BioCer
Entwicklungs-GmbH

Innovative Medical Devices

Made in Germany

Contents

BioCer

Table of Content

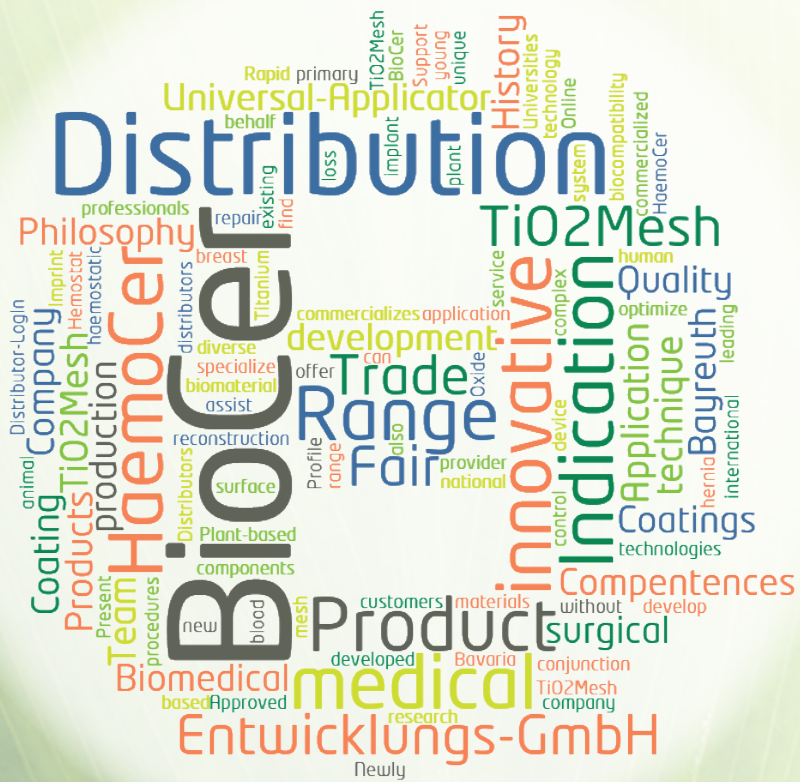
BioCer

Company Profile

BioCer Entwicklungs-GmbH is a young and innovative medical device company located in Bayreuth, Bavaria. We are specialized in research, development and production of innovative medical biomaterial products without animal or human components. Being a service provider, we offer innovative coating systems for existing implant systems and also develop new medical products for our customers.

BioCer Entwicklungs-GmbH commercializes innovative technologies developed in conjunction with leading national and international universities.

BioCer's primary scope is the development and production of plant based haemostatic materials, in order to assist medical professionals in the control of blood loss in a diverse range of complex surgical procedures. BioCer has also commercialized a unique advanced surface coating system made of titanium oxide, in order to improve the biocompatibility of surgical meshes for application in hernia repair and breast reconstruction.



History

BioCer

History of BioCer

1998
- BioCer Entwicklungs-GmbH was founded as a privately financed research company

2003
- Close cooperation with University of Bayreuth

2009
- Reorientation of BioCer
- Certification of our development department according to DIN EN ISO 13485
- Start-up as a medical device manufacturer

2010
- Clean Room Production compliance with DIN EN ISO 13485
- CE approval for HaemoCer™ and TiO2Mesh™
- Market entry: Germany, Europe and Asia

2012
- CE approval for HaemoCer™ Universal Applicator

2013
- Product innovation: HaemoCer™ PLUS
- CE approval for TiO2Mesh BRA
- Other approvals world wide (Asia, Africa, USA, South America)

2014
- Market entry: China

2018
- CE approval for HaemoCer™ PATCH
- CE approval for HaemoCer™ Flex Applicator

2019
- Implementation of HaemoCer™ Universal SET, HaemoCer™ Flex SET
- CE approval for TiO2Mesh™ light, TiO2Mesh™ BRA light

2020
- CE approval for HaemoCer™ Endoscopic Applicator and implementation of HaemoCer™ Endoscopic SET

BioCer

Competences & Expertise

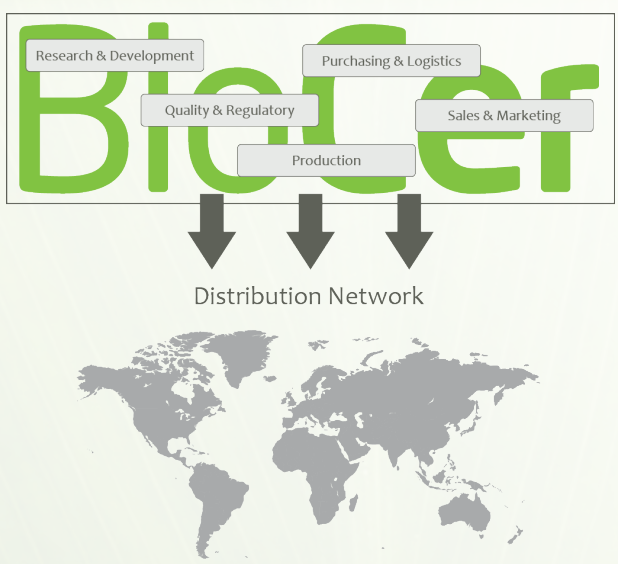
We cover the entire process chain, reaching from developing novel biomaterials, over implementing them in implants and medical devices, to producing and distributing medical devices by means of our global and committed distribution network. For that matter, we made effective cooperation and support of our customers our first priority. We are always looking for new markets and successful distributors.

In order to achieve total customer satisfaction now and in the future, we need to know the requirements of our customers. For this purpose, we collaborate closely with medical practitioners, renowned universities, research institutes and stay in touch with other manufacturers of medical devices. Our work is focused on results and we achieve our goals on schedule. We always seek to exceed our customers' expectations.

„Innovative Medical Devices – Made in Germany"

Medical practitioners can absolutely trust in our knowhow and a high level of innovation. BioCer Entwicklungs-GmbH offers medical devices that are state of the art and beyond. By means of our novel and safe products we both support physicians and patients in healing as well as in the restoration of health.

Our aim is to improve our patients' quality of life on a sustainable basis.



BioCer

Team & Quality Standards

Our employees are the most valuable asset of BioCer Entwicklungs-GmbH. They strongly contribute to the worldwide success, because of their high competence and full commitment. Therefore, satisfied employees are just as important to us as business results.

Relying on team performance and mutual appreciation, the BioCer-Team identifies with there company and feels comfortable at work.

All employees are aware that: “We are responsible for our work area and the quality of the products. We are a part of the success of BioCer!”

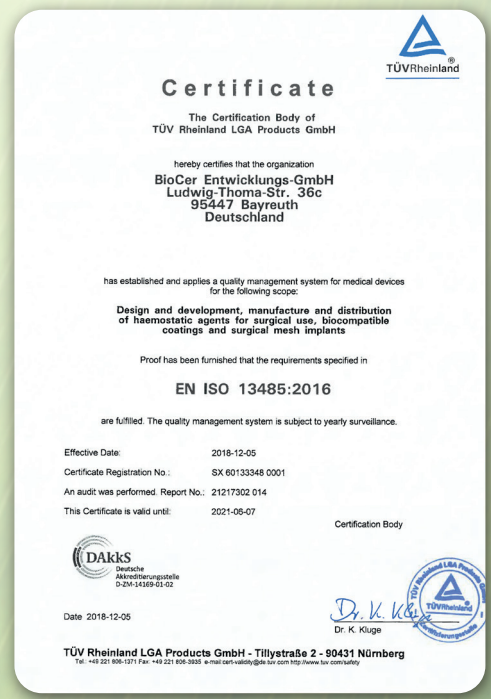
Team BioCer and the associated processes are guided and directed by a high-quality management system, therefore continuous improvement of the organization’s overall performance is a main objective.

As a developer and manufacturer of medical products, we are always aware of our product stewardship.

To us, quality means to develop and to produce at a high level of security, thus living up to the requirements of both medical practitioners and patients.

Our quality management system ensures the implementation of our quality standards and is the basis of our daily work. Therefore, any organizational, commercial and technical occupations that affect quality are planned, controlled and monitored.

All of our products meet the requirements of the directive MDD 93/42/EWG and the standard EN ISO 13485, as well as additional international standards.



TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BioCer Entwicklungs-GmbH
Ludwig-Thoma-Str. 36c
95447 Bayreuth
Deutschland

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacture and distribution of haemostatic agents for surgical use, biocompatible coatings and surgical mesh implants

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-12-05
Certificate Registration No.: SX 60133348 0001
An audit was performed. Report No.: 21217302 014
This Certificate is valid until: 2021-06-07

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date 2018-12-05

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

BioCer

HaemoCer™ PLUS

Haemostasis

HaemoCer™ PLUS is a resorbable plant based haemostatic powder containing no animal nor human components. Haemostasis occurs by rapidly accelerating the normal physiologic clotting cascade without participation of chemical or pharmaceutical ingredients.

Once in contact with blood, HaemoCer™ PLUS enhances the natural clotting cascade by rapidly dehydrating the blood and accelerating the concentration of platelets, red blood cells and coagulation proteins at the bleeding site. The second mode of action of HaemoCer™ PLUS is the formation of a robust gelled matrix that adheres to the bleeding site and forms a mechanical barrier to prevent further bleeding.

HaemoCer™ PLUS is rapidly resorbed by amylase within a few days without leaving any residues behind, depending on the amount of used material and the place of application.

HaemoCer™ PLUS

BioCer

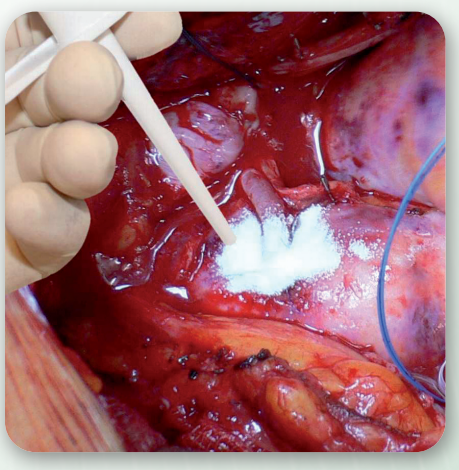
HaemoCer™ PLUS

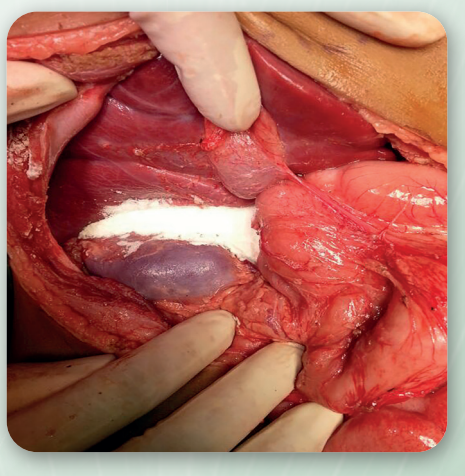
Fields of application:

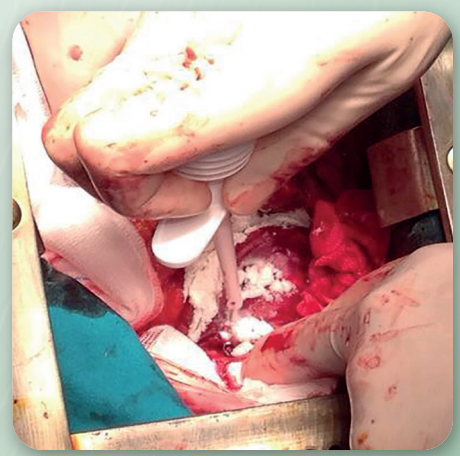
- Cardiac, Vascular and Thoracic Surgery
- General Surgery
- Transplant Surgery
- Traumatology
- Tumour Surgery
- Oral and Maxillofacial Surgery
- ENT Surgery
- Urology / Gynaecology
- Orthopaedics
- Burn Surgery
- Neurosurgery

HaemoCer™ PLUS - versatile use:

- Treatment of diffuse and localized bleeding
- For bleeding around suture lines
- Substitution of fibrin glue for haemostasis in vascular surgery
- Substitution of bone wax in bone bleeding
- Also usable with compatible filter cell-savers







BioCer

HaemoCer™ PLUS

Adhesion Prevention Barrier

Adhesions are scar tissue that can form after inflammations, surgical interventions or tumor diseases. This results in fan- or strand-like adhesions between organs or tissue surfaces in the abdominal cavity that are normally not connected to each other. Adhesions are usually caused by injury to the delicate organ membranes during surgery. Local inflammation also occurs with minute injuries or merely trauma to organs.

To build up the adhesion barrier, the powder is applied generously to the tissue to be protected and then moistened with sterile water or a saline solution. The HaemoCer™ PLUS powder absorbs the liquid and transforms into a protective gel layer. This barrier prevents contact with other tissue during the postoperative healing process.

This adhesion barrier can be created in both open and minimally invasive procedures. For this purpose, we have various HaemoCer™ applicators in our portfolio.

BioCer

HaemoCer™ PLUS

100% resorbable

Plant based

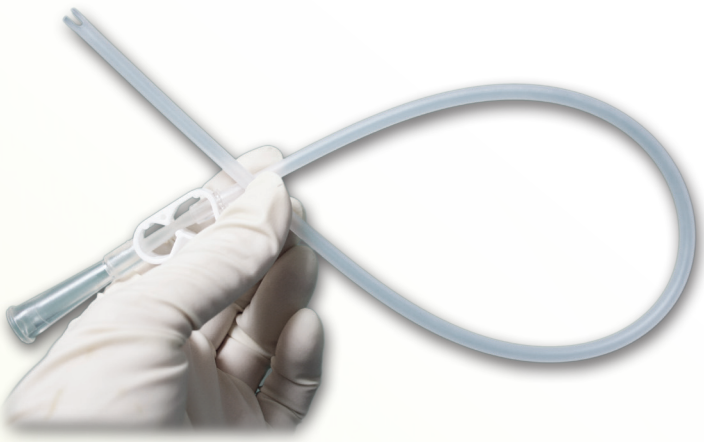
Product Overview HaemoCer™ PLUS		
HFP201	1g	5 pcs
HFP202	2g	5 pcs
HFP203	3g	5 pcs
HFP205	5g	5 pcs

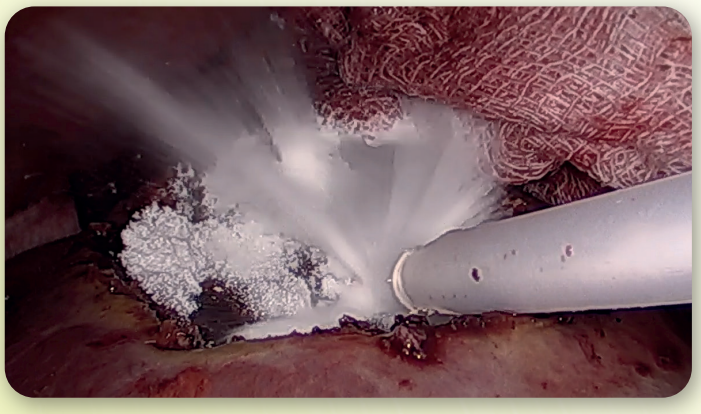
HaemoCer™ PLUS

BioCer

HaemoCer™ Universal Applicator

HaemoCer™ Universal Applicator is designed to deliver the haemostatic HaemoCer™ powder in laparoscopic, ENT, spinal and other MIS procedures. It guarantees precise application of APH particles to the bleeding site where this is mandatory. The delivery instrument can be easily attached to the HaemoCer™ or HaemoCer™ PLUS bellows dispenser and enables hemostat delivery under direction to the wound site for the control of capillary, venous and arteriole bleeding.





- Application in minimally invasive surgical procedures
- Longer applicator for deeper sourced bleeding
- Innovative applicator tip features a design which minimizes risks of blockage in case of contact with moisture
- One hand operated press-and-release locking system facilitating Universal Applicator tip placement without uncontrolled discharge
- Highly flexible enabling precise tip placement and offering enhanced handling and maximizing wound coverage capability
- Push-on coupling sheath offering simple and firm connection to HaemoCer™ or HaemoCer™ PLUS

HaemoCer™
Universal Applicator

Product overview HaemoCer™ Universal Applicator		
HFZ101	440 mm	5 pcs

HaemoCer™ Universal SET

Product Overview HaemoCer™ Universal Set		
HFS115	HaemoCer™ 5g (HFP105) + 440 mm Applicator (HFZ101)	1 pcs
HFS125	HaemoCer™ PLUS 5g (HFP205) + 440 mm Applicator (HFZ101)	1 pcs

BioCer

HaemoCer™ FlexApplicator

HaemoCer™ FlexApplicator is an accessory for our HaemoCer™ powder product line with standard applicator and can be installed easily. Because of its integrated wire, the HaemoCer™ FlexApplicator is bendable in different directions and still dimensionally stable. HaemoCer™ or HaemoCer™ PLUS can be used at blind spots and complex challenging situses. HaemoCer™ FlexApplicator provides high flexibility and ensures a controlled and pinpoint dosage. A special rounded applicator tip prevents surgical lesions during application.

- A simple plug mechanism for fast and firm connection to our HaemoCer™ powder product line with standard applicator
- Longer applicator for bleeding sites that are difficult to access
- HaemoCer™ FlexApplicator is bendable at several points at the same time and dimensionally stable to reach even difficult surgical sites.
- The transparency of the applicator enables a clear view to the amount of HaemoCer™ powder applied, therefore a controlled and pinpointed application is guaranteed
- Even after multiple bendings the powder freely flows through the applicator
- Atraumatic applicator tip prevents surgical lesions

Product Overview HaemoCer™ FlexApplicator		
HFZ201	180 mm	5 pcs

HaemoCer™
FlexApplicator

HaemoCer™ Flex SET

Product Overview HaemoCer™ Flex Set		
HFS215	HaemoCer™ 5g (HFP105) + 180 mm Applicator (HFZ201)	1 pcs
HFS225	HaemoCer™ PLUS 5g (HFP205) + 180 mm Applicator (HFZ201)	1 pcs

BioCer

HaemoCer™ Endoscopic Applicator

HaemoCer™ Endoscopic Applicator is used to apply HaemoCer ™ PLUS for treatment of upper and lower gastrointestinal bleedings. The applicator has a tube length of 2400 mm, an outer tube diameter of 2.5 mm and a pump ball as a pneumatic source. Additionally, it has a built-in HEPA (High Efficiency Particulate Air) filter for filtering ambient air.

This applicator needs no handling devices (air compressor etc.) and enables a simple and uncomplicated use.

The innovative HaemoCer™ Endoscopic Applicator enables the application of HaemoCer™ PLUS resorbable powder directly through the working channel of a standard endoscope.
The application tube is inserted through the instrument channel and positioned to the bleeding. The compressed air flow generated by the pump ball transports the powder directly to the bleeding site.
This system serves as a complementary haemostatic device to control capillary, venous and arteriolar bleedings in upper and lower gastrointestinal tract. It is especially suitable for seeping haemorrhage, but also in cases where conventional haemostasis can not be used.

HaemoCer™
Endoscopic Applicator

- Usable instrument channel: 2.8 mm and above
- Direct and precise application to the bleeding site
- Application under endoscopical sight

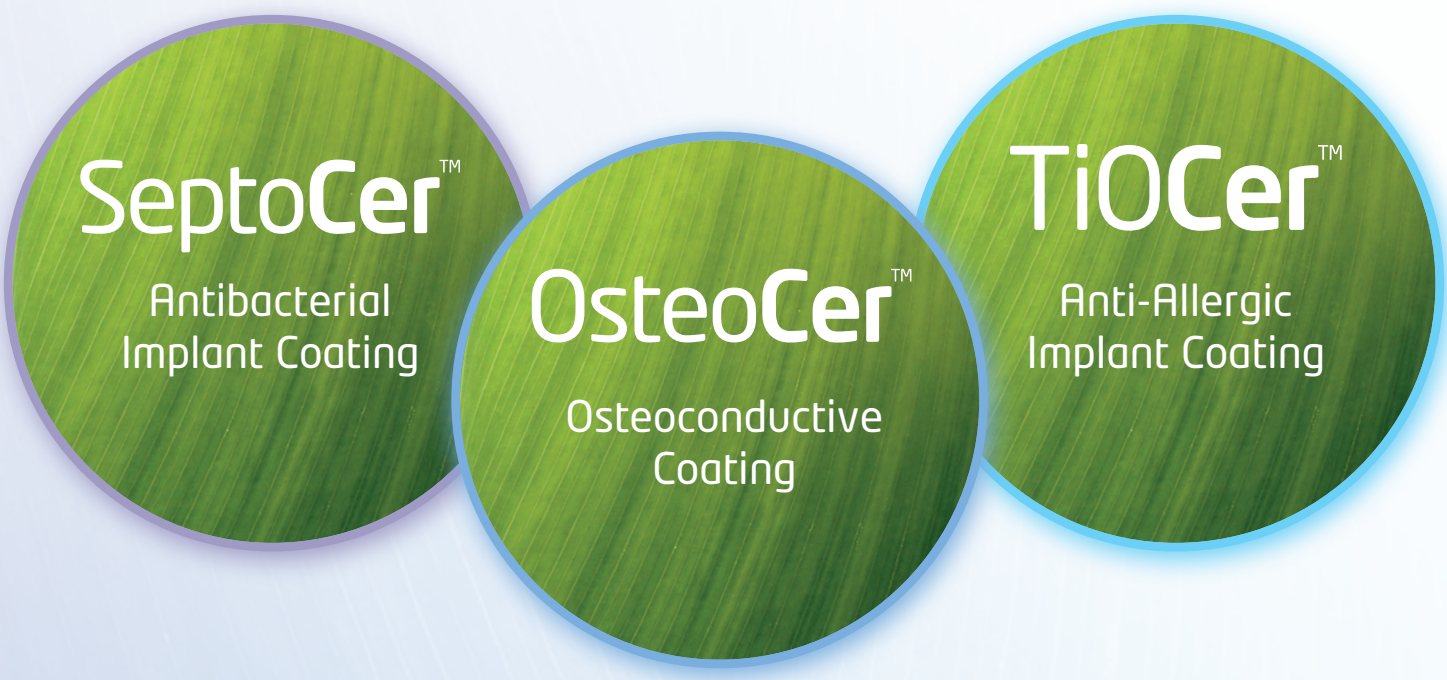
HaemoCer™ Endoscopic SET

Product Overview HaemoCer™ Endoscopic Set		
HFS323	HaemoCer™ PLUS 3 g (HFP203) + Endoscopic Applicator (HFZ103)	1 pcs

BioCer

Coating Technology

At BioCer Entwicklungs-GmbH our interdisciplinary team combines its broad knowledge and experience to build up innovative ideas for medical technologies. Therefore, we cooperate with renowned scientists and physicians to create and realize new concepts for specific modifications of implant surfaces with sophisticated ceramic coatings. By applying coatings with a thickness of only a few nanometers we generate biocompatible, anti-allergic, osteoconductive or antibacterial properties or even combinations thereof. The concepts offer new opportunities for therapies and improve the safety for patients and surgeons.

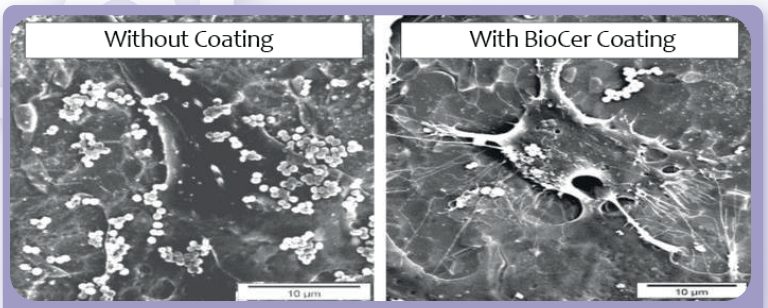


The coatings are based on the principle of the sol-gel-technique. A cost-efficient dip- or spray-coating process is carried out via a solution of organic solvents and organometallic compounds. During subsequent drying, a polymer-like layer is formed on the material. This layer is converted by thermal treatment into a ceramic layer. The functional modification is obtained by the coating material itself or the homogeneous incorporation of active fillers into the coating solution.

BioCer

Coating Technology

Despite its antibacterial effect, **SeptoCer™** provides a high biocompatibility and encourages an improved ingrowth behavior. The coating is functionalized by metal ions. By release of these ions into the body, an antibacterial effect is generated. SeptoCer™ is also effective against formation of bacterial biofilm. Therefore the risk of a late loosening of implants is widely reduced.



Comparison of bacterial colonization (white balls) between standard implant surfaces (left) and antibacterially modified material of BioCer Entwicklungs-GmbH (right) in co-culture.

A zirconium dental implant with an osteoconductive (bone growth promoting) coating - OsteoCer™ from BioCer Entwicklungs-GmbH (The presented materials are demonstrators only)

OsteoCer™ coating system is designed for ceramic implant materials but also for all kinds of implant alloys that are commonly in orthopedic surgery. The implant surface is masked by the improved biocompatible titanium oxide, which is an advantage in many fields of medical applications. At the same time, incorporated calcium ions are released to achieve faster bone ingrowth.

TiOCer™ is a ceramic like titanium oxide coating, which reduces the leaching of metal ions – like cobalt or chrome – out of the implant surfaces. Currently, the TiOCer™ coating is in use to improve the biocompatibility of the TiO_2Mesh™ surgical mesh implants produced and distributed by BioCer Entwicklungs-GmbH, Germany.

Implant samples coated with anti-bacterial and/or anti-allergic TiOCer™ - compared to a human femur (The presented materials are demonstrators only).

Titanium-oxide coating
The coating with titanium oxide improves the integration of implant materials into the human body.

BioCer

TiO_2Mesh^{TM} I TiO_2Mesh^{TM} light

TiO_2Mesh^{TM} is a surgical mesh implant specially indicated for repair of soft tissue defects of the abdominal wall, where a non-absorbable support material is required. Relevant applications include the repair of inguinal and incisional hernias in all common surgical procedures and even IPOM.

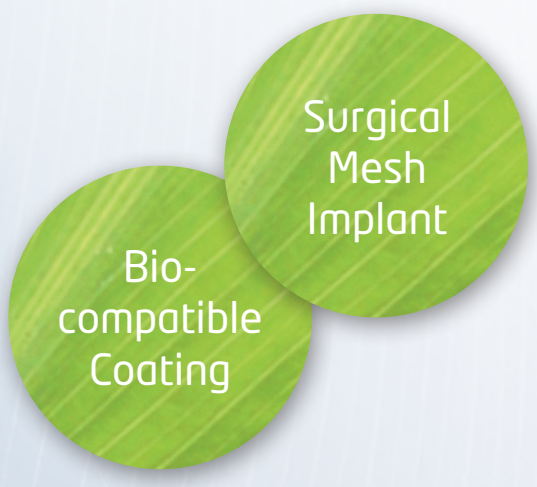
TiO_2Mesh^{TM} is made from a monofilament polypropylene thread and has a large-pored structure with blue orientation stripes. The single fibers of the mesh implants are completely covered by a high-purity and adherent titanium oxide surface coating to enhance the biocompatibility. This layer results in an excellent biocompatibility.

In combination with the lightweight character, the large-pored structure and the reduced material surface lead to improved fibroblastic ingrowth and reduced shrinkage.

TiO_2Mesh^{TM} is highly flexible to react to body dynamics in terms of tensile strength and elasticity. The optimized pore structure results in a biodynamic stress strain behavior.

TiO_2Mesh^{TM} has lasercut edges with blunt fiber ends to reduce micro traumata, irritation and penetration into vessels and nerves.

Customized mesh implants according to the surgeons requirements complete the product portfolio of TiO_2Mesh^{TM}.



FDA CLEARED

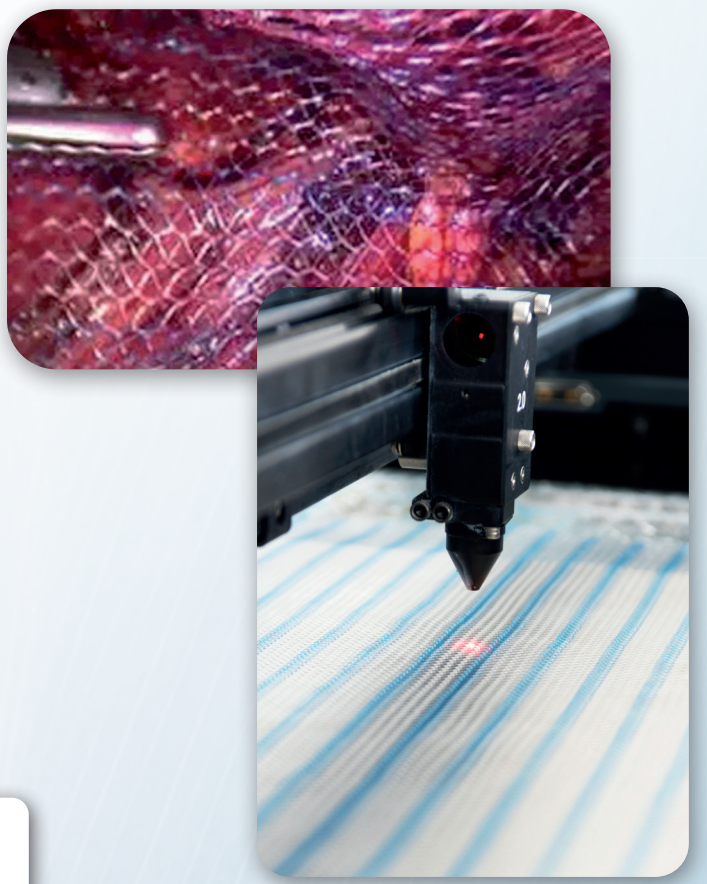
TiO_2Mesh^{TM}

47 g/m²

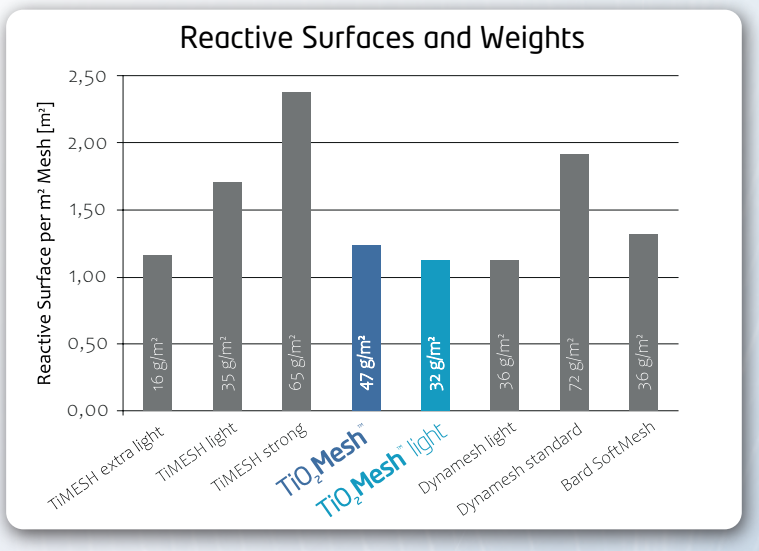
BioCer

TiO_2Mesh™ I TiO_2Mesh™ light

A lighter version of the TiO_2Mesh™ is the TiO_2Mesh™ light. It differs in knitting and has a lower reactive surface.



- The advantages at a glance:
- Lightweight character with 32 g/m² and an extreme low reactive surface
- High tensile strength with 50 N/cm
- Is trimmable in all directions
- Ideal handling in laparoscopic (e.g. TAPP and TEP), IPOM and open procedures
- Solutions for the treatment of inguinal, umbilical and femoral hernias
- Is suitable for all ventral hernias



Less is more!

Dynamic due to unique design

TiO_2Mesh™ light

32 g/m²

BioCer

TiO_2Mesh™ BRA I TiO_2Mesh™ BRA light

TiO_2Mesh™ BRA is a surgical mesh implant for the support, reinforcement and bridging of the body's own tissue in reconstructive and medically indicated plastic-aesthetic breast surgery.

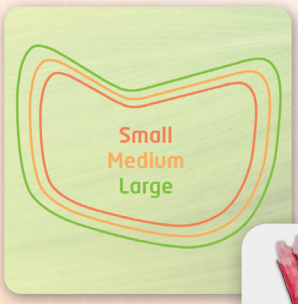
TiO_2Mesh™ BRA can be stretched in both directions and is perfectly aligned with the dynamics of human body tissue in terms of elasticity.

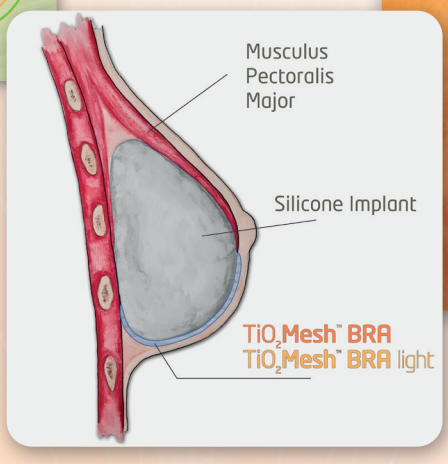
TiO_2Mesh™ BRA is available in different sizes.

Product Overview
TiO_2Mesh™ BRA + TiO_2Mesh™ BRA light

MFP511 MFP611	Small Light Small	13 x 19,5 cm (5.1´´ x 7.7´´)	1 pcs
MFP512 MFP612	Medium Light Medium	15 x 22 cm (6´´ x 8.7´´)	1 pcs
MFP513 MFP613	Large Light Large	17 x 23 cm (6.7´´ x 9´´)	1 pcs

- Titanium oxide coating for excellent biocompatibility
- Large-pored mesh structure for improved fibroblastic ingrowth
- Monofilament polypropylene fibers
- Hydrophilic surface supports connective tissue attachment
- Minimized shrinkage and reduced foreign body reactions
- Light weight character with a grammage of only 47 g/m² or 32 g/m² combined with a high tensile strength
- Biodynamic stress strain behavior for good tissue integration
- Lasercut edges





Imprint

Design, Concept, Texts
BioCer Entwicklungs-GmbH

Pictures
In-house production
Studio Thomas Köhler
Olgemöller Studios
Shutterstock
Adobe Stock

BioCer

BioCer

BioCer Entwicklungs-GmbH
Ludwig-Thoma-Straße 36c
95447 Bayreuth / Germany
Tel: +49 (0)921 787770-0
Fax: +49 (0)921 787770-79

info@biocer-gmbh.de
www.biocer-gmbh.de

ADD102.06/2021-09