

# IPS e.max<sup>®</sup> Ceram



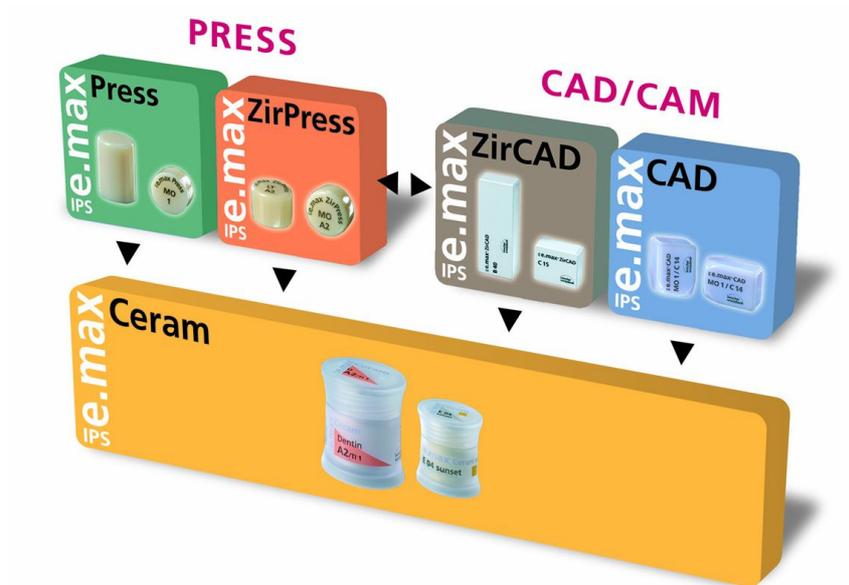
## Scientific Documentation

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# 1. Introduction

## 1.1 Overview of IPS e.max range of products



IPS e.max is an all-ceramic system that consists of the following five components:

- IPS e.max Press (lithium disilicate glass-ceramic ingot for the press technique)
- IPS e.max ZirPress (fluorapatite glass-ceramic ingot for the press-on technique)
- IPS e.max CAD (lithium disilicate glass-ceramic block for the CAD/CAM technique)
- IPS e.max ZirCAD (zirconium oxide block for the CAD/CAM technique)
- IPS e.max Ceram (fluorapatite veneering ceramic)

## 1.2 IPS e.max Ceram

IPS e.max Ceram is a veneering ceramic designed for use in conjunction with all-ceramic systems, consisting of  $\text{SiO}_2\text{-LiO}_2\text{-Na}_2\text{O-K}_2\text{O-Al}_2\text{O}_3\text{-CaO-P}_2\text{O}_5\text{-F}$ . As IPS e.max Ceram uses an optimized combination of low firing temperature and CTE, it can be applied to all IPS e.max framework materials: IPS e.max Press, IPS e.max ZirPress, IPS e.max CAD and IPS e.max ZirCAD.

The composition, physical properties and firing temperature of IPS e.max Ceram are similar to those of IPS Eris for E2. Therefore, the results gained in studies on IPS Eris for E2 also apply to IPS e.max Ceram.

### 1.2.1 Microstructure and aesthetic properties

IPS e.max Ceram contains glass ceramic and fluorapatite crystals, i.e.  $\text{Ca}_5(\text{PO}_4)_3\text{F}$ . The material does not contain feldspar or leucite. The fluorapatite crystals incorporated into the ceramic vary in size (Fig. 1). The crystals can be grown to the desired dimension by means of controlled nucleation and crystallization. The nanoscale fluorapatite crystals are less than 300 nm in length and approx. 100 nm in diameter (Fig. 2). Additionally, fluorapatite crystals that have been grown along the longitudinal axis are also present; they measure 2-5  $\mu\text{m}$  in length and less than 300 nm in diameter (Fig. 1). The surfaces of the cross-sections appear either square or circular, depending on the orientation of the crystals in the ground section of the specimen.

The nanoscale fluorapatite crystals are responsible for the material's *opalescence* (see Fig. 3 -Fig. 5) and thereby decisively contribute to its aesthetic properties. The material's *opacity* (level of transparency) is mainly determined by the larger fluorapatite crystals.

Optical effects, such as opalescence, brightness, opacity and translucency, can be adjusted in a targeted fashion with IPS e.max Ceram due to the light scattering effect produced by the differently sized fluorapatite crystals.



Fig. 1: Microstructure of IPS e.max Ceram (SEM image): fluorapatite crystals in different sizes

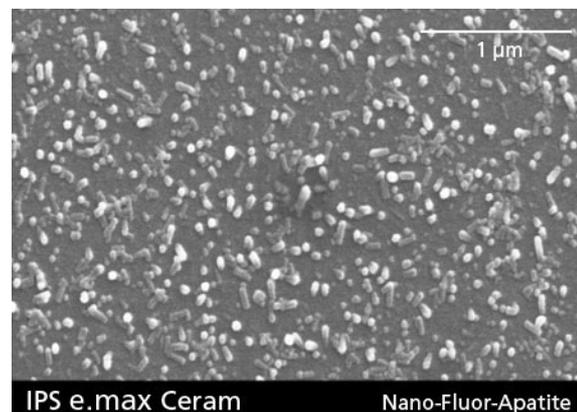


Fig. 2: Microstructure of IPS e.max Ceram (SEM image): fluorapatite crystals in the nanometer range

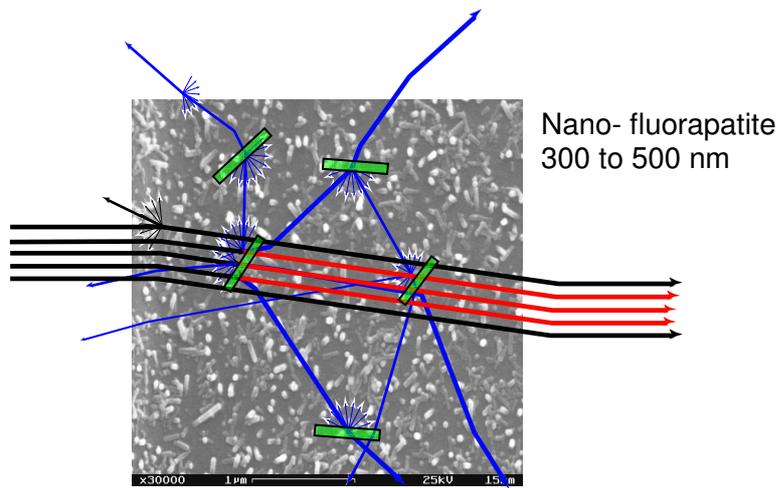


Fig. 3: Opalescence: longwave (red) and shortwave (blue) light is scattered differently by the nano-fluorapatite crystals

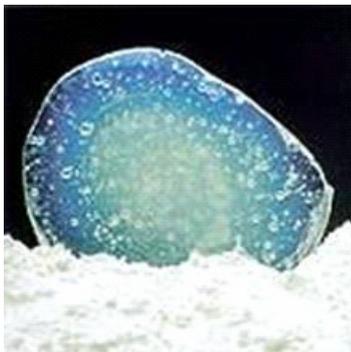


Fig. 4: Opalescence: the material assumes a bluish tinge against incident light



Fig. 5: Opalescence: The material appears reddish/orange against transmitted light

## 2. Technical data

### IPS e.max Ceram

Veneering materials: Dentin, Deep Dentin, Occlusal Dentin, Margin, Incisal Edge, Transpa Incisal, Special, Transpa, Cervical Transpa, Opal Effect, Mamelon

Add-on materials: Dentin, Incisal, Margin

ZirLiner

<b><u>Standard composition:</u></b>	<b>(in wt %)</b>		
	<b>Veneering materials</b>	<b>Add-on materials</b>	<b>ZirLiner</b>
SiO <sub>2</sub>	60.0 - 65.0	61.0 – 68.0	50.0 – 60.0
Al <sub>2</sub> O <sub>3</sub>	8.0 - 12.0	5.0 – 8.0	16.0 - 22.0
Na <sub>2</sub> O	6.0 – 9.0	5.0 – 8.0	6.0 – 11.0
K <sub>2</sub> O	6.0 – 8.0	5.0 – 8.0	4.0 – 8.0
ZnO	2.0 – 3.0	2.0 – 4.0	---
+ CaO, P <sub>2</sub> O <sub>5</sub> , F	2.0 – 6.0	2.0 – 5.0	2.5 – 7.5
+ other oxides	2.0 – 8.5	1.5 – 9.0	1.5 – 8.0
+ Pigments	0.1 – 1.5	0.1 - 0.7	0.1 – 3.0

#### **Physical properties:**

##### ***In compliance with:***

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

		<b>Veneering materials</b>	<b>Add-on materials</b>	<b>ZirLiner</b>
Biaxial flexural strength	MPa	90 ± 10	90 ± 10	90 ± 10
Chemical solubility	µg/cm <sup>2</sup>	15 ± 5	15 ± 5	15 ± 5
Coefficient of thermal expansion (100 - 400 °C)	10 <sup>-6</sup> K <sup>-1</sup>	9.5 ± 0.25	9.5 ± 0.25	9.8 ± 0.25
Glass transition temperature (Tg)	°C	490 ± 10	470 ± 10	645 ± 10

# IPS e.max Ceram

## Shade, Essence, Glaze

### Standard composition:

	(in wt %)			
	Shade	Essence	Glaze powder	Glaze pastes
SiO <sub>2</sub>	61.0 - 68.0	61.0 - 68.0	61.0 - 68.0	61.0 - 68.0
Al <sub>2</sub> O <sub>3</sub>	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0
Na <sub>2</sub> O	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0
K <sub>2</sub> O	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0	5.0 - 8.0
ZnO	2.0 - 4.0	2.0 - 4.0	2.0 - 4.0	2.0 - 4.0
+ other oxides	3.5 – 17.0	3.5 – 17.0	3.5 – 17.0	3.5 – 17.0
+ Pigments	10.0 - 20.0	0.4 - 25.0	0.0 - 1.0	0.0 - 1.0
+ Glycerine	20.0 - 25.0	---	---	20.0 - 25.0
+ 1,3 - Butandiol	15.0 - 20.0	---	---	15.0 - 20.0

### Physical properties:

#### *In compliance with:*

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

		Shade	Essence	Glaze	Glaze pastes
Chemical solubility	μg/cm <sup>2</sup>	30 ± 10	30 ± 10	10 ± 5	10 ± 5
Coefficient of thermal expansion (100 - 400 °C)	10 <sup>-6</sup> K <sup>-1</sup>	9.3 ± 0.5	9.3 ± 2.5	9.5 ± 0.25	9.5 ± 0.25
Glass transition temperature (Tg)	°C	475 ± 10	475 ± 10	470 ± 10	470 ± 10

### 3. Material science investigations

#### 3.1 Comparative data with other veneering ceramics of Ivoclar Vivadent AG

	IPS e.max Ceram	IPS Eris for E2	IPS Empress2 (layering ceramic)
CTE [10 <sup>-6</sup> K <sup>-1</sup> ] 100-400 °C	9.50 ± 0.25	9.75 ± 0.25	9.70 ± 0.50
Glass transition point Tg [°C]	490 ± 10	485 ± 10	525 ± 10
Biaxial strength [MPa]	90 ± 10	85±25	100±25
Vickers hardness [MPa]	5400 ± 200	5600 ± 200	5500 ± 200
Chemical solubility [µg/cm <sup>2</sup> ]	15 ± 5	20 ± 10	20 ± 5
Firing temperature[°C]	750 / 760	755	800
Type of material	fluorapatite glass ceramic		
Amount of fluorapatite in the glass ceramic [% by wt]	19 – 23	28 - 48	42 - 56

Table 1: Comparative data with other veneering ceramics

#### 3.2 Compatibility with IPS e.max materials

##### 3.2.1 Coefficient of thermal expansion

The linear thermal expansion of materials is measured with a dilatometer. A common way of measuring thermal expansion is by taking a length of material, heating/cooling it continuously and recording the resultant changes in length. This change in length may occur in a steady or discontinuous curve. A jump in the curve can be seen if a phase transition occurs in the material. The linear coefficient of thermal expansion (CTE) is determined per unit length for 1 degree change in temperature (1 Kelvin). The CTE largely depends on the temperature range within which it is measured. Hence, it is important to indicate the temperature range over which the CTE is determined, as the CTE alone does not have much informative value. The CTE of dental ceramics is determined within a temperature range that includes temperatures below the glass transition point (Tg). The CTE is utilized to identify potential stress levels that the ceramic may have to endure in conjunction with the framework and/or layering material. Glass ceramics at temperatures above the Tg value are soft and the stress is dissipated by the flow of the material.

According to ISO 9693, the CTE is expressed in [10<sup>-6</sup> K<sup>-1</sup>]; the CTE is often also indicated as [1µm/m·K].

The coefficient of thermal expansion provides a clue as to whether the layering material is compatible with the framework material.

Ceramic materials are very susceptible to tensile stress. As a consequence, the coefficient of thermal expansion (CTE) of the layering material should be lower than that of the more rigid framework material (Fig. 6).

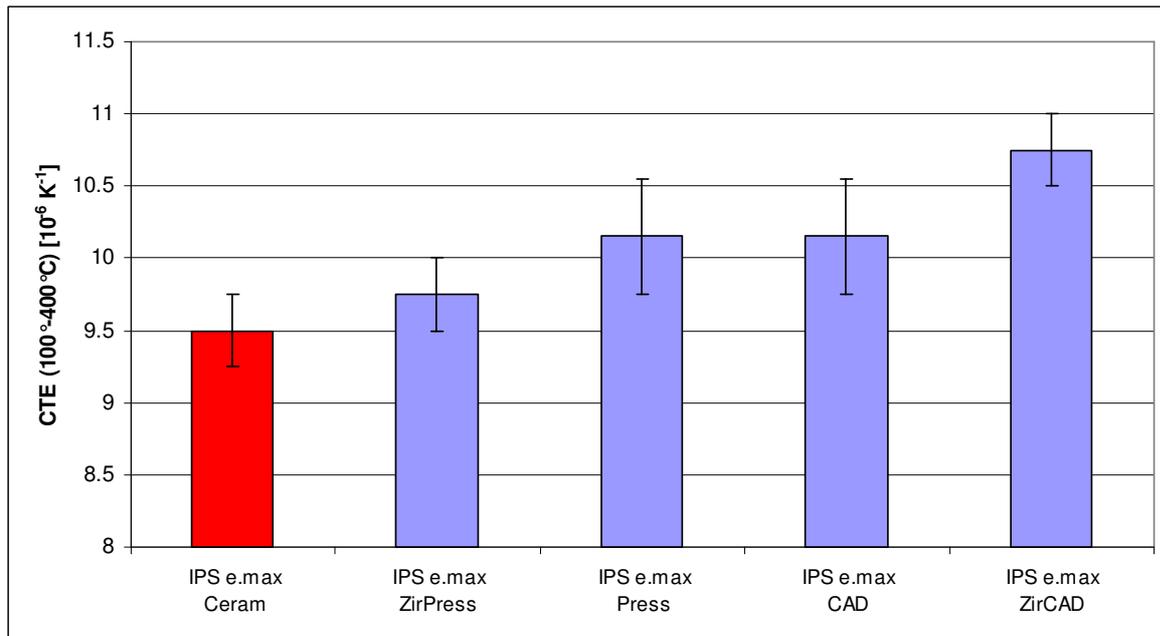


Fig. 6: CTE of IPS e.max materials (Ivoclar Vivadent Schaan, 2005)

- The CTE of the IPS e.max Ceram layering material is lower than that of the framework materials of the IPS e.max range.

### 3.2.2 Bond

The bond between IPS e.max Ceram and the other IPS e.max materials can be clearly seen in the SEM images below. The “compo contrast” image has been produced with a special imaging technique: The different materials of the samples are depicted in various degrees of brightness in line with signal transmitted from the backscattering electrons (BSE). The signal is affected by the composition of the individual materials.

IPS e.max Ceram forms a homogeneous, flawless bond with the materials of the IPS e.max range (Fig. 7 to Fig. 12).

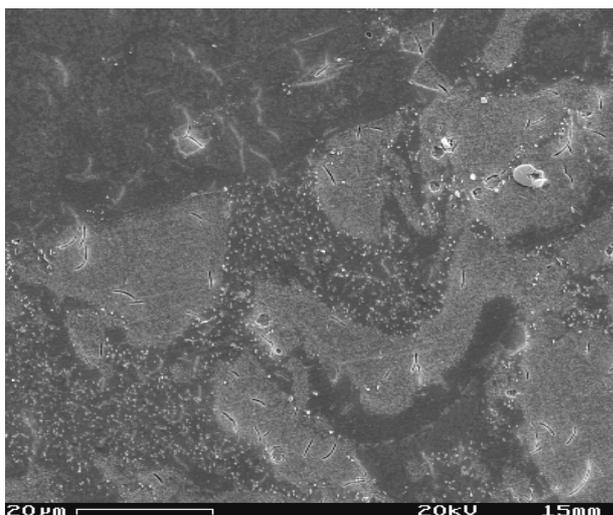


Fig. 7: Transition between IPS e.max Ceram (above) and IPS e.max ZirPress (below); (ground surface, etched)

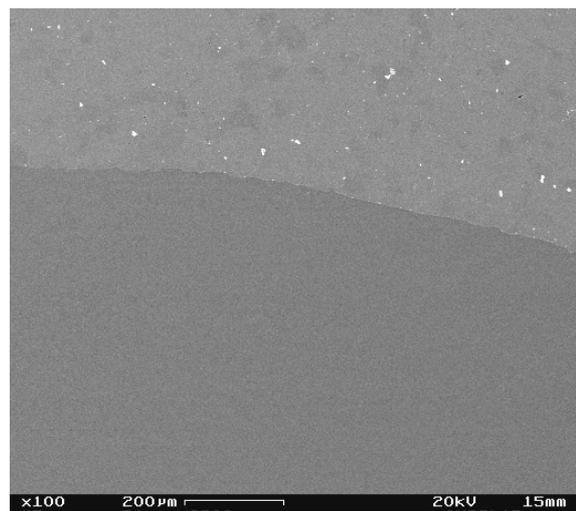


Fig. 8: Homogeneous, flawless bond between IPS e.max Ceram (above) and IPS e.max CAD; (“compo contrast”; polished surface)

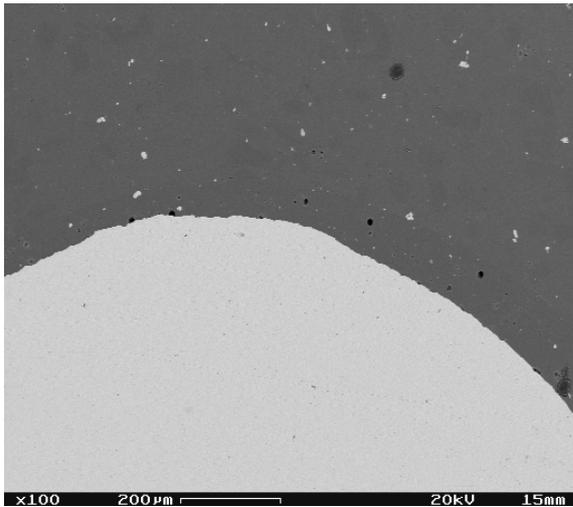


Fig. 9: Homogeneous bond between IPS e.max Ceram (above), IPS ZirLiner and IPS e.max ZirCAD; (“compo contrast”; polished surface)

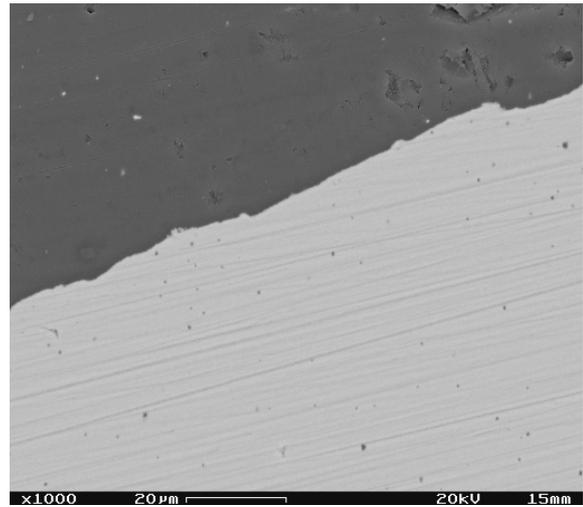


Fig. 10: Homogeneous bond between IPS e.max ZirLiner and IPS e.max ZirCAD; (“compo contrast”; polished surface)

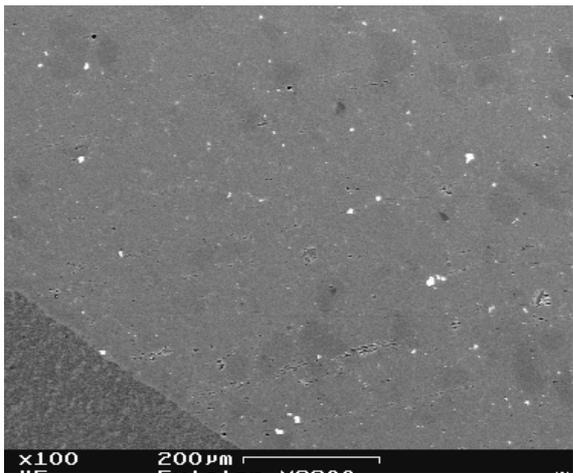


Fig. 11: Homogeneous sintered structure and compact bond between IPS e.max Press (below) and IPS e.max Ceram; (“compo contrast”; polished surface)

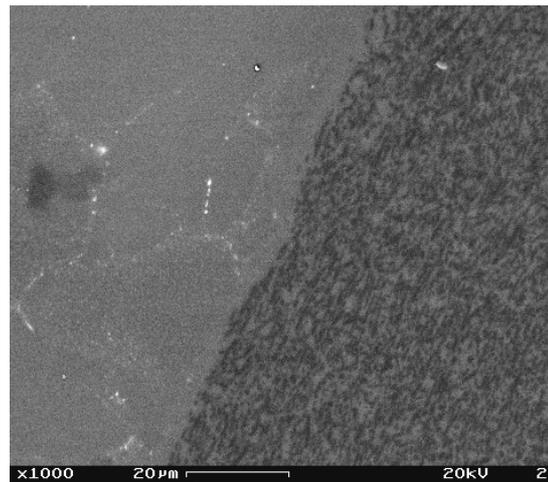


Fig. 12: Compact bond between IPS e.max Press and IPS e.max Ceram; (“compo contrast”; polished surface)

### 3.3 Comparative data of veneering ceramics for zirconium oxide

#### 3.3.1 Coefficient of thermal expansion

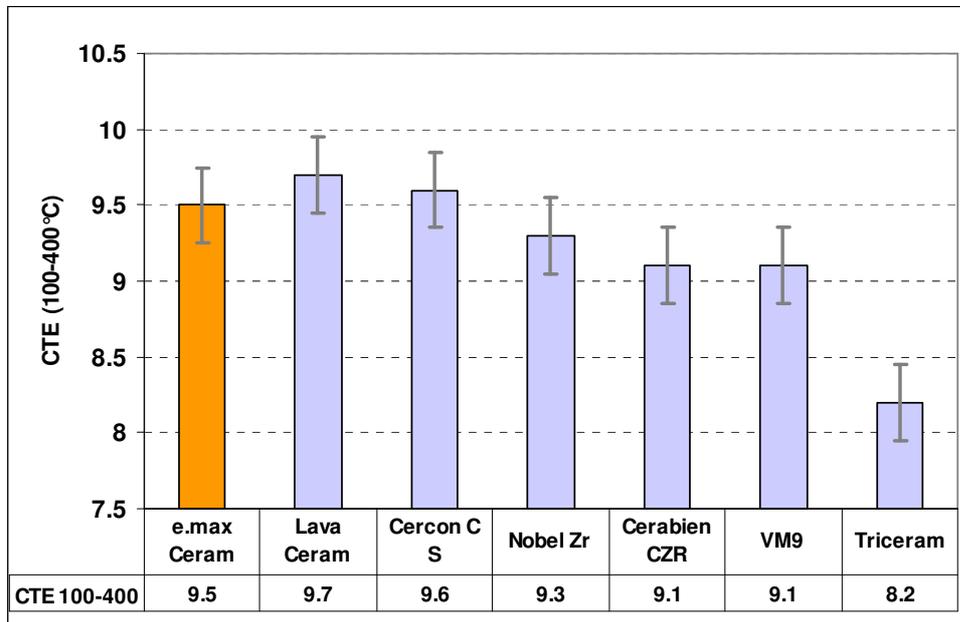


Fig. 13: CTE (100-400°C) of veneering ceramics for use in conjunction with zirconium oxide (Ivoclar Vivadent AG Schaan, 2004/05)

- Most veneering ceramics designed for use in conjunction with zirconium oxide feature a similar coefficient of thermal expansion.

#### 3.3.2 Flexural strength (ISO 6872)

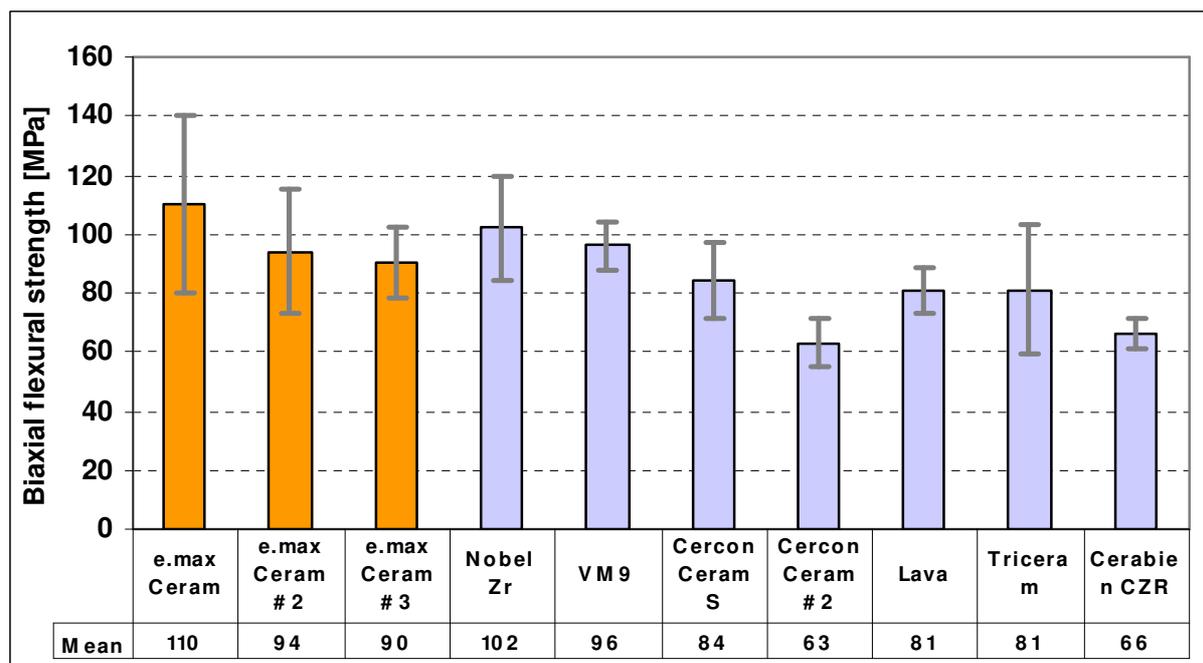


Fig. 14: Flexural strength values of various veneering ceramics (#2, #3: different batches) designed for use in conjunction with zirconium oxide (Ivoclar Vivadent AG Schaan, 2004/05)

- The biaxial flexural strength values are batch-dependent.
- IPS e.max Ceram is among the strongest veneering materials that can be used in combination with zirconium oxide. The biaxial flexural strength of this material by far surpasses the minimum value required by the relevant ISO standard.

### 3.3.3 Firing temperature

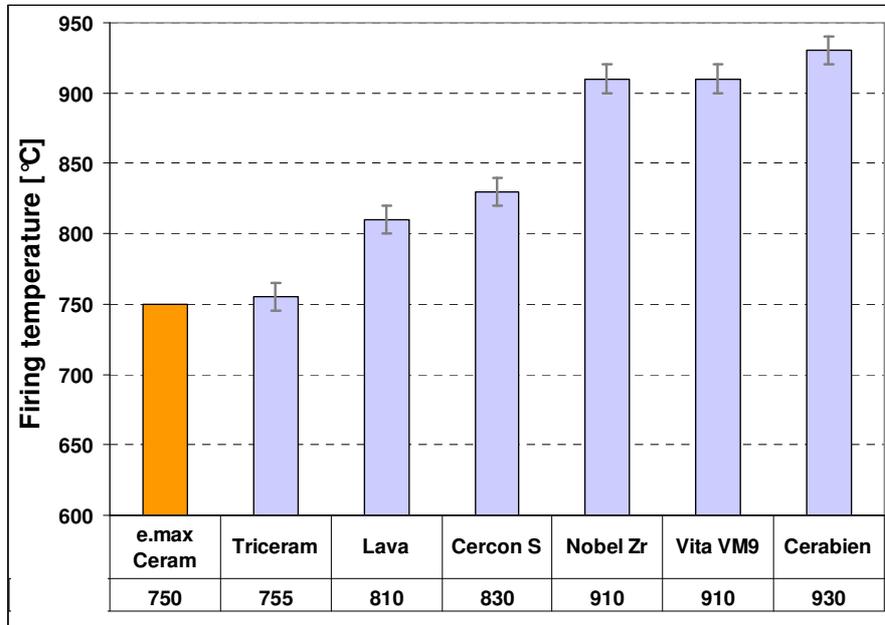


Fig. 15: Firing temperatures of various veneering ceramics for use in conjunction with zirconium oxide (Ivoclar Vivadent AG Schaan, 2004/05)

- IPS e.max Ceram demonstrates the lowest firing temperature of all the ceramic materials examined. Low firing temperatures reduce the processing times required for the fabrication of restorations.

## 4. In vitro investigations

### 4.1 Fracture toughness of veneered bridges

The fracture toughness was examined in veneered bridges without chewing simulation (after storage in water) and with chewing simulation. Eight samples were tested for each material and test method.

The static tests were carried out in a universal testing machine. The load was applied directly to the pontic area.

Those samples that included chewing simulation were placed in a chewing simulator and subjected to 1.2 million chewing cycles at a load of 50 N as well as to thermocycling at a temperature range of 5 °C/55 °C.

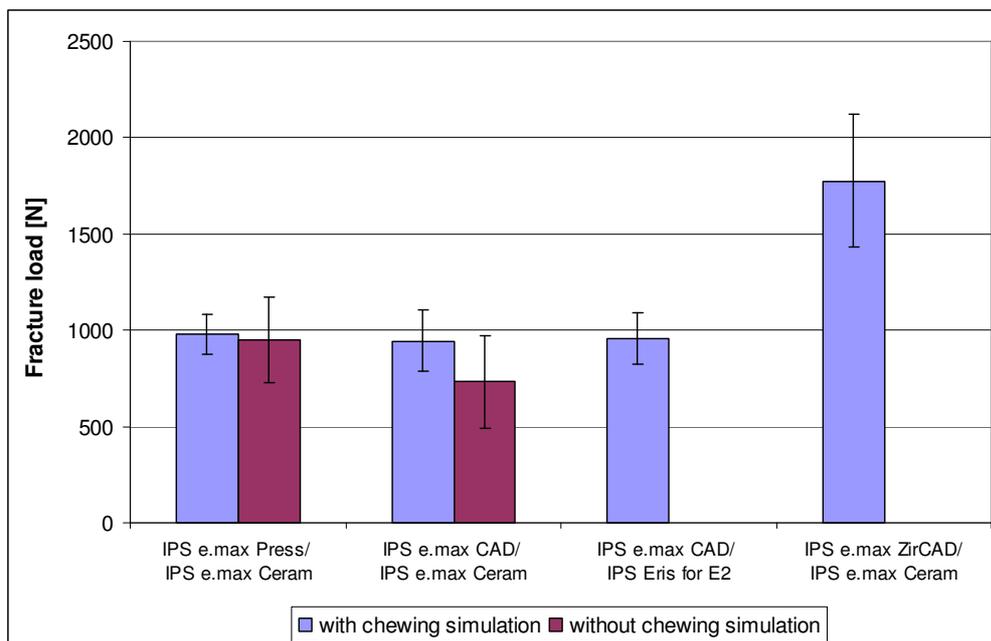


Fig. 16: Fracture toughness of veneered bridges with and without chewing simulation (Schröder/Spiegel, FH Osnabrück, 2005) <sup>1</sup>

- The statistical analysis (Tukey) did not show any significant difference in the mean fracture load between the groups with and without chewing simulation.
- The fracture load of bridges that consisted of IPS e.max ZirCAD (framework) and IPS e.max Ceram (veneering material) was significantly higher than that of all the other bridges examined.
- The veneered bridges made of IPS e.max Press and IPS e.max CAD did not show any statistically relevant difference in terms of fracture load.

### 4.2 Veneering of zirconium oxide frameworks

#### 4.2.1 Studies on the veneering of zirconium oxide frameworks

The two veneering materials IPS e.max Ceram and IPS Eris for E2 are very similar to each other (see Section 3.1). Consequently, the studies carried out in conjunction with IPS Eris for E2 also apply to IPS e.max Ceram.

Sundh et al.<sup>2,3</sup> examined the fracture toughness of zirconium oxide based (Y-TZP) bridges, which were veneered with various layering materials, including IPS Eris for E2. Excellent results were achieved in this study. A detailed description of the test methods and results can be looked up in the corresponding publications<sup>2,3</sup>.

#### 4.2.2 Compatibility of IPS e.max Ceram with zirconium oxide frameworks

The incidence of chipping is an important clinical benchmark to estimate the survival rate, or the potential need for repair, of a dental reconstruction.

This *in vitro* test was carried out to assess the risk of chipping in veneered crowns. For this purpose, veneered crowns are placed on standardized dies and subjected to eccentric loading with a steel antagonist. The eccentric loading cycles were carried out in a Willytec chewing simulator. The antagonist performed a translational motion (depth of stroke = 2.0 mm, length of stroke = 5 mm, travel speed = 40 mm/sec) from the fossa up to 1 mm below the tip of the distobuccal cusp at loads from 3 and 5 to 9 kg. Each loading phase consisted of 100'000 loading cycles and 300 cycles of thermocycling (5 °C/55 °C).

A variety of zirconium oxide materials were veneered with IPS e.max Ceram and tested in the in-house laboratory.

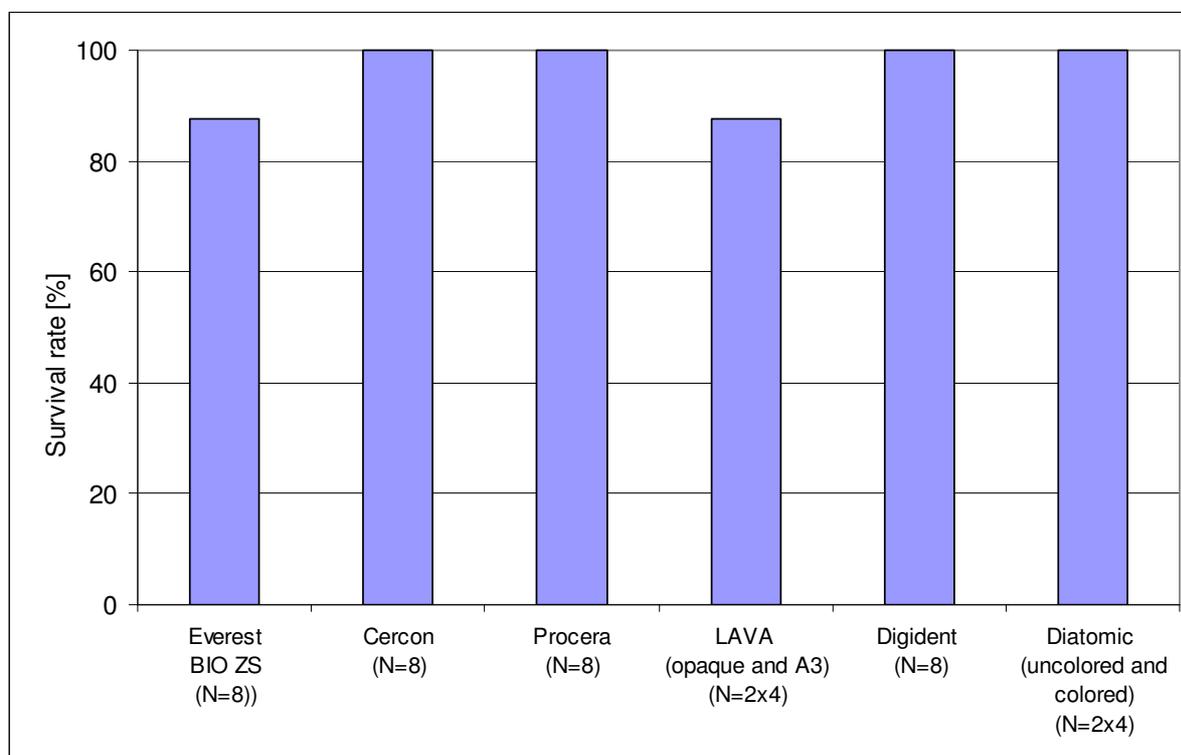


Fig. 17: Proportion of crowns (IPS e.max Ceram/ zirconium oxide) which survived artificial chewing in the chewing simulator without chipping (Ivoclar Vivadent AG Schaan, 2005)

- IPS e.max Ceram produced hardly any chipping (if any at all) in conjunction with various zirconium oxide frameworks.

## 5. External clinical studies

### 5.1 *University of Frankfurt a.M., Germany*

- Head of study: Dr. Weigl, J.W.Goethe-Universität, Frankfurt a.M., Germany
- Title: Clinical performance of a new veneering ceramic in conjunction with zirconium oxide frameworks
- Objective: To test and examine the clinical performance of IPS e.max Ceram in conjunction with different zirconium oxide based restorations
- Experimental: A total of 109 restorations were incorporated in 59 patients:  
- 53 restorations in the anterior region, 56 in the posterior region  
- 71 crowns, 38 bridges (3-, 4- and 5-unit bridges)  
- abutments: 136 abutment teeth and 17 implants
- Results<sup>4</sup>: The following survival rates were reported after a mean period of service of 34 months (according to the Kaplan-Meier method):  
- layering material: 97.1%  
- framework material: 99.1%

### 5.2 *Boston University, U.S.A.*

- Head of study: Prof. Nathanson, Boston University, Massachusetts
- Title: Clinical performance of IPS e.max Ceram in conjunction with IPS e.max CAD crowns
- Objective: To examine the clinical performance of IPS e.max Ceram on crowns made of IPS e.max CAD
- Experimental: Forty crowns made of IPS e.max CAD and veneered with IPS e.max were placed.
- Results: The clinical experience of up to twelve months have not shown a single incidence of failure, such as fracture or chipping of the veneering ceramic.

### 5.3 *University of Connecticut Health Center, U.S.A.*

- Head of study: Prof. Kelly, University of Connecticut Health Center, Farmington
- Title: Clinical performance of IPS e.max Ceram in conjunction with crowns made of IPS e.max CAD
- Objective: To examine the clinical performance of IPS e.max Ceram on crowns made of IPS e.max CAD
- Experimental: Forty crowns made of IPS e.max CAD and veneered with IPS e.max Ceram were placed.

Results: A single case of fracture was reported. This fracture occurred before the final placement of the restoration. Chipping of veneering ceramic was not observed.

#### **5.4 University of Iowa, U.S.A.**

Head of study: Prof. Stanford, Dental Clinical Research Center, University of Iowa, Iowa City

Title: Clinical performance of IPS e.max Ceram on IPS e.max ZirCAD

Objective: To examine the clinical performance of IPS e.max Ceram in conjunction with IPS e.max ZirCAD

Experimental: Forty crowns and 10 bridges made of IPS e.max ZirCAD and veneered with IPS e.max Ceram were placed.

Results: After all the restorations had been incorporated, neither framework fractures nor chipping of veneering material was observed.

#### **5.5 Pacific Dental Institute, U.S.A.**

Head of study: Prof. Sorensen, Pacific Dental Institute, Portland, Oregon

Title: Clinical performance of IPS e.max Ceram in conjunction with IPS e.max ZirCAD

Objective: To examine the clinical performance of IPS e.max Ceram on bridges made of IPS e.max ZirCAD

Experimental: Twenty bridges made of IPS e.max ZirCAD and veneered with IPS e.max Ceram were placed.

Results: Neither framework fractures nor chipping was observed in the course of an observation period of 6 months.

#### **5.6 University of Michigan, U.S.A.**

Head of study: Prof. Fasbinder, University of Michigan, Ann Arbor

Title: Clinical performance of IPS e.max Ceram on IPS e.max ZirPress and IPS e.max ZirCAD

Objective: To examine the clinical performance of IPS e.max Ceram on restorations made of IPS e.max ZirCAD

Experimental: Thirty crowns and 10 bridges made of IPS e.max ZirCAD/IPS e.max ZirPress and veneered with IPS e.max Ceram were placed.

Results: Neither framework fractures nor chipping was observed after all restorations had been incorporated.

### **5.7 University of Munich, Germany**

- Head of study: Dr. Beuer (Prof. Gernet) University, Munich
- Title: Clinical study on zirconium oxide based restorations veneered with a new ceramic material
- Objective: To examine the clinical performance of IPS e.max Ceram on restorations made of IPS e.max ZirCAD
- Experimental: Twenty crowns and 20 bridges (3- to 4-units) made of zirconium oxide (Y-TZP) and veneered with IPS e.max Ceram were placed.
- Results: Chipping was observed in a single restoration in the course of an observation period of up to twelve months.

### **5.8 University of Heidelberg, Germany**

- Head of study: Prof. Rammelsberg, University, Heidelberg
- Title: Clinical study on all-ceramic, zirconium oxide based inlay-retained bridges manufactured using a CAD/CAM technique
- Objective: To examine the clinical performance of IPS e.max Ceram on restorations made of IPS e.max ZirCAD and IPS e.max ZirPress
- Experimental: Thirty inlay-retained bridges were incorporated; each bridge included at least one inlay as bridge anchor. The frameworks were made of zirconium oxide onto which IPS e.max ZirPress was pressed and the resultant restorations were veneered with IPS e.max Ceram.
- Results: Neither framework fracture nor chipping of veneering material has been reported to date.

### **5.9 University of Aachen, Germany**

- Head of study: Dr. Tinschert, University, Aachen, Germany
- Title: Prospective clinical study on the survival rate of posterior zirconium oxide reinforced crowns manufactured using the press-on technique
- Objective: To examine the clinical performance of IPS e.max Ceram on restorations made of IPS e.max ZirCAD and IPS e.max ZirPress.
- Experimental: Thirty posterior crowns comprising zirconium oxide copings made of DC Zirkon, Lava and IPS e.max ZirCAD were incorporated. IPS e.max ZirPress was pressed onto the copings. Subsequently, the copings were veneered with IPS e.max Ceram.
- Results: Neither framework fractures nor chipping of veneering material has been reported to date.

### **5.10 University of Freiburg, Germany**

Head of study:	Prof. Strub, Albert-Ludwigs-University, Freiburg
Title:	Five-year prospective clinical examination of posterior bridges made of an experimental lithium disilicate ceramic
Objective:	To examine the clinical performance of lithium disilicate based restorations veneered with IPS e.max Ceram
Experimental:	Forty three-unit posterior bridges fabricated of IPS e.max CAD and veneered with IPS e.max Ceram were incorporated.
Results:	The restorations have been commended for their accuracy of fit and aesthetic appearance. No failures have been reported in cases where the minimum dimensions stipulated for the connectors were observed. No chipping of veneering ceramic has been reported to date.

### **5.11 Conclusions**

The performance of IPS e.max Ceram was examined in conjunction with lithium disilicate (IPS e.max Press and CAD), zirconium oxide (IPS e.max ZirCAD) and IPS e.max ZirPress in both *in vitro* investigations and clinical studies. The veneering material has proved itself in clinical applications. It offers many possibilities of creating aesthetic reconstructions and this has met with the explicit approval of the examiners.

The parameters specified in the Instructions for Use have to be observed to ensure the reliability and long-term clinical success of these restorations.

## 6. Biocompatibility

### 6.1 Introduction

All-ceramic materials are known for their high levels of biocompatibility<sup>5,6</sup>.

The main ingredients of IPS e.max Ceram (SiO<sub>2</sub>, K<sub>2</sub>O, ZnO, ZrO<sub>2</sub>, Li<sub>2</sub>O, CaO, Na<sub>2</sub>O, Al<sub>2</sub>O<sub>3</sub>) are the same as those of the IPS Eris for E2 and IPS Empress 2 layering ceramic materials, which have been successfully used in clinical applications for many years. Hence, it can be assumed that IPS e.max Ceram offers the same high levels of biocompatibility as these materials.

### 6.2 Chemical durability

Dental materials are exposed to a wide spectrum of pH-values and temperatures in the oral environment. Consequently, high chemical durability is an essential requirement of any dental material.

According to Anusavice<sup>7</sup>, ceramic materials are among the most durable dental materials.

The in-house laboratory determined the chemical durability of IPS e.max Ceram according to the relevant test prescribed by ISO 6872 as well as in a test using artificial saliva:

Test	Chemical solubility [µg/cm <sup>2</sup> ]	Limit value [µg/cm <sup>2</sup> ]
According to ISO 6872	10 - 20	< 100
In artificial saliva	15 – 24	--

(Ivoclar Vivadent AG, Schaan, 2005)

- The chemical solubility of IPS e.max Ceram is far lower than the maximum level permitted by the relevant standard.

### 6.3 In vitro cytotoxicity

IPS e.max Ceram comprises the same ingredients as the IPS Empress 2 and IPS Eris for E2 veneering materials. Hence, it can be concluded that IPS e.max Ceram does not have any toxic potential.

The *in vitro* toxicity of IPS Empress 2 and IPS Eris for E2 was determined in previous investigations:

The *in vitro* toxicity was tested by NIOM, the Scandinavian Institute of Dental Materials, Haslum, Norway by means of a direct cell contact test. The test was conducted according to ISO 10993-5: *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*.

**No cytotoxic potential has been observed under the given test conditions<sup>8</sup>.**

### 6.4 Sensitization, irritation

Cavazos<sup>9</sup>, Henry et al.<sup>10</sup> and Allison et al.<sup>11</sup> demonstrated that dental ceramics – unlike other dental materials – do not induce a negative response when they come into contact with the oral mucous membrane. Mitchell<sup>12</sup> as well as Podshadley and Harrison<sup>13</sup> showed that glazed ceramics, which were used in implant-based trials, caused only very mild inflammatory

reactions and had a far less irritating effect than other accepted dental materials, such as gold and composite resin.

As it can virtually be ruled out that ceramic materials cause direct irritation in the cells of the mucous membrane, possible irritations may generally be attributed to mechanical irritation. Such reactions can normally be prevented by following the Instructions for Use of IPS e.max Ceram.

**Ceramic has no – or, compared to other dental materials – very little potential to cause irritation or sensitizing reactions.**

### **6.5 Radioactivity**

The radioactivity of IPS Eris for E2 and IPS Empress 2 was determined at the Research Centre Jülich. The values measured for IPS Eris for E2 and IPS Empress 2 were <0.03 Bq/g<sup>14</sup> and 0.006 Bq/g<sup>15</sup> respectively and are therefore clearly below the maximum level of 1.0 Bq/g permitted by ISO 6872.

### **6.6 Conclusions**

On the basis of the current data and present level of knowledge, it can be stated that IPS e.max Ceram does not exhibit any toxic potential. If the material is applied in accordance with the manufacturer's directions, it does not pose any risk to the health of patients, dental technicians or dentists.

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