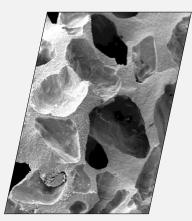
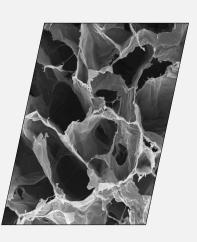


# Regeneration















Bone substitute material

Collagen fleece



# What happens after tooth loss?

## Bone resorption at 30 to 45 years

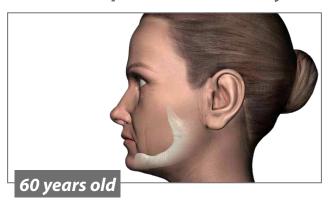


*Initial situation: All teeth are present and the bone volume is stable* 



Loss of first teeth in the molar range: Significant bone resorption occurs after a short time

### Bone resorption at 60 to 75 years



The loss of more teeth in the front aggravates this further



If there is still no load on the alveolar ridge, the jawbone continues to resorb

## **Presentation of problem**

#### From a clinical perspective

Untreated extraction sites and bone defects make it difficult or even impossible at a later stage to provide an affected patient with implant therapy. Instead, expensive surgical procedures are a threat and the risk of additional complications increases.

#### From an aesthetic perspective

Loss of volume in the cheekbones, decreasing soft tissue and less support of the lips result in aesthetic changes of the facial areas and make the patient age visibly faster.

#### Problem regarding the success of therapy

It is important to promptly respond after tooth extraction and bone trauma. If the practitioner waits too long, in the worst case, this results in additional, complex treatment steps, in order to be able to carry out an implantological treatment. These measures that are often preventable not only increase the risk of therapy, but also the costs. Many patients fear these risks.

# Regeneration with **TIXXU**





With the components of the TIXXU therapy, which consists of the TIXXU CONTROL membrane, the TIXXU GRAFT bone substitute material and the TIXXU PROTECT collagen fleece, we provide you with materials to prevent bone loss after extractions. In addition, the carefully matched components help bone regeneration and remodelling of the inserted bone substitute material.

In combination with the HELBO® therapy, you additionally ensure the surgical procedure. The HELBO® process effectively controls bacteria, restores the natural balance in the oral cavity and therefore results in a significant reduction of complications. This has been scientifically proven by numerous studies and specialist articles.

With a combination of these measures, you create optimal conditions for healing the subsequently inserted implants and increase their long-term stability.



# Benefits for you and your patients

#### You preserve the bone

You can start implant therapy in a timely manner and quickly take care of the patient.

This increases patient satisfaction and boosts the success of the practice.



#### You preserve the soft tissue

Give your patients back their face shape and therefore their beautiful smile – they will recommend you.

#### You save on treatment time and costs

With TIXXU, you have a reliable solution that can help you to avoid costly and lengthy bone reconstruction procedures in the future. In the time that you gain you can concentrate on restoring the chewing function and on aesthetics.



# Collagen fleece

## **Characteristics**

Name TIXXU PROTECT collagen fleece

Material Porcine Dermis

Indication Socket Preservation

Resorption approx. 4 weeks

Size 20 mm x 20 mm

REF TIPR2020

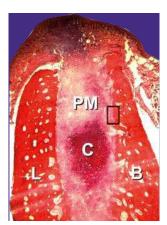


# **Socket Preservation**

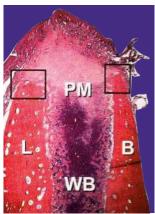
Various scientific studies have revealed that

- bone resorption already begins within a few weeks after extraction of a tooth
- the vestibular bone lamella is particularly affected
- this bone reduction is reducible through the use of various materials for socket preservation
- as a rule, however, the healing process is partially prolonged, since the complete rebuilding of the substitute materials can take time

#### Bone absorption following dental extraction







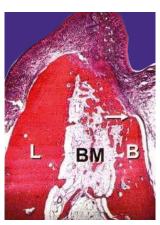
After 2 weeks

The careful extraction with **preservation of the alveolus and the buccal bone lamella** create optimal conditions for the implant restoration. Particularly large-scale osteotomies during extractions or defects mean that complex and expensive augmentations are necessary.

TIXXU PROTECT is a highly biocompatible, rapidly absorbable collagen made of porcine dermis that stabilises the alveolus and supports the buccal lamella. In conjunction with the HELBO® therapy, you additionally ensure the procedure and subsequent implant restoration by significantly reducing the complication rate. This means that patients are taken care of, the risk is minimised by additional procedures and therapy costs are reduced.



After 4 weeks

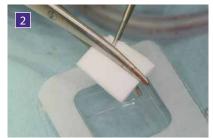


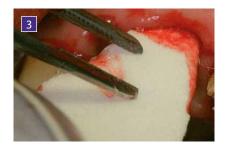
After 8 weeks

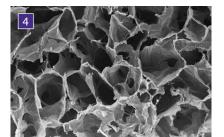
Dimensional ridge alterations following tooth extraction. An experimental study in the dog. Araujo et al., J Clin Periodontol 32: 212-218 (2005)

# Collagen fleece for socket preservation



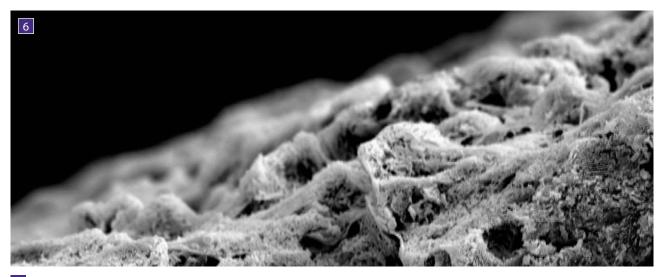








- 1 TIXXU PROTECT collagen fleece
- 2 Cutting of TIXXU PROTECT
- 3 Soaks up wound blood like a sponge
- 4 REM image TIXXU PROTECT (magnification 300x)
- 5 Also suitable for covering augmentations



6 Figure shows an enlarged image of the newly formed bone

#### **Properties**

Hemostatic agent with short-term barrier function, i. e. TIXXU PROTECT

- encourages clot formation of the blood
- stabilises the blood coagulum
- counteracts wound contraction
- protects the wound for approx. 2-4 weeks
- is superficially epithelialised
- encourages new bone formation
- is entirely reabsorbed

## **Processing**

TIXXU PROTECT is easily processed

- depending on the indication, the thickness of TIXXU
   PROTECT is adjustable by moisturising and compression
- is easily cut to the desired size
- absorbs wound blood like a sponge
- is structurally stable, pliable and adapts to its surroundings
- remains location and volume stable after application
- a plastic covering of the alveole is not required

# Clinical case



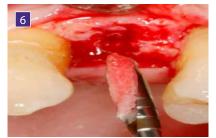


- 1 Use of TIXXU PROTECT collagen fleece
- 2 Atraumatic tooth extraction with subsequent disinfection with HELBO®, after which TIXXU PROTECT collagen fleece is inserted directly into the alveolus
- 3 Wound closure
- 4 Suture removal after 1 week
- 5 Reopening after 8 weeks shows stable bone conditions
- 6 Drill protocol
- 7 Implant insertion
- 8 + 9 Wound closure
- 10 X-ray control

















#### **Benefits**

- TIXXU PROTECT is an ideal frame for the adsorption of thrombocytes, fibroblasts and osteoblasts
- It encourages coagulum formation, as contact with blood leads to an aggregation of thrombocytes
- Due to its high hydrophilic properties and interconnective porosities, TIXXU PROTECT absorbs blood quickly
- The vestibular bone lamella of the extraction alveole is supported
- TIXXU PROTECT is pH-neutral and exerts a positive effect on soft tissue reactions

#### Indications at a glance

- haemostyptic wound care of the extraction alveolus
- reduction of bleeding and secondary bleeding
- tissue regeneration of the extraction alveolus (socket preservation)
- avoidance of wound infection after tooth extraction
- protection of Schneider's membrane from perforation
- biopsy sampling points
- oral wounds
- minor bone defects
- soft tissue dehiscences
- promote wound healing and support tissue regeneration

Clinical images: Dr. Neugebauer, Germany



# Bone substitute material

## **Characteristics**

Name TIXXU GRAFT

Material Synthetic 60% Hydroxyapatite (HA)

40% β-Tricalcium Phosphate (β-TCP)

Indication Bone substitute material

Variants As granules or as putty

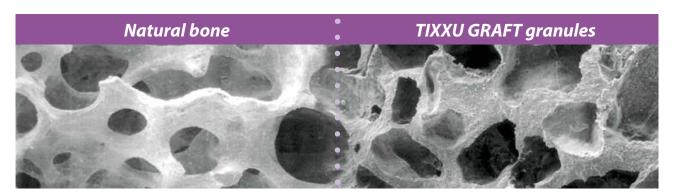
(hydrogel-based)

REF TX0401G50, TX9901G01, TX0302G01,

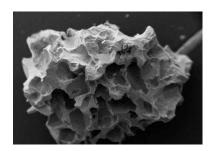


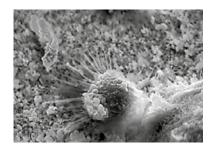
# TIXXU GRAFT Materials from MBCP™ TECHNOLOGY

The micro-macroporous biphasic calcium phosphate mimics the structure of a natural bone.



**Biomimetic surface** 





Safe solution - biocompatible - Synthetic

## **TIXXU GRAFT Granules and Putty**

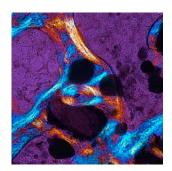
Advantage	Clinical benefit
Osteoconductive, osteogenic	Provides a framework for new bone growth, gives commands for mineralisation and osteogenic cell differentiation
Molecular mixture of: 60% HA and 40% β-TCP	HA alone resorbs too slowly, while $\beta\text{-TCP}$ resorbs too quickly. Biphasic HA and $\beta\text{-TCP}$ provide a resorption rate that is similar to human bone
70% porosity, network of macropores and micropores	The porosity is comparable to that of cancellous bone, it allows the uniform colonisation of bone cells and the formation of biological fluid within the matrix. The right compromise for initial mechanical properties and resorption kinetics
Macroporosity (> 100 micrometres)	Allows deep penetration of bone cells into the matrix
Microporosity (<10 micrometres)	For ion exchange: $\beta\text{-TCP}$ dissolution and bone crystal precipitation New bioactive interface to bone cells
> 30 years of clinical background	Host bone formation in place of the MBCP is systematically detected
Safe	Synthetic with long shelf life: granules, 5 years – putty, 3 years
Easy to use	Available as granules or as putty

Manufacturer: BIOMATLANTE SA

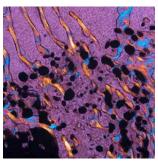
For more information about the MBCP Technology, please visit https://biomatlante.com/en/technology



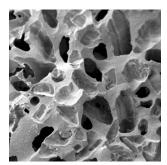
## Ideal bone substitute



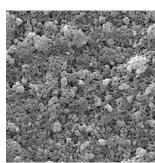




Slow and gradual biodegradation by biodissolution + bioresorption



Macroporous



Microporous

The black colour represents BCP granules – the blue / yellow colours represent newly formed bone

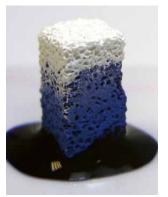
For cell colonisation and osteoconduction

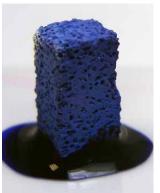
So that biological fluids can spread through the framework

## Fully permeable matrix











< 2 min

#### Literature

- 1. Daculsi G, Laboux O, Malard O, Weiss P. Current state of the art of biphasic calcium phosphate bioceramics. J Mater Sci Mater Med. (2003) Mar;14(3):195-200
- 2. Daculsi G., LeGeros R. Z, Grimandi G., Soueidan A., Aguado E., Goyenvalle E., LeGeros J., Effect of Sintering Process of HA/TCP Bioceramics on Microstructure, Dissolution, Cell Proliferation and Bone Ingrowth, Key Engineering materials Vols 361-363 (2008) pp1139-1142
- 3. Changseong K., Sung Cho K., Daculsi C., Seris E., Daculsi G., Eight-Year Clinical Follow-Up of Sinus Grafts with Micro-Macroporous Biphasic Calcium Phosphate Granules, Key Engineering Materials Vol. 587 (2014) pp 321-324
- 4. Rodriguez C., Jean A., Daculsi G., Five Years Clinical Follow up Bone Regeneration with CaP Bioceramics, Key Engineering Materials Vols. 361-363 (2008) pp. 1339-1342
- 5. Daculsi G., Jegoux F. and Layrolle P., The micro macroporous biphasic calcium phosphate concept for bone reconstruction and tissue engineering. in Advanced Biomaterials: Fundamentals, Processing, and Applications book, Basu B. et al., Wiley J. and sons Inc., (2009) pp 101-141
- 6. Fellah B., Gauthier O., Weiss P., Chappard, D. Layrolle P., Osteogenicity of biphasic calcium phosphate ceramics and bone autograft in a goat model, Biomaterials 29 (2008) 1177-1188
- 7. Lee JH, Jung UW, Kim CS, Choi SH, Cho KS., Histologic and clinical evaluation for maxillary sinus augmentation using macroporous biphasic calcium phosphate in human, Clin Oral Implants Res. (2008) Aug;19(8):767-71.
- 8. Daculsi G., Layrolle P., Osteoinductive properties of Micro Macroporous biphasic calcium phosphate bioceramics., Key Engineering Materials (2004);254-256:1005-8.

Manufacturer: BIOMATLANTE SA

# TIXXU GRAFT bone substitute-putty

## **Description**

TIXXU GRAFT is not only available as granules, but also in a gel variant (putty).

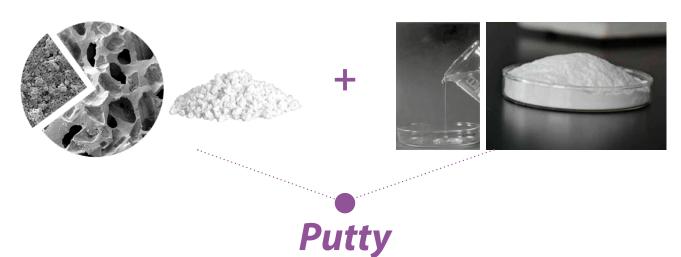
TIXXU GRAFT putty is a malleable and injectable synthetic bone substitute material consisting of biphasic calcium phosphate granules ( $\geq$  50% HA/ $\beta$ -TCP) in combination with a hydrogel.

#### **TIXXU GRAFT granules**

60% Hydroxyapatite 40% β-Tricalcium Phosphate (β-TCP)

#### Hydrogel

Hydroxypropylmethylcellulose (HPMC)







# How to use it



- Hydratation of the granules
   prehydrate with saline solution (to avoid osmotic shock)
- TIXXU GRAFT
  must be brought into contact with living bone
- Never compress or press together otherwise the porosity would be damaged
- Healing
   pay attention to the bone growth cycle:
   5 to 8 months is recommended
   The implant is inserted after approximately 6 months
  - only use the right amount of granules.

To read the complete precautions, please refer to the Instructions of Use.



• No hydratation required ready to use

**Important** 

Never overfill.

- Vascularization
  must be brought into contact with living bone
- Covering
   with an resorbable membrane to fix the graft and protect it from soft-tissue colonization (GBR)
  - the material must be introduced with maximum direct bone contact

To read the complete precautions, please refer to the Instructions of Use.

# The safe, user-friendly bone reconstruction material

TIXXU GRAFT is a fully synthetic, biphasic calcium phosphate ceramic made of

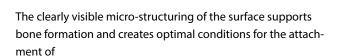
- 60% Hydroxyapatite (HA) and
- 40% β-Tricalcium Phosphate (β-TCP).

Through this mineralogy, the bone-analogous morphology and the resulting resorption properties, the bone regeneration is consistently supported.

While the  $\beta$ -TCP is rapidly osseously organised and replaced by newly formed bone, the hydroxyapatite content ensures that the volume remains stable.

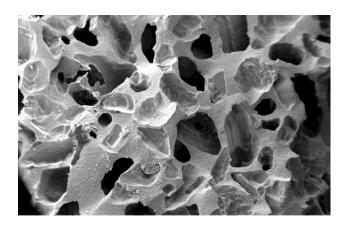
The high porosity in conjunction with the micro-structured surface stimulates bone regeneration via:

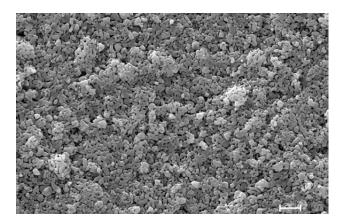
- Microporosity
   For optimal diffusion of biological substances and for fast ion exchange
- Macroporosity
   For fast blood vessel invasion and osseous organisation

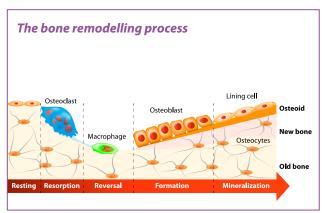


- Serum proteins
- Collagen fibres
- Osteoblasts

In vitro studies show that after only a few days the TIXXU GRAFT particles are colonised by osteoblasts.









# Regeneration process of the bone

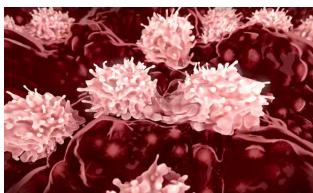
The bone substitute material TIXXU Graft is injected directly into the defect. It comes into contact with living tissues:

Blood.



Clinical Picture: Prof. Maté Sánchez de Val, Spain

Due to the high bioactivity of the bone substitute material, new bone crystals form after a short time.



Cells that have a significant influence on the bone remodeling process continue to spread.

Here in the image: Osteoclasts and osteoblasts.



The bone augmentation material is gradually replaced by a stable and mineralised bone architecture. Filled with blood vessels and collagen fibres, the bone matures to a solid matrix.



# The interaction of bone augmentation material and membranes

The interaction of bone augmentation material and membrane is of crucial importance for the success of bone augmentation measures. With TIXXU GRAFT and TIXXU CONTROL this is implemented in an exemplary manner. The synthetic membrane reliably protects the augmentation from connective tissue ingrowth.

The biphasic highly porous bone augmentation material TIXXU GRAFT has a 3D micro environment enhancing the cells' adhesion, proliferation and differenciation. Therefore, the new bone formation is supported.

Meanwhile, the very slowly absorbing 60% portion of hydroxyapatite (HA) ensures that the augmented volume is maintained.





# Membranes

## **Characteristics**

Name TIXXU CONTROL synt

Material PLGA

Indication Membrane for controlled hard and

soft tissue regeneration

Resorption approx. 6 months

Sizes 15 mm x 20 mm , 20 mm x 30 mm,

30 mm x 40 mm

TICO1520, TICO2030, TICO3040





# A membrane for all patients

Unlike membranes derived from pig, cow or horse tissues, TIXXU CONTROL synt is free of animal components. Our biocompatible, synthetic membrane prevents the risk of the transmission of animal pathogens.

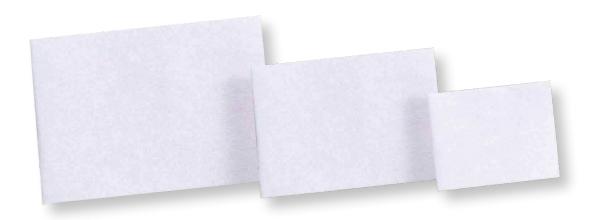


Extended treatable patient group: The synthetic TIXXU CONTROL synt membranes are suitable for patients who avoid animal by-products for religious, cultural or lifestyle reasons.

Medically classified polylactide-glycolic acid provides excellent biocompatibility. As a 100% biodegradable polymer, PLGA has decades of successful use in a variety of medical applications and devices, including absorbable suture material, needles, screws, etc.

## **Key Features – their benefits**

- Free of animal components: Reduces the risk of disease transmission; avoids religious/cultural issues
- High biocompatibility: The PLGA is 100% bioresorbable
- Safe: The PLGA has been used in medical applications for decades
- Simple application
- Supports secondary healing on exposure and wound dehiscence
- Long resorption time of 6 months gives the bone sufficient time for undisturbed growth





# Why use a membrane?

- Prevention of epithelial cell proliferation
- Promote the migration of bone cells in the blood clot
- Prevention of bone loss by up to 25% (Widmark et al., 1997¹)

### Easy to apply

- does not stick to soft tissue or instruments
- no premature moistening, attachment or suture needed
- quickly absorbs biological fluids on the microfibre side
- once TIXXU CONTROL synt has been moistened, it will take the form that you are modelling and hold it
- high tear strength allows use of basting stitches, pins and sutures
- easy to cut
- TIXXU CONTROL synt supports secondary healing in case of bone exposure and epithelialises in two weeks again

## Double-layered structure for optimal barrier effect

The specially designed double-layered structure prevents the ingrowth of (gingival) epithelial tissue on one side (smooth fascia of the dense layer), while on the other side (matte fascia with non-woven microfibres) the infiltration of cells and controlled bone healing are promoted.

## Clinical case

Dr. Alain Hoornaert, France



Wound closure after augmentation and coverage with TIXXU CONTROL membrane



Shortly after the procedure: Suture dehiscence – membrane becomes visible



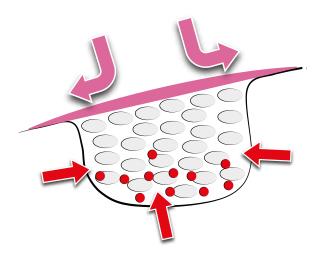
Within 2 weeks, the membrane is covered by newly formed gingiva



No inflammatory reactions detectable – keratinised tissue

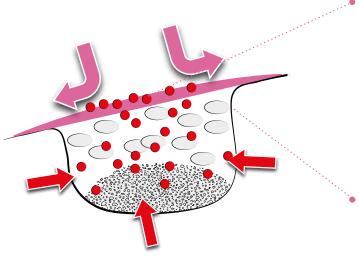
### Literature

# Functionality of a membrane



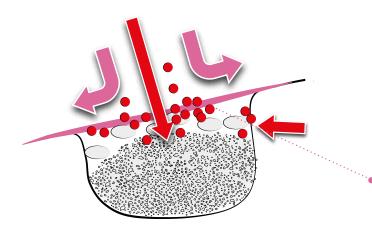
#### Coverage of bone defects

- Stabilisation of bone augmentation materials or bone chips
- Barrier function against the ingrowth of connective tissue as well as migration of the bone substitute material
- Therefore the bone has time for the reconstruction of the augmentation
- Blood vessels only grow from the bone out into the augmentation



 High cell compatibility and porosity for the attachment of fibroblasts and osteoblasts – important for the regeneration of hard and soft tissue

 Membrane ensures dimensional stability of the augmentation – preventing a collapse



 Transmembrane angiogenesis begins, favoured by high porosity of TIXXU CONTROL



# Predictable bone regeneration

## Case 1 Dr. Hrvoje Starcevic, Croatia



Atraumatic extraction



Immediate implantation and augmentation with TIXXU GRAFT



Covering with TIXXU CONTROL

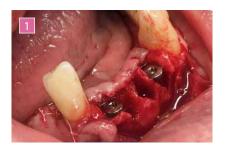


After 7 days: Only a few parts of the membrane still visible, keratinised tissue around the implant



Healing after 3 weeks without any complications

## Case 2 Myriam Dieckhoff, Germany



Significant bone defect in the front



Augmentation within the implantation

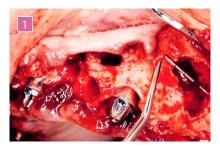


Defect is covered with TIXXU CONTROL

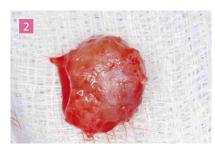


Wound closure

Case 3 Dr. Florian Obadan, Romania



Immediate supply with SKY fast & fixed combined with external sinus lift



Removal of cyst tissue and histological control



Augmentation with TIXXU GRAFT bone substitute material



Coverage with TIXXU CONTROL



Membrane is fixed with pins



Wound closure

## Case 4 Dr. Florian Obadan, Romania



Extraction with immediate implantation and supply with SKYtemp abutment



Bone defect is filled up with TIXXU GRAFT



Cover defect with membrane



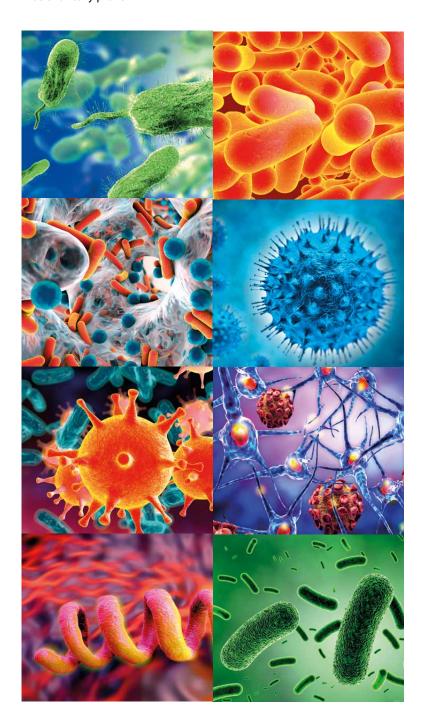
Wound closure

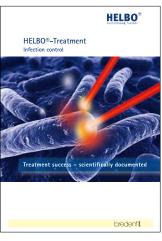


# The HELBO® therapy

# Stops the inflammation

- without antibiotics
- without surgery
- without side effects
- scientifically proven

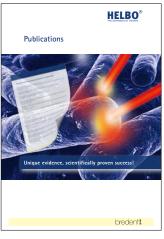




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REF 000461GB

# System overview TIXXU CONTROL GRAFT PROTECT





#### **TIXXU CONTROL synt membrane**



TIXXU CONTROL synt – 15 mm x 20 mm

REF TICO1520

TIXXU CONTROL synt – 20 mm x 30 mm

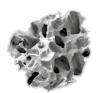
REF TICO2030

TIXXU CONTROL synt – 30 mm x 40 mm

REF TICO3040



#### TIXXU GRAFT synthetic bone substitute



TIXXU GRAFT 0.5 cc (0.5 mm - 1 mm)

REF TX0401G50

TIXXU GRAFT 1 cc (0.5 mm - 1 mm)

REF TX9901G01

TIXXU GRAFT 1 cc (1 mm - 2 mm)

REF TX0302G01

TIXXU GRAFT 2 cc (1 mm - 2 mm)

REF TX9902G02

#### TIXXU GRAFT injectable bone substitute putty



TIXXU GRAFT PUTTY (0.5 ml) REF TX1002PU50DE



#### TIXXU PROTECT collagen fleece



TIXXU PROTECT collagen fleece 20 mm x 20mm, Content 10 pieces per PU

REF TIPR2020

bredent

TIXXU

CONTROL GRAFT PROTECT