

VITA ENAMIC[®] Implant-supported crowns

Instructions for use



VITA shade determination

VITA shade communication

VITA shade reproduction

VITA shade control

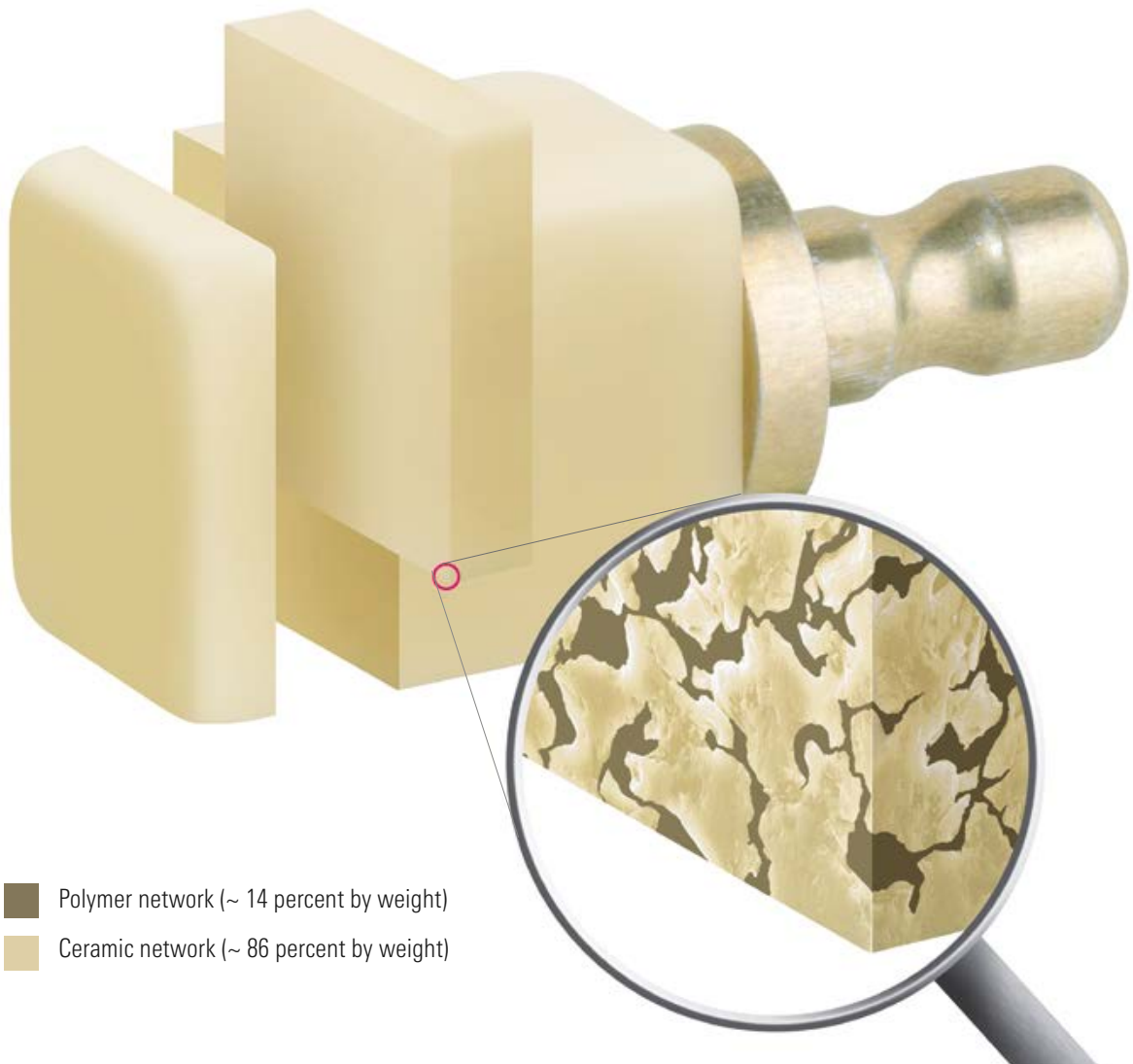
Date of issue 2022-05

VITA – perfect match.

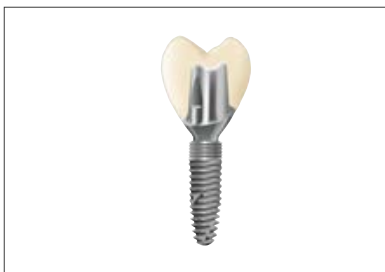
VITA

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**Information about VITA ENAMIC hybrid ceramic
is available at www.vita-enamic.com**



- Polymer network (~ 14 percent by weight)
- Ceramic network (~ 86 percent by weight)



Product description

VITA ENAMIC is the first hybrid dental ceramic in the world with a dual-network structure. In this dental material, the dominant ceramic network is reinforced by a polymer network, with both networks fully integrated with one another. VITA ENAMIC is a dental hybrid material that combines the positive characteristics of a ceramic and a composite.

VITA ENAMIC is indicated for single crowns on implant abutments

Requirements for this indication:

- Reliable adhesive bonding between the VITA ENAMIC crown and the abutment:
 - Sufficient geometry (diameter, height, emergence profile) of the abutment[1]*.
- Full compliance with the requirements for all-ceramic restorations [2]*
 - Avoiding sharply defined margins and edges at the abutment.
- Cervical support of the crown on the abutment shoulder, just like on a natural tooth stump
 - Chamfer or rectangular step with rounded inner angle and a minimum width of 0.8 mm










⚠ Note: The processing instructions for the abutments are general recommendations given without guarantee. Please contact the manufacturer of your implant [3]* if you are not sure which implant to use for the respective indication.

Patient target group:

- No restrictions

Intended user

- Dental professionals only: dentist and dental technician

Overview of indications			
Anterior and posterior crowns implant-supported*			
Anterior and posterior crowns			
Inlays / Onlays / Partial crowns			
Table tops			
Veneers			

* The abutments must be designed in a way to meet the requirements for ceramic-specific preparation and to observe the minimum wall thicknesses of crowns made of VITA ENAMIC. Please observe the processing instructions of the manufacturer of the implant and the adhesive bonding material. For more information: VITA IMPLANT SOLUTIONS Instructions for use, Prod. No. 10150.

Intended purpose:

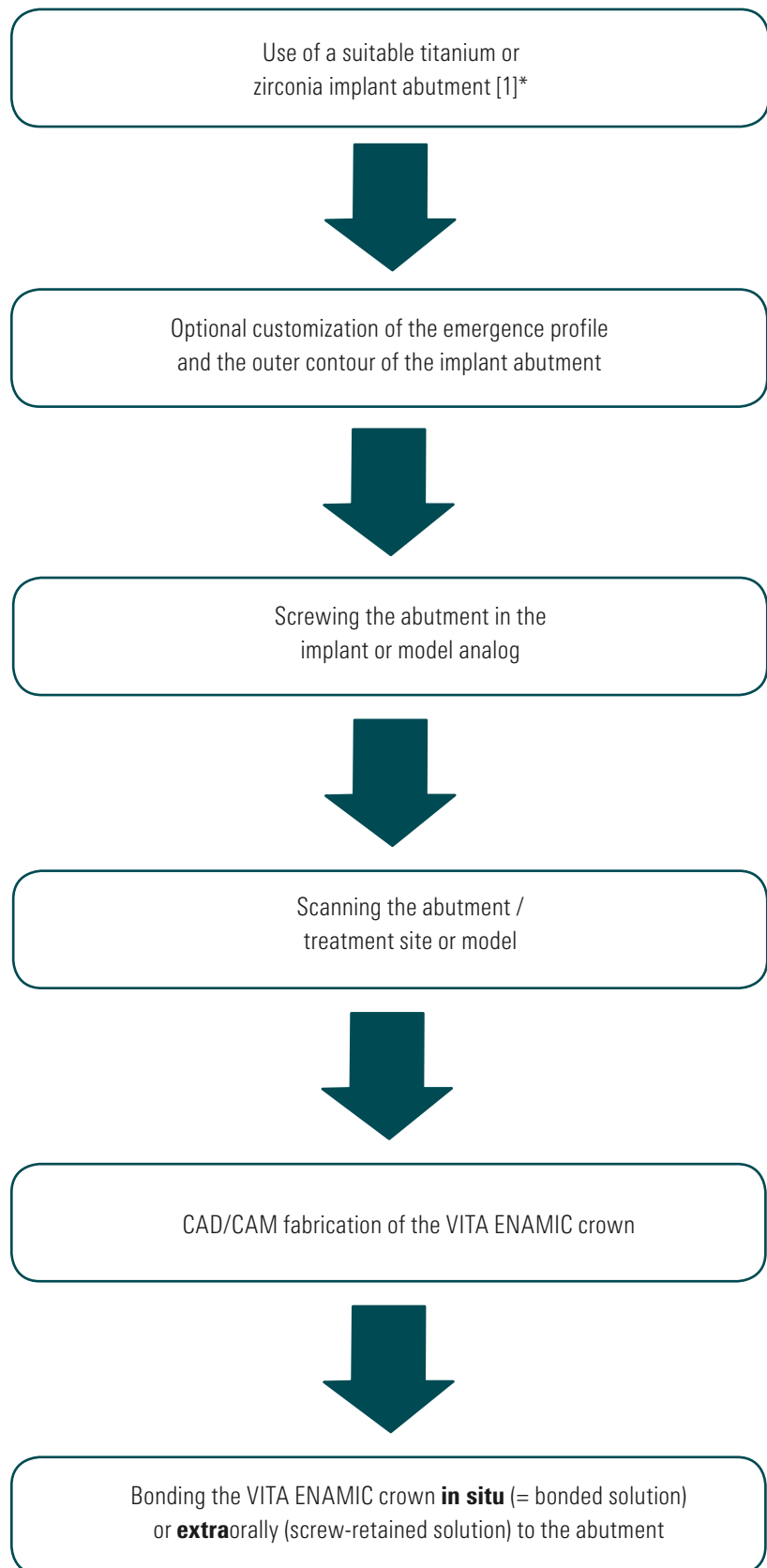
- VITA ENAMIC products are ceramic materials for dental treatments.

Contraindication

- Bridge restorations
- Free-end restorations
- Parafunction (for example bruxism)

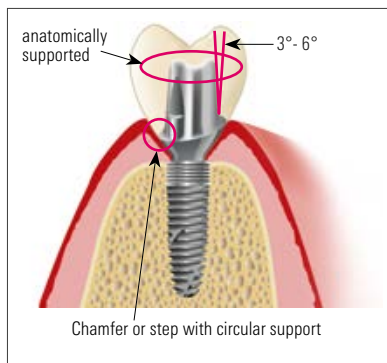
* References, see page 15

Process steps – VITA ENAMIC crown on abutment – adhesively bonded



*References, see page 15

Geometric requirements for the abutment

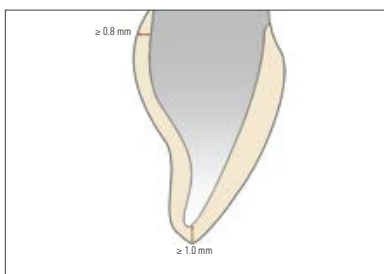


⚠ **Note:** When preparing the abutment, please observe the general guidelines on the preparation of tooth stumps to support an all-ceramic crown and the information of the respective manufacturers on the use of the abutments.

General requirements:

- The diameter or the size must be adapted to the clinical situation and to the implant system selected.
- The abutment may only be processed if the instructions of the respective manufacturer are observed.
- The geometric requirements for safe static of the crown restoration must be fulfilled:
- Avoid sharply defined margins and edges.
- Vertical convergence angle of the abutment: 3°- 6°.

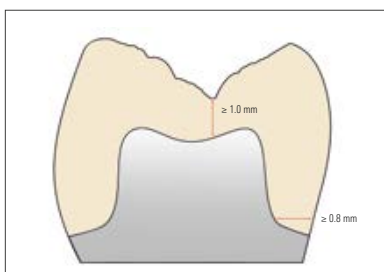
Geometric requirements for the VITA ENAMIC crown



To ensure clinical success of VITA ENAMIC restorations on implants, the following minimum layer thicknesses must be adhered to:

Anterior crowns

Incisal wall thickness: **at least 1.0 mm**
 Circumferential wall thickness: **at least 0.8 mm**



Posterior crowns

Fissure area: **at least 1.0 mm**
 Circumferential wall thickness: **at least 0.8 mm**

⚠ Please note:

- To achieve optimum bonding of VITA ENAMIC crowns on implant abutments, the exclusive use of adhesive bonding is recommended. The use of suitable bonding agents on titanium or zirconia abutments is required to achieve optimal bonding of materials. Special bonding composites or bonding agents are suitable, which contain phosphate monomers and adhesive silanes and form a hydrolysis-resistant chemical bond with titanium or zirconia surfaces.
- Conventional cementing using zinc phosphate, carboxylate or glass ionomer cements is not recommended.
- Precise and careful preparation of the bonding surfaces is the precondition to achieve durable and reliable adhesion of the VITA ENAMIC crown on the abutment.

Please observe the instructions for use of the manufacturers of the corresponding products!

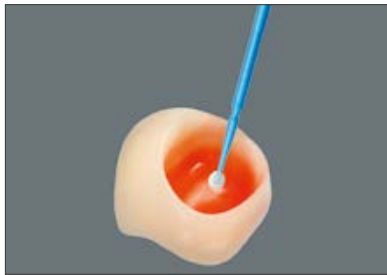


Conditioning the surfaces

1. Conditioning the VITA ENAMIC crown

Use alcohol to degrease the crown prior to adhesive bonding.

Cover any polished outer surface, as needed, in order to avoid accidental etching.



Apply VITA ADIVA CERA-ETCH (hydrofluoric acid gel, 5%) to the surfaces to be bonded.

Etching time: 60 sec.



Completely remove any remaining acid by using water spray or clean in the ultrasonic bath.

Then dry for 20 sec. Do not clean with a brush to avoid the risk of contamination! After drying, the etched surfaces have a white opaque appearance.



Apply silane bonding agent (for example, VITA ADIVA C-PRIME) to the etched surfaces.

Then dry the silane bonding agent gently with air.

2. Conditioning zirconia abutments



Use wax or silicone to protect or to seal the emergence profile and the screw channel of the zirconia abutment. Protect connection geometry with a model analog or polishing cap [3]*.



Use high-grade aluminium oxide (Al_2O_3) and carefully sandblast the bonding surface of the zirconia abutment

- Particle size: 50 μm
- Pressure: 2 bar



Then clean in the ultrasonic bath or with alcohol or steam and dry with oil-free air.

The surface to be bonded must not be touched after cleaning to avoid any contamination, which may have a negative effect on the adhesive bond.



Application of a phosphate monomer-containing bonding agent for zirconia, such as VITA ADIVA ZR-Prime, using a disposable brush or microbrush.



Allow VITA ADIVA ZR-PRIME to act for 10 seconds and then blow gently with oil-free air.

⚠ Note: Please observe the instructions for use of the manufacturers of the corresponding products!

*References, see page 15

Overview of process steps for bonding the VITA ENAMIC crown on a zirconia abutment

	Process steps	Zirconia abutment	VITA ENAMIC crown
1.	Sandblast with high-grade aluminium oxide (Al ₂ O ₃)	50 µm, max. 2.0 bar	–
2.	Cleaning the surface	Ultrasonic, ethanol	Ethanol
3.	Etching (extraoral)	–	VITA ADIVA CERA-ETCH, 5% HF, 60 s
4.	Cleaning the surface	–	with water spray or in the ultrasonic bath.
5.	Bonding agent / silanization	Apply VITA ADIVA ZR-PRIME and allow to act for 10 seconds; then blow gently with air.	Apply VITA ADIVA C-PRIME and blow gently
6.	Full-adhesive/self-adhesive bonding	e.g., VITA ADIVA F-CEM, VITA ADIVA IA-CEM* or VITA ADIVA S-CEM	

* ultra-opaque colored

Disinfection/sterilization

For extraoral bonding of the crown to the abutment, it is recommended to disinfect the VITA ENAMIC superstructures with a surface disinfectant containing ethanol or to sterilize them prior to seating. The local legal regulations and hygiene standards applicable to dental practices need to be observed. Steam sterilization can be carried out with a triple fractionated prevacuum in compliance with the following parameters:

- Sterilization time: 10 minutes
- Steam temperature: 134° C/ 273° F

The superstructure needs to be seated immediately after sterilization and may not be stored temporarily!

Please note:

The user/dentist is responsible for the sterility of the superstructure.

It must be ensured that only suitable equipment and materials, as well as product-specific validated methods, are used for sterilization. The equipment that is used should be maintained properly and serviced regularly.

3. Conditioning titanium abutments



Use wax or silicone to protect the emergence profile and the screw channel of the titanium abutment. Protect connection geometry with a model analog or polishing cap [3]*.



Use high-grade aluminium oxide (Al_2O_3) and carefully sandblast only the bonding surface of the titanium base

- Particle size: 50 μm
- Pressure: 2 bar



until a matte surface is obtained.



Then remove wax or silicone.



Clean titanium base with alcohol or use a steam jet and dry with oil-free air.

* References, see page 16



The surface to be bonded must not be touched after cleaning to avoid any contamination, which may have a negative effect on the adhesive bond.

Application of a suitable metal bonding agent, such as VITA ADVIA M-PRIME, using a disposable brush or microbrush is recommended.

Allow VITA ADIVA M-PRIME to act for 10 seconds and blow gently with oil-free air.

Then dry with oil-free air.






⚠ Note: Please observe the instructions for use of the manufacturers of the corresponding products!


Overview of process steps for bonding the VITA ENAMIC crown on a titanium abutment








	Process steps	Titanium abutment	VITA ENAMIC crown
1.	Sandblast with high-grade aluminium oxide (Al ₂ O ₃)	50 µm, 2.0 bar	–
2.	Cleaning the surface	Ultrasonic, ethanol	Ethanol
3.	Etching (extraoral)	–	VITA ADIVA CERA-ETCH, 5% HF, 60 s
4.	Cleaning the surface	–	with water spray or in the ultrasonic bath.
5.	Conditioning/silanizing	Apply VITA ADIVA M-PRIME, allow to act for 10 seconds, and blow gently with air ¹⁾	Apply VITA ADIVA C-PRIME and blow gently
6.	Adhesive bonding	VITA ADIVA IA-CEM ²⁾	

¹⁾ If the VITA ENAMIC crown is bonded extraorally to the titanium abutment, the superstructure should be sterilized prior to screwing in situ. In this case, we recommend using Monobond Plus (Ivoclar Vivadent): Apply Monobond Plus, allow to act for 60 seconds and disperse with strong blasts of air.

²⁾ ultra-opaque colored bonding composite, especially suited for masking titanium abutments.

Recommended products	
<ul style="list-style-type: none"> • Ceramic etching gel for VITA ENAMIC <ul style="list-style-type: none"> – VITA ADIVA CERA-ETCH, 5% hydrofluoric acid gel (VITA) – Available as a syringe, 3 ml – Available as dropper bottle, 6 ml 	
<ul style="list-style-type: none"> • Silane bonding agent for VITA ENAMIC <ul style="list-style-type: none"> – VITA ADIVA C-PRIME 	
<ul style="list-style-type: none"> • Bonding agent for zirconia <ul style="list-style-type: none"> – VITA ADIVA ZR-PRIME 	
<ul style="list-style-type: none"> • Bonding agent for titanium <ul style="list-style-type: none"> – VITA ADIVA M-PRIME 	
<ul style="list-style-type: none"> • Dual-curing luting composites for VITA ENAMIC on titanium/zirconia abutments <ul style="list-style-type: none"> – VITA ADIVA F-CEM – VITA ADIVA S-CEM – VITA ADIVA IA-CEM 	

The following products require hazard identification:		
<p>VITA ADIVA® CERA-ETCH (hydrofluoric acid ceramic etching gel)</p>	<p>Caustic / Toxic</p> <p>For extraoral use only! Contains hydrofluoric acid. Toxic if swallowed. Fatal in contact with skin. Causes severe skin burns and damage to eyes. Harmful by inhalation. Wear protective gloves/protective clothing/safety goggles. Keep locked up. If swallowed, call the Toxicological Information Center immediately and provide safety data sheet. In case of contact with clothing/skin, remove contaminated clothing immediately and rinse with a copious amount of water. Specific measures, see safety data sheet. In case of contact with eyes, rinse with water for a few minutes and consult a doctor/Toxicological Information Center. This material and its container must be disposed of as hazardous waste.</p>	

The following products require hazard identification:		
<p>VITA ADIVA® C-PRIME (Silane bonding agent)</p>	<p>Danger</p> <p>Highly flammable liquid and vapor. Keep away from heat/sparks/open flame/hot surfaces. No smoking.</p>	
<p>VITA ADIVA® ZR-PRIME (zirconia bonding agent)</p>	<p>Danger</p> <p>Highly flammable liquid and vapor. Causes severe eye irritation. May cause drowsiness and dizziness. Keep away from heat/open flame/hot surfaces. No smoking.</p>	 
<p>VITA ADIVA® M-PRIME (metal bonding agent)</p>	<p>Danger</p> <p>Highly flammable liquid and vapor. Causes severe eye irritation. May cause drowsiness and dizziness. Keep away from heat/open flame/hot surfaces. No smoking.</p>	 
<p>VITA ADIVA® S-CEM (self-adhesive luting composite)</p>	<p>Important</p> <p>Causes skin irritation. Causes severe eye irritation. May cause allergic skin reactions. Respiratory irritation – may cause respiratory irritation.</p>	
<p>Protective clothing</p>	<p>While work is in progress, wear suitable safety goggles/face protection, gloves and safety clothing. In case of formation of dust, use an extraction system or wear a face mask.</p>	







The corresponding safety data sheets can be downloaded at www.vita-zahnfabrik.com/sds.



Storage information/disposal:

- Please observe the storage information for the VITA ADIVA products.
- The products labelled with a pictogram for hazardous substances are to be disposed of as hazardous waste. Recyclable waste (such as attachments, paper and plastics) must be disposed of using appropriate recycling systems. Contaminated product residues must be pretreated if necessary and disposed of separately in accordance with regional regulations.

Symbol explanations

Manufacturer VITA Zahnfabrik		Manufacturing date	
Shelf life		Protect from sunlight	
Storage temperature		Lot number (batch)	LOT
Product number	REF	Medical device	MD
See Instructions for Use			



General notes on handling

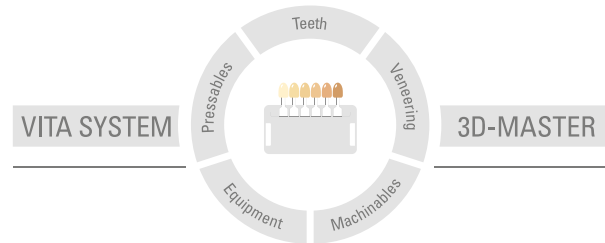
Product safety

- Information on reporting serious incidents in connection with medical devices, general risks associated with dental treatments, residual risks and (if applicable) short clinical safety and performance reports (SSCPs) can be found at https://www.vita-zahnfabrik.com/product_safety

References:

- [1] Prefabricated or individual abutments for cemented or adhesively bonded dental restorations. Please contact the manufacturer of your implant to obtain system-related recommendations.
- [2] "Clinical aspects of all-ceramics," VITA Zahnfabrik, Product No. 1696
- [3] Please contact the manufacturer of your implant to obtain system-related recommendations.

With the unique VITA SYSTEM 3D-MASTER, all natural tooth shades can be systematically determined and perfectly reproduced.



Please note: Our products must be used in accordance with the instructions for use. We accept no liability for any damage resulting from incorrect handling or usage. The user is furthermore obliged to check the product before use with regard to its suitability for the intended area of applications. We cannot accept any liability if the product is used in conjunction with materials and equipment from other manufacturers that are not compatible or not authorized for use with our product and this results in damage. The VITA Modulbox is not necessarily a component of the product. Date of issue of this information: 2022-05

After the publication of this information for use any previous versions become obsolete. The current version can be found at www.vita-zahnfabrik.com

VITA Zahnfabrik has been certified and the following products bear the mark

CE 0124

VITA ENAMIC®

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We would like to thank BEGO Implant Systems, Bremen, Germany for providing the title image and the graphic at the top of page 7, and for the implant components required for visualization.

  Rx Only

 VITA Zahnfabrik H. Rauter GmbH & Co.KG, Bad Säckingen (Germany)
Zweigniederlassung Basel c/o Perrig AG, Max Kämpf-Platz 1, 4058 Basel

VITA

 VITA Zahnfabrik H. Rauter GmbH & Co.KG
Spitalgasse 3 · 79713 Bad Säckingen · Germany
Tel. +49(0)7761/562-0 · Fax +49(0)7761/562-299
Hotline: Tel. +49(0)7761/562-222 · Fax +49(0)7761/562-446
www.vita-zahnfabrik.com · info@vita-zahnfabrik.com
 facebook.com/vita.zahnfabrik