

# IPS e.max<sup>®</sup> ZirPress



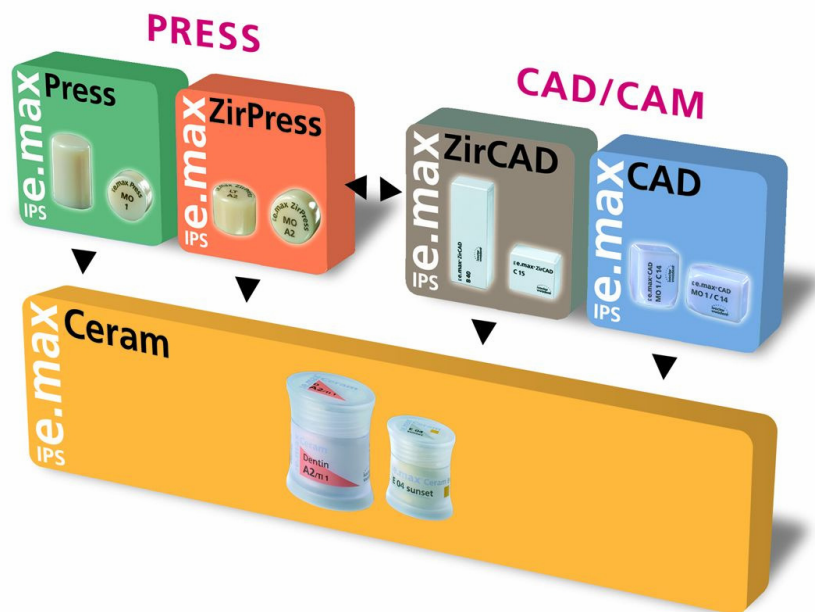
## Scientific Documentation

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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 ZirPress



**Fig. 1: IPS e.max ZirPress**

IPS e.max ZirPress (Fig. 1) assumes the function and properties of the currently conventionally layered and sintered Margin and Dentin materials. IPS e.max ZirPress is used to press the dentin layer onto the zirconium oxide frameworks. The stable pressable ceramic enables cusp-supporting frameworks, so that the layering ceramic can be applied in an even thickness. Due to the ingot delivery form, an improved homogeneity (porosity and bond) of the marginal and dentin areas is achieved. IPS e.max ZirPress can be veneered using IPS e.max Ceram or fully anatomically pressed, stained and glazed.

### 1.2.1 Material

IPS e.max ZirPress contains glass-ceramic and fluorapatite crystals  $\text{Ca}_5(\text{PO}_4)_3\text{F}$ . It does not contain any feldspar or leucite. The fluorapatite crystals incorporated into the ceramic vary in size (Fig. 2). The crystals can be grown to the desired dimension by means of controlled nucleation and crystallization. The nano-scale fluorapatite crystals are less than 300 nm in length and approx. 100 nm in diameter (Fig. 3). In addition, 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. Depending on the orientation of the crystals in the ground section of the specimen, the cross-sections appear either square or circular.

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

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

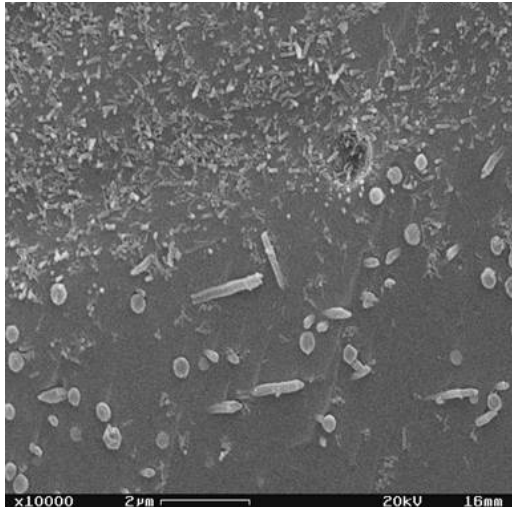


Fig. 2: IPS e.max ZirPress: fluorapatite crystals in different sizes (fracture surface; etched with 3% HF for 10 s)

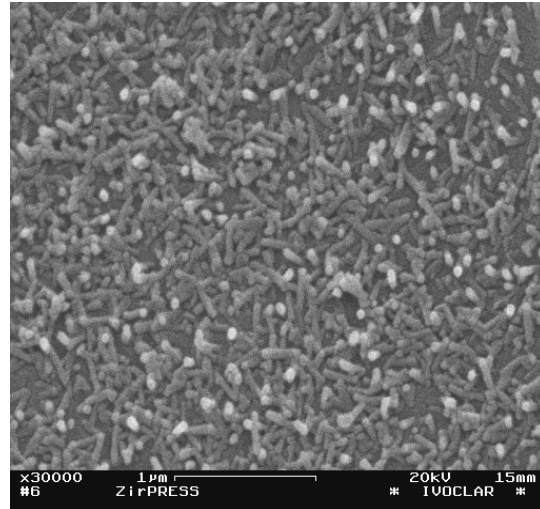


Fig. 3: IPS e.max ZirPress with fluorapatite crystals in the nanometer range (etched with 3% HF for 10 s)

## 2. Technical data

### IPS e.max ZirPress

Pressed ceramic ingot

**Standard composition:**

**(in wt %)**

SiO <sub>2</sub>	57.0 – 62.0
Al <sub>2</sub> O <sub>3</sub>	12.0 – 16.0
Na <sub>2</sub> O	7.0 – 10.0
K <sub>2</sub> O	6.0 – 8.0
CaO	2.0 – 4.0
ZrO <sub>2</sub>	1.5 – 2.5
P <sub>2</sub> O <sub>5</sub>	1.0 – 2.0
F	0.5 – 1.0
+ other oxides	0.0 – 6.0
+ Pigments	0.2 – 0.9

**Physical properties:**

***In accordance with:***

ISO 6872 Dental ceramic

ISO 9693 Metal-ceramic dental restorative systems

**Type II ceramic**

Flexural strength (biaxial)	110 ± 10 MPa
Chemical solubility	30 ± 10 µg/cm <sup>2</sup>
Coefficient of thermal expansion (100 – 400 °C)	9.75 ± 0.25 10 <sup>-6</sup> /K
Coefficient of thermal expansion (100 – 500 °C)	9.85 ± 0.25 10 <sup>-6</sup> /K
Glass transition temperature (T <sub>g</sub> )	530 ± 10 °C

### 3. Materials science investigations

#### 3.1 Physical properties

Tab 1: Physical properties

Feature	Value / Note
Vickers hardness	5400 ± 200 MPa
Biaxial strength (ISO 6872)	see Technical data (Chapter 2)
Glass transition temperature (T <sub>g</sub> )	see Technical data (Chapter 2)
CTE (100 – 400 °C)	see Technical data (Chapter 2)

#### 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. The specimen is continuously heated/cooled and the linear dimensional change recorded. The resulting 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. Therefore, the temperature range has to be stated at all times, 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 (T<sub>g</sub>). The CTE is used 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 T<sub>g</sub> value are soft and the stress is dissipated by the flow of the material.

The CTE is expressed in [ $10^{-6} \cdot K^{-1}$ ] according to ISO 9693. However, [ $1 \mu m/m \cdot K$ ] is also commonly used.

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.

In addition, the coefficients of thermal expansion (CTE) of the materials in use have to be coordinated (Fig. 4).

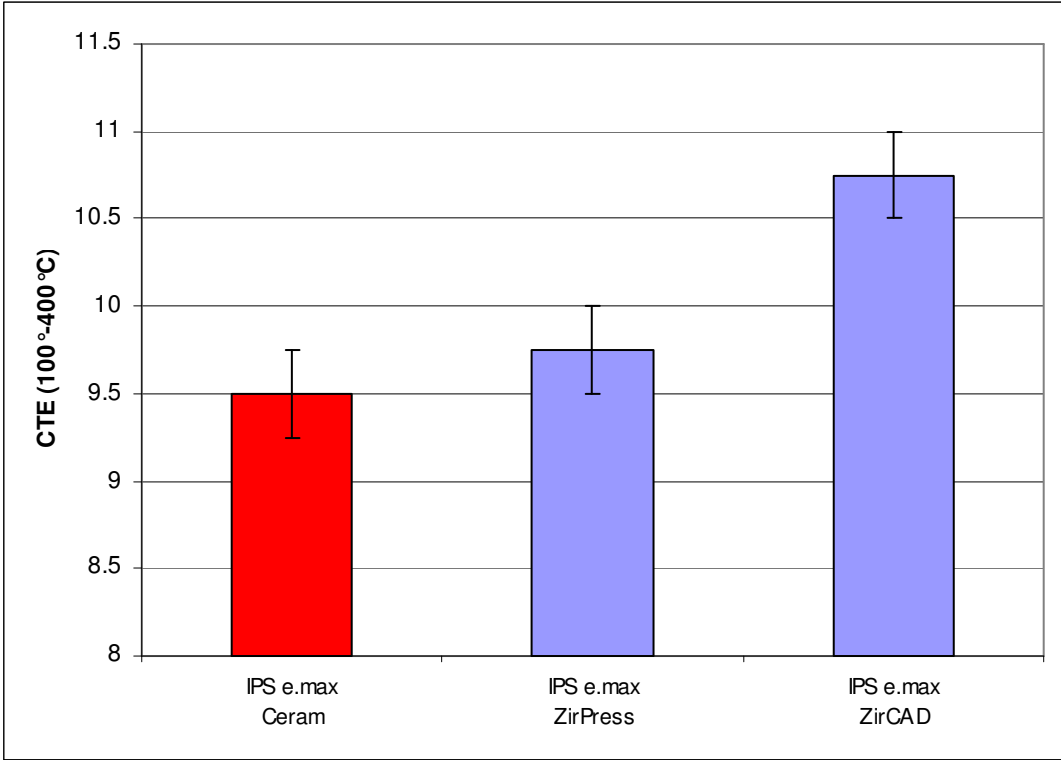


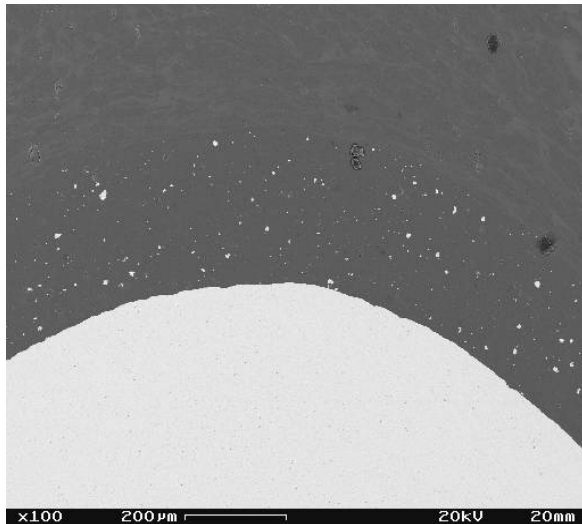
Fig. 4: CTE of the individual material layers in the IPS e.max system

- The CTE of IPS e.max ZirPress is one unit lower than that of the IPS e.max ZirCAD framework material placed underneath.



### 3.2.2 Bond

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



The bond of IPS e.max ZirPress to the IPS e.max ZirCAD (Liner) framework and the IPS e.max Ceram layering material is homogeneous, non-porous and crack-free (Figs. 5 to 7).

Fig. 5: Bond of IPS e.max ZirCAD – ZirLiner – IPS e.max ZirPress (compo contrast)

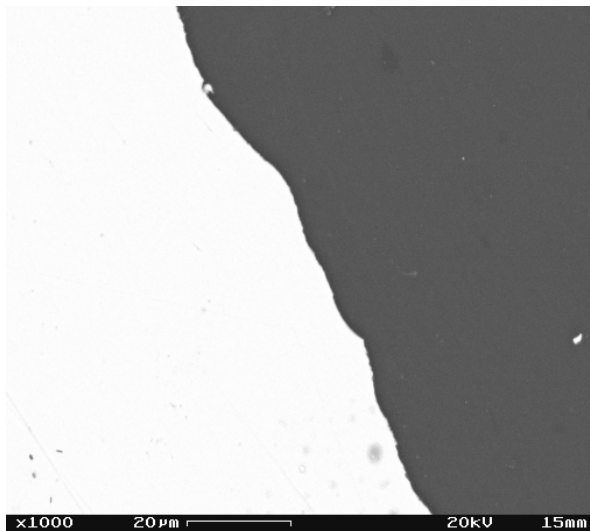


Fig. 6: Bond of IPS e.max ZirCAD to the ZirLiner (compo contrast)

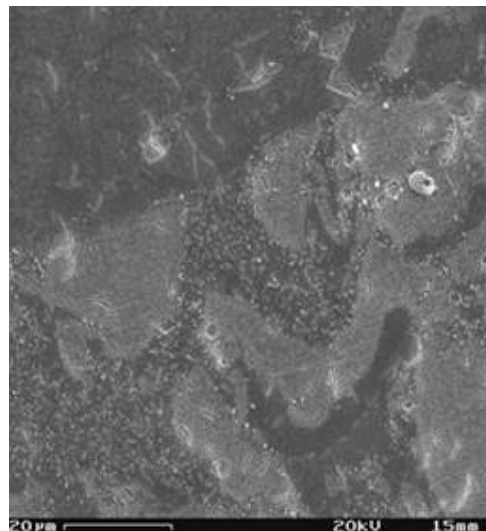


Fig. 7: Transition between IPS e.max Ceram (top left) and IPS e.max ZirPress (bottom right)

### 3.3 Press and firing temperatures (comparison)

The difference between the press temperature of the pressed ceramic and the firing temperature of the veneering ceramic should be as big as possible. This will increase the stability of the pressed component while the veneer is fired. The accuracy of fit of the restoration is thus improved.

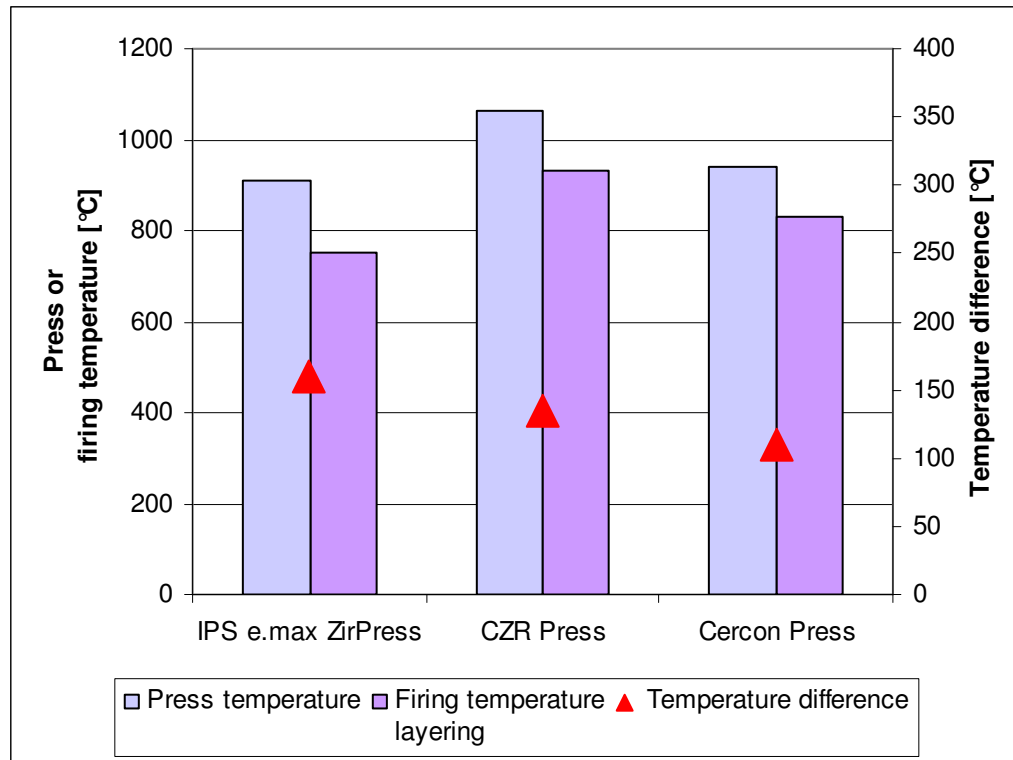


Fig. 8: Press and firing temperatures, as well as temperature differences between pressed and veneering ceramics (Ivoclar Vivadent AG, 2004/2005)

- Among the materials tested, the IPS e.max system with the IPS e.max ZirPress and IPS e.max Ceram components shows the largest difference between the press and firing temperature.

## 4. In vitro examinations

### 4.1 Fracture strength of inlay-retained bridges

Gabbert et al.<sup>1</sup> determined the fracture strength of metal-free inlay-retained bridges. The influence of two different gap widths were examined (molar, as well as premolar and molar). Zirconium oxide frameworks were fabricated by means of the CAD/CAM technique and pressed over with IPS e.max ZirPress. Subsequently, industrially prefabricated zirconium oxide pontics (diameter of 2x2 mm) were veneered with Artglass, a glass-fibre-reinforced composite. These zirconium oxide pontics were placed in two different areas of the inlay preparation: in the occlusal area or in the proximal box. Eight samples were fabricated per test series. The bridges were adhesively cemented (Variolink II). After 60,000 chewing cycles at 50 N and 10,000 thermocycles of 6.5 °C / 60 °C, the bridges were loaded to the point of fracture.

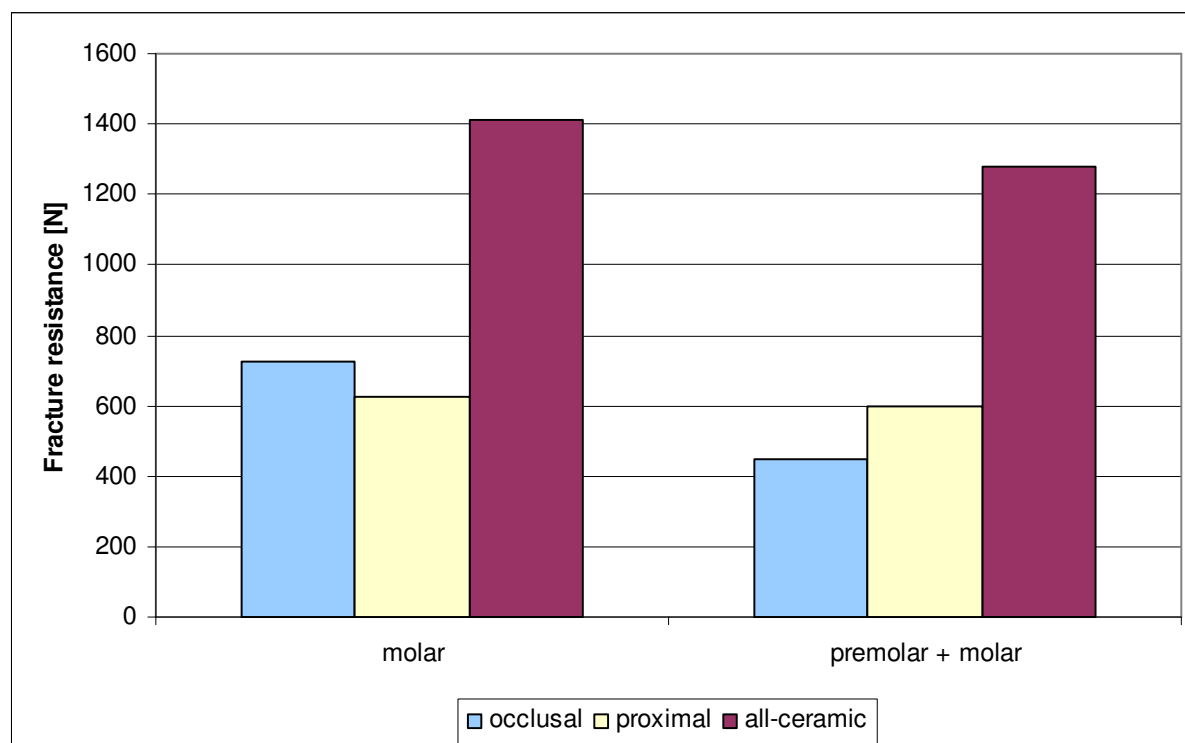


Fig. 9: Fracture resistance of metal-free inlay-retained bridges with zirconium oxide frameworks (Gabbert et al., 2004)<sup>1</sup>

- The position of the pontic and the gap width had no significant influence on the fracture load.
- Bridges veneered with IPS e.max ZirPress showed significantly higher strength values than pontics veneered with Artglass.

### 4.2 Compatibility of IPS e.max ZirPress 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.

For the purpose of testing the pressed-on crowns in the Willytec chewing simulator, the crowns were placed on standardized dies and subjected to eccentric loading with a steel antagonist. The antagonist performed a translational motion (depth of stroke = 2.0 mm,

length of stroke = 5 mm, travel speed = 40 mm/s) 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 pressed over with IPS e.max ZirPress and tested in the in-house laboratory.

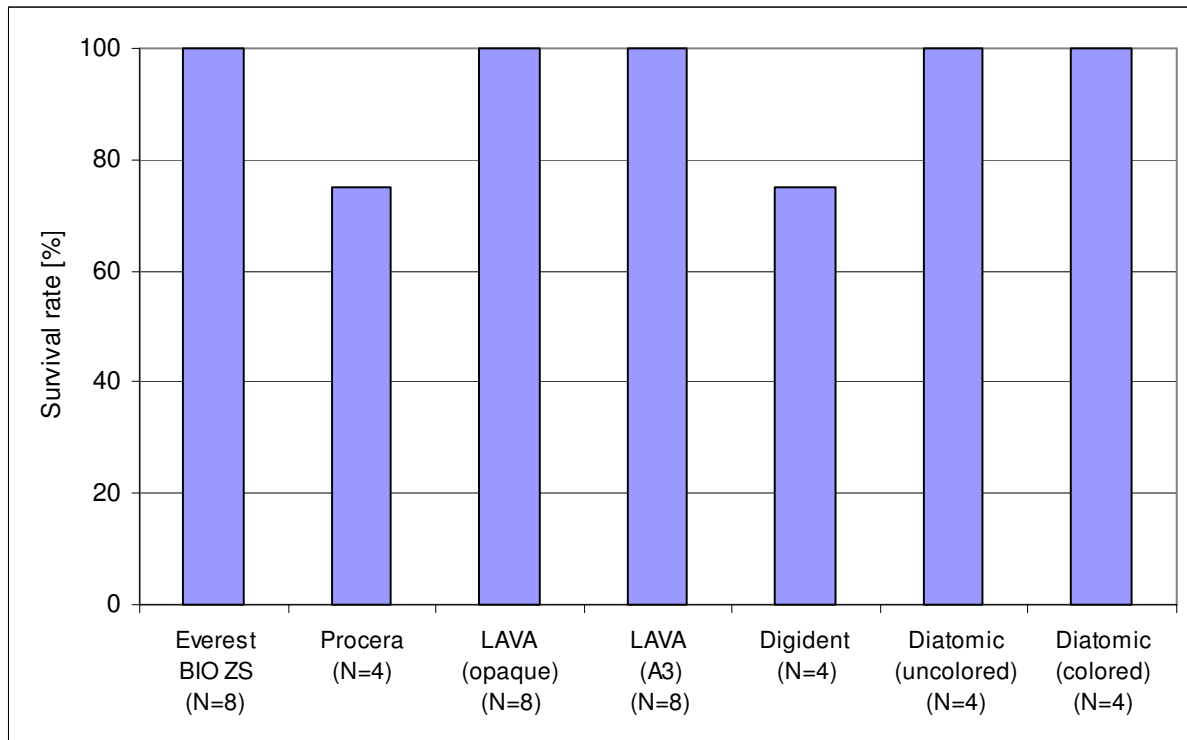


Fig. 10: Proportion of crowns (IPS e.max ZirPress/zirconium oxide) which survived the artificial chewing in the chewing simulator without chipping (Ivoclar Vivadent AG, Schaan, 2005)

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

## 5. External clinical studies

### 5.1 *University of Heidelberg*

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 ZirPress pressed on inlay-retained bridges made of zirconium oxide
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. The resultant restorations were veneered with IPS e.max Ceram.
Results:	Neither framework fractures nor chipping of the veneering material has been reported to date.

### 5.2 *University of Aachen*

Head of study:	Dr. Tinschert, University, Aachen
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 ZirPress pressed on crowns made of zirconium oxide
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 the veneering material has been reported to date.

### 5.3 *University of Michigan*

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 ZirPress pressed on restorations made of IPS e.max ZirCAD
Experimental:	Thirty crowns and 10 bridges made of IPS e.max ZirCAD/IPS e.max ZirPress/IPS e.max Ceram were placed.
Results:	Neither framework fractures nor chipping of the veneering material was observed after all restorations had been incorporated.

## 5.4 Conclusions

The clinical data to date show that the press-on technique in conjunction with zirconium oxide frameworks in general and IPS e.max ZirCAD with IPS e.max ZirPress in particular results in successful and aesthetic restorations. For this purpose, the parameters specified in the Instructions for Use have to be observed.

## 6. Biocompatibility

### 6.1 Introduction

All-ceramic materials are known for their high levels of biocompatibility<sup>2,3</sup>

The main ingredients of IPS e.max ZirPress (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 ceramic layering materials, which have been successfully used in clinical applications for many years. Hence, it can be assumed that IPS e.max ZirPress offers the same high levels of biocompatibility as these materials.

### 6.2 Chemical durability

Dental materials are exposed to a wide range of pH-values and temperatures in the oral environment. Therefore, chemical durability is an important prerequisite for dental materials. According to Anusavice<sup>4</sup> ceramic materials are among the most durable dental materials.

The in-house laboratory determined the chemical durability of IPS e.max ZirPress according to the relevant test described in 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	30 ± 10	< 100
In artificial saliva	30 ± 10	--

(Ivoclar Vivadent AG, Schaan, 2005)

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

### 6.3 In vitro cytotoxicity

IPS e.max ZirPress 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 ZirPress 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*.

**Under the given test conditions, no cytotoxic potential has been observed<sup>5</sup>**

#### **6.4 Sensitization, irritation**

Cavazos<sup>6</sup>, Henry et al.<sup>7</sup> and Allison et al.<sup>8</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>9</sup> as well as Podshadley and Harrison<sup>10</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 be virtually ruled out that ceramic materials cause direct irritations in the cells of the mucous membrane, possible irritations may generally be attributed to mechanical irritation. Normally, such reactions can be prevented by observing the IPS e.max ZirPress Instructions for Use.

**Compared to other dental materials, ceramic has no or 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 were <0.03 Bq/g<sup>11</sup> and 0.006 Bq/g<sup>12</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 standard of knowledge, it can be stated that IPS e.max ZirPress 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.

## 7. Literature

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