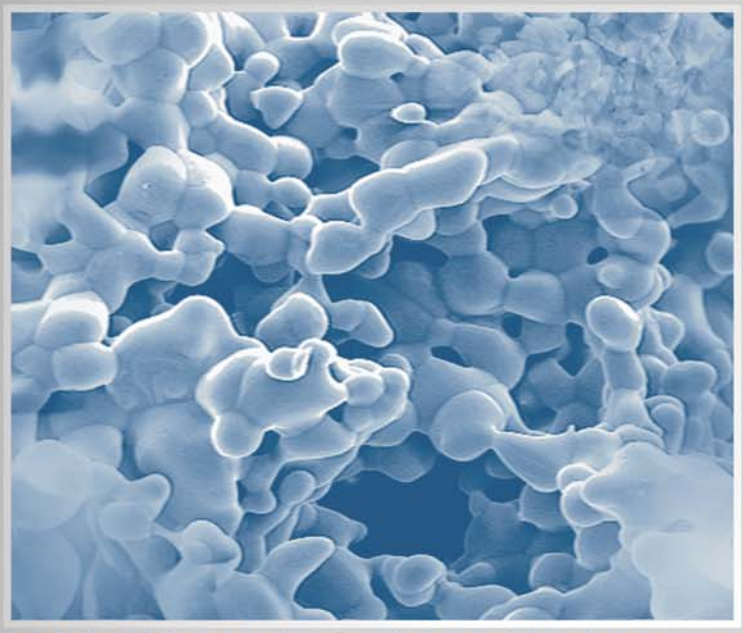
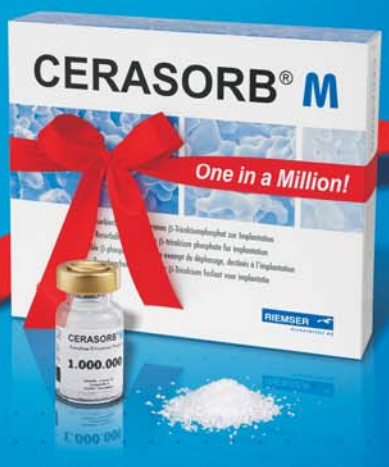
EN



Progress and reliability in oral surgery

CERASORB® M

More space for new bone



RIEMSER

CERASORB®– the one millionth unit!



Ladies and gentlemen:

On March 8, 2010 the chairman of the board of RIEMSER Arzneimittel AG was presented with the one millionth unit of **CERASORB®**. A tremendous success that calls for our heartfelt thanks!

For untold dentists and maxillofacial surgeons, hospital and medical school based clinicians around the world **CERASORB®** has become the first choice for successful bone regeneration.

Benefits appreciated worldwide!

Documented safety!

More than 135 scientific publications make **CERASORB®** one of the best documented synthetic bone grafting materials.

Saves your time!

As **CERASORB®** is synthetic, mandatory patient information can be kept short and simple.

More satisfied patient!

A global standard of reference in ist class, **CERASORB®** is reimbursed by private insurers.



CERASORB® used for bone regeneration in more than 75 countries worldwide.

CERASORB®- its history from 1970 to 2010

The history of β-tricalcium phosphate spans a period of 40 years and coincides with that of insights into bone regeneration and early experiences with biomaterials.

Scientists who were instrumental in biomaterial research were also involved in the development of synthetic β-tricalcium phosphate, which was to become a successful biomaterial labeled **CERASORB®**.

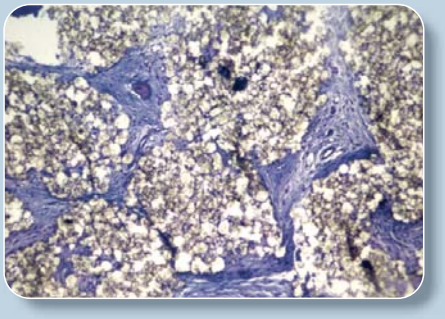
Basic research with synthetic bone grafting began at the Battelle Institute, Frankfurt/Main (Germany), in the early seventies of the past century.
β-tricalcium phosphate was soon found to be superior to other compounds and was used for developing prototype granular materials and blocks. Meanwhile **CERASORB®** has become the base material of an extensive product range with modifications tailored to each and every case for users to choose from.
All of the products feature optimal characteristics in terms of their functional surface, their porosity and their resorption/degradation.

Completely resorbed during bone regeneration, **CERASORB®** does not leave any residues and is replaced by natural bone ➔ „restitutio ad integrum", the ultimate goal of bone regeneration.

The straight road to new bone
CERASORB® - the biofunctional β-tricalcium phosphate

Granular CERASORB® products come in different shapes and porosities, i.e. CERASORB® CLASSIC, CERASORB® PERIO and CERASORB® M. CERASORB® blocks are being used successfully in orthopedic and trauma surgery for repairing major defects.

The entire CERASORB® product range meets the highest standards of excellence



in terms of phase purity, primary granule size, structural stability, porosity and solubility. This makes it superior to many other bone grafting materials.
In addition, CERASORB® optimally supports bone healing.

CERASORB®- safety profile

CERASORB® consists of calcium and phosphate, both factors of the bone mineral phase. It is well tolerated by the body without any immune-mediated risks and risks of infection that can be seen with materials of biologic origin. CERASORB® is non-toxic systemically and locally and is non-allergenic.
Thanks to its homogenous solubility it releases calcium and phosphate ions in physiologic concentrations at the site (Ca/P ratio 1.5). These are easily absorbed by osteoblasts for mineralization. CERASORB® is resorbed, while new bone is formed.



CERASORB® - manufacturing process

CERASORB® is produced under clean room conditions by sintering in a validated computer-controlled high-temperature process. Its base materials are calcium carbonate and calcium hydrogen phosphate. The material is then crushed to a defined grain size and sifted to the desired primary granule size.

Further processing depends on the presentation (CERASORB® CLASSIC, CERASORB® PERIO, CERASORB® M).



While CERASORB® CLASSIC is granulated in a snowball process, the other presentations are processed to a rod shape by cold isostatic compression at 150 - 200 MPa. For CERASORB® M a porosing agent is added to obtain the desired interconnecting multiporosity. The polygonal granules are produced with a special crushing technique and subsequently sifted to different granule sizes.



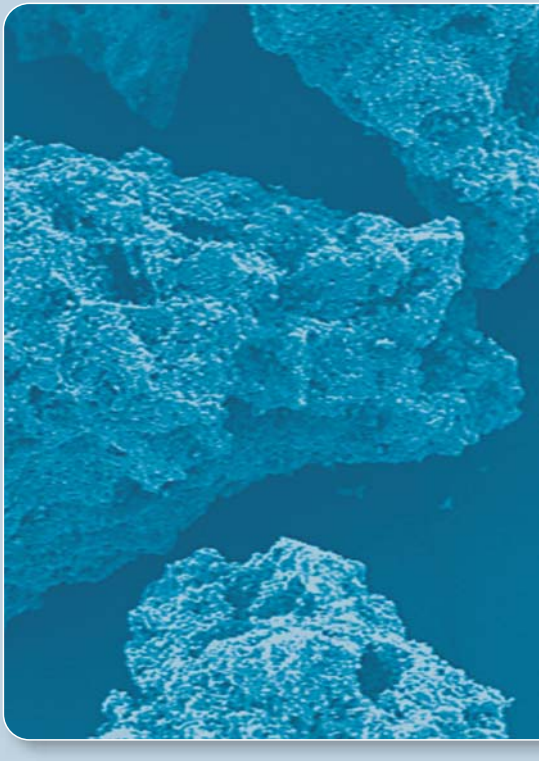
CERASORB®- quality assurance

For quality assurance, the quality of both synthetic base materials and packaging materials is checked as these come in. The synthesis of CERASORB® is accompanied by extensive internal and external chemical and mineralogic tests. The material complies with an internationally accepted standard, i.e. ASTMF-1088-04 (Standard Specification for β-tricalcium phosphate for Surgical Implantation). Its phase purity (99 %) clearly exceeds the 95 % purity required in the standard. The product is packaged under controlled clean room conditions and subsequently subjected to validated gamma irradiation.

CERASORB® M:
More plusses for faster and better regeneration of denta

CERASORB® M is a modification of CERASORB®, a synthetic phase-pure (99 %) β-tricalcium phosphate, which has stood the test of time.

CERASORB® M reflects the latest insights in bone regeneration. Its properties offer a number of benefits.



Properties:

- Interconnecting open multiporosity with micro, meso and macropores (5 µm - 500 µm)
- About 65 vol.% total porosity
- Polygonal granules
- Complete resorption at the rate of new bone formation

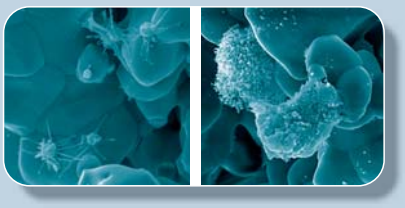
Ladies and gentlemen: Advantages from these CERASORB® M benefits:



CERASORB® M - *for enhanced osteoconductivity*

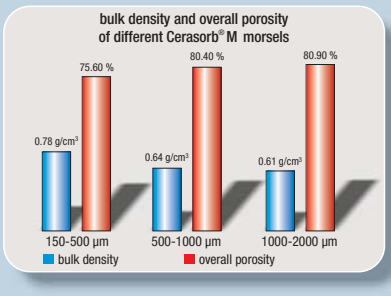
Together with the polygonal granule shape, the characteristic pore distribution of CERASORB® M produces a large surface area of high roughness. This perfect scaffold promotes the ingrowth of host bone osteoblasts into the defect (osteoconduction), so that these act as ideal agents of new bone growth.

The specific surface pattern of CERASORB® M has a positive effect on in-vivo processes, because both the initial physicochemical interaction of the bone grafting material with body fluids and the subsequent biologic response begin right at the surface.



CERASORB® M - *for continual active cell supply*

The specific structure of CERASORB® M supports the diffusion of blood and body fluids and the entry of osteogenic cells as well as the ingrowth of bone into the synthetic matrix. The interconnecting pore system ensures progressive angiogenesis and vascularization so that the cells are actively supplied throughout the regeneration process.



CERASORB® M - *for shorter resorption times*

The micro, meso and macropore structure promotes a rapid ingrowth of local bone and accelerates resorption. Its high porosity boosts its capillary effect. Thanks to the rapid entry of osteogenic elements and blood, the cells are well supplied and resorption is enhanced - both from without and from within. Pore interconnectivity is a major contributor of rapid resorption. As the bulk density of CERASORB® M is low and the resultant total porosity is high, less space making material is needed at the site with less material to be resorbed by the body.

l bone defects



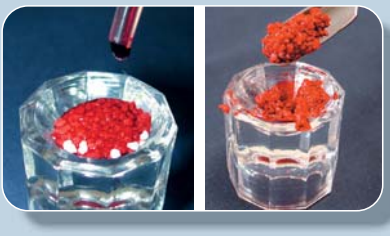
CERASORB® M - *for more site stability*

The polygonal granule structure facilitates wedging and interdigitation of the CERASORB® M granules at the site. This enhances mechanical stability and largely rules out micromotions.



CERASORB® M - *for easy and safe handling*

CERASORB® M comes in different granule sizes. This makes it an ideal grafting material for different needs. In dentistry it has a place in implant treatment and for filling voids left by apicectomies, cystectomies, osteotomies for bite correction and surgical removal of non-erupted teeth. Mixed with autogenous blood, the granular material is easily applied.



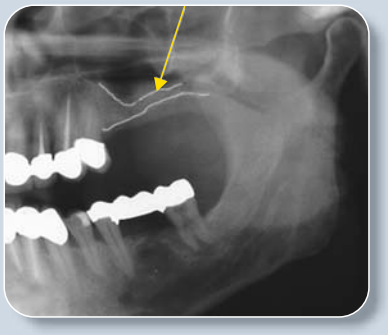
CERASORB® M - *for higher patient acceptance*

Thanks to its synthetic origin and ease of handling, CERASORB® M is readily accepted by the patients.
In addition, it saves time: When using CERASORB® M the potential risks of infection and allergic reactions known from materials of biologic origin need not be addressed during patient information.

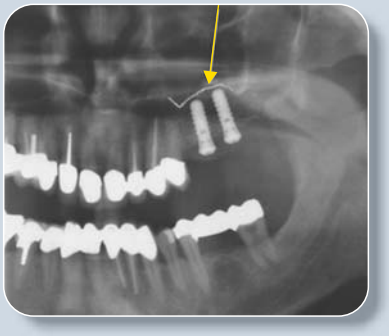


Clinical applications, resorption times and recommended uses

Case # 1



Baseline view: Atrophic maxilla after loss of teeth 25 - 27. Bone density D3



View 6 months post sinus floor elevation with CERASORB® M and simultaneous implant placement.

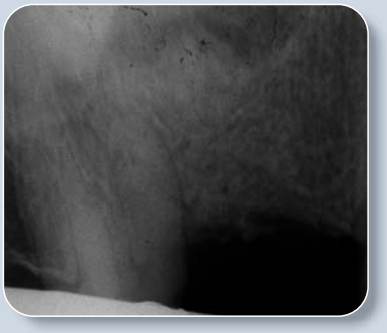
Case # 2



Baseline view, tooth extraction on 06/12/2003



Postoperative view after alveolar ridge preservation with CERASORB® M and PRP on 02/11/2004



View 6 months after grafting (August 2004)



OPG post implant placement on 11/22/2004

CERASORB® M	Defect size	Resorption time
	< 1.5 cm^3	3 - 6 months
	1.5 - 2.5 cm^3	6 - 9 months
	> 2.5 cm^3	6 - 12 months

Indications	CERASORB®- products	Granule size
Periodontal defects	CERASORB® PERIO	63 - 250 µm / 250 - 500 µm
	CERASORB® CLASSIC	50 - 150 µm / 150 - 500 µm
Apicectomies	CERASORB® CLASSIC und CERASORB® M	150 - 500 µm / 500 - 1000 µm
Extraction sockets	CERASORB® CLASSIC und CERASORB® M	500 - 1000 µm
Cystectomies	CERASORB® CLASSIC und CERASORB® M	500 - 1000 µm / 1000 - 2000 µm
Sinus floor elevation	CERASORB® CLASSIC	500 - 1000 µm / 1000 - 2000 µm
	CERASORB® M	500 - 1000 µm / 1000 - 2000 µm
Filling of peri-implant voids	CERASORB® CLASSIC und CERASORB® M	150 - 500 µm / ggf. 500 - 1000 µm at molar sites, if needed
Most widely used sizes	CERASORB® CLASSIC	500 - 1000 µm
	CERASORB® M	500 - 1000 µm und 1000 - 2000 µm

CERASORB® M the safe implant for easy and unproblematic grafting



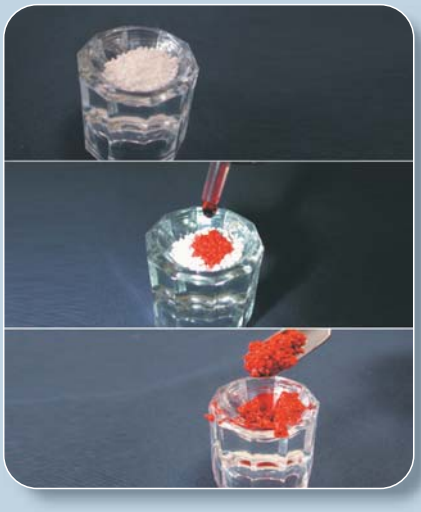
The high quality of CERASORB® M - guarantees users maximal safety.

CERASORB® M is gamma-sterilized and delivered in stable sterile blister packs.

Color-coded vial caps help to select the right granule size.

Caps are easily opened by turning.





For optimal results with CERASORB® M follow the instructions below:

1. Clear the site of bone debris and necrotic tissue before applying CERASORB® M.
2. Freshen the bone at the site thoroughly.
3. Mix CERASORB® M with autogenous blood from the site before applying it.
4. Add PRP after admixing autogenous blood, if indicated.
5. Completely fill the defect with granules. CERASORB® M should make direct contact with vital bone. Avoid excessive condensation or destruction of the granules.
6. Go by the defect size and indication for deciding on membrane coverage.

CERASORB® M	Granule size	How supplied	Product no.	Color code
	150 - 500 µm	5 vials of 0.5 cc each	6000000	
	500 - 1000 µm	5 vials of 0.5 cc each 5 vials of 1.0 cc each 5 vials of 2.0 cc each	6000001 6000011 6000021	
	1000 - 2000 µm	5 vials of 0.5 cc each 5 vials of 1.0 cc each 5 vials of 2.0 cc each	6000002 6000012 6000022	

We are indebted to Professor Dr. Dr. Frank Palm, Klinikum Konstanz, Dr. Achim Schmidt, Munich, and Mr. Dieter Bilk, dentist, for X-rays and clinical photographs.

Typographical and other errors reserved.

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Distributed by:
RIEMSER Arzneimittel AG | An der Wiek 7 | 17493 Greifswald - Insel Riems

CERASORB® - one million units in 12 years.

Thank you for your trust!



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