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

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TECHNICAL

11. Device Description

11.1 Executive Summary

11.1.1 General Description

3M™ ESPE™ Filtek™ Bulk Fill Posterior Restorative material is a visible-light activated, restorative composite optimized to create posterior restorations simpler and faster. This bulk fill material provides excellent strength and low wear for durability. The shades are semi-translucent and low stress curing, enabling up to a 5 mm depth-of-cure. With excellent polish retention, Filtek™ Bulk Fill Posterior Restorative is also useful for anterior restorations that call for a semi-translucent shade. All shades are radiopaque. Filtek™ Bulk Fill Posterior Restorative is offered in A1, A2, A3, B1, and C2 shades.

The fillers are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of agglomerated 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.4% by volume). The principal resins used in Filtek™ Bulk Fill Posterior Restorative are ERGP-DMA, diurethane-DMA and 1, 12-dodecane-DMA. Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as manufactured by 3M™ ESPE™, which permanently bonds the restoration to the tooth structure.

Filtek™ Bulk Fill Posterior Restorative is a modification of predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610), also manufactured by 3M ESPE Dental Products. The formulation was modified to create semi-translucent shades with low polymerization shrinkage stress to enable bulk placement and cure for ease of use.

Both Filtek™ Supreme Ultra Universal Restorative and Filtek™ Bulk Fill Posterior Restorative are packaged in traditional syringes for dispensing restorative on a pad outside the mouth, and single-dose capsules for dispensing restorative intraorally. The 3M ESPE 5707SD Restorative Dispenser (Class 1, per 21CFR872.4565, ProCode 76EID) is used for dispensing the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610) and other 3M ESPE restoratives from capsules. The same 5707SD Restorative Dispenser will also be used to dispense Filtek™ Bulk Fill Posterior Restorative capsules.

11.1.2 Mechanism of Action

When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

11.1.3 Indications for Use

- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

11.2 The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

The following trade name is applicable to this device:

Filtek™ Bulk Fill Posterior Restorative

The common or usual names for this type of product:

Tooth shade resin material
Restorative

The classification name for this device:

Tooth shade resin material (21 CFR 872.3690)

11.3 The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

510(k) submitted by:
3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA
Establishment Registration Number: 3005174370
Owner Operator Number: 2110898

Manufacturing Facility
3M ESPE Dental Products
(b) (4) [redacted]

11.4 The class in which the device is classified under section 513 of the act and, if known, its appropriate classification panel.

21 CFR 872.3690, Tooth Shade Resin Material, Class II

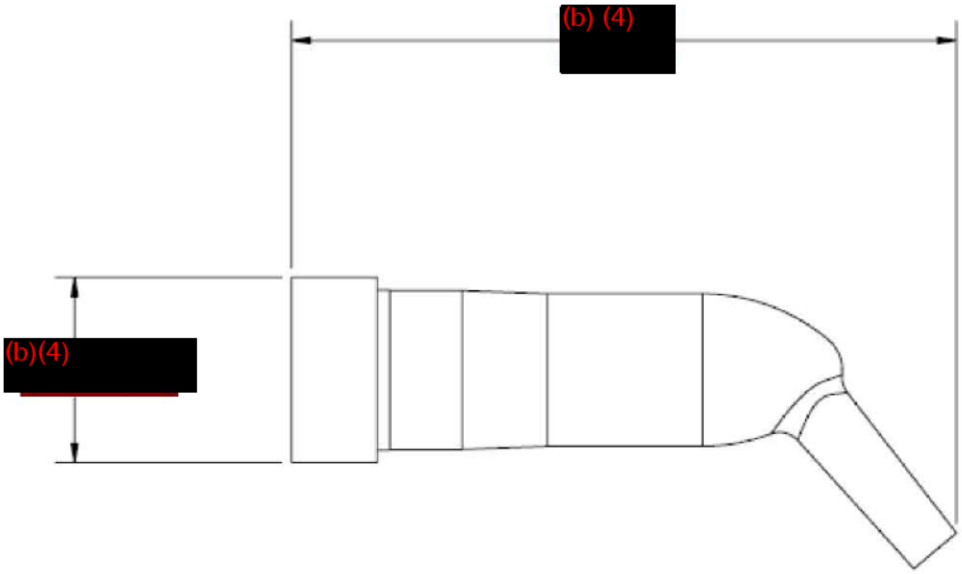
The appropriate classification panel is the Dental Products Panel 76.

Product Code: EBF

11.5 Photo and Drawings

Photo of Filtek™ Bulk Fill Posterior Restorative Syringe & Capsule

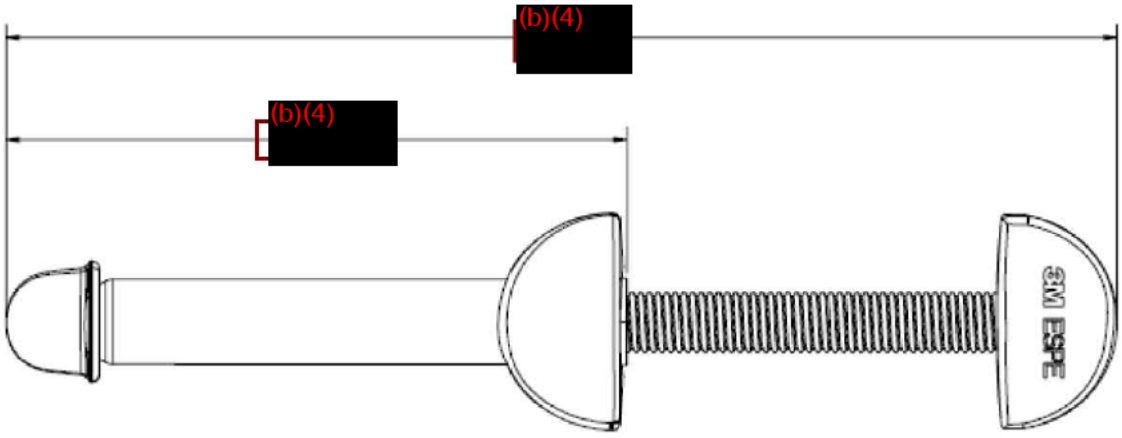
Drawing of of Filtek™ Bulk Fill Posterior Restorative Capsule



Filtek™ Bulk Fill Posterior Restorative Capsule

All dimensions are in inches

Drawing of of Filtek™ Bulk Fill Posterior Restorative Syringe



Filtek™ Bulk Fill Posterior Restorative Syringe

All dimensions are in inches

11.6 Commercial Presentation

Package configurations for Filtek™ Bulk Fill Posterior Restorative:

Item	Catalogue/Order Number
Syringe Refills	
Filtek Bulk Fill Posterior Restorative • 1- 4g A1 Shade Syringe • Instructions for Use	4863A1
Filtek Bulk Fill Posterior Restorative • 1- 4g A2 Shade Syringe • Instructions for Use	4863A2
Filtek Bulk Fill Posterior Restorative • 1- 4g A3 Shade Syringe • Instructions for Use	4863A3
Filtek Bulk Fill Posterior Restorative • 1- 4g B1 Shade Syringe • Instructions for Use	4863B1
Filtek Bulk Fill Posterior Restorative • 1- 4g C2 Shade Syringe • Instructions for Use	4863C2
Capsule Refills	
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g A1 Shade Capsules • Instructions for Use	4864A1
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g A2 Shade Capsules • Instructions for Use	4864A2
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g A3 Shade Capsules • Instructions for Use	4864A3
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g B1 Shade Capsules • Instructions for Use	4864B1
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g C2 Shade Capsules • Instructions for Use	4864C2
Accessories	
Restorative Dispenser*	5707SD

* The currently marketed 3M ESPE 5707SD Restorative Dispenser (Class 1, per 21CFR872.4565, ProCode 76EID) is used for dispensing the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610), from capsules. The same 5707SD Restorative Dispenser will also be used to dispense Filtek™ Bulk Fill Posterior Restorative capsules.

11.7 Device Design Requirements

The design requirements below were set to ensure that Filtek™ Bulk Fill Posterior Restorative has sufficient physical properties to perform as intended.

Physical Property	Unit	Test Method	Minimum Design Requirements*
(b)(4)			

*Based on (b)(4)

(b)(4)

11.8 Performance Specifications

The performance specifications below for Filtek™ Bulk Fill Posterior Restorative consist of device design requirements (above) plus specifications selected from voluntary standards.

Physical Property	Unit	Test Method	Specification
(b)(4)			

11.9 Performance Standards - Action taken by 3M to comply with the requirements of the act under section 514 for performance standards.

No action has been taken to comply with the requirements of the Act under Section 514 for performance standards since no such mandatory standard(s) exist.

11.10 Performance Testing

This 510(k) submission includes data from bench testing to evaluate the performance of Filtek™ Bulk Fill Posterior Restorative compared to the predicate devices Filtek™ Supreme Ultra Universal Restorative, Metamorphosis (trade name: SonicFill, Sonic-Activated Bulk Fill Composite) and Tetric EvoCeram Bulk Fill. Properties evaluated include Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Volumetric Shrinkage, Wear, Depth of Cure, Cusp Deflection and Polish Retention. Voluntary standards utilized include ISO 4049:2009 Dentistry - Polymer-based Restorative Materials and ISO 6874:2005 Dentistry - Polymer-Based Pit and Fissure Sealants. 3M ESPE Dental Products has tested Filtek™ Bulk Fill Posterior Restorative and found that it meets the relevant requirements of these two standards. A subset of this data, useful for comparison with predicate devices, has been included in Section 12.2.4 .

This submission does not include animal or clinical performance testing.

11.11 Risk Management

The environmental, health and safety (EHS) risks for Filtek™ Bulk Fill Posterior Restorative were evaluated using a process compliant with ISO 14971:2007, as well as specific procedures and practices outlined by 3M ESPE Dental Products' Standard Operating Procedures. After application of risk control, all risks identified in the Filtek™ Bulk Fill Posterior Restorative risk assessment were deemed to be broadly acceptable. Please see Risk Management Section 21.

11.12 Biocompatibility

A Diplomate of the American Board of Toxicology has assessed the safety of Filtek™ Bulk Fill Posterior Restorative. Standard risk assessment techniques and consideration of FDA General Program Memorandum G95 and internationally recognized guidelines, including ISO 10993-1:2009 along with Parts 3, 5, 10, 11, 12 and ISO 7405:2008, were used in this evaluation. The conclusion of the assessment is that the product is safe for its intended use. Please see Biocompatibility Section 15.

11.13 Formulation

FDA's October 26, 2005 "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions" recommends that the 510(k) submission include a description of the complete chemical composition, totalling 100 percent by mass, including all additives, fillers, and colorants, and the Chemical Abstracts Service[4] (CAS®) registry number of all components. The guidance also recommends that all colorants should be identified by either the CAS® number or Color Index Number. Please see composition for Filtek™ Bulk Fill Posterior Restorative provided below:

Function	Ingredient	CAS Number	Table*	Quantity (w/w%)*
(b)(4)	[redacted]			
Total				100

* Descriptions of each ingredient (e.g., Chemical Name, Function, Chemical Structure, Molecular Weight and Molecular Formula) are provided on the following pages.

** (b)(4)

(b)(4)

[redacted]

11.14 Ingredients

A.

(b)(4)

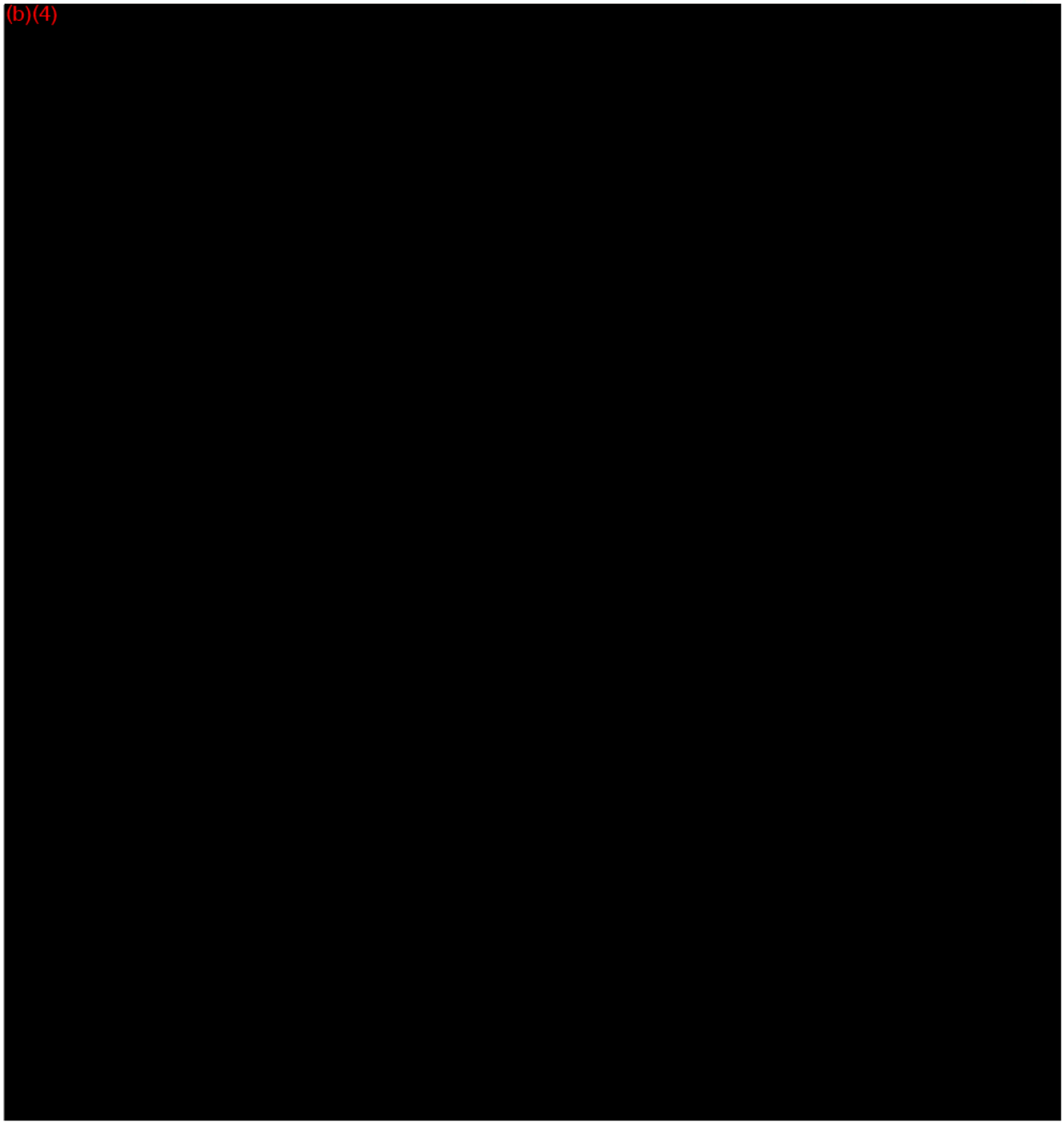
B.

(b)(4)

[redacted]

C.

(b)(4)



D.

(b)(4)

[redacted]

E.

(b)(4)

[redacted]

F.

(b)(4)

[redacted]

G.

(b)(4)

[redacted]

H.

(b)(4)

[redacted]

I.

(b)(4)

[redacted]

J.

(b)(4)

[redacted]

K.

(b)(4)

[redacted]

L.

(b)(4)

[redacted]

M.

(b)(4)

[redacted]

N.

(b)(4)

[redacted]

O.

(b)(4)

[redacted]

P.

(b)(4)

[redacted]

Q.

(b)(4)

[redacted]

R.

(b)(4)

[redacted]

S.

(b)(4)

[redacted]

T.

(b)(4)

[redacted]

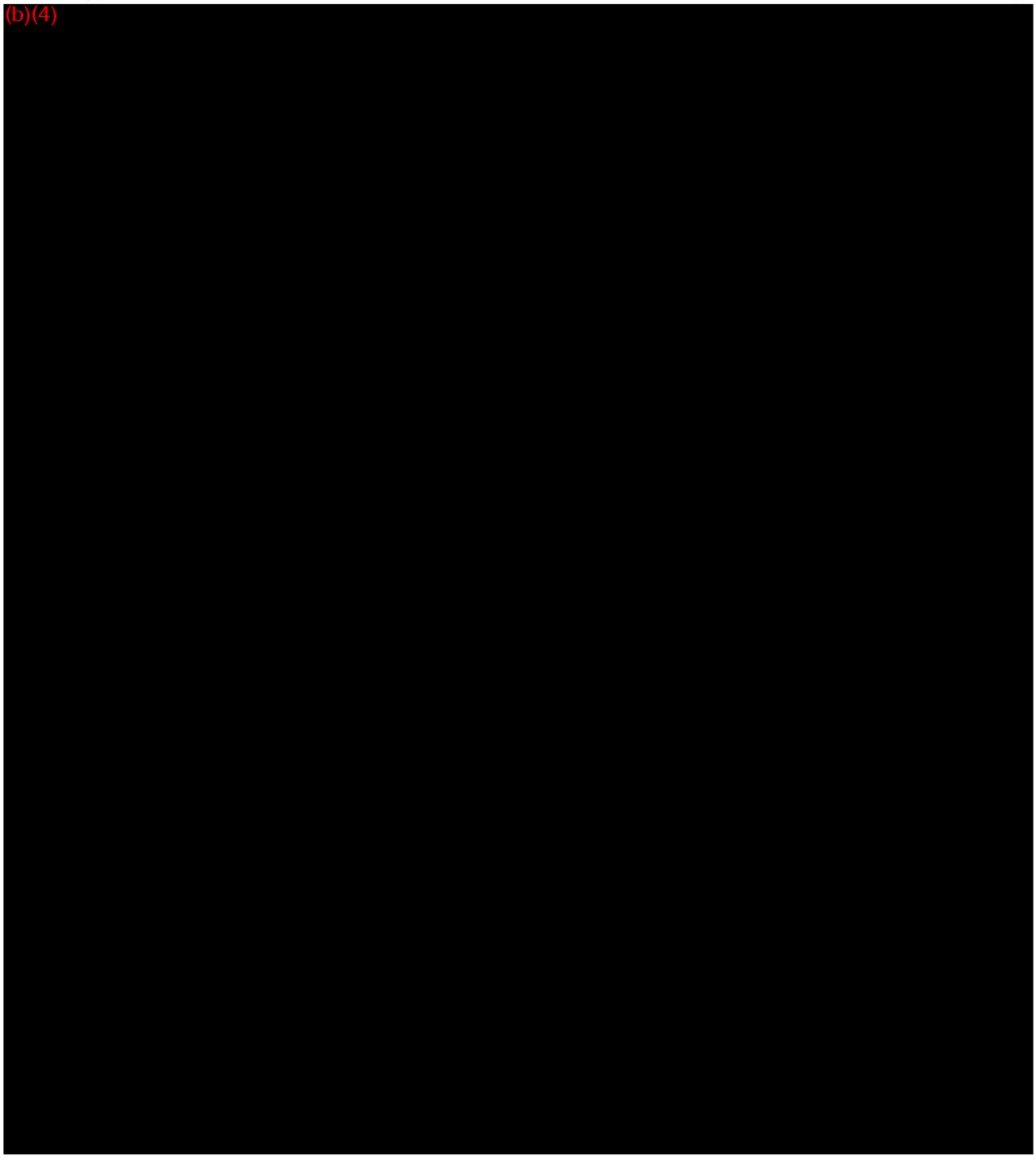
U.

(b)(4)

[redacted]

V.

(b)(4)



12. Substantial Equivalence Discussion

12.1 Identity of Substantially Equivalent (S/E) Devices

Filtek™ Supreme Ultra Universal Restorative
K083610
3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000

Metamorphosis
K091023
Trade Name: SonicFill, Sonic-Activated Bulk Fill Composite
Kerr Corporation
1717 W Collins Avenue
Orange, CA 92867

Tetric EvoCeram Bulk Fill
K111958
Ivoclar Vivadent
Amherst, NY 14228

12.2 Comparison with Substantially Equivalent (S/E) Devices

Filtek™ Bulk Fill Posterior Restorative is a modification of predicate device Filtek™ Supreme Ultra Universal Restorative. The formulation was modified to increase depth of cure, while decreasing polymerization shrinkage stress.

Over the last few years, a number of bulk fill dental restoratives have been introduced by other manufacturers and have gained in popularity with a segment of dentists. These products differ from traditional dental restoratives in that they have been designed to light cure to greater depths (typically $\geq$ 4 mm for bulk fill and $\leq$ 2 mm for traditional). The ability to light cure to greater depths allows the dentist to place and light cure fewer increments of the restorative material, which is a convenience that saves time. The table below shows whether the predicate devices are bulk fill or traditional.

Restorative	Traditional or Bulk Fill
Filtek™ Bulk Fill Posterior Restorative	Bulk Fill
Filtek™ Supreme Ultra Universal Restorative	Traditional
SonicFill, Sonic-Activated Bulk Fill Composite	Bulk Fill
Tetric EvoCeram Bulk Fill	Bulk Fill

12.2.1 Indications Comparison with S/E Devices

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative **K083610**	SonicFill, Sonic-Activated Bulk Fill Composite **K091023**	Tetric EvoCeram Bulk Fill **K111958**
Intended Use			
Dental Restorative	Dental Restorative	Dental Restorative	Dental Restorative
Indications for Use			
Direct anterior and posterior restorations (including occlusal surfaces)	Direct anterior and posterior restorations (including occlusal surfaces)[1,2]	…designed for direct placement. It is indicated for all cavity classes in posterior teeth.[1] Direct placement in all cavity classes in anterior and posterior teeth[2]	Restorations in the posterior region (Classes I and II, including the replacement of individual cusps)[1] Restorations in the posterior region (Classes I and II)[2] Class V restorations (cervical caries, root erosion, wedge-shaped defects)[1,2]
Base/liner under direct restorations		Base/liner material[2]	
Core build-ups	Core build-ups[1,2]	Core buildups[2]	Reconstructive build-up[1]
Splinting	Splinting[1,2]		
Indirect restorations including inlays, onlays and veneers	Indirect restorations including inlays, onlays and veneers[1,2]		
Restorations of deciduous teeth			Restorations of deciduous teeth[1] Restoration of deciduous teeth[2]
Extended fissure sealing in molars and premolars		Pit and fissure sealant[2]	Extended fissure sealing in molars and premolars[1,2]
Repair of defects in porcelain restorations, enamel, and temporaries		Repair of enamel defects, repair of temporaries, repair of porcelain restorations[2]	

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative **K083610**	SonicFill, Sonic-Activated Bulk Fill Composite **K091023**	Tetric EvoCeram Bulk Fill **K111958**
Contraindications			
None	None	None	**Contraindication** Placement of Tetric EvoCeram Bulk Fill restorations is contra-indicated: – if a dry working field cannot be established, or if the stipulated technique cannot be applied; – if a patient is known to be allergic to any of the ingredients in Tetric EvoCeram Bulk Fill.[1] None[2]

1. Indications/Contraindications from product labeling
2. Indications/Contraindications from FDA 510(k) clearance letter enclosure

Difference: The "Contraindication" in the Tetric EvoCeram Bulk Fill Instructions for Use (IFU) is not stated in the FDA 510(k) clearance letter K111958 enclosure. The need for proper isolation is addressed in the Filtek™ Bulk Fill Posterior Restorative IFU under:

"3. Isolation: A rubber dam is the preferred method of isolation. Cotton rolls and an evacuator can also be used." and

"7. Adhesive System: To bond Filtek™ Bulk Fill Posterior Restorative to tooth structure, use of a 3M™ ESPE™ dental adhesive system (for example 3M™ ESPE™ Scotchbond™ Universal) is recommended. Refer to adhesive system product instructions for full instructions and precautions for the products. After curing the adhesive, continue to maintain isolation from blood, saliva and other fluids and proceed immediately to placement of Filtek™ Bulk Fill Posterior Restorative."

Information related to patient allergy is addressed in the Filtek™ Bulk Fill Posterior Restorative IFU under:

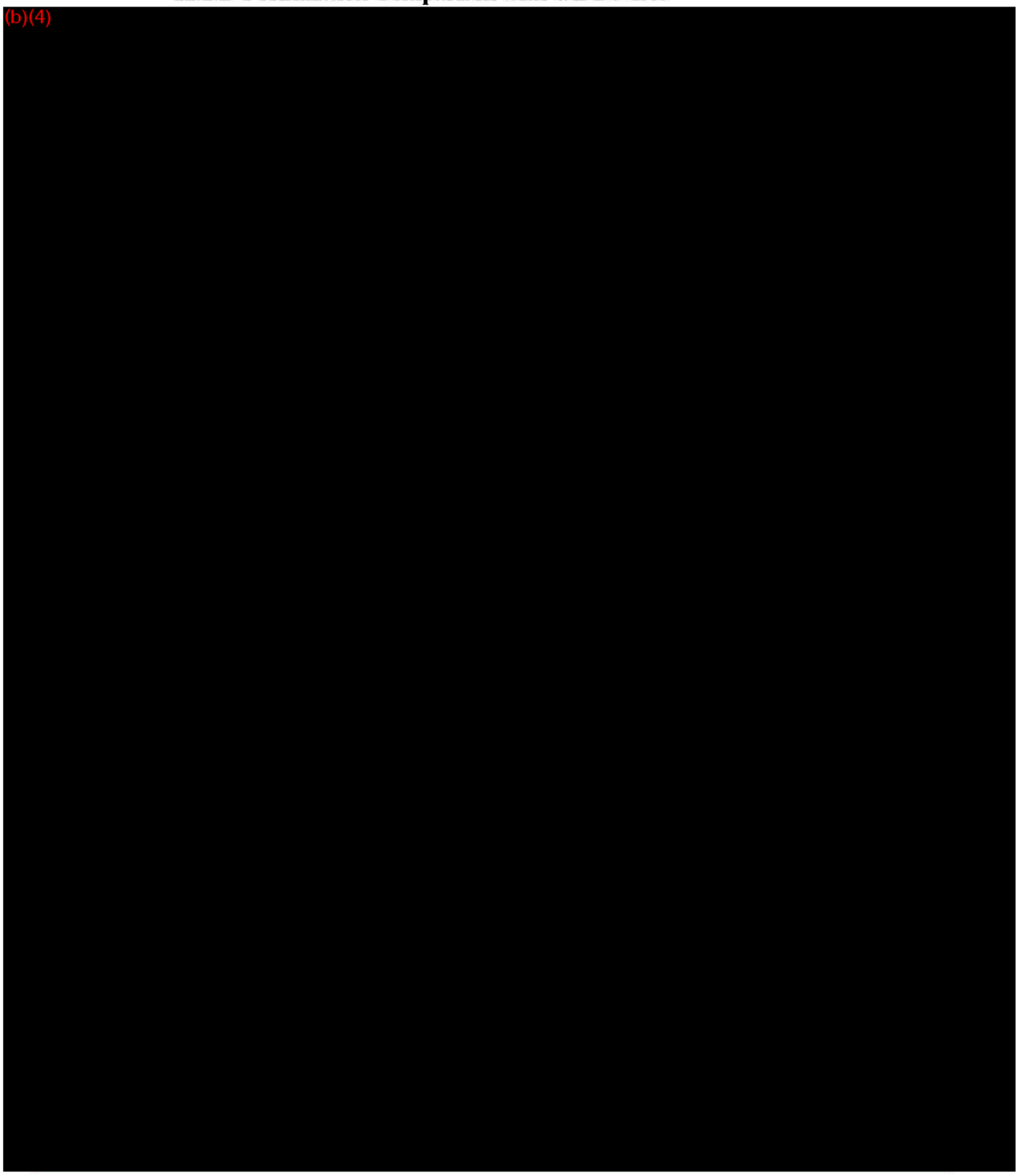
"Precautionary Information for Patients: This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product."

This difference does not affect the safety or efficacy of the device.

The proposed indications for Filtek™ Bulk Fill Posterior Restorative are substantially equivalent to those of the predicate devices.

12.2.2 Formulation Comparison with S/E Devices

(b)(4)



* (b)(4) [redacted]

** *D, E, B shades means Dentin, Enamel and Body shades.*

Detailed formulas are not available for SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill.

(b)(4) [redacted]

3M ESPE dental products has experience using all ingredients in Filtek™ Bulk Fill Posterior Restorative in other marketed 3M ESPE restorative products, except (b)(4) [redacted]

In a more general sense, the formulation of Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the formulations of all of the predicate devices, Filtek™ Supreme Ultra Universal Restorative, SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill, in that (b)(4) [redacted] (b)(4) [redacted]

12.2.3 Physical Property Comparison with S/E Devices

The information below is as described in the product labeling (e.g., IFU, MSDS) and has been summarized below for comparison.

PROPERTIES	Filtek™ Bulk Fill Posterior	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Filler particle size distribution*	The fillers are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of agglomerated 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.4% by volume).	The fillers are a combination of a non-agglomerated/ nonaggregated 20nm silica filler, a non-agglomerated/non-aggregated 4 to11 nm zirconia filler and an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles). The Dentin, Enamel and Body shades have an average cluster particle size of 0.6 to 10 microns. The Translucent shades have an average cluster particle size of 0.6 to 20 microns. The inorganic filler loading is about and 72.5% by wt (55.6% by volume) for the translucent shades and 78.5% by wt (63.3% by volume) for all other shades.	Glass, oxide, chemicals (CAS# 65997-17-3) Silicon dioxide (CAS# 7631-86-9) Particle size distribution not disclosed.	The fillers contain barium glass, ytterbium trifluoride, mixed oxide and prepolymer (79–81% weight). Additional contents: additives, catalysts, stabilizers and pigments (<1.0% weight). The total content of inorganic fillers is 76–77% weight or 53–54% volume. The particle size of the inorganic fillers is between 40 nm and 3,000 nm with a mean particle size of 550 nm.

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PROPERTIES	Filtek™ Bulk Fill Posterior	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Methacrylate-based Resin matrix	(See 12.2.2 Formulation Comparison with S/E Devices table)	(See 12.2.2 Formulation Comparison with S/E Devices table)	Ethoxylated bisphenol-A-dimethacrylate (CAS# 56744-60-6) Bisphenol-A-bis-(2-hydroxy-3-mehacryloxypropyl) ether (CAS# 1565-94-2) Triethyleneglycoldimethacrylate (CAS# 109-16-0)	Bis-GMA (CAS# 1565-94-2) UDMA (CAS# 72869-86-4)
Wavelength (nm) for curing*	400nm to 500nm	400nm to 500nm	Wavelength not disclosed	400nm to 500nm
Intensity (mW/cm^2) for curing*	Instructions provided for 550 to 1000 mW/cm^2 lights and for 1000 to 2000 mW/cm^2 lights	Instructions provided for $\geq$ 400 mW/cm^2 lights	Intensity not disclosed	Instructions provided for $\geq$ 500 mW/cm^2 lights and for $\geq$ 1000 mW/cm^2 lights
Curing time recommendations (sec)*	Classes I, III, IV and V 550 to 1000 mW/cm^2: 40 sec Classes I, III, IV and V 1000 to 2000 mW/cm^2: 20 sec	Body, Enamel and Translucent: 20 sec Dentin, A6B and B5B: 40 sec	Demi/Demi Plus, 20 seconds L.E.Demetron II, 20 seconds Optilux 501: Boost mode, 20 seconds / Ramp Mode, 40 seconds / Regular Mode, 40 seconds	$\geq$ 500 mW/cm^2: 20 sec

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PROPERTIES	Filtek™ Bulk Fill Posterior	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
	Class II 550 to 1000 mW/cm^2: 20 sec occlusal, 20 sec buccal, 20 sec lingual For class II restorations, remove the matrix band prior to the buccal and lingual curing steps.		In the posterior, light cure the recommended time from the occlusal, remove the matrix and cure again from the buccal and lingual. In a Class I, additional cure is still recommended from the facial and lingual.	≥ 1000 mW/cm^2: 10 sec
	Class II 1000 to 2000 mW/cm^2: 10 sec occlusal, 10 sec buccal, 10 sec lingual For class II restorations, remove the matrix band prior to the buccal and lingual curing steps.			
Depth of cure recommendation (mm)*	Classes I, III, IV and V 4 mm	2 mm for all shades except Dentin, A6B and B5B	Up to 5 mm	4 mm
	Class II 5 mm	1.5 mm for Dentin, A6B and B5B shades		

* FDA's "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions," issued October 26, 2005, asks that the properties above be described in the 510(k).

12.2.4 Bench Test Data Comparison with S/E Devices

This 510(k) submission includes data from bench testing to evaluate the performance of Filtek™ Bulk Fill Posterior Restorative compared to the predicate devices Filtek™ Supreme Ultra Universal Restorative, Metamorphosis (trade name: SonicFill, Sonic-Activated Bulk Fill Composite) and Tetric EvoCeram Bulk Fill. Properties evaluated include Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Volumetric Shrinkage, Wear, Depth of Cure, Cusp Deflection and Polish Retention. Voluntary standards utilized include ISO 4049:2009 Dentistry - Polymer-based Restorative Materials and ISO 6874:2005 Dentistry - Polymer-Based Pit and Fissure Sealants. 3M ESPE Dental Products has tested Filtek™ Bulk Fill Posterior Restorative and found that it meets the relevant requirements of these two standards. A subset of this data, useful for comparison with predicate devices, has been included in the table below.

Objective: To use bench tests to evaluate physical properties of Filtek™ Bulk Fill Posterior Restorative and the predicate devices. The data set will be examined to see if it supports a finding of substantial equivalence.

Description: Those physical properties with an asterisk in the first column of the table below are called out in FDA's October 26, 2005 "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions." Additional properties which are also useful for comparison have been included at the discretion of the manufacturer.

Test Methods: Where an ISO standard is listed in the test method column (ISO 4049 or ISO 6874), the test method is described in the standard. Note that Flexural Modulus is not a requirement of ISO 4049, however, Flexural Modulus can be derived from the ISO 4049 method for Flexural Strength. Summaries of 3M ESPE internal test methods (i.e., those other than ISO 4049 and ISO 6874 listed below) are located in Section 18.2.

Specifications: The specifications in the table below include the Performance Specifications in Section 11.8 as well as targets established by 3M ESPE for other tests that are useful for comparison. Note that specifications below for ISO tests are the same as, or more stringent than, the specifications in the ISO standard.

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Results:

PHYSICAL PROPERTIES	Unit	Test Method	Specification	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Compressive strength*	MPa	(b)(4)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Diametral Tensile Strength	MPa	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Flexural strength*	MPa	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Flexural Modulus*	MPa	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Surface hardness (Barcol)*	N/A	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Radiopacity*	mm of Al	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

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PHYSICAL PROPERTIES	Unit	Test Method	Specification	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Water Sorption*	µg/mm³	(b)(4)	[redacted]				
Water Solubility*	µg/mm³						
Release profile*	N/A						
Working & Setting Times*	N/A						
Watts Shrinkage	%vol Shrinkage						
Wear	N/A						
Depth of Cure*	mm						
Depth of Cure*	mm						

3M ESPE

3M CONFIDENTIAL

PHYSICAL PROPERTIES	Unit	Test Method	Specification	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Cusp Deflection 4X4 mm	µm	(b)(4) [redacted]					
Polish Retention	Gloss units						

* FDA's "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions," issued October 26, 2005, asks that these properties be addressed in the 510(k).

** "leading bulk fill composites" in the table above means light-cure bulk fill composites that are placed and cured in increments that are ≥ 4mm in depth. SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill are examples of bulk fill composites.

*** Predicate device Filtek™ Supreme Ultra Universal Restorative was placed in (b)(4) [redacted]

(b)(4) [redacted]

Additional discussion of Depth of Cure and Cusp Deflection testing is provided below.

Depth of Cure

Due to use as both a sealant and a restorative, the depth of cure of Filtek™ Bulk Fill Posterior Restorative was evaluated using two ISO standards (see 2.4 Bench Test Data Comparison with S/E Devices table, Depth of Cure):

Sealant:

ISO6874:2005 Dentistry – Polymer-based pit and fissure sealants requires that the depth of cure shall not be less than 1.5mm. The results are treated such that the length of the cured material in this test is equal to the depth of cure. Filtek™ Bulk Fill Posterior Restorative easily passes this requirement.

Restorative – 4mm Depth of Cure (single-surface light-cure):

ISO 4049 Dentistry – Polymer-based restorative materials Depth of Cure method is used by 3M ESPE to evaluate curing of resin-based restoratives that are light-cured from one surface.

ISO 4049-2009 allows the depth of cure result to be no more than 0.5mm below the value stated by manufacturer (i.e., the length of cured material in this test is divided by 2 and the resulting value can be no more than 0.5mm below the depth stated by the manufacturer). The value stated by 3M ESPE Dental Products for Filtek™ Bulk Fill Posterior Restorative is 4mm for all cavity classes, except Class II. Therefore, where a 4mm depth is stated, the limit in this test is $\geq$ 3.5mm (i.e., 4.0 – 0.5 = 3.5). ISO 4049 also has a second requirement that depth of cure for a shade that is not opaque must be no less than 1.5 mm. For Filtek™ Bulk Fill Posterior Restorative, both requirements are satisfied. See additional discussion related to the ISO 4049 Depth of Cure method below.

Restorative – 5mm Depth of Cure (multi-surface light-cure):

(b)(4) [redacted]

Discussion:

(b)(4) [redacted]

(b)(4)

(b)(4)

(b)(4)

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Cusp Deflection

(b)(4)

Bench Test Data Conclusion:
Filtek Bulk Fill Posterior Restorative performed (b)(4) [redacted] (b)(4) [redacted] This difference does not negatively impact the safety or efficacy of the device. Overall, the Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Volumetric Shrinkage, Wear, Depth of Cure, Cusp Deflection and Polish Retention results generated from the bench tests support a finding of substantial equivalence.

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[8] Halvorson R, Erickson R, Davidson C. Energy dependant polymerization of resin-based composite. 2002 *Dent Mater*; 18:463-469.

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12.2.5 Technology Comparison with S/E Devices

Technological property	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
(b)(4) [redacted] photoinitiator system	X	X	NA[1]	X[2]
Methacrylate-based resin matrix	X	X	X	X
Compatible with methacrylate-based dental adhesives	X	X	NA[1]	X
Inorganic fillers	X	X	X	X
Oxide fillers are silane treated so that they bond to the resin matrix when the restorative is cured	X	X	X[3]	NA[1]
Bulk fill (up to 4 mm depth of cure)	X	-	X	X
Bulk fill (5 mm depth of cure, Class II)	X[4]	-	X[4]	
When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.	X	X	X	X
Dispensing system: single-use capsule (intraoral)[5] reusable syringe (extraoral)[6]	 X X	 X X	 X -	 X X
Recommended for load-bearing occlusal surfaces	X	X	X	X
FDA-Recognized Standards followed	Risk Management: ISO 14971 Biocomp stds[7]: ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds[8]: ISO 4049 ISO 6874	Risk Management: ISO 14971 Biocomp stds[7]: ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds[8]: ISO 4049	NA[1]	NA[1]

1. Not available, details not disclosed by manufacturer.
2. Product also contains a second photoinitiator.
3. Based on disclosure that product contains 3-trimethoxysilylpropyl methacrylate.
4. Similarity: In order to obtain 5 mm depth of cure for Class II restorations, product is light-cured from the occlusal surface and, after the matrix band is removed, light-cured from the buccal and lingual surfaces. See Depth of Cure discussion in section 12.2.4 Bench Test Data Comparison with S/E Devices.

   Difference: The predicate device techniques states up to a 5mm depth of cure for Class I restorations, as well, also using the multi-site light-curing process described above. For Filtek™ Bulk Fill Posterior Restorative, 4mm Depth of Cure is stated for Class I restorations, light-curing from the occlusal aspect only, as supported by ISO 4049 Depth of Cure test results. This difference does not affect the safety or efficacy of the device.
5. Restorative material is dispensed from a single-use capsule in the mouth.

   Difference: The predicate device SonicFill, Sonic-Activated Bulk Fill Composite (K091023) is dispensed from the capsule using the air-driven SonicFill Handpiece, which, per the Instructions for Use "offers sonically activated delivery."

   Similarity: Filtek™ Bulk Fill Posterior Restorative and predicates Filtek™ Supreme Ultra Universal Restorative (K083610) and Tetric EvoCeram Bulk Fill (K111958) all use a traditional manual restorative dispenser (not air-driven) for dispensing capsules. In light of this similarity, the difference mentioned above does not affect the safety or efficacy of the device.
6. Restorative material is dispensed from a reusable syringe outside the mouth (e.g., onto a pad).
7. Newer versions of several biocompatibility standards were applied to Filtek™ Bulk Fill Posterior Restorative, due to time elapsed since the predicate device was evaluated. This difference is not significant because for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610):
   a. A Diplomate of the American Board of Toxicology assessed the safety of the product.
   b. Standard risk assessment techniques and consideration of internationally recognized guidelines were used in the evaluation.
   c. The conclusion of the assessment is that the device is safe for its intended use.
8. ISO 4049 data in this submission for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal

Restorative (K083610), was generated using the current version of the standard, ISO 4049:2009.

Difference: ISO 6874:2005 was not used to evaluate the predicate device, Filtek™ Supreme Ultra Universal Restorative for the 510(k) submission, K083610, because it does not have a sealant indication. The only test in ISO 6874 that is applicable for a light-cure material, like Filtek™ Bulk Fill Posterior Restorative, is Depth of Cure. The Depth of Cure test method in ISO 4049:2009 is the same as in ISO 6874, except the measured value is divided by 2 in ISO 4049 and not divided by 2 in ISO 6874. As a result, a material that passes the ISO 4049 Depth of Cure requirement easily passes the ISO 6874 Depth of Cure requirement. This submission includes data showing both Filtek™ Bulk Fill Posterior Restorative and predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610) readily pass the ISO 6874 Depth of Cure requirement. Therefore, this difference is not significant and does not affect the safety or efficacy of the device. See ISO 4049 and ISO 6874 Depth of Cure specifications and test results in section 12.2.4 Bench Test Data Comparison with S/E Devices. Therefore, this difference is not significant and does not affect the safety or efficacy of the device.

12.2.6 Instructions for Use (IFU) Comparison with S/E Devices

The minor differences described in the table below do not affect the safety or efficacy of the device.

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Cautions/Precautions in the respective IFU			
Caution: U.S. Federal Law restricts the device to sale or use on the order of a dental professional.	**Caution:** U.S. Federal Law restricts this device to sale or use on the order of a dental professional.	(No corresponding Caution in IFU)	"Rx ONLY" "Keep material out of children's reach. For use in dentistry only."
"Precautionary Information for Patients This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product. **Precautionary Information for Dental Personnel** This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these	**"Precautionary Information for Patients** This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product. **Precautionary Information for Dental Personnel** This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these	**"CAUTION:** Uncured methacrylate resin may cause contact dermatitis and damage the pulp. Avoid contact with skin, eyes and soft tissue. Wash thoroughly with water after contact."	**"Side effects** In individual cases, components of Tetric EvoCeram Bulk Fill may lead to sensitization. Tetric EvoCeram Bulk Fill should not be used in such cases. To avoid possible irritation of the pulp, areas close to the pulp should be protected with a suitable pulp/dentin protector (selectively apply a calcium hydroxide-based preparation in areas close to the pulp and cover with suitable cavity liner)."

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed. 3M ESPE MSDS information can be obtained from www.3MESPE.com or contact your local subsidiary." "Pulp protection: If a pulp exposure has occurred and the situation warrants a direct pulp capping procedure, use a minimum amount of calcium hydroxide on the exposure followed by an application of 3M™ ESPE™ Vitrebond™ or Vitrebond™ Plus Light Cure Glass Ionomer. Vitrebond or Vitrebond Plus liner/bases may also be used to line areas of deep cavity excavation."	materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed. 3M ESPE MSDSs can be obtained from www.3MESPE.com or contact your local subsidiary." "Pulp Protection: If a pulp exposure has occurred and if the situation warrants a direct pulp capping procedure, use a minimum amount of calcium hydroxide on the exposure followed by an application of Vitrebond™ or Vitrebond™ Plus Light Cure Glass Ionomer Liner/Base, manufactured by 3M ESPE. Vitrebond liner/bases may also be used to line areas of deep cavity excavation. See the Vitrebond liner/base instructions for details."		
Cautions/Precautions – similarities/differences between Filtek Bulk Fill Posterior and Predicate Device IFU			

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
	No significant difference between this predicate and Filtek Bulk Fill Posterior Restorative.	IFU does not include prescription use statement or "Rx only" symbol. Information related to acrylates and plup protection is provided, but more abbreviated than 3M ESPE's IFUs for Filtek Bulk Fill Posterior Restorative and Filtek Supreme Ultra Universal Restorative.	IFU includes "Rx only" symbol. Information related to acrylates and pulp protection included in IFU under "Side effects."
Isolation & Adhesive System recommendations in the respective IFU			
"**3. Isolation:** A rubber dam is the preferred method of isolation. Cotton rolls and an evacuator can also be used." Under "**General Information**:" "Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as manufactured by 3M ESPE, which permanently bonds the restoration to the tooth structure." Under "**5. Placement of Matrix**:" "**Note:** The matrix may be placed following the enamel etching and adhesive application steps if	"**3. Isolation:** A rubber dam is the preferred method of isolation. Cotton rolls plus an evacuator can also be used." Under "**General Information**:" "A dental adhesive, such as manufactured by 3M ESPE, is used to permanently bond the restoration to the tooth structure." Under "**3.2 Posterior restorations**:" "**Note:** The matrix may be placed following the enamel etching and adhesive application steps if preferred." "**4. Adhesive System:** Follow the	"**PRIOR TO PLACEMENT -- RECOMMENDATIONS ON PROPER BONDING** • Isolation throughout adhesive steps and composite placement is important. Rubber dam is ideal. • Please closely follow bonding agent directions for use. • Please take care to ensure that your air line is free of oil and other contaminants."	"**2. Isolation** Appropriate isolation, best with a rubber dam (e.g. OptraDam® Plus), is required." "**Cavity preparation** Cavity preparation is carried out according to the requirements of the adhesive technique, i.e. protecting the tooth structure." "**Conditioning / Application of the bonding agent** Condition and apply the bonding agent according to the Instructions for Use of the product in use. We recommend using Syntac® (with phosphoric

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
preferred." "**7. Adhesive System**: To bond Filtek™ Bulk Fill Posterior Restorative to tooth structure, use of a 3M™ ESPE™ dental adhesive system (for example 3M™ ESPE™ Scotchbond™ Universal) is recommended. Refer to adhesive system product instructions for full instructions and precautions for the products. After curing the adhesive, continue to maintain isolation from blood, saliva and other fluids and proceed immediately to placement of Filtek™ Bulk Fill Posterior Restorative. **Note**: Follow the adhesive system instructions for use for recommended silane treatment during repair of ceramic restorations, followed by the adhesive application."	manufacturer's instructions regarding etching, priming, adhesive application, and curing, for example 3M ESPE adhesives."		acid etching) or ExciTE® F (with phosphoric acid etching) or the self-etching adhesive AdheSE®."
Isolation & Adhesive System recommendations – similarities/differences between Filtek Bulk Fill Posterior and Predicate Device IFU			
	IFU addresses isolation and adhesive system in a similar manner. The Filtek Bulk Fill Posterior Restorative IFU provides additional details about compatibility with dental adhesives and placement of restorative after curing the adhesive.	IFU addresses isolation and adhesive system in a more abbreviated manner.	IFU addresses isolation and adhesive system.

12.2.7 Statement of Substantial Equivalence

Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the predicate devices, Filtek™ Supreme Ultra Universal Restorative, SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill in terms of intended use, indications for use, physical properties, and technological characteristics. Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the predicate device, Filtek™ Supreme Ultra Universal Restorative in terms of formulation.

13. Proposed Labeling

13.1 FDA Guidance – Properties for Device Labeling

FDA Guidance Document "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions," issued October 26, 2005, recommends that the properties below (bullet points) should be included in the device labeling.

The Filtek™ Bulk Fill Posterior Restorative Instructions for Use address:
- light intensity (mW/cm^2) for curing
- wavelength (nm) for curing
- depth of cure (mm)
- curing time (sec) (for photoinitiated resins)

The Filtek™ Bulk Fill Posterior Restorative Technical Product Profile addresses:
- compressive strength (MPa)
- flexural strength (MPa)
- other properties relevant to the device

The following are not applicable for a light-cure composite, like Filtek™ Bulk Fill Posterior Restorative (these properties are relevant for self-cure composites):
- working time (sec)
- setting time (min)

3M ESPE Dental Products has developed a Technical Product Profile for Filtek™ Bulk Fill Posterior Restorative that addresses compressive strength, flexural strength and other relevant properties. 3M ESPE Dental Products provides Technical Product Profiles for marketed products to practitioners free of charge upon request. Such requests can be made using the 3M ESPE Customer Care phone number provided in the Instructions for Use. Technical Product Profiles for marketed products are also available at the 3M ESPE Dental Products web site.

This same approach was used with predicate device Filtek™ Supreme Ultra Universal Restorative, K083610, also from 3M ESPE Dental Product.

13.2 Instructions for Use

3M™ ESPE™
Filtek™ Bulk Fill Posterior Restorative

General Information

3M™ ESPE™ Filtek™ Bulk Fill Posterior Restorative material, is a visible-light activated, restorative composite optimized to create posterior restorations simpler and faster. This bulk fill material provides excellent strength and low wear for durability. The shades are semi-translucent and low stress curing, enabling up to a 5 mm depth-of-cure (refer to curing recommendations in table below). With excellent polish retention, Filtek™ Bulk Fill Posterior Restorative is also useful for anterior restorations that call for a semi-translucent shade. All shades are radiopaque. Filtek™ Bulk Fill Posterior Restorative is offered in A1, A2, A3, B1, and C2 shades. The fillers are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of agglomerated 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.4% by volume). Filtek™ Bulk Fill Posterior Restorative contains ERGP-DMA, diurethane-DMA, and 1, 12-dodecane-DMA. Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as manufactured by 3M ESPE, which permanently bonds the restoration to the tooth structure. Filtek™ Bulk Fill Posterior Restorative is packaged in traditional syringes and single-dose capsules.

Indications:
Filtek™ Bulk Fill Posterior Restorative is indicated for use in:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

Precautionary Information for Patients
This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

Precautionary Information for Dental Personnel

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

3M ESPE MSDS information can be obtained from www.3MESPE.com or contact your local subsidiary.

Instructions for Use

Preparation

1. Prophy: Teeth should be cleaned with pumice and water to remove surface stains.

2. Shade Selection: Prior to isolation of tooth, select the appropriate shade(s) of Filtek™ Bulk Fill Posterior Restorative using a standard VITAPAN® classical shade guide.

Note: As Filtek™ Bulk Fill Posterior Restorative is semi-translucent, the location of the restoration, underlying tooth color or adjacent restorations may influence the final appearance of the restoration.

3. Isolation: A rubber dam is the preferred method of isolation. Cotton rolls and an evacuator can also be used.

Directions

Direct Restorations

4. Cavity Preparation:

4.1 Anterior restorations: Use conventional cavity preparations for all Class III, IV and V restorations.

4.2 Posterior restorations: Prepare the cavity. Line and point angles should be rounded. No residual amalgam or other base material should be left in the internal form of the preparation that would interfere with light transmission and therefore, the hardening of the restorative material.

5. Placement of Matrix:

5.1 Anterior restorations: Mylar strips and crown forms may be used to minimize the amount of material used.

5.2 Posterior restorations: Place a thin dead-soft metal, or a pre-contoured-mylar or a pre-contoured-metal matrix band and insert wedges firmly. Burnish the matrix band to establish proximal contour and contact area. Adapt the band to seal the gingival area to avoid overhangs.

Note: The matrix may be placed following the enamel etching and adhesive application steps if preferred.

6. Pulp protection: If a pulp exposure has occurred and the situation warrants a direct pulp capping procedure, use a minimum amount of calcium hydroxide on the exposure

followed by an application of 3M™ ESPE™ Vitrebond™ or Vitrebond™ Plus Light Cure Glass Ionomer. Vitrebond or Vitrebond Plus liner/bases may also be used to line areas of deep cavity excavation.

7. Adhesive System: To bond Filtek™ Bulk Fill Posterior Restorative to tooth structure, use of a 3M™ ESPE™ dental adhesive system (for example 3M™ ESPE™ Scotchbond™ Universal) is recommended. Refer to adhesive system product instructions for full instructions and precautions for the products. After curing the adhesive, continue to maintain isolation from blood, saliva and other fluids and proceed immediately to placement of Filtek™ Bulk Fill Posterior Restorative.

Note: Follow the adhesive system instructions for use for recommended silane treatment during repair of ceramic restorations, followed by the adhesive application.

8. Delivery:
Follow the directions corresponding to the dispensing system chosen.
Dispensing the Composite:

8.1 Syringe: Dispense the necessary amount of restorative material from the syringe onto the mix pad by turning the handle slowly in a clockwise manner. To prevent oozing of the restorative when dispensing is completed, turn the handle counterclockwise a half turn to stop paste flow. Immediately replace syringe cap. If not used immediately, the dispensed material should be protected from light.

8.2 Single-Dose Capsule: Insert capsule into 3M™ ESPE™ Restorative Dispenser. Refer to separate restorative dispenser instructions for full instructions and precautions. Extrude restorative directly into cavity.

9. Placement:

9.1. Avoid intense light in the working field. Exposure of paste to intense light may cause premature polymerization.

9.2. Capsule: Start dispensing in the deepest portion of the preparation, holding the tip close to the preparation surface. Withdraw the capsule tip slowly as the cavity is filled, and avoid lifting the tip out of dispensed material while dispensing, to reduce voids. When dispensing has been completed, drag the capsule tip against the cavity wall while withdrawing from the operative field. For proximal areas, hold the tip against the matrix to aid material flow into the proximal box.

9.3 Slightly overfill the cavity to permit extension of composite beyond cavity margins. Contour and shape with appropriate composite instruments.

10. Curing: This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of 550 mW/cm^2 in the 400-500 nm range. Cure each increment by exposing its entire surface to a high intensity visible light source, such as a 3M ESPE curing light. Hold the light guide tip as close to the restorative as possible during light exposure. Use light cure chart to determine appropriate cure times and conditions for all shades.

Caries Classification	Increment Depth	All halogen lights (with output of 550-1000 mW/cm^2)	3M™ ESPE™ LED lights (with output 1000-2000 mW/cm^2)
Classes I, III, IV and V	4 mm	40 sec	20 sec
Class II	5 mm	20 sec occlusal, 20 sec buccal, 20 sec lingual	10 sec occlusal, 10 sec buccal, 10 sec lingual

Note: For class II restorations, remove the matrix band prior to the buccal and lingual curing steps.

11. Contouring: Contour restoration surfaces with fine finishing diamonds, burs or stones. Contour proximal surfaces with Sof-Lex™ Finishing Strips, manufactured for 3M ESPE.

12. Adjust Occlusion: Check occlusion with a thin articulating paper. Examine centric and lateral excursion contacts. Carefully adjust occlusion by removing material with a fine polishing diamond or stone.

13. Finish and Polishing: Polish with the Sof-Lex™ Finishing and Polishing System.

Indirect Procedure for Inlays, Onlays or Veneers

1. Dental Operatory Procedure

1.1 Shade selection: Choose the appropriate shade(s) of Filtek™ Bulk Fill Posterior Restorative prior to isolation.

1.2 Preparation: Prepare the tooth.

1.3 Impressioning: After preparation is complete, make an impression of the prepared tooth by following the manufacturer's instructions of the impressioning material chosen. An impressioning material, such as manufactured by 3M ESPE, may be used.

2. Laboratory Procedure

2.1 Pour the impression of the preparation with die stone. Place pins at the preparation site at this time if a "triple tray" type of impression was used.

2.2 Separate the cast from the impression after 45 to 60 minutes. Place pins in die and base the cast as for a typical crown and bridge procedure. Mount or articulate the cast to its counter model on an adequate articulator.

2.3 If a second impression was not sent, pour a second cast using the same impression registration. This is to be used as a working cast.

2.4 Section out the preparation with a laboratory saw and trim away excess or, expose the margins so they can be easily worked. Mark the margins with a red pencil if needed. Add a spacer at this time if one is required.

2.5 Soak the die in water, then with a brush, apply a very thin coat of separating medium to the preparation, let it dry somewhat, then add another thin layer.

2.6 Add the first increment of composite to the floor of the preparation, stay short of the margins, and follow the cure recommendations described in the Direct Restoration section (Step 10).

2.7 Place and cure additional increments of composite. Allow for the last increment (incisal) to include the contact areas.

2.8 Place the die back into the articulated arch. Add the last increment of composite to the occlusal surface. Overfill very slightly mesially, distally, and occlusally. This will allow for the mesiodistal contacts and the proper occlusal contact when the opposing arch is brought into occlusion with the uncured increment. Light cure for only ten seconds, then remove the die to prevent adhering to adjacent surfaces. Finish the curing process following the cure times in the Direct Restoration section (Step 10).

2.9 With the occlusal contacts already established, begin removing the excess composite from around the points of contact. Develop the inclines and ridges as per remaining occlusal anatomy.

2.10 Care must be taken when removing the prosthesis from the die. Break off small amounts of the die from around the restoration, the die stone should break away cleanly from the cured restoration, until all of the restoration is recovered.

2.11 Using the master die, check the restoration for flash, undercuts, and fit. Adjust as necessary, and then polish as noted above in Direct Restorative steps 11-13.

3. Dental Operatory Procedure

3.1 Roughen the interior surfaces of the indirect restoration.

3.2 Clean the prosthesis in a soap solution in an ultrasonic bath and rinse thoroughly.

3.3 Cementation: Cement the prosthesis using a 3M™ ESPE™ resin cement system.

Storage and Use

1. This product is designed to be used at room temperature. If stored in cooler allow product to reach room temperature prior to use. Shelf life at room temperature is 36 months. Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life. See outer package for expiration date.
2. Do not expose restorative materials to elevated temperatures, or to intense light.
3. Do not store materials in proximity to eugenol containing products.

Disinfect this product using an intermediate level disinfection process (liquid contact) as recommended by the Centers for Disease Control and endorsed by the American Dental Association. Guidelines for Infection Control in Dental Health-Care Settings – 2003 (Vol. 52; No. RR-17), Centers for Disease Control and Prevention.

Disposal

See the Material Safety Data Sheet (available at www.3MESPE.com or through your local subsidiary for disposal information).

Customer information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Caution: U.S. Federal Law restricts the device to sale or use on the order of a dental professional.

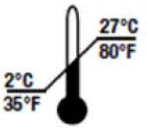
Warranty

3M ESPE warrants this product will be free from defects in material and manufacture.

3M 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 products for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE 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.

			
Use By	Caution, see instructions for use	Storage	Do Not Reuse

End of Instructions for Use... ... ...

13.3 Technical Product Profile

3M ESPE

Filtek™ Bulk Fill Posterior Restorative

I. Background

3M™ ESPE™ Filtek™ Bulk Fill Posterior Restorative material, is a visible-light activated, restorative composite optimized to create posterior restorations simpler and faster. This bulk fill material provides excellent strength and low wear for durability. The shades are semi-translucent and low stress curing, enabling up to a 5 mm depth-of-cure. With excellent polish retention, Filtek™ Bulk Fill Posterior Restorative is also useful for anterior restorations that call for a semi-translucent shade. This material serves to fill an absence in the 3M™ ESPE™ lineup of restorative materials by incorporating a bulk fill product that is capable of being filled up to occlusion, and was developed according to customer demand. Customer response encouraged the following material properties:

1) Optimized depth-of-cure

2) Designed for bulk filling up to the occlusal surface

3) Optimized handling for enhanced adaptation to the cavity prep

4) Enhanced wear properties for use on occlusal surface

Filtek Bulk Fill Posterior Restorative will be available in 5 shades (based on the Classic Vitapan shade system): A1, A2, A3, B1 and C2.

II. Filtek™ Bulk Fill Posterior Restorative

A. Technology:

General Information

3M™ ESPE™ Filtek Bulk Fill Posterior Restorative material, is a visible-light activated, restorative composite optimized to create posterior restorations simpler and faster. This bulk fill material provides excellent strength and low wear for durability. The shades are semi-translucent and low stress curing, enabling up to a 5 mm depth-of-cure (refer to curing recommendations in table below). With excellent polish retention, Filtek™ Bulk Fill Posterior Restorative is also useful for anterior restorations that call for a semi-translucent shade. All shades are radiopaque. Filtek™ Bulk Fill Posterior Restorative is offered in A1, A2, A3, B1, and C2 shades. The fillers are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of agglomerated 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.4% by volume). Filtek Bulk Fill Posterior restorative contains ERGP-DMA, diurethane-DMA and 1, 12-dodecane-DMA. Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as manufactured by 3M™ ESPE™, which permanently bonds the restoration to the tooth structure. Filtek™ Bulk Fill Posterior Restorative is packaged in traditional syringes and single-dose capsules.

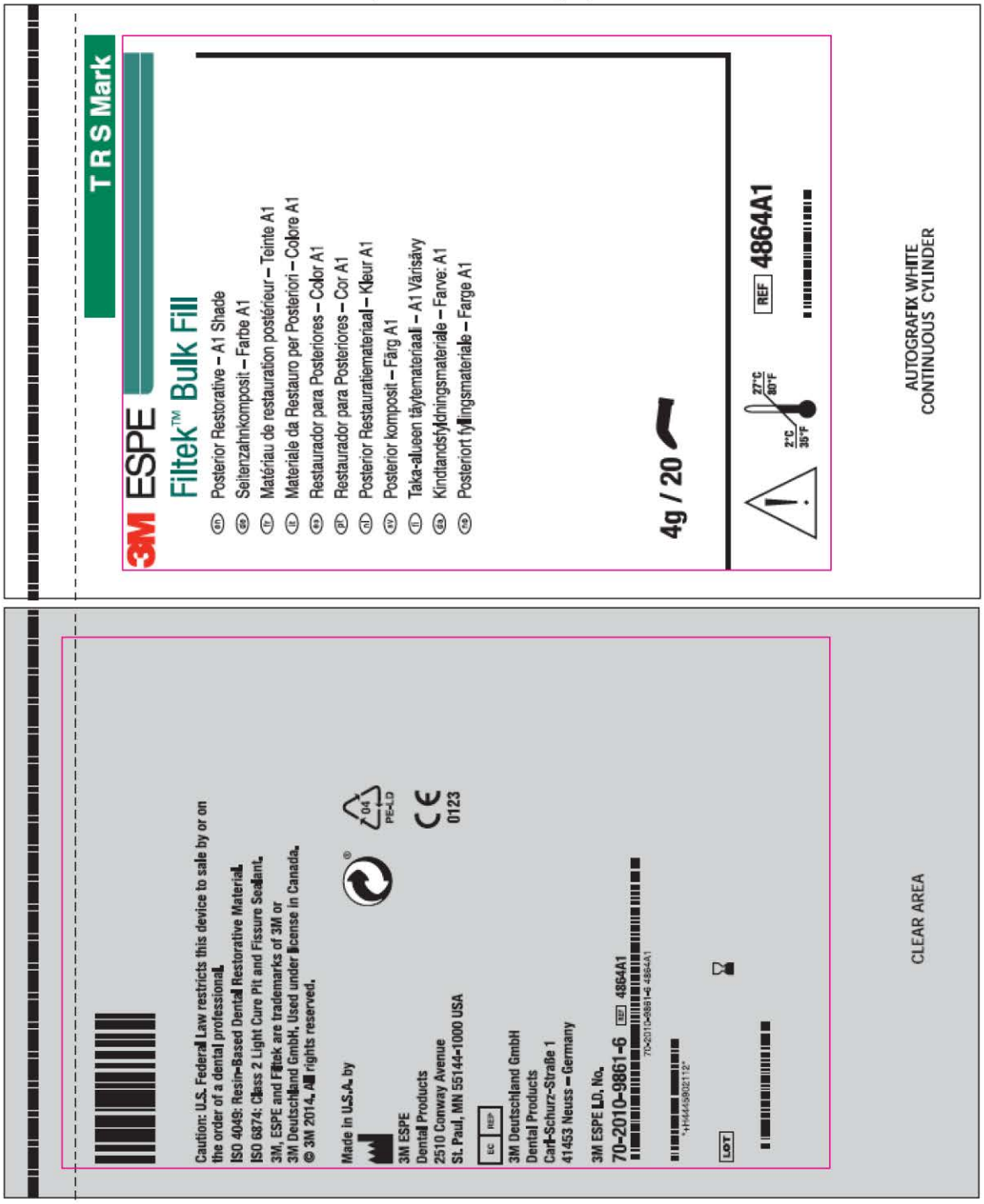
B. Physical Properties:

	Units	Filtek Bulk Fill Posterior A2 Shade (b)(4)
Compressive Strength	Mpa	[redacted]
Diametral Tensile Strength	MPa	
Flexural Strength	MPa	
Flexural Modulus	GPa	
Polish retention (after 6000 toothbrush cycles)	Gloss Units	
Wear	Relative to Filtek™ Z250™	
Radiopacity	Ratio to 1 mm Al	
Polymerization shrinkage	%	

13.4 Labels

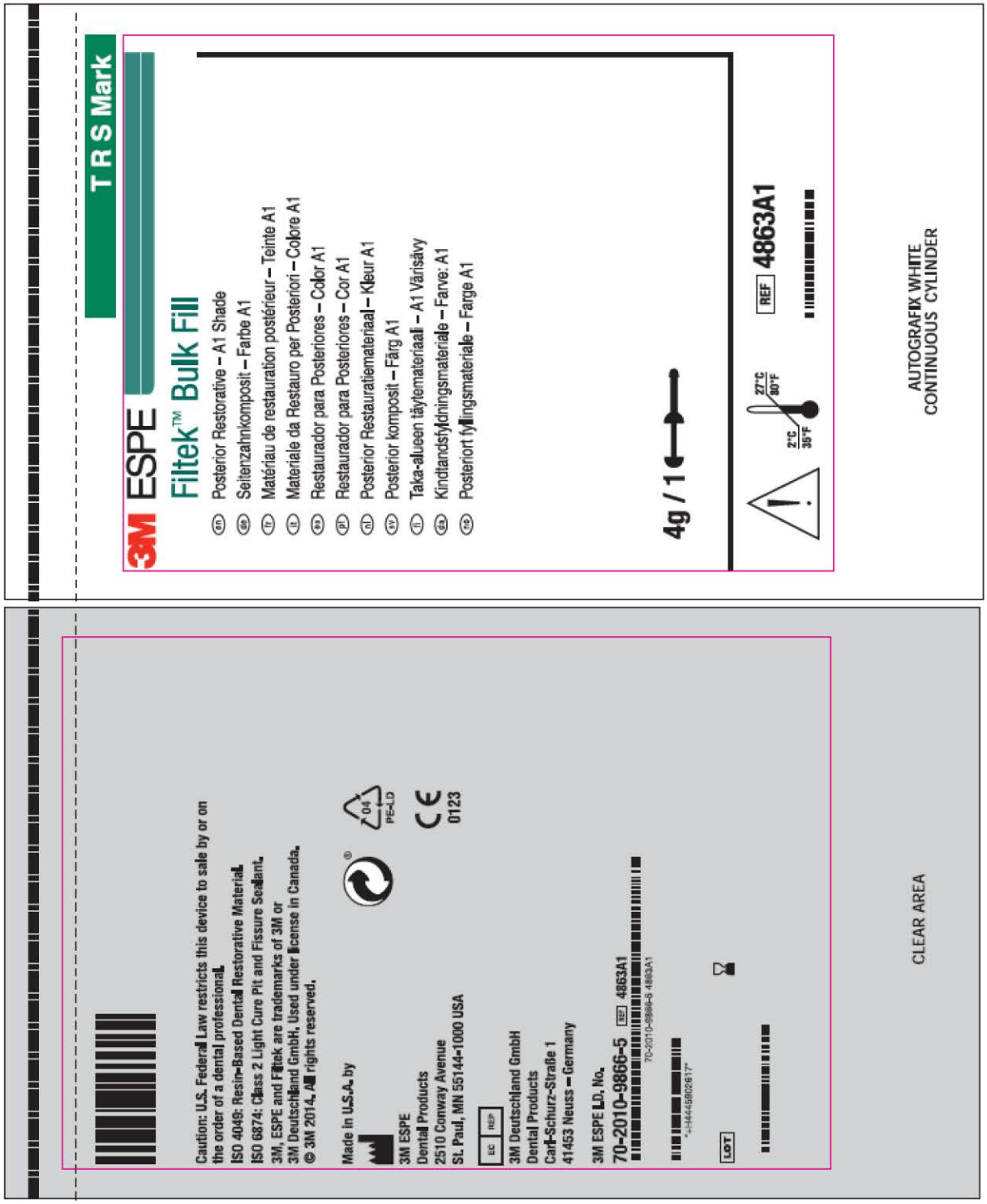
Note: Lot number and expiration date are added to the labels in this section when the product is packaged.

Filtek™ Bulk Fill Posterior Restorative Capsule Pouch Label (A1 Shade example):



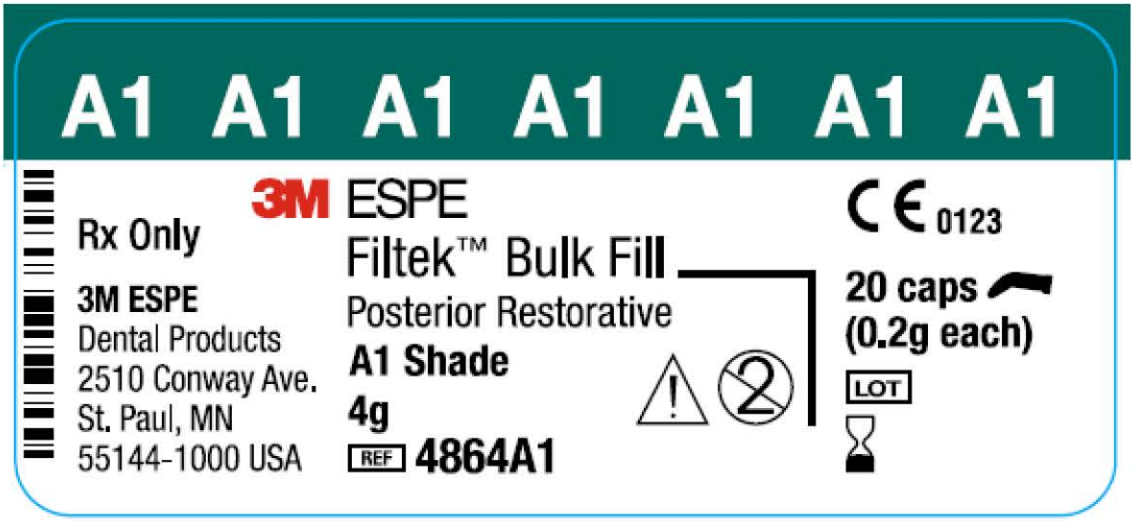
3M ESPE

Filtek™ Bulk Fill Posterior Restorative Syringe Pouch Label (A1 Shade example):

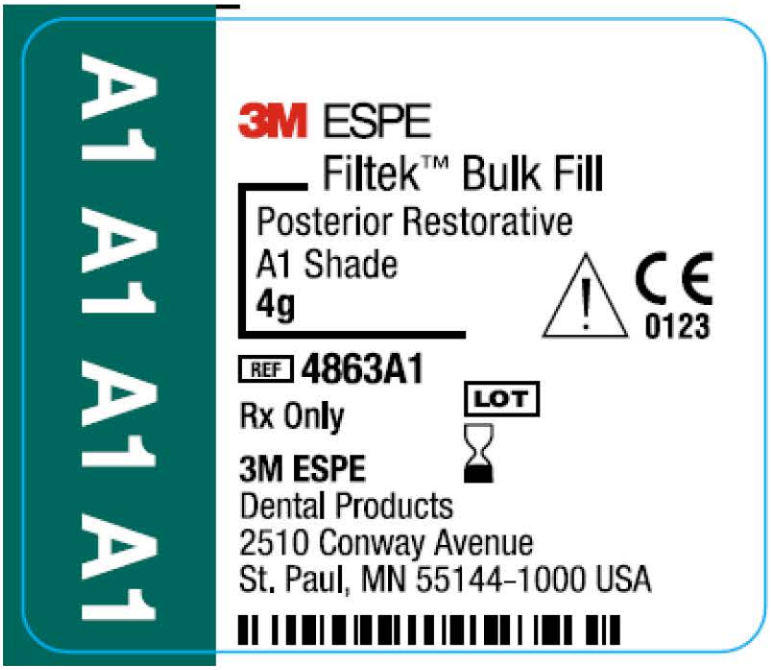


3M ESPE

Filtek™ Bulk Fill Posterior Restorative Capsule Bottle Label (A1 Shade example):



Filtek™ Bulk Fill Posterior Restorative Syringe Label (A1 Shade example):



13.5 Promotional materials

No advertisements are proposed at this time.

14. Sterilization and Shelf Life

14.1 Sterilization

Sterilization is not applicable. Filtek™ Bulk Fill Posterior Restorative is not labeled nor otherwise represented as sterile, nor is it intended to be sterilized by the user. Filtek™ Bulk Fill Posterior Restorative is not sterile when used.

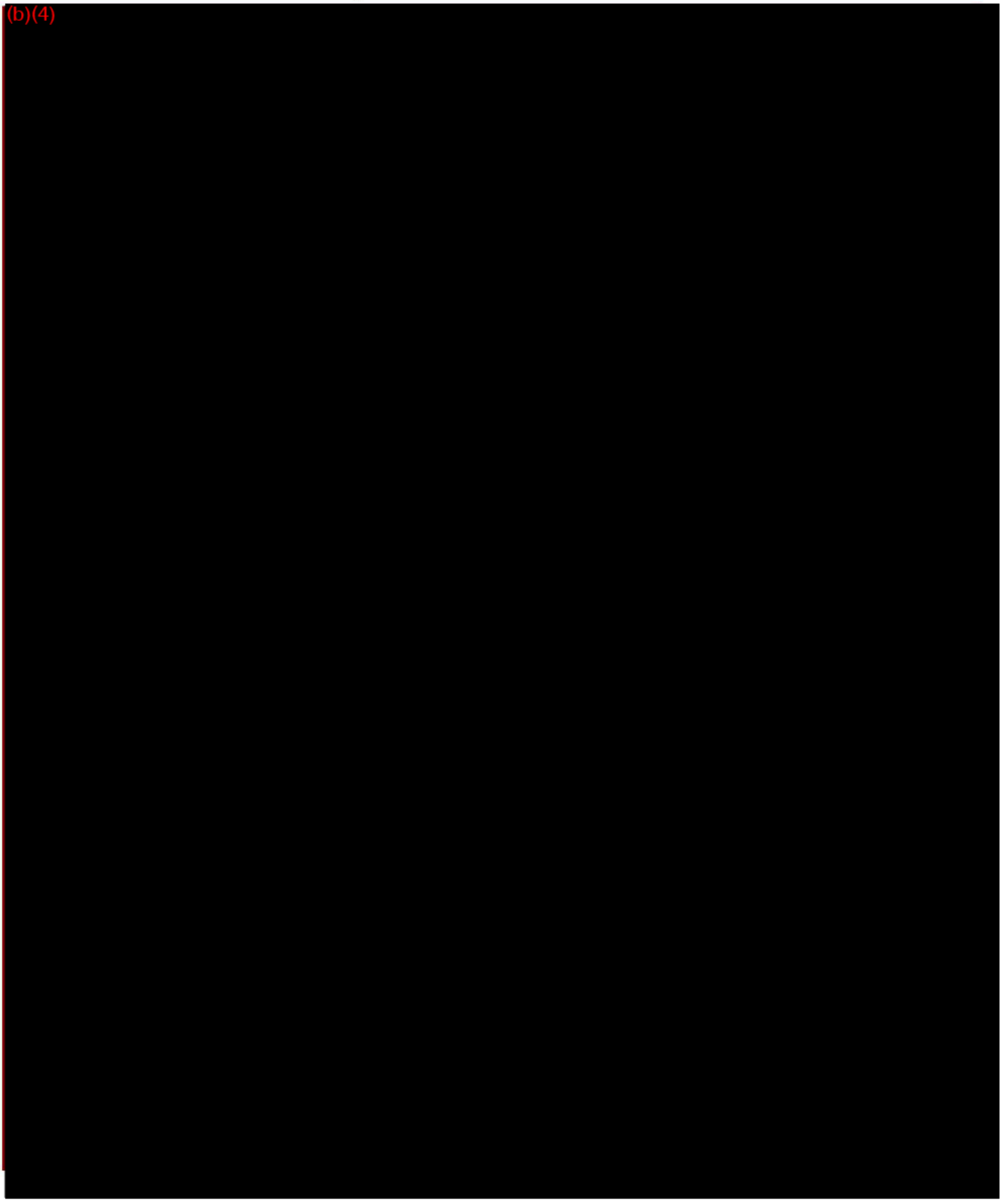
14.2 Shelf Life

Shelf life at room temperature is 36 months. Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life.

See following pages for Shelf Life Report.

14.2.1 Shelf Life Report

(b)(4)



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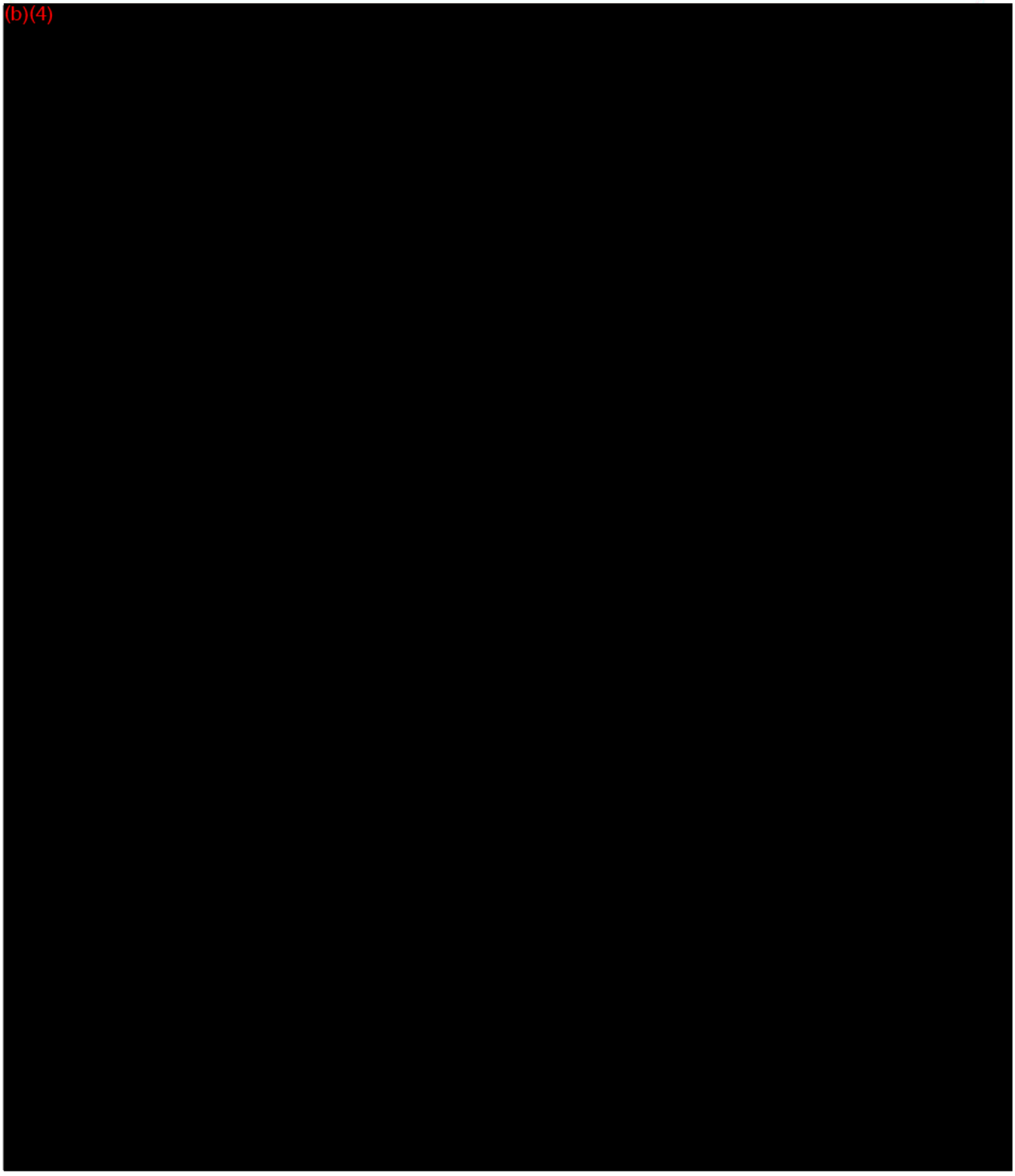

15. Biocompatibility

15.1 Biocompatibility Assessment

3M ESPE

29 January 2014

Biocompatibility Statement for 3M™ ESPE™ Filtek™Bulk Fill Posterior Restorative

A Diplomate of the American Board of Toxicology has assessed the safety of this product. Standard risk assessment techniques and consideration of internationally recognized guidelines were used in this evaluation.

3M ESPE Filtek Bulk Fill Posterior Restorative is safe for its intended use based on the following considerations:

1) Favorable test results for the product in GLP- and guideline compliant biocompatibility tests;
2) A review of the extraction data for the product; and
3) A review of the hazards of the product ingredients and primary packaging ingredients in relation to the amount used in the product

The biocompatibility assessment for this product was conducted in accordance with the following standards:

1) Testing guidelines outlined in the FDA General Program Memorandum G95.
2) ISO 10993-1:2009(E) Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process; in addition, relevant detailed guidance in ISO Standards 10993-3:2003 (Tests for genotoxicity, carcinogenicity and reproductive toxicity), 10993-5:2009 (Tests for in vitro cytotoxicity), 10993-10:2010 (Tests for irritation and skin sensitization); and 10993-11:2006 (Tests for systemic toxicity) was considered;
3) ISO 7405:2008 Dentistry-- Evaluation of Biocompatibility of Medical Devices in Dentistry;
4) Japan: PFSB/ELD/OMDE Notification No.0301-1; March 1, 2012 (as translated by 3M Health Care Japan, August 6, 2012)
5) 3M ESPE Standard Operating Procedure 04-200.

3M ESPE Filtek Bulk Fill Posterior Restorative was assessed as an external communicating device that is intended to be in contact with the body for greater than 30 days (ISO 10933 and ISO 7405, G95) and a coupling instrument between the inside and outside of the body (PFSB).

Test Results for 3M ESPE Filtek Bulk Fill Posterior Restorative

(b)(4)

3M ESPE

3M CONFIDENTIAL

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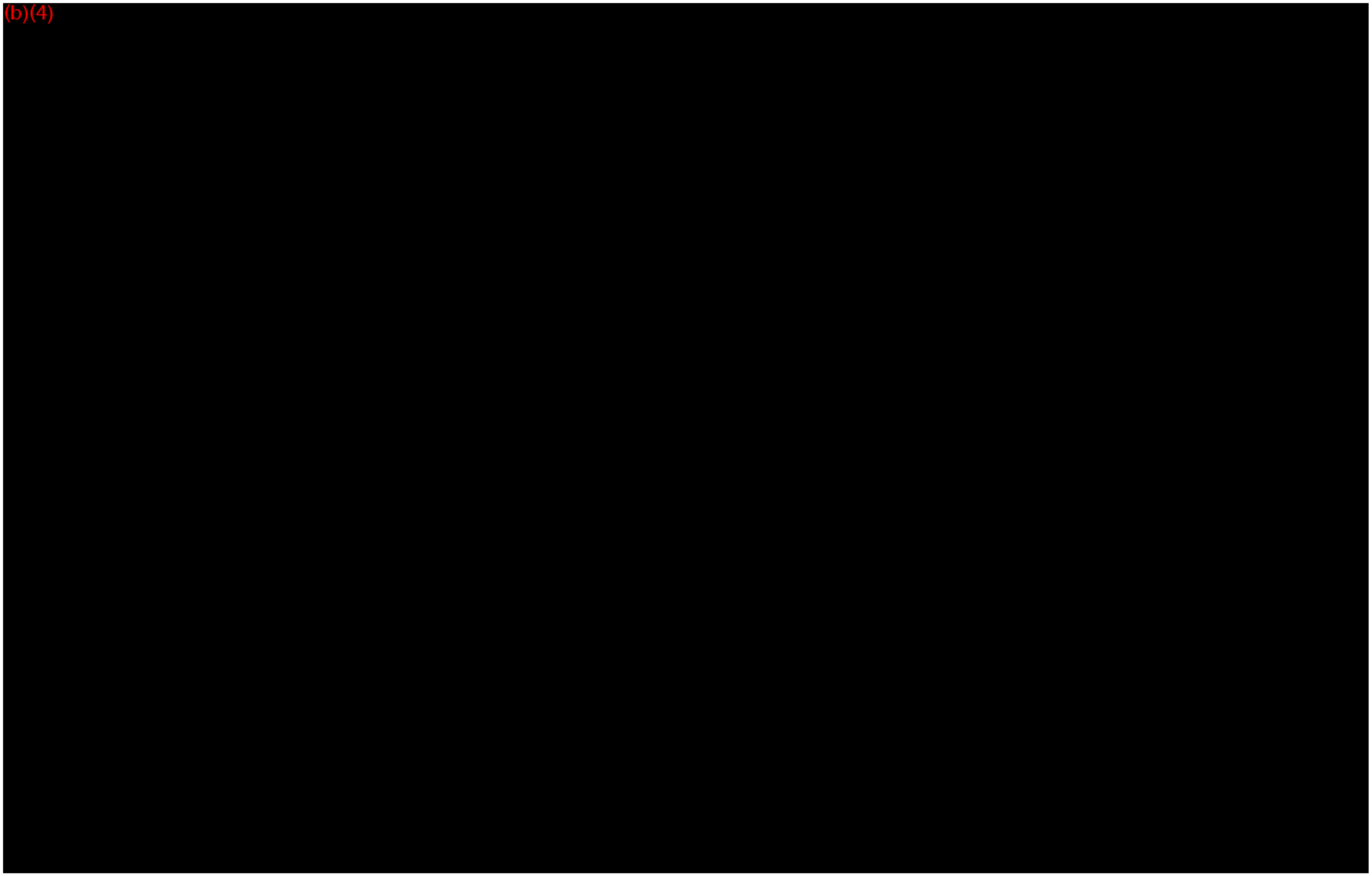
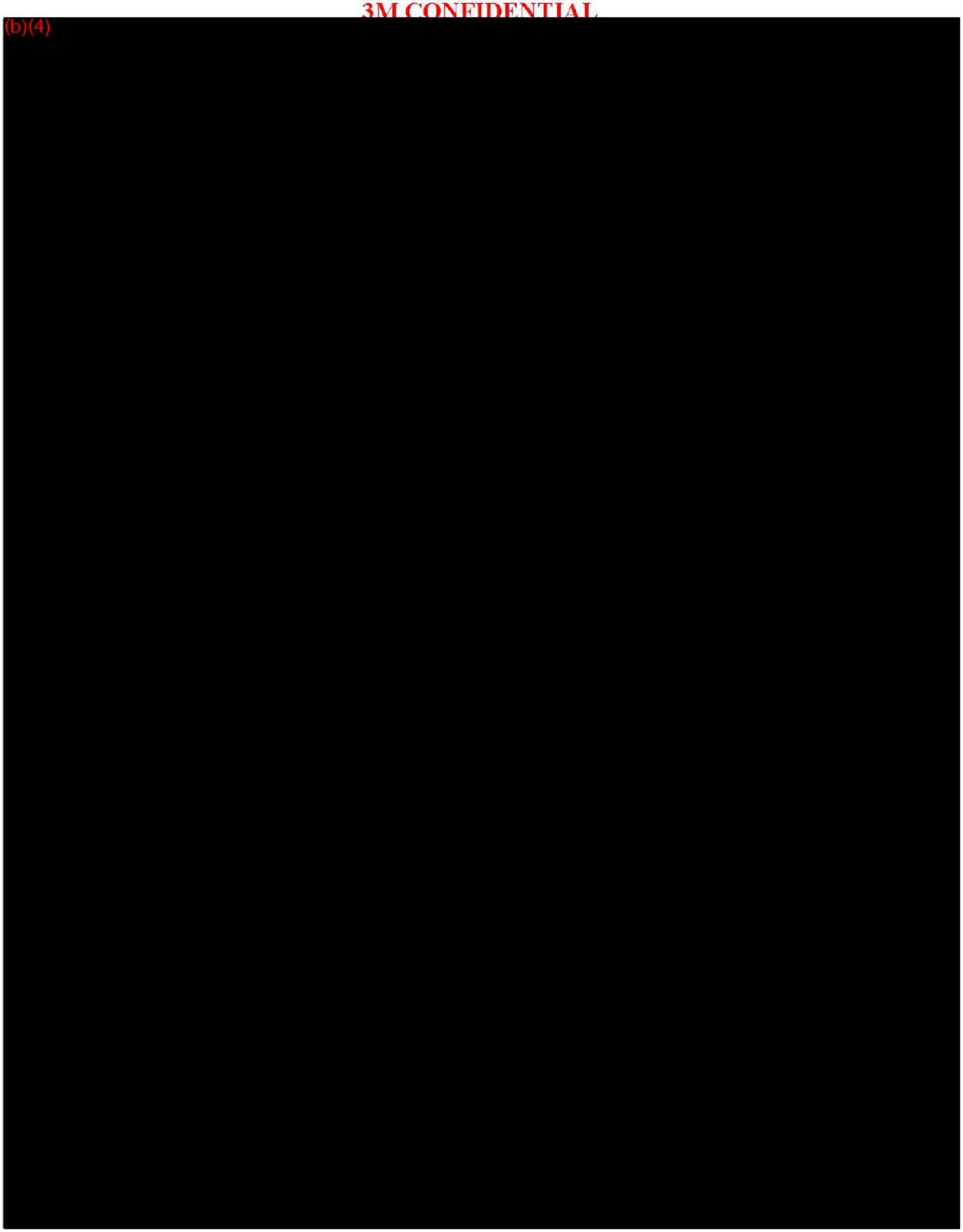
(b)(4)



(b)(4)

(b)(4)



(b)(4)

[redacted]

15.2 Material Safety Data Sheet

Safety Data Sheet

Document Group:	33-1594-2	**Version Number:**	1.00
Issue Date:	02/19/14	**Supercedes Date:**	Initial Issue

SECTION 1: Identification

1.1. Product identifier
3M™ ESPE™ FILTEK™ BULK FILL POSTERIOR RESTORATIVE

1.2. Recommended use and restrictions on use

Recommended use
Dental Product, Dental Restorative
Restrictions on use
For use only by dental professionals

1.3. Supplier's details

MANUFACTURER:	3M
DIVISION:	3M ESPE Dental Products
ADDRESS:	3M Center, St. Paul, MN 55144-1000, USA
Telephone:	1-888-3M HELPS (1-888-364-3577)

1.4. Emergency telephone number
1-800-364-3577 or (651) 737-6501 (24 hours)

SECTION 2: Hazard identification

2.1. Hazard classification
Skin Sensitizer: Category 1.

2.2. Label elements
Signal word
Warning

Symbols
Exclamation mark |

Pictograms

Hazard Statements
May cause an allergic skin reaction.

Precautionary Statements

Prevention:
Avoid breathing dust/fume/gas/mist/vapors/spray.
Contaminated work clothing must not be allowed out of the workplace.

Response:
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.

Disposal:
Dispose of contents/container in accordance with applicable local/regional/national/international regulations.

2.3. Hazards not otherwise classified
None.

31% of the mixture consists of ingredients of unknown acute oral toxicity.

SECTION 3: Composition/information on ingredients

Ingredient	C.A.S. No.	% by Wt
SILANE TREATED CERAMIC	444758-98-9	60 - 70 Trade Secret *
AROMATIC URETHANE DIMETHACRYLATE	1431303-59-1	10 - 20 Trade Secret *
YTTERBIUM FLUORIDE (YbF3)	13760-80-0	1 - 10 Trade Secret *
DIURETHANE DIMETHACRYLATE (UDMA)	72869-86-4	1 - 10 Trade Secret *

SILANE TREATED SILICA	248596-91-0	1 - 10 Trade Secret *
1,12-DODECANE DIMETHYCRYLATE (DDDMA)	72829-09-5	< 5 Trade Secret *
SILANE TREATED ZIRCONIA	Unknown	< 5 Trade Secret *
WATER	7732-18-5	< 5 Trade Secret *
AFM-1 MONOMER	1429648-13-4	< 1 Trade Secret *
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	10287-53-3	< 0.5 Trade Secret *
BENZOTRIAZOL	96478-09-0	< 0.5 Trade Secret *
Titanium Dioxide	13463-67-7	< 0.2 Trade Secret *

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation:
Remove person to fresh air. If you feel unwell, get medical attention.

Skin Contact:
Immediately wash with soap and water. Remove contaminated clothing and wash before reuse. If signs/symptoms develop, get medical attention.

Eye Contact:
Flush with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms persist, get medical attention.

If Swallowed:
Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed
See Section 11.1. Information on toxicological effects.

4.3. Indication of any immediate medical attention and special treatment required
Not applicable.

SECTION 5: Fire-fighting measures

5.1. Suitable extinguishing media
In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture
None inherent in this product.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide	During Combustion
Carbon dioxide	During Combustion

5.3. Special protective actions for fire-fighters
No unusual fire or explosion hazards are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Ventilate the area with fresh air. Refer to other sections of this SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

6.2. Environmental precautions
Avoid release to the environment.

6.3. Methods and material for containment and cleaning up
Contain spill. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue. Seal the container. Dispose of collected material as soon as possible.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Avoid breathing of dust created by cutting, sanding, grinding or machining. A no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly-used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wash contaminated clothing before reuse. Avoid contact with oxidizing agents (eg. chlorine, chromic acid etc.)

7.2. Conditions for safe storage including any incompatibilities
Store away from heat. Store away from oxidizing agents.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Ingredient	C.A.S. No.	Agency	Limit type	Additional Comments
Titanium Dioxide	13463-67-7	Amer Conf of Gov. Indust. Hyg.	TWA:10 mg/m3	
Titanium Dioxide	13463-67-7	Chemical Manufacturer Rec Guid	TWA(as respirable dust):5 mg/m3	
Titanium Dioxide	13463-67-7	US Dept of Labor - OSHA	TWA(as total dust):15 mg/m3	
FLUORIDES	13760-80-0	Amer Conf of Gov. Indust. Hyg.	TWA(as F):2.5 mg/m3	
FLUORIDES	13760-80-0	US Dept of	TWA(as dust):2.5	

		Labor - OSHA	mg/m3;TWA(as F):2.5 mg/m3	

Amer Conf of Gov. Indust. Hyg. : American Conference of Governmental Industrial Hygienists
American Indust. Hygiene Assoc : American Industrial Hygiene Association
Chemical Manufacturer Rec Guid : Chemical Manufacturer's Recommended Guidelines
US Dept of Labor - OSHA : United States Department of Labor - Occupational Safety and Health Administration
TWA: Time-Weighted-Average
STEL: Short Term Exposure Limit
CEIL: Ceiling

8.2. Exposure controls

8.2.1. Engineering controls
Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapors/spray. If ventilation is not adequate, use respiratory protection equipment.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended:
Safety Glasses with side shields

Skin/hand protection
See Section 7.1 for additional information on skin protection.

Respiratory protection

Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

General Physical Form:	Solid
Specific Physical Form:	Paste
Odor, Color, Grade:	Slight acrylate odor, tooth colored
Odor threshold	*No Data Available*
pH	*Not Applicable*
Melting point	*No Data Available*
Boiling Point	*Not Applicable*
Flash Point	No flash point
Evaporation rate	*Not Applicable*

Flammability (solid, gas)	Not Classified
Flammable Limits(LEL)	*Not Applicable*
Flammable Limits(UEL)	*Not Applicable*
Vapor Pressure	*Not Applicable*
Vapor Density	*Not Applicable*
Density	1.9 g/cm3
Specific Gravity	1.9 [*Ref Std:* WATER=1]
Solubility in Water	Negligible
Solubility- non-water	*No Data Available*
Partition coefficient: n-octanol/ water	*Not Applicable*
Autoignition temperature	*No Data Available*
Decomposition temperature	*No Data Available*
Viscosity	*No Data Available*

SECTION 10: Stability and reactivity

10.1. Reactivity
This material may be reactive with certain agents under certain conditions - see the remaining headings in this section.

10.2. Chemical stability
Stable.

10.3. Possibility of hazardous reactions
Hazardous polymerization will not occur.

10.4. Conditions to avoid
Heat
High shear and high temperature conditions

10.5. Incompatible materials
Strong oxidizing agents

10.6. Hazardous decomposition products

Substance	Condition
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labeling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1. Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation:
Respiratory Tract Irritation: Signs/symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.

Skin Contact:
Contact with the skin during product use is not expected to result in significant irritation. Allergic Skin Reaction (non-photo induced): Signs/symptoms may include redness, swelling, blistering, and itching.

Eye Contact:
Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion:
May be harmful if swallowed.
Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, stomach upset, nausea, vomiting and diarrhea.

Carcinogenicity:

Exposures needed to cause the following health effect(s) are not expected during normal, intended use:
Contains a chemical or chemicals which can cause cancer.

Ingredient	C.A.S. No.	Class Description	Regulation
Titanium Dioxide	13463-67-7	Grp. 2B: Possible human carc.	International Agency for Research on Cancer

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

Name	Route	Species	Value
Overall product	Ingestion		No data available; calculated ATE 2,614.4 mg/kg
SILANE TREATED CERAMIC	Dermal		LD50 estimated to be > 5,000 mg/kg
SILANE TREATED CERAMIC	Ingestion		LD50 estimated to be 2,000 - 5,000 mg/kg
SILANE TREATED SILICA	Dermal		LD50 estimated to be > 5,000 mg/kg
SILANE TREATED SILICA	Ingestion		LD50 estimated to be > 5,000 mg/kg
ETHYL 4-DIMETHYL AMINOBENZOATE (EDMAB)	Ingestion		LD50 estimated to be 300 - 2,000 mg/kg
Titanium Dioxide	Dermal	Rabbit	LD50 > 10,000 mg/kg
Titanium Dioxide	Inhalation-Dust/Mist (4 hours)	Rat	LC50 > 6.82 mg/l
Titanium Dioxide	Ingestion	Rat	LD50 > 10,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	No significant irritation
SILANE TREATED SILICA		No significant irritation
Titanium Dioxide	Rabbit	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	Mild irritant
SILANE TREATED SILICA		No significant irritation
Titanium Dioxide	Rabbit	No significant irritation

Skin Sensitization

Name	Species	Value
SILANE TREATED CERAMIC	similar compounds	Some positive data exist, but the data are not sufficient for classification
AFM-1 MONOMER	similar compounds	Some positive data exist, but the data are not sufficient for classification
Titanium Dioxide	Human	Not sensitizing

	and animal	

Respiratory Sensitization

Name	Species	Value

Germ Cell Mutagenicity

Name	Route	Value
Titanium Dioxide	In Vitro	Not mutagenic
Titanium Dioxide	In vivo	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
SILANE TREATED CERAMIC	Inhalation	similar compounds	Some positive data exist, but the data are not sufficient for classification
Titanium Dioxide	Ingestion	Multiple animal species	Not carcinogenic
Titanium Dioxide	Inhalation	Rat	Carcinogenic

Reproductive Toxicity

Reproductive and/or Developmental Effects

Name	Route	Value	Species	Test Result	Exposure Duration

Target Organ(s)

Specific Target Organ Toxicity - single exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration

Specific Target Organ Toxicity - repeated exposure

Name	Route	Target Organ(s)	Value	Species	Test Result	Exposure Duration
SILANE TREATED CERAMIC	Inhalation	pulmonary fibrosis	Some positive data exist, but the data are not sufficient for classification	similar compounds	NOAEL Not available	
Titanium Dioxide	Inhalation	respiratory system	Some positive data exist, but the data are not sufficient for classification	Rat	LOAEL 0.010 mg/l	2 years
Titanium Dioxide	Inhalation	pulmonary fibrosis	All data are negative	Human	NOAEL Not available	occupational exposure

Aspiration Hazard

Name	Value

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

Ecotoxicological information

Please contact the address or phone number listed on the first page of the SDS for additional ecotoxicological information on this material and/or its components.

Chemical fate information

Please contact the address or phone number listed on the first page of the SDS for additional chemical fate information on this material and/or its components.

SECTION 13: Disposal considerations

13.1. Disposal methods
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Incinerate in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes. Empty drums/barrels/containers used for transporting and handling hazardous chemicals (chemical substances/mixtures/preparations classified as Hazardous as per applicable regulations) shall be considered, stored, treated & disposed of as hazardous wastes unless otherwise defined by applicable waste regulations. Consult with the respective regulating authorities to determine the available treatment and disposal facilities.

EPA Hazardous Waste Number (RCRA): Not regulated

SECTION 14: Transport Information

For Transport Information, please visit **http://3M.com/Transportinfo** or call 1-800-364-3577 or 651-737-6501.

SECTION 15: Regulatory information

15.1. US Federal Regulations

Contact 3M for more information.

311/312 Hazard Categories:

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - Yes Delayed Hazard - No

This material contains a chemical which requires export notification under TSCA Section 12[b]:

Ingredient (Category if applicable)	C.A.S. No	Regulation	Status
BENZOTRIAZOL	96478-09-0	Toxic Substances Control Act (TSCA) 5 SNUR or Consent Order Chemicals	Applicable

This material contains a chemical regulated by an EPA Significant New Use Rule (TSCA Section 5)

Ingredient (Category if applicable)	C.A.S. No	Reference
BENZOTRIAZOL	96478-09-0	40CFR721.8450

15.2. State Regulations

Contact 3M for more information.

15.3. Chemical Inventories

This material contains one or more substances not listed on the TSCA Inventory. Commercial use of this material is regulated by the FDA.

Contact 3M for more information.

15.4. International Regulations

Contact 3M for more information.

This SDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

SECTION 16: Other information

NFPA Hazard Classification
Health: 2 Flammability: 1 Instability: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

Document Group:	33-1594-2	**Version Number:**	1.00
Issue Date:	02/19/14	**Supercedes Date:**	Initial Issue

DISCLAIMER: The information in this Safety Data Sheet (SDS) is believed to be correct as of the date issued. 3M MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR COURSE OF PERFORMANCE OR USAGE OF TRADE. User is responsible for determining whether the 3M product is fit for a particular purpose and suitable for user's method of use or application. Given the variety of factors that can affect the use and application of a 3M product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the 3M product to determine whether it is fit for a particular purpose and suitable for user's method of use or application.

3M provides information in electronic form as a service to its customers. Due to the remote possibility that electronic transfer may have resulted in errors, omissions or alterations in this information, 3M makes no representations as to its completeness or accuracy. In addition, information obtained from a database may not be as current as the information in the SDS available directly from 3M

3M USA SDSs are available at www.3M.com

16. Software

Software is not applicable. Filtek™ Bulk Fill Posterior Restorative does not contain software/firmware.

17. Electromagnetic Compatibility and Electrical Safety

Filtek™ Bulk Fill Posterior Restorative is not an electrical device. It does not require EMC or Electrical Safety Evaluation

18. Test Method Summaries

(b) (4)

[redacted]

(b) (4) Test Method Summaries

(b) (4) Test Method Summaries

(b) (4) Test Method Summaries

(b) (4) Test Method Summaries

3M ESPE

19. Performance Testing – Animal

Not applicable. This submission does not contain animal performance testing.

3M ESPE

20. Performance Testing – Clinical

Not applicable. This submission does not contain clinical performance testing.

21. Risk Management

21.1 FDA Guidance

FDA has identified the risks/mitigation measures below generally associated with the use of dental composite resin devices. The bold text in the table below is from Section 6, Table 4 of FDA's 2005 "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions." The section numbers listed in the table below are the corresponding sections of this 510(k) submission:

Identified Risks	Recommended Mitigation Measures
Mechanical Failure	**Composition and Physical Property Specifications** Please see: Section 11.13 Formulation Section 12.2.2 Formulation Comparison with S/E Devices Section 11.7 Device Design Requirements Section 11.8 Performance Specifications Section 12.2.4 Bench Test Data Comparison with S/E Devices
Toxicity and Adverse Tissue Reaction	**Biocompatibility** Please see Section 15. Biocompatibility
Improper Use	**Labeling** Please see Section 13. Proposed Labeling

21.2 Risk Management Report

Please see next page for 3M ESPE Risk Management Report.

3M ESPE

ISO 14971 Risk Management Report

3M™ ESPE™ Filtek™ Bulk Fill Posterior Restorative

February 2014

(b) (4)

(b) (4)

22. Predicate Labeling

22.1 Filtek™ Supreme Ultra Universal Restorative, K083610

Note: Lot number and expiration date are added to the labels in this section when the product is packaged.

22.1.1 Filtek™ Supreme Ultra Universal Restorative Labels

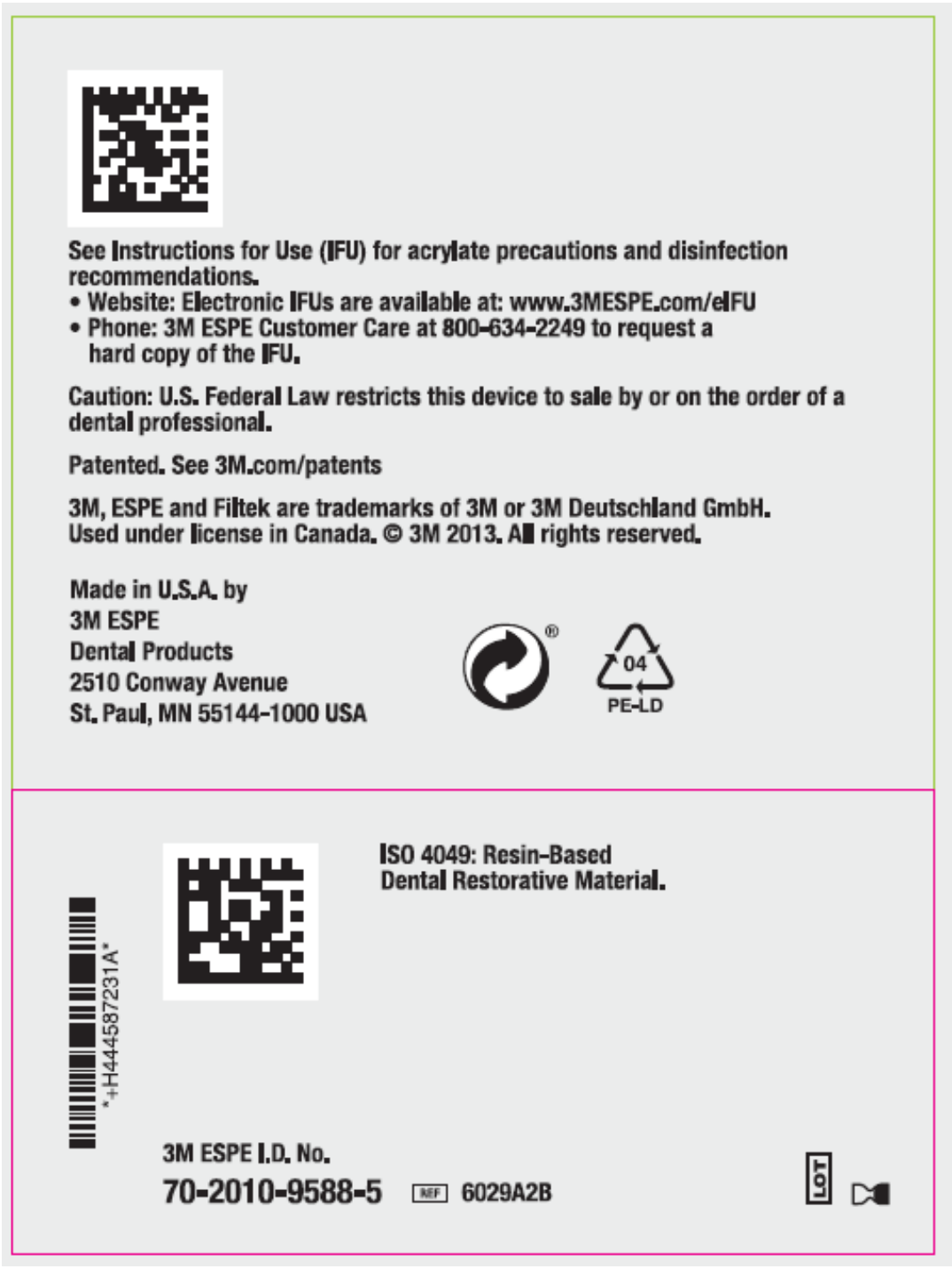
Filtek™ Supreme Ultra Universal Restorative Capsule Pouch Label (A2B Shade example):

Front

3M ESPE

3M CONFIDENTIAL

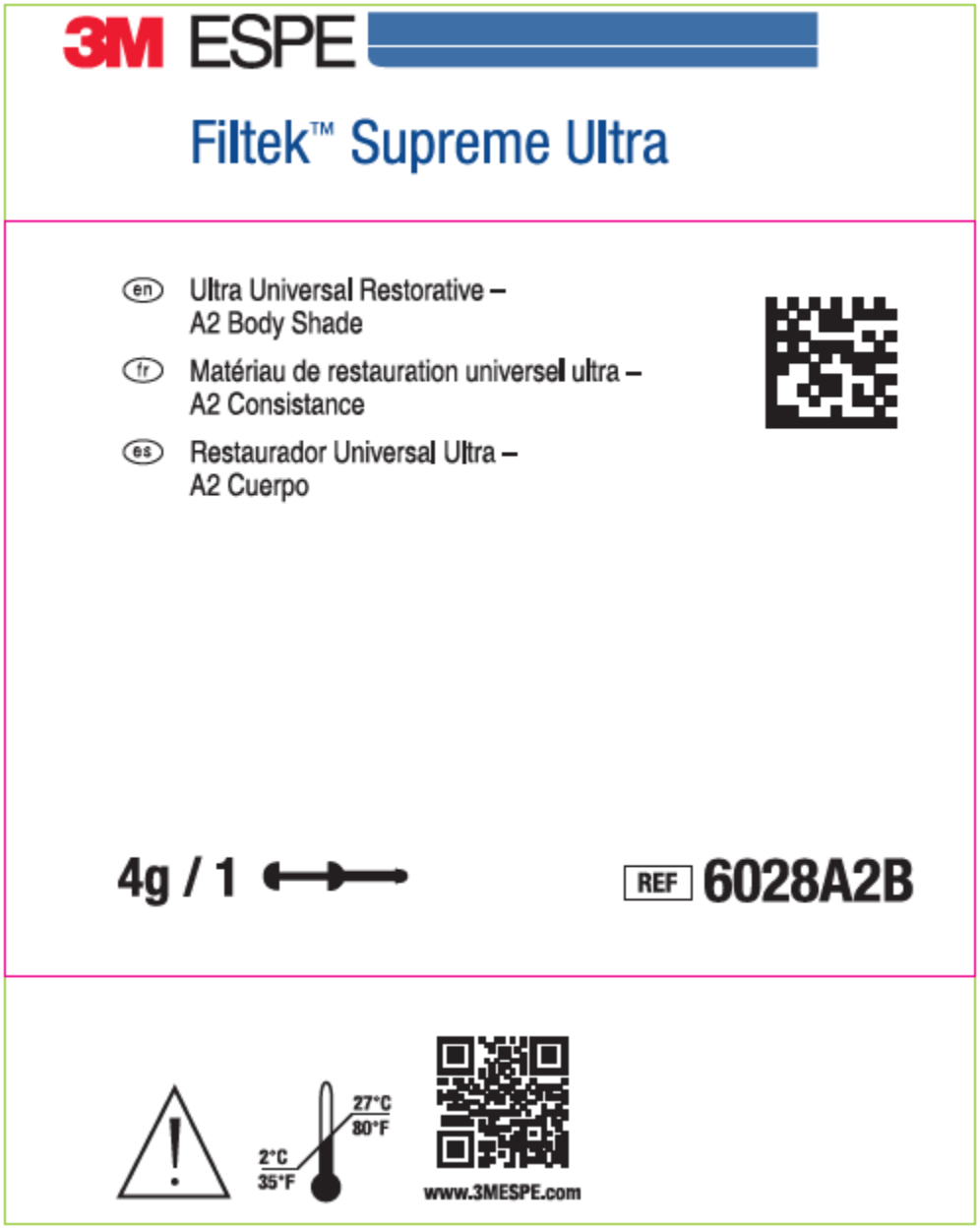
Back



3M CONFIDENTIAL

Filtek™ Supreme Ultra Universal Restorative Syringe Pouch Label (A2B Shade example):

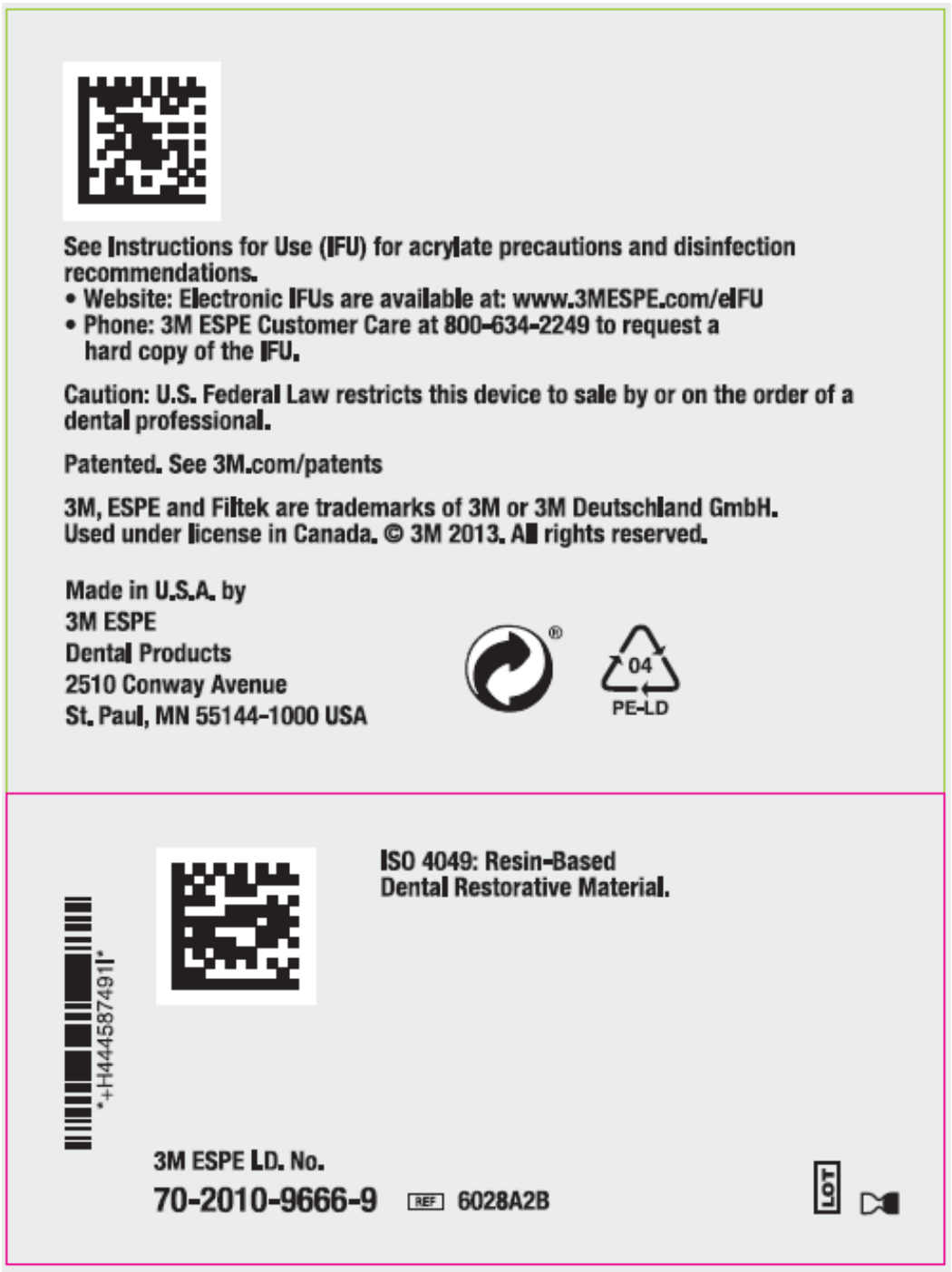
Front



3M ESPE

3M CONFIDENTIAL

Back



3M CONFIDENTIAL

Filtek™ Supreme Ultra Universal Restorative Capsule Bottle Label (A2B Shade example):

Filtek™ Supreme Ultra Universal Restorative Syringe Label (A2B Shade example):

3M ESPE

3M CONFIDENTIAL

Filtek™ Supreme Ultra Universal Restorative Capsule Bottle, Capsules and Syringe

22.1.2 Filtek™ Supreme Ultra Universal Restorative IFU

3M ESPE

Filtek™ Supreme Ultra Universal Restorative

ENGLISH

General Information

3M™ ESPE™ Filtek™ Supreme Ultra Universal Restorative material, is a visible-light activated, restorative composite designed for use in anterior and posterior restorations. All shades are radiopaque. The fillers are a combination of a non-agglomerated/non-aggregated 20nm silica filler, a non-agglomerated/non-aggregated 4 to11 nm zirconia filler and an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles). The Dentin, Enamel and Body shades have an average cluster particle size of 0.6 to 10 microns. The Translucent shades have an average cluster particle size of 0.6 to 20 microns. The inorganic filler loading is about and 72.5% by wt (55.6% by volume) for the translucent shades and 78.5% by wt (63.3% by volume) for all other shades. Filtek Supreme Ultra universal contains bis-GMA, UDMA, TEGDMA, PEGDMA and bis-EMA resins. A dental adhesive, such as manufactured by 3M ESPE, is used to permanently bond the restoration to the tooth structure. The restorative is available in a wide variety of dentin, body, enamel and translucent shades. It is packaged in traditional syringes and single-dose capsules.

Indications

Filtek Supreme Ultra universal restorative is indicated for use in:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

Precautionary Information for Patients

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

Precautionary Information for Dental Personnel

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

3M ESPE MSDSs can be obtained from www.3MESPE.com or contact your local subsidiary.

Instructions for Use

Preparation

1. Prophy: Teeth should be cleaned with pumice and water to remove surface stains.
2. Shade Selection: Before isolating the tooth, select the appropriate shade(s) of restorative material using a standard VITAPAN® Classic shade guide. Shade selection accuracy can be enhanced by the following hints.
   - 2.1 Shade: Teeth are not monochromatic. The tooth can be divided into three regions, each with a characteristic color.
     - a) Gingival area: Restorations in the gingival area of the tooth will have various amounts of yellow.
     - b) Body area: Restorations in the body of the tooth may consist of shades of gray, yellow or brown.
     - c) Incisal area: The incisal edges may contain a blue or gray color. Additionally, the translucency of this area and the extent of the translucent portion of the tooth to be restored and neighboring teeth should be matched.
   - 2.2 Restoration depth: The amount of color a restorative material exhibits is affected by its thickness. Shade matches should be taken from the portion of the shade guide most similar to the thickness of the restoration.
   - 2.3 Mock-up: Place the chosen shade of the restorative material on the unetched tooth. Manipulate the material to approximate the thickness and site of the restoration. Cure. Evaluate the shade match under different lighting sources. Remove the restorative material from the unetched tooth with an explorer. Repeat process until an acceptable shade match is achieved.
3. Isolation: A rubber dam is the preferred method of isolation. Cotton rolls plus an evacuator can also be used.

Direct Restorations

1. Cavity Preparation:
   - 1.1 Anterior restorations: Use conventional cavity preparations for all Class III, IV and V restorations.
   - 1.2 Posterior restorations: Prepare the cavity. Line and point angles should be rounded. No residual amalgam or other base material should be left in the internal form of the preparation that would interfere with light transmission and therefore, the hardening of the restorative material.
2. Pulp Protection: If a pulp exposure has occurred and if the situation warrants a direct pulp capping procedure, use a minimum amount of calcium hydroxide on the exposure followed by an application of Vitrebond™ or Vitrebond™ Plus Light Cure Glass Ionomer Liner/Base, manufactured by 3M ESPE. Vitrebond liner/bases may also be used to line areas of deep cavity excavation. See the Vitrebond liner/base instructions for details.
3. Placement of Matrix:
   - 3.1 Anterior restorations: Mylar strips and crown forms may be used to minimize the amount of material used.
   - 3.2 Posterior restorations: Place a thin dead-soft metal, or a pre-contoured-mylar or a pre-contoured-metal matrix band and insert wedges firmly. Burnish the matrix band to establish proximal contour and contact area. Adapt the band to seal the gingival area to avoid overhangs.
     Note: The matrix may be placed following the enamel etching and adhesive application steps if preferred.
4. Adhesive System: Follow the manufacturer's instructions regarding etching, priming, adhesive application, and curing, for example 3M ESPE adhesives.
5. Dispensing the Composite: Follow the directions corresponding to the dispensing system chosen.
   - 5.1 Syringe: Dispense the necessary amount of restorative material from the syringe onto the mix pad by turning the handle slowly in a clockwise manner. To prevent oozing of the restorative when dispensing is completed, turn the handle counterclockwise a half turn to stop paste flow. Immediately replace syringe cap. If not used immediately, the dispensed material should be protected from light.
   - 5.2 Single-Dose Capsule: Insert capsule into 3M ESPE Restorative Dispenser, manufactured for 3M ESPE. Refer to separate restorative dispenser instructions for full instructions and precautions. Extrude restorative directly into cavity.
6. Placement:
   - 6.1 Place and light cure restorative in increments as indicated in Section 7.
   - 6.2 Slightly overfill the cavity to permit extension of composite beyond cavity margins. Contour and shape with appropriate composite instruments.
   - 6.3 Avoid intense light in the working field.
   - 6.4 Posterior placement hints:
     - a) To aid in adaptation, the first 1 mm layer may be placed and adapted to the proximal box.
     - b) A condensing instrument (or similar device) can be used to adapt the material to all of the internal cavity aspects.
7. Curing: This product is intended to be cured by exposure to a halogen or LED light with a minimum intensity of 400mW/cm² in the 400-500nm range. Cure each increment by exposing its entire surface to a high intensity visible light source, such as a 3M ESPE curing light. Hold the light guide tip as close to the restorative as possible during light exposure.

Shades	Incremental depth	Cure time
Body, Enamel, Translucent	2.0 mm	20 sec.
Dentin, A6B and B5B	1.5 mm	40 sec.

8. Contouring: Contour restoration surfaces with fine finishing diamonds, burs or stones. Contour proximal surfaces with Sof-Lex™ Finishing Strips, manufactured for 3M ESPE.
9. Adjust Occlusion: Check occlusion with a thin articulating paper. Examine centric and lateral excursion contacts. Carefully adjust occlusion by removing material with a fine polishing diamond or stone.
10. Finish and Polishing: Polish with the Sof-Lex™ Finishing and Polishing System.

Indirect Procedure for Inlays, Onlays or Veneers

1. Dental Operatory Procedure
   - 1.1 Shade selection: Choose the appropriate shade(s) of Filtek Supreme Ultra universal restorative prior to isolation. If the restoration is of sufficient depth, use of a dentin shade is recommended. Use of a translucent shade on the occlusal surface will help to achieve esthetic appearance.

1.2 Preparation: Prepare the tooth.

1.3 Impressioning: After preparation is complete, make an impression of the prepared tooth by following the manufacturer's instructions of the impressioning material chosen. An impressioning material, such as manufactured by 3M ESPE, may be used.

2. Laboratory Procedure

2.1 Pour the impression of the preparation with die stone. Place pins at the preparation site at this time if a "triple tray" type of impression was used.

2.2 Separate the cast from the impression after 45 to 60 minutes. Place pins in die and base the cast as for a typical crown and bridge procedure. Mount or articulate the cast to its counter model on an adequate articulator.

2.3 If a second impression was not sent, pour a second cast using the same impression registration. This is to be used as a working cast.

2.4 Section out the preparation with a laboratory saw and trim away excess or, expose the margins so they can be easily worked. Mark the margins with a red pencil if needed. *Add a spacer at this time if one is required.*

2.5 Soak the die in water, then with a brush, apply a very thin coat of separating medium to the preparation, let it dry somewhat, then add another thin layer.

2.6 Add the first increment of composite to the floor of the preparation, stay short of the margins, and follow the cure recommendations described in the Direct Restoration section (Step 7).

2.7 Place and cure additional increments of composite. Allow for the last increment (incisal) to include the contact areas.

2.8 Place the die back into the articulated arch. Add the last increment of composite to the occlusal surface. Overfill very slightly mesially, distally, and occlusally. This will allow for the mesiodistal contacts and the proper occlusal contact when the opposing arch is brought into occlusion with the uncured increment. Light cure for only ten seconds, then remove the die to prevent adhering to adjacent surfaces. Finish the curing process following the cure times in the Direct Restoration section (Step 7).

2.9 With the occlusal contacts already established, begin removing the excess composite from around the points of contact. Develop the inclines and ridges as per remaining occlusal anatomy.

2.10 Care must be taken when removing the prosthesis from the die. Break off small amounts of the die from around the restoration, the die stone should break away cleanly from the cured restoration, until all of the restoration is recovered.

2.11 Using the master die, check the restoration for flash, undercuts, and fit. Adjust as necessary, and then polish as noted above in Direct Restorative steps 8-10.

3. Dental Operatory Procedure

3.1 Roughen the interior surfaces of the indirect restoration.

3.2 Clean the prosthesis in a soap solution in an ultrasonic bath and rinse thoroughly.

3.3 Cementation: Cement the prosthesis using a 3M ESPE resin cement system, manufactured by 3M ESPE following manufacturer's instructions.

Storage and Use

1. This product is designed to be used at room temperature. If stored in cooler allow product to reach room temperature prior to use. Shelf life at room temperature is 36 months. Ambient temperatures routinely higher than 27° C/80° F may reduce shelf life. See outer package for expiration date.
2. Do not expose restorative materials to elevated temperatures, or to intense light.
3. Do not store materials in proximity to eugenol containing products.

Disinfect this product using an intermediate level disinfection process (liquid contact) as recommended by the Centers for Disease Control and endorsed by the American Dental Association. Guidelines for Infection Control in Dental Health-Care Settings - 2003 (Vol. 52; No. RR-17), Centers for Disease Control and Prevention.

Disposal – See the Material Safety Data Sheet (available at www.3MESPE.com or through your local subsidiary) for disposal information.

Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE 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 ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE 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.

3M ESPE Customer Care/MSDS Information:
U.S.A. 1-800-634-2249 and Canada 1-888-363-3685.

3M ESPE
Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

44-0007-4754-1-B

22.1.3 Restorative Dispenser (5707SD) IFU

ENGLISH

General Information

The 3M™ ESPE™ Restorative Dispenser is a device used to dispense 3M ESPE capsule materials.

Indications

Dispensing of 3M ESPE dental materials contained in capsules.

Precautionary Information for Dental Personnel

- Seat capsules securely in dispenser barrel and engage capsule as directed.
- Do not use excessive dispensing force. Excessive force may cause the capsule to dislodge and may result in patient injury.
- This product is recommended to be used with 3M ESPE capsules.
- Follow all instructions for proper use. Any deviation from the instructions for use shall be at the discretion and the sole responsibility of the dental practitioner.

Instructions for Use

Directions

1. Load the capsule into the top opening of the dispenser barrel as shown in figure 1. Pull the capsule forward manually and/or by squeezing the handle so that the plunger pushes the capsule forward into the engaged position. The engaged position is shown in figure 2.

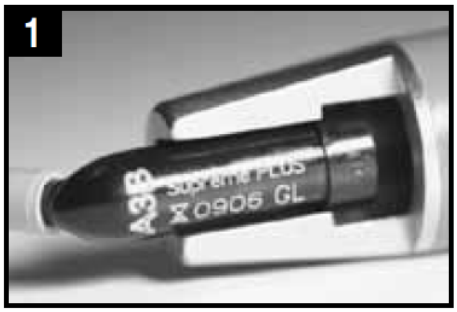


figure 1

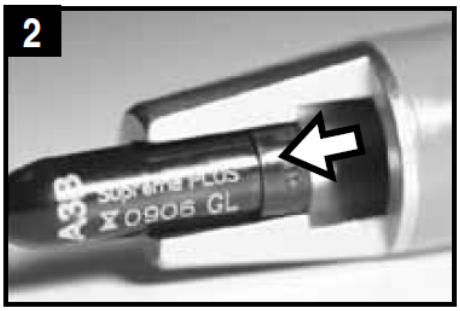


figure 2

2. With the plunger and capsule lightly engaged, rotate the capsule to the desired angle.
3. Dispense paste by applying slow, steady pressure to dispenser handle.
4. Lift the handle to disengage the plunger and lift the capsule out of the dispenser barrel.

Storage and Use

Sterilization Recommendations. Raise handle up and remove plunger. Thoroughly remove any material build up from the dispenser prior to sterilizing.

Listed below are four different steam sterilization cycle types that will effectively sterilize the dispenser:

15 minutes at 121°C/250°F wrapped

10 minutes at 121°C/250°F unwrapped

10 minutes at 132°C/270°F wrapped

3 minutes at 132°C/270°F unwrapped

Do not use chemi-clave. Do not use temperatures exceeding 140°C/285°F. Repeated exposure to high temperature can degrade plastic. Discard product should deterioration in product appearance or performance occur.

The sterilization instructions above have been validated by 3M ESPE as being capable of preparing this device for multiple uses. It is the responsibility of the dental professional to ensure that desired results are achieved and the process is conducted using proper equipment, materials and trained personnel. This requires validation and routine monitoring of the process. Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE 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 ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE 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.

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Instructions for Use
Инструкция по применению
Указания за употреба
Upute za uporabu
Használati utasítás
Instrukcja użycia
Instrucţiuni de utilizare
Návod na použitie
Navodila za uporabo
Návod k použití
Kullanma Talimatları
Käsutusjuhend
Lietošanas instrukcija
Naudojimo instrukcija
Інструкції з використання

44-0007-4823-4-B

3M ESPE
Dental Products

2012-10

CE

3M ESPE

Restorative Dispenser	Dávkovacia pištoľ
Реставрационный диспенсер	Restavracijski dispenzer
Дозатор за възстановителен материал	Dispenzer výplňového materiálu
Dispenzer kapsula	Restoratif Tabancası
Tömőanyag adagoló	Täidismaterjali kapslipüstol
Podajnik do materiałów do wypełnień	Restaurācijas materiāla izspiešanas ierīce
Dispenser pentru materiale de restaurare	Plombinių medžiagų dalytuvas
	Диспенсер для реставраційних матеріалів

3M ESPE
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2510 Conway Avenue
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EC REP

3M Deutschland GmbH
Dental Products
Carl-Schurz-Straße 1
D-41453 Neuss – Germany

2012-10

44-0007-4823-4-B

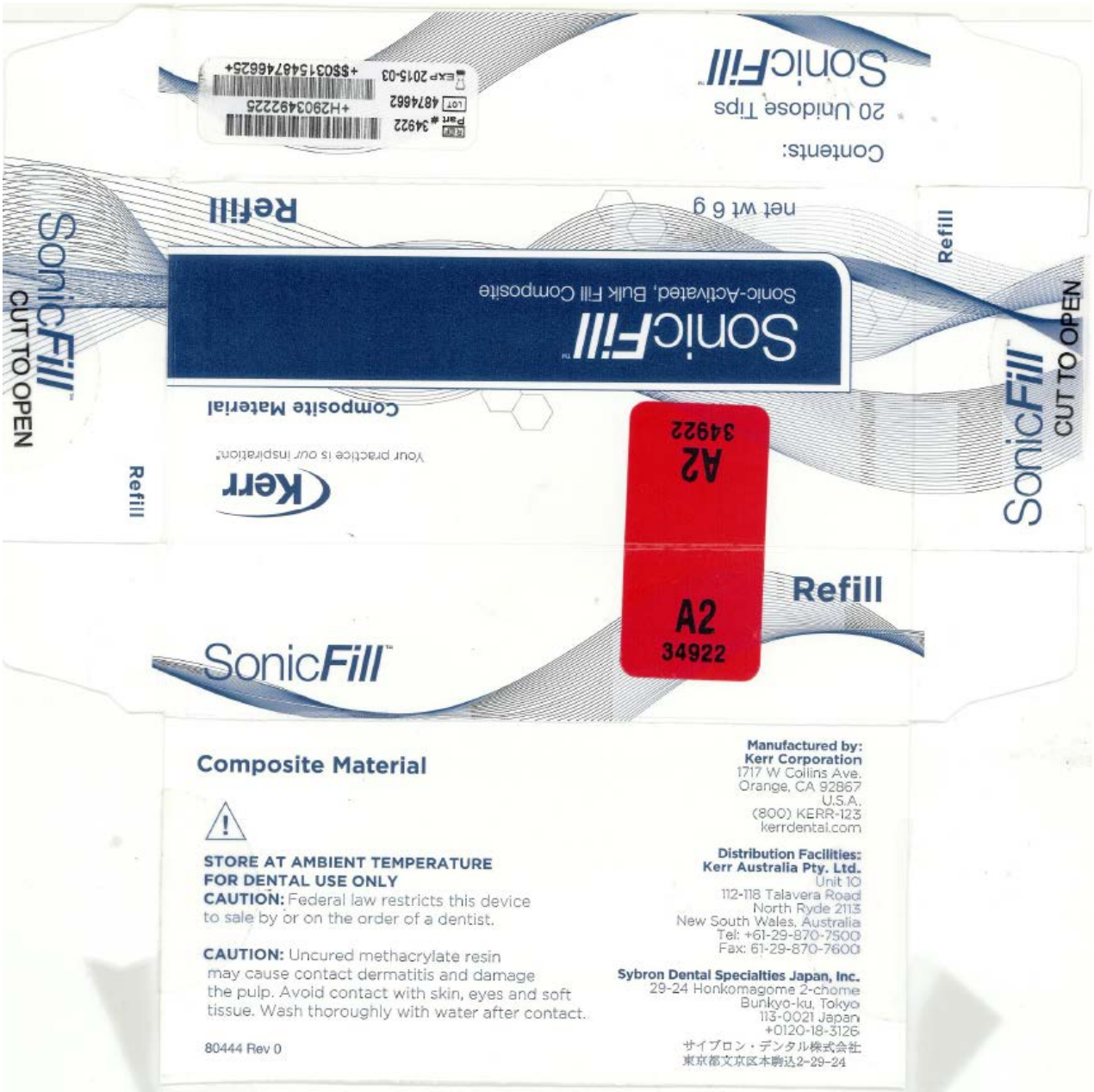
End of Instructions for Use (other languages omitted for brevity)……

22.2 SonicFill, Sonic-Activated Bulk Fill Composite, K091023

[Name used for 510(k): Metamorphosis]

22.2.1 SonicFill, Sonic-Activated Bulk Fill Composite Labels

SonicFill, Sonic-Activated Bulk Fill Composite Capsule Refill Box (A2 Shade example):



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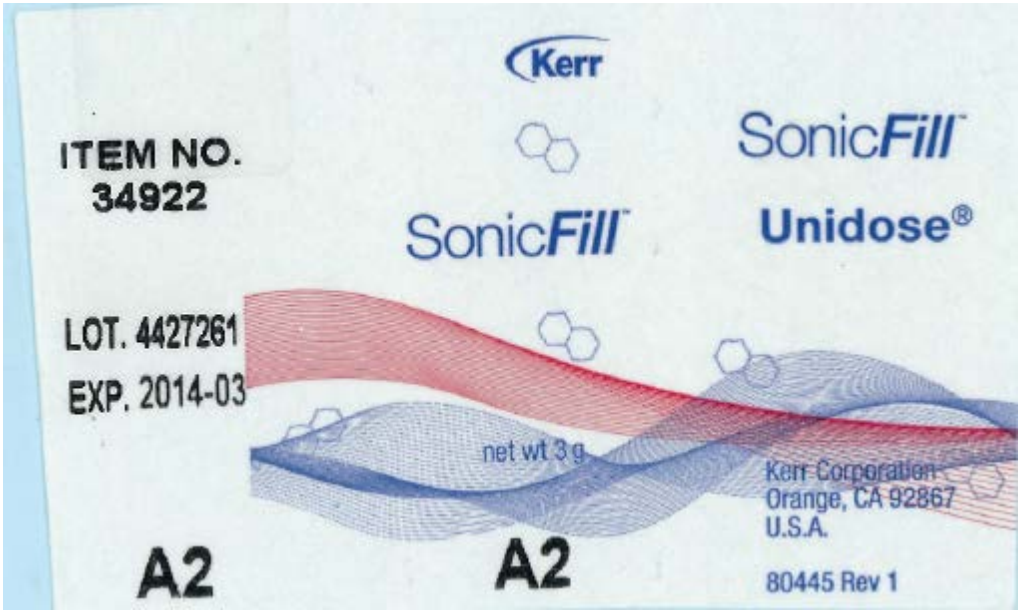
SonicFill, Sonic-Activated Bulk Fill Composite Capsule Container (A2 Shade example):



22.2.2 SonicFill, Sonic-Activated Bulk Fill Composite IFU

Kerr
Sybron Dental Specialties

SonicFill™
Sonic-Activated, Bulk Fill Composite

Directions For Use

ENGLISH

SonicFill

Nanohybrid Composite Restorative

SonicFill is a light-cured, low-shrink, resin-based, dental restorative designed for direct placement. It is indicated for all cavity classes in posterior teeth. SonicFill is used in combination with the SonicFill Handpiece and offers sonically activated delivery. This delivery produces a significant drop in viscosity upon extrusion, allowing intimate adaptation of the composite to the cavity walls. When the cavity is filled and the Handpiece is deactivated, the viscosity of the restorative resin increases retaining desired physical properties. The non-sticky, non-slumping nature of the material allows for quick, easy shaping and sculpting. These benefits combined with a high depth of cure allow a technique in which a cavity up to 5mm in depth can be filled and cured in a single bulk increment.

Storage Conditions and Shelf Life:

SonicFill should be stored at ambient temperature. The expiration date is marked on packaging. Do not use after expiration date. Every effort should be made to protect the composite from visible light prior to use.

PLEASE NOTE THE FOLLOWING:

The Unidose® tips are designed for SINGLE PATIENT USE ONLY. Do not re-cap and/or re-use the Unidose® tip once material has been dispensed for that patient. This is to prevent cross-contamination between patients.

PRIOR TO PLACEMENT --
RECOMMENDATIONS ON PROPER BONDING

- Isolation throughout adhesive steps and composite placement is important. Rubber dam is ideal.
- Please closely follow bonding agent directions for use.
- Please take care to ensure that your air line is free of oil and other contaminants.

SonicFill Handpiece

The SonicFill Handpiece is packaged with a Use and Care guide. To receive the best use from your Handpiece, read and follow the use and care instructions included with the device.

2

PLACEMENT OF
SonicFill

1. Select the desired shade. If Class II, place matrix of choice.
2. Verify air pressure of dental unit is at least 36 PSI. If the unit is set to a higher pressure, it will be automatically regulated to 36 PSI inside the instrument.
3. Accurately position the Handpiece on the MULTIflex coupling and press it firmly until securely (audibly) locked.
4. Remove protective covers from tip by pulling them straight off without twisting to prevent disassembling the tip. Discard any disassembled tips.
5. Insert Unidose capsule with moderate pressure and rotate SonicFill Handpiece into tip in a clockwise direction – this will screw tip into place. If the tip will not screw on easily, it has likely cross-threaded. Unscrew the tip and start again. If you are not able to easily screw the tip onto the handpiece, discard the tip.
6. Using foot pedal, briefly activate handpiece outside mouth to ensure tip is fully engaged.
7. The dispensing rate/speed is set with the switch at the bottom of the Handpiece. Setting 5 is the fastest speed; setting 1 is slowest. Set desired speed at base of Handpiece. For your first several uses, you may wish to place the speed at setting "3" until you become familiar with the flow rate. When you are comfortable with the device, setting "5" will be appropriate for many restorations.
8. Place Unidose® tip at the deepest portion of the preparation to avoid trapping air.
9. Activate SonicFill Handpiece by depressing foot pedal and fill entire cavity (up to 5 mm). It is recommended to use full air pressure when activating the Handpiece. Use the dispensing rate switch to control the flow rate and speed of the device. In a deep cavity (>5mm) or when placing core buildup in a deep pulp chamber, 2 separately cured increments are recommended.
10. After placement, define anatomy using hand instrument(s).
11. Light Cure*.
12. Adjust occlusion, finish and polish in the usual manner.

13. Remove tip by unscrewing it counterclockwise with finger pressure.
14. Between patients, follow the infection control and maintenance guidelines specified in the SonicFill Handpiece Use and Care Guide.

Recommended Cure Times:
Demi/Demi Plus, 20 seconds
L.E.Demetron II, 20 seconds
Optilux 501: Boost mode, 20 seconds / Ramp Mode, 40 seconds / Regular Mode, 40 seconds
For all other lights, see manufacturer's recommendation.

* In the posterior, light cure the recommended time from the occlusal, remove the matrix and cure again from the buccal and lingual.
In a Class I, additional cure is still recommended from the facial and lingual.

CAUTION: Uncured methacrylate resin may cause contact dermatitis and damage the pulp. Avoid contact with skin, eyes and soft tissue. Wash thoroughly with water after contact.

Limited Warranty - Limitation of Kerr's Liability
Kerr's technical advice, whether verbal or in writing, is designed to assist dentists in using Kerr's product. The dentist assumes all risk and liability for damages arising out of the improper use of Kerr's product. In the event of a defect in material or workmanship, Kerr's liability is limited, at Kerr's option, to replacement of the defective product or part thereof, or reimbursement of the actual cost of the defective product. In order to take advantage of this limited warranty, the defective product must be returned to Kerr. In no event shall Kerr be liable for any indirect, incidental, or consequential damages.
EXCEPT AS EXPRESSLY PROVIDED ABOVE, THERE ARE NO WARRANTIES, BY KERR, EXPRESS OR IMPLIED, INCLUDING WARRANTIES WITH RESPECT TO DESCRIPTION, QUALITY, OR FITNESS FOR A PARTICULAR PURPOSE.

Kerr

Manufactured by:
Kerr Corporation
1717 W Collins Ave.
Orange, CA 92867
U.S.A.
(800) KERR-123
kerrdental.com

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80853 Rev 1

End of Instructions for Use (other languages omitted for brevity)……

22.3 Tetric EvoCeram Bulk Fill, K111958

22.3.1 Tetric EvoCeram Bulk Fill Labels

Tetric EvoCeram Bulk Fill Capsule Pouch Label

3M ESPE

3M CONFIDENTIAL

Tetric EvoCeram Bulk Fill Syinge Pouch Label

3M ESPE

3M CONFIDENTIAL

Tetric EvoCeram Bulk Fill Syinge Label

22.3.2 Tetric EvoCeram Bulk Fill IFU

Tetric EvoCeram® Bulk Fill

EN Instructions for Use
– Light-curing resin-based dental restorative material

DE Gebrauchs-information
– Lichthärtendes zahnärztliches Füllungscomposite

FR Mode d'emploi
– Composite de restauration photopolymérisable

ES Istruzioni d'uso
– Materiale dentale da otturazione fotoindurente

IT Instrucciones de uso
– Material de restauración dental en base a resina fotopolimerizable

DA Brugsanvisning
– Lyshærdende dentalt plastfyldningsmateriale

FI Käyttöohjeet
– Valokovetteinen resiinipohjainen täytemateriaali hammas-lääketieteelliseen käyttöön

NO Bruksanvisning
– Lysherdende odontologisk fyllingsmateriale

NL Productinformatie
– Lichtuithardend composiet-vulmateriaal voor tandheelkundig gebruik

EL Οδηγίες Χρήσεως
– Οδοντιατρικό αποκαταστατικό υλικό,

English

Description
Tetric EvoCeram® Bulk Fill is a state-of-the-art, light-curing, radiopaque, nano-hybrid composite for direct restorations in posterior teeth. Tetric EvoCeram Bulk Fill cures with light in the wavelength range of 400–500 nm (blue light) and can be applied in layers of up to 4 mm.

Shades
Tetric EvoCeram Bulk Fill is available in the following 3 shades:
- Universal shades: IVA, IVB, IVW

Composition
The monomer matrix is composed of dimethacrylates (20–21% weight). The fillers contain barium glass, ytterbium trifluoride, mixed oxide and prepolymer (79–81% weight). Additional contents: additives, catalysts, stabilizers and pigments (<1.0% weight). The total content of inorganic fillers is 76–77% weight or 53–54% volume. The particle size of the inorganic fillers is between 40 nm and 3,000 nm with a mean particle size of 550 nm.

Indication
- Restorations of deciduous teeth
- Restorations in the posterior region (Classes I and II, including the replacement of individual cusps)
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Reconstructive build-up
- Extended fissure sealing in molars and premolars

Contraindication
Placement of Tetric EvoCeram Bulk Fill restorations is contra-indicated:
- if a dry working field cannot be established, or if the stipulated technique cannot be applied;
- if a patient is known to be allergic to any of the ingredients in Tetric EvoCeram Bulk Fill.

Side effects
In individual cases, components of Tetric EvoCeram Bulk Fill may lead to sensitization. Tetric EvoCeram Bulk Fill should not be used in such cases. To avoid possible irritation of the pulp, areas close to the pulp should be protected with a suitable pulp/dentin protector (selectively apply a calcium hydroxide-based preparation in areas close to the pulp and cover with suitable cavity liner).

Interactions
Materials containing phenolic substances, e.g. eugenol/clove oil, inhibit the polymerization of methacrylate-based materials. Consequently, application of such materials together with Tetric EvoCeram Bulk Fill must be avoided. Discolouration may occur in combination with cationic mouthwashes, plaque disclosing agents and chlorhexidine.

Application
1. Shade determination
Clean the teeth prior to shade determination. The shade is selected with the tooth still moist.

2. Isolation
Appropriate isolation, best with a rubber dam (e.g. OptraDam® Plus), is required.

3. Cavity preparation
Cavity preparation is carried out according to the requirements of the adhesive technique, i.e. protecting the tooth structure. Do not prepare sharp, internal edges and angles or additional undercuts in caries-free areas. The dimensions of the cavity are generally determined by the extent of the caries or the size of the old restoration. Bevel enamel edges in the anterior region. For the posterior region, only the sharp enamel edges should be rounded (finishing diamonds, 25–40 µm). Caries-free cervical defects are not prepared, only cleaned with pumice or other suitable cleaning pastes with the help of rubber cups or rotary brushes. Subsequently, remove all residue in the cavity with water spray and dry with water- and oil-free air.

4. Pulp protection / Base
Do not apply a base material when using an enamel/dentin bonding agent. Only cover very deep areas close to the pulp with a calcium hydroxide material (e.g. ApexCal®) and subsequently use a pressure-resistant cement (e.g. a glass ionomer cement, such as Vivaglass® Liner). Do not cover other cavity walls, since they can be used to support the bond with an enamel/dentin adhesive.

5. Matrix / Interdental wedge
Use a wrap around matrix for cavities affecting the proximal area or a sectional matrix and wedge it.

6. Conditioning / Application of the bonding agent
Condition and apply the bonding agent according to the Instructions for Use of the product in use. We recommend using Syntac® (with phosphoric acid etching) or ExciTE® F (with phosphoric acid etching) or the self-etching adhesive AdheSE®.

7. Application of Tetric EvoCeram Bulk Fill
- For an optimum result, apply Tetric EvoCeram Bulk Fill in layers of max. 4 mm and adapt with a suitable instrument (e.g. OptraSculpt). Use a special contact point instrument (e.g. the bifurcated OptraContact) for large cavities where the contacts are difficult to create.
- Sufficient exposure to the curing light prevents incomplete polymerization. For the recommendations regarding exposure time and light intensity see Table 1.
- When using a metal matrix, additionally polymerize the composite material from the buccal or lingual/palatal aspect after removing the matrix, if no Bluephase polymerization light is used or the light probe cannot be ideally positioned, e.g. distant to composite or diverging scattering angle.
- In many cases, a flowable composite is used today as an initial layer to create an even cavity floor and to facilitate the adaptation of the subsequently used restorative material. A flowable composite (e.g. Tetric EvoFlow®) can be used as a thin initial layer. This optional layer has to be cured separately (please refer to the respective Instructions for Use).

3M ESPE

8. Finishing / Checking the occlusion / Polishing

Remove excess material with suitable finishers or fine diamonds after polymerization. Remove proximal excess with diamond or tungsten carbide finishers, finishing strips, or flexible finishing discs. Check the occlusion and articulation and apply appropriate grinding corrections to prevent premature contacts or undesired articulation paths on the surface of the restorations. Use silicone polishers (e.g. OptraPol® Next Generation) as well as polishing discs and polishing strips to polish the restorations to a durable high gloss.

Additional information

1. Tetric EvoCeram Bulk Fill can be used in combination with Tetric EvoCeram and Tetric EvoFlow.
2. In the case of repair, additional Tetric EvoCeram Bulk Fill can be directly applied to polymerized material. If the Tetric EvoCeram Bulk Fill restoration has already been polished, it must first be roughened and wetted with Heliobond before fresh Tetric EvoCeram Bulk Fill is applied.
3. Tetric EvoCeram Bulk Fill should have ambient temperature when applied. Cool temperatures render the material difficult to extrude.
4. For single use only. If Tetric EvoCeram Bulk Fill is applied from the Cavifil directly in the mouth of the patient, the Cavifil must not be used for more than one patient due to hygienic reasons (prevention of cross-contamination between patients).
5. Syringes or Cavifils should not be disinfected with oxidizing disinfection agents.
6. The recommended increment thickness is based on hardness profile measurements.

Warning

Unpolymerized Tetric EvoCeram Bulk Fill should not come in contact with skin, mucous membrane, or eyes. Unpolymerized Tetric EvoCeram Bulk Fill may have a slight irritating effect and may lead to a sensitization against methacrylates. Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

Storage

- Storage temperature 2–28 °C / 36–82 °F.
- Close syringes / Cavifils immediately after usage. Exposure to light causes premature polymerization.
- Do not use Tetric EvoCeram Bulk Fill after the indicated date of expiration.
- Shelf life: see information on Cavifils, syringes and packages.

Keep material out of children's reach.
For use in dentistry only.

The material has been developed solely for use in dentistry. Processing should be carried out strictly according to the Instructions for Use. Liability cannot be accepted for damages resulting from failure to observe the Instructions or the stipulated area of application. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in the Instructions. Descriptions and data constitute no warranty of attributes and are not binding.

3M ESPE

Table 1

Program \ Unit	Bluephase C8	Bluephase Style	Bluephase	Bluephase 20i
Turbo	–	–	–	5 s
High Power	15 s	10 s	10 s	10 s
Soft Start	20 s	–	15 s	15 s

Light Intensity	Exposure Time
≥ 500 mW/cm²	20 s
≥ 1000 mW/cm²	10 s

PT Instruções de Uso

– Material de restauração, baseado em resina e foto-polimerizável

SV Bruksanvisning

– Material de restauração, baseado em resina e foto-polimerizável

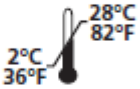
φωτοπολυμεριζόμενο, με ακρυλική βάση

TR Kullanma Talimatları

– Işıkla sertleşen dental restoratif kompozit

Rx ONLY

CE 0123



Date information prepared:
2013-07-25/Rev.2
638630/WW

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End of Instructions for Use (other languages omitted for brevity)……

23. Literature

23.1 **Halvorson R, Erickson R, Davidson C. An energy conversion** relationship predictive of conversion profiles and depth of cure of resin-based composite. Oper Dent 2003; 28:307-314.

©Operative Dentistry, 2003, **28-3**, 307-314

An Energy Conversion Relationship Predictive of Conversion Profiles and Depth of Cure for Resin-Based Composite

RH Halvorson • RL Erickson • CL Davidson

Clinical Relevance

Conversion throughout resin-based composite can be predicted at various light-curing conditions by using an energy conversion relationship. In addition, using a modified ISO standard for depth of cure, the conversion at 1/2 the scrape-back length was correlated to approximately 90% of the maximum measured conversion.

SUMMARY

Predicting the polymerization throughout resin-based composite (RBC) has been reduced to a set of variables involving irradiance of the light source, exposure duration and RBC transmission properties, together with an energy-conversion relationship (ECR) derived from Fourier Transform Infrared Spectroscopic analysis (FTIR) of a single shade of photo-polymerized RBC. The ECR describes the localized energy density required to achieve a desired conversion independent of shade. Using this ECR, conversion was predicted and experimentally verified throughout different opacities of RBC based on knowledge of their transmission properties and the incident radiant energy density (irradiance times exposure time). Also, using RBC transmission properties, a critical scrape-back energy of approximately 32 mJcm^{-2} was determined from cylindrical samples of photo-polymerized RBC in which the poorly polymerized material was removed. This value correlates to approximately 22% conversion. The critical scrape-back energy was then used to predict scrape-back lengths obtained from samples polymerized at various energy densities. These results confirm the logarithmic relationship between depth of cure and energy of exposure and the reciprocal relationship between irradiance and time of exposure.

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INTRODUCTION

A number of methods have been explored to characterize depth of polymerization of photoactivated resin-based composite (RBC) and understand the variables involved. The "scrape-back" technique (Cook, 1980) is perhaps the simplest of such methods and essentially delineates a polymerization boundary beyond which the resin is either grossly underpolymerized or completely unpolymerized. The length of the remaining composite has a logarithmic dependence for both the intensity of the light source and exposure time for UV (Cook, 1980) and visible light (Cook & Standish, 1983) polymerized RBC. The logarithmic relationship was

predicted using a mathematical model for depth of cure based on the rate of initiation of free radical polymerization and incorporates the exponential attenuation of light intensity through composite thickness. This attenuation severely limits the length of the scrape-back sample that can be obtained as revealed in a study that reported only a modest increase in length (<25%) upon doubling the exposure time (Ruyter & Øysaed, 1982). Similar depths of cure (scrape-back) have also been obtained when the product of the irradiance and the exposure time is kept constant (Cook, 1982; Nomoto, Uchida & Hirasawa, 1994). It was suggested that the depth of cure corresponds to the minimum amount of energy required to initiate polymerization.

To determine polymerization throughout composite requires more extensive methods, such as hardness measurements (Cook, 1980; De Lange, Bausch & Davidson, 1980) or infrared spectroscopy (Eliades, Vougiouklakis & Caputo, 1987; Dewald & Ferracane, 1987). These techniques generally reveal a rapid decrease in hardness or conversion of methacrylate double bonds beyond a certain depth. Consistent with studies utilizing the scrape-back technique, the irradiance of the light source, the exposure time and light transmission of composite are significant variables that affect the hardness or conversion profile (variation with depth). It has been shown that similar conversion profiles (via FTIR) were obtained when an RBC was exposed under reciprocal irradiance-exposure time relationships (Nomoto & others, 1994). This suggests that the conversion at any point within the RBC is dependent upon the radiant energy available at that point. It is, therefore, useful to construct the relationship between the conversion of photopolymerized RBC and the exposure energy (the energy-conversion relationship or ECR). This has been performed for various commercial RBCs in a thin film via transmission FTIR, together with confirmation of the reciprocal nature of irradiance and exposure time (Halvorson, Erickson & Davidson, 2002). This ECR is applicable toward the goal of predicting conversion at the surface of photopolymerized RBC given the irradiance and time of exposure. Similarly, prediction of conversion at any point within an RBC may be accomplished from an ECR for bulk curing and knowledge of the light transmission of the RBC. The transmission curves are readily determined radiometrically, and, based on prior work, it should be possible to define a unique ECR by measuring the conversion versus depth for a single shade of RBC at maximum irradiance. This data, combined with the transmission data, can relate conversion to energy, thereby, providing the ECR.

The goals of this investigation were to 1) determine the energy-dependent conversion relationship (ECR) of commercial RBC and confirm that this describes a reciprocal relationship between irradiance and exposure time, 2) show that this relationship, together with transmission properties, can be used to predict the conversion profile for various exposure energies and RBC opacities and 3) define a critical exposure energy that is predictive of scrape-back length for various exposure energies and RBC opacities.

METHODS AND MATERIALS

Energy Conversion Relationship

Two small particle hybrid resin-based composites of similar shade (A3.5) were examined to construct the ECRs: XRV Herculite (Kerr Corp, Orange, CA, USA) and 3MZ100 Restorative (3M, St Paul, MN, USA). The composition of these RBC materials has previously been described (Halvorson & others, 2002). Cylindrically-shaped samples were prepared by packing RBC into a split stainless steel mold with an approximate 6-mm diameter by 16-mm length. The mold was assembled to include two stainless steel wedges positioned along the length of the mold, on opposite sides, with their internal edges protruding into the cylinder approximately one-half millimeter and their outside edges extending outside the sides of the mold. Two machine screws held the assembly in place during the packing and polymerization phase. Transparent polyester film was placed over the ends of the cylinder to confine the composite within the mold. The mold was then placed on a white background and positioned directly under the 7-mm diameter light guide of a tungsten-halogen lamp (3MXL 3000 Curing Lamp, 3M) with a nominal power density of 600mWcm^{-2}. This lamp was checked periodically throughout the experiment to monitor any deviations in its output. Samples were exposed for 30 seconds (18 Jcm^{-2}) and kept in the dark at room temperature for 24 hours. The screws were than removed, and one of the wedges was gently tapped with a hammer, splitting the sample lengthwise down its center. The two halves were then separated, carefully teasing the unpolymerized end of the sample apart with a scalpel.

To determine conversion with depth, microscopic specimens were dissected with a scalpel at selected intervals down the length of each half using a binocular microscope. The microscope's reticle was used to determine the depth along the cylinder at which the specimen was dissected and its lamp was filtered to prevent additional polymerization. Dissection was confined to approximately the central-third of the sample. Conversion of the dissected specimens was measured using transmission FTIR microspectroscopy. Specimens were placed on a KBr disc and measured in transmission with a Nic-Plan Microscope combined with a Magna-IR 750 spectrometer (Nicolet, Madison, WI, USA) co-adding 90 scans at a resolution of 4 cm^{-1}. Three cylinders were prepared and analyzed for each group with three-to-five specimens measured at each

depth from each cylinder. Conversion was determined by measuring the decreasing absorbance of the methacrylate carbon double-bond vibration at 1638cm^{-1}, using the aromatic skeletal absorbance from BIS-GMA at 1582cm^{-1} as an internal reference. Integrated areas of both peaks were determined using a standard baseline technique. The radiation energy density of the curing lamp was determined using a power meter (Power Max 500D Laser Power Meter, Molectron Detector Inc, Portland, OR, USA) that integrated the radiant power density over the 30-second exposure time. Power density was determined by dividing the measured power by the cross-sectional area of the light guide.

The transmittance ($T=P/P_o$) at thicknesses for each RBC shade was determined by polymerizing the respective materials in 6-mm diameter stainless steel molds of various lengths. The polymerized sample, together with its mold, was placed on the detector of a power meter (351 Power Meter, UDT Instruments, Baltimore, MD, USA), centering the light guide of the curing lamp over the mold and in contact with the sample. The power measured in this fashion (P) was divided by the unattenuated power (P_o) obtained by placing the light guide in direct contact with the detector head. A minimum of three replications was done for each condition and a mean value was determined. Transmission as a function of thickness was determined by regression analysis of the data. Small errors may be introduced by using only transmission data from cured composite, but the benefits in simplifying the analysis justify this procedure. The energy exposure at depths (E_d) where FTIR specimens were dissected was determined from the incident energy (E_o) and the transmittance ($E_d=\%T_d x E_o$). This permitted conversion to be related to energy and, thereby, define an ECR for the Z100 and Herculite RBC materials.

Predicted Conversion Profiles

Predicted conversion profiles were obtained by determining the energy density transmitted to various depths from the transmittance curves and the incident energy density. The corresponding conversions obtained from the Z100 ECR were plotted as a function of depth that yielded the predicted conversion profiles. Profiles for Z100, shades A1, A3.5 and CY were predicted at various exposure conditions (Figure 4). The curves were experimentally verified by FTIR microspectroscopy using methods described above.

Scrape-Back Length: Measured and Predicted

Identical molds as those described for FTIR sampling (without wedges) were used to determine the depth of cure via the scrape-back technique. The samples were prepared as described above and exposed to the curing light at various energy densities. After 24 hours at room temperature, the molds were disassembled and the poorly polymerized material gently scraped off with a rigid plastic spatula. Three replicates were prepared and the length along the cylinder axis was measured to the nearest 0.01 mm. Average scrape-back lengths for Herculite and Z100 (A3.5 shade) exposed to 18 Jcm^{-2} were used to define a critical energy density associated with the scrape-back lengths utilizing the transmission data and incident energy density. The critical energy density, together with transmission data, was subsequently used to predict scrape-back lengths for other materials and curing conditions. Conversions at the scrape-back lengths were determined from the ECR for the critical energy density.

RESULTS

Figure 1 shows the conversion profiles, as measured with FTIR microspectroscopy for shade A3.5 of Herculite and Z100 at an exposure energy of 18 Jcm^{-2}. Maximum conversion for Herculite is greater than for Z100 and reflects differences in the formulation of these

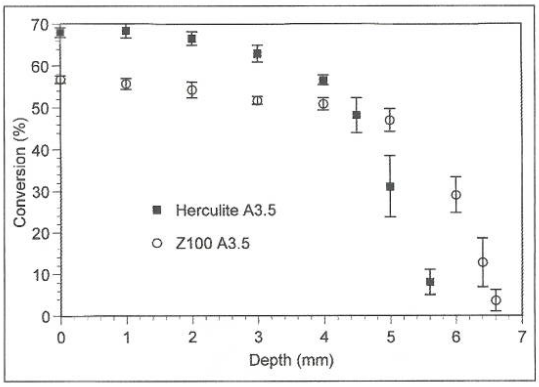

Figure 1: *Conversion profiles for shade A3.5 of Herculite and Z100 exposed with 18 Jcm^{-2} (30s/600 mWcm^{-2}).*

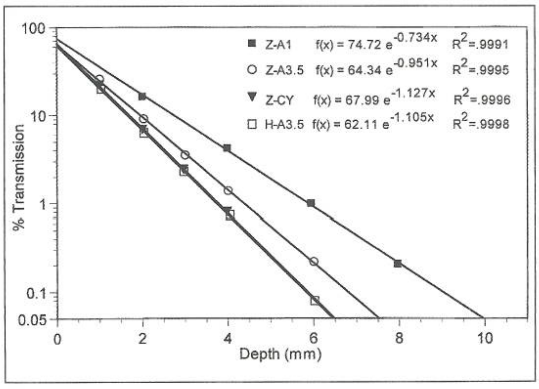

Figure 2: *Percent transmittance versus depth. H:Herculite, Z:Z100.*

two RBC materials. Although both materials are designated as A3.5 shades, there is a greater depth of cure for Z100 because of its lower opacity (Figure 2). Figure 2 shows the percent transmittance curves for the materials investigated and describes the expected exponential decrease in energy with depth. Regression analysis reveals an exponential relationship between transmittance and depth with the attenuation coefficient defined by the slope of the line and R^2 values very close to 1.000. Using the regression equations and the incident light energy density, the energy density at depths

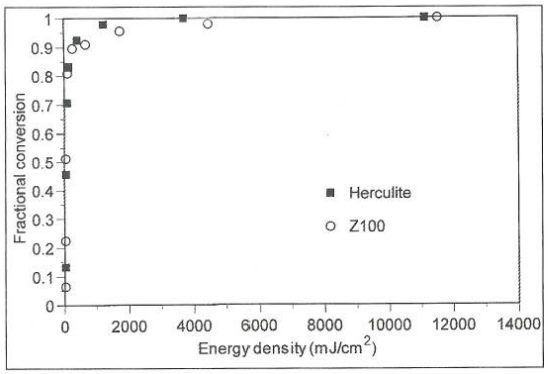

Figure 3: *Energy conversion relationship (ECR) for Herculite and Z100 derived from their respective conversion profiles and transmittance curves. Conversion is expressed relative to the maximum 24-hour conversion.*

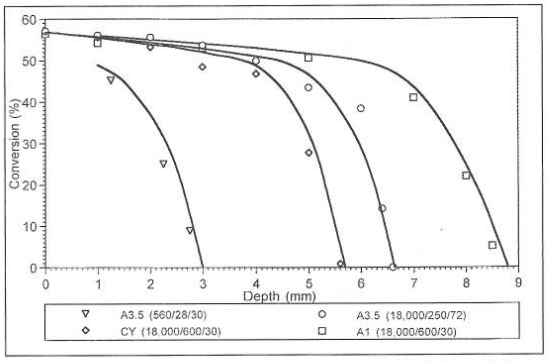

Figure 4: *Predicted conversion profiles (solid lines) for the indicated shades and exposure conditions for Z100 together with experimental values from FTIR analysis. Legend: (incident energy density,mJcm⁻²/irradiance, mWcm⁻²/exposure time(s)).*

corresponding to the measured conversion in Figure 1 was calculated and ECRs were plotted as shown in Figure 3. In this comparison, the conversion for both materials has been expressed relative to their maximum measured conversion, and it is apparent that the ECR curves on a relative conversion basis are very similar.

Using the ECR for Z100, together with transmittance curves and the incident energy density, conversion profiles for Z100 shades A1, A3.5 and CY were predicted as shown in Figure 4. Experimental values obtained by FTIR microspectroscopy are also shown in Figure 4 and depict a reasonably good fit to the predicted curves. The variability of the experimental values is similar to the variability of the average values for the conversion profiles depicted in Figure 1 and is greatest at the steepest portion of the curve. The precision of the predicted curves will be affected mostly by the precision represented in the conversion profile for Z100 (Figure 1) from which the ECR was derived.

The scrape-back lengths and exposure conditions for shade A3.5 of both materials are shown in Table 1. Comparison of conversion profiles in Figure 1 to their respective scrape-back values in Table 1 reveal that the latter are several tenths of millimeters shorter than the extrapolated depth at zero conversion and that conversion at the scrape-back depth is approximately 20% for Herculite and 22% for Z100. These conversions represent a local exposure of approximately 32 $mJcm^{-2}$ for each of the materials as determined from the ECR. This energy density will be defined as the critical scrape-back energy density. Figure 5 presents a photograph of material Z100-A3.5 prepared as described for sample dissection after 24 hours, together with the corresponding conversion-depth profile from Figure 1. To enhance the contrast between cured and uncured material, the split sample has been stained with a dye (Astra Blue) that has an affinity for the dimethacrylate monomers (de Gee, ten Harkel-Hagenaar & Davidson, 1984). The scrape-back length and associated conversion (Table 1) are indicated in the figure. Beyond the scrape-back depth, there is a region that exhibits very low cohesion and terminates as a granular appearing zone with a gelatinous consistency. The terminus of this zone, at approximately 6.7 mm, corresponds to the extrapolated depth at zero conversion. The corresponding energy density was determined from the ECR to be $21mJcm^{-2}$.

Predicted scrape-back lengths are shown in Table 2, together with experimentally derived values. Predicted values were determined using the critical scrape-back energy ($32mJcm^{-2}$). The good agreement between the predicted and measured values suggests

Table 1: *Scrape-Back Lengths*

Material	Scrape-Back Length (mm)	Conversion at Scrape-Back (%)	Energy Density (mJ/cm^2)	Irradiance (mW/cm^2)	Exposure Time (s)
Herculite-A3.5	5.27 (0.07)	20	18,000	600	30
Z100-A3.5	6.19 (0.10)	22	18,000	600	30

that the critical energy is unique for both RBC materials and applies to varying shades of material and curing conditions. Figure 6 shows predicted curves relating scrape-back length and exposure energy for Z100 shades A1, A3.5 and CY. Measured scrape-back lengths for selected exposure energies are superimposed. Corresponding results for Herculite are shown in Figure 7. The experimental scrape-back values agree with the predicted curves and verify the logarithmic dependence between scrape-back length and exposure energy.

Figure 8 shows conversion profiles, each for an incident energy density of 18 Jcm^{-2} but with different incident irradiance and time of exposure for Z100-A3.5. The excellent overlap of these two profiles confirms a reciprocity relationship between irradiance and time. Similar confirmations of reciprocity are seen in Table 2, where similar scrape-back lengths are observed when total energy density is conserved. One-factor ANOVA showed that the scrape-back values obtained with constant energy densities were equivalent.

DISCUSSION

In this study, predicting the extent of polymerization of RBC material throughout its thickness has been reduced to a set of variables by considering the energy-conversion relationship (ECR), the light transmitting properties of the RBC and the applied radiant energy. The results have shown that an ECR, derived from a single shade of RBC, can be used to predict conversion profiles for a range of shades at various exposure conditions. Specifically, the ECR describes the local energy density required to obtain a given normalized conversion at any depth in the material, independent of shade and reflects the combined polymerization efficiency of the monomer composition and photoinitiating system. The ECR has previously been described for other commercial RBCs using a thin film technique that predicts surface conversion (Halvorson & others, 2002). Predicting conversion within RBC using the thin film technique, however, is limited to exposure conditions that yield near maximum conversion. This limitation is possibly due to an inhibition mechanism and requires further investigation. Both techniques are consistent, though, in describing similar ECRs across different RBC compositions and both confirm reciprocity between time and irradiance. The similar ECRs are likely a consequence of the widespread use of resins based on the dimethacrylate, BIS-GMA and photoinitiator consisting of camphorquinone and amine.

For a given chemistry, the ECR suggests that transmission properties of the RBC ultimately determine the conversion profile and depth of cure. This is shown by the transmission curves for Z100 (Figure 2) and the predicted and experimental conversion profiles obtained with an 18 Jcm^{-2} exposure (Figure 4). The significance of similar ECRs across materials is shown for Herculite A3.5 and Z100 CY, where identical scrape-back lengths at an18 Jcm^{-2} exposure are predicted from their nearly identical transmission curves (Figure 2). The regression equations in Figure 2, that describe the exponential decrease in percent transmittance with depth, conform to the Lambert Law (Christian, 1977) and represent the combined effects of reflection, scattering and absorption. Analysis of the regression equations revealed that surface reflected radiation, identified by the y-intercept, is as much as 38% of the incident radiation. Thus, the maximum fractional conversion, observed in Figure 3 (relating to surface measurements in Figure 1), correspond to energy densities significantly less than the 18 Jcm^{-2} incident energy. This loss is considerable, though less than that measured for similar commercial RBCs

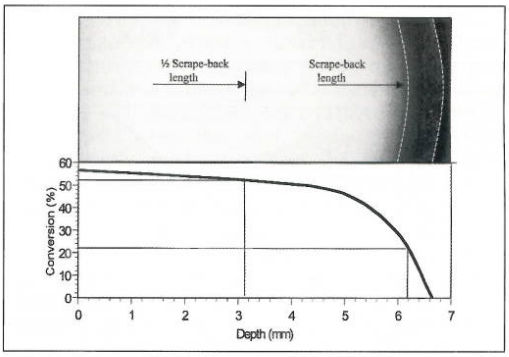

Figure 5: *Sample of Z100 A3.5 exposed with 18,000mJcm^{-2} (600mWcm^{-2}/30s) prepared as described for specimen dissection and FTIR analysis (24 hours). Sample has been stained with a dye (astra blue) that has an affinity for dimethacrylate monomers. The conversion profile for Z100-A3.5 depicted in Figure 1 and exposed under identical conditions is shown for comparison.*

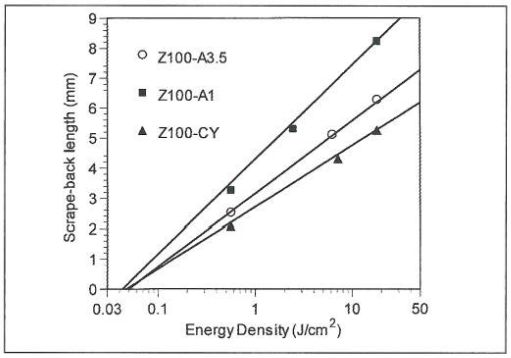

Figure 6: *Predicted scrape back lengths (solid lines) as a function of the incident energy density together with experimental values for the indicated shades of Z100.*

Table 2: *Predicted and Experimental Scrape-Back Lengths*

Material	Scrape-Back Length (mm) Predicted	Experimental	Energy Density ($mJcm^{-2}$)	Irradiance ($mWcm^{-2}$)	Exposure Time(s)
H-A3.5	NA	5.27 (0.07)	18,000	600	30
	5.30	5.29 (0.04)	18,000	250	72
	4.33	4.21 (0.08)	6160	560	11
	4.33	4.30 (0.10)	6160	310	20
	4.33	4.31 (0.14)	6160	170	37
	2.16	2.14 (0.08)	560	28	20
Z-A3.5	NA	6.19 (0.01)	18,000	600	30
	6.19	6.29 (0.19)	18,000	250	72
	5.07	5.06 (0.16)	6160	560	11
	5.07	5.14 (0.13)	6160	310	20
	5.07	5.16 (0.09)	6160	170	37
	2.54	2.54 (0.01)	560	28	20
Z-A1	8.23	8.09 (0.08)	18,000	600	30
	5.50	5.31(0.02)	2430	122	20
	3.50	3.27 (0.12)	560	28	20
Z-CY	5.27	5.26 (0.10)	18,000	600	30
	4.45	4.31(0.04)	7110	355	20
	2.20	2.10 (0.06)	560	28	20

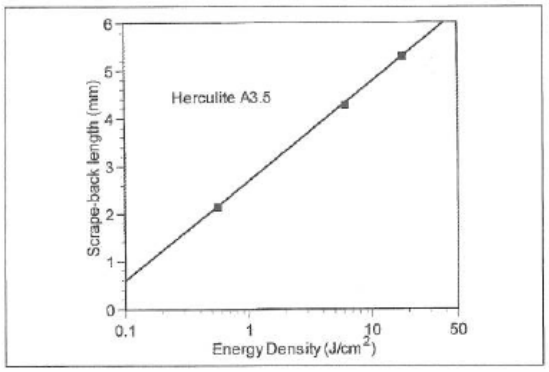

Figure 7: *Predicted scrape back lengths (solid line) as a function of the incident energy density together with experimental values for Herculite A3.5.*

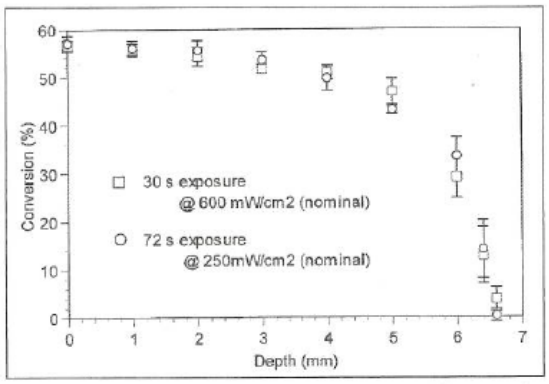

Figure 8: *Conversion profiles for Z100 A3.5 produced from samples exposed with equivalent doses.*

in another study (Watts & Cash, 1994). The effect of shade on attenuation reveals the expected result for Z100, showing progressively decreasing attenuation from the darkest (CY) to the lightest (A1) shade corresponding to a progressive change in opacity. However, shade designations, are not necessarily a predictor of the relative curing potential (Ferracane & others, 1986; Matsumoto & others, 1986). Similar shade designations of various commercial materials may show substantial differences in attenuation and depth of cure due to differences in opacity (Shortall, Wilson & Harrington, 1995) as indicated in Figure 1 for the A3.5 shades of Z100 and Herculite.

The value of the ECR as a predictive tool relies on the dose-dependent conversion and the reciprocal nature of irradiance and exposure time. The dose dependency has previously been described from a kinetic model of the free radical polymerization of methacrylates that relates depth of cure to the product of the intensity and exposure time (Cook, 1980; Cook, 1982). Support for reciprocity in this investigation is noted in the scrape back-values for the A3.5 shade of Herculite and Z100 light-cured with different irradiances and exposure times to yield total exposures of either 18 Jcm^{-2} or 6160 $mJcm^{-2}$ (Table 2), and with depth profiles for Z100 A3.5 shown in Figure 8. The latter compares the data in Figure 1 for Z100 A3.5 with the experimental data of the same material in Figure 4, where a 60% reduction in irradiance has been compensated for with an equivalent increase in exposure time. These results verify similar findings obtained for thin films over a multiple dose range (Halvorson & others, 2002). Additional evidence for the reciprocal irradiance/exposure time relationship has been presented for bulk-polymerized specimens (Nomoto & others, 1994; Miyazaki & others, 1996).

The usefulness of the ECR in predicting conversion profiles for various shades of RBC and various incident-curing exposures is demonstrated by the results shown in Figure 4. The predicted conversion profiles mostly agree with the measured values. An implicit assumption in predicting profiles for various shades of material is that there are no changes in the formulations of

monomer content or photoinitiator levels. This is generally a good assumption for commercially available materials.

The extent of cure at the terminus of the scrape-back sample has generally been considered to be significantly less than the maximum attained conversion. In studies characterizing the hardness or conversion profile through RBC, extrapolated depths at zero hardness or conversion were felt to correspond favorably to the length remaining after gently removing the uncured material (Cook, 1980; Nomoto & others, 1994). Under a kinetic model (Cook, 1980), the exposure energy at this depth relates to the minimum energy required to initiate polymerization. However, in this study, the scrape-back length corresponds to approximately 20% conversion and a related unique critical scrape-back energy of 32 $mJcm^{-2}$. This length obviously does not identify the minimum required polymerization energy. The latter can be identified by the split sample shown in Figure 5, where the sample terminates at a clearly visible delineation. This length corresponds to an energy density of approximately 21 $mJcm^{-2}$ for all the materials investigated. The difference in results between the current and the studies referenced above with respect to the extent of cure at the scrape-back terminus are, perhaps, related to a small inaccuracy in extrapolating conversion to the zero point (Nomoto & others, 1994) and the definition of the scrape-back conversion in the kinetic model (Cook, 1980). It is expected that even with great care to keep it intact, the gelled material, identified in Figure 5, will be readily lost during scrape-back. It is likely that the scrape-back length is determined by a degree of polymerization, where sufficient mechanical properties are developed to resist moderate abrasive forces and, in this study, this is characterized to be about 20-22% conversion. The scrape-back measurements have also demonstrated that the scrape-back length is logarithmically related to the exposure as shown in Figures 6 and 7, where the predicted cures and experimental values agree. This is reflective of the logarithmic attenuation of light intensity and its affect on free radical generation as described by the model referenced above (Cook, 1980).

Though the minimum cure required for maintenance of acceptable clinical performance of an RBC material is not known, a recommendation has evolved, based on comparative analysis of scrape-back, hardness, solubility and sorption measurements (Fan & others, 1986). From these measurements, the depth at one-half the scrape-back length corresponded to the depth at which the relative solubility started to increase and was marginally less than the depth corresponding to 80% of the maximum Knoop Hardness. The current ISO standard also defines an acceptable cure depth as one-half the scrape-back length as measured immediately after curing (International Organization for Standardization, 2000). In this study, this value corresponds to approximately 90% of the maximum measured conversion at 24 hours for the materials investigated. It should be noted that the test method defined by this standard was modified in this investigation to conform to the sample preparation for FTIR analysis. Scrape-back lengths determined using a 4-mm diameter mold as per the standard have been observed to be around 1/2 mm shorter than values described in this report (personal observation). Similar mold effects have been reported previously (Fan & others, 1984). While mold geometry may have an impact on scrape-back length, the cohesion at the scrape-back length is expected to represent a unique conversion independent of mold geometry. As shown, this conversion is approximately 20% for both materials and is expected to be similar for other RBCs formulated with similar chemistry.

Some results of this investigation are expected to depend on certain experimental conditions. Light transmission through the composite is likely to include interactions with the walls of the metal mold. In this investigation, such interactions are equalized by using the same mold materials and geometry throughout. Consequently, predictions from the described ECRs would be accurate only for samples prepared in similar molds; for different molds, new transmission curves would be needed for use with the ECR. The reaction temperature will have an impact on the final conversion attained in free-radical polymerization of RBC (Maffezzoli & others, 1994). Hence, ECRs derived from samples prepared at different temperatures may not correspond to those described here. The impact of different reaction temperatures may be minimized, however, by expressing the conversion relative to the maximum attained conversion as in Figure 3. However, it is expected that conversion at scrape-back will be unaffected by these experimental factors. Finally, ECRs derived from samples cured with plasma arc lamps or devices based on light-emitting diodes may be different due to radiated heat associated with the former and possibly greater polymerization efficiency of the latter.

CONCLUSIONS

This study has shown that an energy-conversion relationship that is predictive of the conversion profiles for a family of RBC materials under variable light-curing conditions can readily be determined. It has further been confirmed that depth of cure is logarithmically related to the energy of exposure and that reciprocity between time and irradiance still exists. From these results it is suggested that scrape-back lengths are correlated with about 20% to 22% conversion.

(Received 6 June 2002)

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Correlation between hardness and degree of conversion during the setting reaction of unfilled dental restorative resins

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Ferracane JL. Correlation between hardness and degree of conversion during the setting reaction of unfilled dental restorative resins. Dental Materials 1985; 1: 11–14.

Abstract. – Knoop hardness was correlated to degree of conversion (DC) of carbon double bonds, determined by IR, during the setting reaction of three unfilled dental resins. For a specific resin, increase in hardness correlates well with increases in DC during setting. However, an absolute hardness number cannot be used to predict a DC when comparing different resins. The two techniques for determining extent of cure in dental resins cannot always be used interchangeably, since each is sensitive to different variables.

Key words: hardness, degree of conversion, resins, composites, extent of cure.

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Accepted for publication 21 August 1984.

It is desirable for a dental restorative resin to convert all of its monomer to polymer during the polymerization reaction. However, with Bis-GMA-based resins there is always a significant concentration of unreacted carbon double bonds remaining in the resin when it is cured at or near the oral temperature. This is believed to be due mainly to limitations on the mobility of reactive species imposed by the rapid formation of a cross-linked polymeric network. Since the extent of cure may exert an effect on nearly every physical property of the resin system (including: mechanical properties, solubility, dimensional stability, color change and biocompatibility), degree of conversion may play an important role in determining the ultimate success of the restorative.

The degree of conversion in Bis-GMA-based restorative resins has been analyzed with infrared spectroscopy by several researchers and has been shown to be in the range of 50 to 80% (1–4). However, it is common practice to measure mechanical properties as a means of indirectly evaluating degree of cure.

In 1982, Tirtha *et al.* (5) evaluated the Barcol hardness and transverse strength of a series of light-cured dental composite resins to determine depth of cure. Barcol hardness was also used by Leung *et al.* (6) to determine depth of cure in visible light-cured composites as a function of curing and illumination time. Although there are several more reports in the literature in which degree of cure has been evaluated indirectly by measuring mechanical properties, there are only a few studies which have compared these indirect modes to IR techniques.

Asmussen (7) reported a good correlation between Wallace hardness, diametral tensile strength and degree of conversion by IR for experimental composite formulations in 1982. More recently, Ferracane (8) measured the degree of conversion in unfilled resins by IR and correlated the results with those obtained from tests of several mechanical properties. He found a good correlation between the degree of conversion and the storage modulus and glass transition temperature results obtained by performing dynamic mechanical testing over a broad temperature range. The correlation between degree of conversion and ambient temperature properties was not as strong, however.

Objectives

The objective of this study was to determine the nature of the correlation between the Knoop hardness and the degree of conversion of carbon double bonds, as determined by IR analysis, for unfilled dental restorative resins. An attempt was also made to compare the time frames at which maximum hardness and degree of conversion are acquired in these quick-setting resins.

Methods

Three commercially available, chemically-cured Bis-GMA-based resins were used in this study. They were: Delton Pit and Fissure Sealant (Johnson & Johnson, East Windsor, NJ), Profile bonding agent (S. S. White Dental Products International, Philadelphia, PA) and Concise Enamel Bond (Dental Products/3M, St. Paul, MN). The Profile bonding agent (Profile BA) and the Concise Enamel Bond (Concise EB) were supplied with their respective composite resin restoratives. These unfilled resins were chosen on the basis of differences in monomer compositions (9) and viscosities, which were expected to produce

resins with differences in degree of conversion (8).

The degree of conversion (DC) was analyzed with a Fourier Transform Inrared (FTIR) Spectrometer (FX6250-Analect Instruments, Irvine, CA) in transmission mode. The conversion during the first 30 min of the reaction was followed by polymerizing the resin between AgCl windows in the path of the IR. Spectra were acquired at time intervals of 1 min, 2 min, 3 min, 4 min, 5 min, 10 min, 20 min and 30 min under a nitrogen gas purge to insure a clean, stable background*. During this time period, the temperature in the specimen chamber rose from 34°C to 40°C. Three runs were made for each resin system.

The DC values for the curing periods of 60 min, 120 min, 6 h and 24 h were determined by polymerizing a drop of mixed resin between glass slides at 37°C for the appropriate time period. A thin resin film (20–40 μm) was produced in this manner. These films were peeled from the slides and analyzed on the FTIR in transmission, according to a procedure outlined in detail previously (4). Three films were tested for each resin at each time period.

The DC was calculated by comparing the absorbance ratio of the C = C peak at 1640 cm^{-1} to the unchanging aromatic ring peak at 1610 cm^{-1} for the pre- and post-polymerized resins, using standard baseline procedures (2, 4).

Specimens were made for Knoop hardness (KHN) testing by curing the resins in a 6 mm × 3 mm steel disk mold for the appropriate time periods (5 min, 10 min, 20 min, 30 min, 60 min, 120 min, 6 h and 24 h) at 37°C. The specimens were sanded flat with 320 emery paper before the initial test to insure that any air-inhibited surface layer of resin had been removed. At least 10 specimens were made for each resin. An individual specimen was tested at alternate time periods to insure that it had been allowed to cure at 37°C for the entire specified time before testing. Each hardness reading was made at 23°C under a 100 g load on a Tukon hardness tester (Page-Wilson Corp., Bridgeport, Conn.) using a Knoop diamond indenter. At least five values were recorded at each time interval from five different specimens for each resin.

The DC and hardness results were analyzed by analysis of variance and Scheffes test for making multiple comparisons between unconfounded means at the $p \leq 0.05$ level (10). Regression analysis was performed to determine the correlation between DC and KHN. The correlation coefficient was analyzed for significance at the $p \leq 0.05$ level using a t-test for each resin (11).

* Collection of the spectra took approximately 30 sec at each time period.

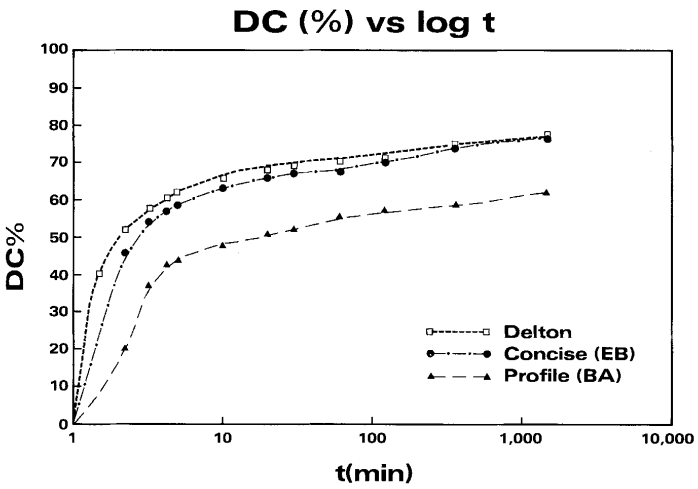

Fig. 1. Degree of Conversion (DC) vs. log time for three unfilled resins. Each point represents an average of three values.

Results

The three self-curing unfilled resins hardened very rapidly, with initial setting times of approximately 1½ min for Delton and Concise (EB) and 2 min for Profile (BA). Analysis of the DC with respect to time (Fig. 1) revealed that initial setting occurred when fewer than 40% of the available carbon double bonds had reacted in these systems. After the first 5 to 10 min of curing, the increase in DC was approximately linear with time through 24 h. No increase in DC was observed for any resin at 48 h. Therefore, DC at 24

Table 1. Hardness (KHN) vs DC during setting

Time	Delton		Profile (BA)		Concise (EB)	
	DC (%)*	KHN (kg/mm²)+	DC	KHN	DC	KHN
5 min	62.4±2.0	9.8±0.2	43.4±2.8	8.1±0.8	58.5±1.0	6.4±0.3
10 min	65.8±0.7	10.0±0.9	47.5±1.6	9.4±0.9	62.7±1.3	7.6±0.3
20 min	68.2±0.7	10.9±0.9	50.6±1.9	10.6±0.5	66.0±1.4	9.1±0.7
30 min	69.4±0.7	12.0±0.7	51.8±1.5	11.2±0.4	66.9±2.0	9.7±0.2
60 min	70.5±0.6	13.3±0.8	55.7±0.5	13.1±0.5	67.7±1.1	11.2±0.4
120 min	71.2±0.7	14.9±0.9	57.2±0.9	15.3±0.6	70.1±0.3	12.7±0.5
6 h	74.7±0.5	19.0±1.0	58.6±0.2	18.2±1.4	72.2±0.7	17.5±0.3
24 h	77.6±1.8	18.6±1.5	62.0±0.8	18.9±0.8	76.9±0.6	17.6±0.7

Values are mean ± standard deviation.
Means connected by bars were not significantly different ($p \leq 0.05$).
* b = 2.
\+ b ≥ 5.

h will be referred to as maximum DC.

The DC values at 24 h were equivalent for Delton and Concise (EB) and were approximately 15% greater than that of Profile (BA) (Table 1). Despite the differences in DC between the resins, there were no significant differences between the hardness values at 24 h. In fact, the hardness values for Delton and Profile (BA) were statistically equivalent at all time periods, even though the DC was always 15 to 20% greater for Delton. The hardness of Concise (EB) was significantly lower than that of Delton at 5 and 10 min and at 30 through 120 min, but the DC values for the two resins were statistically equivalent at all time periods.

It is apparent from the results in Table 1 that both the hardness and DC continue to increase with time after setting for these resins. However, the acquisition of maximum (24 h) hardness and DC are not synchronized. Fig. 2 reveals that at 5 min, DC for Delton has reached 70–80% of its maximum value, while less than 55% of the maximum hardness has been attained. Both properties showed rather linear increases with time from 10 min to 6 h, but the slope for hardness was much greater. The curves for Profile (BA) and Concise (EB) were similar to that for Delton. There was no significant increase in hardness beyond 6 h, and the only significant increase in DC after 6 h occurred with Concise (EB).

Regression analysis revealed a strong ($r \geq 0.937$) and significant ($p \leq 0.05$) correlation between DC and hardness with time for all three resins (Fig. 3). However, the correlation between hardness and DC was very poor ($r = 0.498$) when the regression analysis was repeated to include all three resins at all time periods (Fig. 3).

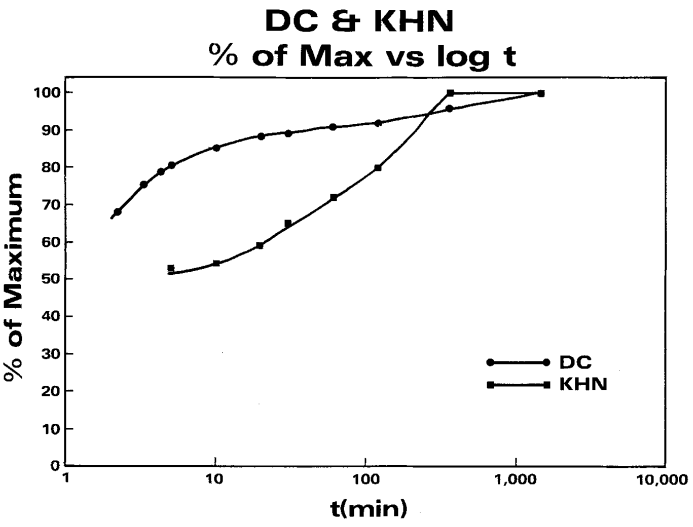

Fig. 2. Comparison of the percent of maximum DC and maximum hardness (KHN) vs. log time for Delton. Each point represents an average of three values for DC and at least 5 values for KHN.

Discussion

For a dental restorative resin, there appears to be a good correlation between increasing hardness and increasing degree of conversion during the setting reaction. However, the acquisition of hardness chronologically lags behind the conversion of carbon double bonds. The mechanical properties of these resins are influenced by the crosslinking and network formation taking place during setting. This network formation occurs after an initial stage of polymer chain propagation (12). A much greater percentage of carbon double bonds are reacted to form polymer chains than are reacted to crosslink existing chains. Therefore, the greatest increase in hardness occurs during a period in which very subtle changes in DC take place, i.e. after 85% of the total conversion has been achieved.

Despite the correlation between hardness and DC during setting, a specific hardness value cannot be correlated to a specific DC when comparing different resin formulations. For example, Delton achieves a DC of 62.4% at 5 min with a hardness value of 9.8 KHN. Concise (EB) achieves 62.7% conversion at 10 min, with a hardness value of 7.6 KHN. The maximum DC for Profile (BA) is

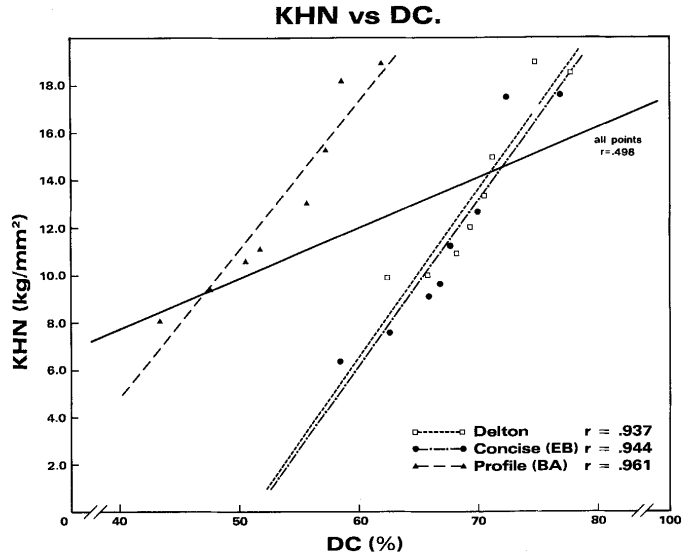

Fig. 3. Correlation between KHN and DC for three individual resins and for all resins combined (solid line). Each point represents an average value for the different time periods.

62.0%. At this DC, Profile (BA) has a hardness of 18.9, approximately twice that of Delton and Concise (EB). Although the higher concentration of BIS-GMA in Profile (BA) contributes to its higher viscosity and to a lower DC (8), the hardness at ambient temperature is not similarly reduced. The discrepancy lies in the nature of the two experiments.

Infrared spectroscopic analysis of the degree of conversion of monomer to polymer in dental resins is a very accurate and reproducible technique. However, the conversion of a carbon double bond to a single bond during the setting of dimethacrylate resins may occur via several mechanisms, including: chain elongation, cross-linking, reaction with initiator radicals.

As stated previously, the mechanical properties of a resin system are very much dependent upon the cross-linking density and the quality of the network which forms during polymerization. Of less importance is the overall conversion of reactive species. The two modes for evaluating degree of cure are sensitive to different variables. Therefore, it is possible that two resins with significantly different degrees of conversion may have identical properties when tested at ambient temperature, as has been shown previously (8) and in this study. This restricts the use of indirect modes for testing degree of conversion. It would not be correct to indirectly determine the degree of cure in two different resin systems by evaluating their hardness, when one is interested in the effect of residual reactive species on biocompatibility or dimensional change.

Conclusions

The acquisition of hardness during the setting of unfillled dental restorative resins correlates well with the increase in degree of conversion for a specific resin. However, an absolute hardness value cannot be used to predict an absolute value for degree of conversion in all resins. This is due to the fact that the mechanical properties of the resin are very much dependent upon network formation, which is not equivalent to conversion in these materials. Therefore, indirect methods for measuring the degree of cure for comparison among resins are limited. It does appear to be valid, however, to use these indirect tests to predict the relative degree of conversion for a specific resin at different time periods or under variable conditions.

Acknowledgements – The author would like to thank Analect Instruments, Irvine, CA for the use of the FX6250 FTIR spectrophotometer used in this study.

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23.3 **Bouschlicher M, Rueggeberg F, Wilson B, Correlation of bottom-to-**top surface microhardness and conversion ratios for a variety of resin composite compositions. Oper Dent 2004; 29:698-704.

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Correlation of Bottom-to-Top Surface Microhardness and Conversion Ratios for a Variety of Resin Composite Compositions

MR Bouschlicher • FA Rueggeberg • BM Wilson

Clinical Relevance

Bottom-to-top surface Knoop hardness ratios (B/T-KHN) of resin composite samples were highly correlated with bottom-to-top degree of conversion ratios (B/T-DC) and were independent of filler type and filler loading for the three composites tested. B/T-KHN ratios, therefore, provide an accurate, simple method of assessing the efficacy of photoinitiation strategies (curing light/exposure duration) instead of using more complex FTIR methods to determine degree of conversion.

SUMMARY

Knoop microhardness (KHN) and degree of conversion (DC) values were obtained from the bottom and top surfaces of 1-, 2- and 3-mm thick samples of three types of resin composite: an anterior microfill, an anterior hybrid and a posterior hybrid, all having differing filler size and loading but similar shade (A2) and basic monomeric content. Sample infrared spectra were obtained using attenuated total reflectance (ATR) in a Fourier transform infrared (FTIR) spectrometer. The samples were exposed using a 40-second exposure to a quartz-tungsten-halogen light source with an irradiance of ≈ 560 mW/cm². They were stored for 24 hours in complete darkness at 37°C and 100% humidity prior to obtaining cured spectra and KHN readings. KHN and DC values were obtained from the same sample specimen made at similar surface depths, but separate groups were made for obtaining top and bottom values. Cure and hardness data were analyzed with one- and two-way ANOVAs followed by the Tukey-Kramer post-hoc test. Linear regression was also applied. Statistical testing was performed at a pre-set 0.05 level of significance. KHN and DC were significantly different according to composite type and depth (p=0.0001), with an interaction effect (p=0.0022). KHN, DC and corresponding bottom/top surface (B/T) ratios decreased with depth. Regression revealed a linear relationship between DC and KHN for each composite type, with no r^2 less than 0.96. When B/T ratios were correlated, a B/T-KHN ratio of 0.80 corresponded to a narrow range of B/T-DC

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ratios (between 88 to 91%) for the three composites tested. When combining results from composite types, linear regression of B/T-DC and B/T-KHN produced a very predictable relationship (r^2=0.959), for which a B/T-KHN ratio of 0.80 corresponded to a B/T-DC ratio of 0.90. As a measure of completeness of conversion, B/T-KHN was approximately 2.5 times more sensitive than the B/T-DC ratio. In summary, while KHN cannot be used to directly compare conversion of the different composites tested, the use of B/T ratios for both hardness and conversion resulted in a linear relationship independent of filler size or loading.

INTRODUCTION

The physical properties of resin composites are related to filler type, size and loading (Chung, 1990; Kim, Ong & Okuno, 2002; Suh, Ferber & Baez, 1990) and are tailored for the intended clinical use as either anterior or posterior restorations. The intended area of usage has traditionally included a tradeoff between composite polishability and strength, based on filler size (microfill or hybrid) and loading. Composite physical properties are also dependent on the degree of conversion of the resin matrix (DC) (Asmussen, 1982a; Ferracane & Greener, 1986; Rueggeberg & Craig, 1988). DC can be assessed by indirect measures, such as scrape-back length (Cook, 1980) and microhardness testing (DeWald & Ferracane, 1987), or by direct methods, such as infrared spectroscopy (Asmussen, 1982a,b; Eliades, Vougiouklakis & Caputo, 1987; Ferracane & Greener, 1984; Rueggeberg & Craig, 1988; Ruyter & Svendsen, 1978). However, the indirect methods cannot be used to directly compare composites with differing monomer composition, filler type and size or loading (Chung 1990; Ferracane, 1985). Additionally, differing comonomers in the resin matrix may result in composition-dependent variation in the maximum DC achievable (Ferracane & Greener, 1986). Both matrix and filler characteristics affect absolute post-cure DC and hardness (Asmussen, 1982; Chung 1990). A positive correlation has been established between composite hardness and inorganic filler content (Chung, 1990; Raptis, Fan & Powers, 1979). Ferracane (1985) demonstrated good correlation between increasing hardness and increasing DC but concluded that an absolute hardness number could not be used to predict DC when different composites were compared. In fact, DC declines more rapidly than hardness with increasing sample depth (DeWald & Ferracane, 1987; Eliades & others, 1987; Rueggeberg & Craig, 1988).

Curing light irradiance, exposure duration and composite light transmission are variables significantly affecting hardness and conversion profiles with sample depth (Halvorson, Erickson & Davidson, 2003). Bottom-to-top (B/T) hardness ratios ranging from 0.80-0.90 have been used as criteria for adequate conversion at a specific sample depth (DeWald & Ferracane, 1987; Johnston, Leung & Fan, 1985). Johnston and others (1985) used composite samples with significantly different hardness and described the use of B/T ratios as a means of circumventing composite-specific hardness properties. These ratios are considered to reflect the relative extent of conversion of a deeper surface to that of the top exposed surface, but this assumption has never been validated directly.

To date, B/T-hardness ratios have not been directly correlated with B/T-DC ratios. B/T-hardness or DC ratios may be independent of filler content if they are normalized relative to the maximum obtainable value for a specific material (maximal hardness or DC achieved at the sample's top, exposed surface).

This study explores the relationship between B/T-microhardness and B/T-degree of conversion ratios of three commercially available composites selected for having similar co-monomer composition but different filler content (particle size and loading). The correlation of B/T ratios for DC with those for hardness may establish a composition-independent relationship between B/T-hardness and B/T-DC ratios and validate use of the simpler microhardness hardness test over that of a more complex method used to determine monomer conversion.

METHODS AND MATERIALS

Samples 1, 2 and 3 mm in thickness (n=5) were fabricated from a variety of commercially available, photocured resin composites having similar shade (A2), resin matrix and photoinitiator but differing in filler size proportion and weight percent loading (Table 1): anterior hybrid (AH), anterior microfill (AM) and posterior hybrid (P) composites (Matrixx AM, AH and P, Discus Dental, Culver City, CA, USA). Composite was expressed into 6-mm diameter cylindrical brass rings atop a Mylar strip on a glass slide. The uncured samples were inverted and pressed against the diamond element of a horizontal attenuated total reflectance (ATR) attachment (Golden Gate, SPECAC, Inc, Smyrna, GA, USA) in a Fourier Transform Infrared (FTIR) spectrophotometer (FTS-40, Digilab, Bio-Rad, Cambridge, MA, USA). A quartz-tungsten-halogen light curing unit (Optilux 501, Kerr/Demetron, Danbury, CT, USA) with an 8-mm diameter light guide (irradiance ≈ 560 mW/cm^2) was positioned 1 mm above the Mylar surface of each sample, and an individual, uncured spectra consisting of 16 scans was obtained at 2 cm^{-1} resolution. Irradiance was monitored periodically by using a hand held digital dental curing radiometer (Hilux Curing Light Meter, pn 950-700, Benlioglu Dental Inc, Ankara, Turkey). Samples were exposed directly on the ATR for 40 seconds. After five minutes,

the samples were removed and stored for 24 hours in complete darkness at 37°C and 100% humidity prior to determining the degree of conversion (DC) and Knoop hardness (KHN). After 24 hours, cured spectra and microhardness values were obtained from the readily identifiable smooth-surface area left by contact of the composite with the ATR crystal. To ensure adaptation of the cured samples to the diamond surface when obtaining cured spectra, a standardized torque of 85 cN-M was applied using a torque driver (Torqueleader, Model: Quickset Minor, MHH Engineering Co LTD, Surrey, UK). DC was calculated by comparing the ratio of aliphatic carbon-to-carbon double bonds (C=C) at 1636 cm^{-1} and aromatic C=C at 1608 cm^{-1} in the cured and uncured states (Rueggeberg & Craig, 1988).

Table 1: *Approximate wt-% Compositions of Composites Tested**

Components (wt-%)	Anterior Hybrid (AH)	Anterior Microfill (AM)	Posterior Hybrid (P)
Bis-GMA	<10	<10	<10
UDMA	<20	<15	<10
TEGDMA	<10	<20	<5
Ba-glass filler	<65	<40	<65
Silica filler	<25	<40	<25
Others	0.5	0.5	0.5
Lot #	02085016	01201020	02098027

*approximate wt-% data supplied by manufacturer; vol-% unavailable from manufacturer
Products are all part of the Matrixx Composite system, distributed by Discus Dental, Culver City, CA, USA

Surface microhardness indentations for Knoop hardness (KHN) were made with a Tukon hardness tester using a load of 0.5Kg and 10x magnification (Knoop attachment, model MO, Wilson Instrument Division, American Chain and Cable Co, Inc, New York, NY, USA) within the sampling area used for DC measurements. After measuring DC values, the samples were flush mounted with heated dental compound (impression compound, Type 1, Gray, pn 00455, Kerr Manufacturing, Romulus, MI, USA) in a gimbaled holder, allowing the test surface to be easily positioned rigidly at right angles to the hardness indenter. Indentation lengths were measured digitally from stored images (NIH Image software, version 1.61, National Institutes of Health, Bethesda, MD, USA). Knoop hardness values were then calculated from the lengths of the indentation readings using standard formulas.

Since heat from the molding compound could have altered the DC and KHN values if both the top and bottom surfaces of the same sample had been tested, a separate group of 1-mm thick, top-surface-only samples was made. These samples were prepared and treated as described above, except that the bottom surface was embedded in compound and cured spectra and KHN readings were obtained from the top surface only. The two different sample groups (bottom and top) were then used to calculate B/T surface ratios of 1-, 2- and 3-mm samples for both DC and KHN.

Data were analyzed using one-way and two-way analysis of variance with the Tukey-Kramer post-hoc test for pair-wise comparison. Linear regression analysis was also performed. All statistical testing was made at a pre-set 0.05 level of significance.

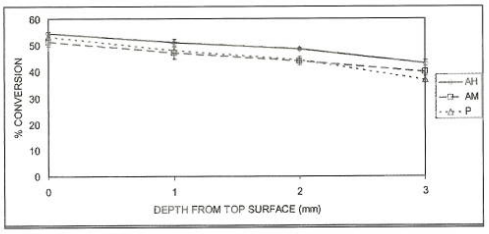

Figure 1A. *Composite conversion as a function of depth from top surface (1, 2, and 3 mm) for AH, AM and P composites. Degree of conversion (DC) decreased with depth for all composites. Vertical bars = ±1 standard deviation. N = 5 samples per group.*

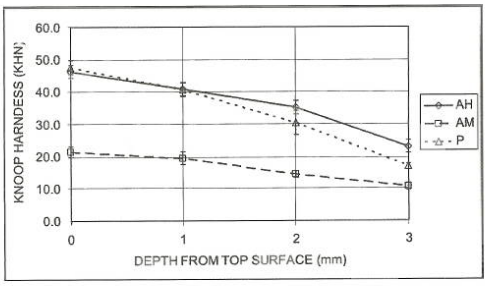

Figure 1B. *KHN as a function of depth from top surface (1, 2 and 3 mm) for AH, AM, and P composites. KHN of all composites decreased with depth. AM had the lowest KHN at all depths. Vertical bars = ±1 standard deviation. N = 5 samples per group.*

RESULTS

The two-way ANOVA showed that both DC and KHN were significantly different according to composite type and depth (p=0.0001), with a significant interaction effect (p=0.0022). Both KHN and DC decreased with increasing sample thickness (depth) (Figures 1A and 1B). One-way ANOVA showed that DC was significantly different among composite types at each depth, with the exception of the 1- and 2-mm depths of AH (Table 2). KHN also decreased significantly with an increase in depth for all materials, with the exception of the top surface and 1-mm depth of AM (Table 2).

Table 2: *One-way ANOVA and Tukey Post-hoc Statistical Results* Summary for Effects of Depth*

Depth	Effect of Composite on DC			Effect of Composite on KHN			Effect of Composite on BT/DC			Effect of Composite on BT/KHN		
Composite	AH	P	AM	P	AH	M						
Top Mean	54.6	53.3	51.3	47.6	46.4	21.4	-			-		
(SD)	(0.7)	(0.7)	(1.7)	(2.4)	(1.8)	(1.7)						
Composite	AH	P	AM	AH	P	AM	AH	AM	P	AM	AH	P
1 mm Mean	51.2	48.1	47.1	41.0	40.6	19.4	93.9	92.0	90.2	90.6	88.2	85.6
(SD)	(1.6)	(1.4)	(2.1)	(2.0)	(1.9)	(2.1)	(3.0)	(4.2)	(2.6)	(9.0)	(4.3)	(4.3)
Composite	AH	P	AM	AH	P	AM	AH	AM	P	AH	AM	P
2 mm Mean	48.4	44.4	44.1	35.0	30.4	14.2	88.9	85.9	83.2	75.7	67.0	63.7
(SD)	(0.4)	(1.3)	(1.7)	(2.0)	(3.8)	(1.1)	(0.7)	(3.3)	(2.4)	(4.2)	(5.4)	(7.9)
Composite	AH	AM	P	AH	P	AM	AH	AM	P	AH	AM	P
3 mm Mean	43.0	39.5	36.6	22.8	16.6	10.4	78.8	77.1	68.5	49.0	48.3	34.7
(SD)	(1.2)	(1.4)	(1.5)	(1.9)	(1.1)	(0.9)	(2.3)	(2.6)	(2.8)	(4.1)	(4.4)	(24.0)

**Pre-set level of significance = 0.05; horizontal bar indicates groups that were not significantly different.*

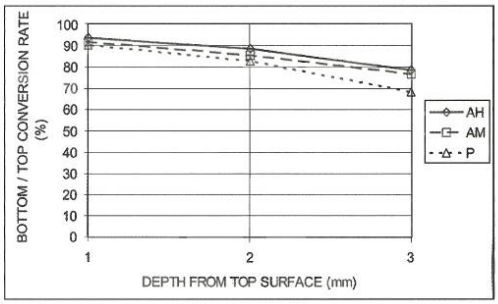

Figure 2A. *B/T degree of conversion (DC) as a function of depth from top surface (1, 2 and 3 mm) for AH, AM, and P composites. B/T-DC decreased with depth for all composites. DC of P was lowest and decreased with depth faster than AM or AH.1*

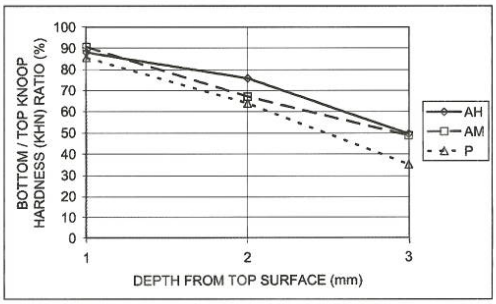

Figure 2B. *B/T-KHN as a function of depth from top surface (1, 2 and 3 mm) for AH, AM, and P composites. B/T-KHN decreased with depth for all composites. B/T-KHN of P was lowest and decreased with depth faster than AM or AH.*

Table 3: *One-way ANOVA and Tukey Post-hoc Statistical Results* Summary for Effects of Composite Type*

Composite		Effect of Depth on DC				Effect of Depth on KHN				Effect of Depth on BT/DC			Effect of Depth on BT/KHN		
Combined	Depth	Top	1 mm	2 mm	3 mm										
	Mean	53.1	48.8	45.7	39.5										
	(SD)	(1.8)	(2.4)	(2.4)	(3.0)										
AH	Depth	Top	1 mm	2 mm	3 mm	Top	1 mm	2 mm	3 mm	1 mm	2 mm	3 mm	1 mm	2 mm	3 mm
	Mean	54.6	51.2	48.0	43.0	46.4	41.0	35.0	22.8	93.9	88.9	78.8	88.2	75.7	49.0
	(SD)	(0.7)	(1.6)	(0.4)	(1.2)	(1.8)	(2.0)	(2.0)	(1.9)	(3.0)	(0.7)	(2.3)	(4.3)	(4.2)	(4.1)
AM	Depth	Top	1 mm	2 mm	3 mm	Top	1 mm	2 mm	3 mm	1 mm	2 mm	3 mm	1 mm	2 mm	3 mm
	Mean	51.3	47.1	44.0	39.5	21.4	19.4	14.2	10.4	92.0	85.9	77.1	90.7	67.0	48.3
	(SD)	(1.7)	(2.1)	(1.7)	(1.4)	(1.7)	(2.1)	(1.1)	(0.9)	(4.2)	(3.3)	(2.6)	(9.0)	(5.4)	(4.4)
P	Depth	Top	1 mm	2 mm	3 mm	Top	1 mm	2 mm	3 mm	1 mm	2 mm	3 mm	1 mm	2 mm	3 mm
	Mean	53.0	48.1	44.4	36.6	47.6	40.6	30.4	16.6	90.2	83.2	68.5	85.6	63.7	34.7
	(SD)	(0.7)	(1.4)	(1.3)	(1.5)	(2.4)	(1.9)	(3.8)	(1.1)	(2.6)	(2.4)	(2.8)	(4.3)	(7.9)	(2.0)

**Pre-set level of significance = 0.05; horizontal bar indicates groups that were not significantly different.*

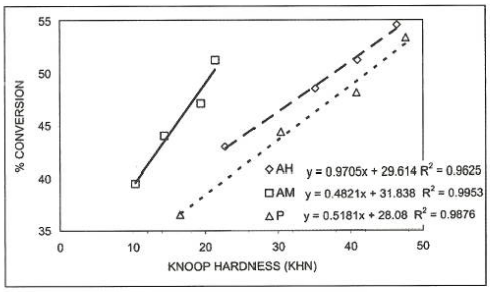

Figure 3. *Relationship between microhardness (KHN) and degree of conversion (DC) at top surface (0 mm), 1-, 2- and 3-mm depths for AH, AM and P composites.*

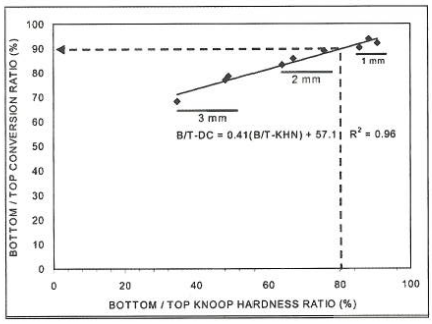

Figure 5. *Combined linear regression, relationship between B/T-KHN and B/T-DC at 1-, 2- and 3-mm depths for three composites: AM, AH and P. A B/T-KHN of 0.80 (80%) corresponds to a B/T-DC of 0.90 (90%).*

Bottom/top degree of conversion ratios (B/T-DC) decreased with increasing depth (sample thickness) (Figure 2A). B/T-DC ratios were significantly different at each depth among all materials (Table 2). Bottom/top hardness ratios (B/T-KHN) also decreased with increasing depth (sample thickness) (Figure 2B) and were significantly different at each depth among all materials (Table 2).

AH had the highest DC at 1- to 3-mm depths, while AM had the lowest hardness at all depths (Table 3). The B/T-KHN and B/T-DC ratios of AH were statistically similar to AM at all depths. The B/T-KHN and B/T-DC ratios of P were statistically different from AH at 2 mm and P<AH and AM at 3 mm. The plotted relationship between KHN and DC varies widely by composite type as shown in Figure 3. However, when B/T-KHN ratios were plotted against B/T-DC ratios (Figure 4), the resulting linear regression equations for all three composites had similar intercepts and slopes with r^2 values ranging from 0.9695 to 0.9999. The 80% B/T hardness ratio, often used as a criterion for adequate depth of

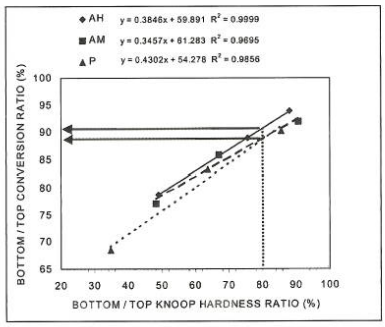

Figure 4. *Relationship between B/T-KHN and B/T-DC ratios among 1-, 2- 3-mm depths for the three composites AM, AH, and P. A B/T-KHN ratio of 0.80 (80%) corresponded to a B/TDC ratio between 0.89 and 0.91 (89 to 91%). Regression equations resulted in $r^2 \geq 0.97$.*

cure, corresponded to B/T-DC ratios between 0.89 and 0.91 for all composites tested. Linear regression of B/T-DC and B/T-KHN, when combining results from all three composite types (Figure 5), resulted in a relationship where a B/T-KHN ratio of 80% corresponded to a B/T-DC ratio of 90% (r^2=0.959).

DISCUSSION

As expected, Knoop hardness and degree of conversion decreased with increasing sample depth. Both parameters also varied with composite type. Most clinicians are aware that microfills are typically more difficult to adequately cure than their hybrid counterparts, requiring additional exposure duration. The smaller filler particles in microfills are most likely to scatter light, especially those similar in size to wavelengths of light emitted from the curing source. It was assumed that the 0.04 µm diameter fumed silica filler particles used in the AM would result in higher light attenuation than the filler particles used in hybrids. Surprisingly, the DC of AM was similar to the P hybrid at 1-mm and 2-mm depths and was statistically higher than P at 3-mm depth. While the resin matrix constituents (Bis-GMA, UDMA, TEGDMA) were similar for all three composites, the wt-% concentration of TEGDMA varied the most between P (<5 wt-%) and AM (<20 wt-%). This higher TEGDMA concentration, a low molecular weight comonomer diluent that increases the monomer's mobility/reactivity by decreasing resin viscosity, was probably responsible for the unexpectedly high DC of the AM relative to P (Lovell, Newman & Bowman, 1999).

The relationship between monomer conversion and inorganic filler loading is inversely proportional, as light transmission decreases with increased filler loading (Barron, Rueggeberg & Schuster, 1992). Since the AH and P products had similar filler loading, one would

have expected similar KHNs and DC based on their similar resin matrix and filler compositions (Table 1). However, anterior hybrid (AH) had the highest DC of the three materials at all depths. with DC at the top surface and at 1-mm depth of AH being statistically similar. While the anterior hybrid's DC was greater than the posterior hybrid (P) at 1-, 2- and 3-mm depths, the DC of the top surface of these two materials was similar. Similar DC of these two materials at the top surface, where equivalent radiant energy was applied, suggests that the lower DC of the posterior hybrid at depth is the result of lower levels of available radiant energy, as the intensity of transmitted light versus composite thickness obeys the Lambert equation (Cook, 1980). The higher overall degree of conversion and the similarity in conversion between the top surface and 1-mm depth of AH is probably due to the higher translucency (light transmission) of this material, which was designed to serve primarily as an enamel replacement in anterior teeth.

As expected, AM had the lowest KHN at all depths. There is a significant correlation between volume fraction of filler and Knoop hardness (Chung & Greener, 1990), and since AM filler loading (<80 Wt-%) was lower than that of AH and P hybrids (<90 Wt-%), it would be expected that AM would have the lowest KHN at all depths. Also, what constitutes "filler particles" in a microfilled material is often nebulous. One could measure only inorganic material, or also take the combined inorganic content along with the amount of prepolymerized ground fillers, as well. Doing so would result in vastly different values for filler content in the same material.

Accordingly, hardness numbers cannot be used to directly compare composites with differing filler type, size or loading. This concept is illustrated by the plots of the relationship between KHN and DC for the three composites tested (Figure 3). The slope of the regression equation for AM was decidedly different from the others and occupies an entirely different location distinct from those of AH and P. AH and P had similar slopes due to similar filler size and loading values. Again, the effects of sample depth and, thus, light attenuation, had a more dramatic effect on P, as evidenced by the more extended range of KHN vs DC values plotted. The markedly lower range of hardness values plotted for AM does not overlap the lower end of the range of AH values, even though most of the DC values overlap. This finding is in agreement with Chung and Greener (1990), who found no correlation between degree of conversion and mechanical properties of resin composite.

The use of B/T ratios normalizes the plotted relationship between hardness and DC relative to the maximal parameter value obtainable at the sample's top surface, irrespective of composite composition. The relationship between B/T-KHN and B/T-DC (Figure 4) supports the use of B/T hardness as an accurate indirect measure of B/T-DC for individual composites. Linear regression, showing the relationship between B/T-KHN and B/T-DC at 1-, 2- and 3-mm depths for all three composites (Figure 5,) demonstrates that a 0.80 B/T-KHN ratio corresponds to 0.90 B/T-DC or 90% of maximum conversion possible at the composite's top surface. Figure 5 also illustrates that adequate physical properties only coincide with higher degrees of conversion as B/T-DC increases from 0.70 to 0.95, while B/T-KHN increases from 0.35 to 0.90. Within the range tested, B/T-KHN is approximately 2.5 times (1.0/0.41—slope of the regression analysis in Figure 5) more sensitive than B/T-DC as an index of percent maximum cure obtainable at the composite's top surface.

Since the plotted relationship between ratios in Figure 5 was independent of composite filler type, one can make direct comparisons of the adequacy of composite cure with similar resin matrix but different filler content by using B/T-KHN ratios. This method allows for rapid but accurate assessment of photoinitiation strategies with the more easily performed B/T-KHN ratios. The ease of sample preparation and the use of less costly test equipment make this technique more widely applicable than complex, costly FTIR methods. B/T hardness ratios can be used to compare the relative extent of cure of different composites with different curing strategies, as long as each composite is normalized for maximal hardness (conversion) at the sample's top surface. Maximal hardness would be obtained by ensuring the top surface conversion process could go no further, requiring exposure duration exceeding that which is recommended by the manufacturer. Thus, caution should be exercised with use of ratioed values. If the top surface demonstrates higher hardness than that of a deeper surface, but the to surface has not yet reached a maximal value, both the numerator and denominator are increasing concurrently and high ratios may occur over a range of radiant exposures (mJ/cm^2) before the stop surface reaches an asymptotic value. Also, only microhardness testing was used in this study to evaluate the correlation between hardness and conversion values. The use of other hardness methods may not provide similar results and should be tested as well.

CONCLUSIONS

The simpler methodology used to obtain the bottom-to-top surface microhardness hardness ratios of a variety of composite materials proved to be an accurate, indirect reflection of bottom-to-top degree of conversion ratios. Both bottom-to-top microhardness and degree of conversion ratios were independent of composite composition, with respect to the three composites tested.

Thus, bottom-to-top surface microhardness ratios can be used as a simple test for adequate polymerization at a given sample depth independent of composite composition, with respect to the composites tested.

(Received 7 August 2003)

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23.4 **Ernst CP, Meyer GR, Müller J, Stender E, Ahlers MO, Willershausern** B., Depth of cure of LED vs QTH light-curing devices at a distance of 7 mm. J Adhes Dent. 2004; 6(2):141-50.

Depth of Cure of LED vs QTH Light-curing Devices at a Distance of 7 mm

Claus-Peter Ernst[a]/Gerrit R. Meyer[b]/Julia Müller[c]/Elmar Stender[d]/M. Oliver Ahlers[e]/Brita Willershausen[f]

Purpose: To determine the depth of cure of 5 blue LED curing devices compared to that obtained with 3 QTH curing devices.

Materials and Methods: The LED curing devices tested were 1) e-Light: 40 s; 2) Elipar FreeLight: 40 s; 3) Elipar FreeLight 2: 20 s and 40 s; 4) Ultra-Lume LED 2: 20 s and 40 s; 5) LEDemetron 1: 20 s and 40 s. The QTH curing devices tested were 1) Optilux 501: standard light guide 20 s and 40 s, turbo light guide 20 s; 2) Elipar TriLight: 40 s; 3) Astralis 10: 20 s. Surface hardness was measured (Zwick Z2.5/TS1S) 10 min after exposure on the top and bottom surface of resin samples (Tetric Ceram A3, 1 to 5 mm; 0.5 mm increment, diameter 5 mm, n = 9) which were cured at a distance of 7 mm from the bottom of the sample to the light-guide tip to simulate a Class II curing situation. A reference sample was cured under direct contact with the light guide. The reference sample with the greatest top surface hardness of all devices measured served as the overall control. A bottom/top surface hardness ratio of ≥ 80% of the reference sample cured at zero distance was defined as clinically acceptable for safe curing. A descriptive statistical analysis was carried out.

Results: With QTH lamps, the mean maximum resin composite sample thickness which cured sufficiently (relative surface ratio ≥ 80%) was: 3 mm for Optilux 501, standard light guide, 40 s; 2.5 mm for Trilight, 40 s; and 1.5 mm for Astralis 10, 20 s. The first-generation LED curing devices FreeLight and GC e-Light, both applied for 40 s, and the Optilux 501 operated for 20 s with the standard and the turbo light guide could not sufficiently cure a 1-mm-thick sample at a distance of 7 mm. The new FreeLight 2 and the Ultra-Lume LED 2 cured resin samples up to 2.5 mm thick in 40 s with a relative surface ratio ≥ 80%, while no sufficient depth of cure was found after 20 s exposure time for the FreeLight 2. However, a 1.5-mm depth of cure with the Ultra-Lume LED 2 and the LEDemetron 1 with the 13/11 mm light guide was obtained after 20 s. The LEDemetron 1 equipped with a 13/8 mm light guide reached a depth of cure of 2.0 mm. No significant difference was found between the Elipar FreeLight 2, Ultra-Lume LED 2, and LEDemetron 1 in their overall curing potential (linear statistical model, 5% level, Bonferroni-correction) given 40 s or 20 s of exposure time.

Conclusion: Application of the first-generation LED curing devices FreeLight and e-Light did not ensure clinically sufficient depths of cure, while the new high-power LED curing devices FreeLight 2, Ultra-Lume LED 2, and LEDemetron 1 showed a curing potential equal to the Optilux 501, given 40 s of exposure time.

Key words: blue LED curing devices, QTH curing devices, depth of cure, clinically relevant distance, posterior teeth.

J Adhes Dent 2004; 6: 141–150. *Submitted for publication: 20.03.03; accepted for publication: 09.07.03.*

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When resin composite restorations in posterior teeth became a standard procedure in most dental offices, different issues regarding depth of cure arose compared to those pertinent to anterior teeth. In anterior resin composite restorations, the layer thickness exposed at once rarely exceeded 1 to 2 mm, and the light-guide tip

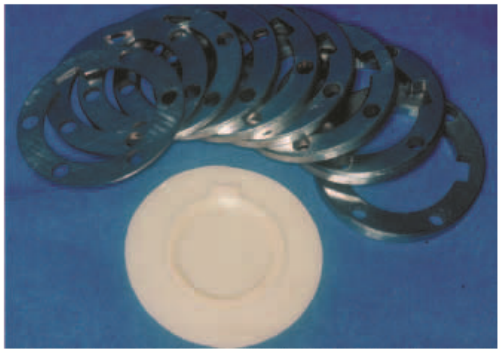

Fig 1 Stainless steel molds 5 mm in diameter and height varying from 1 to 5 mm in 0.5 steps. The steel molds were placed on a dentin-colored base socket to obtain light reflection and sorption phenomena comparable to a clinical cavity preparation. Each steel ring contains 5 holes which will be filled with composite,

could be placed very close to the resin composite. When the use of resin composites was extended to posterior cavity preparations, the thickness of incremental layers was not as easy to control as in anterior restorations, and frequently reached 2 to 3 mm. Therefore, demands arose to obtain sufficient depths of cure by more powerful curing devices, even when the light-guide tip could not be placed as close to the composite as is possible in anterior cavities.[20]

The literature shows that a distance of 7 mm from the light-guide tip to the gingival floor must be assumed in a typical Class II preparation.[9,18,24] Due to the fact that a light-guide tip mostly rests on the occlusal edge of the cavity,[20] these 7 mm must be taken as a clinically relevant distance between the light-guide tip and the lower surface of a resin composite increment in the approximal box of a Class II cavity preparation. In this context, it is important to recognize that increasing the distance between the light-guide tip and the resin composite surface to more than 6 mm can cause a significant difference in the polymerization of the resin composite 2 mm below the resin surface, although there is little change in the light intensity determined on the surface.[20] Pires et al[16] reported a remaining power density of 78% at a distance of 2 mm and of 47% at a distance of 6 mm. Similarly, Prati et al[17] found that the mean power output had fallen to 61% at a distance of 2 mm and to 23% at 6 mm. As shown recently,[12] the light intensity of conventional QTH curing devices decreased 56% to 76% at a distance of 10 mm compared to a 100% power output at zero distance to a radiometer. In that particular study, the blue LED[13] curing devices showed a significantly greater decrease in power output with increasing distance between light-guide tip and radiometer compared to the QTH devices. As a consequence of these findings, there was a strong need for further investigations on the depth of cure in contrast to ISO 4049:2000, where the light-guide tip is placed directly on top of the resin sample. A clinically relevant distance of 7 mm between the light-guide tip and the bottom side of the resin composite increment should be maintained, as this represents an average maximum of approximal box depth.

Therefore, the aim of this study was to compare the maximum depth of cure obtained at a distance of 7 mm using first-generation and recently introduced high-power blue LED curing devices to that of conventional QTH curing devices. Sufficient cure was defined as a surface hardness ratio of ≥ 80% between the bottom and top sides of resin composite samples.

MATERIALS AND METHODS

Stainless steel molds 5 mm in diameter and with heights ranging from 1 to 5 mm in 0.5-mm steps were bulk filled with a standard hybrid resin composite (Tetric Ceram A3, Vivadent, Schaan, Liechtenstein, lot D 63754, n = 3 per thickness and light-curing device; 3 measurments were take per sample: 3 x 3 = 9). Both resin sample surfaces were covered with a cellophane strip (Frasaco, Tettnang, Germany) to avoid oxygen inhibition. The steel molds were placed on a dentin-colored base socket (Charisma OB 3, Heraeus-Kulzer, Hanau, Germany) (Fig 1) to ensure light reflection and sorption phenomena comparable to a clinical cavity preparation. The light-guide tip was placed 7 mm from the bottom side of the resin sample to simulate a clinical situation involving a Class II approximal box. A metal matrix system (Automatrix, Dentsply, Konstanz, Germany) was wrapped around the light-guide tip, reaching up to the top surface of the resin composite sample (Fig 2). This experiment was carried out to simulate reflection phenomena of a metal matrix system used in a Class II cavity restoration process. The resin composite was exposed for 20 s or 40 s according to recommendations by the manufacturers of the curing devices or the resin composite.

Five blue LED curing devices (Table 1) were investigated mainly using a 40-s standard exposure mode. Due to the fact that the manufacturers of the FreeLight 2, UltraLume LED 2, and LEDemetron 1 claim that a 20-s exposure time is enough to cure Tetric Ceram sufficiently, these devices were additionally tested in a 20-s exposure trial. The LEDemetron 1, equipped with a 13/11-mm focusing light guide was investigated in a separate trial using the 13/8-mm focusing light guide recommended for the Optilux 501. Three QTH curing devices (Table 1) served as control. While the Elipar TriLight and the Optilux 501, both using a standard light guide, were operated in the 40-s standard exposure mode, the depth of cure obtained with Optilux 501 was also investigated after a 20 s exposure time using the standard light guide, as well as a 13/8 focusing light guide ("Turbo" light guide). As recommended by the manufacturer for curing resin composite fillings, the Astralis 10, equipped with a 13/8 light guide comparable to that of the Optilux 501, was operated in the 20-s pulsed mode, where intensity increases

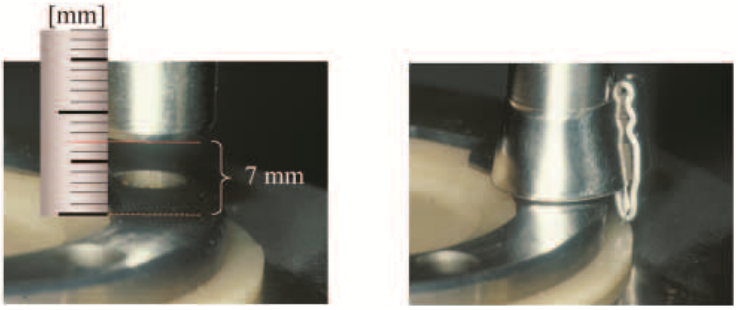

Fig 2 Experimental setup with the light-guide tip placed 7 mm from the bottom side of the resin sample to simulate the clinical situation of a Class II approximal box. A metal matrix system was wrapped around the light-guide tip, reaching up to the top surface of the resin composite sample.

Table 1 Visible light curing devices tested in this study. Conventional QTH curing devices are shown with a white background; first-generation LED curing devices are marked with a light grey background, high-power blue LED curing devices with a dark grey background. The ticks in the right columns mark the exposure times investigated with the particular curing devices

Visible light curing device	Light guide	Light intensity [mW/cm²]	Manufacturer	Serial number	20 s exposure time	40 s exposure time
Elipar TriLight	8 mm standard	0 mm: ~ 500 7 mm: ~ 300	3M ESPE, Seefeld, Germany	3900402		❑
Optilux 501	11 mm standard	0 mm: ~ 500 7 mm: ~ 300	SDS Kerr Demetron, Danbury, CT, USA	53100227	❑	❑
Optilux 501	13/8 mm focusing	0 mm: ~ 800 7 mm: ~ 200	SDS Kerr Demetron, Danbury, CT, USA	53100227	❑	
Astralis 10, "Pulse"-mode	13/8 mm focusing	0 mm: altern. ~ 500–900 7 mm: altern. ~ 100–200	Vivadent, Schaan, Liechtenstein	010072	❑	
GC e-Light	8 mm standard	0 mm: ~ 200 7 mm: ~ 60	GC Europe N.V., Leuven, Belgium	01/29/00474G		❑
Elipar FreeLight	10/8 mm focusing	0 mm: ~ 250 7 mm: ~ 100	3M ESPE, Seefeld, Germany	939800000047		❑
Elipar FreeLight 2	10/8 mm focusing	0 mm: ~ 680 7 mm: ~ 200	3M ESPE, Seefeld, Germany	34 (Prototype)	❑	❑
Ultra-Lume LED 2	13 x 6 mm light emitting surface	0 mm: ~ 420 7 mm: ~ 200	Ultradent Products Inc., South Jordan, UH, USA	000839	❑	❑
LEDemetron 1	13/11 mm focusing	0 mm: ~ 750 7 mm: ~ 420	SDS Kerr Demetron, Danbury, CT, USA	921544	❑	❑
LEDemetron 1	13/8 mm focusing	0 mm: ~ 1000 7 mm: ~ 380	SDS Kerr Demetron, Danbury, CT, USA	921544	❑	

from 150 mW/cm² to 650 mW/cm² within the first 10 s und then alternately pulses between 650 mW/cm² and 1200 mW/cm² every 2 s (information obtained from the instruction manual) for another 10 s.

Ten minutes after light exposure, the surface hardness (universal hardness) of the resin composite samples was measured under a load of 4.9 N (Zwick Z2.5/TS1S, Ulm, Germany, loading speed 1 mm/min) on the top and bottom surface at three different spots, in order to take possibly unequal light exposure into consideration. Thus, nine measurements for each sample thickness and for every exposure variation were obtained from the total of three samples exposed (3 samples x 3 measurements/surface each: n = 9). In contrast to the measurement of the original "Vickers" hardness – where the diameter of the impression generated by the Vickers diamond (136 degrees) is measured optically through the diamond itself which is connected to an optical system – this device, using a comparable diamond under load, measures the depth of the impression, from which the diameter and thus the hardness can be calculated mathematically. This hardness is then defined as "universal hardness", determined under loading, in contrast to "Vickers" hardness, originally not determined under loading; this marks the different modes of generating data from the same diamond penetration corpus.

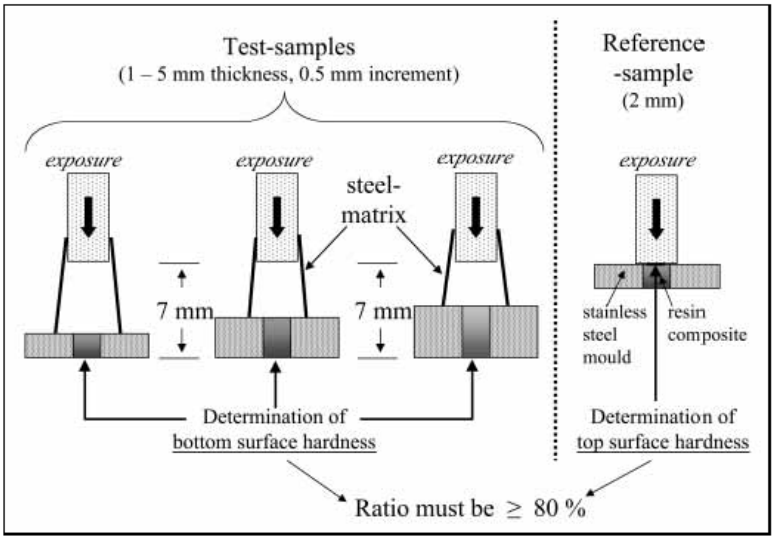

Fig 3 Schematic representation of the test setup to investigate the depth of cure of Tetric Ceram resin composite samples (shade A3). The test samples were exposed at a distance of 7 mm from the light-guide tip to the bottom of the resin sample, while the reference sample (2 mm thickness) was cured under direct contact to the light-guide tip. A ratio of ≥ 80% of test sample bottom to reference sample top surfaces was defined as sufficient curing.

In addition, three reference samples (2 mm thickness, 3 measurements each on bottom and top, n = 9) were exposed to each of the curing devices under direct contact to the light-guide tip to obtain an optimally polymerized resin composite sample. Of these 2-mm-thick reference samples, the sample with the highest surface hardness was selected as the overall reference sample to represent the best polymerized surface that could be expected. The bottom surface hardness data obtained from all samples cured 7 mm from the light-guide tip were compared to this (Fig 3). A bottom (test sample) to top (reference sample) relative surface hardness ratio ≥ 80% was defined as sufficiently cured.

According to the manufacturer of Astralis 10, the "esthetic cementation system" (ECS) – delivering 1200 mW/cm² for 30 s – in direct light-guide contact could be expected to result in the highest surface hardness; thus, three additional reference samples were exposed in this curing mode.

The light intensity of all curing devices was determined by means of a Demetron 100 Curing Radiometer (Kerr-Demetron, Danbury, CT, USA) at 0 and 7 mm from the light-guide tip with a metal matrix wrapped around the light guide as it was performed in the depth-of-cure experiments.

For statistical analysis, the difference in bottom hardness between different light-curing devices was assessed in a linear model which included "thickness" as a covariate in addition to the factor "device". Because a total of 105 comparisons was carried out, a Bonferroni correction was used to adjust for multiple testing. Therefore, only p-values below 0.0005 could be considered significant at the global 5% level.

RESULTS

The results of the radiometer measurements at 0 and 7 mm are shown in Table 1. In Fig 4, the mean surface hardness data from the bottom and top surfaces of all the reference samples are shown. The highest mean surface hardness (290.8 ± 19.1 N/mm²) of the reference sample was obtained with the Elipar FreeLight 2 after 40 s of exposure. Therefore, the mean top surface hardness of these samples was used as the overall reference sample for the further investigation of depth of cure at 7 mm from the light-guide tip. In addition, Elipar FreeLight 2 produced the highest bottom surface hardness of the 2-mm reference samples, 324.6 ± 10.9 N/mm². Thus, the 2-mm reference samples cured with the Elipar FreeLight reached the highest cure rate of all samples investigated, followed by the QTH curing devices, in which 40 s of exposure time was used (Optilux 501: 284.9 ± 26.9 N/mm² top surface hardness, 295.3 ± 22.0 N/mm² bottom surface hardness; and Elipar TriLight: 273.9 ± 12.7 N/mm² top surface hardness, 286.4 ± 14.70 N/mm² bottom surface hardness). The reference sample surface hardness obtained with the Astralis 10 operated in 20-s pulsed mode was comparable to that of the QTH curing devices using 40 s of exposure time: the mean top surface hardness was 274.3 ± 20.3 N/mm² and the mean bottom surface hardness 262.6 ± 1.1 N/mm². The 30-s ECS mode of the Astralis 10 was originally integrated in the investigation to obtain a maximally cured resin composite surface. Surprisingly, this mode did not show better results than the 20-s pulsed mode. However, it should be mentioned that before starting to expose the reference samples to the Astralis 10 ECS mode, the halogen bulb had to be changed,

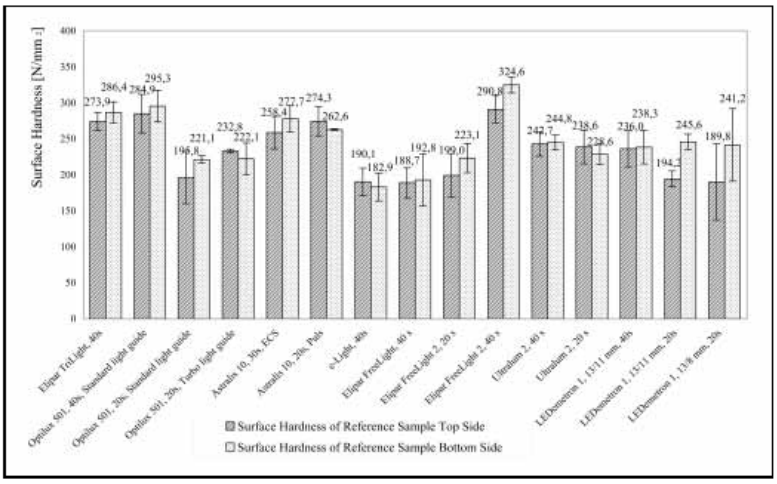

Fig 4 Surface hardness of reference samples, top and bottom surfaces, by device and exposure time.

so that a direct comparison between the reference samples exposed with the different modes of the Astralis 10 was not possible. The mean surface hardness data of the other reference samples were far below the reference samples mentioned above, as can be seen from Fig 4.

Table 2 shows the mean (± SD) values for surface hardness measured at the top and bottom surfaces of the resin composite samples cured with the light-guide tip 7 mm from the bottom surface of the sample. As expected, the mean bottom surface hardness decreased with increasing resin sample thickness, while the mean top surface hardness increased with increasing sample thickness due to a shorter distance to the light-guide tip.

Table 3 shows the ratios of the mean bottom surface hardness of test samples to the overall reference sample, defined as the best-cured resin composite surface from this investigation (Elipar FreeLight, 40-s exposure time, 290.8 N/mm^2). In some cases, a relative bottom:top surface hardness ratio of > 100% was found. The limit for sufficient cure the sample thickness was defined as the value after which the relative surface hardness ratio dropped below 80% the first time. A later, higher relative surface ratio was not included in maximum depth of cure. As can be seen from Table 3, the mean maximum resin composite sample thickness which cured sufficiently (relative surface ratio ≥ 80%) was: 3 mm for Optilux 501 with standard light guide, 40 s; 2.5 mm for Trilight, 40 s; and 1.5 mm for Astralis 10, 20 s. The first generation LED curing devices FreeLight and the GC e-Light, both applied for 40 s, as well as the Optilux 501 operated for 20 s with the standard and the Turbo light guide were not able to cure a 1-mm-thick sample sufficiently at 7 mm. The high-power blue LED curing device FreeLight 2 cured resin samples up to 2.5 mm thick with a relative surface ratio of 80% in 40 s, but 20 s of exposure did not produce a sufficient depth of cure. The FreeLight 2, applied for 20 s, showed comparable results to 20 s of the Optilux 501 with both the standard and the Turbo light guide. The Ultra-Lume LED 2 produced a sufficient depth of cure in samples up to 2.5 mm thick when the samples were exposed for 40 s, and sufficient depth of cure in up to 1.5-mm-thick samples when a 20 s exposure time was used. The LEDemetron 1, equipped with the 13/11-mm light guide and operated for 20 s, reached the same depth of cure in 1.5 mm samples as the Ultra-Lume LED 2, when a 80% relative surface hardness was taken as the limit. When equipped with the 13/8-mm light guide taken from the Optilux 501, the LEDemetron 1 reached a sufficient depth of cure up to a sample thickness of 2 mm.

A mean relative surface hardness ratio of > 80% was found with the Elipar FreeLight 2 for the 3.5-mm sample thickness and with the LEDemetron 1 for the 3.0-mm sample thickness, even when the 0.5-mm thinner sample showed a relative surface hardness ratio below 80% (Table 3). However, due to the fact that the maximum sample thickness with sufficient depth of cure was defined as the sample thickness after which the relative surface hardness was below 80%, these data were not taken into consideration for the definite determination of depth of cure.

Statistical analyses are shown in Table 4. Due to the Bonferroni correction, only differences resulting in a respective p-value of < 0.0005 could be defined as statistically significant. The QTH curing devices, given 40 s of exposure time (Elipar TriLight and Optilux 501), are not significantly different from the global 5% level ($p = 0.09$). Twenty seconds of exposure time (Optilux 501, Astralis 10) showed a statistically significantly lower curing potential ($p < 0.0005$) than a 40-s exposure time (Optilux 501). The Astralis 10 applied for 20 s resulted in a significantly superior curing potential compared to the Optilux 501, both using a comparable 13/8-mm focusing light guide.

First-generation blue LED curing devices showed a significantly lower curing potential ($p < 0.0005$) than the

Table 2 Mean bottom and top surface hardness data (± SD, N/mm²) of the different sample thicknesses (1.0 to 5.0 mm, in 0.5-mm steps, n = 9) exposed at a clinically relevant distance of 7 mm between the light-guide tip and the bottom side of the resin composite sample

		Sample thickness [mm]									
Curing device		1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	
TriLight	Top	236.9 ± 17.1	247.8 ± 23.5	268.9 ± 29.8	276.8 ± 24.8	235.7 ± 18.4	255.7 ± 10.8	305.6 ± 14.5	298.8 ± 12.2	296.7 ± 15.6	
	Bottom	237.3 ± 35.8	251.6 ± 24.2	255.3 ± 15.8	232.7 ± 22.0	164.4 ± 18.0	167.3 ± 21.3	187.7 ± 10.4	123.7 ± 6.3	76.6 ± 6.7	
Optilux 501 40 s	Top	240.6 ± 11.8	177.2 ± 35.1	244.6 ± 4.5	241.4 ± 45.4	285.2 ± 47.6	272.8 ± 24.5	276.1 ± 41.8	294.6 ± 13.4	290.1 ± 20.4	
	Bottom	230.4 ± 48.3	214.4 ± 26.1	278.8 ± 14.5	279.6 ± 19.8	235.0 ± 39.0	219.1 ± 4.6	195.8 ± 13.5	132.1 ± 8.5	72.0 ± 10.4	
501 20 s, Standard	Top	187.4 ± 28.9	204.3 ± 25.8	244.4 ± 15.0	274.9 ± 16.5	200.1 ± 54.3	158.7 ± 42.8	155.7 ± 54.2	274.2 ± 29.3	255.0 ± 14.4	
	Bottom	169.6 ± 25.4	230.3 ± 24.9	190.7 ± 40.1	198.8 ± 34.9	122.1 ± 40.2	118.8 ± 6.7	78.2 ± 14.8	37.2 ± 10.5	24.3 ± 18.5	
501 20 s, Turbo	Top	188.6 ± 12.0	214.0 ± 5.8	219.0 ± 40.1	234.0 ± 2.3	247.0 ± 5.4	251.6 ± 31.4	283.8 ± 7.4	293.3 ± 6.4	289.0 ± 3.5	
	Bottom	171.1 ± 18.7	188.3 ± 44.2	144.1 ± 8.3	148.6 ± 11.3	128.9 ± 5.3	104.0 ± 8.6	82.9 ± 5.4	68.6 ± 10.2	32.3 ± 7.8	
Astralis 10, Pulsed mode	Top	227.2 ± 34.2	286.2 ± 17.2	280.6 ± 15.8	289.7 ± 17.0	283.3 ± 25.9	303.6 ± 24.4	318.7 ± 16.7	306.4 ± 15.2	306.0 ± 30.7	
	Bottom	235.2 ± 15.4	274.2 ± 21.4	227.8 ± 6.6	198.8 ± 16.8	162.1 ± 14.9	128.9 ± 8.3	96.4 ± 10.1	57.2 ± 9.4	27.2 ± 12.1	
e-Light	Top	161.3 ± 12.7	154.1 ± 20.2	190.1 ± 19.1	209.9 ± 21.7	221.9 ± 15.8	238.6 ± 20.7	244.0 ± 18.4	289.4 ± 17.5	281.7 ± 15.5	
	Bottom	162.4 ± 62.5	153.2 ± 69.3	182.3 ± 19.2	149.8 ± 15.5	123.2 ± 14.7	93.3 ± 15.0	57.1 ± 11.5	26.0 ± 13.5	*	
FreeLight	Top	165.8 ± 15.1	196.9 ± 14.3	173.8 ± 36.0	274.4 ± 8.4	240.3 ± 29.2	276.9 ± 23.7	289.8 ± 15.2	308.1 ± 24.8	229.7 ± 9.6	
	Bottom	161.6 ± 31.5	189.0 ± 29.1	148.9 ± 61.1	220.2 ± 14.8	165.1 ± 8.0	147.9 ± 43.4	108.9 ± 25.3	74.6 ± 11.1	39.0 ± 12.5	
FreeLight 2, 20s	Top	189.8 ± 23.7	191.9 ± 21.1	254.1 ± 20.8	241.3 ± 18.2	236.2 ± 34.6	304.1 ± 14.9	307.7 ± 11.0	303.8 ± 13.4	317.6 ± 16.9	
	Bottom	189.0 ± 22.8	214.7 ± 30.1	228.9 ± 13.8	220.6 ± 9.8	203.4 ± 21.2	179.2 ± 13.9	125.9 ± 11.4	69.8 ± 5.2	31.6 ± 8.6	
FreeLight 2, 40s	Top	205.0 ± 20.1	222.3 ± 55.1	310.9 ± 11.4	262.8 ± 10.6	239.0 ± 22.8	303.1 ± 5.6	305.4 ± 5.7	324.8 ± 8.4	303.8 ± 50.0	
	Bottom	241.7 ± 33.8	234.4 ± 18.7	262.1 ± 29.7	253.7 ± 13.9	207.1 ± 34.3	240.7 ± 11.2	216.1 ± 15.5	156.6 ± 33.7	113.2 ± 18.6	
Ultra-Lume LED 2, 20s	Top	253.4 ± 19.2	296.1 ± 19.4	278.9 ± 12.9	278.8 ± 27.7	286.4 ± 7.6	266.6 ± 8.9	274.6 ± 15.0	217.4 ± 12.3	260.6 ± 57.4	
	Bottom	268.7 ± 16.4	249.7 ± 25.1	219.9 ± 19.1	183.3 ± 14.9	110.9 ± 23.6	80.9 ± 12.6	43.7 ± 17.5	19.2 ± 14.4	*	
Ultra-Lume LED 2, 40s	Top	264.3 ± 32.9	255.7 ± 22.3	291.2 ± 19.7	290.0 ± 27.4	309.7 ± 15.3	307.2 ± 13.6	308.9 ± 6.6	269.0 ± 37.8	255.6 ± 14.2	
	Bottom	288.1 ± 6.8	298.4 ± 18.7	274.2 ± 18.9	235.6 ± 30.3	215.6 ± 10.1	173.3 ± 11.8	135.1 ± 16.9	64.9 ± 89.0	43.4 ± 61.1	
LEDemetron 13/11 mm, 20s	Top	175.6 ± 54.2	240.1 ± 57.2	219.8 ± 43.5	232.7 ± 20.5	258.0 ± 24.1	225.8 ± 64.6	241.6 ± 74.8	286.2 ± 19.7	284.9 ± 15.0	
	Bottom	255.2 ± 19.5	243.4 ± 38.6	227.7 ± 47.1	199.3 ± 13.7	171.6 ± 26.6	169.7 ± 10.6	103.0 ± 20.7	52.9 ± 8.3	23.7 ± 26.8	
LEDemetron 13/11 mm, 40s	Top	240.7 ± 23.9	270.8 ± 14.9	273.6 ± 26.9	234.4 ± 44.3	261.3 ± 19.9	279.6 ± 41.4	300.8 ± 30.4	248.4 ± 25.7	256.4 ± 10.8	
	Bottom	227.7 ± 20.7	273.7 ± 20.0	263.5 ± 18.5	236.4 ± 25.7	217.3 ± 18.9	229.7 ± 14.7	209.8 ± 29.2	115.4 ± 8.7	65.3 ± 8.1	
LEDemetron 13/8 mm, 20s	Top	225.4 ± 28.2	244.8 ± 25.4	254.0 ± 26.2	212.3 ± 39.9	286.8 ± 32.4	305.9 ± 19.7	303.7 ± 42.4	315.8 ± 31.0	310.4 ± 17.9	
	Bottom	225.7 ± 31.1	266.4 ± 23.0	256.9 ± 17.6	188.6 ± 26.5	242.6 ± 14.4	201.1 ± 8.9	136.9 ± 29.4	77.7 ± 17.1	30.9 ± 7.5	

Table 3 Mean ratio [%] of bottom:top surface hardness of the reference sample with the overall highest surface hardness of all reference samples investigated. Dark grey background indicates sample thicknesses with relative surface ratios ≥ 80%. Light grey background indicates sample thicknesses with a relative surface ratio < 80%, but which were followed by a thicker sample, resulting in a relative surface ratio ≥ 80% again

		Sample thickness [mm]								
	Curing device	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0
Mean ratio of bottom surface hardness to top surface hardness of reference sample with the overall highest surface hardness [= 290.8 N/mm², Elipar FreeLight 2, 40 s]	TriLight	82	87	88	80	57	58	65	43	26
	Optilux 501, 40 s, 11 mm standard	79	74	96	96	81	75	67	45	25
	Optilux 501 20 s, 11 mm standard	58	79	66	68	42	41	27	13	8
	Optilux 501 20 s, 13/8 mm focusing	59	65	50	51	44	36	29	24	11
	Astralis 10, 20 s, "Pulse"-mode	81	94	78	68	56	44	33	20	9
	e-Light, 40s	55	52	62	51	42	32	19	9	–
	FreeLight, 40s	55	64	51	75	56	50	37	25	13
	FreeLight 2, 20s	60	73	78	75	69	61	43	24	11
	FreeLight 2, 40s	82	80	89	86	71	82	74	53	39
	Ultra-Lume LED 2, 20s	92	86	76	63	38	28	15	7	–
	Ultra-Lume LED 2, 40s	99	103	94	81	74	59	46	22	15
	LEDemetron 1, 20s 13/11 mm focusing	88	84	78	69	59	58	35	18	8
	LEDemetron 1, 40s 13/11 mm focusing	78	94	90	81	74	78	72	39	22
	LEDemetron 1, 20s 13/8 mm focusing	78	92	88	65	84	69	47	27	11

QTH curing devices at 40 s of exposure time. With the same exposure time of 40 s, statistically significant differences were no longer found between the QTH control group and the high-power blue LED curing devices Elipar FreeLight 2, Ultra-Lume LED 2, and LEDemetron 1. No statistically significant difference exists within the group of the high-power blue LED curing devices for either 40-s or 20-s exposure times ($p = 0.01$ to 1.0). The use of the 13/8-mm focusing light guide in the LEDemetron 1 resulted in a greater depth of cure (2 mm vs 1.5 mm) compared to the 13/11-mm standard light guide, but this did not prove to be statistically significant ($p = 0.1$) when the overall performance of the light-curing device was taken into consideration. In contrast, no improvements in depth of cure at 7 mm were found with the Optilux 501 when the 13/8-mm light guide was used instead of the 11/11-mm standard light guide. The group of the high-power blue LED curing devices showed a significantly higher ($p < 0.0005$) curing potential than the first-generation curing devices Elipar FreeLight and GC e-Light.

DISCUSSION

The determination of surface hardness was used to assess the depth of cure of different curing devices in this study. While the determination of the degree of conversion[11,22] appears to be the most sensitive and reliable method to evaluate depth of cure,[2,8] surface hardness measurements seem to come relatively close to the results obtained with FTIR spectroscopy.[19] Besides the use of a penetrometer,[13] the testing of material properties such as flexural strength and modulus[21] are suitable methods to compare resin composite samples exposed according to different protocols. However, the determination of surface hardness is still the most frequently employed method to compare different exposure techniques and procedures.[4,14,15,23] An 80% ratio in relative surface hardness as the defined limit for sufficient depth of cure has been used by other authors[25] and in other studies,[5,7] as has a 7-mm distance from the light tip to the sample base.[3] Daronch et al[1] discussed that the distance between the light tip and the composite may be responsible for lower surface hardness at greater depths.

In some cases, a relative bottom:top surface hardness ratio of > 100% was found. This can be explained by reflection phenomena of the steel mold into which the resin composite samples were inserted. This effect has also been observed in several studies on depth of cure[6,7] in which stainless steel rings were also used. It is possible that comparable reflection phenomena may occur in Class II approximal boxes, if they are bordered by a metal matrix system. In the present study, this kind of reflection was taken into consideration by wrapping a metal matrix system around the light-guide tip, which came closer to the real clinical situation. This effect of metal reflection made it more difficult to evaluate absolute depths of cure; nevertheless, the experimental setup was appropriate for evaluating comparative depths of cure. The determination of the surface hardness was done 10 min after curing directly on the composite surface, which was covered by a cellophane strip. It must be borne in mind that

Table 4 Statistical analysis using a linear model. Due to Bonferroni correction, only p-values < 0.0005 can be considered statistically significant

	Elipar TriLight 40 s	Optilux 501, 11 mm, 40 s	Optilux 501, 11 mm, 20 s	Optilux 501, 13/ 8 mm, 20 s	Astralis 10, 20 s	GC e-Light, 40 s	Elipar FreeLight, 40 s	Elipar FreeLight 2, 40 s	Elipar FreeLight 2, 20 s	Ultra-Lume LED, 40 s	Ultra-Lume LED, 20 s	LEDemetron, 13/ 11, 40 s	LEDemetron, 13/ 11, 20 s	LEDemetron, 13/ 8, 20 s
Elipar TriLight 40 s		0.09	< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005	0.002	0.002	0.9	< 0.0005	0.3	0.002	0.3
Optilux 501, 11 mm, 40 s	0.09		< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005	0.3	< 0.0005	0.1	< 0.0005	0.5	< 0.0005	0.2
Optilux 501, 11 mm, 20 s	< 0.0005	< 0.0005		< 0.0005	0.002	0.03	0.6	< 0.0005	0.006	< 0.0005	0.7	< 0.0005	0.003	< 0.0005
Optilux 501, 13/8 mm, 20 s	< 0.0005	< 0.0005	< 0.0005		< 0.0005	0.5	< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005	0.006	< 0.0005
Astralis 10, 20 s	< 0.0005	< 0.0005	0.002	< 0.0005		< 0.0005	0.04	< 0.0005	0.9	0.003	0.007	< 0.0005	0.8	0.06
GC e-Light, 40 s	< 0.0005	< 0.0005	0.03	0.5	< 0.0005		0.02	< 0.0005	< 0.0005	< 0.0005	0.01	< 0.0005	< 0.0005	< 0.0005
FreeLight, 40 s	< 0.0005	< 0.0005	0.6	< 0.0005	0.04	0.02		< 0.0005	0.04	< 0.0005	0.9	< 0.0005	0.03	0.001
FreeLight 2, 40 s	0.002	0.3	< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005		< 0.0005	0.01	< 0.0005	0.08	< 0.0005	0.001
FreeLight 2, 20 s	0.002	< 0.0005	0.006	< 0.0005	0.9	< 0.0005	0.04	< 0.0005		0.02	0.04	0.001	1.0	0.1
Ultra-Lume LED 2, 40 s	0.9	0.1	< 0.0005	< 0.0005	0.003	< 0.0005	< 0.0005	0.01	0.02		< 0.0005	0.4	0.01	0.4
Ultra-Lume LED, 20 s	< 0.0005	< 0.0005	0.7	< 0.0005	0.007	0.01	0.9	< 0.0005	0.04	< 0.0005		< 0.0005	0.01	0.001
LEDemetron 1, 13/11, 40 s	0.3	0.5	< 0.0005	< 0.0005	< 0.0005	< 0.0005	< 0.0005	0.08	0.001	0.4	< 0.0005		0.001	0.09
LEDemetron 1, 13/11, 20 s	0.002	< 0.0005	0.003	0.006	0.8	< 0.0005	0.03	< 0.0005	1.0	0.01	0.01	0.001		0.1
LEDemetron 1, 13/8, 20 s	0.3	0.2	< 0.0005	< 0.0005	0.06	< 0.0005	0.001	0.001	0.1	0.4	0.001	0.09	0.1	

this layer is enriched with monomer and the hardness values might be lower compared to a finished and polished surface. However, because the relative bottom:top surface hardness was determined and both surfaces were covered with the cellophane strip, this factor should not influence the outcome of this study. To remove the first ca. 100 microns, the samples had to be removed from the sample holder. After finishing, it would not have been possible to replace them into the stainless steel molds in a way that the system could have measured the hardness afterwards. Yet finishing and polishing might, in fact, reduce the standard deviation of the results. A measurement after 24 h would have taken the post-curing process into account, but in terms of clinical relevance, a resin composite should have a distinct hardness right after placement, when the patient leaves the dental office. Therefore, although the post-curing process was not taken into account here, the study design should allow proper comparison of light-curing devices. It is also of clinical relevance that curing a second layer of resin composite placed on another, already cured increment might positively influence the overall polymerization of the increment cured first. This should be the subject of further investigations on depth of cure, especially for Class II cavity preparations.

As expected, the conventional QTH curing devices Elipar TriLight and Optilux 501 proved their ability to sufficiently cure a resin composite sample of at least 2.5 mm thickness with an exposure time of 40 s. In contrast, the results of this study show clearly that first-generation blue LED curing devices were not capable of providing a sufficient depth of cure at a clinically relevant distance. Not even a 1-mm increment of Tetric Ceram resin composite (color A3) was cured with a resulting surface hardness ratio > 80%. These findings thus support the supposition of Meyer et al,[12] which arose after their radiometer measurements, which showed a tremendous drop in power output with increasing distance to the radiometer. The results obtained by maintaining a distance between the light-guide tip and resin composite differ from those of an earlier investigation on depth of cure with the same curing devices, Elipar FreeLight and Elipar TriLight:[6] the light-guide tip was placed on top of the resin composite samples, yielding comparable depths of cure with the Elipar TriLight and the Elipar FreeLight. A big step forward seems to be the second-generation blue LED curing devices, which consist of only one high-power LED. When operated in a 40 s exposure mode, the Elipar FreeLight 2 and the Ultra-Lume LED 2 showed comparable results to that of the Optilux 501 regarding depth of cure. In contrast, the Elipar FreeLight 2 was not able to produce a sufficient depth of cure in 20 s (as claimed by the manufacturer); the same happened with the Optilux 501 as well, when operated for only 20 s. The LEDemetron 1, equipped with the 13/11-mm light guide, and the Ultra- Lume LED 2 were at least able to cure a 1.5-mm increment sufficiently, while the LEDemetron 1, equipped with the 13/8-mm light guide, was the only curing device investigated to reach a 2-mm depth of cure within 20 s. Therefore, the Elipar FreeLight 2 and the Ultra-Lume LED 2 seem to possess a curing potential comparable to the Optilux 501, while the curing potential of the LEDemetron 1 tended to be slightly higher, although this was not statistically significant. Taking into account that the Astralis 10 is also equipped with a 13/8-mm focusing light guide, which is similar to that used with the Optilux 501 and LEDemetron 1, the LEDemetron 1 showed obvious, but not significantly better results than the Astralis 10 given 20 s exposure time.

In contrast to first-generation blue LED curing devices,[4,12-14,22] high-power blue LED curing devices combine the advantages of LED technology – such as constant power output and longevity of the LEDs[10] – with the curing potential of high-power QTH curing devices.[14] This can be seen from the radiometer measurements in this study as well. Nevertheless, it is not admissible to compare radiometer data between LED and QTH curing devices; these data were reported only to obtain some rough information on power output within LED and QTH groups. The quality of polymerization, of course, does not automatically correlate with the light intensity measured with a radiometer. The absorption curve of the photoinitiator camphoroquinone ranges from 360 nm to 520 nm, with a maximum at 468 nm. For this reason, the optimal emission spectrum of a curing device should be in the range of 440 nm to 480 nm. In conventional QTH devices, 95% of the emission spectrum is in the range of about 400 to 510 nm. The emission spectrum maximum of a blue LED is 465 nm, which is relatively close to that of the photoinitiator camphoroquinone; thus, the probability that a photon emitted by a blue LED curing device will be absorbed by camphoroquinone is obviously higher than in the case of a halogen device. Hence, LED curing devices have a lower measurable power output than conventional QTH curing devices, but the emitted blue light is nevertheless capable of starting a polymerization process.[12] The Demetron radiometer used here is a good device to follow up the power output of a single curing device but not to compare different devices. As discussed in a previous paper,[12] it was necessary to use a more complex measurement system.

The results of this study show that the use of the Optilux 501's "turbo" (focusing) light guide compared to the standard light guide had no positive influence on depths of cure when a distance of 7 mm to the bottom surface of the resin composite was maintained, while the surface hardness of the reference sample, exposed under direct contact to the light-guide tip, showed a significantly higher surface hardness when the 13/8-mm focusing light guide was used instead of the standard one (232.8 $\pm$ 2.5 N/mm^2 compared to 195.8 $\pm$ 36.0 N/mm^2). As known from the literature,[12,18] the use of a turbo light guide results only in a higher power output when the light guide is placed very close to the radiometer. In both studies,[12,18] due to the focusing effect of the turbo light guide, the light energy diffuses at a much greater rate than from the standard light guide with increasing distance to the surface. Just the opposite was observed with the LEDe-

metron 1 using the minimal focusing standard light guide (13/11 mm) vs the 13/8 mm focusing light guide.

The mean ratios of surface hardness between bottom and top were comparable in the Elipar FreeLight and the GC e-Light. As the Elipar FreeLight consisted of 19 LEDs and the e-Light of 64 LEDs, a higher power output at zero distance was expected for the e-Light. The reverse results might be explained by a focusing effect as well: while the FreeLight has a distinct focusing light-guide tip (not as strong as the turbo light guide of the Optilux 501, which focuses 1:1.6 vs 1:1.3 of the FreeLight) which seems to be able to compensate for the scattering of the emitting light, the e-Light is equipped with a parallel light guide without any kind of focusing. Therefore, distinct focusing light guides seem to be able to compensate the scattering of the light emitted by a blue LED curing device. The LEDemetron 1 is equipped with a 13/11-mm focusing light guide, with a resulting compression ratio of 1:1.2. This comes close to the focusing ratio of the FreeLight (1:1.3). The 13/8-mm focusing light guide from the Optilux 501 improved the depth of cure of the LEDemetron 1, in contrast to its use in the Optilux 501, where it caused almost a reverse effect, as described by Price et al.[18] Hence, focusing light guides must be rated differently in blue LED curing devices than in conventional QTH curing devices.

CONCLUSION

The new high-power blue LED curing devices showed promising depths of cure at clinically relevant distances between light-guide tip and the resin composite. Their curing potential is comparable to or even better than that obtained with high-power QTH curing devices. Except for the LEDemetron 1, which was the only device (if equipped with the 13/8-mm light guide) that cured a 2-mm resin composite increment of Tetric Ceram A3 sufficiently within 20 s, all the other devices investigated (QTH as well as blue LED) should be operated at an exposure time of 40 s when this type of medium-shade conventional hybrid resin composite is used. To increase the depths of cure, the use of distinct focusing light guides seems only to be of advantage in blue LED but not in QTH curing devices.

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Clinical relevance: The newest generation of blue LED curing devices are capable of curing resin composites comparable to or even better than high-power QTH curing devices, but a significant reduction in exposure time has not yet been reached. The exposure time required to cure a resin composite might be determined more by the type of resin composite than by the light source.

3M ESPE

3M ESPE

23.5 **Vandevalle K, Ferracane J, Hilton T, Erickson R, Sakaguchi R, Effect** of energy density on properties and marginal integrity of positerior resin composite restorations. Dent Materials 2004; 20:96-106.

Dental Materials (2004) 20, 96–106

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Effect of energy density on properties and marginal integrity of posterior resin composite restorations

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Received 3 December 2002; received in revised form 27 May 2003; accepted 29 May 2003

KEYWORDS
Resin composite restorations; Marginal integrity; Degree of conversion; Knoop hardness; Thermal-mechanical stressing; Microleakage; Visual rating

Summary *Objectives.* The purpose of this study was to determine the minimal extent of cure required by the base of a Class 2 resin composite restoration (*Z250, 3M ESPE, St Paul, MN, USA*) that allows it to support the rest of the restoration and maintain its marginal seal under simulated clinical conditions.

Methods. Resin composite (Z250, 3M ESPE, St Paul, MN, USA) was placed incrementally or in bulk into Class 2 preparations in extracted human molar teeth and exposed to various light-curing energy densities. The restorations were subjected to 1000 thermal cycles (5–55 °C) and 500,000 fatigue cycles from 18 to 85 N using a stainless-steel sphere. Marginal integrity was evaluated using visual rating (ridit analysis) and microleakage. Degree of conversion (DC) and Knoop hardness (KHN) were determined at the occlusal and gingival surfaces using a reusable tooth template with identical preparation dimensions. Percentage of maximum DC and KHN were determined. Mechanical properties were tested in resin composite bars having similar KHN values as the resin composite at the gingival margins.

Results. Energy density had a significant effect on gingival marginal defects as determined by ridit analysis but not on microleakage. Water had a significant dissolving effect on gingival margin integrity at very low degrees of conversion and energy densities (4000 mJ/cm^2). There was no overall significant effect of thermal-mechanical stressing on gingival marginal defects or microleakage.

Significance. Based on ridit analysis, a recommended lower limit of gingival margin acceptability in the bulk-filled Z250 resin composite restoration was created by 80% of maximum conversion, 73% of maximum hardness and approximately 70% of maximum flexural strength and modulus in the gingival marginal area.

Introduction

Studies have shown that resin composites exhibit lower strength and greater wear if they are not

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doi:10.1016/S0109-5641(03)00124-6

optimally polymerized.[1,2] New light activation protocols (PAC lights and lasers) and new composites (packables) claim the advantage of shorter exposure times and bulk curing.[3] Laboratory research shows that many of the suggested new protocols do not produce composites with maximum depth of cure or uniform properties.[4] The negative consequences of these approaches, therefore, would be a composite with regions of compromised properties at the base of the restoration.

Studies have suggested that depth of cure is affected by composite-related and light-related factors. Composite-related factors include shade, translucency, and filler particle size, load and distribution. Light-related factors include light intensity, spectral distribution and exposure time.[5,6] The more intense the light source, the more photons available for absorption by the photosensitizers. With more photons, more camphoroquinone molecules are raised to the excited state, react with the amine and form free radicals for polymerization. At the top surface, polymerization is more efficient because of the ample number of photons. However, deeper in the composite, attenuation of light leads to a potential gradation of cure within the depths of the material and is responsible for what has become known as 'depth of cure'.[7] To compensate for this gradation of cure, the duration of exposure can be increased, within practical limits determined by the properties of the material and light source, providing enhanced opportunity for creation of free radicals.[7] Reduced degree of conversion (DC) may lower the mechanical properties of resin composites. There appears to be a good correlation between decreasing DC and decreasing hardness,[1] fracture toughness,[8] and abrasive wear resistance.[2]

Current light-curing techniques may produce adequate marginal integrity although the properties of the base of these restorations may be significantly less than the properties on the surface.[9] The question is: "Are these lower properties clinically significant?" One danger is that repeated cyclic stresses of the interface between the base of the restoration and the tooth may deteriorate the marginal seal and integrity with time as a consequence of the insufficient cure. However, a decrease in DC may be beneficial and lead to a decrease in polymerization shrinkage and reduced contraction stress.[10] In bonded restorations, would enough occlusal force be transferred to the cavity walls allowing for acceptable marginal integrity that did not deteriorate with fatigue?

As yet, there is no agreement on what degree of cure constitutes an adequately cured composite. Using only a mathematical model, Johnston and others[11] suggested that the depth of cure may be defined as the level at which the hardness value is equivalent to at least 90% of the hardness at the top of the composite. Others have only suggested that this top-to-bottom gradient should not be less than 80%[12] and should be considered a realistic measure of depth of cure.[13] The purpose of this study was to determine the minimal extent of cure required by the base of a Z250 resin composite restoration that allows it to support the restoration and maintain its marginal seal under thermal and mechanical stress conditions. The study is divided into three parts—effects of energy density on hardness and DC, effects of DC on marginal integrity and effects of DC on mechanical properties. The null hypotheses to be tested were that the marginal seal of a posterior resin composite restoration was not affected by variable energy density or by thermal or mechanical stresses.

Materials and methods

Effect of energy density on hardness and degree of conversion

The first objective was to determine which energy densities would produce sequentially decreasing degrees of conversion and hardness in the gingival margin of posterior resin composite restorations. One extracted human molar served as a reusable template. After flattening the occlusal surface with a 180 grit belt sander (Surfmet I, Buehler, Lake Bluff, IL, USA), a tapered Class II slot cavity preparation was created with a #57 carbide bur and high-speed handpiece with water coolant with the following dimensions: buccolingual (occlusal), 4.5 mm; buccolingual (gingival), 4.0 mm; mesiodistal (gingival), 1.5 mm; occlusalgingival height of 5 mm with gingival margins 0.5 mm below the cementoenamel junction (Fig. 1). Composite specimens were created as outlined below. The tooth was stored in 37 °C tap water while not in use.

A thin layer of Bis-GMA and TEGDMA (50% each by weight) containing no polymerization promoters was placed in the cavity preparation to act as a lubricant and allow removal of the polymerized specimen from the tooth template. A metal matrix band was placed on the tooth and held in place with a hemostat. A minifill resin composite (Table 1) was placed in bulk (Z250, Shade A-2, 3M, St Paul, MN, USA) using a resin composite syringe system (CR tubes, Centrix, Inc., Shelton, CT, USA) until the preparation was full. Also, a control group was

Figure 1 Class 2 slot preparation in flattened human third molar.

created with a 2 mm horizontal incremental placement of the resin composite. The first increment was only 1 mm in thickness. Large condensers were used to smooth the occlusal portion. The composite was cured from the occlusal with a curing light (VIP, Bisco, Schaumburg, IL, USA) after utilizing its internal calibration feature. The emitted light output of the curing light was confirmed using a power meter (Power Max 5200, Molectron, Portland, OR, USA). A 10.25 mm curing tip was utilized and held in place with a mounting jig. To standardize the distances, the edge of the light tip rested

Table 1 Adhesive and composite systems used in study.

System	Ingredients	Batch number
Single Bond (3M ESPE)		20000123
Etchant	35% phosphoric acid Silica thickener	
Adhesive	Bis-GMA Polyalkenoic acid co-polymer Dimethacrylates HEMA Photoinitiators Ethanol Water	
Z250 (3M ESPE)		20000625
	Bis-GMA UDMA Bis-EMA TEGDMA Zirconium silicate Photoinitiators Inhibitors Pigments	

Bis-GMA: bisphenol-glycidyl-methacrylate; HEMA: hydroxyethyl methacrylate; UDMA: urethane-dimethacrylate; TEGDMA: triethyleneglycol dimethacrylate.

Table 2 Selected energy densities based on power density over time.

Energy density (mJ/cm^2)	Power density (mW/cm^2)	Time (s)
4000	400	10
6000	600	10
8000	400	20
12,000	600	20
24,000	600	40
Control 24,000 × 3	600	40 × 3

on a piece of folded electrical tape, 0.75 mm in thickness, placed on the occlusal surface of the tooth. The approximate center of the light guide was over the center of the occlusal composite surface. The power density of the curing light was 400 or 600 mW/cm^2 and the time was varied between 10 and 40 s to produce the various levels of cure at the gingival margin at various total energy densities (Table 2). These energy densities were selected based on the results from a pilot study using a similar technique, but with more groups.[14] Following cure, each composite specimen was removed from the tooth template for analysis. A total of three specimens were created per group. The DC of the Z250 resin composite was determined using micro-Fourier Transform Infrared Spectroscopy (FTIR) analysis (DS20/XAD, Analect Instruments, Irvine, CA, USA). Testing was conducted 24 h after dry storage at room temperature in a black film canister. The 5 mm long specimens were evaluated directly on the gingival and occlusal edges after lightly sanding away 0.1 mm with 600 grit sand paper to remove any unfilled resin and oxygen-inhibited layer. Tiny chips of composite approximately 50 × 100 μm in size to be placed in the FTIR were removed with a scalpel from the occlusal or gingival area of the specimen in a darkened room. The chips were analyzed in transmission at 8 cm ^{1} resolution. The average of three DC values per specimen was determined per gingival or occlusal surface. Also, the percentage of maximum DC was determined at 5 mm. Maximum DC was defined as the highest DC value determined from the average of three measurements on any single specimen surface. The intensities of the double carbon bond (C=C) absorbance peak at 1637.3 cm ^{1} and the aromatic (C···C) reference peak at 1608.3 cm ^{1} were measured. The C···C peak originates from the aromatic rings in the Bis-GMA molecule and remains unchanged during the polymerization reaction. The ratio of the absorbance intensities of C=C/C···C was compared before and after polymerization using the following equation to determine the percent of reacted

carbon double bonds or DC:

$$1 - [Abs(C{=}C)/Abs(C\cdots C)]cured\ resin/[Abs(C{=}C)/Abs(C\cdots C)]uncured\ resin \times 100$$

A new set of removable specimens was evaluated for Knoop hardness (KHN) based on the same flattened tooth template. A total of three specimens were created per group. These 5 mm long specimens were mounted vertically in a square acrylic tube with epoxy resin (Buehler, Lake Bluff, IL, USA) with the occlusal and gingival portions exposed. These specimens were tested after 24 h after dry storage at room temperature in a black film canister directly on the gingival and occlusal surfaces after gently sanding away 0.1 mm to remove any unfilled resin and the oxygen-inhibited layer as before. The average of three KHN values per occlusal or gingival surface was determined. Also, the percentage of maximum KHN was determined at 5 mm. Maximum KHN was defined as the highest KHN value determined from the average of three measurements on any single specimen surface. The values of KHN were determined using the following formula

$$KHN = L/l^2 \times Cp$$

where L is the load in kilograms; l, the length of the indentation in millimeters; Cp is the constant 0.07028. A 200 g load was used with a dwell time of 10 s (Kentron Microhardness, Torsion Balance Co., Clifton, NJ, USA).

Effect of degree of conversion on marginal integrity

Next, identical energy densities (as used in Section 2.1; Table 2) were used to bond resin composite restorations in prepared teeth to find the minimal extent of cure required by the base of the resin composite restoration that allowed it to support the rest of the restoration and maintain its marginal seal under thermal and mechanical stress conditions.

Extracted human molars were mounted in acrylic rings with epoxy resin (Buehler, Lake Bluff, IL, USA). An occlusally tapered Class II slot cavity preparation was created as before (Fig. 1). A 0.5 mm bevel was placed on the buccal and lingual proximal box margins. The teeth were stored in 37 °C tap water while not in use.

A metal matrix band was placed on the tooth and held in place with a hemostat. The preparation was acid-etched for 15 s with 35% phosphoric acid, gently rinsed for 15 s with water from a three-way syringe, and lightly dried leaving the dentin moist. Two consecutive thin layers of Single Bond (Table 1) bonding agent (3M, St Paul, MN, USA) were placed in the cavity, gently air-thinned for 5 s and light cured for 10 s at 600 mW/cm^2 after internally calibrating as before (VIP, Bisco, Schaumburg, IL, USA). A minifill composite resin was placed in bulk (Z250, Shade A-2, 3M, St Paul, MN) as before. Two control groups were created (Table 2). One group was cured at 4000 mJ/cm^2 without any thermal or mechanical cycling to see the effects of water storage only on the marginal defects. The second control group included 2 mm incremental placement of the resin composite and 40 s exposure at 600 mW/cm^2 per increment. The first increment was only 1 mm in thickness. Eight specimens were made per group.

Completed specimens were finished immediately with polishing discs (Soflex, 3M, St Paul, MN, USA), photographed with 2× magnification (Elite Chrome, Kodak, Rochester, NY, USA), impressed with polyvinylsiloxane impression material (Express, 3M, St Paul, MN, USA), and then stored in 37 °C water for 24 h. The specimens received 1000 thermocycles with a 30 s dwell time at 5 and 55 °C in a thermocycler. After thermocycling, the specimens were photographed and impressed as before.

Next, the specimens were cyclically loaded in a mechanical fatigue-cycling machine, employing an eccentric cam driven by a DC motor (Fig. 2). Loading was applied with dead weights. A 2 mm diameter stainless steel ball was cemented onto the occlusal surface of the restoration with a chemically curing resin cement. (C&B Cement, Bisco, Schaumburg, IL, USA). The specimens were then placed in the fatigue-cycler and loaded with a stainless steel bolt contacting the ball for a total of 500,000 cycles under a cyclic load of 18–85 N at

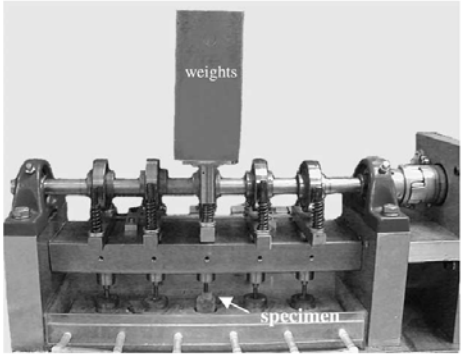

Figure 2 Custom fatigue-cycler showing a mounted molar under a weight assembly driven by an eccentric cam and DC motor.

1.25 Hz. The specimens were constantly bathed in re-circulated 37 °C water. After 100,000 and 500,000 cycles the specimens were removed from the fatigue machine and photographed and impressed as before.

Replicas of the specimens were created using epoxy resin (Buehler, Lake Bluff, IL, USA). The replicas were mounted on aluminum stubs and sputter-coated with 50 nm of gold–palladium (Hummer VII, Anatech Ltd, Alexandria, VA, USA). Examination of the marginal breakdown took place for each specimen at the pre-stressed, post-thermal, and post-100,000 and post-500,000 mechanical fatigue steps. The gingival margins were assessed by visual rating of the sputter-coated epoxy replicas by three examiners at 50 × magnification (SMX-10, Nikon, Oak Ridge, TN, USA). A ridit scale from 1 to 11 was created using techniques modeled after Mahler et al.[15] This scale uses a numbered scale of images that exhibit progressively increasing degrees of marginal defects (Fig. 3). The scale was developed from images of actual specimens created during the experiment. The procedure involves assigning the number of the scale image to which it is most similar to the restoration being evaluated. The data is then analyzed using parametric or non-parametric statistical methods. A pilot study determined that the ridit analysis was more informative in assessing the depth of marginal defects in addition to width and length compared to Scanning Electron Microscopy.

Marginal leakage of these specimens was determined with silver nitrate dye penetration (J.T. Baker, Palmyra, NJ, USA) after completion of the fatigue-cycling. In addition, new preparations and resin composite restorations were created with identical energy densities as the fatigued specimens and served only as unstressed specimens for marginal leakage examination. Specimens were polished and left in 37 °C water overnight. Eight unstressed and eight stressed specimens were tested per group. All tooth surfaces were covered with two coats of fingernail polish to within 1.0 mm of the tooth-restoration margin. The specimens were immersed in 3 mol/l silver nitrate for 24 h in a dark drawer. They were then removed, rinsed with de-ionized water, and placed in film developer (Eastman Kodak, Rochester, NY, USA) under fluorescent lights for 24 h. On removal from the developer, the teeth were rinsed in de-ionized water, embedded in epoxy resin (Buehler, Lake Bluff, IL, USA) and allowed to set overnight. Three mesiodistal sections were made through the restorations using a 0.3 mm thick diamond saw blade (Isomet, Buehler, Lake Bluff, IL, USA) in order to assess marginal leakage along the entire length of the preparation interface. Leakage scores were assessed on the six resultant surfaces using IP Lab software (Scanalytics, Fairfax, VA, USA) and the extent of the dye penetration was expressed as a percentage of the entire cross-sectional length of the preparation interface. The most severe dye penetration of the six surfaces was used as the score representing that specimen.

Effect of degree of conversion on mechanical properties

A supplementary goal of this work was to determine the flexural strength and modulus of the resin composite at the marginal area at various degrees of conversion. Resin composite bars were produced having the same approximate DC as the composite at the gingival margins created by various energy densities. KHN testing was used to approximate the DC based on the results from the first part of the study. Specimens were made in square glass rods with dimensions of 2 mm × 2 mm × 25 mm.

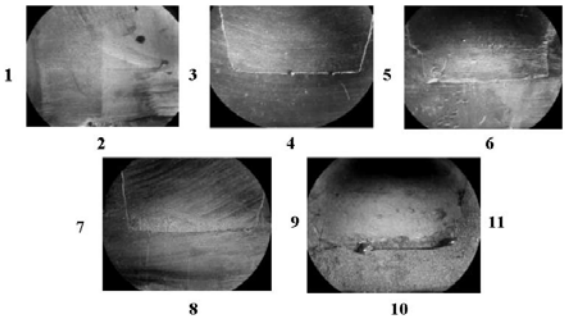

Figure 3 Ridit scale of actual gingival margins from 1 (best) to 11 (worst) at 50 × magnification. The photos represent gingival margin ratings of 2, 4, 6, 8 and 10. The gingival margin ratings of 1, 3, 5, 7, 9 and 11 were interpolated by the examiner.

The Z250 resin composite (shade A-2) was light-cured in a Triad II (Dentsply, York, PA, USA) laboratory curing unit for various time intervals to produce surface KHN levels corresponding to the KHN levels found at the gingival margin in the previous procedures. The specimens were cured in a vertical position in the center of a rotating platform in the center of the Triad unit to produce the most uniform DC possible. The specimens were stored and polished as before and then tested in three-point flexure (20 mm span) on a universal testing machine (Model TT-B1, Instron Engineering Corp., Canton, MA, USA) at a crosshead speed of 0.254 mm/min. The flexure strengths were determined from the maximum load using the equation

$$\text{flexural strength} = 3Fl/2bh^2$$

where F is the force; l, the length of the specimen over the support beams (20 mm); b and h are the width and height of the bar. The flexural modulus was determined from the initial slope of the force-deflection curve using the following equation:

$$E = L^3/4bh^3 \times F/Y$$

with F (force) determined on a linear portion of the curve and Y as the cross-head speed (0.01 in./min) multiplied by the chart time (min) with L, b and h as before. Five specimens of each group were tested. Specimens from the flexure strength tests were evaluated for KHN in the Kentron hardness tester as before. The specimens were polished on each side and loaded as before. The length of the indention was measured and a hardness number calculated. At lower energy densities the slowly rotating specimen may not have been cured uniformly in the Triad oven, therefore, three measurements were made on two opposing sides of each bar and averaged. The average from three bars was calculated ($n = 3$). These averages were then expressed as a percentage of maximum hardness (71.8 kg/mm^2) from this test and compared with the previous data of KHN values produced in the gingival margin of the 5 mm specimens under various energy densities. In addition to the surface hardness, the center hardness of each bar was tested by embedding the previously fractured bars vertically in epoxy resin (Buehler, Lake Bluff, IL, USA) in an acrylic ring and allowing them to cure overnight in a light proof container. To determine if a gradient of cure existed, especially at lower energy densities, one hardness value was also taken at the center of both ends of a bar and an average taken. The average of three bars was expressed as a percentage of maximum hardness.

Results

Effect of energy density on hardness and degree of conversion

Table 3 lists the occlusal and gingival degrees of conversion and KHN for the various energy densities. The percentage of maximum DC or KHN was determined at 5 mm. A one-way analysis of variance (ANOVA) was used to test the effect of energy density on DC or KHN at the gingival margin (SPSS, Inc., Chicago, IL, USA). Tukey's post hoc test was used for multiple comparisons ($\alpha = 0.05$; Table 3). All of the KHN numbers were significantly different from each other at each energy density at the gingival margin. However, there was no significant difference between the DC within the following energy densities (mJ/cm^2) 6000 and 8000, 8000 and 12,000, and 12,000 and 24,000 at the gingival margin. Linear regression analysis ($R^2 = 0.99$) was performed to relate KHN with DC at 5 mm (Fig. 4).

Effect of degree of conversion on marginal integrity

Table 4 shows the results of the ridit analysis of marginal defects. A paired t-test was completed comparing the pre-stressed margins with

Table 3 Occlusal and gingival degree of conversion (DC) and Knoop Hardness (KHN) with percentage of maximum DC (58.2%) or KHN (72.7 kg/mm^2) of gingival increment ($n = 3$).

Energy density (mJ/cm^2)	Degree of conversion (%)			Knoop hardness (kg/mm^2)		
	Occlusal	Gingival	Ging. % max	Occlusal	Gingival	Ging % max
4000	54.1(1.0)	14.3(5.1)	24.5a	69.3(2.3)	2.1(3.6)	2.8a
6000	53.4(1.9)	26.2(4.4)	44.9b	69.9(2.3)	16.4(0.8)	22.6b
8000	55(1.2)	33.4(0.2)	57.3b,c	69.1(3.1)	28.5(4.5)	39.2c
12,000	55.2(1.9)	39.4(2.3)	67.6c,d	68(2.1)	39.3(0.3)	54.1d
24,000	56.2(1.9)	46.5(0.9)	80d	68.8(1.7)	52.9(0.3)	72.8e
Control 24,000 × 3	57.4(0.7)	56.4(1.6)	97e	71.7(1.1)	70.2(1.2)	96.5f

ANOVA and Tukey's multiple comparisons ($\alpha = 0.05$). a–f denotes significant differences in columns.

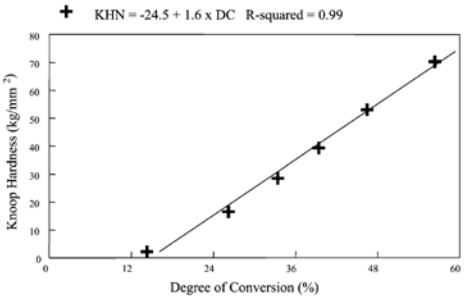

Figure 4 Correlation between Knoop hardness and degree of conversion at the gingival surface.

the margins cycled 500,000 times. A significant degradation was found only in the 4000 mJ/cm^2 groups ($p < 0.05$).

A two-way ANOVA was completed to test the effect of energy density or thermal-mechanical stressing on gingival marginal defects (ridit scores). Significant differences in the ridit scores were found based on energy levels. Tukey's post hoc test was used to determine differences between individual groups ($\alpha = 0.05$). No overall significant difference was seen after fatigue-cycling ($p = 0.167$). Differences were seen based on energy density ($p = 0.0001$). There were no significant differences between the incrementally filled control group, and the bulked-filled 24,000 and 6000 mJ/cm^2 groups.

The results of the microleakage study are summarized in Table 5. An unpaired t-test was completed comparing microleakage of unstressed with stressed gingival margins (1000 thermal cycles and 500,000 fatigue cycles). No significant difference was seen between these two comparisons at any energy density. A two-way ANOVA was completed to test the effect of energy density or thermal-mechanical stressing on microleakage. No overall significant difference was seen based on stressing or energy density ($p = 0.167$ and 0.212). A one-way ANOVA was used to test the effect of energy density on microleakage unstressed and also stressed. No significant differences were found ($\alpha = 0.05$).

Effect of degree of conversion on mechanical properties

Table 6 shows the various hardness ratios and mechanical properties obtained at various curing times in the Triad II. By comparing the hardness ratios with those from the tooth model (second column in Table 6), the results showed that curing times of 4, 8, 16 and 80 s roughly corresponded to energy densities of 6000, 12,000, 24,000 mJ/cm^2 and the control group, respectively. A one-way ANOVA was used to test the effect of curing time on KHN (surface or center), flexural modulus and strength. Tukey's post hoc test was used to

Table 4 Ridit analysis of gingival marginal defects ($n = 8$).

Energy density (mJ/cm^2)	Pre-stress	Post-thermal	100,000 cycles	500,000 cycles	Paired t-test pre-500,000	Two-way ANOVA
4000 (water only)	4.0 (1.9)	4.5 (2.0)	5.6 (2.0)	6.3 (2.4)	0.002	c
4000	4.7 (2.7)	4.8 (3.0)	5.4 (3.2)	6.0 (3.8)	0.035	c
6000	2.5 (1.2)	2.9 (1.2)	2.7 (1.0)	2.8 (1.3)	0.402	a
8000	3.3 (1.4)	4.3 (0.8)	4.2 (1.1)	4.2 (1.0)	0.113	b,c
12,000	3.9 (0.9)	4.1 (1.4)	4.0 (0.9)	4.1 (0.8)	0.407	b,c
24,000	3.0 (0.6)	3.3 (0.6)	3.3 (0.5)	3.2 (0.6)	0.516	a,b
Control (24,000 × 3)	2.4 (1.2)	2.2 (0.8)	2.3 (0.9)	2.3 (0.8)	0.487	a

ANOVA and Tukey's multiple comparisons ($\alpha = 0.05$). a–c denotes significant differences in columns.

Table 5 Microleakage scores (percent of margin; $n = 8$).

Energy density (mJ/cm^2)	Unstressed (%) avg.	Stressed (%) avg.	Unpaired t-test	Two-way ANOVA
4000 (water only)	53 (31)	52 (21)	0.96	a
4000	53 (31)	56 (27)	0.86	a
6000	58 (28)	55 (30)	0.85	a
8000	57 (25)	47 (24)	0.44	a
12,000	59 (18)	56 (31)	0.84	a
24,000	38 (14)	30 (5)	0.15	a
Control (24,000 × 3)	68 (25)	41 (32)	0.11	a

ANOVA and unpaired t-tests ($\alpha = 0.05$). No significant differences were found (in columns).

Table 6 Mechanical Properties of flexure bars compared with gingival KHN.

Energy density (mJ/cm^2)	Gingival KHN % of max	Triad (s)	Surface KHN % of max	Center KHN % of max	Flexural modulus		Flexure strength	
					GPa	% of max	GPa	% of max
4000	2.8(3.6)							
6000	22.6(0.8)	4	31.4(3.9)	22(0.9)	2.5(0.5)	20.0	35.2(5.5)	26.1
8000	39.2(4.5)							
12,000	54.1(0.3)	8	50(2.7)	50.7(3.1)	6(0.6)	47.5	71.4(5.8)	52.8
24,000	72.8(0.3)	16	70.1(1.3)	69.1(2.1)	9.1(1.2)	72.5	90.2(12.4)	66.7
Control (24,000 × 3)	96.5(1.2)	80	91.1(0.9)	91.2(5.5)	12.3(0.3)	97.4	125.2(7.4)	92.6

ANOVA and Tukey's multiple comparisons ($\alpha = 0.05$). All values within each column were significantly different from each other.

determine differences between individual groups ($\alpha = 0.05$). All KHN and flexural values were significantly different from each other at each energy density. An excellent correlation was found relating the surface KHN of the flexure bars with flexural modulus ($R^2 = 0.100$) or flexural strength ($R^2 = 0.98$).

Discussion

There was a strong correlation (Fig. 4) between KHN and DC ($R^2 = 0.99$). The rate of hardness acquisition was slightly delayed in energy density compared to the DC of the carbon double bonds (Table 3), and this could be due to the later formation of networking links in the polymer chains.[1] A greater increase in hardness relative to maximum hardness may have occurred with higher energy levels and subsequent increases in cross-linking.

It was interesting to observe no significant effect of thermal-mechanical stressing on microleakage or marginal defects. Several studies suggest that thermocycling resin composite restorations may not significantly affect microleakage in Class 2 resin composite restorations.[16-18] In a recent study, Wibowo[18] used Z100 and Single Bond in Class 2 restorations with gingival margins in dentin. He found no significant difference in microleakage between the thermal-cycled and non-thermal-cycled groups using a computer imaging technique of the gingival floor after breaking away the entire resin restoration.

Studies have shown conflicting results of load cycling, reinforcing the need for careful evaluation and interpretation due to differences in experimental designs.[19-30] Several researchers found no effect on microleakage from load cycling of resin composite restorations.[17,21-26] However, several authors did find an effect from load cycling[20,22,28] and other investigators found an effect from a simultaneous combination of thermal-cycling and loading[19,27,31] while another had mixed results.[32] Virtually all of the studies cited evaluated only microleakage with thermal-mechanical loading. However, two recent studies have found conflicting results when evaluating marginal gap formation and a combination of thermal-mechanical loading. Friedl et al.[33] found no significant increase in marginal gaps using ProBond and Prisma TPH in testing conditions fairly similar to this study (5000 thermal cycles and 500,000 load cycles at 1.7 Hz and 72.5 N in Class 2 restorations), but found a significant increase using Scotchbond MP and Z100. Interestingly, these investigators used a measurement technique similar to that used in this study and found an actual decrease in microleakage at the dentinal gingival margin in both groups after thermal-mechanical loading. They theorized that the decrease could have been due to hygroscopic expansion. However, a recent study by Lutz and Krejci[19] utilizing a three-dimensional scanner found an increase in the percentage of marginal gap formation in MOD resin composite restorations after a combination of simultaneous thermal and load cycling (3000 thermal cycles and 1,200,000 load cycles at 1.7 Hz and 49 N).

Several studies have found no correlation between gap formation and microleakage.[32,34-36] Similar results were found in this investigation. A linear regression analysis was performed relating the ridit scores and the microleakage values and found a poor correlation with an $R^2 = 0.24$. Any significant increase in marginal gap or defect would probably not contribute to an increase in microleakage, once the threshold width for dye penetration is met.

Various techniques have been utilized to assess dye penetration in microleakage studies. Many utilize a single section through the center of the restoration.[22-25,28,37,38] A three-dimensional technique whereby the entire restoration is removed has been shown to reveal more extensive dye penetration,[39-42] but it is more time consuming and does not allow good visualization of dentin tubule leakage.[42] Using multiple sections, as used in

this study, seems to be a practical compromise.[16,21,27,29,42] It was not surprising to see extensive leakage between resin composite and the dentinal gingival margin. This agrees with many studies utilizing dentin bonding agents.[20,16,21,24,26,42] A recent study by Hagge and others[37] found extensive microleakage under composite using a fifth generation bonding agent with and without flowable liners. The only group not to suffer heavy leakage utilized a resin-modified glass ionomer in an open sandwich technique. The enhanced performance of resin-modified glass ionomer liners on dentinal gingival margins has been substantiated in several laboratory and clinical studies.[33,38,43]

There was a significant loss in marginal integrity in the gingival margins with the lowest degrees of conversion after thermal-mechanical stressing. However, an identical group stored only in water suffered similar degradation. Strains at the gingival margin of the restoration were probably not significant during loading and thermocycling. This suggests that water, not the thermal-mechanical stressing, contributed to the increase in marginal defects in these susceptible groups. The lesser the extent of the polymerization reaction, the more residual monomers are available to be leached.[44] This inverse relationship ($R^2 = 0.95$) between degree of cure and percent elution was confirmed in a study by Rueggeberg and Craig.[45]

There was no significant difference in marginal defects between the incrementally filled control group and the bulk-filled 24,000 and 6000 mJ/cm^2 groups. Although the 6000 mJ/cm^2 group was statistically similar to the control and 24,000 mJ/cm^2 groups, it was on the edge of significant marginal deterioration as seen by the 4000 mJ/cm^2 groups and could not be recommended clinically. Perhaps the 6000 mJ/cm^2 produced a good combination of reduced shrinkage stress and just enough DC to prevent degradation primarily from water. However, at this low level of exposure, any slight variation in light guide angulation or loss in power density could result in severe marginal degradation due to the production of an under-cured gingival increment. Also, these lower energy groups could be more susceptible to solvents and enzymes not tested in this study. Subjectively, an increase in discoloration and opacity was seen in the marginal areas of many of the 4000 and 6000 mJ/cm^2 specimens. Therefore, a recommended lower limit of gingival margin acceptability in a bulk-filled Z250 resin composite restoration was created by 80% of maximum conversion, 73% of maximum hardness and approximately 70% of maximum flexural strength and modulus in the gingival marginal area as seen in the 24,000 mJ/cm^2 group (40 s at 600 mW/cm^2). Caution should be exercised when attempting to extrapolate the results of this study to resin composites other than minifilled hybrid Z250. Direct comparisons of the sufficiency of irradiation using absolute surface hardness are not generally appropriate because the hardness is influenced by both the nature of the resin matrix and the inorganic filler.[11]

Various studies have advocated incremental instead of bulk placement and curing for resin composite to decrease the effects of polymerization shrinkage and to provide complete polymerization in deeper cavities.[4,46-48] Incremental-placement may also reduce the ratio of bonded to unbonded surfaces and reduce the stress by making more resin available for flow.[49] However, other studies found no difference between bulk and incremental placement on marginal gap formation[50] or fluid permeability.[51] A computer simulation by Versluis and others[52] using finite element analysis showed that incremental filling yields higher polymerization shrinkage stresses. Polymerization contraction of each individual filling increment causes some deformation of the cavity, forcing the walls to bend and decreasing cavity volume. Less composite placed for the next filling increment results in a cavity that is volumetrically filled with less composite material than the original volume of the cavity and that results in a higher stress state.[52] However, this study is limited in that it takes the deformation of the composite to be the result of the final modulus and free shrinkage. Net deformation would be much lower if the change in modulus over time is considered. Using photoelastic material, Jedrychowski and others[53] found that bulk resin composite placement generated the lowest shrinkage stresses compared with various other incremental techniques. Perhaps there is more opportunity for stress relaxation in bulk cure because of volume of resin composite.

This study found no significant difference in gingival marginal defects between incremental cure (72,000 mJ/cm^2) and bulk curing at an energy density of 24,000 mJ/cm^2. The reasons for these findings, despite the great disparity in total energy density between the groups, may be due to a complex interaction of multiple factors. With incremental curing, mechanical properties of the resin composite adjacent to the gingival margin and bond between resin composite and adhesive are maximized. These factors favoring improved gingival margin performance are balanced with the increased polymerization shrinkage that occurs with the high energy density. With bulk cure, polymerization shrinkage is lessened due to a decrease in applied energy density.[10,54] Counteracting this is a decrease in the mechanical properties

of the resin composite adjacent to the gingival margin.[9] However, with the higher energy density group (24,000 mJ/cm^2) adequate mechanical properties at the gingival margin may result since functional forces through the restoration are likely dissipated to the tooth via adhesion. Another factor opposing gingival margin integrity in the bulk cure group may be a decreased adhesion of resin composite at the gingival margin as a result of the reduced energy density. Also, the small cavity design used in this study would produce less volumetric shrinkage and less stress development.

The maximum load of 85 N used in this study could have been increased in an attempt to produce gingival marginal degradation or until the restoration failed catastrophically. However, the clinical significance of such high forces and the likelihood of producing localized damage in the gingival area would be questionable.

Future studies are needed to determine the effect of energy density on caries resistance, interproximal wear resistance and post-operative sensitivity. Also, a less photosensitive material other than Z250 should be evaluated under similar conditions of this study to evaluate other available restorative resin composites. This additional information may provide a more general description of the minimum hardness ratio necessary at the base of a resin composite restoration to maintain marginal integrity.

Conclusion

Based on the limitations of this study, the following conclusions can be made concerning Z250 shade A-2 resin composite in Class 2 slot preparations with gingival margins in dentin with various degrees of conversion.

1. The first null hypothesis was partially satisfied: energy density had no significant effect on microleakage, however, it had a significant effect on gingival marginal defects.
2. The second null hypothesis was satisfied: there was no overall significant effect of thermal-mechanical stressing on gingival marginal defects or microleakage.
3. Water had a significant effect on the resin composite with very low DC at the gingival margin producing defects that appeared to be the result of dissolution of the composite.
4. Based on ridit analysis, a recommended lower limit of gingival margin acceptability in a bulk-filled Z250 resin composite restoration was created by 80% of maximum conversion or 73% of maximum hardness as seen in the 24,000 mJ/cm^2 group (600 mW/cm^2 for 40 s).

Disclaimer

The views expressed in this article are those of the author and do not reflect the official policy of the Department of Defense or other departments of the United States Government.

Acknowledgements

This study was supported, in part, by 3M ESPE, NIH/NIDCR Grants DE 09431 and DE 07079. We thank Drs Lawrence Musanje and John C. Mitchem for their ridit evaluation of specimens, Jerry Adey for his Scanning Electron Microscopy support and John Condon for his technical guidance with the fatigue machine.

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23.6 **Campodonico C, Tantbirojn D, Olin P, Versluis A, Cuspal deflection** and depth of cure in resin-based composite restorations filled by using bulk, incremental and transtooth-illumination techniques. J Am Dent Assoc 2011; 142:1176-1182.

RESEARCH

Cuspal deflection and depth of cure in resin-based composite restorations filled by using bulk, incremental and transtooth-illumination techniques

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ABSTRACT

ARTICLE 3

Background. Restoration techniques affect shrinkage stress and depth of cure. The authors tested cuspal deflection and depth of cure resulting from the use of different techniques (bulk, incremental, bulk/transtooth illumination) and two resin-based composites (deep curing and conventional).

Methods. The authors restored extracted teeth with deep-curing X-tra fil (VOCO, Cuxhaven, Germany) (by using bulk and incremental techniques) and Filtek Supreme Plus (3M ESPE, St. Paul, Minn.) (by using bulk, incremental and bulk/transtooth-illumination techniques). The sample size for each technique was five. They determined cuspal deflections as changes in buccal and lingual surfaces before and after restoration. To determine the extent of cure, they measured hardness 0.5 to 3.5 millimeters deep on the sectioned restorations.

Results. The authors found no difference in cuspal deflection between filling techniques within the same materials ($P > .05$). They found no difference in hardness for X-tra fil at any depth with either the bulk or the incremental technique ($P > .05$). Filtek Supreme Plus had higher hardness values at depths of less than 1.5 mm with the bulk/transtooth-illumination technique, whereas the bulk technique resulted in lower hardness values at depths of 2.0 mm and below ($P < .05$).

Conclusions. Cuspal deflection was not affected by filling techniques. X-tra fil cured up to a depth of at least 3.5 mm; Filtek Supreme Plus had lower curing values below a depth of 2 mm. The transtooth-illumination technique improved curing depth for restorations placed in bulk.

Clinical Implications. When using resin-based composite restorative materials, clinicians should be more concerned about the effect of filling techniques on curing depth than about how these techniques affect shrinkage stresses.

Key Words. Composite; cuspal flexure; cure; bulk; increment; transtooth illumination; hardness.

JADA 142(10):1176-1182.

Polymerization shrinkage of restorative resin-based composites has been associated with microleakage, debonding, secondary caries and postoperative sensitivity.[1-5] Among the techniques suggested to reduce polymerization shrinkage stress is the incremental placement of composite material, in which the clinician typically places the material in small increments of 2 millimeters or less and then photoactivates it from an occlusal direction.[6,7] Although the incremental technique may be necessary for adequate light penetration, its disadvantages include the possibility of trapping voids or contamination between layers and the increased time required to place the restoration. The benefit of using an incremental technique for reducing shrinkage stresses has been questioned on the basis of numerical and experimental analyses.[8,9] Idriss and colleagues[10] found no significant difference between bulk and incremental filling techniques when they examined marginal gap size in Class II composite restorations in vitro.

Besides filling techniques, the direction of shrinkage also often is regarded as an important factor in controlling shrinkage patterns in restorations. It once was believed that resin-based composite shrinks toward the source of light and thus could be manipulated to obtain a beneficial shrinkage orientation during photo-

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activation. Versluis and colleagues[11] pointed out that composite does not shrink toward the light and that, rather, the direction of shrinkage is determined predominantly by the presence or absence of a bond. This observation has been helpful for rationalizing curing protocols. Belvedere[12] proposed that a transenamel illumination technique involving light curing of a bulk-placed composite from buccal and lingual directions, and thus through the tooth enamel, can achieve the advantages of bulk placement while avoiding the disadvantages of incremental techniques. Light transmitted through the tooth structure initially polymerizes the most critical areas along the interfaces, establishing adequate bonding before polymerization shrinkage of the inner bulk interferes.[12]

Although low residual stress and good adaptation are important, thorough polymerization is an equally important consideration for any filling technique. The main concern regarding a bulk technique is whether the composite cures fully enough in the deeper portions to create a material that has acceptable physical and biocompatible properties. Using microhardness at various restoration depths as an indicator, Lazarchik and colleagues[13] showed that the extent of polymerization was not different between bulk-filled and incrementally filled restorations of a light-shade composite, whereas the bulk technique resulted in significantly lower microhardness values in a material of a darker shade. However, Amaral and colleagues[14] found no difference in microhardness at any depth between the bulk-placed or incrementally placed restorations, provided that the restorations were exposed to light from occlusal, buccal and lingual directions. Thus, the transtooth-illumination technique also may overcome the concern regarding depth of cure that is associated with bulk placement.

We conducted an in vitro study to investigate whether a bulk-placement technique affects shrinkage stress, and whether the clinician can prevent a compromised depth of cure by using a more deeply curing composite or by using the transtooth-illumination technique. Because shrinkage stress itself cannot be measured directly, we assessed its effect by measuring cuspal deflection of restored teeth. We assessed the extent of cure by measuring microhardness at various depths. To compare the effect of shrinkage stress between bulk-restored and incrementally restored teeth, we used a composite designed to cure up to a depth of 4 mm.

Figure 1. A. Mounted tooth in custom-made stainless steel ring with reference spheres. **B.** Cavity preparation, digitized with the LavaScan ST optical scanning system (3M ESPE, St. Paul, Minn.). Image B reproduced with permission of 3M ESPE.

This provided sufficient depth of cure to allow comparison of shrinkage stress effects from the two techniques. We used a conventional composite to compare the effects of transtooth illumination of a restoration placed in bulk with conventional bulk and incremental techniques.

METHODS

We chose for the study a hybrid composite that its manufacturer claims has a curing depth of 4 mm (X-tra fil, Universal shade, VOCO, Cuxhaven, Germany) and a nanocomposite (Filtek Supreme Plus, A2D shade, 3M ESPE, St. Paul, Minn.).

Sample preparation and digitization. The study protocol, which the institutional review board of the University of Minnesota, Minneapolis, designated as exempt, involved the use of 25 extracted human teeth. We secured the teeth in stainless steel rings (Figure 1A) and kept them immersed in water throughout the protocol to prevent desiccation. Each ring contained four embedded spheres surrounding the tooth sample, which functioned as stable reference areas. We sandblasted the spheres and etched the tooth enamel with 37 percent phosphoric acid solution to obtain dull surfaces suitable for optical scanning.

We prepared a large, slot-shaped mesiooccluso-distal cavity (4 mm deep, 4 mm buccolingual width) with a no. 245 carbide bur in a high-speed handpiece under copious amounts of water. The mean (standard deviation [SD]) wall thickness, measured at the middle of the restoration wall, was 2.39 (0.34) mm. After preparation, we digitized images of the teeth along with their reference spheres with an optical scanning system (LavaScan ST, 3M ESPE); the digital models had an estimated resolution of 60 micrometers and 5-µm accuracy (Figure 1B). We calibrated the scanner each day before conducting the experiments.

ABBREVIATION KEY. TT: Transtooth.

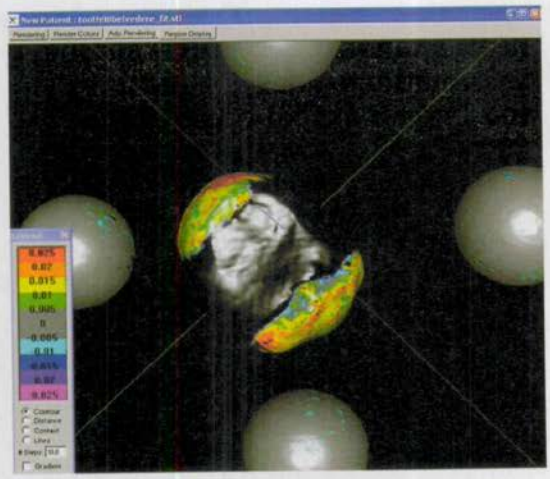

Figure 2. Coronal deformation as seen on Cumulus software (copyright Regents of the University of Minnesota, Minneapolis), with the reference spheres. The color scale in red, yellow and green shows the cusp movement toward the center of the tooth.

Experimental groups. We carried out two independent sets of experiments, one in which we restored teeth with X-tra fil and the other in which we restored teeth with Filtek Supreme Plus. We determined the sample size needed to enable us to detect a mean difference of one SD with a 95 percent confidence, on the basis of previous studies in which investigators used the same methodology.[15,16]

X-tra fil. We divided 10 teeth (six premolars and four molars) to be restored with X-tra fil into two groups (each n = 5) of matched pairs for shape and size; hence, each group contained three premolars and two molars. We filled each pair randomly with an incremental or a bulk technique. There was no significant difference in wall thickness between the two groups ($P = .05$).

Filtek Supreme Plus. We divided 15 matched premolars to be restored with Filtek Supreme Plus into three groups (each n = 5). We randomly filled the sets of three matched teeth with a bulk, an incremental or a transtooth-illumination bulk technique. There was no significant difference in wall thickness between the three groups ($P = .05$).

Filling and curing techniques. For the bulk technique, we placed the composite in one increment (4 mm) and light cured it for 40 seconds (20 seconds from the occlusobuccal direction and 20 seconds from the occlusolingual direction). For the incremental technique, we placed the composite in two horizontal increments approximately 2 mm thick and light cured it for 20 seconds (10 seconds from the occlusobuccal direction and 10 seconds from the occlusolingual direction). For the bulk/transtooth-illumination technique, we placed the composite in one increment (4 mm) and light cured it for 20 seconds simultaneously with two curing lights through the buccal and lingual surfaces, followed by 20 seconds from the occlusal direction. We used two high-intensity curing units (CureMax V LED Curing Light, Maximum Dental, Secaucus, N.J., and Allegro High-Intensity LED, Den-Mat, Santa Maria, Calif.). The light intensities, measured with the radiometer built into the Allegro charging unit, were 1,238 milliwatts per square centimeter and 1,294 mW/cm^2, respectively.

Bonding protocol. We used the same bonding protocol in each technique. We etched the cavity surfaces with 34 percent phosphoric acid (Caulk 34% Tooth Conditioner gel, Dentsply Caulk, Milford, Del.) for 15 seconds, rinsed them with water for 10 seconds, blotted them dry, applied Prime & Bond NT (Dentsply Caulk) for 20 seconds, lightly air dried them for five seconds and light cured them for 20 seconds. After we finished the restorations, we wiped the composite surfaces with an alcohol pad to remove the oxygen-inhibition layer. We did not polish the restorations. Immediately after restoration, we digitized the teeth in the LavaScan system.

Cusp flexure analysis. We accurately aligned the digitized tooth surfaces before and after restoration by using Cumulus software (copyright Regents of the University of Minnesota), fitting the stainless steel reference sphere surfaces in three dimensions.[17] By using a custom-developed software (CuspFlex), we calculated contour changes perpendicular to the original tooth surfaces. We selected the buccal and lingual surfaces above the gingival level of the restoration up to the cusp ridges as the areas subjected to cuspal deflection. We defined cuspal deflection as the difference between the restored tooth and the prepared tooth, determining the differences perpendicular to the buccal or lingual surfaces. A linear color scale was used to visualize changes in the tooth surfaces (Figure 2). We determined the average cuspal deflection of each surface by calculating the notional volume change (difference integrated over the buccal and lingual surfaces) divided by the surface area. The coronal deformation was the sum of buccal and lingual cuspal deflections.[15,16]

Microhardness determination. After scanning, we cross-sectioned the restored teeth buccolingually at the highest point of the cusp, perpendicular to the long axis of the tooth. We embedded the two halves in Orthodontic Resin (LD Caulk, Milford, Del.), and we polished the cross-sectioned surfaces serially by using a grinder-polisher

(EcoMet 3 Grinder-Polisher, Buehler, Lake Bluff, Ill.) and 400- and 600-grit silicon carbide paper (Buehler), followed by 1.0-µm and 0.05-µm alumina suspensions (Buehler).

We measured microhardness of the composite restorations by using a hardness tester (MicroMet 5104, Buehler) with a Vickers indentor at 200*g* load. We made a series of indentations along the long axis of the tooth in the center of the restoration at 0.5, 1.0, 1.5, 2.0, 2.5, 3.0 and 3.5 mm from the occlusal surface. We evaluated both halves of the restorations. The hardness value at each depth was the average of both sides.

Statistical analysis. To analyze the differences between the filling techniques for coronal deformation and for microhardness at each depth, we used the *t* test for X-tra fil and one-way analysis of variance (ANOVA) followed by the Student-Newman-Keuls (SNK) post hoc test for Filtek Supreme Plus. In addition, we analyzed the hardness differences among various depths for the same filling technique and the same composite by using one-way ANOVA followed by the SNK test. We performed all statistical analyses at a significance level of .05. We made no comparison between X-tra fil and Filtek Supreme Plus.

RESULTS

Cuspal deflection. The cusps of all teeth moved inward after restoration (Figure 2). In general, Filtek Supreme Plus caused more cuspal deflection than did X-tra fil. Table 1 lists the coronal deformation values, defined as the sum of the buccal and lingual cuspal deflection values. We found no significant difference among the filling techniques within the same composite material ($P > .05$).

Microhardness. Table 2 and Figure 3 (page 1181) show the measured microhardness values of the restorations at various depths. In general, X-tra fil restorations had hardness values higher than those of Filtek Supreme Plus. Figure 3 contains statistical results of the hardness differences among filling techniques (within the same composite material) at each depth. For X-tra fil, we found no significant difference between the bulk and incremental techniques at any depth ($P > .05$). For Filtek Supreme Plus, the hardness values of composite restored with the bulk/transtooth-illumination technique were significantly higher than those of composite restored with the bulk or incremental techniques at depths of 0.5, 1.0 and 1.5 mm, and the hardness values of composite restored with the bulk technique were significantly lower than those of composite restored with the bulk/transtooth-illumination or incremental techniques at depths of 2.0, 2.5, 3.0 and 3.5 mm ($P < .05$). The bulk/transtooth-illumination technique tended to produce hardness values higher than those of the other two techniques.

TABLE 1

Mean (standard deviation) coronal deformations (sum of buccal and lingual cuspal flexure).

MATERIAL AND TECHNIQUE	DEFORMATION (MICROMETERS)
X-tra fil*	
Bulk	15.6 (1.1)[a†]
Incremental	15.0 (3.7)[a]
Filtek Supreme Plus	
Bulk	16.2 (1.7)[a]
Incremental	17.7 (1.9)[a]
Bulk/transtooth illumination	17.3 (2.9)[a]

* X-tra fil is manufactured by VOCO, Cuxhaven, Germany.
† Same letters denote mean values that were not significantly different within the same resin-based composite material (according to *t* test for X-tra fil and analysis of variance/Student-Newman-Keuls post hoc test for Filtek Supreme Plus [3M ESPE, St. Paul, Minn.], $P > .05$).

Table 2 contains statistical results of the hardness differences among various depths for each filling technique. For X-tra fil, there was no significant difference in hardness between various depths for either filling technique (bulk or incremental, $P > .05$). For Filtek Supreme Plus, we found some differences between hardness values at various depths with all filling techniques. In Filtek Supreme Plus restorations placed with the bulk technique, hardness values at 2.5, 3.0 and 3.5 mm were significantly lower than those at 0.5 and 1.0 mm ($P < .05$). The hardness profile in the Filtek Supreme Plus group restored incrementally showed values decreasing between 0.5 and 1.5 mm, increasing at 2.0 mm and then decreasing again. Hardness values at 3.0 and 3.5 mm were significantly lower than those at 0.5 mm. In Filtek Supreme Plus restorations placed with the bulk/transtooth-illumination technique, the hardness values at 3.0 and 3.5 mm were significantly lower than those at 0.5 mm ($P < .05$), and the hardness values from 0.5 to 2.5 mm were not significantly different ($P > .05$).

DISCUSSION

Polymerization shrinkage has been of major concern to dental clinicians placing direct composite restorations in posterior teeth. On the one hand, a good adhesive seal helps prevent microleakage and ensure that the composite will reinforce the tooth structure, but, at the same time, such a bond will constrain polymerization shrinkage and thus induce stresses in the tooth structure. Use of

TABLE 2

Mean (standard deviation) Vickers hardness numbers at various depths.

MATERIAL AND TECHNIQUE	VICKERS HARDNESS NUMBER AND DEPTHS IN MILLIMETERS						
	0.5	1.0	1.5	2.0	2.5	3.0	3.5
X-tra fil*							
Bulk	121.8 (10.1)[a†]	118.2 (12.7)[a]	117.3 (7.9)[a]	115.3 (4.8)[a]	112.1 (6.4)[a]	115.2 (8.9)[a]	111.1 (5.5)[a]
Incremental	121.9 (18.2)[a]	117.78 (8.5)[a]	116.2 (10.4)[a]	117.8 (5.3)[a]	118.1 (2.4)[a]	113.5 (9.2)[a]	114.9 (10.3)[a]
Filtek Supreme Plus‡							
Bulk	101.3 (1.7)[a]	101.12 (1.7)[a]	97.2 (4.5)[a,b]	93.1 (4.4)[a,b,c]	88.5 (5.9)[b,c]	83.0 (6.3)[c,d]	75.1 (12.9)[d]
Incremental	102.3 (1.8)[a]	99.8 (4.5)[a,b]	95.6 (4.8)[a,b,c]	100.2 (3.9)[a,b]	97.3 (2.6)[a,b]	94.9 (3.1)[b,c]	90.6 (4.2)[c]
Bulk/transtooth illumination	107.4 (5.2)[a]	106.9 (3.3)[a]	106.5 (2.9)[a]	104.0 (3.8)[a]	101.3 (1.7)[a,b]	98.3 (2.3)[b,c]	95.0 (3.4)[c]

* X-tra fil is manufactured by VOCO, Cuxhaven, Germany.
† Same letters denote mean values that were not significantly different among depths within the same resin-based composite material and technique (according to analysis of variance/Student-Newman-Keuls post hoc test, $P > .05$).
‡ Filtek Supreme Plus is manufactured by 3M ESPE, St. Paul, Minn.

bulk placement has been suggested to produce lower shrinkage stresses,[8] but sufficient depth of cure may require an incremental technique.

Bulk versus incremental placement.

Shrinkage stresses. First, we tested the effect of bulk versus an incremental technique on shrinkage stresses by recording cuspal deflection. Often, clinicians fill deep restorations in more than two increments. Additional increments may increase the cuspal deflection owing to accumulation of incremental deformations of the weakened cavity walls,[8] but they still can be necessary to ensure good cure and bonding. We chose a two-layer incremental method because 2 mm usually is regarded as the maximum thickness for curing a composite and because the placement procedure was more controllable and thus more consistent. We found no significant difference in cuspal deflection between the bulk and incremental methods. Although deflection is not a stress itself, it is a manifestation of internal stress conditions within a tooth. For similar tooth and restoration shapes and properties, cuspal deflection provides a reasonable reflection of internal stresses. We obtained comparable shapes by matching teeth and standardizing cavity sizes, and we assumed tooth properties to be similar. To ensure similar composite properties in both bulk and incrementally filled restorations, we used X-tra fil composite, which the manufacturer claims can cure to a depth of as much as 4 mm. The microhardness values confirmed that curing levels with both methods were similar at all depths, and they showed no statistically significant differences (Table 2 and Figure 3A). The X-tra fil thus delivered the deep curing claimed by the manufacturer regardless of filling technique. Given that the conditions and cure were similar between the bulk and incrementally filled restorations and that the cuspal deflections were not significantly different, we conclude that differences in shrinkage stresses between the bulk and two-layer incremental placement methods could not have been substantial.

Curing depth. If the difference in shrinkage stress between bulk and incremental techniques thus was not a major issue, the next question is whether adequate cure could be ensured with a bulk technique. To test this, we used Filtek Supreme Plus, which the manufacturer recommends using in increments of no more than 2 mm thick. We compared conventional bulk and incremental techniques with a bulk/transtooth-illumination technique, which has been reported to cure the deep part of a restoration effectively.[12] The cuspal deflection results did not show significant differences among the three curing techniques. However, microhardness, which within a resin-based material has a good correlation with degree of cure for a broad range of conversion levels,[18-20] was affected by the different filling techniques. For the conventional bulk technique, we noted a continuous drop in the hardness values as the depth increased (Figure 3B). At 2.0 mm and below, hardness values of Filtek Supreme Plus applied in the bulk technique were significantly lower than those of the same material placed with the incremental and bulk/transtooth-illumination techniques. This confirms the general concern that a conventional bulk technique compromises depth of cure and the consequent recommendation for incremental methods. Since light attenuation in composite is the same regardless of whether the material was placed in bulk or with an incremental technique, the hardness values of material placed with the incremental technique followed the same con-

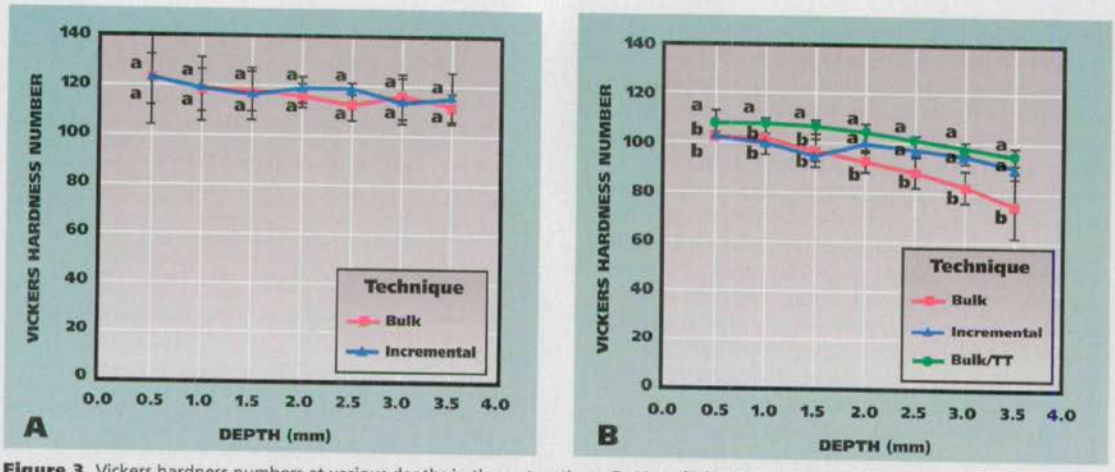

Figure 3. Vickers hardness numbers at various depths in the restorations: **A.** X-tra fil (VOCO, Cuxhaven, Germany) and **B.** Filtek Supreme Plus (3M ESPE, St. Paul, Minn.). Same letters denote mean values that were not significantly different between filling techniques at the same depth (*t* test for X-tra fil and analysis of variance and Student-Newman-Keuls post hoc test for Filtek Supreme Plus, $P > .05$). mm: Millimeters. TT: Transtooth (illumination technique).

tinuous drop as found in material placed with the bulk technique, except that there was a step increase at a depth of 2.0 mm (Figure 3B). The step increase in hardness at 2.0 mm corresponded well with the boundary between the first and second increments and thus represented the superficial composite of the first increment, which received more light energy (and higher cure) than the deeper composite of either increment. Incremental techniques thus improved the overall cure within a restoration.

Transtooth illumination. Little published information exists about the effectiveness of transtooth-illumination techniques. Although there is some skepticism about the effectiveness of techniques that involve curing through tooth structure, investigators in two studies reported that light could penetrate enamel and dentin walls and cure the inner portion of a restoration with no difference compared with the incremental technique, provided that the composite was cured from the buccal, lingual and occlusal directions.[13,14] In this study, we found that Filtek Supreme Plus restorations had significantly higher hardness when we used a bulk/transtooth-illumination technique than when we used the conventional bulk technique and also had significantly higher hardness values up to a depth of 1.5 mm than did restorations placed with an incremental technique (Figure 3B). In addition, the hardness values did not drop significantly until a depth of 3.0 mm (Table 2), which suggests a good overall polymerization. The superior performance of the transtooth-illumination technique in our study could be a result of the ability of light to penetrate enamel walls,[13] or it simply could arise from the fact that the amount of light energy applied with this technique was higher. In the bulk/transtooth-illumination technique, we cured the material for 20 seconds simultaneously with two curing lights through the buccal and lingual surfaces, followed by curing for 20 seconds from the occlusal direction (total, 60 seconds), whereas for the bulk and incremental techniques we cured for 20 seconds from the occlusobuccal and for 20 seconds from the occlusolingual direction (total, 40 seconds). Note that the light sources we used in the study were current-generation curing lights with high outputs that could cure adequately through the tooth structures. The bulk/transtooth-illumination technique resulted in coronal deformation values that were slightly higher than those found with the incremental and bulk techniques, but these were not statistically significantly different (Table 1). Therefore, there was no indication that the extra energy applied in the bulk/transtooth-illumination technique had increased shrinkage stresses significantly.

Hardness values. There is no clear consensus about how much conversion should be considered adequate. A bottom-to-top hardness ratio of 0.8 represents a bottom-to-top degree of cure of 0.9 and may be considered adequate curing.[21] In this study, we found that when cured with a conventional bulk technique, a Filtek Supreme Plus restoration at depths of 3.0 and 3.5 mm had hardness values lower than about 80 percent of the value at 0.5 mm depth, whereas with an incremental or bulk/transtooth-illumination technique, values at all measured depths were higher than 80 percent. X-tra fil had relative hardness values higher than 90 percent at all depths, regardless of

the filling technique used. Note that we could not calculate a bottom-to-top ratio because our hardness measurements started at 0.5 mm below the top surface. Readers also should be aware that we sectioned, embedded and polished the composite restorations to achieve a surface suitable for microhardness measurements. Any of these procedures could have increased the hardness values. Cheng and Douglas[22] found that hardness values increased more than 25 percent after restorations underwent polishing. Thus, hardness values of clinical restorations with the composites chosen for this study may be lower than the values reported here. On the other hand, clinical values could turn out to be higher for a less opaque shade of Filtek Supreme Plus that most clinicians prefer because it cures better than the relatively opaque A2D shade used in this study.[13] We selected the A2D shade to allow the LavaScan ST optical scanner to digitize the restoration.

In summary, the effect of different filling techniques on cuspal flexure was not significant in this study. Although shrinkage stress levels cannot be simply extrapolated from cuspal flexure, the results of our study suggest that clinicians should be more concerned about a thorough cure of a restoration than about placement technique. Long-term performance of a restoration is likely to depend more on the quality and physical properties of a restoration than on the minor differences in initial shrinkage stresses caused by placement techniques.

CONCLUSIONS

Within the limitations of this in vitro study, we conclude that the filling techniques we used resulted in no significant difference in the amount of cuspal deflection between the composites we evaluated.

We found that X-tra fil had adequate curing up to at least 3.5 mm when placed in one bulk increment, with no significant difference in hardness from that of X-tra fil placed with the incremental technique.

Filtek Supreme Plus had lower hardness values, and thus a lesser extent of cure, when restored with bulk technique than when restored with the incremental or bulk/transtooth-illumination techniques. In addition, the bulk/transtooth-illumination technique produced higher hardness values in the superficial layer of the Filtek Supreme Plus in comparison with the incremental technique.

The transtooth-illumination technique, which requires light curing from buccal, lingual and occlusal directions, can improve the depth of cure of composites placed in bulk without increasing cuspal deflection. ■

Disclosure. None of the authors reported any disclosures.

This study was supported in part by Non-tenured Faculty Grants to Drs. Versluis and Tantbirojn from the 3M Foundation, St. Paul, Minn.

The authors thank David G. Augustson for his technical support.

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Please see Section 22.2.2 SonicFill IFU

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Dental Materials 18 (2002) 463–469

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Energy dependent polymerization of resin-based composite

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Received 16 January 2001; revised 21 May 2001; accepted 19 June 2001

Abstract

Objective: This study explores the relationship between the extent of polymerization and the radiant energy (dose) applied during the photopolymerization of resin-based composites.

Method: FTIR was used to measure the 5-min and 24-h conversion of four resin-based composites prepared in a thin film and polymerized under conditions of decreasing intensity and a constant exposure time (30 s) using a tungsten halogen curing light. The measured conversion was obtained over a wide range of applied radiant energy. Additionally, samples for two of the materials were polymerized at various intensities and exposure times such that the dose remained constant. This process was performed at four dose levels representing approximately 75% of the conversion range.

Results: The curing profiles (percent conversion versus applied radiant energy) depict a gradual decrease in conversion with decreasing energy followed by a rapid descent. Though there are differences in the maximum conversion attained between the materials, when conversion is represented as a fractional conversion relative to the maximum 24-h value, their 5-min and 24-h curing profiles appear quite similar. Additionally, very similar conversion was measured when the films were exposed using equivalent doses providing evidence for a reciprocal relationship between irradiance (power density) and exposure time. For the 24-h measurements, statistical equivalence (Fishers protected LSD at the 0.05 level) was noted for most of the combinations of exposure time and power density within a given dose. Generally, the exceptions occurred with the shortest exposure times.

Significance: A reciprocal relationship between exposure time and power density adds significance to the study of conversion as a function of the total applied dose. This relationship establishes the curing profile as a universal correlation between exposure time and power density.

Keywords: Dental material; Resin-based composite; Composite; Conversion; Extent of cure; Energy; Intensity; Cure time; FTIR; Reciprocity

1. Introduction

The understanding of methacrylate-based polymerization of dental restorative materials is becoming increasingly important. This is due to a number of factors including the recent introduction of non-traditional curing sources (e.g. plasma arc lamps and lasers), curing techniques that promote a reduction in polymerization stress, and claims of curing resin-based composite (RBC) in thickness significantly greater than has been historically advocated. In all of these instances, the extent of polymerization (conversion) is a desired parameter to characterize since it relates to ultimate mechanical and dynamic mechanical properties [1], hardness and monomer solubility [2], fracture toughness [3] and wear [4].

Conversion of methacrylate functionalized dental restorative materials via photoinitiated polymerization is dependent upon several parameters. Monomer formulation has been shown to impact conversion of unfilled resins [1,5,6] and resin-based composite [7]. Even with the most reactive monomers, the fraction of reacted functional groups is significantly less than unity due to the highly cross-linked structure of the developing polymer. Increasing temperature increases the molecular mobility with a subsequent increase in conversion [8,9]. Conversion is also dependent upon the rate of polymerization and the exposure time. Since the former is impacted by the radiant intensity absorbed by the photoinitiator, the irradiance of the curing source and its spectral distribution become critical variables [10]. The efficiency of the photoinitating system and oxygen quenching also affect the polymerization rate [10] and hence, the conversion. This inhibition is particularly noted at the outer surface of materials incorporating acrylate and methacrylate

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0109-5641/02/$20.00 + 0.00
PII: S0109-5641(01)00069-0

Table 1
Materials investigated

Material	Code	Shade	Manufacturer	Lot no.
Heliomolar® radiopaque	HL	A3	Vivadent, Schaan, Lichtenstein	AO2845
3M™Silux Plus™ Anterior Restorative	SP	U	3M Dental Products, St. Paul, MN, USA	8EL
XRV™ Herculite®	XR	A3	Kerr Corporation, Orange, CA, USA	712399
3M™ Z100™ Restorative	Z	A3	3M Dental Products, St. Paul, MN, USA	8WR

resins. Of all these variables, the irradiance of the light source and the exposure time are of particular interest since they, in practice, are amenable to manipulation by the clinician.

The exposure time and intensity dependence on conversion of resin-based dental materials or their conversion dependant properties has been a topic of much investigation. Rarely, however, has the interdependence of intensity and exposure time on conversion been explored. Of particular interest is determining the conversion of acrylates and methacrylates polymerized under conditions of equivalent radiant energy (dose) by adjusting the irradiance (power density) and exposure time. Establishing a reciprocal relationship between these two parameters would add significance to the analysis of conversion as a function of radiant energy rather than as two separate variables. The post-vitrification polymerization of hexanediol diacrylate using differential scanning calorimetry and FTIR has been reported [11]. In one set of experiments, similar conversion for thin film samples measured via FTIR was reported when maximally polymerized with equivalent doses using a UV source. The exposure conditions, however, were well outside the range encountered in dentistry (from over 7 min up to 125 h). For bulk-cured dental RBC materials, similar depths of cure utilizing a scrape-back method and similar conversion profiles from FTIR measurements were found when cylindrical samples were polymerized with equivalent doses [12]. Finally, equivalent fracture toughness, flexural strength, and modulus values were found for four RBC materials when equivalent doses were applied [13]. Although equivalent conversion with an equivalent dose was inferred from these two studies, it was demonstrated only through a limited range of conversions [12] or under exposure conditions that are assumed to yield near maximum properties [13].

It was the intent of the present study to explore the energy dependency on conversion of resin-based composite by measuring conversion via FTIR at doses sufficient to span the full conversion range and to examine the reciprocal relationship between power density and exposure time at selected points within this range.

2. Methods and materials

The materials evaluated are identified in Table 1 and their composition described in Table 2. All contain Bisphenol A diglycidyl ether dimethacrylate (Bis-GMA) together with one or more other dimethacrylate diluents.

2.1. Conversion profiles

Transmission FTIR was utilized to determine monomer conversion as a function of radiant energy. Specimens were prepared by forming a thin film of composite (approximately 50–75 μ) between polyester film (25 μ) and a KBr plate. This assembly was placed on a slab of composite of the same type being measured and irradiated with a tungsten halogen curing light (3M™XL 3000 Curing Lamp, 3M, St. Paul, MN, USA). The radiation energy of the curing lamp at full output was determined using a power meter (Power Max 500D Laser Power Meter, Molectron Detector Inc., Portland, OR, USA) integrating the radiant power with respect to time over the interval of zero to 30 s (a constant irradiation time of 30 s was chosen to determine the curing profiles). Bandpass filters were used to limit the measured bandwidth between 400 and 500 nm. Power density was

Table 2
Material composition (Bis-GMA: Bisphenol A diglycidyl ether dimethacrylate; TEGDMA: Triethyleneglycol dimethacrylate; UDMA: Urethane dimethacrylate; DDMA: Decandiol dimethacrylate; Bis-EMA: Ethoxylated bis-phenol A dimethacrylate). All data obtained from manufacturer literature except as indicated

Code	Monomers	Fillers	Filler size	% filler content
HL	Bis-GMA, UDMA, DDMA	Colloidal Silica, copolymer, ytterbium trifuoride	0.04–0.2 μm (range)	78/59 (wt/vol)
SP	Bis-GMA, TEGDMA	Colloidal Silica, copolymer	0.04 μm (avg.)	56/40
XR	Bis-GMA[a], TEGDMA[a], Bis-EMA[a]	Colloidal Silica, Barium-aluminum boro silicate	0.6 μm (avg.)	67/46
Z	Bis-GMA, TEGDMA	Zirconia silicate	0.6 μm (avg.)	84.5/66

[a] Ref. [14].

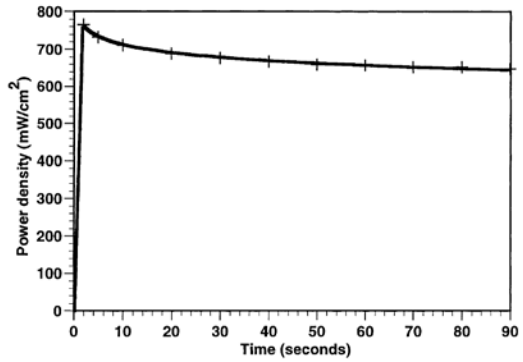

Fig. 1. Unattenuated power output of curing light.

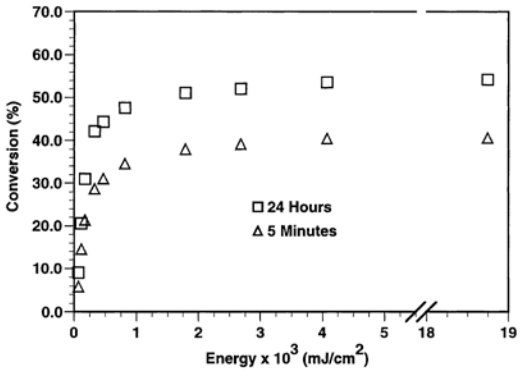

Fig. 2. Heliomolar—conversion vs applied energy. Each point represents an average of three measurements.

determined by dividing the measured power by the cross sectional area of the light guide. Because of the limited response time of the above meter when determining the light output immediately after being switched on, a second power meter was used (351 Power Meter, UDT Instruments, Baltimore, MD, USA) to measure the power output of the curing lamp during the first 5 s. This data was then included in the determinations of the integrated energy after cross calibration of the two meters. Attenuation was achieved by neutral density filters placed between the light guide and the KBr plate. The attenuation factor of the filters together with the KBr plates were determined using the latter power meter (351 Power Meter) and the aforementioned curing lamp. The spectral output of the curing lamp with and without filtering was recorded with a spectroradiometer to ensure that the filters attenuated the spectral output without changing the spectral distribution.

Infrared spectra were recorded with a Magna 550 FTIR spectrometer (Nicolet, Madison, WI, USA) using 32 scans at a resolution of 4 cm^{-1}. Spectra were collected at 5 min from start of cure and 24 h post-irradiation. A background spectrum of the polyester film was made prior to each sample spectrum. Conversion was calculated from the decreasing absorbance of the methacrylate carbon double-bond vibration at 1638 cm^{-1} using as an internal reference the aromatic skeletal absorbance from Bis-GMA at 1582 cm^{-1}. Integrated areas of both peaks were determined using a standard baseline technique. After the 5-min measurement was complete, samples were stored at room temperature in nitrogen until the 24-h spectra were recorded. Each test condition was run in triplicate.

2.2. Power density/exposure time reciprocity

Reciprocity was examined for materials XR and Z at four applied energy levels. A series of samples prepared as above were irradiated with equivalent doses by adjusting the exposure time and power density. This process was accomplished by determining the exposure time required to yield a desired energy level through integration of the unattenuated lamp output and accounting for a filtering factor. Spectra were recorded after 5 min from start of irradiation and again after 24 h. Conversion was determined using the same method described above. Results within each energy level were analyzed with one-factor ANOVA and compared for differences using Fisher Protected LSD at a 0.05 significance level. Each test condition was run in triplicate.

3. Results

Fig. 1 shows the unattenuated power output of the curing lamp. As with many tungsten halogen curing devices, the power decays after reaching a maximum output shortly after being switched on. An alternative would have been to let the power stabilize before initiating exposure. It was the intent of the present investigation, however, to operate the lamp as it would be used in practice. Figs. 2–5 show conversion as a function of radiant energy at 5 min and 24 h for the four materials evaluated. The abscissa has been split to increase the resolution of the data at low energies. It is also instructive to compare the curing profiles between materials by expressing the conversion as a percentage of the maximum 24-h conversion. This is shown in Figs. 6 and 7 for the 5-min and 24-h measurements respectively. These two figures show the full data collected. Although no statistical differences within a material were measured over the upper three-quarters of the exposure energy range, a trend towards maximum conversion with increasing power density is seen. Finally, Tables 3 and 4 show conversions obtained at equivalent energy doses for materials XR and Z. Statistically significant differences between means ($p = 0.05$) within an energy level are identified with letter designation for both the 5-min and 24-h values. There appears to be a slightly greater range for the 5-min measurements compared to the 24-h values within a given dose, though this is not true

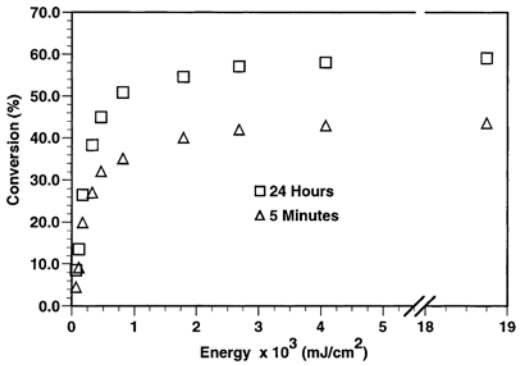

Fig. 3. Silux Plus—conversion vs applied energy. Each point represents an average of three measurements.

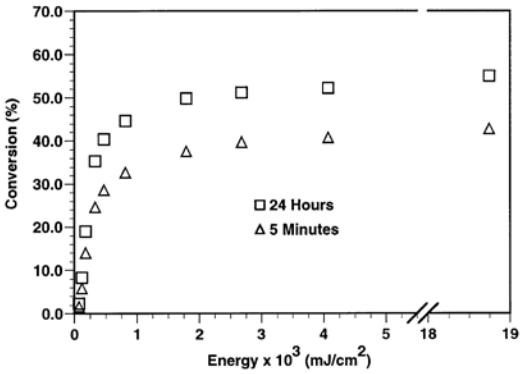

Fig. 5. Z100—conversion vs applied energy. Each point represents an average of three measurements.

for all groups. The 24-h values show quite similar conversion at a given dose for the four levels.

4. Discussion

Consistent with previous studies on dental resins [1] and resin based composite [7] a limiting conversion was found at maximum intensity. This result is characteristic of highly crosslinked polymers in which the developing network severely restricts the mobility of the reacting constituents. It is also apparent from the figures that significant conversion occurs post-irradiation in the interval between 5 min and 24 h. For each material, the extent of the 'dark-cure' is consistent throughout the plateau extending into the 'knee' of the curing profile. This additional cure from 5 min to 24 h represents, depending upon the material, as much as 19–26% of the final conversion. Below the knee of the curing profile, the dark-cure measured within this interval decreases though it is still measurable even at very low intensities. Due to the lag between the end of exposure and the first measurement (41/2 min) the full extent of post-irradiation conversion is not represented throughout the curing profile. Though data was not collected within this time interval at low conversion, supporting experiments have shown the additional cure to be as much as 35% when measured from the end of a 30 s exposure for material Z when converted maximally (unpublished data). Approximately 37 and 62% of this occurs within the first 5 and 60 min respectively. Post-irradiation conversion for RBC inlay materials from measurements made immediately after irradiation and 24 h later have been reported [15]. Additional conversion approaching 30% relative to the final measurement was found for some of the materials when polymerized maximally. Although the post-irradiation polymerization of resin based composite has been described previously via hardness measurements [16], a non-linear correlation with conversion [2] prevents a direct comparison. These previous experiments are in agreement with the results of this study that extensive post-irradiation polymerization does occur over the first 24 h.

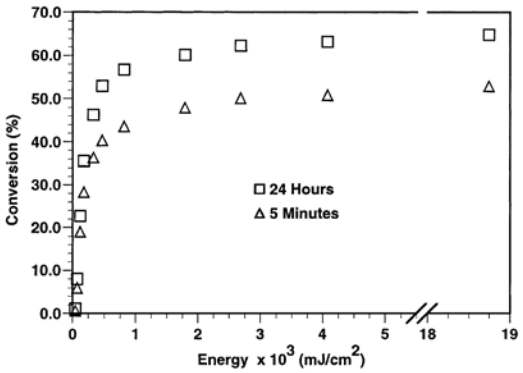

Fig. 4. Herculite XRV—conversion vs applied energy. Each point represents an average of three measurements.

As noted previously, the conversion within an increment of a given thickness of material will be related to the efficiency of the photoinitiating system, the intensity at the increment and the irradiation time. Figs. 6 and 7 reveal similar curing profiles when conversion is represented relative to the maximum 24-h conversion. While this was not predicted, it might be understood, in part, by considering the widespread use of photoinitiating systems based on camphorquinone (CPQ) and tertiary amines. While no attempt was made to identify the specific amine present in all the materials investigated, manufacturer's data, together with gas chromatographic results, revealed that all materials use CPQ. Below the knee of the curing profile, a greater range in fractional conversion between the materials is noticed at a given energy. Structural differences in the dimethacrylate monomers used in these materials may account for this effect either through differences in chemical

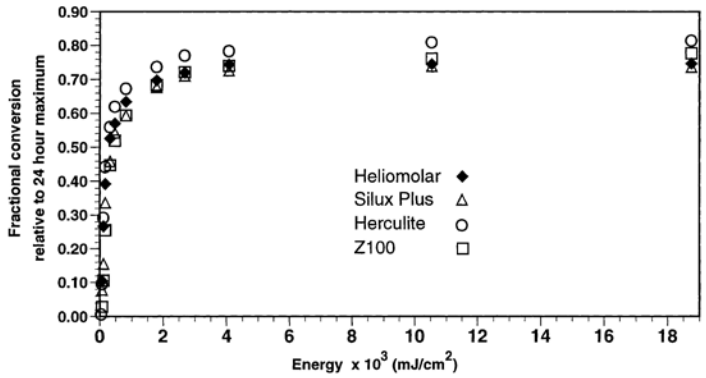

Fig. 6. 5-min curing profile: 5-min conversion values are shown relative to the maximum 24 h conversion.

reactivity due to steric or polar differences [17], or to pendant group mobility [18]. The differences noted may also be due, in part, to filler composition through a radical termination mechanism [19].

The influence of power density on the extent of conversion is readily illustrated through its relationship to the polymerization rate. With continuous illumination, the rate of free radical polymerization of acrylates and methacrylates follows a characteristic pattern throughout the course of the reaction due to diffusion limitations on the reacting species. This pattern is manifested early in the reaction by a decrease in the radical termination rate and a concurrent increase in the radical concentration. As a consequence, the rate of polymerization accelerates (autoacceleration) through a maximum despite a decreasing monomer concentration. After having passed through this maximum, the rate begins to decrease due to continuation in monomer consumption. As the network develops further, the rate of radical propagation eventually becomes diffusion limited and the polymerization rate decelerates, often towards a limited conversion in the presence of unreacted monomer and a significant population of radicals. Decreasing power density will decrease the rate of polymerization and shift the maximum rate to longer times [20]. Provided the irradiation time is not limited, conversion will continue through to its diffusion limited maximum. If irradiation is terminated while propagation is chemically controlled, the final conversion will be reduced from its maximum. The severity of this reduction is observed in Fig. 7 where the rapid descent in conversion is observed to occur over a relatively narrow applied energy range relative to the full exposure. The conversions measured in this interval (0–500 mJ/cm^2) suggest that the rate of propagation has not yet come under appreciable diffusional control [6] and incomplete conversion results from terminating the reaction during the chemically controlled phase of propagation. A significantly greater energy expenditure is required for a much smaller change in conversion near the knee of the curing profile and into the plateau. This result is expected due to the greater diffusional limitations present at increased conversion.

In the previous discussion, it was noted that in order to increase conversion with lower power density, longer exposure times are required. Tables 3 and 4 reveal that increasing the exposure time under conditions of declining intensity

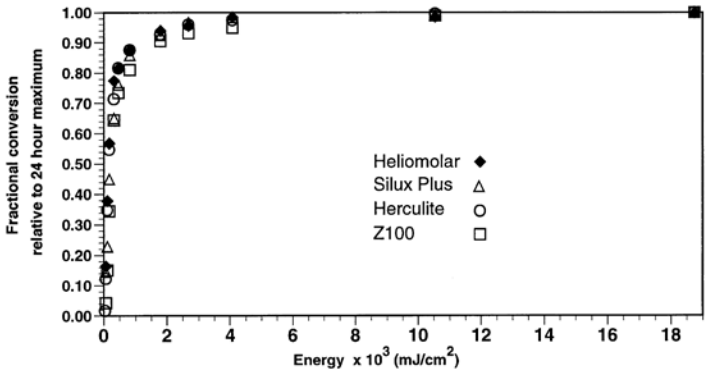

Fig. 7. 24-h curing profile: 24-h conversion values are shown relative to the maximum 24 h conversion.

Table 3
Conversion at equivalent radiant energy for material XR (mean values within an energy level designated with the same superscripts are statistically equivalent, $p = 0.05$, $n = 3$ per group)

Energy (mJ cm^{-2})	Exposure time (s)[a]	Conversion (%)	
		5 min	24 h
3931	7	47.7(0.8)[a]	60.3(1.4)[a]
3931	30	48.7(1.2)[a]	60.7(1.0)[a]
3931	70	50.6(0.9)[b]	61.8(0.5)[a]
3931	158	51.9(0.6)[b]	61.0(0.5)[a]
1724	6	44.7(0.9)[a]	57.5(1.5)[a]
1724	13	45.6(0.3)[a,b]	58.1(0.3)[a,b]
1724	30	46.6(0.7)[b,c]	58.7(1.0)[a,b]
1724	67	48.0(0.7)[c,d]	59.2(0.7)[b]
1724	120	49.2(0.9)[d]	59.2(0.7)[b]
314	3	36.2(0.4)[a]	46.6(0.9)[a,b]
314	6	35.8(0.4)[a]	45.8(1.0)[a]
314	12	37.4(0.8)[b,b]	46.2(1.8)[a]
314	21	38.0(0.5)[b,c]	46.0(1.4)[a]
314	40	38.8(0.5)[c]	48.1(1.8)[a,b]
314	86	39.8(0.4)[d]	48.8(1.4)[b]
69	8	13.8(2.3)[a]	14.6(2.5)[a]
69	14	13.0(1.3)[a]	13.2(2.5)[a]
69	30	11.8(1.2)[a]	11.3(2.6)[a]

[a] Determined from integration of unattenuated power output and a filtering factor to yield the desired energy.

Table 4
Conversion at equivalent radiant energy for material Z (mean values within an energy level designated with the same superscripts are statistically equivalent, $p = 0.05$, $n = 3$ per group)

Energy (mJ cm^{-2})	Exposure time (s)[a]	Conversion (%)	
		5 min	24 h
3931	7	37.2(0.7)[a]	48.5(0.7)[a]
3931	30	39.5(0.9)[b]	50.3(0.9)[b]
3931	70	40.4(1.0)[b,c]	50.3(1.0)[b]
3931	158	41.7(0.7)[c]	51.6(0.7)[b]
1724	6	34.7(1.4)[a]	45.0(1.1)[a]
1724	13	35(0.2)[a]	45.7(0.5)[a,b]
1724	30	36.5(1.3)[a,b]	46.9(1.1)[b]
1724	67	37.4(0.9)[b]	46.8(.03)[b]
1724	120	37.3(0.7)[b]	46.7(1.4)[a,b]
314	3	24.6(0.8)[a,b]	31.8(1.5)[a,b]
314	6	24.2(1.0)[a]	30.6(1.3)[a]
314	12	26.5(1.3)[c]	34.4(1.7)[b,c]
314	21	26.4(0.5)[a,b,c]	33.5(1.2)[b,c]
314	40	27.1(1.7)[c]	35.5(1.2)[c]
314	86	26.4(1.8)[a,b,c]	35.3(2.2)[c]
113	7	11.7(1.0)[a]	12.6(0.9)[a]
113	16	12.2(0.4)[a]	14.7(1.7)[a]
113	30	11.5(0.8)[a]	12.6(0.6)[a]

[a] Determined from integration of unattenuated power output and a filtering factor to yield the desired energy.

such that the total energy remains constant has resulted in similar conversion. This result was consistent throughout the curing profile for both materials. Similar results were noted under conditions producing maximum conversion for a multifunctional diacrylate [11]. In the aforementioned study, while increased conversion was noted at the lowest intensities, this result occurred using extremely long exposure times (greater than 12 h) and was explained from kinetic theory as being due to the dependency of kinetic chain length on intensity. In the present investigation, the exposure time was considerably less. Except as indicated in Tables 3 and 4, equivalent conversion at 24 h was found at the doses investigated. Exceptions were generally found only at the shortest exposure times. Inadequate resolution of the measured lamp power (Fig. 1) within the first 10 s, during which it is changing most rapidly, is a likely contributing factor. For example, a single half-second temporal error will result in an approximate 25% error in integrated energy at an exposure time of 3 s. A consistent underexposure error of this magnitude in this timeframe is not unrealistic considering the procedure used to measure the energy. At 30 s, this magnitude of temporal error results in negligible error in integrated energy. The differences noted within a group are not expected to be a result of temperature increase at extended exposure times as photoinitiated copolymerization of acrylates between KBr plates has been shown to be isothermal [9]. It is presumed, in the present case, that a single KBr plate will yield similar conditions. Despite these slight differences in conversion, the reciprocity between exposure time and power density from a practical standpoint is amply demonstrated.

The observation of reciprocity for these materials extends the significance of the curing profiles since any combination of exposure time and power density within the range investigated will reproduce a similar curve. At the surface of bulk-cured RBC isolated from air, it is expected that the profile will be directly applicable in predicting the final conversion from the power density and exposure time. Insufficient conversion at this surface generally is not a concern since nearly maximum conversion can be achieved with relatively low power density and short exposure times (e.g. a 10 s exposure with an incident irradiance of 200 mW/cm^2 is sufficient to achieve 90% of the maximum conversion—Fig. 7). This profile is also expected to pertain within the depth of a composite where decreasing light intensity will shift the energy for a given exposure time toward the lower part of the curve. The decrease in energy will mirror the exponential decay of intensity with depth and will be composition dependent. Ideally, the transmission properties of light through RBC in conjunction with the conversion profile are sufficient to describe the percent conversion with depth. Preliminary data suggests this hypthesis to be true, and further work is in progress to verify this. Non-isothermal polymerization may limit the applicability of estimating conversion from a curing profile generated under presumed isothermal conditions.

5. Conclusion

Very similar curing profiles for four, commercially available, photoinitiated resin-based composite materials were observed when thin films were exposed to decreasing power density. Conversion at distinct points along this conversion profile can be duplicated with equivalent applied energy, which documents the reciprocal relationship between power density and exposure time over a timeframe of practical interest. The significance of these results is that given the curing profile for a resin based composite and its transmission properties for a curing light, the conversion at any point within the material can, in theory, be determined for any applied dose.

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DENTAL MATERIALS 24 (2008) 1501–1505

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How should composite be layered to reduce shrinkage stress: Incremental or bulk filling?

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ARTICLE INFO

Article history:
Received 26 July 2007
Accepted 3 March 2008

Keywords:
Composite restoration
Cusp deflection
Bulk filling
Horizontal incremental filling
Oblique incremental filling

ABSTRACT

Objectives. The purpose of this study was to determine the effect of different layering techniques on cuspal deflection in direct composite restorations.

Methods. Aluminum blocks were used to prepare MOD cavities divided into three groups. Each cavity was restored with composite using three different filling techniques. Group 1 was filled in bulk, group 2 was restored by a horizontal increment technique, and group 3 by an oblique increment technique. Cuspal deflection was measured with LVDT probes and compared among groups using ANOVA and Scheffe's post hoc test ($\alpha = 0.05$).

Results. The cuspal deflections in groups 1–3 were $21.6 \pm 0.90\,\mu m$, $19.3 \pm 0.73\,\mu m$ and $18.4 \pm 0.63\,\mu m$, respectively. The bulk filling technique yielded significantly more cuspal deflection than the incremental filling techniques, while there was no significant difference between the horizontal and oblique increment methods.

Significance. Cuspal deflection resulting from polymerization shrinkage can be reduced by incremental filling techniques to obtain optimal outcomes in clinical situations.

1. Introduction

With the increase in esthetic demand and the development of adhesive techniques, resin composite has, for many, become the material of choice for posterior tooth restoration. In spite of the many advantages of the material, polymerization shrinkage, and its associated stress, continues to be a concern for direct resin composite restorations [1–5]. The polymerization shrinkage stress may cause the movement of cusps, debonding or enamel cracks [6–9], and also has the potential to result in microleakage, postoperative sensitivity and secondary caries [10–13]. Various clinical methods have been proposed to reduce the shrinkage stress, such as the control of the curing light intensity [14,15], flowable resin liner application [16], indirect resin restoration [8], and incremental layering techniques [6–8]. However, no method has been shown to be totally effective in abating the effects of polymerization shrinkage.

Versluis et al. [17] assessed the developing stress fields for different incremental filling techniques using finite element analysis (FEA), concluding that the incremental filling technique increased the deformation of the restored tooth and led to a more highly stressed tooth-composite structure. Abbas et al. [18] showed, in cuspal deflection measurements using premolars, that multiple increments induced greater cuspal movement than a single increment. In contrast, Segura

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doi:10.1016/j.dental.2008.03.013

and Donly [6], and McCullock and Smith [7], suggested that incremental build up resulted in significantly less initial cuspal deflection. More recently, Lee et al. [8] reported that incremental filling and indirect restoration decreased cuspal movement by 34.1% and 32.2%, respectively, compared to bulk filling.

In other studies, different layering techniques have been shown to be unrelated to polymerization shrinkage stresses and cuspal deformation. Kuijs et al. [19] used 3D FEA to show that the differences produced by various filling techniques were smaller than expected. In the experimental setups with tooth models, it was shown that the magnitude of the cuspal deflection was not significantly different among the groups using different filling techniques [20,21]. It may be that many variables in the study designs contributed to their inconsistent results. While FEA can integrate the parameters for geometry and material properties, it cannot exactly simulate the transitional change of resin flow during polymerization [17,19]. In addition, when teeth are used in the experiment, one must consider that the anatomical features are not identical among specimens. Dissimilarity between teeth can be caused by differences in the histochemical characteristics of each individual tooth substrate.

Despite the controversy over the advantages of incremental build-up of composites, this technique has been broadly recommended in direct resin composite restoration, because it is expected to decrease the C-factor (the ratio of bonded surface to unbonded free surface), allowing a certain amount of flow to partially dissipate the shrinkage stress. But it is not yet clear what incremental technique is most appropriate, despite the fact that many propose oblique layering in order to avoid or delay the bonding together of opposing cusps, thus reducing the stress levels within the restoration.

In this study, aluminum molds with an identical shape and size were used for the purpose of minimizing the substrate variation inherent with the use of natural teeth. Time-dependent measurements were performed using linear variable differential transformers (LVDT) to compare the effect of incremental techniques and bulk filling on polymerization shrinkage stress. The null hypothesis was that there would be no difference in cuspal deflection among the various layering techniques.

2. Materials and methods

2.1. Measurement devices

Two LVDT probes (AX-1, Solartron Metrology, West Sussex, UK) were set on two XYZ tables (Macro Motion Technology, Bucheon, Korea) with three attached micrometers (Mitutoyo, Kawasaki, Japan) (Fig. 1). The sensitivity of the LVDT probes exceeded 0.1 μm in the range of ±1 mm. Calibration was carried out to set the output voltage to 10 mV for each one micrometer of displacement. Cuspal deflection was detected by the LVDT and the measured value was stored on a computer using a data acquisition board, PCI-6024 (National Instruments, Austin, TX, USA) with data acquisition and analysis software Labview (National Instruments).

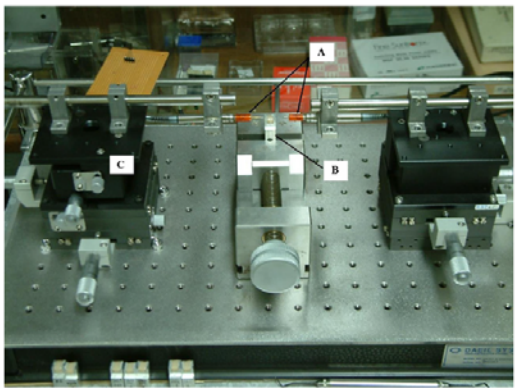

Fig. 1 – Instrument for measurement of cuspal deflection: (a) LVDT probes, (b) aluminum block, and (c) XYZ table with micrometer.

2.2. Specimen preparation

A milling machine was used to prepare fifteen MOD cavities in aluminum blocks (10 mm × 8 mm × 40 mm) (Fig. 2a). The cavity size was 6 mm (*W*) × 8 mm (*L*) × 4 mm (*D*) and the remaining cusp width and length were 2 mm and 4 mm, respectively. The inside of the cavity was air-abraded with a 50-μm aluminum oxide powder and thoroughly rinsed using water and acetone. After being dried, Porcelain primer (Bisco Inc., Schaumburg, IL, USA) was applied on all of the cavity walls and dried. Single-bond adhesive (3M ESPE. St. Paul, MN, USA) was applied to all the cavity walls, dried, and light cured for 10 s with an Elipar Freelight 2 (3M ESPE. St. Paul, MN, USA). The intensity of the curing light was 800 mW/cm^2.

2.3. Measurement of cuspal deflection

The aluminum blocks were randomly divided into three groups and fixed on the measuring device with a metal vise. The tips of two LVDT probes were positioned at the highest point of each cusp (Fig. 2b). The cavity in the aluminum block was restored with dental composite (Z 250, 3M ESPE. St. Paul, MN, USA) in the following ways (Fig. 3):

- *Group 1: Bulk filling technique*. Composite was placed in one increment and light cured from the upper surface for 40 s, the mesial side for 20 s, and the distal side for 20 s (total 80 s).
- *Group 2: Horizontal incremental technique*. Composite was placed in three horizontal consecutive layers. Each increment was light cured for 20 s and additionally for 20 s from the upper surface to make curing time identical (total 80 s).
- *Group 3: Oblique incremental technique*. Composite was placed in three oblique increments with each increment being light cured for 20 s followed by an additional 20 s curing from the upper surface (total 80 s).

For each cavity, placement of an equal amount of composite was ensured by weighing the material before use. In groups

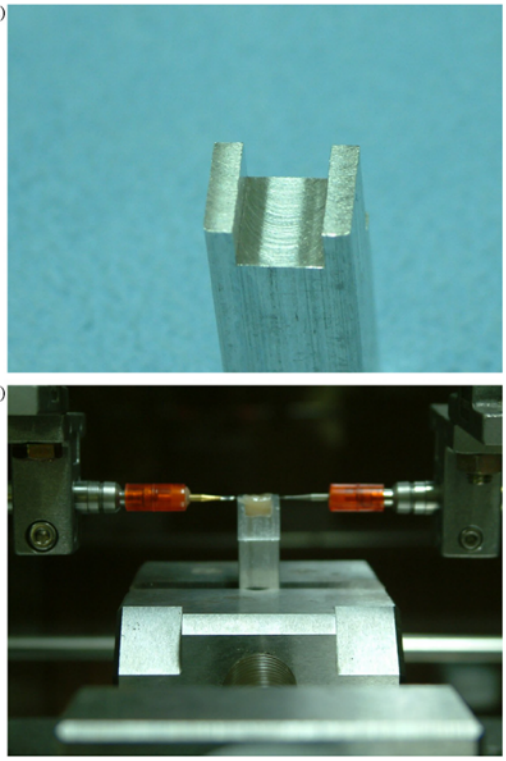

Fig. 2 – (a) Aluminum block machined for MOD cavity and (b) positioning of LVDT probes.

2 and 3, the composite was equally divided into three portions with each portion representing a single increment.

Data acquisition was initiated 30 s before the composite was light cured. While storing the data, the second and third composite layers were applied and light cured for groups 2 and 3. Data was collected at the rate of 2 data points/s and data recording was continued for 3700 s. The amounts of displacement measured on both sides of the cavity walls were summed to produce a single value for total deflection. Five measurements were made for each group at a temperature of $25 \pm 0.5^{\circ}$. The data was analyzed by ANOVA and Scheffe's post hoc test at the $\alpha < 0.05$ level.

3. Results

The representative deflection curves vs. time during polymerization shrinkage are shown in Fig. 4a–c. Most of the cusp displacement occurred within 500 s, with little change occurring thereafter. In group 1, the cusp deflections in the right and left side occurred simultaneously from the start of curing, while in groups 2 and 3, the displacement occurred in a stepwise manner. In group 3, the deflection mode followed the order of the increments, which were placed first on the left side, followed by the right side, and then finally connecting both sides. The mean value of deflection in group 1 was $21.6 \pm 0.90\,\mu m$, in group 2 $19.3 \pm 0.73\,\mu m$, and in group 3 $18.4 \pm 0.63\,\mu m$ (Fig. 5). The deflection in group 1 was significantly higher than in group 2 or 3 ($p < 0.05$). There was no significant difference between the deflections in groups 2 and 3 ($p > 0.05$).

4. Discussion

The goal of this study was to determine the most efficient way to layer dental composite to reduce polymerization shrinkage stresses. Measurement of cuspal deflection has been used as the representative index for polymerization shrinkage stress. In this study three different filling techniques were compared. To produce accurate measurements, it was important that every experimental step be precise and detailed, because the detection of cuspal deflection was highly sensitive (i.e. between 5 μm and 25 μm) [8,18,20,23–25].

There are several critical factors to be considered in the experimental procedures. First, the variable nature of tooth substrate needs to be reflected. Tooth displacement can be influenced by physical factors such as the modulus of viscoelasticity [27], anatomical features like cusp size and shape, and structural defects (e.g. presence of internal crazes and enamel cracks) [8]. Considering that hydrated teeth have shown less deflection than dried teeth [24], using extracted teeth which were stored and manipulated using different conditions may have been related to the highly variable nature of the results. In previous studies, data has shown large coefficients of variance that have exceeded the mean value in most of the groups. The authors have explained that this high variation may be caused by the geometric and biological diversity of the tooth substrates [6]. This was the motivation for using the precisely fabricated aluminum blocks in this study. Aluminum was chosen for the tooth simulating material because

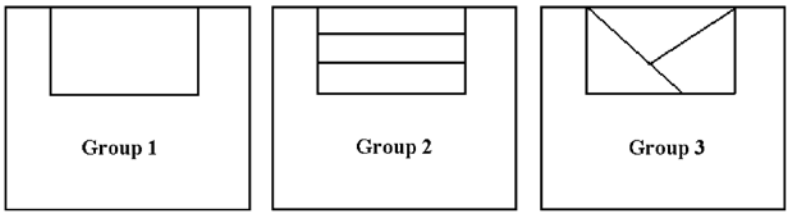

Fig. 3 – Three filling techniques (group 1: bulk filling; group 2: horizontal incremental filling; group 3: oblique incremental filling).

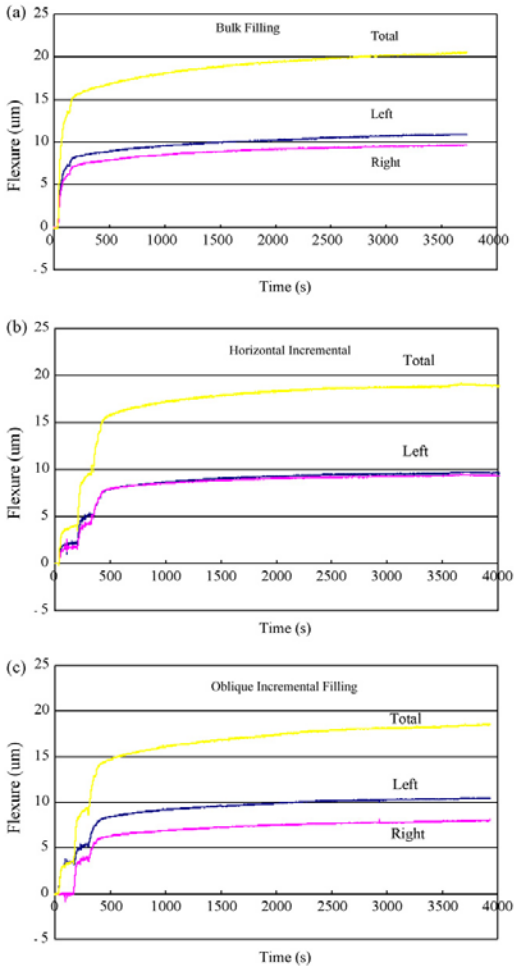

Fig. 4 – Representative curves of deflection as a function of time: (a) bulk filling, (b) horizontal incremental filling, and (c) oblique incremental filling.

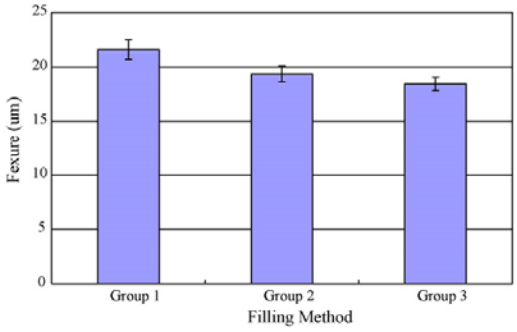

Fig. 5 – Mean value of cuspal deflection for each group.

it has an elastic modulus of 68.5 GPa, which is within the range of that of tooth enamel: 84.1 GPa, and dentin: 18.5 GPa [26]. In supplemental experimentation, it was determined that the compliance of the aluminum "cusp" used in this study was 0.803 μm/N, which is approximately 1/3–1/4 of the compliance of a premolar MOD cavity [27]. As a result, the data obtained from each measurement was relatively consistent (S.D. was lower than 4.2% of the mean value).

The width and depth of the prepared cavity can also influence the measurements of deflection produced by composite contraction stresses. Hood [28] considered the cavity wall as a cantilever beam and reported that the deflection is proportional to the cube of cusp height and inversely proportional to the cube of cusp thickness. Lee et al. [8] measured the buccolingual width of teeth and evenly grouped specimens by their size, which resulted in a small S.D. (5–18% of mean value). The aluminum blocks used in this study had identical-sized cavities in an attempt to standardize this parameter.

The amount of composite used to fill each cavity also needs to be standardized. If the cavity is deformed from shrinkage produce by the first increment, there is less volume and therefore less composite needed for the next increment when compared to the undeformed cavity. This difference in material can also affect the total shrinkage [17]. In this study the same amount of composite was weighed in advance and applied in the cavity for each increment. The additional variables that were controlled in this study were the irradiation mode and curing time in an attempt to reduce the number of variables that might have affected the outcomes.

In this study, the bulk filling group showed more cuspal deflection than the horizontal and oblique filling groups, which was in agreement with the authors' previous study [8]. It is well known that polymerization shrinkage stress is influenced by the C-factor of the cavity [22]. An increase in the C-factor restricts the flow of the shrinking composite material, because more of the material is constrained at the interface between the cavity walls and the composite [1,8,22]. The C-factor calculated in the aluminum block was largest in the bulk filling group (2.33), followed by the horizontal filling group (1.44 for each layer) and the oblique filling group (first layer: 1.31, second layer: 1.83, and third layer: 1.34). This correlates with the deflection patterns recorded in the experiments, where bulk filling produced a sudden shrinkage and "tooth" deflection during the initial stage of polymerization. In the other two groups, shrinkage occurred concurrently with each increment, but the total amount of deflection was still smaller than in the bulk filling method. This result is in contrast to that from the study using FEA [17].

The aluminum molds used in this study did not represent the histological and morphological properties of natural tooth, but successfully excluded the significant specimen variance. This study showed that the incremental filling technique significantly reduced cuspal deflection from polymerization shrinkage ($p < 0.05$), and therefore the null hypothesis was rejected. While this technique contributed to lessen the shrinkage stress, there are some drawbacks related to the technique such as increased chair time, the inclusion of voids between the layers, etc. The final proof of the benefit of this technique, however, can only be obtained through a clinical comparison of these methods.

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K141081

Date: April 23, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Premarket Notification

To Whom It May Concern:

Enclosed in duplicate is the following information:

A. Purpose of Submission: New Device

B. Name and Address of the Third Party:

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

C. Name and Address of the Manufacturer:

3M ESPE Dental Products

2510 Conway Avenue, Building 275-2W-08

St. Paul, MN 55144

D. Device Name

Trade or Proprietary Name: Filtek Bulk Fill Posterior Restorative

Classification Name: Tooth Shade Resin Material

Regulation Number: 21 CFR 872.3690

Recommendation: Substantially Equivalent

Date Submission was received by Regulatory Technology Services LLC: April 17, 2014

We have enclosed the following materials:

E. Authorization Letter from the applicant (MAL-F-0006).
F. Complete 510(k) application submitted by the applicant.
G. Documented review of the 510(k) application (RPP-F-0012, RPP-F-14 and all correspondence and documents related to the review).
H. Conflict of Interest Certification (COI-F-0018)
I. Certification (RPP-F-0020)

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420 or email at mark@markjob.com. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

Date: April 23, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
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Sincerely,

Mark Job
Responsible Third Party Official

Submission Certification

1. I certify that Regulatory Technology Services LLC continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by the FDA;

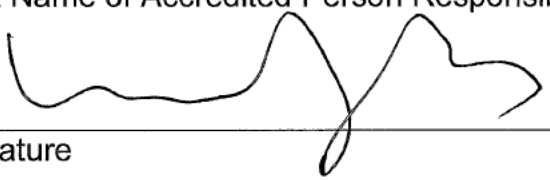
2. In addition, I state that Regulatory Technology Services LLC believes that statements made in the review are true and accurate to the best knowledge of Regulatory Technology Services LLC;

3. Regulatory Technology Services LLC's review is based on the 510(k) that is attached with the review; and

4. Regulatory Technology Services LLC understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 33(q).

Mark Job

Print Name of Accredited Person Responsible Official



Signature

Date: 23 APRIL 2014

Conflict of Interest
Declaration and Certification
For the review of the 510(k) submission from

Applicant: 3M ESPE Dental Products

Device Name or Model Name: Filtek Bulk Fill Posterior Restorative

Initials

MJ I have read and understand Regulatory Technology Services LLC's Conflict of interest and Confidentiality Procedure (COI-S-0023), regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

MJ I have not been employed within the last twelve months by the firm who submitted the 510(k) for evaluation.

MJ I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).

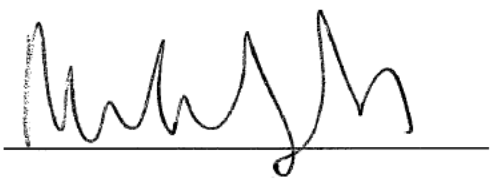
MJ I have not performed testing in connection with this specific device 510(k).

MJ I understand that the Accredited Persons (AP) Program requires that the Accredited Person or any of its personnel involved in 510(k) reviews, which includes those who have authority over the review process, have no ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest.

MJ I do not participate in the design, manufacture or distribution of any medical device.

MJ I do not provide consultative services to any device manufacturer or distributor regarding specific device 510(k) or participate in the preparation of 510(k.

MJ I have not performed a 510(k) review where I have a personal relationship with the sponsor or the application correspondent.

Signed: 

Printed Name: Mark Job

Date: 16 APR 2014

Conflict of Interest
Declaration and Certification
For the review of the 510(k) submission from

Applicant: 3M ESPE Dental Products

Device Name or Model Name: Filtek™ Bulk Fill Posterior Restorative

Initials

CS I have read and understand Regulatory Technology Services LLC's Conflict of interest and Confidentiality Procedure (COI-S-0023), regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

CS I have not been employed within the last twelve months by the firm who submitted the 510(k) for evaluation.

CS I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).

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CS I have not performed a 510(k) review where I have a personal relationship with the sponsor or the application correspondent.

Signed: Carole Stamp

Printed Name: Carole Stamp

Date: 4/16/14

Third Party Review
Reviewer Memorandum

Third Party Organization: Regulatory Technology Services LLC

Signature: [signature] Date: 4/23/14

Print Name: Carole Stamp Title: Reviewer

Signature: [signature] Date: 4/23/14

Print Name: Todd J Shopp Title: Program Supervisor

510(k) Applicant's Name: **3M ESPE Dental Products**

Device Name: **Filtek™ Bulk Fill Posterior Restorative**

Contact Person: **Scott Erickson, RAC**

I. Purpose and Submission Summary:

The 510(k) holder (**3M ESPE Dental Products**) would like to introduce the **Filtek™ Bulk Fill Posterior Restorative** into interstate commerce. Filtek™ Bulk Fill Posterior Restorative is a modification of predicate device Filtek™ Supreme Ultra Universal Restorative cleared under K083610. The formulation was modified to increase depth of cure, while decreasing polymerization shrinkage stress. During the review of the original submission dated April 15, 2014 one request for clarification was emailed to the sponsor on April 22, 2014. The email response dated April 23, 2014 was provided by the sponsor to respond to the clarification questions. All clarification questions have been adequately addressed. The submission includes performance testing methods/protocols, pass/fail criteria, and a summary of the results.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription Use) Page Number: **Page 32 of original submission**	X		
Truthful and Accuracy Statement Page Number: **Page 33 of original submission**	X		
510(k) Summary Page Number: **Pages 27-31 of original submission**	X		
Standards Form (FDA Form 3654) Page Number: **Pages 42-67 of original submission**	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are “cleaning” instructions included for the end user?		X	

The device description begins on page 71 of the original submission. The 3M™ ESPE™ Filtek™ Bulk Fill Posterior Restorative material is a visible-light activated, restorative composite optimized to create posterior restorations simpler and faster. This bulk fill material provides excellent strength and low wear for durability. The shades are semi-translucent and low stress curing, enabling up to a 5 mm depth-of-cure. With excellent polish retention, Filtek™ Bulk Fill Posterior Restorative is also useful for anterior restorations that call for a semi-translucent shade. All shades are radiopaque. Filtek™ Bulk Fill Posterior Restorative is offered in A1, A2, A3, B1, and C2 shades.

The fillers are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica cluster

filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of agglomerated 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.4% by volume). The principal resins used in Filtek™ Bulk Fill Posterior Restorative are ERGP-DMA, diurethane-DMA and 1, 12-dodecane-DMA. Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as manufactured by 3M™ ESPE™, which permanently bonds the restoration to the tooth structure.

Filtek™ Bulk Fill Posterior Restorative is a modification of predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610), also manufactured by 3M ESPE Dental Products. The formulation was modified to create semi-translucent shades with low polymerization shrinkage stress to enable bulk placement and cure for ease of use.

Both Filtek™ Supreme Ultra Universal Restorative and Filtek™ Bulk Fill Posterior Restorative are packaged in traditional syringes for dispensing restorative on a pad outside the mouth, and single-dose capsules for dispensing restorative intraorally. The 3M ESPE 5707SD Restorative Dispenser (Class 1, per 21 CFR 872.4565, Product Code 76EID) is used for dispensing the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610) and other 3M ESPE restoratives from capsules. The same 5707SD Restorative Dispenser will also be used to dispense Filtek™ Bulk Fill Posterior Restorative capsules.

The following is a listing of the packaging configurations and catalog numbers covered in this submission.

Item	Catalogue/Order Number
Syringe Refills (each includes Instructions for Use)	
Filtek Bulk Fill Posterior Restorative • 1- 4g A1 Shade Syringe	4863A1
Filtek Bulk Fill Posterior Restorative • 1- 4g A2 Shade Syringe	4863A2
Filtek Bulk Fill Posterior Restorative • 1- 4g A3 Shade Syringe	4863A3
Filtek Bulk Fill Posterior Restorative • 1- 4g B1 Shade Syringe	4863B1
Filtek Bulk Fill Posterior Restorative • 1- 4g C2 Shade Syringe	4863C2
Capsule Refills (each includes Instructions for Use)	
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g A1 Shade Capsules	4864A1
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g A2 Shade Capsules	4864A2
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g A3 Shade Capsules	4864A3
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g B1 Shade Capsules	4864B1
Filtek Bulk Fill Posterior Restorative • 20 - 0.2g C2 Shade Capsules	4864C2
Accessories	
Restorative Dispenser*	5707SD

* The currently marketed 3M ESPE 5707SD Restorative Dispenser (Class 1, per 21 CFR 872.4565, Product Code 76EID) is used for dispensing the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610), from capsules. The same 5707SD Restorative Dispenser will also be used to dispense Filtek™ Bulk Fill Posterior Restorative capsules.

Mechanism of Action

When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

A product photo is provided on page 74 and the device drawings are provided on page 75 of the original submission. Below is the photo of the **Filtek Bulk Fill Posterior Restorative** Syringe and Capsule copied from page 74 of the submission.

Filtek Bulk Fill Posterior Restorative Syringe and Capsule

Material Description

The material functions, ingredients, CAS Numbers, and weight percentage ratios are shown in the following table.

* Descriptions of each ingredient (e.g., Chemical Name, Function, Chemical Structure, Molecular Weight and Molecular Formula) are provided in Tables A through V on pages 81 through 93 of the original submission.

** (b) (4)

(b) (4)

(b) (4)

Composition for Filtek™ Bulk Fill Posterior Restorative

Function	Ingredient	CAS Number	Table*	Quantity (w/w%)**
(b) (4)				

Manufacturing Facility

3M ESPE Dental Products

(b) (4)

Device Performance Specifications

The following table outlines the design requirements/specifications for the **Filtek Bulk Fill Posterior Restorative**. These design requirements were set to ensure that Filtek Bulk Fill Posterior Restorative has sufficient physical properties to perform as intended.

Physical Property	Unit	Test Method	Minimum Design Requirements*
(b) (4)			

*Based on currently marketed 3M ESPE composite restorative materials used to restore teeth.

The performance specifications below for Filtek™ Bulk Fill Posterior Restorative consist of device design requirements (above) plus specifications selected from voluntary standards.

Physical Property	Unit	Test Method	Specification
(b) (4)			

Voluntary standards utilized include ISO 4049:2009 Dentistry - Polymer-based Restorative Materials and ISO 6874:2005 Dentistry - Polymer-Based Pit and Fissure Sealants. 3M ESPE Dental Products has tested Filtek™ Bulk Fill Posterior Restorative and found that it meets the relevant requirements of these two standards.

Note that Flexural Modulus is not a requirement of ISO 4049, however, Flexural Modulus can be derived from the ISO 4049 method for Flexural Strength. Summaries of 3M ESPE internal test methods (i.e., those other than ISO 4049 and ISO 6874) are located in Section 18.2 of the original submission. These test methods are very similar to those used for the clearance of the Filtek™ Supreme Ultra Universal Restorative (K083610). Refer to **Section XI Performance Testing - Bench** of this Reviewer Memorandum for description of test method differences.

The device description is very similar to the predicate devices and does not raise any new questions related to safety and effectiveness.

IV. Indications for Use

The proposed indications for use for the **Filtek Bulk Fill Posterior Restorative** are as follows:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Base/liner under direct restorations
- Core build-ups

- Splinting
- Indirect restorations including inlays, onlays and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

There are no contraindications for the Filtek Bulk Fill Posterior Restorative. The Filtek Bulk Fill Posterior Restorative is a single use, non-sterile, prescription use device. The proposed indications for use for the Filtek Bulk Fill Posterior Restorative device are the same as stated in the Indications for Use form, the 510(k) Summary, and the Instructions for Use.

V. Predicate Device Comparison

The Substantial Equivalence comparison tables start on page 95 of the original submission. The following are the three predicate devices utilized in this submission: Filtek™ Supreme Ultra Universal Restorative K083610, 3M ESPE Dental Products; Metamorphosis K091023, (Trade Name: SonicFill, Sonic-Activated Bulk Fill Composite) Kerr Corporation; and Tetric EvoCeram Bulk Fill K111958, Ivoclar Vivadent.

The Filtek Bulk Fill Posterior Restorative is compared to the predicates in the following categories: Intended Use/Indications for Use/Contraindications (Section 12.2.1 of submission), Formulation (Section 12.2.2 of submission), Physical Properties (Section 12.2.3 of submission), and Bench Test Data/Performance (Section 12.2.4 of submission).

Intended Use/Indications for Use/Contraindications Comparison

The following table compares the Intended Use/Indications for Use/Contraindications.

Filtek™ Bulk Fill Posterior Restorative	**Filtek™ Supreme Ultra Universal Restorative K083610**	**SonicFill, Sonic-Activated Bulk Fill Composite K091023**	**Tetric EvoCeram Bulk Fill K111958**
Intended Use			
Dental Restorative	Dental Restorative	Dental Restorative	Dental Restorative
Indications for Use			
Direct anterior and posterior restorations (including occlusal surfaces)	Direct anterior and posterior restorations (including occlusal surfaces)[1,2]	…designed for direct placement. It is indicated for all cavity classes in posterior teeth.[1] Direct placement in all cavity classes in anterior and posterior teeth [2]	Restorations in the posterior region (Classes I and II, including the replacement of individual cusps)[1] Restorations in the posterior region (Classes I and II)[2] Class V restorations (cervical caries, root erosion, wedge-shaped defects)[1,2]
Base/liner under direct restorations		Base/liner material[2]	
Core build-ups	Core build-ups[1,2]	Core buildups[2]	Reconstructive build-up[1]
Splinting	Splinting[1,2]		
Indirect restorations including inlays, onlays and veneers	Indirect restorations including inlays, onlays and veneers[1,2]		
Restorations of deciduous teeth			Restorations of deciduous teeth[1] Restoration of deciduous teeth[2]

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Extended fissure sealing in molars and premolars		Pit and fissure sealant[2]	Extended fissure sealing in molars and premolars[1,2]
Repair of defects in porcelain restorations, enamel, and temporaries		Repair of enamel defects, repair of temporaries, repair of porcelain restorations[2]	
Contraindications			
None	None	None	Placement of Tetric EvoCeram Bulk Fill restorations is contra-indicated: – if a dry working field cannot be established, or if the stipulated technique cannot be applied; – if a patient is known to be allergic to any of the ingredients in Tetric EvoCeram Bulk Fill.[1] None[2]

1. Indications/Contraindications from product labeling
2. Indications/Contraindications from FDA 510(k) clearance letter enclosure

The sponsor supported the difference in indications for use as follows:

> Difference: The "Contraindication" in the Tetric EvoCeram Bulk Fill Instructions for Use (IFU) is not stated in the FDA 510(k) clearance letter K111958 enclosure. The need for proper isolation is addressed in the Filtek™ Bulk Fill Posterior Restorative IFU under:
> "3. Isolation: A rubber dam is the preferred method of isolation. Cotton rolls and an evacuator can also be used." and
> "7. Adhesive System: To bond Filtek™ Bulk Fill Posterior Restorative to tooth structure, use of a 3M™ ESPE™ dental adhesive system (for example 3M™ ESPE™ Scotchbond™ Universal) is recommended. Refer to adhesive system product instructions for full instructions and precautions for the products. After curing the adhesive, continue to maintain isolation from blood, saliva and other fluids and proceed immediately to placement of Filtek™ Bulk Fill Posterior Restorative."
>
> Information related to patient allergy is addressed in the Filtek™ Bulk Fill Posterior Restorative IFU under:
> "Precautionary Information for Patients: This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product."

This difference does not affect the safety or efficacy of the device. The proposed indications for Filtek™ Bulk Fill Posterior Restorative are substantially equivalent to those of the predicate devices.

The reviewer agrees with this explanation of the indications for use difference and that the indications of the new device are equivalent to the predicate devices combined.

Formulation Comparison

The following table compares the Formulation for the new device to the predicate Filtek™ Supreme Ultra Universal Restorative K083610.

(b) (4)

* (b) (4)
(b) (4)

** D, E, B shades means Dentin, Enamel and Body shades.

The sponsor supported the differences in formulations as follows:

Detailed formulas are not available for SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill.

(b) (4)

(b) (4)

3M ESPE dental products has experience using all ingredients in Filtek™ Bulk Fill Posterior Restorative in other marketed 3M ESPE restorative products, except ERGP-
(b) (4)
(b) (4) Please see Section 15 Biocompatibility in the original submission for summary of toxicity testing conducted on in Filtek™ Bulk Fill Posterior Restorative. Please see Section 12.2.4 for Bench Test Data Comparison with S/E Devices.

In a more general sense, the formulation of Filtek™ Bulk Fill Posterior Restorative is substantially equivalent to the formulations of all of the predicate devices, Filtek™ Supreme Ultra Universal Restorative, SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill, in that (b) (4)
(b) (4)

The reviewer agrees with this explanation of the formulation differences and that the formulation of the new device is equivalent to the predicate devices.

Physical Properties Comparison

The following table compares the Physical Properties for the new device to the predicate devices. Properties marked with an asterisk (*) are provided per the FDA's "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions," issued October 26, 2005.

PROPERTIES	**Filtek™ Bulk Fill Posterior**	**Filtek™ Supreme Ultra Universal Restorative K083610**	**SonicFill, Sonic-Activated Bulk Fill Composite K091023**	**Tetric EvoCeram Bulk Fill K111958**
Filler particle size distribution*	The fillers are a combination of a non-agglomerated/non-aggregated 20 nm silica filler, a non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles), and a ytterbium trifluoride filler consisting of agglomerated 100 nm particles. The inorganic filler loading is about 76.5% by weight (58.4% by volume).	The fillers are a combination of a non-agglomerated/ nonaggregated 20nm silica filler, a non-agglomerated/non-aggregated 4 to11 nm zirconia filler and an aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles). The Dentin, Enamel and Body shades have an average cluster particle size of 0.6 to 10 microns. The Translucent shades have an average cluster particle size of 0.6 to 20 microns. The inorganic filler loading is about and 72.5% by wt (55.6% by volume) for the translucent shades and 78.5% by wt (63.3% by volume) for all other shades.	Glass, oxide, chemicals (CAS# 65997-17-3) Silicon dioxide (CAS# 7631-86-9) Particle size distribution not disclosed.	The fillers contain barium glass, ytterbium trifluoride, mixed oxide and prepolymer (79–81% weight). Additional contents: additives, catalysts, stabilizers and pigments (<1.0% weight). The total content of inorganic fillers is 76–77% weight or 53–54% volume. The particle size of the inorganic fillers is between 40 nm and 3,000 nm with a mean particle size of 550 nm.

PROPERTIES	Filtek™ Bulk Fill Posterior	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Methacrylate-based Resin matrix	(See 12.2.2 Formulation Comparison with S/E Devices table)	(See 12.2.2 Formulation Comparison with S/E Devices table)	Ethoxylated bisphenol-A-dimethacrylate (CAS# 56744-60-6) Bisphenol-A-bis-(2-hydroxy-3-mehacryloxypropyl) ether (CAS# 1565-94-2) Triethyleneglycoldimethacrylate (CAS# 109-16-0)	Bis-GMA (CAS# 1565-94-2) UDMA (CAS# 72869-86-4)
Wavelength (nm) for curing*	400nm to 500nm	400nm to 500nm	Wavelength not disclosed	400nm to 500nm
Intensity (mW/cm^2) for curing*	Instructions provided for 550 to 1000 mW/cm^2 lights and for 1000 to 2000 mW/cm^2 lights	Instructions provided for ≥ 400 mW/cm^2 lights	Intensity not disclosed	Instructions provided for ≥ 500 mW/cm^2 lights and for ≥ 1000 mW/cm^2 lights
Curing time recommendations (sec)*	Classes I, III, IV and V 550 to 1000 mW/cm^2: 40 sec	Body, Enamel and Translucent: 20 sec Dentin, A6B and B5B: 40 sec	Demi/Demi Plus, 20 seconds L.E.Demetron II, 20 seconds Optilux 501: Boost mode, 20 seconds / Ramp Mode, 40 seconds / Regular Mode, 40 seconds In the posterior, light cure the recommended time from the occlusal, remove the matrix and cure again from the buccal and lingual.	≥ 500 mW/cm^2: 20 sec
	Classes I, III, IV and V 1000 to 2000 mW/cm^2: 20 sec			
	Class II 550 to 1000 mW/cm^2: 20 sec occlusal, 20 sec buccal, 20 sec lingual For class II restorations, remove the matrix band prior to the buccal and lingual curing steps.			≥ 1000 mW/cm^2: 10 sec

PROPERTIES	Filtek™ Bulk Fill Posterior	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
	Class II 1000 to 2000 mW/cm^2: 10 sec occlusal, 10 sec buccal, 10 sec lingual For class II restorations, remove the matrix band prior to the buccal and lingual curing steps.		In a Class I, additional cure is still recommended from the facial and lingual.	
Depth of cure recommendation (mm)*	Classes I, III, IV and V 4 mm	2 mm for all shades except Dentin, A6B and B5B	Up to 5 mm	4 mm
	Class II 5 mm	1.5 mm for Dentin, A6B and B5B shades		

Bench Test Data/Performance Testing Comparison

The following table compares the Bench Test Data/Performance Testing for the new device to the predicate devices. Voluntary standards utilized include ISO 4049:2009 Dentistry - Polymer-based Restorative Materials and ISO 6874:2005 Dentistry - Polymer-Based Pit and Fissure Sealants. 3M ESPE Dental Products has tested Filtek™ Bulk Fill Posterior Restorative and found that it meets the relevant requirements of these two standards. A subset of this data, useful for comparison with predicate devices, has been included in the table below.

Note that Flexural Modulus is not a requirement of ISO 4049, however, Flexural Modulus can be derived from the ISO 4049 method for Flexural Strength. Summaries of 3M ESPE internal test methods (i.e., those other than ISO 4049 and ISO 6874 listed below) are located in Section 18.2 of the original submission.

The specifications in the table below include the Performance Specifications from the Device Performance Specifications on pages 5-6 of this Reviewer Memorandum as well as targets established by 3M ESPE for other tests that are useful for comparison. Note that specifications below for ISO tests are the same as, or more stringent than, the specifications in the ISO standard.

PHYSICAL PROPERTIES	Unit	Test Method	Specification	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Compressive strength*	MPa	(b) (4)					
Diametral Tensile Strength	MPa						
Flexural strength*	MPa						
Flexural Modulus*	MPa						
Surface hardness (Barcol)*	N/A						
Radiopacity*	mm of Al						
Water Sorption*	$\mu g/mm^3$						
Water Solubility*	$\mu g/mm^3$						
Release profile*	N/A						

PHYSICAL PROPERTIES	Unit	Test Method	Specification	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Working & Setting Times*	N/A	(b) (4)					
Watts Shrinkage	%vol Shrink-age						
Wear	N/A						
Depth of Cure*	mm						
Depth of Cure*	mm						
Cusp Deflection 4X4 mm	µm						
Polish Retention	Gloss units						

* FDA's "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions," issued October 26, 2005, asks that these properties be addressed in the 510(k).

** "leading bulk fill composites" in the table above means light-cure bulk fill composites that are placed and cured in increments that are ≥4mm in depth. SonicFill, Sonic-Activated Bulk Fill Composite and Tetric EvoCeram Bulk Fill are examples of bulk fill composites.

*** Predicate device Filtek™ Supreme Ultra Universal Restorative was placed (b) (4)
(b) (4)

Extracts from the sponsor's additional discussion of Depth of Cure and Cusp Deflection testing on pages 105-110 of the original submission are provided below.

Depth of Cure
Due to use as both a sealant and a restorative, the depth of cure of Filtek™ Bulk Fill Posterior Restorative was evaluated using two ISO standards (see 2.4 Bench Test Data Comparison with S/E Devices table, Depth of Cure).

Sealant:
ISO 6874:2005 Dentistry – Polymer-based pit and fissure sealants requires that the depth of cure shall not be less than 1.5mm. The results are treated such that the length of the cured material in this test is equal to the depth of cure. Filtek™ Bulk Fill Posterior Restorative easily passes this requirement.

Restorative – 4mm Depth of Cure (single-surface light-cure):
ISO 4049 Dentistry – Polymer-based restorative materials Depth of Cure method is used by 3M ESPE to evaluate curing of resin-based restoratives that are light-cured from one surface. ISO 4049-2009 allows the depth of cure result to be no more than 0.5mm below the value stated by manufacturer (i.e., the length of cured material in this test is divided by 2 and the resulting value can be no more than 0.5mm below the depth stated by the manufacturer). The value stated by 3M ESPE Dental Products for Filtek™ Bulk Fill Posterior Restorative is 4mm for all cavity classes, except Class II. Therefore, where a 4mm depth is stated, the limit in this test is > 3.5mm (i.e., 4.0 – 0.5 = 3.5). ISO 4049 also has a second requirement that depth of cure for a shade that is not opaque must be no less than 1.5 mm. For Filtek™ Bulk Fill Posterior Restorative, both requirements are satisfied. See additional discussion related to the ISO 4049 Depth of Cure method below.

Restorative – 5mm Depth of Cure (multi-surface light-cure):
(b) (4) [redacted]

The sponsor provided a detailed discussion of test methods for Depth of Cure on pages 106-109 and Cusp Deflection on page 110 of the original submission. This discussion was reviewed and found acceptable.

Bench Testing Data/Performance Testing Conclusion:
Filtek Bulk Fill Posterior Restorative performed (b) (4) [redacted] (b) (4) [redacted] Overall, the Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Volumetric Shrinkage, Wear, Depth of Cure, Cusp Deflection and

Polish Retention results generated from the bench tests support the conclusion that the new device has similar performance characteristics as the predicate devices.

Technology Comparison with S/E Devices

The following table compares the Technologies for the new device to the predicate devices.

Technological property	Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric Evo Ceram Bulk Fill K111958
(b) (4) photoinitiator system	X	X	NA[1]	X[2]
Methacrylate-based resin matrix	X	X	X	X
Compatible with methacrylate-based dental adhesives	X	X	NA[1]	X
Inorganic fillers	X	X	X	X
Oxide fillers are silane treated so that they bond to the resin matrix when the restorative is cured	X	X	X[3]	NA[1]
Bulk fill (up to 4 mm depth of cure)	X	-	X	X
Bulk fill (5 mm depth of cure, Class II)	X[4]	-	X[4]	
When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.	X	X	X	X
Dispensing system: single-use capsule (intraoral)[5] reusable syringe (extraoral)[6]	 X X	 X X	 X -	 X X
Recommended for load-bearing occlusal surfaces	X	X	X	X
FDA-Recognized Standards followed	Risk Mgmt: ISO 14971 Biocomp stds[7]: ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds[8]: ISO 4049 ISO 6874	Risk Mgmt: ISO 14971 Biocomp stds[7]: ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 7405 Product stds[8]: ISO 4049	NA[1]	NA[1]

1. Not available, details not disclosed by manufacturer.
2. Product also contains a second photoinitiator.

3. Based on disclosure that product contains 3-trimethoxysilylpropyl methacrylate.
4. Similarity: In order to obtain 5 mm depth of cure for Class II restorations, product is light-cured from the occlusal surface and, after the matrix band is removed, light-cured from the buccal and lingual surfaces. See Depth of Cure discussion in section 12.2.4 Bench Test Data Comparison with S/E Devices.
   Difference: The predicate device techniques states up to a 5mm depth of cure for Class I restorations, as well, also using the multi-site light-curing process described above. For Filtek™ Bulk Fill Posterior Restorative, 4mm Depth of Cure is stated for Class I restorations, light-curing from the occlusal aspect only, as supported by ISO 4049 Depth of Cure test results. This difference does not affect the safety or efficacy of the device.
5. Restorative material is dispensed from a single-use capsule in the mouth.
   Difference: The predicate device SonicFill, Sonic-Activated Bulk Fill Composite (K091023) is dispensed from the capsule using the air-driven SonicFill Handpiece, which, per the Instructions for Use "offers sonically activated delivery."
   Similarity: Filtek™ Bulk Fill Posterior Restorative and predicates Filtek™ Supreme Ultra Universal Restorative (K083610) and Tetric EvoCeram Bulk Fill (K111958) all use a traditional manual restorative dispenser (not air-driven) for dispensing capsules. In light of this similarity, the difference mentioned above does not affect the safety or efficacy of the device.
6. Restorative material is dispensed from a reusable syringe outside the mouth (e.g., onto a pad).
7. Newer versions of several biocompatibility standards were applied to Filtek™ Bulk Fill Posterior Restorative, due to time elapsed since the predicate device was evaluated. This difference is not significant because for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610):
   a. A Diplomate of the American Board of Toxicology assessed the safety of the product.
   b. Standard risk assessment techniques and consideration of internationally recognized guidelines were used in the evaluation.
   c. The conclusion of the assessment is that the device is safe for its intended use.
8. ISO 4049 data in this submission for both Filtek™ Bulk Fill Posterior Restorative and the predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610), was generated using the current version of the standard, ISO 4049:2009.
   Difference: ISO 6874:2005 was not used to evaluate the predicate device, Filtek™ Supreme Ultra Universal Restorative for the 510(k) submission, K083610, because it does not have a sealant indication. The only test in ISO 6874 that is applicable for a light-cure material, like Filtek™ Bulk Fill Posterior Restorative, is Depth of Cure. The Depth of Cure test method in ISO 4049:2009 is the same as in ISO 6874, except the measured value is divided by 2 in ISO 4049 and not divided by 2 in ISO 6874. As a result, a material that passes the ISO 4049 Depth of Cure requirement easily passes the ISO 6874 Depth of Cure requirement. This submission includes data showing both Filtek™ Bulk Fill Posterior Restorative and predicate device, Filtek™ Supreme Ultra Universal Restorative (K083610) readily pass the ISO 6874 Depth of Cure requirement. Therefore, this difference is not significant and does not affect the safety or efficacy of the device. See ISO 4049 and ISO 6874 Depth of Cure specifications and test results in section 12.2.4 Bench Test Data Comparison with S/E Devices. Therefore, this difference is not significant and does not affect the safety or efficacy of the device.

Instructions for Use (IFU) Comparison with S/E Devices

The following table compares the Instructions for Use for the new device to the predicate devices.

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Cautions/Precautions in the respective IFU			
Caution: U.S. Federal Law restricts the device to sale or use on the order of a dental professional.	**Caution:** U.S. Federal Law restricts this device to sale or use on the order of a dental professional.	(No corresponding Caution in IFU)	"Rx ONLY" "Keep material out of children's reach. For use in dentistry only."
"Precautionary Information for Patients This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product. **Precautionary Information for Dental Personnel** This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact	**"Precautionary Information for Patients** This product contains substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product. **Precautionary Information for Dental Personnel** This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact	**"CAUTION:** Uncured methacrylate resin may cause contact dermatitis and damage the pulp. Avoid contact with skin, eyes and soft tissue. Wash thoroughly with water after contact."	**"Side effects** In individual cases, components of Tetric EvoCeram Bulk Fill may lead to sensitization. Tetric EvoCeram Bulk Fill should not be used in such cases. To avoid possible irritation of the pulp, areas close to the pulp should be protected with a suitable pulp/dentin protector (selectively apply a calcium hydroxide-based preparation in areas close to the pulp and cover with suitable cavity liner)."

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed. 3M ESPE MSDS information can be obtained from www.3MESPE.com or contact your local subsidiary." "Pulp protection: If a pulp exposure has occurred and the situation warrants a direct pulp capping procedure, use a minimum amount of calcium hydroxide on the exposure followed by an application of 3M™ ESPE™ Vitrebond™ or Vitrebond™ Plus Light Cure Glass Ionomer. Vitrebond or Vitrebond Plus liner/bases may also be used to line areas of deep cavity excavation."	occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed. 3M ESPE MSDSs can be obtained from www.3MESPE.com or contact your local subsidiary." "Pulp Protection: If a pulp exposure has occurred and if the situation warrants a direct pulp capping procedure, use a minimum amount of calcium hydroxide on the exposure followed by an application of Vitrebond™ or Vitrebond™ Plus Light Cure Glass Ionomer Liner/Base, manufactured by 3M ESPE. Vitrebond liner/bases may also be used to line areas of deep cavity excavation. See the Vitrebond liner/base instructions for details."		

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Cautions/Precautions – similarities/differences between Filtek Bulk Fill Posterior and Predicate Device IFU			
	No significant difference between this predicate and Filtek Bulk Fill Posterior Restorative.	IFU does not include prescription use statement or "Rx only" symbol. Information related to acrylates and plup protection is provided, but more abbreviated than 3M ESPE's IFUs for Filtek Bulk Fill Posterior Restorative and Filtek Supreme Ultra Universal Restorative.	IFU includes "Rx only" symbol. Information related to acrylates and pulp protection included in IFU under "Side effects."
Isolation & Adhesive System recommendations in the respective IFU			
"**3. Isolation:** A rubber dam is the preferred method of isolation. Cotton rolls and an evacuator can also be used." Under **"General Information**:" "Filtek™ Bulk Fill Posterior Restorative is applied to the tooth following use of a methacrylate-based dental adhesive, such as manufactured by 3M ESPE, which permanently bonds the restoration to the tooth structure." Under "**5. Placement of Matrix**:" "**Note:** The matrix may be placed following the enamel etching and adhesive application steps if preferred." "**7. Adhesive System**: To bond	"**3. Isolation:** A rubber dam is the preferred method of isolation. Cotton rolls plus an evacuator can also be used." Under **"General Information**:" "A dental adhesive, such as manufactured by 3M ESPE, is used to permanently bond the restoration to the tooth structure." Under "**3.2 Posterior restorations**:" "**Note:** The matrix may be placed following the enamel etching and adhesive application steps if preferred." "**4. Adhesive System:** Follow the manufacturer's instructions regarding etching, priming,	**"PRIOR TO PLACEMENT - - RECOMMENDATIONS ON PROPER BONDING** • Isolation throughout adhesive steps and composite placement is important. Rubber dam is ideal. • Please closely follow bonding agent directions for use. • Please take care to ensure that your air line is free of oil and other contaminants."	**"2. Isolation** Appropriate isolation, best with a rubber dam (e.g. OptraDam® Plus), is required." **"Cavity preparation** Cavity preparation is carried out according to the requirements of the adhesive technique, i.e. protecting the tooth structure." **"Conditioning / Application of the bonding agent** Condition and apply the bonding agent according to the Instructions for Use of the product in use. We recommend using Syntac® (with phosphoric acid etching) or ExciTE® F (with phosphoric acid etching) or the self-etching adhesive

Filtek™ Bulk Fill Posterior Restorative	Filtek™ Supreme Ultra Universal Restorative K083610	SonicFill, Sonic-Activated Bulk Fill Composite K091023	Tetric EvoCeram Bulk Fill K111958
Filtek™ Bulk Fill Posterior Restorative to tooth structure, use of a 3M™ ESPE™ dental adhesive system (for example 3M™ ESPE™ Scotchbond™ Universal) is recommended. Refer to adhesive system product instructions for full instructions and precautions for the products. After curing the adhesive, continue to maintain isolation from blood, saliva and other fluids and proceed immediately to placement of Filtek™ Bulk Fill Posterior Restorative. **Note**: Follow the adhesive system instructions for use for recommended silane treatment during repair of ceramic restorations, followed by the adhesive application."	adhesive application, and curing, for example 3M ESPE adhesives."		AdheSE®."
Isolation & Adhesive System recommendations – similarities/differences between Filtek Bulk Fill Posterior and Predicate Device IFU			
	IFU addresses isolation and adhesive system in a similar manner. The Filtek Bulk Fill Posterior Restorative IFU provides additional details about compatibility with dental adhesives and placement of restorative after curing the adhesive.	IFU addresses isolation and adhesive system in a more abbreviated manner.	IFU addresses isolation and adhesive system.

Conclusion

Any differences between the new device and the predicate devices have been adequately supported with information and data in the submission. The comparison tables above illustrate the new device has the same indications for use as the predicate devices combined, similar formulation/composition as K083610, similar physical properties, similar bench test data/performance characteristics, similar technology, and similar Instructions for Use information as the predicate devices. These differences do not raise new questions of safety or effectiveness as compared to the predicate devices. The new device has been evaluated through the performance testing summarized above which demonstrates the new device performance is equivalent to the predicate devices.

VI. Labeling

The proposed labeling for the **Filtek Bulk Fill Posterior Restorative** is provided in the original submission and includes the Instructions for Use (pages 122-127), Technical Product Profile (pages 128-130), and labels for the Capsule Pouch, Syringe Pouch, Capsule Bottle, and Syringe (pages 131-133).

The Filtek™ Bulk Fill Posterior Restorative Instructions for Use addresses:
- light intensity (mW/cm^2) for curing
- wavelength (nm) for curing
- depth of cure (mm)
- curing time (sec) (for photoinitiated resins)

The Filtek™ Bulk Fill Posterior Restorative Technical Product Profile addresses:
- compressive strength (MPa)
- flexural strength (MPa)
- other properties relevant to the device

The following are not applicable for a light-cure composite, like Filtek™ Bulk Fill Posterior Restorative (these properties are relevant for self-cure composites):
- working time (sec)
- setting time (min)

3M ESPE Dental Products has developed a Technical Product Profile for Filtek™ Bulk Fill Posterior Restorative that addresses compressive strength, flexural strength and other relevant properties. 3M ESPE Dental Products provides Technical Product Profiles for marketed products to practitioners free of charge upon request. Such requests can be made using the 3M ESPE Customer Care phone number provided in the Instructions for Use. Technical Product Profiles for marketed products are also available at the 3M ESPE Dental Products web site. This same approach was used with predicate device Filtek™ Supreme Ultra Universal Restorative, K083610, also from 3M ESPE Dental Products.

Labeling for the currently marketed predicate device Filtek Supreme Ultra Universal Restorative (K083610) is included in Section 22.1 of the original submission (labels, instructions for use, and the Restorative Dispenser (5707SD) instructions for use).

Labeling for the currently marketed predicate device SonicFill, Sonic-Activated Bulk Fill Composite (K091023) is included in Section 22.2 of the original submission (labels, instructions for use).

Labeling for the currently marketed predicate device Tetric EvoCeram Bulk Fill (K111958) is included in Section 22.3 of the original submission (labels, instructions for use).

The proposed labels were reviewed and compared to the predicate device labels provided for the Filtek Supreme Ultra Universal Restorative (K083610). The proposed labels include the FDA prescription caution statement (or Rx Only statement), ISO 4049 and ISO 6874 standard information, trade name, common name, shade identification, quantity (4g/20 on capsule pouch or 4g/1 on syringe pouch), do not reuse on the capsule bottle label, REF/Cat #, Lot #, Use By date, storage temperature range of 2°C/35°F to 27°C/80°F, caution see instructions for use, made in U.S.A., manufacturer name and address. The proposed labels were found to include all the required information.

The proposed Instructions for Use were reviewed and compared to the predicate Instructions for Use provided for the Filtek Supreme Ultra Universal Restorative (K083610). The proposed Instructions for Use were found to include all the required information. The proposed Instructions for Use includes the exact same Indications for Use statement as is listed on the Indications for Use form in Section 4, detailed instructions for Preparation, Direct Restorations, Indirect Procedure for Inlays, Onlays, or Veneers, storage instructions, disposal, warranty information, the Manufacturer's name, address, and the issue/revision date. The proposed Instructions for Use are very similar to the current Instructions for Use of the Filtek Supreme Ultra Universal Restorative (K083610) predicate device.

No other claims are made in the labeling which would raise questions of safety and effectiveness. The proposed labeling for the new device is equivalent to the labeling for the predicate device.

VII. Sterilization/Shelf Life/Reuse

Sterilization/Reuse

The sterilization information is included on page 135 of the original submission. The **Filtek Bulk Fill Posterior Restorative** is a non-sterile device. Sterilization is not applicable. Filtek Bulk Fill Posterior Restorative is not labeled nor otherwise represented as sterile, nor is it intended to be sterilized by the user. It is not intended to be reused.

Product Packaging

Filtek Bulk Fill Posterior Restorative is packaged in traditional syringes, for dispensing restorative on a pad outside the mouth, and single-dose capsules for dispensing restorative intraorally. The capsules are dispensed using the 3M ESPE Restorative Dispenser.

Shelf Life and Storage

The shelf life at room temperature is 36 months for the **Filtek Bulk Fill Posterior Restorative** device. Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life. The Filtek Bulk Fill Posterior Restorative device is labeled with a storage temperature range of

2°C/35°F to 27°C/80°F. Refer to pages 136-137 for the Shelf Life Report (stability certificate).

(b) (4)

(b) (4) All results passed which supports the proposed 36 months shelf life at room temperature.

The sponsor provided the following explanation in the email dated April 23, 2013 regarding the two tests selected for shelf life testing (b) (4)) being different from the one test (b) (4) that was previously selected for shelf life testing and accepted by FDA for the predicate Filtek™ Supreme Ultra Universal Restorative K083610.

(b) (4)

The explanation for the selected shelf life tests was reviewed and found acceptable. In addition the stability certificate for (b) (4) testing showed passing results supporting the 36 month shelf life.

The submission includes all required information regarding sterilization, shelf life, and reuse.

VIII. Biocompatibility

The material functions, ingredients, CAS Numbers, and weight percentage ratios are shown in the following table.

Composition for Filtek™ Bulk Fill Posterior Restorative

Function	Ingredient	CAS Number	Table*	Quantity (w/w%)**
(b) (4)				
Total				100

* Descriptions of each ingredient (e.g., Chemical Name, Function, Chemical Structure, Molecular Weight and Molecular Formula) are provided in Tables A through V on pages 81 through 93 of the original submission.

** (b) (4)

(b) (4)

3M ESPE Filtek Bulk Fill Posterior Restorative is categorized as an external communicating device that is intended to be in contact with tissue/bone/dentin for greater than 30 days (ISO 10933, ISO 7405, and G95-1). As such the minimum recommended testing by inclusion or

rationale per FDA G95-1 would be cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, sub-chronic toxicity, genotoxicity, and implantation.

A Diplomate of the American Board of Toxicology has assessed the safety of this product. Standard risk assessment techniques and consideration of internationally recognized guidelines were used in this evaluation.

3M ESPE Filtek Bulk Fill Posterior Restorative is safe for its intended use based on the following considerations:

1) Favorable test results for the product in GLP- and guideline compliant biocompatibility tests;
2) A review of the extraction data for the product; and
3) A review of the hazards of the product ingredients and primary packaging ingredients in relation to the amount used in the product.

The biocompatibility assessment for this product was conducted in accordance with the following standards:

1) Testing guidelines outlined in the FDA General Program Memorandum G95-1.
2) ISO 10993-1:2009(E) Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process; in addition, relevant detailed guidance in ISO Standards 10993-3:2003 (Tests for genotoxicity, carcinogenicity and reproductive toxicity), 10993-5:2009 (Tests for in vitro cytotoxicity), 10993-10:2010 (Tests for irritation and skin sensitization); and 10993-11:2006 (Tests for systemic toxicity) was considered;
3) ISO 7405:2008 Dentistry-- Evaluation of Biocompatibility of Medical Devices in Dentistry;
4) Japan: PFSB/ELD/OMDE Notification No.0301-1; March 1, 2012 (as translated by 3M Health Care Japan, August 6, 2012)
5) 3M ESPE Standard Operating Procedure 04-200.

3M ESPE Filtek Bulk Fill Posterior Restorative was assessed as an external communicating device that is intended to be in contact with tissue/bone/dentin for greater than 30 days (ISO 10933 and ISO 7405, G95-1) and a coupling instrument between the inside and outside of the body (PFSB). The passing results from biocompatibility testing are presented in the following table.

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

[redacted]

The biocompatibility testing that was submitted was reviewed and found acceptable. No additional biocompatibility testing is required for the new device. The new device meets the requirements for biocompatibility for its intended use and type/duration of contact in accordance with ISO 10993-1 and FDA Blue Book Memorandum #G95-1. No new questions related to safety are raised.

IX. Software

This device does not employ software.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This device is not electrically powered.

XI. Performance Testing – Bench

The Bench Test Data/Performance Testing Comparison summary and table for the new device and predicate devices can be found beginning on page 13 of this Reviewer Memorandum. Voluntary standards utilized include ISO 4049:2009 Dentistry - Polymer-based Restorative Materials and ISO 6874:2005 Dentistry - Polymer-Based Pit and Fissure Sealants. 3M ESPE Dental Products has tested Filtek™ Bulk Fill Posterior Restorative and found that it meets the relevant requirements of these two standards. A subset of this data, useful for comparison with predicate devices, has been included in that table.

Note that Flexural Modulus is not a requirement of ISO 4049, however, Flexural Modulus can be derived from the ISO 4049 method for Flexural Strength. Summaries of 3M ESPE internal test methods (i.e., those other than ISO 4049 and ISO 6874) are located in Section 18.2 of the original submission. These test methods are very similar to those used for the clearance of the Filtek™ Supreme Ultra Universal Restorative (K083610). Differences in these test methods as explained by the sponsor in the email dated April 23, 2014 are described below.

Test Method	Purpose	Filtek™ Bulk Fill Posterior Restorative (new device), Section 18 Test Method Summaries	Filtek™ Supreme Ultra Universal Restorative K083610, Section 18 Test Method Summaries	Comparison
Surface Hardness*	(b) (4)			
Compressive Strength*				
Diametral Tensile Strength				
Shrinkage				
Wear				
Cusp Deflection				
Polish Retention				
Fluorescence				

FDA Guidance:
*Surface Hardness and Compressive Strength are called out in FDA's October 26, 2005 "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions."

The remaining properties above are supplemental (i.e., not called out in FDA's October 26, 2005 "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions").

Shrinkage, Wear & Cusp Deflection:
Shrinkage, Wear and Cusp Deflection were included in the Filtek™ Bulk Fill Posterior Restorative 510(k) because (b) (4)
(b) (4)
.

Polish Retention:
(b) (4)

Fluorescence
(b) (4)

(b) (4)

The specifications in the Bench Test Data/Performance Testing Comparison table beginning on page 13 of this Reviewer Memorandum include the Performance Specifications from the Device Performance Specifications on pages 5-6 of this Reviewer Memorandum as well as targets established by 3M ESPE for other tests that are useful for comparison. Note that specifications for ISO tests are the same as, or more stringent than, the specifications in the ISO standards.

In summary, the safety and effectiveness of the **Filtek Bulk Fill Posterior Restorative** has been demonstrated by the Performance Testing summarized in **Section V – Predicate Device Comparison** and the Biocompatibility Testing summarized in **Section VIII – Biocompatibility**. The bench performance testing results show that the Filtek Bulk Fill Posterior Restorative has been tested by appropriate methods and meets all of the relevant performance specifications. The Filtek Bulk Fill Posterior Restorative performance characteristics are substantially equivalent to the performance characteristics of the predicate devices. No new safety or effectiveness concerns related to performance of the new device

are raised.

XII. Performance Testing – Animal

This submission does not include animal testing or data.

XIII. Performance Testing – Clinical

This submission does not include human clinical testing or data.

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: Document the decision path by marking the arrows followed on the FDA flowchart.

Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

The submission includes the descriptive characteristics but performance testing is needed to verify the new device is substantially equivalent to the predicate

devices. The performance testing will provide evidence that the new device and the predicate devices employ similar technological characteristics.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods cannot be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

As the reviewer of this submission I have reviewed the instructions for use, the labeling, and the sponsor's description of the device and compared this information against the information relating to the predicate devices that was provided by the sponsor. The specifications for the predicate devices and the new device have been compared and they are very similar. The predicate devices comparison tables outline the similarities and differences between the new device and predicate devices. The submission includes biocompatibility testing which demonstrates the new device is biocompatible. Results of the new device performance testing demonstrated acceptable performance. In addition, these performance tests were compared side by side with results from the predicate devices. The comparison testing demonstrated that the new device has similar performance characteristics as the predicate devices. Based on these satisfactory test results the new device is substantially equivalent to the predicate devices. There are no new questions of safety and effectiveness raised during this review.

Based upon the above summary, a substantially equivalent decision is recommended.

XV. Deficiencies

During the review of the original submission dated April 15, 2014 one request for clarification was emailed to the sponsor on April 22, 2014. The email response dated April 23, 2014 was provided by the sponsor to respond to the clarification questions. All clarification questions have been adequately addressed.

XVI. Contact History

All correspondence is included in the submission.

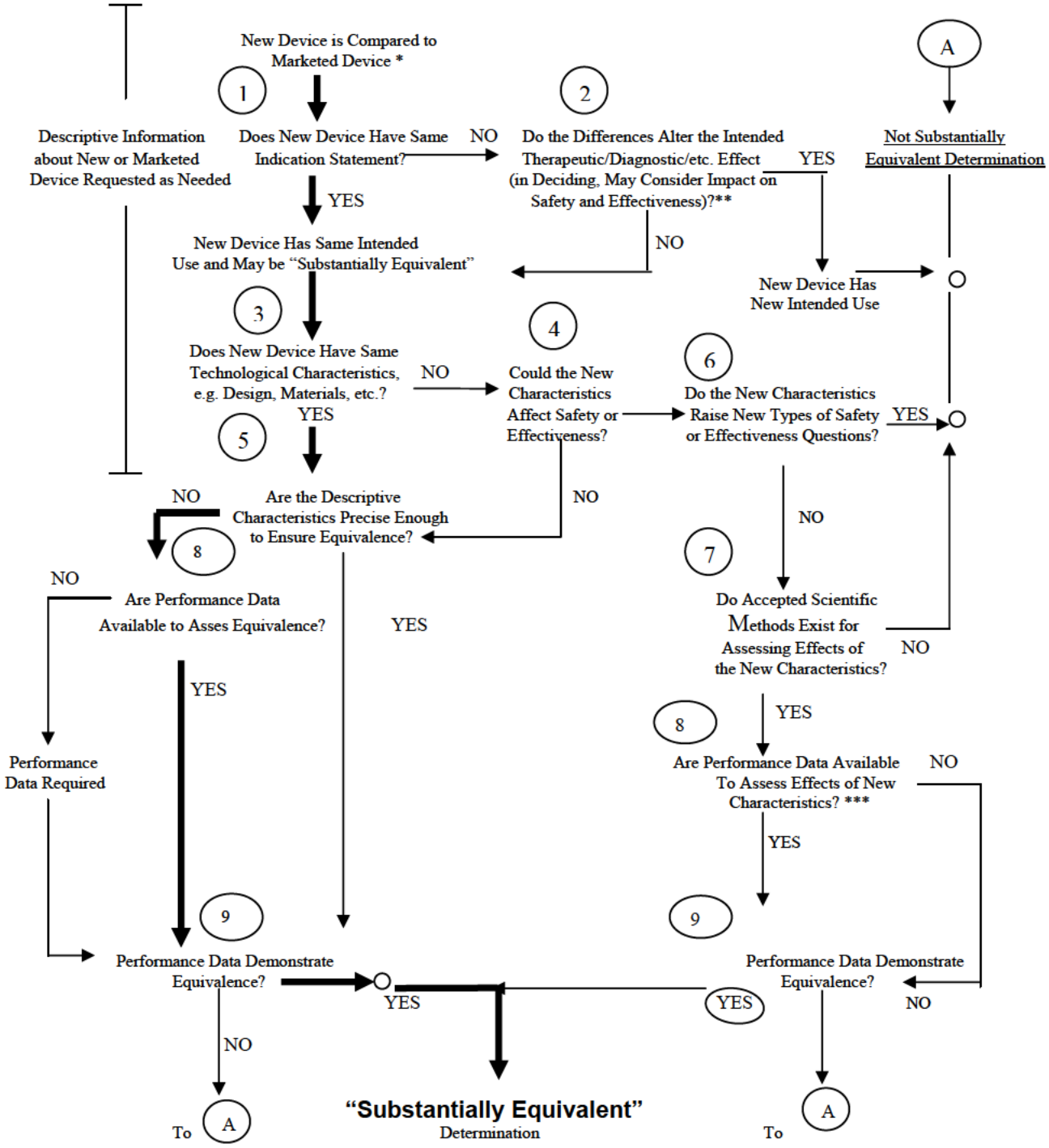
XVII. Recommendation

Regulation Number:	21 CFR 872.3690
Regulation Name:	Tooth Shade Resin Material
Regulatory Class:	Class II
Product Code:	EBF

3M ESPE Dental Products

Filtek Bulk Fill Posterior Restorative

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.

Gmail by Google

Mark Job <mark@markjob.com>

Questions on 3M ESPE FiltekT Bulk Fill Posterior Restorative 510(k)

sterickson@mmm.com <sterickson@mmm.com> Wed, Apr 23, 2014 at 3:40 PM
To: Carole Stamp <stamp.carole@gmail.com>
Cc: MARK JOB <mark@markjob.com>

Dear Carole:

This is in response to the two questions sent to me yesterday in your attached e-mail:

Question 1:

"In Section 14, can you clarify for me whether the two tests selected for shelf life testing (b) (4) (b) (4) are the same two tests previously selected for shelf life testing and accepted by FDA for the predicate Filtek™ Supreme Ultra Universal Restorative K083610."

Answer 1:

(b) (4)

Question 2:

"In Section 18, can you clarify for me whether the test methods listed are the same test methods previously followed and accepted by FDA for the predicate Filtek™ Supreme Ultra Universal Restorative K083610."

Answer 2:

Test Method	Purpose	Filtek™ Bulk Fill Posterior Restorative 510(K), Section 18 Test Method Summaries	Filtek™ Supreme Ultra Universal Restorative K083610, Section 18 Test Method Summaries	Comparison
Surface Hardness*	(b) (4)			
Compressive Strength*				
Diametral Tensile Strength				

Shrinkage	(b) (4) [redacted]
Wear	
Cusp Deflection	
Polish Retention	
Fluorescence	

FDA Guidance:
*Surface Hardness and Compressive Strength are called out in FDA's October 26, 2005 "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions."

The remaining properties above are supplemental (i.e., not called out in FDA's October 26, 2005 "Guidance for Industry and FDA Staff Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions").

Shrinkage, Wear & Cusp Deflection:
Shrinkage, Wear and Cusp Deflection were included in the Filtek™ Bulk Fill Posterior Restorative 510(k) because (b) (4) [redacted]

Polish Retention:
(b) (4) [redacted]

Fluorescence
(b) (4) [redacted]

(b) (4) [redacted]

Best regards,
Scott

Scott T. Erickson, RAC | Senior Regulatory Affairs Specialist
3M ESPE Dental Products Division
3M Center, 275-2W-08 | St. Paul, MN 55144-1000 USA
Office: 651 736 9883 | Fax: 651 736 1599
sterickson@mmm.com | www.3M.com

From: "Carole Stamp" <stamp.carole@gmail.com>
To: <sterickson@mmm.com>
Cc: "'MARK JOB'" <mark@markjob.com>
Date: 04/22/2014 08:33 AM
Subject: Questions on 3M ESPE FiltekT Bulk Fill Posterior Restorative 510(k)

[Quoted text hidden]

Bulk Fill Posterior Stability Cert Ext 23Apr2014.pdf
398K

3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000

3M ESPE

Stability Certificate

(b) (4)

[redacted]

3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000

3M ESPE

Stability Certificate

(b) (4)

[redacted]

Gmail by Google

Mark Job <mark@markjob.com>

Questions on 3M ESPE FiltekT Bulk Fill Posterior Restorative 510(k)

Carole Stamp <stamp.carole@gmail.com> Tue, Apr 22, 2014 at 8:28 AM
To: sterickson@mmm.com
Cc: MARK JOB <mark@markjob.com>

Dear Scott,

We have nearly completed our administrative and substantive review of your submission and have the following two clarification questions for you.

1. In Section 14, can you clarify for me whether the two tests selected for shelf life testing (b) (4) (b) (4) are the same two tests previously selected for shelf life testing and accepted by FDA for the predicate Filtek™ Supreme Ultra Universal Restorative K083610.

2. In Section 18, can you clarify for me whether the test methods listed are the same test methods previously followed and accepted by FDA for the predicate Filtek™ Supreme Ultra Universal Restorative K083610.

Sincerely,

Carole Stamp

Reviewer

Regulatory Technology Services LLC

Date: April 16, 2014

Scott Erickson
3M ESPE Dental Products
2510 Conway Avenue, Building 275-2W-08
St. Paul, MN 55144

Re: Filtek Bulk Fill Posterior Restorative

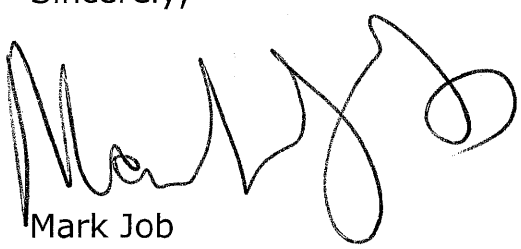
Dear Mr. Erickson,

This letter is to acknowledge on April 16, 2014 Regulatory Technology Services LLC received the 510(k) dated April 15, 2014 for the Filtek Bulk Fill Posterior Restorative.

We have begun the administrative review according to the 510(k) checklist and the following FDA guidance documents: "FDA Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s" dated August 12, 2005, and the "Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions – Guidance for Industry and FDA Staff" dated October 26, 2005. We will keep you informed as the review progresses.

If you have any questions, please do not hesitate to contact me. You may reach me at 763 682 4139.

Sincerely,



Mark Job

Part Acceptance / Non-acceptance

1. Accredited Person:

Name: Regulatory Technology Services LLC

Address 1394 25th Street NW

Buffalo, MN 55313

Contact: Mark Job

Telephone: 763 682 4139 Fax: 763 682 4420

2. Foreign Accredited Person, Specify a Domestic Correspondent:

Name: N/A

Address

Contact:

Telephone: Fax:

3. 510(k) Owner (Applicant, Manufacturer, other persons preparing 510(k))

Name: 3M ESPE Dental Products

Address 3M Center, Building 275-2W-08, 2510 Conway Avenue

St. Paul, MN 55144

Contact: Scott Erickson, RAC

Telephone: 651-736-9883 Fax: 651-736-1599 (sterickson@mmm.com)

STOP!

Before completing items 4 to 9 below, complete pages 3 – 6 of this document.

4. Device Name:

Trade or Proprietary Name: Filtek™ Bulk Fill Posterior Restorative

Classification Name: Tooth Shade Resin Material, product code EBF

5. CFR Classification Citation: 21 CFR 872.3690 (see 21 CFR 862 through 892)

6. Classification Panel: Dental

7. Based on my completion of this document, I recommend that this 510(k):

☒ Be accepted for substantive review and I have notified the 510(k) owner using RPP-F-0016.

☐ Not be accepted for substantive review and I have listed the deficiencies on RPP-F-0016.

8. Primary Reviewer

Carole Stamp 4/16/14

Signature Date

Carole Stamp

Print Name

9. Supervisor

Todd J Shopp 4/23/16

Signature Date

Todd J Shopp

Print Name

Checklist Questions:	YES	NO	Instructions
1. a). Is the device one that FDA has determined as being acceptable for third party review?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
1 b). Have you confirmed that the manufacturer has not engaged in forum shopping?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
2. Is the device trade or proprietary name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
3. Is the device common or usual name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
4. Is the device classification name, class of the device, and regulation number (21 CFR 872.3690, product code EBF) included?	☒	☐	If NO, note deficiency on RPP-F-0013.
5. Is the classification panel included?	☒	☐	If NO, note deficiency on RPP-F-0013.
6. Has the applicant complied with Section 514 of the Act? (Section 514 relates to performance standards for class II devices. At this time, there are no 514 standards. Therefore, your answer should be yes.)	☒	☐	If NO, note deficiency on RPP-F-0013.
7. Does the submission include proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (ODE Guidance Memorandum #G91-1)?	☒	☐	If NO, note deficiency on RPP-F-0013.
8. Does the submission contain the "Indications for Use" form?	☒	☐	If YES, indicate page number page 32. If NO, note deficiency on RPP-F-0013.

Checklist Questions:	YES	NO	Instructions
9. Does the submission contain an acceptable 510(k) Summary of Safety and Effectiveness (per 21 CFR 807.92) OR an acceptable 510(k) Statement (per 21 CFR 807.93) that safety and effectiveness information will be made available to any person upon request?	☒	☐	If YES, indicate page number pages 27-31. If NO, note deficiency on RPP-F-0013.
10. Does the submission contain photographs of the device if applicable?	☒	☐	If NO, note deficiency on RPP-F-0013.
11. Does the submission contain drawings for the device with dimensions and tolerances if applicable?	☒	☐	If NO, note deficiency on RPP-F-0013.
12. Does the submission identify the device to which equivalence is claimed?	☒	☐	
13. If the answer to question 12 is YES, did the applicant identify:			
a. Predicate device (referred to as marketed device)?	☐	☒	
b. Legally marketed device (referred to as marketed device)?	☒	☐	Note deficiency on RPP-F-0013.
Note: A predicate device is a device that was legally in commercial distribution in the U.S. on or before May 28, 1976 (referred to as a pre-amendments device) or a device that was marketed after May 28, 1976 (referred to as a post amendments device) that was reclassified from class III to class I or II. A marketed device can be a predicate device but is most often a device that FDA has determined is SE to another marketed device (21 CFR 807.92(a)3). IT IS YOUR RESPONSIBILITY TO MAKE SURE THAT THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE IDENTIFIED IS LEGITIMATE. If it is not, the review must STOP. Telephone DSMA for assistance.			List all 510(k) control numbers: K083610 (SE 12/17/2008) K091023 (SE 05/21/2009) K111958 (SE 10/14/2011)

Checklist Questions:	YES	NO	Instructions
14. Does the submission contain information about the marketed device(s) identified in questions 12 and 13 above to which equivalence is claimed, including labeling and a description of the device?	☒	☐	If NO, note deficiency on RPP-F-0013.
15. Does the submission contain a statement/comparison of similarities and/or differences between the new device and the marketed device? (The new device that is the subject of this 510(k) can be either a new device or a modification to the existing device.)	☒	☐	If NO, note deficiency on RPP-F-0013.
16. Does the submission contain the Truthful and Accurate Statement (per 21 CFR 807.87(j))?	☒	☐	If YES, indicate page number page 33. If NO, note deficiency on RPP-F-0013.
17. Does the submission contain the submitter's name, address, contact person, telephone number, and fax number?	☒	☐	If NO, note deficiency on RPP-F-0013.
18. If there is a representative or consultant, does the submission contain their name, address, contact person, telephone number, and fax number?	☒	☐	If NO, note deficiency on RPP-F-0013.
19. Does the submission contain a table of contents with pagination?	☒	☐	If NO, note deficiency on RPP-F-0013.
20. If the submitter has a manufacturing facility (contract or owned), and/or a sterilization facility (contract or owned), is the address(es) contained in the submission?	☒	☐	If NO, note deficiency on RPP-F-0013.
21. Does the submission contain a comparison table of the new device to the marketed device?	☒	☐	If NO, note deficiency on RPP-F-0013.
22. Does the submission contain information about the action taken to comply with voluntary standards?	☒	☐	If NO, note deficiency on RPP-F-0013.

Checklist Questions:	YES	NO	Instructions
23. Does the submission contain performance data (can be bench or animal but not clinical), i.e.: Is there performance data for the marketed device? a. Bench testing? b. Animal testing? Is there performance data for the new device? a. Bench testing? b. Animal testing?	☒ ☐ ☒ ☐	☐ ☒ ☐ ☒	If NO, note deficiency on RPP-F-0013. Animal testing not needed for marketed device. If NO, note deficiency on RPP-F-0013. Animal testing not needed for new device.
24. If the device is labeled as sterile, does the submission contain sterilization data?	☐	☒	If NO, note deficiency on RPP-F-0013. Not sterile
25. Does the device incorporate a computer or computer software? a. If YES, is there information about the hardware? b. If YES, is there information about the software?	☐ ☐ ☐	☒ ☐ ☐	If NO, note deficiency on RPP-F-0013. No software
26. a) Is there a specific guidance document for this type of device? Title: Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions – Guidance for Industry and FDA Staff issued on October 26, 2005	☒	☐	If YES, continue review with checklist from the specific guidance document and return to question 27. If NO, proceed to question 26 b).
26 b) Contact the appropriate ODE Branch Chief to obtain information for reviewing this type of device. Has a summary of this discussion been documented?	☐	☐	If YES, answer question 27. If NO, do not proceed to question 27; stop review until summary completed.
27 Is this 510(k) sufficiently complete to allow substantive review?	☒	☐	If YES, continue review using specific guidance document or if no specific guidance document, continue the review using documentation forms. If NO, note deficiency on RPP-F-0013.

3M ESPE

1. Letter of Authorization for 3rd Party Review

3M ESPE
Dental Products

2510 Conway Avenue
St. Paul, MN 55144-1000

3M ESPE

Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Subject: Authorization for Accredited Person Review of 510(k) for Filtek™ Bulk Fill Posterior Restorative

To Whom it May Concern:

Enclosed is the Premarket Notification 510(k) for Filtek™ Bulk Fill Posterior Restorative, manufactured by 3M ESPE Dental Products.

We at 3M ESPE Dental Products hereby authorize Regulatory Technology Services, LLC, to submit the enclosed 510(k) to the Food and Drug Administration (FDA) on our behalf, discuss its contents with the FDA, and function as the Accredited Person to perform the third party review.

We certify that we have not contacted another Accredited Person to perform the review of this 510(k) submission.

We accept the quote for 510(k) review services including the Regulatory Technology Services LLC Terms and Conditions.

Sincerely,

Scott Erickson, RAC
Senior Regulatory Affairs Specialist
3M ESPE Dental Products

15 Apr 2014
Date