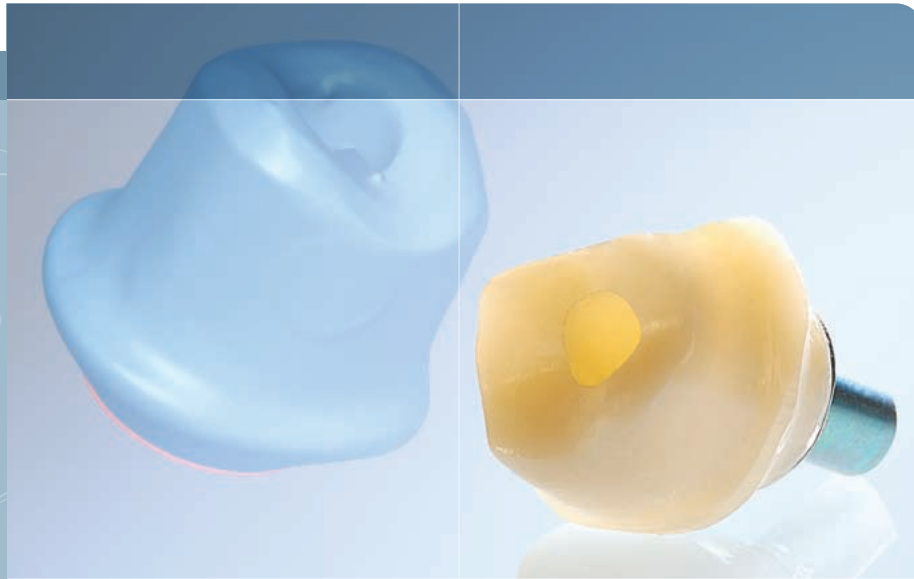


Cementation and Sterilization Guidelines
for Labs and Dentists

Lava™

Zirconia for Implant Abutments



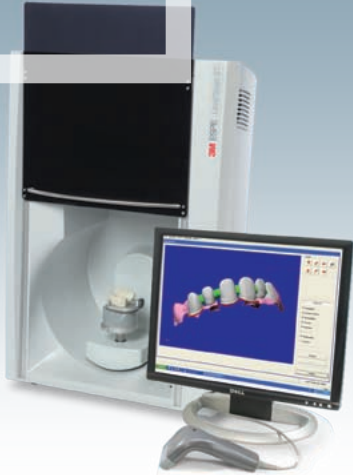
Cementation and Sterilization Made Easy

3M ESPE

Lava™

Use your Lava™ Scan ST Design System to produce custom implant abutments.

Now you can create custom implant abutments with the esthetics of shaded Lava™ Zirconia and the productivity of the Lava Digital Platform. When you use the Lava™ Scan ST System, you have complete design control. To create the abutment, Lava zirconia is cemented to a prefabricated titanium abutment interface. The abutment head is bonded to the interface without creating torque pressure to the zirconia. This method provides compatibility with a wide variety of implant systems. And because it's produced with the productive Lava system, your Milling Center will be able to provide zirconia for implant abutments just as quickly as copings and frameworks.

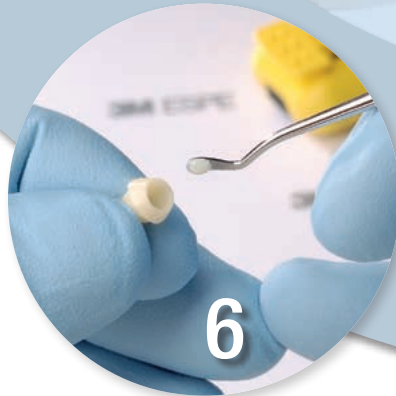


7



Now your implant abutment can be custom shade matched to your Lava™ Crown.

6



5



This guide should be given to all partner labs and dentists who cement, clean and sterilize the implant abutment. Additional copies can be ordered through Lava Milling and Design Centers or downloaded from our web site at www.3MESPE.com/lava.

How it works.



- 1 Create or customize a pre-made wax-up for the zirconia head
- 2 Scan implant abutment interface
- 3 Scan custom wax-up
- 4 Prepare the customized abutment for milling with Lava™ Design Software
- 5 Mill and sinter as any Lava™ Zirconia unit¹
- 6 Bond zirconia head to metal interface
- 7 Create Lava zirconia crown following conventional process



¹ Refer to Lava™ Frame Zirconia Instructions for Use

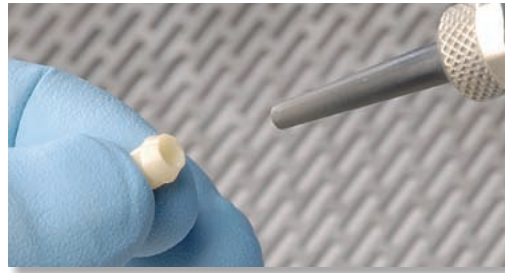
² Torque pressures are fully contained within the titanium interface

Lava™



Cementation of Lava™ Zirconia to titanium abutment interfaces/bases.

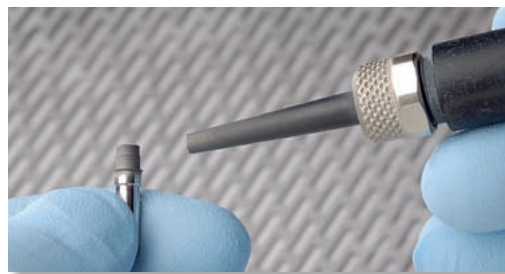
Implant abutments need to be cemented adhesively to the titanium interface. We recommend using RelyX™ Unicem Self-Adhesive Universal Resin Cement from 3M ESPE.



Sandblasting zirconia

Pre-treatment Lava™ Zirconia

Sandblast zirconia surface which will be in contact with the cement with aluminum oxide $\leq 50 \mu\text{m}$ and 2 bar. Afterwards clean surface with ethanol.

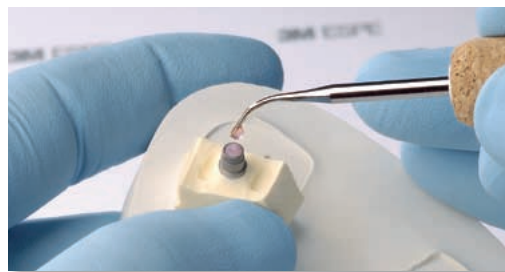


Sandblasting titanium interface

Pre-treatment titanium interface

Sandblast the surface which will be in contact with the cement and clean it with ethanol.

NOTE: Before sandblasting, protect the implant connection (e.g. Erkoskin by Erkodent or with a lab implant).



Screw path protection

Screw path protection

The screw should be closed with wax before cementation.



Cementation

Cementation³

Apply RelyX Unicem cement to pretreated surfaces of both devices. Press and hold together with finger pressure and pre-polymerize with a light curing unit.



Tabletop light curing



Handheld light curing

Pre-polymerization

Pre-polymerize using tabletop lamp or a handheld light curing unit (e.g. 3M™ ESPE™ Visio™ Alfa Light Curing Unit or Elipar™ Freelight 2). Assuming four quadrant surfaces of the luted abutment, each quadrant surface needs 20 seconds of exposure in the fixed position. Total 80 seconds exposure.

³ Refer to RelyX™ Unicem Self-Adhesive Universal Resin Cement Instructions for Use for additional information including storage instructions and precautions.

Final polymerization

Final polymerization is done in a light furnace (e.g. 3M™ ESPE™ Visio™ Beta Vario, program 1) Use 15 minutes of light exposure plus vacuum. Excess cement is removed and the interface between implant abutment/titanium base is polished and smoothed with a silicon rubber.

Cleaning, disinfection, and sterilization

The implant abutments should be cleaned, disinfected and in specific clinical procedures and cases be sterilized (no liability on disregard). Effective cleaning and disinfection is an indispensable requirement for effective sterilization of the implant abutments. Prior to sterilization, please keep implant abutments clean when handling in the dental laboratory and operatory.

Additionally, please pay attention to the legal regulations valid for your local area as well as to the hygienic instructions of your dental practice. This applies particularly to the different guidelines regarding the inactivation of prions.

Cleaning:

- 1) Clean rinsing under flowing water while brushing outer and inner side with adequate brushes.
- 2) Immerse in compatible cleaning solutions (e.g. Cidezyme/Enzol, Johnson & Johnson). The cleaner or disinfectant should not contain any of the following ingredients: strong organic acids or mineral acids, strong lye, organic solvents (e.g. acetone, ether, hexane, benzin), oxidizing agents (e.g. peroxide), halogens (chlorine, iodine, bromine) or aromatic, halogenated hydrocarbons.
- 3) Post-rinse the implant abutment at least three times with water.

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

- 1) Soak the implant abutments in the disinfectant solution for the required amount of time. See instructions for use of Cidex OPA.
- 2) Remove the implant abutment from the disinfectant solution.
- 3) Rinse at least three times with highly purified water.
- 4) Air-dry and package the implant abutment immediately.

Packaging: Insert the cleaned and disinfected implant abutment in a single-use sterilization package which fulfills the following requirements (one implant abutment per package):

- EN ISO/ANSI AAMI ISO 11607
- suitable for steam sterilization
- adequate protection of the implant abutment to prevent mechanical damage

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

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

Steam sterilization:

- fractionated vacuum procedure or gravity procedure (with sufficient product drying)
- steam sterilizer according to ISO 17665: 2006 or EN 13060 and EN 285 respectively or equivalent national standards
- validated according to EN ISO/ANSI AAMI 17665 (in past: EN 554/ANSI AAMI ISO 11134) (valid IQ/OQ (commissioning and product specific performance qualification)
- sterilization time 20 minutes at 121 °C (250 °F) or 3 minutes at 132 °C (270 °F) (listed exposure times are at sterilization temperature)



You are responsible for the sterility of the abutment made from Lava zirconia cemented to the titanium interface. Therefore, ensure that only appropriate equipment, materials and product specific validated procedures will be used for cleaning, disinfection, and sterilization. It is your responsibility to ensure procedures are validated and that the equipment and devices (disinfectant, sterilizer) will be maintained and routinely checked.



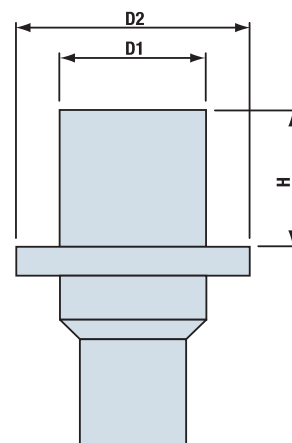
Recommended dimensions of titanium abutment interfaces/bases for cementation to Lava™ Zirconia.

Lava zirconia can be bonded to titanium abutment interfaces/bases with a cylindrical shape.

The manufacturer's titanium interface is screw retained into the corresponding implant. A direct connection of Lava zirconia to the implant without a titanium interface is not allowed.

For secure cementation of the zirconia abutment head to the titanium interface, the interface needs to meet the following specifications:

- Cylindrical shaped interfaces made of titanium or titanium alloys approved for dental applications.
- Overall cementation surface area (cylinder barrel + cylinder flange) $\geq 33.0 \text{ mm}^2$
- Cylinder diameter: **D1 $\geq 2.9 \text{ mm}$**
- Outer diameter of the titanium interface: **D2 $\geq 4.5 \text{ mm}$**
- Cylinder height: **H 2.6 to 6.0 mm**



Frequently asked questions.

Can Lava zirconia be cemented to other alloys besides titanium to create custom implant abutments (e.g. gold cast to abutments)?

Although clinical studies show that zirconia copings can be cemented to gold, 3M ESPE has not tested cementation of Lava zirconia to gold abutment parts. Due to mechanical and physical surface area variations, 3M ESPE cannot recommend cementation to gold alloy until further testing is conducted.

Can custom implant abutments be designed over a conical shape with Lava zirconia?

3M ESPE is still in the process of testing conical shapes. Therefore, conical shapes are not recommended at this time.

Can custom angulated implant abutments be designed with Lava zirconia?

3M ESPE is still in the process of testing angulated abutments. Therefore, angulated implant abutments are not recommended at this time.

How thick should the implant abutment wall thickness be?

3M ESPE does not recommend going under 1 mm.

RelyX™ Unicem Self-Adhesive Universal Resin Cement delivery options

Aplicap™ Capsule

- Hygienic unidose (295mg per capsule)
- Consistent mix with triturator

Maxicap™ Capsule

- Hygienic unidose (936mg per capsule)
- Consistent mix with triturator
- Longer working time (2:30 minutes)

Clicker™ Dispenser

- Choose the amount dispensed—11g dispensed in 80 clicks (approx. sign 40 applications)
- Delivers pre-measured amount for consistent, easy, economical mixing
- No need for mixer, activator, appliers, mixing tips or other devices



Ordering Information

| Item # | Product Information |
|--------------|--|
| 56829 | RelyX™ Unicem Self-Adhesive Universal Resin Cement Aplicap™ Capsule Trial Kit: 20 capsules assorted shades with hardware. Kit includes: 10 of A2 Universal, 6 of Translucent, 4 of A3 Opaque; Activator/Applier set for Aplicap capsules; Instructions; Technique Card |
| | RelyX™ Unicem Self-Adhesive Universal Resin Cement Aplicap™ Capsule Refills |
| 56816 | Shade Translucent, 50 Capsules |
| 56817 | Shade A3 Opaque, 50 Capsules |
| 56818 | Shade A2 Universal, 50 Capsules |
| 56815 | Shade Assorted, 50 Capsules |
| 56819 | Shade A1, 20 Capsules |
| 56820 | Shade White Opaque, 20 Capsules |
| | RelyX™ Unicem Self-Adhesive Universal Resin Cement in the Clicker™ Dispenser Single Packs: Includes: 1 Clicker Dispenser*, 1 Mix Pad, Instructions, Technique Card |
| 56838 | Shade Translucent |
| 56837 | Shade A2 Universal |
| 56836 | Shade A3 Opaque |
| | *Each Clicker dispenser contains 11.0 grams of material, dispensed in 80 clicks (approximately 40 applications). |

RelyX™ Unicem Self-Adhesive Universal Resin Cement can be purchased from a 3M ESPE Certified Distributor. Please call the 3M ESPE Customer Care Center at 1-800-634-2249 or visit our web site at www.3MESPE.com



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