

# ORIGIN<sup>®</sup>

Classic - HS Premium Quality YZ Zirconia • German Engineered

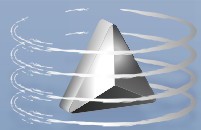




The Cologne Cathedral is the seat of the Archbishop of Cologne, under the administration of the Roman Catholic Church and is renowned as a monument of Christianity, of Gothic architecture and of the faith and perseverance of the people of the city in which it stands. It is dedicated to Saint Peter and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

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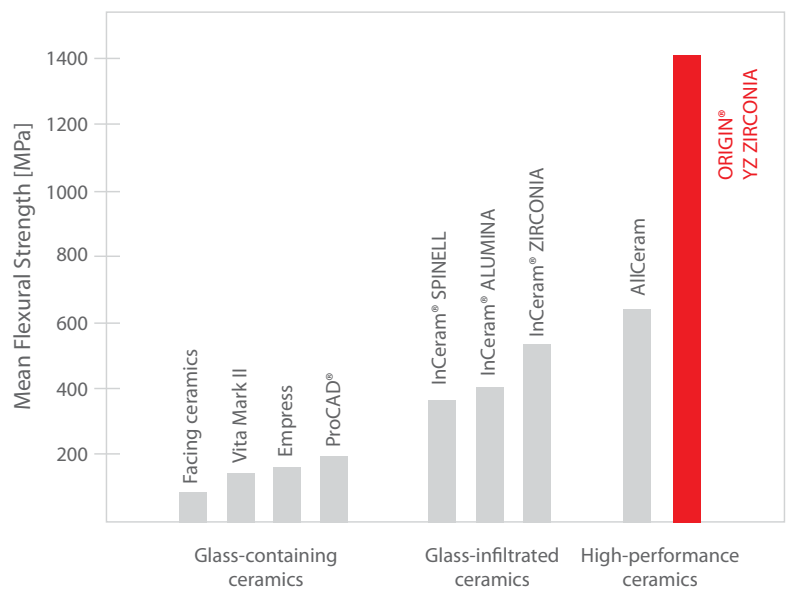
# ORIGIN® YZ Zirconia

German PRECISION, STRENGTH & QUALITY

Yttrium-stabilized  
Tetragonal  
Zirconia  
Polycrystals

## 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





# ORIGIN<sup>®</sup>

## 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.



20 X 15 mm  
20 X 19 mm



40 X 15 mm  
40 X 19 mm



55 mm  
65 mm



Single Crown



Splinted Crowns



3-unit Bridges



4-unit Bridges



5-unit Bridges



6-unit Bridges



# ORIGIN<sup>®</sup> YZ Zirconia Disks

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.



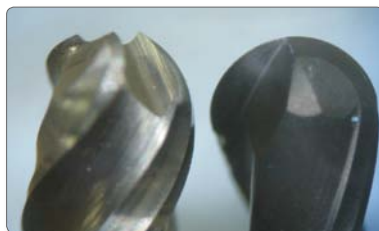
98 X 10 • 98 X 12 mm • 98 X 14 mm • 98 X 18 mm • 98 X 20 mm

## 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



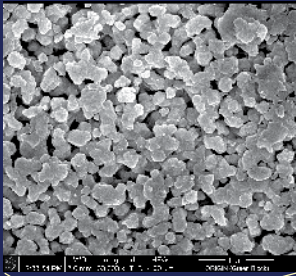
Tool A

Tool B



Tool A

Tool C

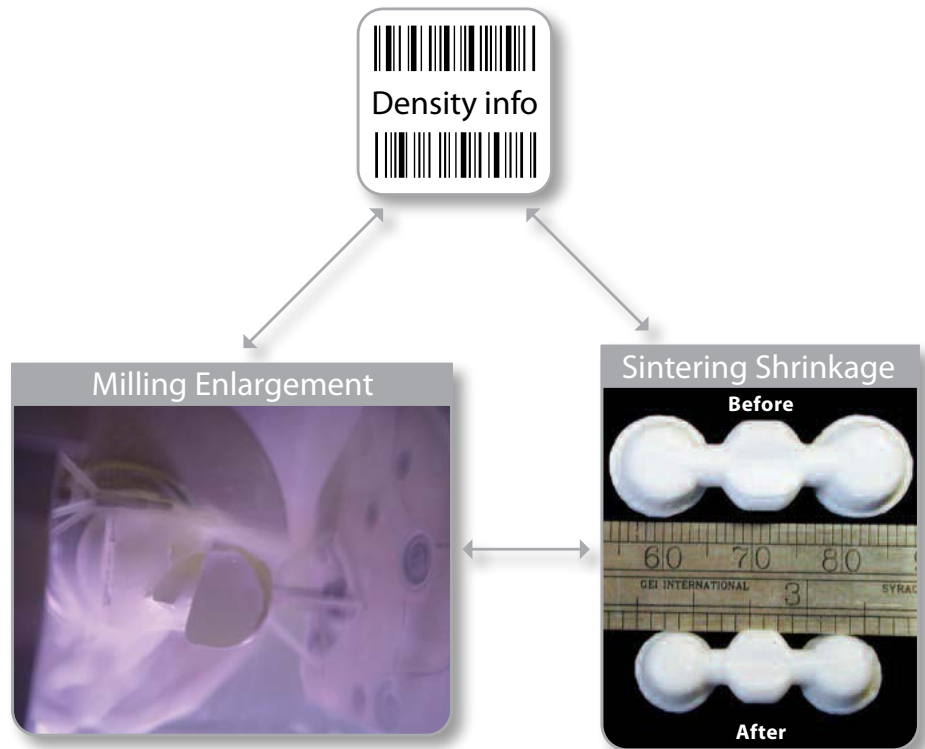


30,000 X



20.07%  
20.23%  
21.15%  
21.77%  
22.32%

# With the **Bar Code**, ORIGIN<sup>®</sup> 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.

Enlargement	shrinkage	Final
125.109%	20.07%	100.00%
125.235%	20.15%	100.00%
125.298%	20.19%	100.00%
125.360%	20.23%	100.00%
125.423%	20.27%	100.00%
125.502%	20.32%	100.00%
125.865%	20.55%	100.00%
126.406%	20.89%	100.00%
126.582%	21.00%	100.00%
126.823%	21.15%	100.00%
127.097%	21.32%	100.00%
127.535%	21.59%	100.00%
127.828%	21.77%	100.00%
128.172%	21.98%	100.00%
128.551%	22.21%	100.00%
128.733%	22.32%	100.00%



# Comparison of 3 Major YZ Zirconia Brands

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

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.

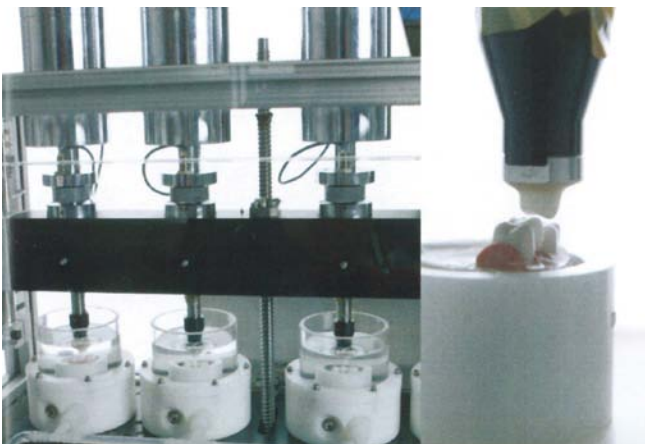
- **ORIGIN Has the Highest Mean Flexural Strength of 1,400 MPa**
- **ORIGIN Has the Highest Fracture Toughness (K<sub>IC</sub>) of 7.0**

Data compiled from the company websites, technical working instructions and scientific documentation.

## The Strongest Zirconia

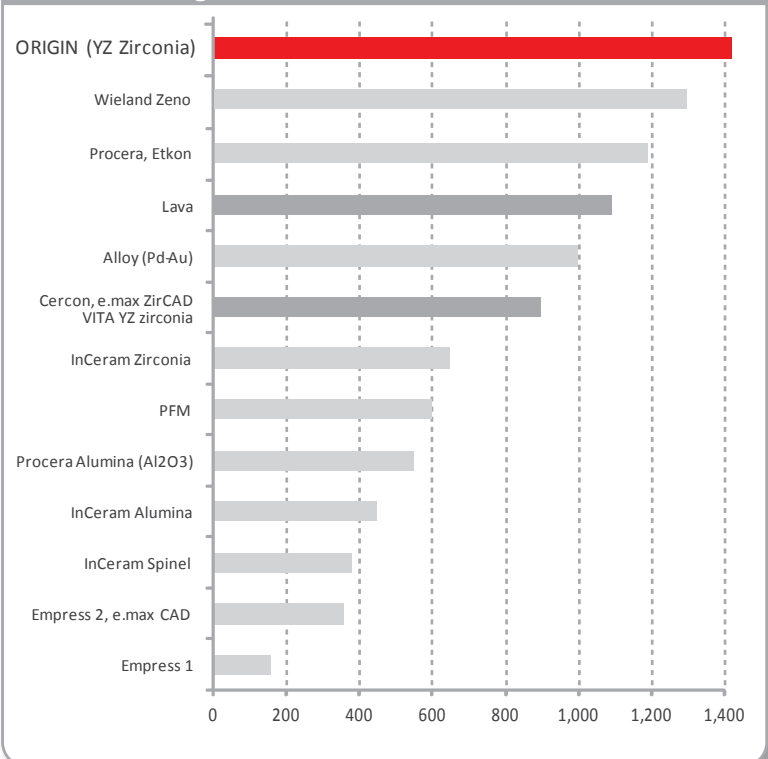
On the assumption of a maximum chewing strength of 290 N, it is postulated that an endurance limit of approximately 500 N is required, which is given at an initial strength of at least 1000 N. The characteristics of ORIGIN YZ zirconia can be summed up as follows:

ORIGIN YZ Zirconia	(K <sub>IC</sub> ) = 7.0 MPa m <sup>1/2</sup>	(Fracture toughness)
	m = 14;2	(Weibull Parameter)



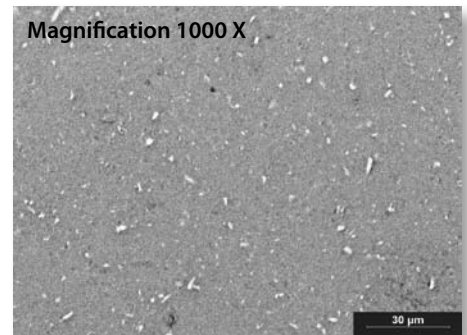
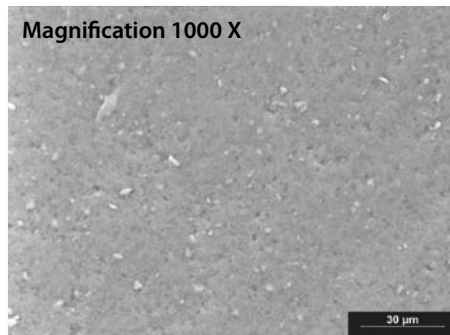
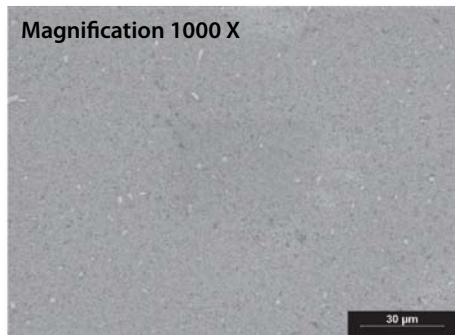
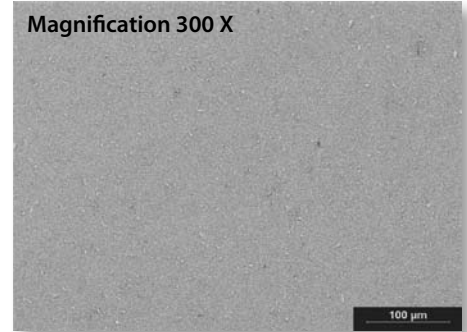
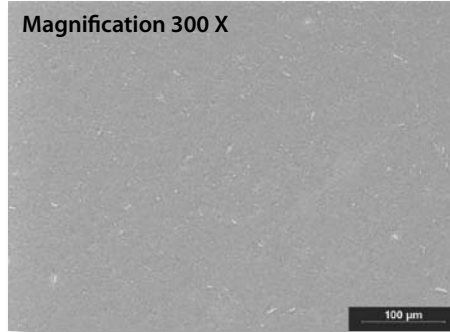
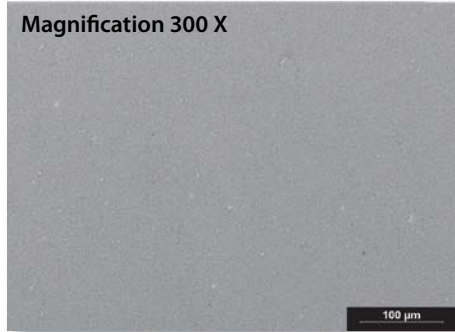
ORIGIN withstands extremely high stress: millions of normal chewing cycles at 120 N impact force and a chewing frequency of 1Hz.

Flexural Strength (MPa) of Various Restorative Materials



# What is the Difference in Strength? Why ORIGIN<sup>®</sup> zirconia is more chip resistant than other brands

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

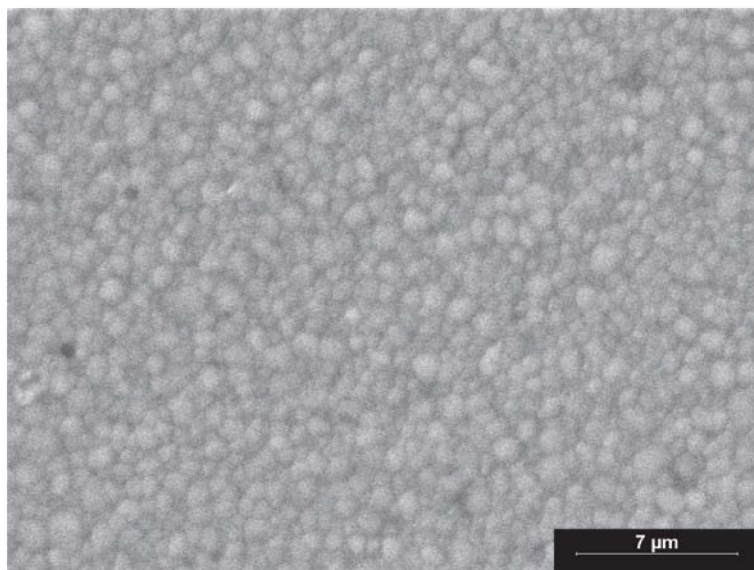


**ORIGIN**

**Competitor Z**

**Competitor W**

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



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 thermally etched at 1500 C for 1 hour) using an electron microscope SEM/EDX (25kV, spattered with gold). The size of the ZrO<sub>2</sub> grains are 0.5 to 1 micron.

## 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 partial size and distribution, which is a key factor in chip resistance.

**Finer Particle Size**

**Purity**

**Less Porosity**



■ **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**

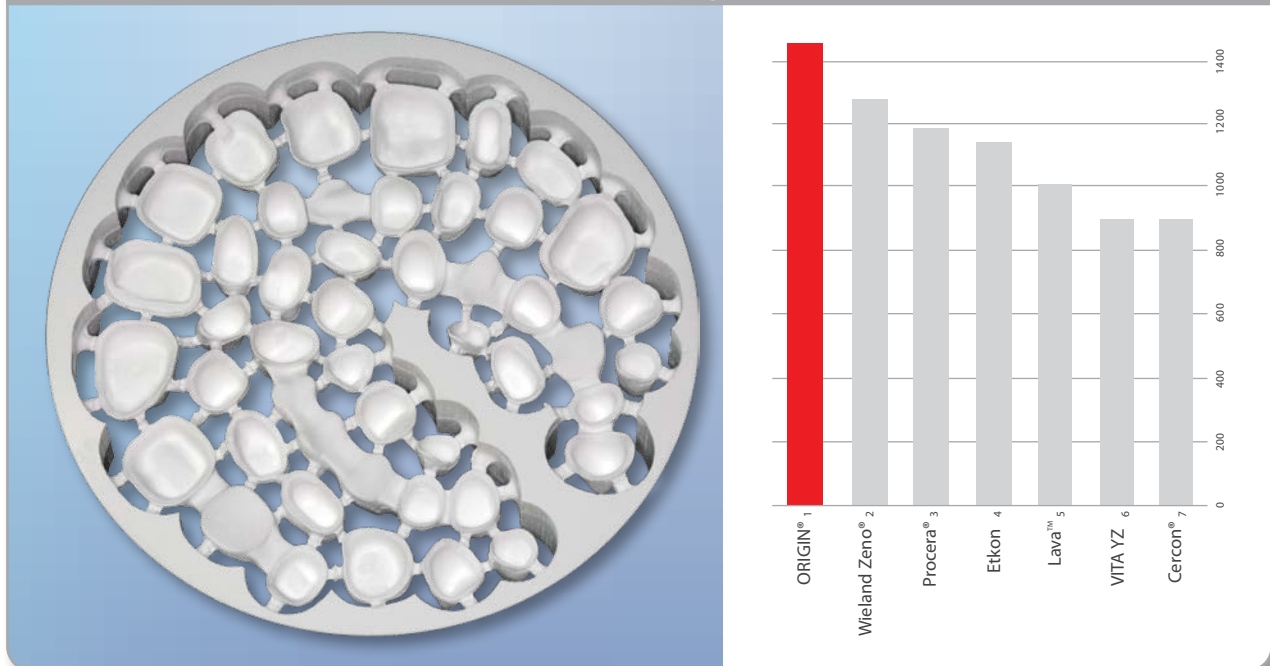
ORIGIN YZ zirconia discs boast an MPa of 1,400, one of the highest in the industry. So you will experience far less chipping while finishing the coping before the sintering as well as after the sintering.

**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 ORIGIN's high strength, it withstands the amazing task of nesting coping-to-coping with less wall support.



Flexural Strength (MPa) of Various Restorative Materials



**Optimized For Fast Milling**

**Documented 1,400 MPa**



**ORIGIN**

# We Understand the Components that Determine the Final Strength and Long-term Stability of the Prosthesis

**ORIGIN Source**  
Material manufacturer: Tosoh Corp, Japan  
TZ - 3YS-E

## 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

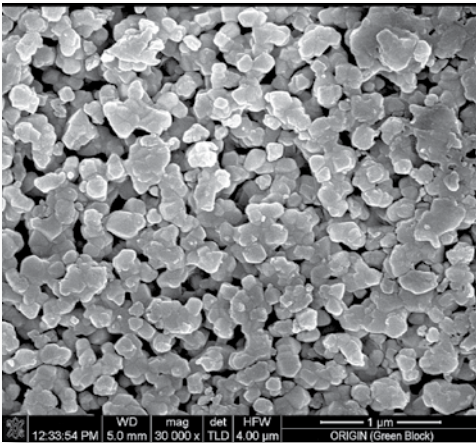
Not only is the particle size important but also the particle size distribution. The particle size, or "inherent particle porosity" as the manufacturer refers to it, affects how the pressed block is formed and the density of the blank after pressing.

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.

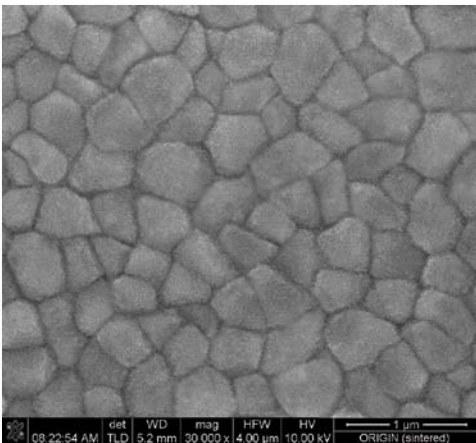
So, particle size distribution relates to the density of the green milling block and the density of the block determines the amount of shrinkage the end-user experiences upon final sintering.

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.

30,000 X (Green block, Partly sintered)



30,000 X (Fully sintered)



## 3. Green Block Processing

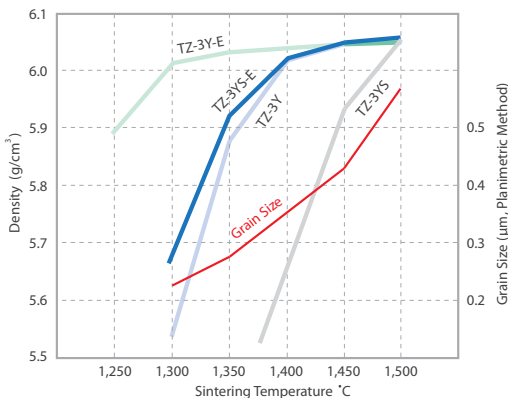
The raw material is purified by using an advanced chemical process to remove as many impurities as possible. The purified powder then is infiltrated with additives and an acrylic binder to make the material easy to press and handle.

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.



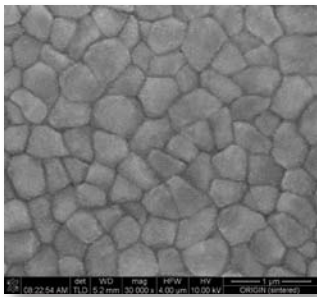
The relationship between green density, milling, and the final sintering temperature profile requires considerable research to optimize and considerable manufacturing experience to control.

# Looking Through the Electron Microscope...

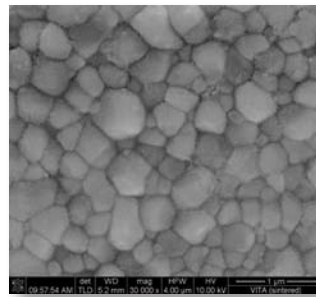
## 3 Major Brands of High Quality YZ Zirconia Blocks (ORIGIN, VITA, emax.ZirCAD)

Small grain size (< 0.3µm), no vitreous glass phase, high density, high purity and absence of defects

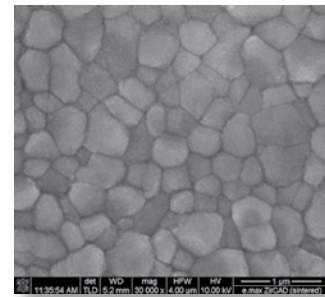
ORIGIN®



VITA



e.max ZirCAD

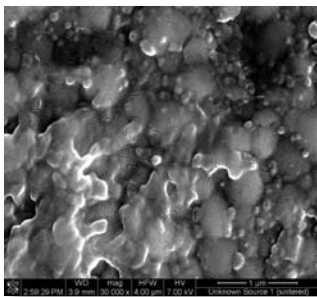


(30,000 X SEM (Scanning Electron Microscope) picture of 3 major brands after being fully-sintered)

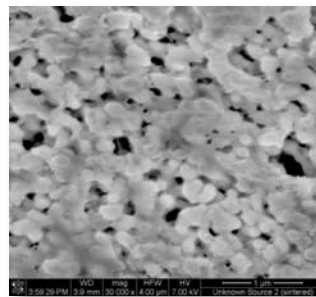
## Low Quality, Commercially Available Zirconia Blocks From an Unknown Source with Unknown Components

A wide distribution of uneven grain sizes, high porosity & weak strength will likely lead to premature breakage

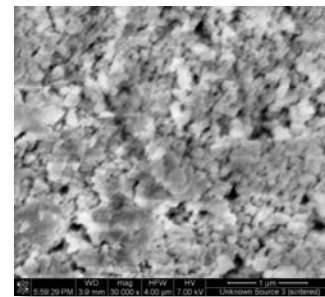
Unknown Source 1



Unknown Source 2



Unknown Source 3



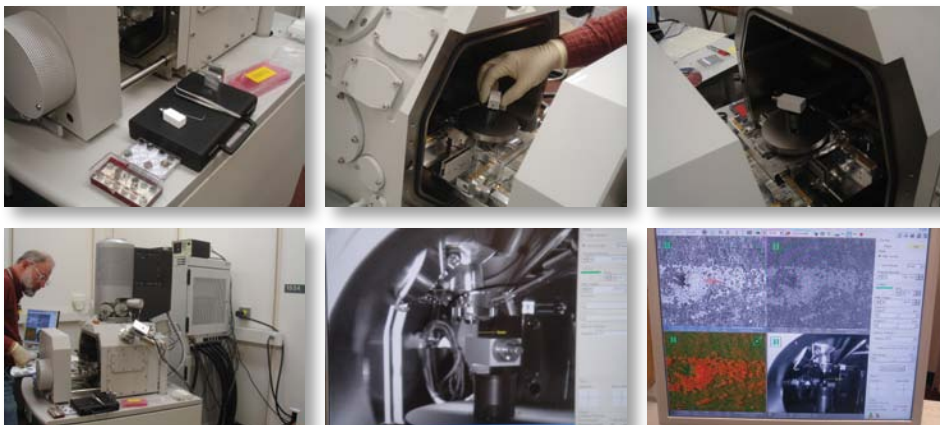
The grain structure is very haphazard, with a wide distribution of grain sizes and very visible pores. Flexural strength is only 600 MPa. The typical values for quality sintered zirconia are between 1,000 and 1,200 Mpa.

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



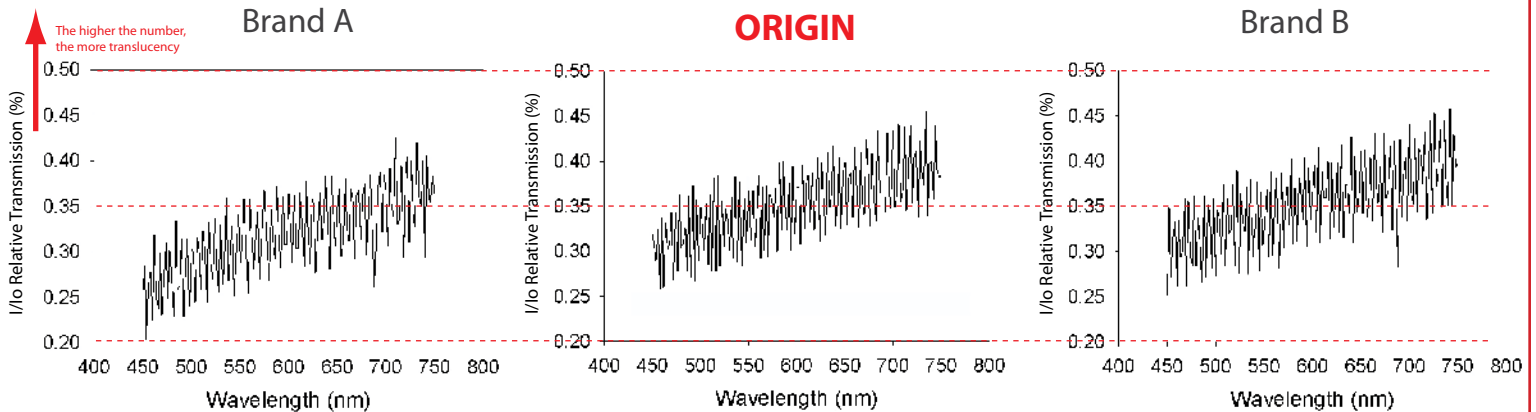
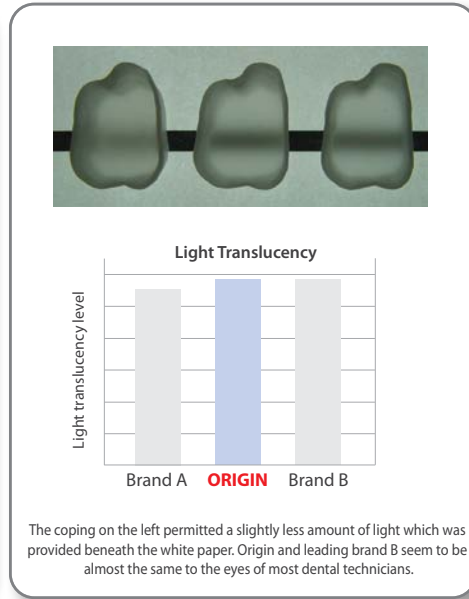
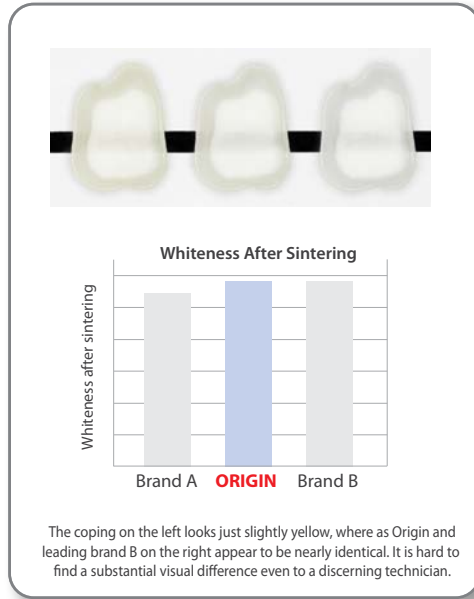
At the end of the day,  
we are all patients and want to have  
safe and reliable products with  
close-to-nature esthetics.

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.



Equipment: Perkin-Elmer UV/VIS/NIR Spectrophotometer OptoElectric Materials Lab University of Utah

**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**

# Safety and Reliability

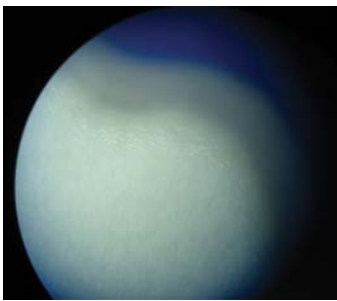
## ORIGIN<sup>®</sup> is European CE Certified & FDA Approved

# CE 0483

### 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 its products, the manufacturer certifies that they conform entirely to legal requirements, thus enabling the free movement of goods on the EU internal market.



mdc medical device certification GmbH  
Kriegerstraße 6  
D-70191 Stuttgart, Germany



## 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 its medical applications.



TOSOH CORPORATION  
SINOJO COMPLEX  
4940, Kasato-cho, Shimon, Yamaguchi-ken 740-0201, JAPAN.

Certificate of Analysis

This is to certify that we have performed the analysis of the product below:

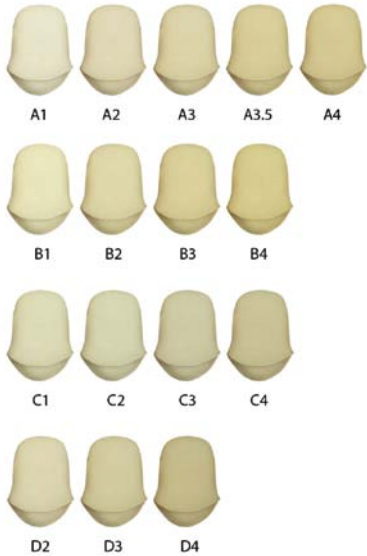
Commodity : TOSOH ZIRCONIA POWDER  
Grade : ZP-3330-0  
Lot No. : 50000510

		Specification	Result of Analysis
T <sub>2</sub> O <sub>3</sub>	%	4.95 ~ 5.25	5.25
Al <sub>2</sub> O <sub>3</sub>	%	0.10 ~ 0.30	0.213
SiO <sub>2</sub>	%	Max. 0.02	0.003
Fe <sub>2</sub> O <sub>3</sub>	%	Max. 0.01	Max. 0.002
Na <sub>2</sub> O	%	Max. 0.01	0.014
10-ppm	%	2.1 ~ 3.9	3.22
Crystallite Size	Å	Not specified	300

This certificate is produced electronically and it is valid without a signature.

K. Iwada  
Manager  
Quality Control  
Sinojo Complex

# 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 - 500° 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 ( $10.5 \times 10^{-6} \cdot K^{-1}$ ).

Company	Trade Name	All-ceramic	Press-to-zirconia
Aurident Inc	Press-i-dent	<input checked="" type="checkbox"/>	
Dentsply Prosthetics	Ceramco Press	<input checked="" type="checkbox"/>	
	Finesse All-Ceramic	<input checked="" type="checkbox"/>	
	Ceramco PFZ Press		<input checked="" type="checkbox"/>
	Cergo KISS	<input checked="" type="checkbox"/>	
	Cercon Ceram Press		<input checked="" type="checkbox"/>
European Dental Imports	Carrara Volumia		
	Sakura Voumia		<input checked="" type="checkbox"/>
GC America Inc.	Initial PC	<input checked="" type="checkbox"/>	
Glidewell Direct	Prismatik CZ Press		<input checked="" type="checkbox"/>
	Prismatik ThinPress	<input checked="" type="checkbox"/>	
Heraeus Kulzer Inc.	HeraCeramPress	<input checked="" type="checkbox"/>	
Ivoclar Vivadent Inc.	IPS e.max Press	<input checked="" type="checkbox"/>	
	IPS e.max ZirPress		<input checked="" type="checkbox"/>
	IPS Empress Esthetic	<input checked="" type="checkbox"/>	
Jensen Industries Inc.	Authentic	<input checked="" type="checkbox"/>	
	Creation CP	<input checked="" type="checkbox"/>	
	Pulse Interface		

Company	Trade Name	All-ceramic	Press-to-zirconia
Leach & Dillon	Cerpress SL	<input checked="" type="checkbox"/>	
Mirage	Fortress Pressable	<input checked="" type="checkbox"/>	
Monarch Metals Inc / Swiss NF	Press-Ceram Inlay Ingots	<input checked="" type="checkbox"/>	
	Press Ceram System	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Nobel Biocare	Nebel Rondo Press		<input checked="" type="checkbox"/>
Shofu Dental Corp	Vintage Press Over	<input checked="" type="checkbox"/>	
Talladium Inc	Luminesse EZ-Press	<input checked="" type="checkbox"/>	
Vision USA	Vision Low	<input checked="" type="checkbox"/>	
	Vision Esthetic	<input checked="" type="checkbox"/>	
Wieland Dental Systems	Imagine PressX	<input checked="" type="checkbox"/>	
	PressX ZR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Zahn Dental Div.	Pentron 3G OPC	<input checked="" type="checkbox"/>	
	Pentron Avente	<input checked="" type="checkbox"/>	
	Pentron Avente VCH	<input checked="" type="checkbox"/>	
	Noritake CZR Press		<input checked="" type="checkbox"/>

(Source: Dental Lab Product magazine, June 2007)

# **ORIGIN<sup>®</sup> Limited 10 - Year Warranty**



B & D Dental is so confident in the quality and integrity of our zirconia blanks, we provide a 10 year warranty from the date of placement. This warranty states that copings or substructures (other than porcelain) made out of ORIGIN<sup>®</sup> YZ block material will not break if fabricated in compliance with manufacturer's approved indications and instructions for use for ORIGIN crowns and bridges (ORIGIN YZ Working Instructions, Lit. No. 325).

In the event of any breakage of the framework, B & D Dental Corp will either provide a free blank, or replace the milled and sintered framework through our milling center, or at B & D's option, reimburse the milled and sintered framework at a fair market price.

For detailed information please refer to the ORIGIN YZ zirconia 10-Year Warranty program.

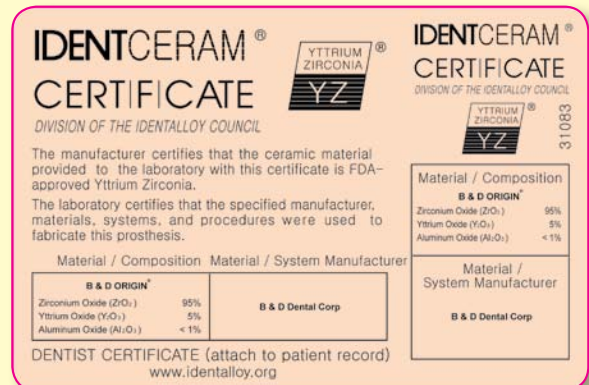
## **IDENTCeram<sup>®</sup> Certificate Provided FREE**

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.



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ORIGIN® Dental Systems GmbH  
Essen, Germany



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Die Akkreditierung gilt für die in der Urkunde  
aufgeführten Prüfverfahren.

July 09th, 2008  
Service: Dipl.-Min. Körber  
fon: ++49 (0) 228 / 91508-29

**Certificate: 93-348-00-07**

<b>Order date</b>	January 16th, 2008
<b>Specification of order</b>	<b>Flexural Strength (MPa, Determination of modulus of rupture) Determination of cold crushing strength Micro-analysis by SEM</b>
<b>Sample name</b>	<b>ORIGIN (ORIGIN Dental Systems) W 200 (reference material from the German dental market) Z 200 (reference material from the German dental market)</b>
<b>Delivery</b>	<b>January 17th, 2008 and February 26, 2008</b>

\* 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

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**Flexural Strength (MPa)**

**(Determination of Modulus of Rupture (MOR))**

Determined According to DIN EN 993-6

Date of Testing: June 19<sup>th</sup>, 2008

Loading Rate 0.5mm/min

			<b>ORIGIN®</b> (ORIGIN Dental Systems) Fired at 1460°
MOR	[MPa]	Sample 1	<b>1426</b>
MOR	[MPa]	Sample 2	<b>1423</b>
Young Modulus (stat.)	[GPa]	Sample 1	152
Young Modulus (stat.)	[GPa]	Sample 3	204

Loading Rate 0.5MPa/sec

			<b>ORIGIN®</b> (ORIGIN Dental Systems) Fired at 1460°
MOR	[MPa]	Sample 1	<b>1554</b>
Young Modulus (stat.)	[GPa]	Sample 2	<b>185</b>

**Determination of Cold Crushing Strength**

**Determined According to DIN EN 993-5**

Date of Testing: February 4<sup>th</sup>, 2008

Sample	CCS [MPa]
<b>ORIGIN®</b> (ORIGIN Dental Systems) /1 Prefired	90.5
<b>ORIGIN®</b> (ORIGIN Dental Systems) /2 Prefired	162
<b>ORIGIN®</b> (ORIGIN Dental Systems) /3 Prefired	35.7
<b>Mean</b>	<b>96.1</b>

Cylindrical Sample: 24.7mm Diameter and 23.8mm Height

Sample	CCS [MPa]
<b>ORIGIN®</b> (ORIGIN Dental Systems) /1 Fired at 1460°C	1893
<b>ORIGIN®</b> (ORIGIN Dental Systems) /2 Fired at 1460°C	1973
<b>ORIGIN®</b> (ORIGIN Dental Systems) /3 Fired at 1460°C	2321
<b>Mean</b>	<b>2062</b>

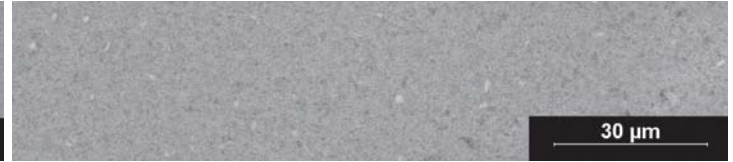
Sample Size: : 16x16x20mm

**Microscopic Documentation by SEM on a Prefired Sample**

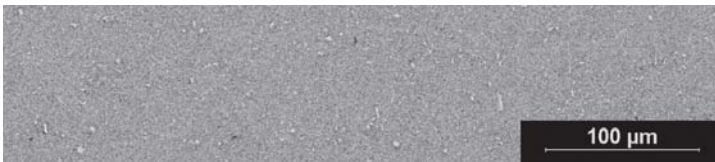
The following pictures show the structure of the sintered bodies using an electron microscope SEM/EDX (25 kV, spattered with gold).



**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

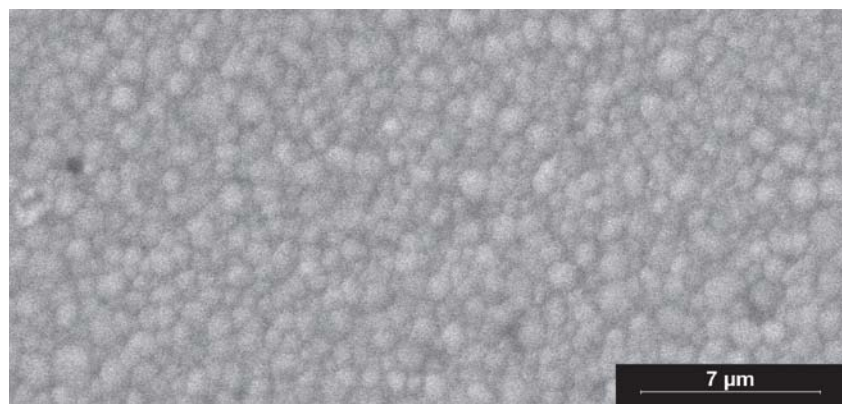


**Picture 6: Sample Z 200**  
(Reference Material from the German Dental Market)  
Prefired, Magnification 1000X

**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 thermally 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 ZrO<sub>2</sub> grains are 0.5 to 1 micron

**ANALYSIS REPORT**

**Custom** ORIGIN Dental Systems GmbH, Essen, Germany

**Analysis Task** Activity measurement of the nuclides <sup>232</sup>Th and <sup>238</sup>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 <sup>152</sup>Eu-doped 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 <sup>232</sup>Th and <sup>238</sup>U are  $\gamma$ -emitting nuclides and can be measured by  $\gamma$ -ray spectrometry. Activities of <sup>232</sup>Th and <sup>238</sup>U were calculated with the assumption of radioactive equilibrium.

Detection limits were calculated according to DIN 25482.

Sample	<sup>238</sup> U [Bq/g]	<sup>232</sup> Th [Bq/g]
ZrO <sub>2</sub>	< 0.03	< 0.03

**Remarks:**

The activity of <sup>238</sup>U is far below the allowable threshold of 1 Bq/g according to ISO-Norm 6872. For comparison, the mean activities of <sup>238</sup>U and <sup>232</sup>Th in the earth's crust are in the range of 0.03 Bq/g.

Sincerely yours



(Dr. E., Joußen)



(Dr. G. Küppers)

**PROF. DR. MED. H. - P. WERNER**  
**FACHARZT FÜR HYGIENE**

Prof. Dr. H. - P. Werner - c/o HygCen GmbH - Bornhövedstr. 7B - D 19055 Schwerin



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**ORIGIN Dental Systems GmbH**  
**Essen, Germany**

**Dental Ceramic: Sample C2/C3**

**06/06/2008**

## 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**

**ORIGIN Dental Systems GmbH**  
Essen, Germany



**Cytotoxicity Test to DIN EN ISO 10993-5**  
SOP 09-001

**06/06/2008**

## Test Protocol

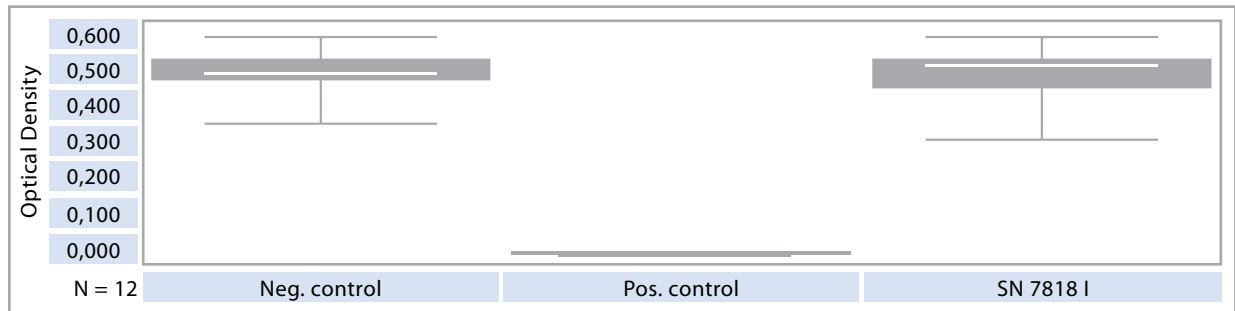
<b>Identification of the test laboratory:</b>	SN 7918 I
<b>Delivery date:</b>	16/05/2008
<b>Product:</b>	Dental ceramic: Sample Copran without color
<b>Customer:</b>	White Peaks Dental Systems GmbH
<b>Test method:</b>	Cytotoxicity of eluates according to the DIN EN ISO 10993-5,1999-11 Biological evaluation of medical devices Part 5: tests for cytotoxicity: in vitro SOP 09-001
<b>Test time period:</b>	03/06/2008 - 05/06/2008
<b>Test conditions:</b>	Examining climate: 22°C /45% rel. humidity Incubation: 24 hours The samples were checked in the delivery state.

## Description of the method

<b>Extraction conditions:</b>	1.6g material into 16 ml MEM + 9 % serum +1 % antibiotic solution at 37C for 24 h = extraction medium
<b>Cell culture</b>	<p>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.</p> <p>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.</p>
<b>Exposition</b>	<p>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).</p> <p>An incubation for 24h is following .</p>
<b>Measuring principle</b>	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.
<b>Measurement</b>	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.
<b>Controls</b>	<p>As a negative control culture medium without a test solution was established.</p> <p>To verify the sensitivity of the test system a positive control (1 % Triton X) in culture medium was exposed in the cell culture system.</p>
<b>Evaluation</b>	The optical density of 12 parallel tests was determined and used for statistical evaluation.

## Results

**Figure 1:** Box plot of the cellvitality



## Results

**Table 1:** Descriptive statistics (cellvitality)

	N	Mean	Cell vitality (%)	Minimum	Maximum	Std. Deviation	p*
Negative control	9	0,480	100,00	0,339	0,568	0,065	-
Positive control	9	0,051	10,67	0,047	0,054	0,002	-
SN 79181	12	0,458	95,53	0,302	0,563	0,068	0,9872

\*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



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