The Cologne Cathedral is the seat of the Archbishop of Cologne, under the administration of the Roman Catholic Church and is renowned as a monument of Christianity, of Gothic architecture and of the faith and perseverance of the people of the city in which it stands. It is dedicated to Saint Peter and the Blessed Virgin Mary.

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3  Benefits of ORIGIN® YZ Zirconia
4-5  General Indications of ORIGIN Zirconia Blocks and Disks
6  Barcode Implementation for Consistency After Final Sintering
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BENEFITS

- Excellent aesthetics and 100% biocompatibility
- High degree of clinical safety
- Proven strength (1,400 MPa) and all-ceramic beauty
- Engineered with bar codes for full control of consistent sintering shrinkage
- Conventional cementation
- Excellent marginal accuracy
- European CE, FDA and U.S. IdentCeram® certified
General Indications with the YZ Zirconia Cube Blocks

Designed for use with Sirona’s inLab and MC XL milling machines, ORIGIN YZ zirconia milling blocks are used as a milled substructure using CAD/CAM technology both for veneering and the press-on technique. ORIGIN YZ zirconia is formulated using a small grain size (< 0.3 µm) to reduce porosity. ORIGIN YZ zirconia undergoes an advanced manufacturing process to ensure uniform density, no warping during the sintering process, and quality control for large ceramic blanks. The yttrium-stabilized high quality zirconium oxide blocks display exceptional physical properties including a flexural strength of 1100 MPa.
We have a solid and proven expertise regarding the relationship between blank density, the milling enlargement factor and the sintering shrinkage rate that lead to the consistency of the prosthesis from single copings to large bridge framework.

From this high-quality, yttrium stabilized zirconium oxide material you can make bridge frames up to 16 units or customized implant abutments.

ORIGIN YZ zirconia is biocompatible and particularly resistant to ageing. This material differs from conventional zirconium oxides in that it is extremely homogeneous. This is achieved by means of an advanced manufacturing process and results in an excellent fit, even for large bridgeworks.

Once you’ve chosen ORIGIN, you’ll benefit from high quality zirconia at the most affordable material price in the industry.

- **ORIGIN YZ Zirconia Discs Have Been Tested & Proven to Be Superior When Using Various Milling Tools and Methods with No Margin Chipping**

Margin chipping can occur for many reasons including: incorrect calibration, tool wear, a margin design that is too weak, etc. In addition, weak zirconia material may not withstand the stress of the aggressive milling process, possibly leaving small visible chips along the margin as well as invisible micro-cracks in the coping or framework.

ORIGIN YZ zirconia discs have been tested successfully for different milling tools including both conventional designs (tool B & C) and advanced burs (tool A) designed to cut faster and more aggressively. It also can be milled under both wet milling and dry milling conditions.

**Tool A: Faster and more aggressive milling**

**Tool B & C: Conventional milling**

98 X 10 • 98 X 12 mm • 98 X 14 mm • 98 X 18 mm • 98 X 20 mm
With the Bar Code, ORIGIN® Provides Consistency In the Final Shrinkage of Your Bridge Framework

### Milling a Partially Sintered Zirconia Blank

Partially sintered blanks are about 50% dense. Because they are only partially sintered, the blanks are weak but easy to mill. However, the milled framework must be fired for 6 to 8 hours to increase the density & strength of the restoration. During firing, a large amount of shrinkage occurs, and this must be compensated for during the milling process (The picture on the right shows the framework before and after final sintering to indicate the typical amount of shrinkage that occurs).

Oversized frameworks are fabricated, relying on a computer to enlarge the pattern correctly to compensate for shrinkage and provide a reliable fit. Each block has a barcode containing the density for that specific block. The milling system then computes the proper degree of oversizing needed to compensate for the shrinkage to full density. Thus, the homogeneity of the block and exact density measurement is a key to the success of the manufacturing of the block.
Comparison of 3 Major YZ Zirconia Brands

<table>
<thead>
<tr>
<th>Physical Properties (Standard values after sintering)</th>
<th>ORIGIN®</th>
<th>VITA YZ</th>
<th>e.max® ZirCAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexural Strength (biaxial, MPa)</td>
<td>1,400 MPa</td>
<td>&gt; 900 MPa</td>
<td>900 MPa</td>
</tr>
<tr>
<td>Fracture Toughness (Kc)</td>
<td>7.0 MPa·m$^{1/2}$</td>
<td>5.9 MPa·m$^{1/2}$</td>
<td>6.0 MPa·m$^{1/2}$</td>
</tr>
<tr>
<td>Density (g/cm$^3$)</td>
<td>6.00</td>
<td>n/a</td>
<td>6.00</td>
</tr>
<tr>
<td>Medium size of Crystallites (µm)</td>
<td>&lt; 0.3 µm</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>CTE (Coefficient of Thermal Expansion, 10$^{-6}$/°C)</td>
<td>10.5 X 10$^{-6}$/°C (100°C - 500°C)</td>
<td>10.5 X 10$^{-6}$/°C (100°C - 500°C)</td>
<td>10.8 X 10$^{-6}$/°C (100°C - 500°C)</td>
</tr>
<tr>
<td>Sintering Temp.</td>
<td>1500°C</td>
<td>1530°C</td>
<td>1500°C</td>
</tr>
<tr>
<td>Data Available as of</td>
<td>01/2008</td>
<td>04/2005</td>
<td>09/2007</td>
</tr>
<tr>
<td>Raw Material Source</td>
<td>Tosoh (Japan)</td>
<td>Tosoh (Japan)</td>
<td>Tosoh (Japan)</td>
</tr>
</tbody>
</table>

Since the mid-1980s, zirconia has held a steady position in high-performance ceramics. More than 300,000 artificial hip joint implants and several thousand dental implants are impressive testimonies to the biological compatibility of zirconium dioxide.

There are no uncontrollable risks or long-term deficiencies to be expected in the area of dentistry associated with the use of high quality yttrium stabilized zirconia blocks.

Almost all manufacturers of major brands of YZ zirconia use medical grade high quality zirconia raw material from the Japanese company Tosoh corp.

- **ORIGIN Has the Highest Mean Flexural Strength of 1,400 MPa**
- **ORIGIN Has the Highest Fracture Toughness (Kc) of 7.0**

**The Strongest Zirconia**

On the assumption of a maximum chewing strength of 290 N, it is postulated that an endurance limit of approximately 500 N is required, which is given at an initial strength of at least 1000 N. The characteristics of ORIGIN YZ zirconia can be summed up as follows:

| ORIGIN YZ Zirconia | (Kc) = 7.0 MPa·m$^{1/2}$ (Fracture toughness) | m = 14.2 (Weibull Parameter) |

ORIGIN withstands extremely high stress: millions of normal chewing cycles at 120 N impact force and a chewing frequency of 1Hz.
What is the Difference in Strength? Why ORIGIN® zirconia is more chip resistant than other brands

- ORIGIN YZ Zirconia Implements a Manufacturing Process that Produces Finer Particles with Less Porosity

![Magnification 300 X](image1)
![Magnification 300 X](image2)
![Magnification 300 X](image3)

![Magnification 1000 X](image4)
![Magnification 1000 X](image5)
![Magnification 1000 X](image6)

Source: DIFK (Deutsches Institute fur Feuertest und Keramik GmbH, Bonn, Germany, Certificate 93-348-00-07, July 09th, 2008)

Factors determining the quality of a zirconia milling blank.

1. **Composition and purity of the powder.**
   Zirconia is a mineral and as such, always contains some traces of foreign material such as uranium and thorium. For this reason, medical-grade qualities must be purified in a very tightly controlled process.

2. **Preparation of zirconia powder.**
   After the chemical purification process, zirconia is calcined and ground to obtain a fine powder. For automated processing, the powder must be spray-dried before it can be pressed or handled. The precise quality control of the spray-drying strongly influences the amount of porosity or defects introduced into the final ceramic product and, therefore, how well the powder can be compacted in the pressing process.

The composition and preparation of the zirconia powder determines the uniformity of the particle size and distribution, which is a key factor in chip resistance.

---

**Finer Particle Size**

![Magnification 300 X](image1)

**Purity**

![Magnification 300 X](image2)

**Less Porosity**

![Magnification 300 X](image3)
ORIGIN® YZ Zirconia Discs Have Been Formulated to Withstand the Highest Speed of 60,000 RPMs for Fast Milling and Advanced Coping-nesting Designs

Documented 1,400 MPa - Highest Strength
ORIGIN YZ zirconia discs boast an MPa of 1,400, one of the highest in the industry. So you will experience far less chipping while finishing the coping before the sintering as well as after the sintering.

Optimized for Both Higher Milling Speeds and Conventional Milling Speeds
ORIGIN YZ zirconia discs produce excellent margins for a higher speed milling system (60,000 RPMs for faster milling) as well as for conventional systems with a speed of 40,000 RPMs. In addition, due to ORIGINs high strength, it withstands the amazing task of nesting coping-to-coping with less wall support.

Optimized For Fast Milling
Documented 1,400 MPa
We Understand the Components that Determine the Final Strength and Long-term Stability of the Prosthesis

1. Quality of the Powder: A Dependable and Traceable Source

All the ORIGIN YZ zirconia products use high-quality zirconia from Tosoh corp, Japan - the world leader in quality dental zirconia compounds. The company is the best known zirconia powder manufacturer and supplies more than 70% of all zirconia powder used by dental milling block manufacturers. Tosoh developed the E-grade yttrium stabilized zirconia powders which exhibit superior sintering properties and higher aging resistance.

2. Particle Size & Distribution - The Relationship Between the Particle Size of the Powder & the Quality of the Pressed Blank

Not only is the particle size important but also the particle size distribution. The particle size, or “inherent particle porosity” as the manufacturer refers to it, affects how the pressed block is formed and the density of the blank after pressing.

A uniform particle size distribution is important because when pressing the block, you would like the material to compress uniformly and consistently, thereby creating uniform density within the blank.

So, particle size distribution relates to the density of the green milling block and the density of the block determines the amount of shrinkage the end-user experiences upon final sintering.

It’s vitally important, of course, that the density remains consistent between different blocks and between different batches of blocks to provide high consistency in the final restorative product.

3. Green Block Processing

The raw material is purified by using an advanced chemical process to remove as many impurities as possible. The purified powder then is infiltrated with additives and an acrylic binder to make the material easy to press and handle.

Then the powder is spray-dried to form particles with a reasonably tight, uniform particle distribution. The precise quality control of the spray-drying strongly influences the amount of porosity or defects introduced into the final ceramic product.

High-quality zirconia-based crowns and bridges are made not only from high-grade zirconia material, but from milling blanks that are precisely processed. The surface finish, for example, is as important to the final properties exhibited by a crown or bridge as the sintering temperature is.

4. Pre-sintering process

To know the temperature at which a particular zirconia blank should be fired, we have to measure density, to control density grain size, and to determine fatigue strength. False zirconia pre-sintering leads to chipping during the milling process and prevents the material from reaching its proper density and strength. By over-firing, zirconia fatigue strength will decrease.

The relationship between green density, milling, and the final sintering temperature profile requires considerable research to optimize and considerable manufacturing experience to control.
Looking Through the Electron Microscope...

3 Major Brands of High Quality YZ Zirconia Blocks (ORIGIN, VITA, emax.ZirCAD)
Small grain size (< 0.3µm), no vitreous glass phase, high density, high purity and absence of defects

(30,000 X SEM (Scanning Electron Microscope) picture of 3 major brands after being fully-sintered)

Low Quality, Commercially Available Zirconia Blocks From an Unknown Source with Unknown Components
A wide distribution of uneven grain sizes, high porosity & weak strength will likely lead to premature breakage

The grain structure is very haphazard, with a wide distribution of grain sizes and very visible pores. Flexural strength is only 600 MPa. The typical values for quality sintered zirconia are between 1,000 and 1,200 Mpa.

These poor quality blocks are characterized, in their post sintered state, by pores in the grain structure and a grain structure that isn’t uniform. The presence of porosity in the final framework would weaken the material and could lead to premature breakage (or a short life cycle). Porosity in the final sintered material could allow moisture to be present in the oral environment to penetrate the framework, again with the effect of reducing the expected lifetime of the restoration.

The effect of using substandard material may not be seen straightaway. If a framework starts out at 600 MPa, and this inferior material loses strength over time, then the patient could very well have something in their mouth that will not meet ISO standards. Perhaps worse, the patient runs the risk of a restorative failure and ultimate premature breakage.

In addition, if labs purchase blanks from an unknown source, there may be some guesswork involved when trying to determine the correct sintering conditions and hope that their final restoration is sintered to its optimum final condition.

Testing Equipment We Used

At the end of the day, we are all patients and want to have safe and reliable products with close-to-nature esthetics.

NOVA nanoSEM 600,
Prof. Matthew C. DeLong,
Dept. of Physics & Applied Science, Univ. of Utah
Light Translucency Comparison for 3 Major Brand of YZ Zirconia Copings

(VITA, ORIGIN® and e.maxZirCAD, after sintering)

An identical coping was milled with the Cerec machine using all three of the major brands listed above. The translucency of the material depends not only on the material properties of the ceramic, but also on the recommended thickness of the layer, i.e. the wall thickness. So we followed the minimum wall thickness requirement (0.7mm) of the inLab system for all three copings with the same design.

Method: Light transmitted through the specimen was determined in a spectrophotometer (Perkin-Elmer, Lambda 9) by direct transmission coefficient (%) for wavelengths from 440 to 750 nanometer(nm).

Results: The spectrophotometer confirmed what was suggested in the visual Light Translucency Test performed above - when measuring wavelengths from 440 to 750 nanometers (nm), Origin and leading brand B exhibited a range of relative transmission that averaged 35%, while leading brand A averaged a slightly lower level of relative translucency.

- Excellent Esthetic Properties -
A Translucent Substructure That is Comparable To or Better Than Leading Brands
What does the CE marking signify?

1. CE signifies that a product conforms to European laws, meaning it meets all the legal requirements for its intended use.

To comply with Council Directive 93/42/EWG and the Medizinproduktegesetz (German medical devices law which implements the Directive), the manufacturer must present to the notified body, product documentation proving that all the essential requirements pertaining to the sale and use of the products have been met.

2. The essential requirements are:

   • Manufacture of product in such a way to ensure that it is safe
   • High degree of technical safety ensured by meeting chemical and physical requirements (e.g. manufacture according to ISO standards)
   • Risk management (risk/benefit analysis, conformity to standards, continuous assessment)
   • Biocompatibility
   • Clinical assessment
   • Continuous monitoring of marked goods (reporting of incidents, safety plan)

By CE marking it’s products, the manufacturer certifies that they conform entirely to legal requirements, thus enabling the free movement of goods on the EU internal market.

Material Traceability

Every batch of material we purchase comes with a certificate of analysis form Tosoh Corporation, the world leader in quality dental zirconia compounds, to guarantee it’s medical applications.
Shading the Substructure with COLORING LIQUIDS for ORIGIN® YZ Zirconia

16 Shades Possible for All Classic-V Shades

- ORIGIN zirconia can be colored by dipping the coping into the Color Liquids prior to sintering.

- ORIGIN YZ zirconia blocks can be colored according to the 16 different colors covering the entire classic-V shade range.

- The color becomes indelible through the sintering process thus avoiding the possibility of having white margins.

- After dipping, the excess liquid is removed by blow drying.

- Does not degrade or compromise.

- Coloring liquid has no negative effects on the physical material properties such as flexural strength or fracture toughness.

Veneering & Pressing with Porcelain

ORIGIN is Compatible with Most Zirconia Porcelain

Most of the veneering porcelain for use with zirconia that is available in the market has been specially adapted to the thermal expansion behavior of zirconia (CTE 10.0 ~10.5ppm/K. 100 - 500º C). Your lab can continue using your current zirconia porcelain with no question of compatibility.

In addition, below is a sample list of porcelain brands that are commonly used for all-ceramic and press-to-zirconia applications. All of the press-to-zirconia porcelains below match the CTE of ORIGIN zirconia substructures (10.5 X 10^{-6} • K^{-1}).

<table>
<thead>
<tr>
<th>Company Trade Name</th>
<th>All-ceramic</th>
<th>Press-to-zirconia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurident Inc</td>
<td>Press-i-dent</td>
<td>☒</td>
</tr>
<tr>
<td>Dentsply Prosthetics</td>
<td>Ceramco Press</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Finesse All-Ceramic</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Ceramco PFZ Press</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Cero KISS</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Cerecon Ceram Press</td>
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</tr>
<tr>
<td>European Dental Imports</td>
<td>Carrara Volumnia</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Sakura Voumia</td>
<td>☒</td>
</tr>
<tr>
<td>GC America Inc.</td>
<td>Initial PC</td>
<td>☒</td>
</tr>
<tr>
<td>Glidewell Direct</td>
<td>Prismatik CZ Press</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Prismatik ThinPress</td>
<td>☒</td>
</tr>
<tr>
<td>Heraeus Kulzer Inc.</td>
<td>HeraCeramPress</td>
<td>☒</td>
</tr>
<tr>
<td>Ivoclar Vivadent Inc.</td>
<td>IPS e.max Press</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>IPS e.max ZirPress</td>
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<tr>
<td></td>
<td>IPS Empress Esthetic</td>
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<tr>
<td>Jensen Industries Inc.</td>
<td>Authentic</td>
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</tr>
<tr>
<td></td>
<td>Creation CP</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Pulse Interface</td>
<td>☒</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Company Trade Name</th>
<th>All-ceramic</th>
<th>Press-to-zirconia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leach &amp; Dillon</td>
<td>Carpress SL</td>
<td>☒</td>
</tr>
<tr>
<td>Mirage</td>
<td>Fortress Pressable</td>
<td>☒</td>
</tr>
<tr>
<td>Monarch Metals Inc / Swiss NF</td>
<td>Press-Ceram Inlay Ingots</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Press Caram System</td>
<td>☒</td>
</tr>
<tr>
<td>Nobel Biocare</td>
<td>Nobel Rondo Press</td>
<td>☒</td>
</tr>
<tr>
<td>Shofu Dental Crop</td>
<td>Vintage Press Over</td>
<td>☒</td>
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<tr>
<td>Talladium Inc</td>
<td>Luminesse EZ-Press</td>
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<tr>
<td>Vision USA</td>
<td>Vision Low</td>
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<tr>
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<td>Vision Esthetic</td>
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<td>Wieland Dental Systems</td>
<td>Imagine PressX</td>
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<td>PressX ZR</td>
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<td>Zahn Dental Div.</td>
<td>Pentron 3G OPC</td>
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<td>Pentron Avente</td>
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<td></td>
<td>Pentron Avente VCH</td>
<td>☒</td>
</tr>
<tr>
<td></td>
<td>Noritake CZR Press</td>
<td>☒</td>
</tr>
</tbody>
</table>
IDENTCeram® Certificate Provided FREE

ORIGIN YZ zirconia carries certification by the IdentCeram division of the Identalloy Council. This designation certifies that B & D ORIGIN restorations are made only from FDA-registered Yttrium Zirconia. Similar to the Identalloy program for alloys, IdentCeram provides documentation as to the authenticity and composition of all ceramic materials used in dental restorations.

For every order of B & D ORIGIN YZ Zirconia, you will obtain a two-part IDENTCeram certificate. Retain one copy with your case file and send the second part to the prescribing dentist for retention with the patient file.

Having confidence in the material used in a prosthetic restoration is invaluable for future treatment planning and decision-making, as well as for documenting insurance claims.

Utilizing the IDENTCeram certificate gives your dentists complete assurance that your laboratory is providing only the highest quality zirconium product available today with ORIGIN YZ Zirconia. This program is provided by B & D Dental and there is no cost to you or your dentists to participate.

Safe  Reliable  Accurate  Consistent  Affordable
Certificate: 93-348-00-07

Order date January 16th, 2008

Specification of order Flexural Strength (MPa, Determination of modulus of rupture)
Determination of cold crushing strength
Micro-analysis by SEM

Sample name ORIGIN (ORIGIN Dental Systems)
W 200 (reference material from the German dental market)
Z 200 (reference material from the German dental market)

Delivery January 17th, 2008 and February 26, 2008

* The test results relate only to the items tested. The accredited test methods are marked with an asterisk. Without approval of DIFK this report shall only be reproduced in full and unchanged.

Dipl.-Min. Körber
Flexural Strength (MPa)

(Determination of Modulus of Rupture (MOR))

Determined According to DIN EN 993-6

Date of Testing: June 19th, 2008
Loading Rate 0.5mm/min

<table>
<thead>
<tr>
<th>Sample</th>
<th>MOR [MPa]</th>
<th>Young Modulus (stat.) [GPa]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>1426</td>
<td>152</td>
</tr>
<tr>
<td>Sample 2</td>
<td>1423</td>
<td>204</td>
</tr>
</tbody>
</table>

Loading Rate 0.5MPa/sec

<table>
<thead>
<tr>
<th>Sample</th>
<th>MOR [MPa]</th>
<th>Young Modulus (stat.) [GPa]</th>
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<tbody>
<tr>
<td>Sample 1</td>
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<td>185</td>
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Determination of Cold Crushing Strength

Determined According to DIN EN 993-5

Date of Testing: February 4th, 2008

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<tr>
<th>Sample</th>
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<tbody>
<tr>
<td>Prefired ORIGIN® (1)</td>
<td>90.5</td>
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<tr>
<td>Prefired ORIGIN® (2)</td>
<td>162</td>
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<tr>
<td>Prefired ORIGIN® (3)</td>
<td>35.7</td>
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<tr>
<td>Mean</td>
<td>96.1</td>
</tr>
</tbody>
</table>

Cylindrical Sample: 24.7mm Diameter and 23.8mm Height

<table>
<thead>
<tr>
<th>Sample</th>
<th>CCS [MPa]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fired at 1460°C ORIGIN® (1)</td>
<td>1893</td>
</tr>
<tr>
<td>Fired at 1460°C ORIGIN® (2)</td>
<td>1973</td>
</tr>
<tr>
<td>Fired at 1460°C ORIGIN® (3)</td>
<td>2321</td>
</tr>
<tr>
<td>Mean</td>
<td>2062</td>
</tr>
</tbody>
</table>

Sample Size: 16x16x20mm
Microscopic Documentation by SEM on a Prefired Sample

The following pictures show the structure of the sintered bodies using an electron microscope SEM/EDX (25 kV, spattered with gold).

Picture 1: Sample ORIGIN® (ORIGIN Dental Systems) Prefired, Magnification 300X

Picture 2: Sample ORIGIN® (ORIGIN Dental Systems) Prefired, Magnification 1000X

Picture 3: Sample W 200 (Reference Material from the German Dental Market) Prefired, Magnification 300X

Picture 4: Sample W 200 (Reference Material from the German Dental Market) Prefired, Magnification 1000X

Picture 5: Sample Z 200 (Reference Material from the German Dental Market) Prefired, Magnification 300X

Picture 6: Sample Z 200 (Reference Material from the German Dental Market) Prefired, Magnification 1000X

Microscopic Documentation by SEM on a Sample of ORIGIN® (ORIGIN Dental Systems) after firing at 1460°C

The picture to the right shows the structure of the ORIGIN® (ORIGIN Dental Systems) sample after firing at 1460°C (to improve the contrast of the crystallites the polished section was thermically etched at 1500°C for 1 hour) using an electron microscope SEM/EDX (25kV, spattered with gold).

Picture 7: Sample ORIGIN® (ORIGIN Dental Systems) Fired at 1460°C. The size of the ZrO₂ grains are 0.5 to 1 micron
ANALYSIS REPORT

Custom	ORIGIN Dental Systems GmbH, Essen, Germany

Analysis Task	Activity measurement of the nuclides $^{232}\text{Th}$ and $^{238}\text{U}$ in dental ceramic.

Analyst	Dr. G. Küppers (Tel. 02461-614663)

Sample preparation and measurement:
An amount of about 30g of the ceramic sample was measured with a well-shielded $\gamma$-ray spectrometer for 20 hours. Calibration of the detector was carried out with a $\text{La}_{2}\text{Eu}$-doted sand standard of the same geometry. By the use of the sand standard the $\gamma$-self-absorption within the sample matrix was taken into account.

Results:
Some decay products of the decay chains of $^{232}\text{Th}$ and $^{238}\text{U}$ are $\gamma$-emitting nuclides and can be measured by $\gamma$-ray spectrometry. Activities of $^{232}\text{Th}$ and $^{238}\text{U}$ were calculated with the assumption of radioactive equilibrium.

Detection limits were calculated accords to DIN 25482.

<table>
<thead>
<tr>
<th>Sample</th>
<th>$^{238}\text{U} \text{[Bq/g]}$</th>
<th>$^{232}\text{Th} \text{[Bq/g]}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZrO₂</td>
<td>$&lt; 0.03$</td>
<td>$&lt; 0.03$</td>
</tr>
</tbody>
</table>

Remarks:
The activity of $^{238}\text{U}$ is far below the allowable threshold of 1 Bq/g according to ISO-Norm 6872. For comparison, the mean activities of $^{238}\text{U}$ and $^{232}\text{Th}$ in the earth's crust are in the range of 0.03 Bq/g.

Sincerely yours

(Dr. E. Joußen) (Dr. G. Küppers)
Judgement

After testing the cytotoxicity of the Sample “C2/C3” according to the DIN EN ISO 10993-5, 1999-11 -- test report of 06/06/2008 (Testreport SN 7918 II) -- I give the following statement:

From the tested material only minimal cytotoxic compounds were extracted at 37°C. The extract of the test material reduced the cell growth to 98.30% of control. This is statistically not significant. (Fig. 1 and Tab. 1).

Using the test material as mentioned before described by the manufacturer no cytotoxic effects should be expected.

Prof. Dr. med. H.-P. Werner
Cytotoxicity Test to DIN EN ISO 10993-5
SOP 09-001
06/06/2008

Test Protocol

Identification of the test laboratory: SN 7918 I

Delivery date: 16/05/2008

Product: Dental ceramic: Sample Copran without color

Customer: White Peaks Dental Systems GmbH

Test method: Cytotoxicity of eluates according to the DIN EN ISO 10993-5, 1999-11

Biological evaluation of medical devices
Part 5: tests for cytotoxicity: in vitro
SOP 09-001

Test time period: 03/06/2008 - 05/06/2008

Test conditions: Examining climate: 22°C/45% rel. humidity
Incubation: 24 hours
The samples were checked in the delivery state.
Description of the method

**Extraction conditions:** 1.6g material into 16 ml MEM + 9 % serum +1 % antibiotic solution at 3rC for 24 h = extraction medium

**Cell culture**
FI-cells are derived from the human amnion. The stock cultures were carried out into 250 ml culture flasks (Greiner GmbH). The cells were trypsinised all 4 days. Only cells up to 100 passages were used. Trypsinised cells were seeded in tissue culture plates. The culture medium consists of MEM (Minimum Essential Medium) supplemented with 9 % calf serum, 1 % antibiotic solution (Penicilline G, Streptomycin sulfate, Neomycin) and L-glutamine.

**Exposition**
After 24hours of cultivation the cells were available as monolayer. A medium change with extraction medium was accomplished. Therefore the culture medium was decanted and the extraction medium carefully pipetted into the wells (0.1 ml per well).
An incubation for 24h is following.

**Measuring principle**
Vital cells incorporate the dye neutral red. Destroyed cells cannot incorporate the dye and remain unstained. The intensity of colour of the elution solution can be measured with a photometer.

**Measurement**
At the end of the incubation time the microtiterplate will be washed with PBS (Phosphate Buffered Saline). Culture medium containing the dye neutral red (50~g/ml) was given to the cells. After an incubation time of 3 hours the microtiterplate was washed again to remove the spare dye. With a special elution solution (1 % acetic acid in 50% ethyle alcohol) the dye was solved out of the cells. After 1 hour of elution the photometric measurement was conducted.

**Controls**
As a negative control culture medium without a test solution was established.
To verify the sensitivity of the test system a positive control (1 % Triton X) in culture medium was exposed in the cell culture system.

**Evaluation**
The optical density of 12 parallel tests was determined and used for statistical evaluation.
Results

Figure 1: Box plot of the cellvitality

![Box plot of cellvitality](image)

Table 1: Descriptive statistics (cellvitality)

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>Cell vitality (%)</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Std. Deviation</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative control</td>
<td>9</td>
<td>0.480</td>
<td>100,00</td>
<td>0.339</td>
<td>0.568</td>
<td>0.065</td>
<td>-</td>
</tr>
<tr>
<td>Positive control</td>
<td>9</td>
<td>0.051</td>
<td>10,67</td>
<td>0.047</td>
<td>0.054</td>
<td>0.002</td>
<td>-</td>
</tr>
<tr>
<td>SN 79181</td>
<td>12</td>
<td>0.458</td>
<td>95,53</td>
<td>0.302</td>
<td>0.563</td>
<td>0.068</td>
<td>0.9872</td>
</tr>
</tbody>
</table>

*U test (Man Whitney) vs, Control

HygCen
Centrum für Hygiene und medizinische Produktsicherheit

Prof. Dr. med. H.-P. Werner
Manager of scientific-technical affairs

Dipl. Umweltwiss. J. Köhnlein
Vice department manager
Premium Quality YZ Zirconia. German Engineered

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(800) 255-2839