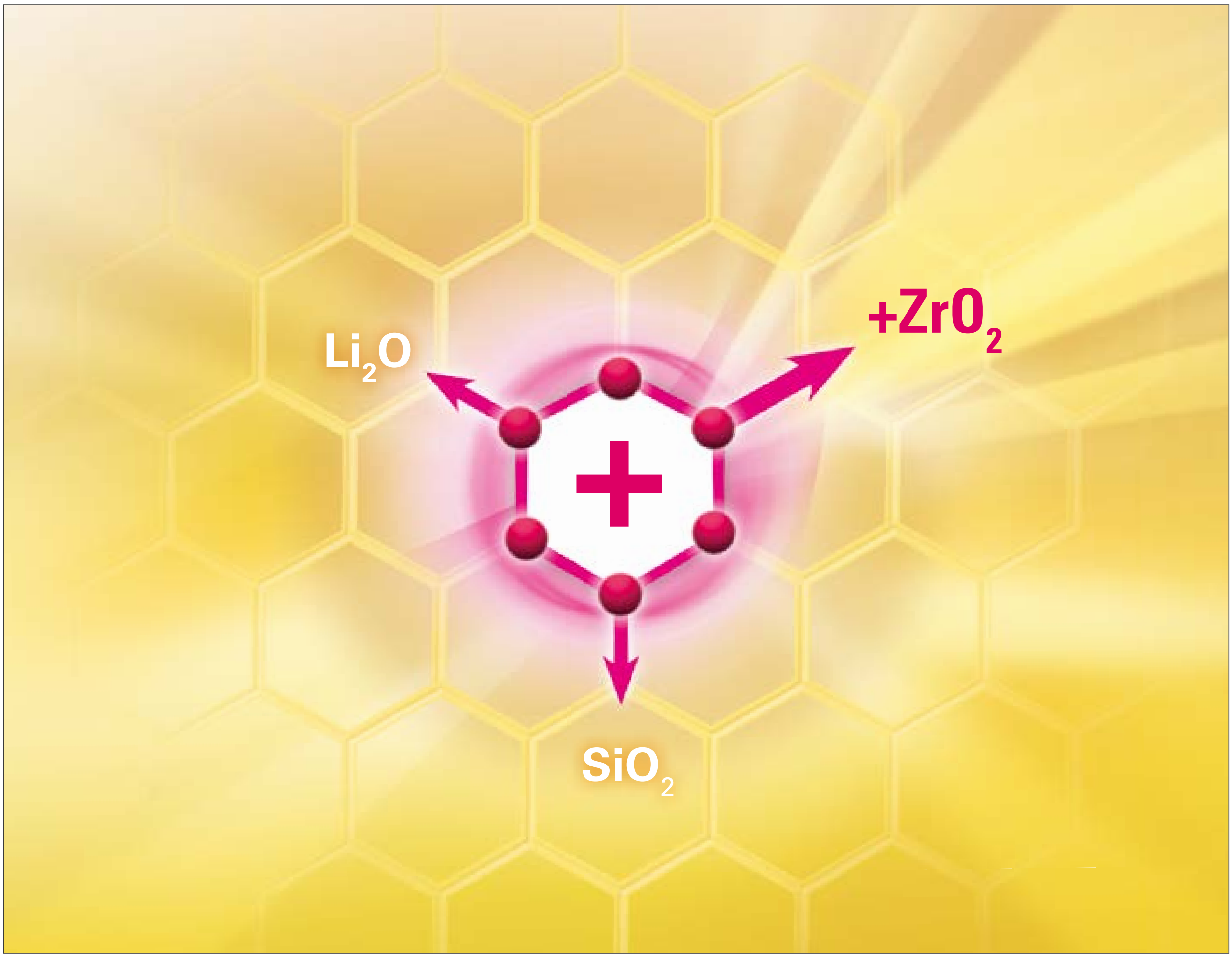
VITA SUPRINITY®

Technical and scientific documentation



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Date of issue: 04.14

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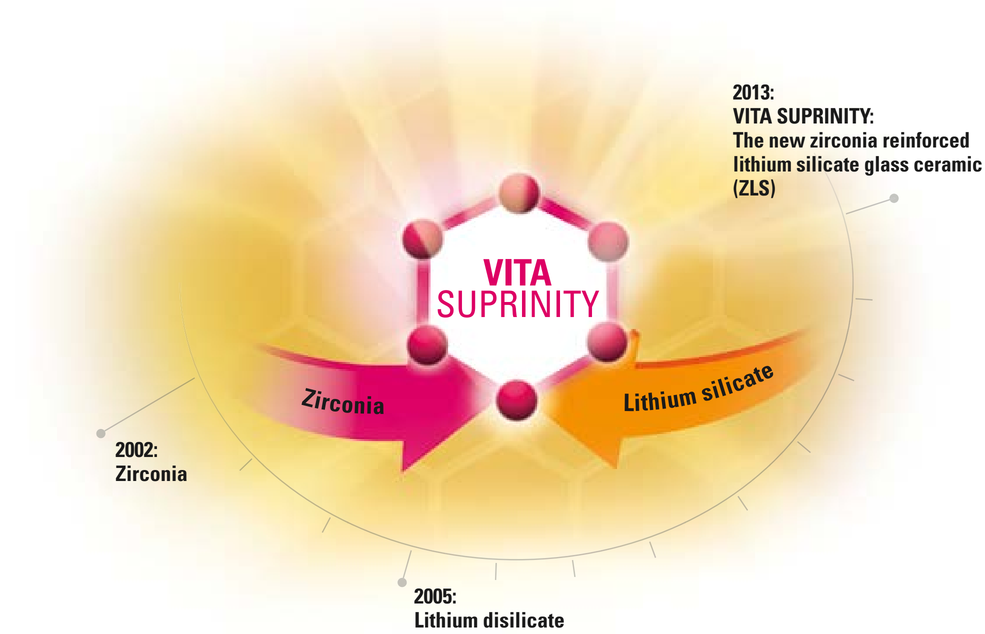
VITA

1. Introduction

CAD/CAM techniques have become established in dentistry for roughly 10 years. These techniques date back more than 25 years when the first commercially successful dental CAD/CAM system, the CEREC system, was developed. This system enabled scanning of the oral situation and digitized and automated fabrication of all-ceramic restorations for the first time. In the process of further development of CAD/CAM technology, new materials were developed for digital dentistry over time. Three-dimensional visualization and the calculation of sinter shrinkage or its compensation enabled the use of densely sintered oxide ceramic for the fabrication of substructures.



At the beginning of the new millennium, the use of zirconia in the dental sector was an important milestone since the material enabled the fabrication of multi-unit, all-ceramic bridges for the first time.

An additional material has been available to dental users all over the world since the introduction of a lithium disilicate-based glass ceramic in 2005. After similar glass-ceramic products had proven their reliability in applications, including telescope mirrors and hotplates, this new composition combined high strength and a tooth-colored appearance. VITA SUPRINITY also reflects the systematic progress in this field.

The new zirconia reinforced lithium silicate glass ceramic material (ZLS) was developed in cooperation with Degudent GmbH and the Fraunhofer Institute for Silicate Research ISC. This newly developed generation of glass ceramic materials combines the positive material characteristics of zirconia (ZrO_2) and glass ceramic. Thanks to a ZrO_2 content of approx. 10 percent by weight, a structure is obtained after crystallization, which exhibits excellent mechanical properties and fulfills the highest esthetic requirements.
The following results of numerous laboratory tests as well as internal and external in-vitro studies demonstrate the effects of these material properties and how VITA SUPRINITY differs from current CAD/CAM materials.

1.1 Chemical composition

Components	Wt.-%
SiO_2	56 – 64
Li_2O	15 – 21
K_2O	1 – 4
P_2O_5	3 – 8
Al_2O_3	1 – 4
ZrO_2	8 – 12
CeO_2	0 – 4
Pigments	0 – 6

1.2 Physical/mechanical properties

Test	VITA SUPRINITY	Standard ISO 6872
3-point flexural strength	approx. 420 MPa*[1]	> 100 MPa
3-point flexural strength, precrystallized	approx. 180 MPa	None specified
Biaxial strength	approx. 540 MPa*[2]	> 100 MPa
Modulus of elasticity	approx. 70 GPa	None specified
Weibull modulus	approx. 8.9	None specified
Fracture toughness (SEVNB)	approx. 2.0 MPa $m^{-0.5}$	None specified
Hardness	approx. 7000 MPa	None specified
CTE	approx. 12.3 10^{-6}/K	None specified
Transformation temperature (TG)	approx. 620 °C	None specified
Softening temperature	approx. 800 °C	None specified
Chemical solubility	approx. 40 µg/cm²	< 100 µg/cm²

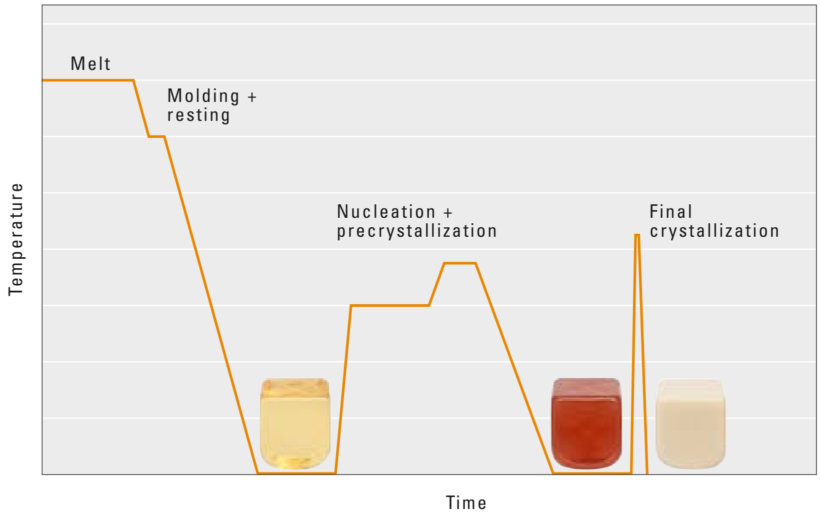
*[1]) The 3-point flexural strength value indicated is the average of numerous lot tests performed by VITA's Quality Control with partially automated preparation of specimens, which resulted in lower strength values than those obtained for careful manual preparation of specimens.

*[2]) cf. Materials and method, p. 8

1.3 Manufacturing process

The zirconia reinforced lithium silicate ceramic blanks are produced in three stages. After the first process, molding, the block is in the glass state. In this state, the material is relatively brittle and not suitable for machine processing, so the blocks are subject to thermal pretreatment. After initial nucleation, crystals start to form and grow. In this stage, the glass features ceramic properties, so it can also be processed in a way to save time and costs using suitable tools.
The block exhibits its final esthetic and physical properties only after final crystallization in a dental furnace in practices and laboratories.

Temperature and time curve of VITA SUPRINITY



1.4 Microstructure

A particularly fine-particle structure of the ZLS glass ceramic is achieved thanks to the addition of zirconia and the ensuing nucleation process. The homogeneous structure ensures good milling and polishing characteristics of the material even in its fully crystallized form.

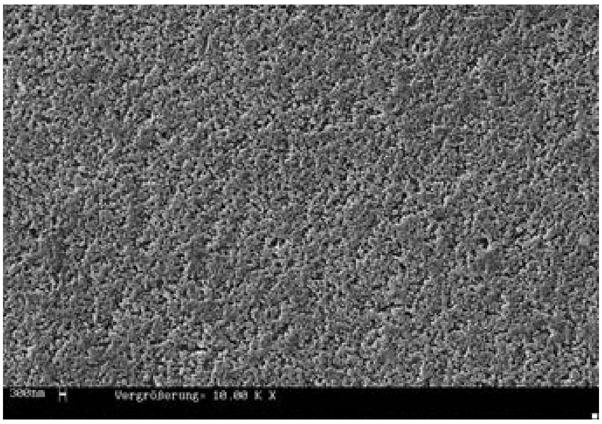
a) Materials and method

Plates were sawed out of a VITA SUPRINITY block and a block of the lithium disilicate ceramic, lapped and crystallized. Then the surface of the specimens were etched with diluted hydrofluoric acid. Afterwards, the surfaces were examined under the scanning electron microscope (SEM) with the same magnification level.

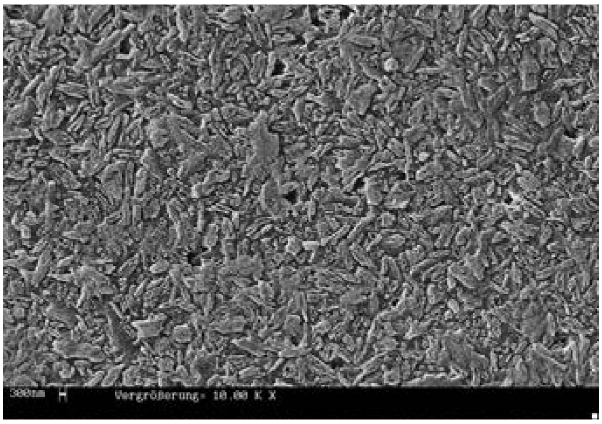
b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result



VITA SUPRINITY, SEM picture, 10,000x

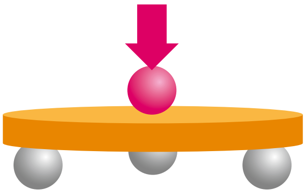


Lithium disilicate, SEM picture, 10,000 x

d) Conclusion

In the case of VITA SUPRINITY, the analysis of the image reveals a homogeneous, fine crystalline structure with an average crystal size of approx. 0.5 µm. In the case of lithium disilicate ceramic, a structure with needle-shaped crystals and an average crystal size of approx. 1.5 µm* is formed.

*) Source: Measurement, Ivoclar Vivadent, Inc., IPS e.max lithium disilicate – The Future of All-Ceramic Dentistry, 2/2009



2. Physical/mechanical properties in vitro

2.1 Biaxial strength

a) Materials and methods

The test was carried out based on ISO 6872 with a modified geometry of specimens. To reduce defects of margins, the blocks were not turned first, but rectangular discs were prepared from the blocks with comparable geometries using a diamond wire saw. Then a uniform layer thickness of approx. 1.2 mm was milled using a lapping machine and final crystallization was carried out according to the manufacturer's instructions.

Twenty specimens of each material were loaded until fracturing occurred (Zwick universal testing machine) and the strength was determined.

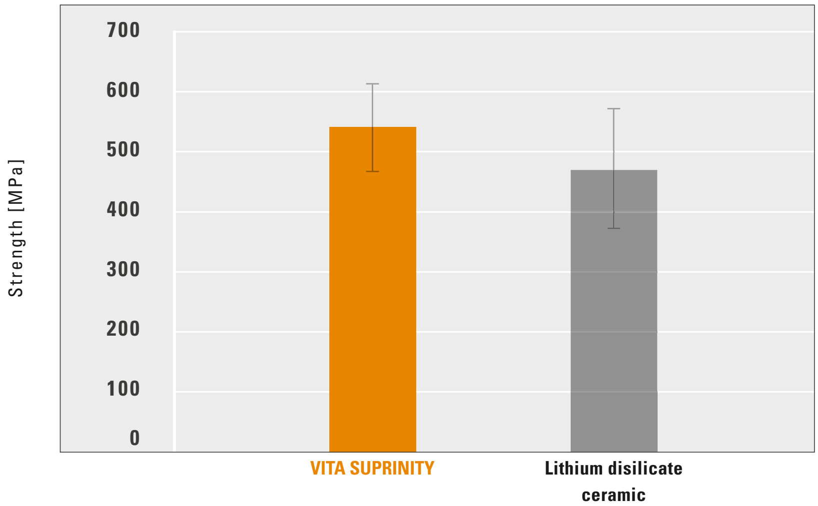
To calculate the stress, the diameter used in the formula was replaced by the length of the shorter side of the rectangle.

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

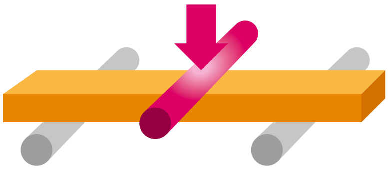
c) Result

Biaxial strength



d) Conclusion

In this test series, VITA SUPRINITY produced an average biaxial strength of 541 MPa (± 74 MPa). The value for lithium disilicate ceramic is 471 MPa (± 102 MPa). VITA SUPRINITY features both higher average strength and lower standard deviation in this test.



2.2 3-point flexural strength

a) Materials and method

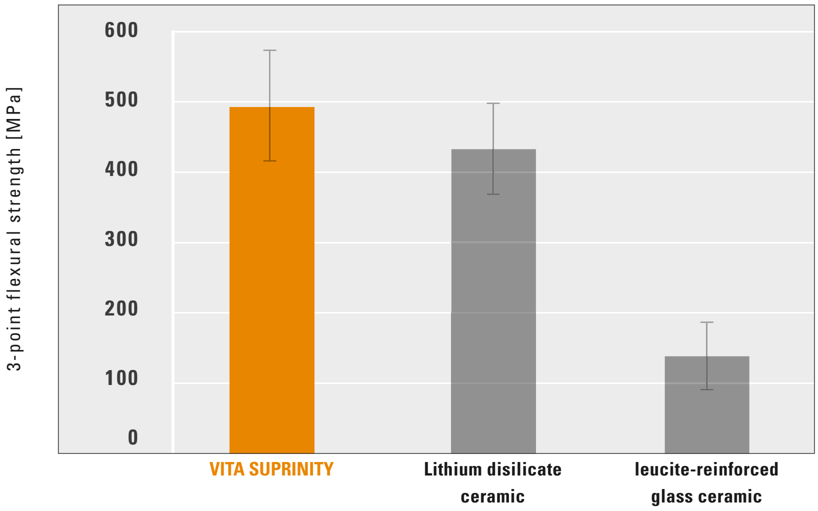
The test was carried out in accordance with ISO 6872. A diamond saw was used to prepare bending rods from the blocks.
Using a SiC suspension (grain size 1200), the specimens were milled manually to a uniform layer thickness of approx. 1.2 mm, a chamfer was added and crystallization was carried out according to the manufacturer's instructions.
No additional tempering process was carried out for the leucite reinforced glass ceramic.Ten specimens of each material were loaded until fracturing occurred (Zwick universal testing machine) and the 3-point flexural strength was determined.

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

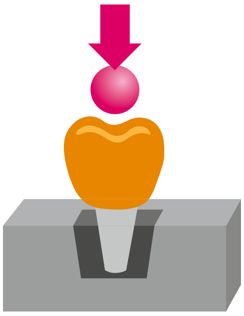
c) Result

3-point flexural strength after milling



d) Conclusion

In this test series, VITA SUPRINITY produced an average flexural strength of 494.5 MPa. This value is more than three times higher than the value determined for traditional leucite reinforced glass ceramic (138.7 MPa). The result for the lithium disilicate ceramic in this test is 435.0 MPa.
The value of approx. 420 MPa indicated for VITA SUPRINITY within the scope of the physical data (cf. p. 5), represents the average of numerous lot tests of VITA's Quality Control for which partially automatic specimen preparation is used as part of the time optimization process. As a result, lower strength values are achieved than during careful manual preparation of the specimen.



2.3 Static fracture load

2.3.1 Molar crowns

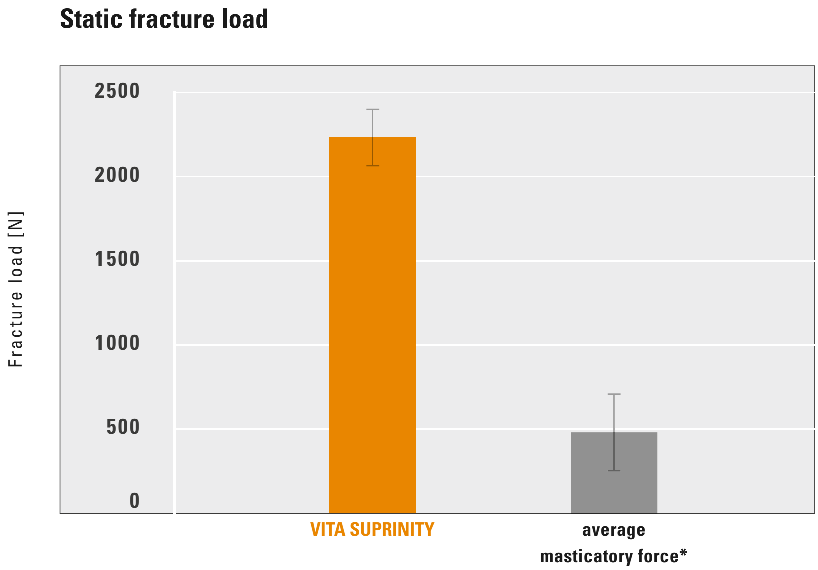
a) Materials and method

Molar crowns made of VITA SUPRINITY were milled using the MC XL system and then polished and crystallized. The crowns were bonded to hybrid ceramic dies (modulus of elasticity: 23 GPa) using RelyX Unicem (self-adhesive, 3M ESPE) and then immersed for accelerated aging in warm water (37°C) for one week. In a testing machine, static load was applied to the crowns until fracturing occurred. The bars represent the average value obtained based on 6 crowns.

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result



d) Conclusion

In this test setup, VITA SUPRINITY bonded with a self-adhesive cement withstands a load of approx. 2,262 N. The average maximum masticatory force, however, ranges from approx. 490 N to 725 N (*[2], cf. p. 23). Accordingly, the molar crowns that were used (thickness of occlusal layer approx. 1.0 mm) are able to withstand significantly higher loads.

2.3.2 Fracture load on implant abutments

a) Materials and method

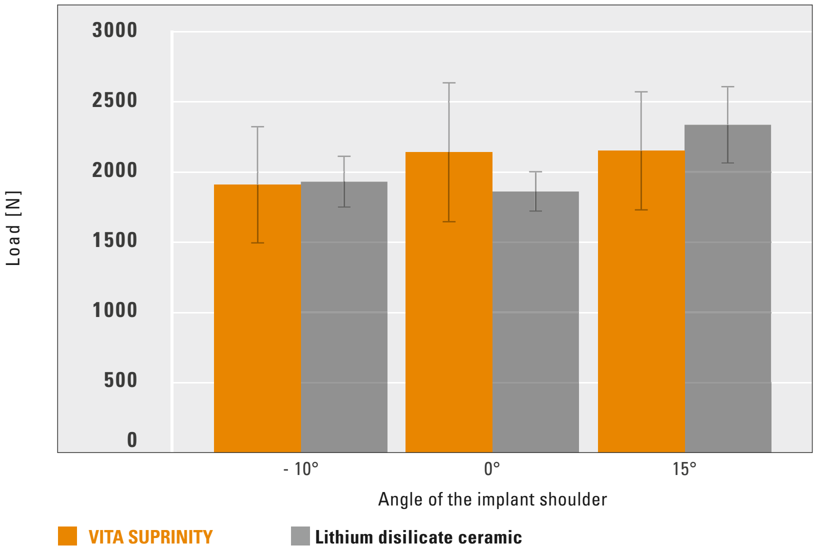
First implant bodies were fabricated (non-precious metal) which had only different shoulder angles. Angles of -10°, 0° and 15° were used for this test setup. The implants were embedded in a resin with an modulus of elasticity similar to the one of bone (Ren Cast CW20/Ren HY49, Huntsman). Then the milled crowns (Sirona's MC XL-System) were cemented to the implants using Multilink Implant (Ivoclar Vivadent).
A series of five crowns of each material was tested for each angle. In a universal testing machine, static load was applied to the crowns until fracturing occurred.

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result

Determination of fracture load of implant crowns

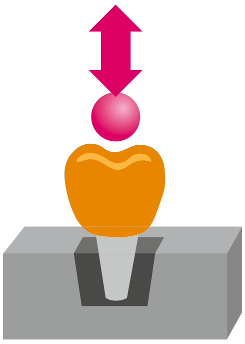


d) Conclusion

With values of approximately 2,000 N, the static tests on implants for VITA SUPRINITY produced a result that was similar to the one for dies made of a hybrid material (see 2.3.1).

2.4 Dynamic fracture load

2.4.1 Dynamess method



a) Materials and method

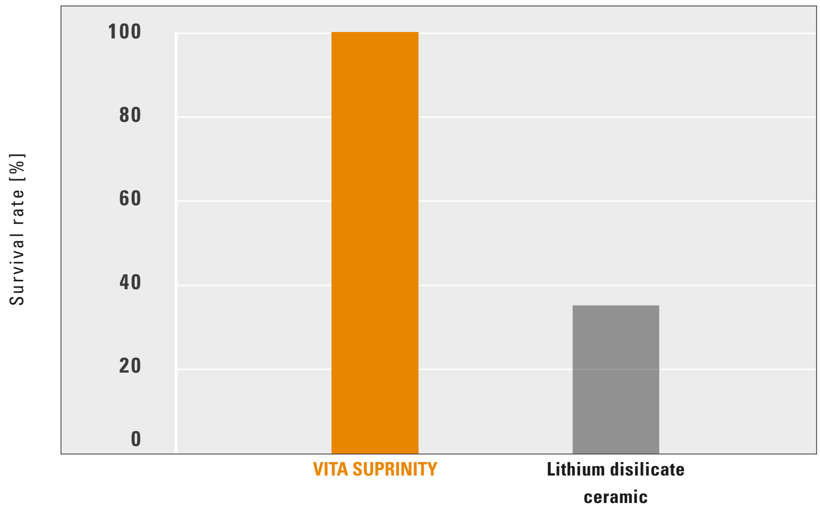
Six crowns of each material (VITA SUPRINITY, lithium disilicate ceramic) were tested in the Dynamess machine. Following etching, the crowns were cemented to dies made of a hybrid material (modulus of elasticity approx. 23 GPa) using RelyX Unicem (3M ESPE). The specimens were embedded in Technovit 4000 (Heraeus Kulzer) and immersed in warm water (37 °C) for at least one week.
Following accelerated aging, the crowns were subjected to a cyclic load : 1,200 N for 1.2 million cycles, frequency of 2.0 Hz, 5 mm steel beads as the antagonist, temperature: 37 °C.

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result

Dynamic load test



d) Conclusion

During dynamic masticatory loading, none of the VITA SUPRINITY crowns showed any defects. Fracturing occurred in 4 crowns when the lithium disilicate was exposed to loading. The survival rate of the VITA SUPRINITY crowns in this test was 100%. The masticatory force used is 1,200 N, far exceeding the force normally applied by human jaw muscles.

2.5 Weibull modulus / reliability

a) Materials and method

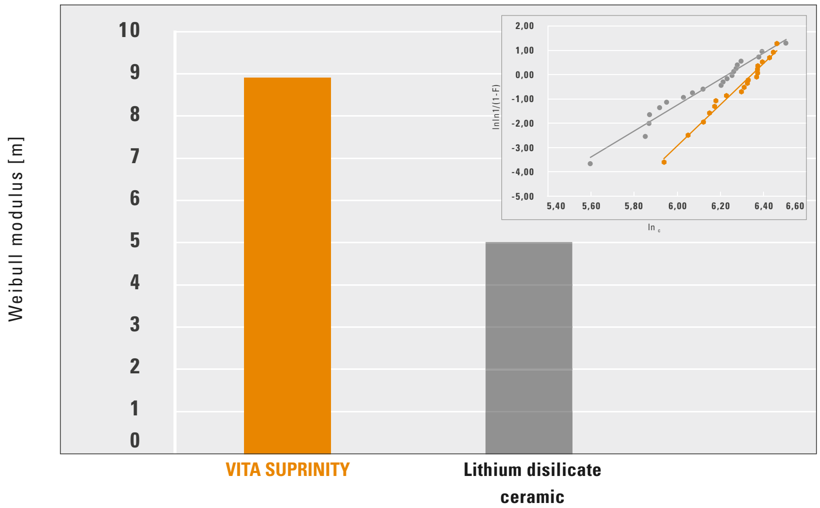
The Weibull modulus was determined based on the flexural strength of 20 biaxial specimens (see 2.1). Using a theory developed by Weibull, based on the concept of failure of the weakest link, the strength distribution of ceramic materials can be described effectively in mathematical terms. [...] Accordingly, if the distribution parameters are known, there is a clear correlation between the load and the probability of fracture." ([3], cf. p. 23).
In simple terms, this means that a high Weibull modulus indicates uniform material quality. In addition to the high load capacity values, this is an indicator for the reliability of a material.

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result

Weibull modulus



d) Conclusion

In this test, VITA SUPRINITY exhibits the highest Weibull modulus in this class of materials. The Weibull modulus (m) is 8.9; this is a good value with regard to the level of strength of high-strength glass ceramic materials. A Weibull modulus of 5.0 was determined for lithium disilicate ceramic.

2.6 Abrasion

2.6.1 Two-body abrasive wear

a) Materials and methods

To determine the abrasion level, a pin-on-block wear test in the chewing simulator was carried out at the University of Regensburg using the following parameters:

- Steatite beads as the antagonist
- 50 N load force
- 1.2 x 10^5 cycles, 1.6 Hz
- 600 thermal cycles, 5 – 55 °C

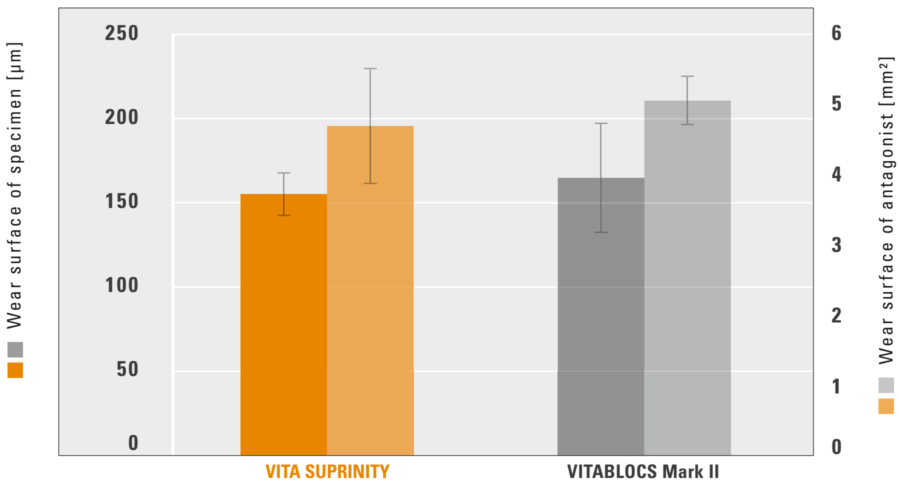
Evaluation: measurement of substance loss

b) Source

Source: University of Regensburg, Priv.-Doz. Dr. Rosentritt ([4], cf. p. 23)

c) Result

Wear study



d) Conclusion

The abrasion level of VITA SUPRINITY is approx. 155 µm, which falls in the range of VITABLOCS Mark II with an abrasion behavior clinically proven for decades. The levels of antagonist wear for feldspar ceramic and the ZLS ceramic are on a similar level in this test setup.

2.7 Vickers hardness

a) Materials and method

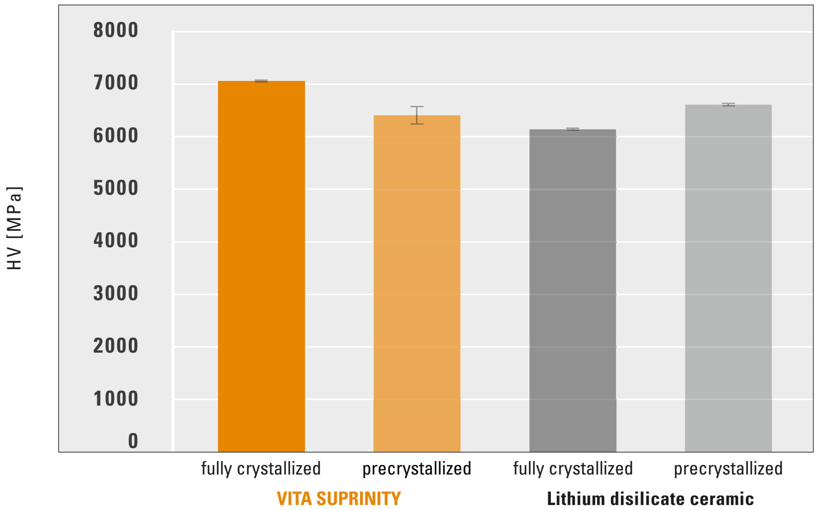
According to the current definition, hardness is the resistance of a solid body set against the intrusion of another, harder matter (Physikalisch-Technische Bundesanstalt). This definition of hardness differs from the one of strength, which describes the resistance of material against deformation and separation.
For this test, the materials embedded in epoxy (VITA SUPRINITY, lithium disilicate ceramic) were polished to a high-luster finish. The polished specimens were clamped into position in the hardness tester. In each case, 3 indent impressions were made for each material with a load of 10 N. Once the maximum load had been reached, this was maintained for 20 seconds before release. Hardness in megapascal (MPa) was calculated by measuring the diagonals of the indent. The bars in the diagram correspond to the average values obtained based on three measurements in each case.

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result

Vickers hardness



d) Conclusion

After crystallization, the hardness of VITA SUPRINITY is approx. 7,000 MPa.
Prior to thermal treatment, the material is slightly softer (hardness: approx. 6,400 MPa) and more suitable for machine processing.

2.8 Machinability

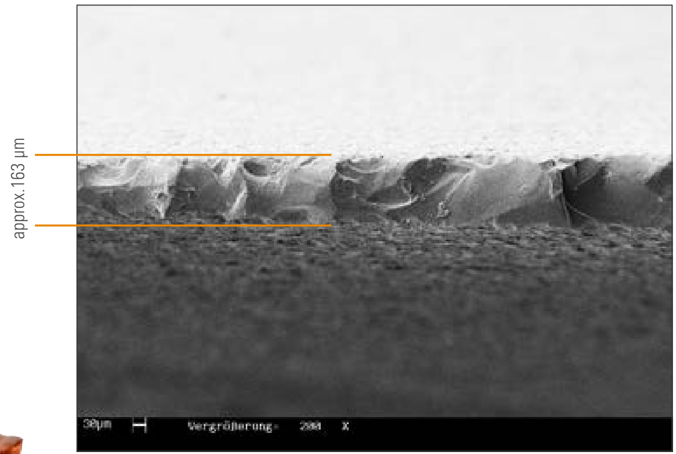
a) Materials and method

Using Sirona's MC XL system, wedge-shaped 30° test specimens made of two glass ceramic materials (VITA SUPRINITY and lithium disilicate) were milled from blocks in normal milling mode. To evaluate the edge stability, the width of the wedge tip was measured under the scanning electron microscope.

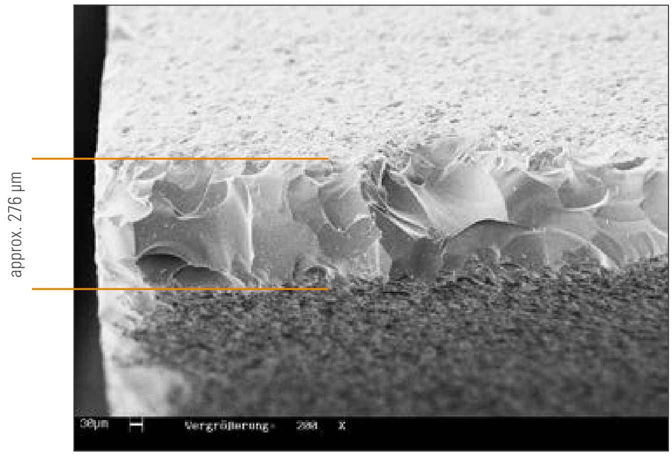
b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result



VITA SUPRINITY, SEM picture, 200x



Lithium disilicate ceramic, SEM picture, 200 x

d) Conclusion

When using the default milling programs for the respective materials (normal mode), VITA SUPRINITY exhibits higher marginal accuracy than the lithium disilicate ceramic. The use of VITA SUPRINITY provides the ability to achieve margins with a thickness of approx. 0.16 mm for this geometry.

2.9 Milling times

a) Materials and method

For reasons of comparison, the milling times of three types of restorations (inlay, anterior crown and posterior crown) were determined using three CAD/CAM materials (VITA SUPRINITY and VITABLOCS Mark II, both from VITA Zahnfabrik and IPS e.max CAD from Ivoclar Vivadent). The milling tests were performed using Sirona's MC XL milling system. The respective material was selected from the material selection and five restorations of each material were milled in normal and fast milling mode. The milling times were taken from the log files.

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result

Milling times (minutes:seconds) in normal and fast milling mode for VITA SUPRINITY, VITABLOCS Mark II and IPS e.max CAD. The times correspond to the average value determined on the basis of five measurements.

				
VITA SUPRINITY	**Normal**	**11:11**	**11:04**	**13:32**
	Fast	**7:50**	**6:57**	**8:38**
Feldspar ceramic (VITABLOCS Mark II)	Normal	10:27	10:35	13:29
	Fast	6:24	7:03	9:26
Lithium disilicate (IPS e.max CAD)	Normal	12:17	12:36	14:58
	Fast	10:00	8:11	12:14

d) Conclusion

Restorations made of VITA SUPRINITY, milled in normal and fast milling mode, can be completed one to three minutes faster than with lithium disilicate.

2.10 Polishing characteristics / manual reworking

a) Materials and method

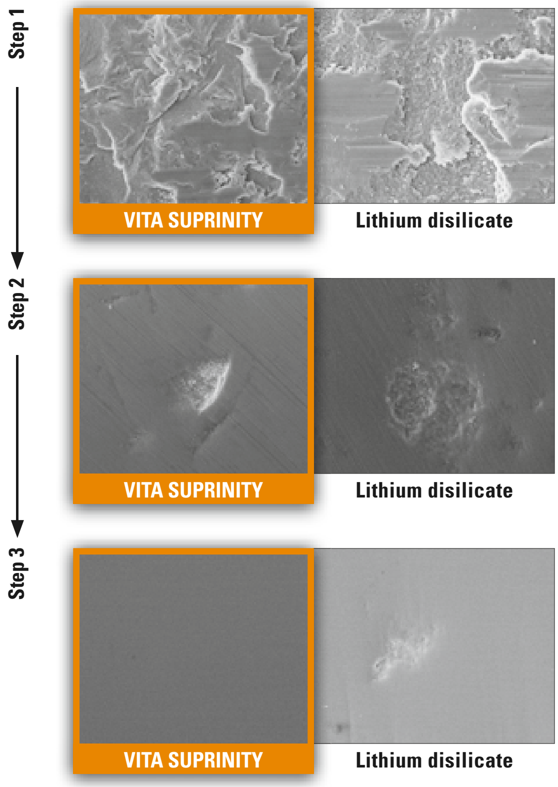
Various coarse and fine polishers were tested within the process of material development. The tools with the best performance - from a subjective point of view - were used for polishing tests. Plates with an area of 20 x 20 mm were prepared. Manual polishing was carried out. Three tools were used for reworking: fine diamond, prepolisher and fine polisher. The processing time for each stage was 30 seconds.

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result

SEM pictures of the polished surfaces after the first, second and third stage.



Surfaces after grinding with a diamond bur.

Surfaces after grinding with a diamond bur and additional coarse polishing.

Surfaces after grinding with a diamond bur and additional coarse and fine polishing.

SEM pictures, 2,000 x

d) Conclusion

In the case of VITA SUPRINITY, the test geometry can be polished to high gloss within 90 seconds using the instruments recommended.
In addition to these tests, the use of polishers for processing zirconia produced comparable results.

2.11 Biocompatibility

All tests regarding biocompatibility were carried out by North American Science Associates Inc. (NAMSA) to obtain CE approval.

In this context, the following aspects were evaluated:

- Cytotoxicity
- Sensitization
- Irritation
- Subchronic systemic toxicity
- Genotoxicity

VITA SUPRINITY was deemed biocompatible in all aspects.

3. VITAVM®11 veneering material

3.1 Physical/mechanical properties

VITA VM 11	Unit of measure	Value
CTE (coefficient of thermal expansion)	10^{-6}/K	11,2 - 11,6
Softening temperature	°C	approx. 600
Transformation temperature (TG)	°C	approx. 540
Solubility in acid	µg/cm^2	approx. 8
Average particle size	µm (d_{50})	approx. 18
3-point flexural strength	MPa	approx. 100

3.2 Chemical composition

Components	Wt.-%
SiO_2	62 – 65
Al_2O_3	8.5 – 12
Na_2O	5 – 7.5
K_2O	9 –12
CaO	1 – 2
ZrO_2	< 1
B_2O_3	4 – 6

3.3 Dilatometer measurement

a) Materials and method

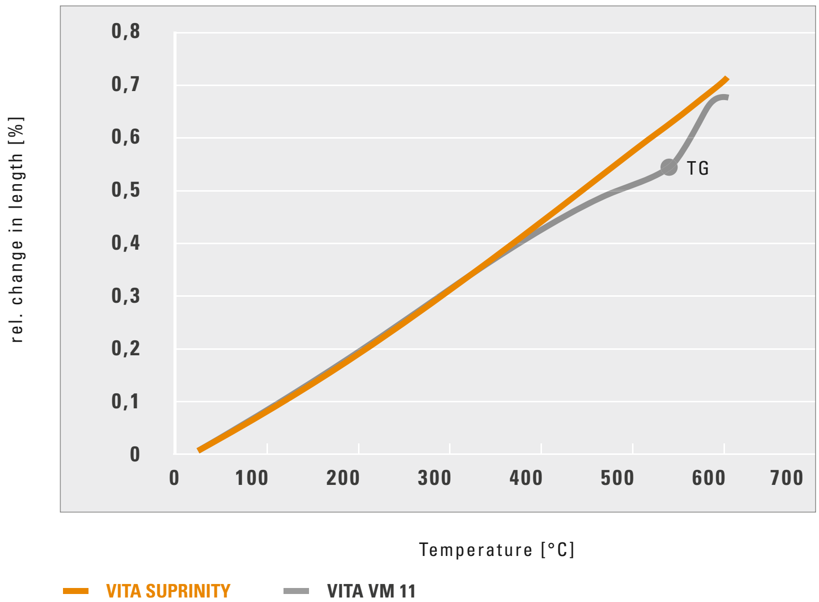
In a direct comparison, specimens made of VITA SUPRINITY and VITA VM 11 were measured in the dilatometer (Netzsch). The specimens were heated up to the softening temperature with a heating rate of 5 °C/min. The coefficient of thermal expansion (CTE) for the respective material is obtained from the measured, relative change in length up to a defined temperature (500 °C).

b) Source

Internal study, VITA R&D, ([1], cf. p. 23)

c) Result

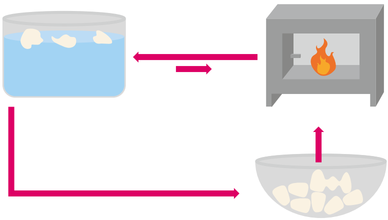
Dilatometer measurement of VITA SUPRINITY and VITA VM 11



d) Conclusion

VITA SUPRINITY has a CTE of approx. 12.3 10^{-6}/K. To ensure optimal stress ratios, the CTE of VITA VM 11 veneering material is slightly lower at approx. 11.2 10^{-6}/K*. The softening temperature of the veneering material determined in this method of measurement is approx. 600 °C and hence almost 200 °C below the one of VITA SUPRINITY substructure material.

*) Detailed information on the subject of "stress ratios" can be found in the working instructions of the VITA veneering materials.



3.4 Thermal shock resistance

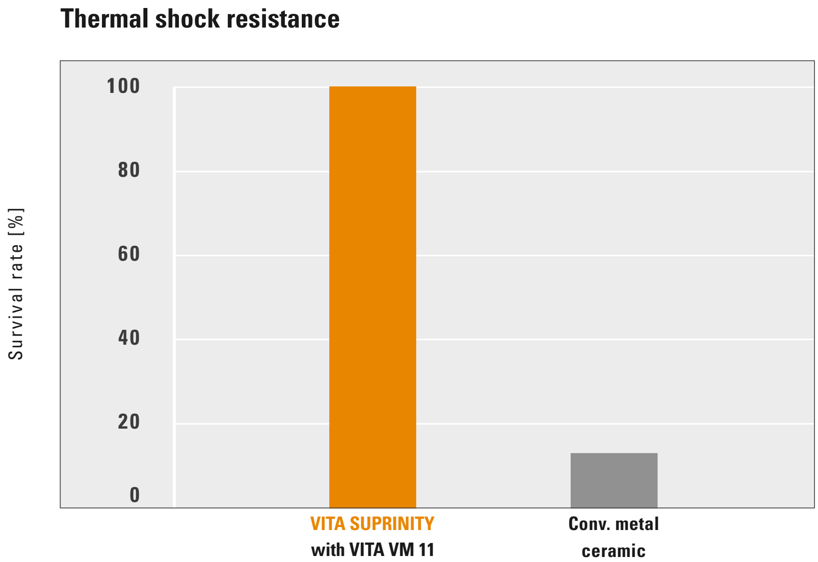
a) Materials and method

The thermal shock resistance (TSR) test is an internal test procedure used to evaluate the interaction of substructure material and veneering material, or of the residual stress in the overall system.
For this internal test procedure, six crowns were fabricated using VITA SUPRINITY in accordance with the working instructions; then they were veneered with VITA VM 11. Afterwards, the crowns were heated to 105 °C in a furnace, left in the furnace for 30 minutes and subsequently quenched in ice water. After the crowns had been checked for cracks and flaking, the undamaged specimens are heated up to 120 °C and steps of 15 °C are used until a temperature of 165 °C is reached. The average values of a series of tests over numerous years of VMK generations in combination with non-precious metal alloys were used for the comparison.

b) Source

Internal study, VITA R&D, ([1], cf. page 23)

c) Result



d) Conclusion

The higher the survival rate, the lower the risk of cracks or flaking of the veneering material based on long-term experience in daily use. The values determined were compared with the average results of non-precious metal studies of the past years. In combination with VITA VM 11, VITA SUPRINITY reveals perfect thermal shock resistance. When using conventional metal ceramics, in most cases the first cracks are formed at temperatures starting at 135 °C.

4. Bibliography

1. Internal studies, VITA R&D:

   VITA Zahnfabrik H. Rauter GmbH & Co. KG
   Research and Development
   Inorganic Chemistry
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   79713 Bad Säckingen

   Dipl.-Ing. Michael Gödiker, Research Unit Manager, R&D Inorganic Chemistry, Bad Säckingen

   Prof. Dr. Dr. Jens Fischer, Head of department, R&D Inorganic Chemistry, Bad Säckingen
   Date of issue: 07.13

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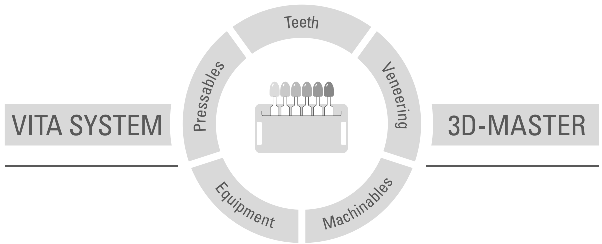
   Author: Priv.-Doz. Dr.-Ing. Martin Rosentritt, Research Unit Manager, Universitätsklinikum Regensburg, Poliklinik für Zahnärztliche Prothetik, Regensburg

More information about VITA SUPRINITY is available at:
www.vita-suprinity.de / www.vita-suprinity.com



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 application. 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. Furthermore, our liability for the accuracy of this information is independent of the legal basis and, in as far as legally permissible, shall always be limited to the value as invoiced of the goods supplied, excluding value-added tax. In particular, as far as legally permissible, we do not assume any liability for loss of earnings, indirect damages, ensuing damages or for third-party claims against the purchaser. Claims for damages based on fault liability (culpa in contrahendo, breach of contract, unlawful acts, etc.) can only be made in the case of intent or gross negligence. The VITA Modulbox is not necessarily a component of the product. Date of issue of this information: 04.14

After the publication of these working instructions any previous versions become obsolete. The current version can be found at www.vita-zahnfabrik.com

VITA Zahnfabrik has been certified in accordance with the Medical Device Directive and the following product bears the CE mark CE 0124:

VITA SUPRINITY® · VITA**VM®11**

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VITA

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