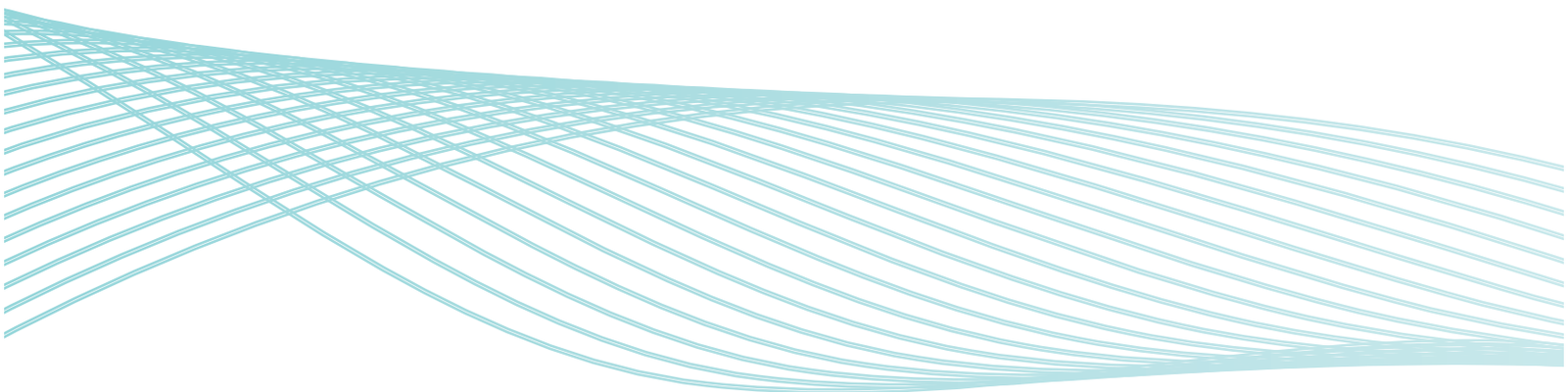
HYPRO-OSS & HYPRO-SORB

Leading patented bioregenerative biomaterial innovations for the 21th century

bioimplon

BiotechInnovationPioneers



Bioimplon GmbH

is a leading patented biomaterial innovation company.

Bioimplon focus is to development, manufacture and market patented,unique, natural bioregenerative biomaterial products . Our extensive product offerings cover the fields of bone and tissue regeneration, tissue engineering, and wound healing for dental, spinal, orthopedic, general and plastic surgery applications. They are used by oral & maxillofacial surgeons, periodontists and dental implantologists, as well as by orthopedic, spinal, general & plastic surgeons.Patient safety, ease of handling, reliable and predictable treatment results are our first priorities. The products have proven their success in safety, efficacy,reliability and superior handling characteristics in clinical studies, documented cases and in the daily clinical work with many hundreds thousands of patients world-wide.

Today Bioimplon is;

A world leader in the field of pure crystalline atelo-collagenated lyophilized soft tissue and atelo-collagen incorporated bone graft regenerative products .In addition to our patented " Hypro-Oss" granules, the company has developed a future -Oriented product pipeline such as moldable bone graft block forms and injectable gel forms. The company invests continuously in the development of research and technology and relies on its highly experience , qualified and specialized staff.

Our products portfolio incorporates wide range of unique soft tissue and bone tissue regenerative material; Hypro-Sorb M, F, R, X, Z, O, NT & Hypro-Oss

1. HYPRO-SORB: Our Atelo-collagen products portfolio includes all forms and extended selection of soft tissue regenerative product sizes that has been especially concepted and processed in order to meet different and wide range of clinical indications , all Hypro-Sorb forms & sizes (Hypro-Sorb M,F,R,X,Z,O,NT) are composed of the same bovine , 99.9% pure crystalline Atelo-collagen type I , a biocompatible , non-immunogenic , telopeptide free collagen. The source of the collagen is the bovine Achilles tendon. Atelo-collagen is the most effective hemostatic product with bacteriostatic effect.

2. HYPRO-OSS: is a patented bone graft Innovation, it is the first native bovine bone substitute material that is composed of about 30% Atelo-collagen integrated within the Hydroxyapatite particles of each bone granule structure. It is manufactured in lyophilization processing technology, Atelopeptidized, biocompatible and histologically proven that Hypro-Oss completes a high quality new bone formation within the shortest period of time ever.

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Hypro-Oss

Hypro-Oss is a patented, lyophilized natural bovine bone graft incorporated with Atelo-collagen Type I resulting from 6 years of intensive research and experimental cooperation between the scientific teams of the companies BIOIMPLON GmbH and HYPRO OTROKOVICE S.R.O.; both teams include very experienced chemistry engineers under the leadership of engineer **Antonin Galatik** and medical researchers under the leadership of **Dr. med. Sami Watad**, who initiated the Hypro-Oss project and cooperated very closely with several biomaterial academic institutes and universities in Europe, this continuous, intensive cooperation and focused work, following the vision of innovation, resulted in a revolutionary bone graft material that has superior properties: Hypro-Oss.





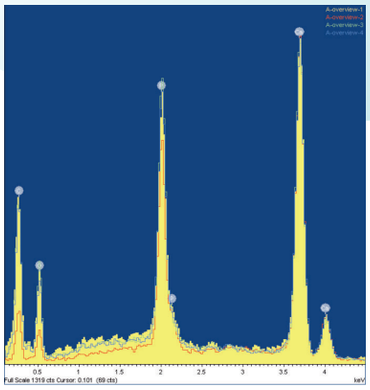
Hypro-Oss - innovative concept and properties

Our concept for the development of the Hypro-Oss product line was conceived with the idea of an ideal biomaterial in mind, a material with the highest biocompatibility and affinity to the new endogenous bone. In order to accomplish this purpose, we implemented our proprietary atelopeptidation and lyophilization technologies that preserve natural collagen components of bone material within bone structure after modifying the collagen to a non-immunogenic Atelo-collagen. This preserves the natural crystalline structure of the hydroxyapatite as well as the collagen components by completely avoiding the heating (thermo) processing method that other manufacturers still use.

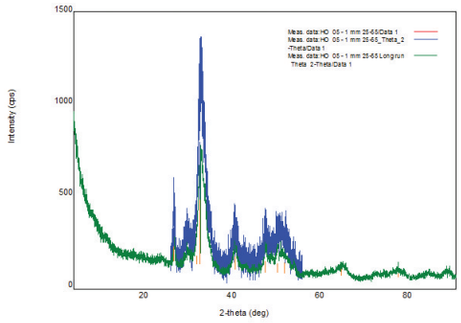
Thanks to our proprietary innovative processing technology, Hypro-Oss has the following important characteristics:

1. Native bovine bone graft components for enhanced new bone formation
2. Telopeptide free collagen components; non-immunogenic peptide
3. Acceleration of physiological tissue healing process
4. Protects grafting site from infection (bacteriostatic effect of Atelo-collagen)
5. Hydrophilic property, optimal cell adhesion and blood absorption and capability to carry medication to the surgical site
6. Highest biocompatibility; absence of any foreign body response
7. Natural structures of collagen and hydroxyapatite due to lyophilization processing
8. Osteoinductive Atelo-collagen components & Osteoconductive hydroxyapatite components
9. Native crystalline structure guarantees long-term dimensional stability

These characteristics allow enhanced and consistent new bone formation, and persistent integration between mature new formed bone and existing bone material



Hypro-Oss - EDS-energy dispersive spectroscopy

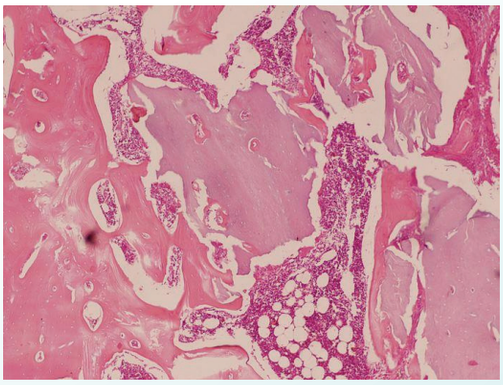


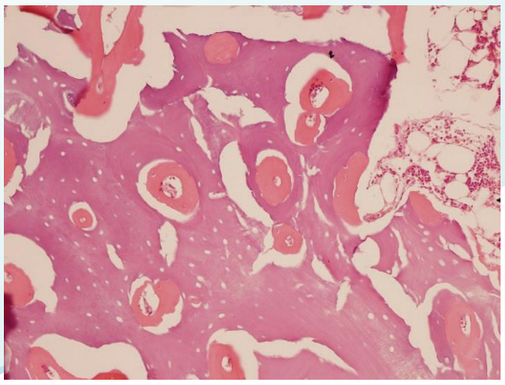
Hypro-Oss - X Ray Diffraction

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Atelo-collagen's vital Role in Bone Regeneration Process

Atelo-collagen Type I is the most appropriate carrier for promoting osteoinductive signal activity. In vitro studies show that collagen is capable of inducing differentiation of mesenchymal osteoprogenitor stem cells into osteoblasts, and that the association of Atelo-collagen Type I with a scaffold of natural hydroxyapatite significantly enhances the proliferation rate of osteoblasts. This important scientific evidence provides the rationale behind the development of Hypro-Oss products' line.Hypro-Oss atelo-collagenated bone graft provides the natural substrate for correct bone tissue regeneration and repair, facilitating and accelerating the physiological regeneration process, and allowing optimal results within a reasonable period of time





Histology after 14 weeks , Hypro-oss intraosseous implantation in beagle dogs

Hypro-Oss accelerates bone formation

clinical application of Hypro-Oss guarantees maximal possible safety and predictability. The atelo-collagenated bone graft material of bovine origin Hypro-Oss facilitates and accelerates the physiological regeneration process, allowing optimal new bone formation and consolidation results within a reasonable short period of time. Hypro-Oss covers a broad spectrum of indications and offers so many options for effective and safe prognoses in everyday clinical routine.

Storage conditions:

Hypro-Oss must be stored in a dry place at room temperature. Hypro-Oss is not damaged by temperatures from 0°C to +50°C. It needs to avoid sources of heat and direct sun light.

Readings	Human (%)	CI*95%	Bovine (%)	CI*95%
Fat	0.06	0.1	0.1	0.1
Nitrogen	4.3	0.1	4.3	0.1
Proteins	27.5	0.2	27.2	0.2
Phosphorus	11.9	0.1	11.9	0.2
Total P205	27.1	0.2	27.2	0.7
Calcium	24.6	0.7	23.7	0.6
Total sodium	0.57	0.01	0.46	0.01
Ashes	64.8	0.6	64.3	0.1
Chlorides	1.3	0.06	1.3	0.2
Water	7.93	-	7.75	-
Ca/P	2.06	-	1.99	-

Human bone compared with lyophilized Bovine bone,chemical composition



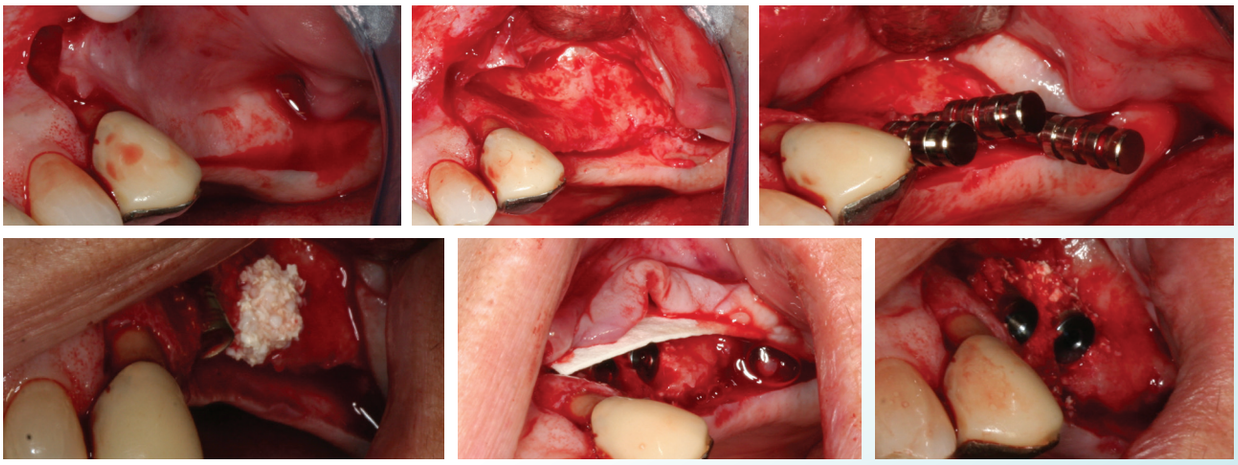
Hypro-oss granules

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Hypro-Oss – Indications

Implantology, Periodontology and Oral Surgery

Sinus lift
Vertical & Horizontal augmentation
Intraosseous defects
Peri-implant defects
Extraction sockets
Furcation defects
Filling of cyst
Periodontal defects



courtesy of Dr. Amir Gazmawe DMD prosthodontist
Hypro-sorb F & Hypro-oss

Hypro-Oss-Indications

in orthopedic & spinal surgery

- filling of bone defects in juxta-articular fractures
- filling of defects of the acetabulum on change of prosthesis
- filling of bone defects after excision of benign tumors
- filling of bone cysts
- filling of tissue defects in cartilage and bone transplants
- filling of bone defects at donor sites after harvest of autogenous bone.

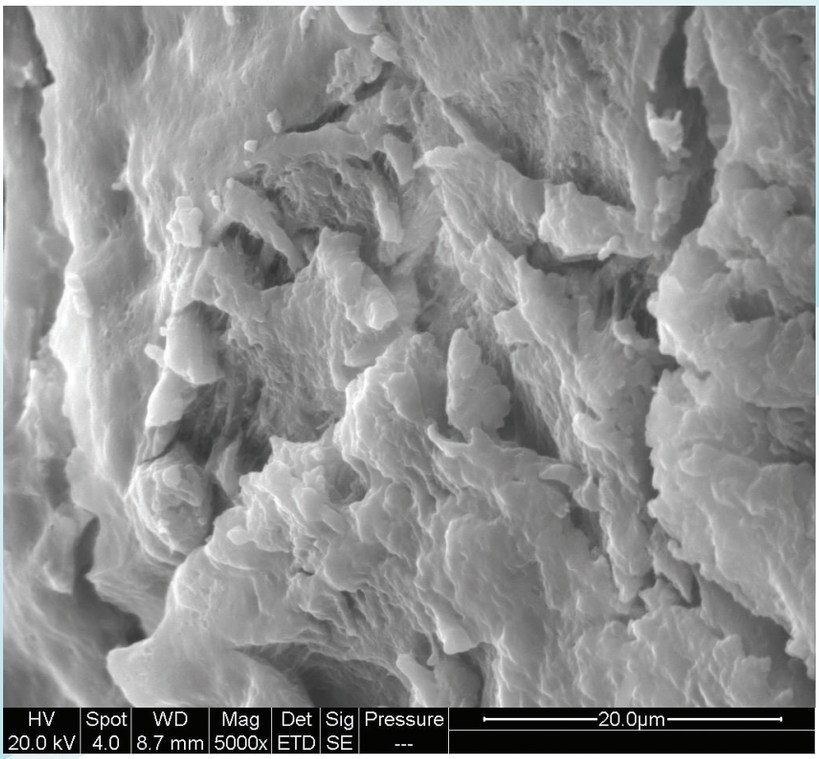
Hypro-Oss Granules are available in the following volumes.

Cat. No.	Product Name	Volume	Grain Size
70	Hypro-Oss	0.5ml	0.5 – 1.0mm
71	Hypro-Oss	1.0ml	0.5 – 1.0mm
72	Hypro-Oss	3.0ml	0.5 – 1.0mm
73	Hypro-Oss	5.0ml	0.5 – 1.0mm
74	Hypro-Oss	0,5ml	1.0 – 2.0mm
75	Hypro-Oss	1.0ml	1.0 – 2.0mm
76	Hypro-Oss	3.0ml	1.0 – 2.0mm
77	Hypro-Oss	5.0ml	1.0 – 2.0mm

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Hypro-oss Composition

Hypro-Oss is a natural bovine bone graft material , consists of approximately 70% pure Hydroxyapatite and about 30% pure crystalline Atelocollagen type I.it is manufactured in a patented atelopeptidation processing method and lyophilization technology for preserving the native bone structure as is ,but sterile and safe.



Hypro-oss - electron microscopy

Collagen treatment - sterility and safety

BSE prevention regulations;

The manufacturer has documents at its disposal confirming that the country has established compulsory notification of BSE and that all slaughtered animals older than 30 months are subject to obligatory examination based on the Notices of the Department of Agriculture no. 286/1999, Coll. of Laws, DOA no. 399/2001, Coll. of Laws, and DOA no. 400/2001, Coll. of Laws. The manufacturer monitors and reacts to current requirements or directives issued by the European Union, including the OIE notice Terrestrial Animal Health Code

Deactivation & removal of infectious agents ;

The method of collagen treatment includes several repeated extractions that are employed to remove non-collagen globular proteins from the connective tissue, since prion (the infectious agent of BSE) belongs to the category of globular proteins. The extraction process is an additional safeguarding procedure that results in reduced prion content, in case there is any in the tissue. Another technological process that is appropriate in view of deactivation of prions is the action of a saturated calcium hydroxide solution with pH-value of 12.5. The prion protein (globular protein) contains an elongated conformation of the beta-pleated sheet type that changes to a physiologically normal conformation (non-infectious) through the action of hydrotropic substances (saturated calcium hydroxides with PH 12.5). The action of hydroxides is recommended in the WHO Document CPMPaCVMP EMEA/410/01, Rev. 2 as an effective measure to reduce the risk of TSE transfer through medical devices.These procedures induce structural changes such as decrystallization of prion protein (sensitive to proteolysis), which results in irreversible, non-toxic conformation of the prion protein. Collagen treated this way and used in the production of Hypro-Oss consists of prion-free tissues, which are fully safe as TSE is concerned.

Sterilization method ;

After final packaging of Hypro-Oss's glass bottles in a double blister packaging,Hypro-Oss undergoes Gamma Irradiation as final sterilization step. Gamma radiation sterilization is a process that effectively kills or eliminates almost all microorganisms like fungi, bacteria, viruses and spore forms. Gamma irradiation is a physical means of decontamination, because it kills bacteria by breaking down bacterial DNA, thus inhibiting bacterial division.

Hypro-oss is a sterile medical device class III , ISO and CE certified

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Hypro-sorb products portfolio

Hypro-Sorb M-F-X-Z-R

Hypro-sorb-membranes (M & F)

for GTR/GBR- Guide tissue & bone regeneration

Guided tissue regeneration (GTR) has nowadays become an essential therapeutic procedure not only for the treatment of periodontal bone defects but also for bone and peri-implant defects, and for augmentation procedures prior to implant placement. In the latter situation, its sometimes termed guided bone regeneration (GBR). The method of guided tissue regeneration (GTR), which began in the mid-1980s, became an important part of periodontal practice. Research results show that with the help of barrier membranes it is possible to prevent penetration of epithelial cells or fibroblasts into the bone defect and thus allow for gradual growth and reconstruction of the bone tissue. This procedure was applied in the cure of periodontal defects. The barrier helped the isolation of the defect with resulting reconstruction of cement, periodontal connection and the bone. During wide used dental implant. it became obvious that the GTR conception is useful for the cure of bone defects in the vicinity of implant . In such cases, the membrane prevents penetration of fibroblasts into the bone defect and bone cells have the necessary time for regenerate the bone tissue in such a way that optimal conditions are created for introduction of an implant.

Hypro-Sorb M



Hypro-Sorb M is a natural pure crystalline atelocollagen type I of bovine origin , a biphasic bioabsorbable matrix for guided tissue and bone regeneration.

Hypro-Sorb M is the result of many years of experience and intensive research cooperation of Bioimplon GmbH scientific team under the leadership of **"Dr.med.Sami Watad"** and Hypro Otrokovice s.r.o, under the leadership of the polymer chemistry world-expert **"engineer Antonin Galatik"**. Hypro-Sorb M was especially prepared, purified and modificated utilizing the proprietary technology of Hypro Otrokovice s.r.o of atelopeptidation and lyophilization . The membrane is biocompatible, deantigenated, sterile for 5 years . Hypro-Sorb M is completely bioresorbed within 6 months after implantation.

Hypro-sorb M Composition & activity

Hypro-sorb M, is a natural pure crystalline atelocollagen type I of bovine origin , free of telopeptide due to the atelopeptidation and Lyophilization processing applied technique .Hypro-Sorb M has a specific activity to thrombocytes and releases clotting factors , which together with plasma binding factors promote fibrinogenesis. Other tissue interactions are the inhibition of collagenolytic activity of wound excretions. Hypro-sorb M support of granulation and epithelisation, promotes soft tissue healing and guided tissue regeneration "GTR" . Hypro-Sorb M is also an excellent agent for guided bone regeneration "GBR" , due to its potent release of growth factors (IGF I ,TGF and PDGF) from the highly concentrated thrombocytes ,TGF and BDGF, natural peptides are responsible for triggering the cell proliferation and accelerated bone regeneration.

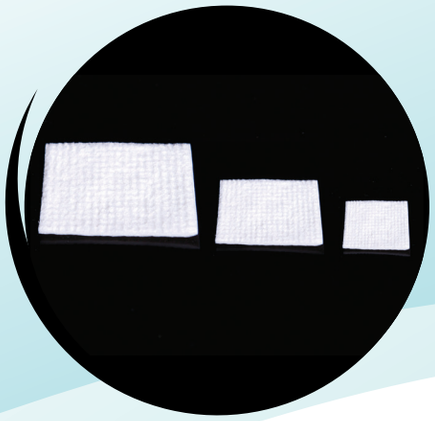
Storage condition & Shelf life

Hypro-Sorb M must be stored in a dry place and at a normal temperature. Hypro-Sorb M is not damaged by temperatures from -25C/-13F to +50C/+122F. It needs to avoid direct sun light. The product is sterile for 5 years.

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Hypro-Sorb M properties

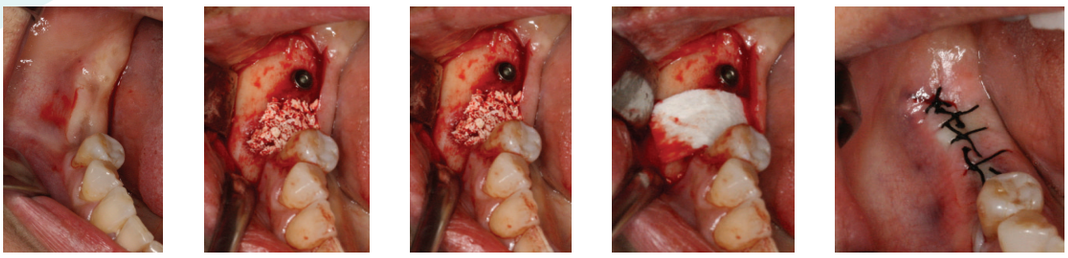
- A pure crystalline atelo-collagen type I free of the antigenic telopeptide.
- Highest degree of tissue biocompatibility and safety with excellent wound healing characteristics.
- Quickly adaptable to the wound/defect due to it is potent hydrophilic property.
- Reduced risk by dehiscence formation due to the especially designed 0.8mm thick matrix.
- Can be attached with pins and suturing material.
- Barrier function is sufficiently long and is completely bioresorbed within 6 months.
- Bioabsorbable , a second operation for membrane removal is not necessary.
- Unmistakably visible rough side and smooth side
- Hypro Sorb M is a dual sterile matrix



Hypro-Sorb M membrane

Hypro-sorb M Indications

sinus Lifting
Segmental growing of the alveolar tissue
Periimplantitis
Furcation treatment
vertical & segmental augmentation
Cystectomy
maxillofacial and Periodontal surgery



courtesy of Dr. Labazanov Ashab maxillofacial surgery - moscow ,russia.
Hypro-sorb M & Hypro-Oss

Postoperative care

In case of wound dehiscence with membrane exposure the usual antimicrobial precautions are recommended.Removal of the membrane is not necessary. The resorption time may be accelerated by external influences such as saliva, etc. the properties of collagen may favour rapid healing of the wound dehiscence.

Hypro-Sorb M available sizes

Cat. No.	Product Name	Size	Description
30	Hypro-Sorb M	16 x 20 mm	biphasic Matrix for GTR&GBR
31	Hypro-Sorb M	22 x 32 mm	biphasic Matrix for GTR&GBR
32	Hypro-Sorb M	32 x 42 mm	biphasic Matrix for GTR&GBR

Hypro-Sorb M is a sterile medical device class III , ISO and CE certified

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Hypro-sorb F



Hypro-sorb F membrane

Hypro-sorb F is a bilayer pure crystalline atelo-collagen Membrane

Hypro-Sorb F natural pure atelo-collagen structure is of bovine origin. The bilayer membrane presents an excellent atelo-collagen type I matrix for bone integration on the rough porous side as well as for soft tissue adhesion and healing on the smooth membrane side.

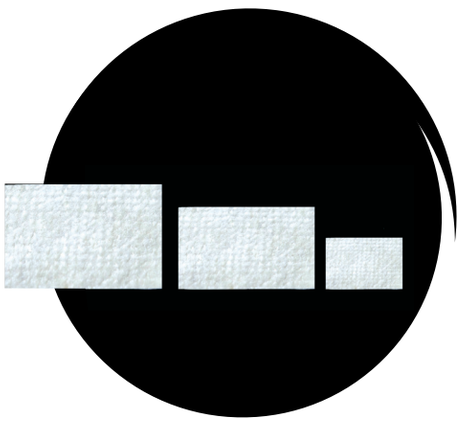
Hypro-Sorb F unique composition

The membrane consists of pure crystalline atelo-collagen types I. a special method of preparation, utilizing the atelopeptidation and lyophilization technique,results in a concept of rigid bilayer structure with one smooth and one rough layer. The smooth membrane layer which has a compact surface is cell occlusive surface to guarantee protection against connective tissue invasions . The properties of collagen favour cell attachment. The smooth side of membrane is turned towards the soft tissue. The rough layer of the membrane consists of collagen fibers in a loose porous arrangement to enable cell invasion.This rough side is turned toward the bone defect in order to enhance the integration of bone forming cells and to stabilize the blood clot.Hypro-Sorb F is composed of highly purified bovine atelocollagen type I, free of the immunogenic telopeptide , sterile and biocompatibility.

Hypro-Sorb F properties

A bilayer membrane , lyophilized crystalline atelo-collagen type I,free of the antigenic telopeptide

- Highest degree of tissue biocompatibility and safety with excellent wound healing characteristics.
- Quickly adaptable to the wound/defect due to it is potent hydrophilic property
- Rigid consistency , bacteriostatic effect of atelo-collagen reduce the risk by dehiscence formation . 0.3 mm thick bilayer matrix with rigid consistency , can be attached with pins and suturing material.
- Barrier function is sufficiently long , completely bioresorbed within 6 months.
- enzymatic bioabsorbable, a second operation for membrane removal is not necessary.
- Unmistakably visible rough side and smooth side
- Hypro Sorb F is a biocompatible, safe and sterile atelo-collagen matrix



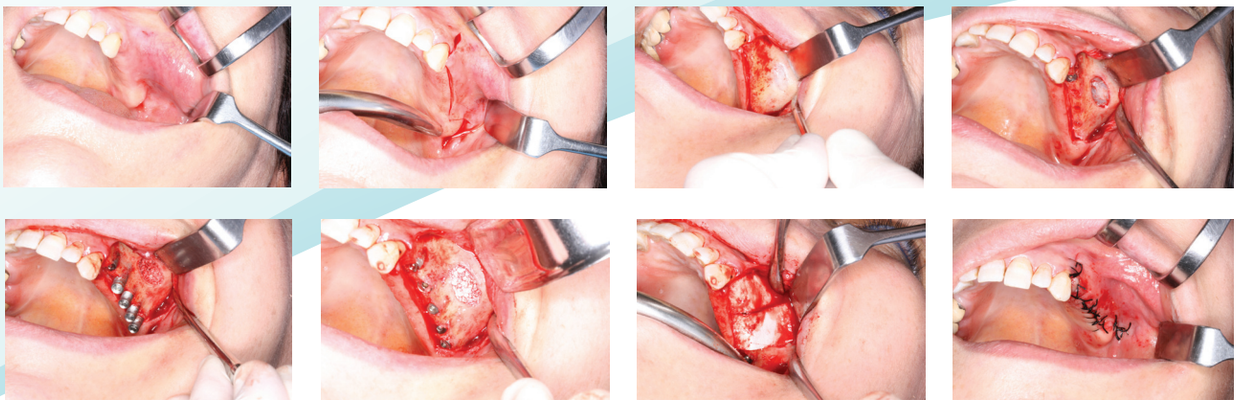
Hypro-Sorb F

long Shelf life time, safe and sterile for 5 Years

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Indications - Hypro-sorb F

sinus Lifting
Segmental growing of the alveolar tissue
Periimplantitis
Furcation treatment
vertical & segmental augmentation
Cystectomy
maxillofacial and Periodontal surgery



courtesy of Dr.med.dent Fahim Atamni
Hypro-sorb F & Hypro-Oss cases

Postoperative care

In case of wound dehiscence with membrane exposure the usual antimicrobial precautions are recommended.Removal of the membrane is not necessary. The resorption time may be accelerated by external influences such as saliva, etc. the properties of collagen may favour rapid healing of the wound dehiscence.

Storage condition & Shelf life

Hypro-Sorb F must be stored in a dry place and at a normal temperature. Hypro-Sorb M is not damaged by temperatures from -25C/-13F to +50C/+122F. It needs to avoid direct sun light. The product is sterile for 5 years.

Hypro-Sorb F available sizes

Cat. No.	Product Name	Size	Description
23	Hypro-Sorb F	15 x 20 mm	bilayer Matrix for GTR&GBR
24	Hypro-Sorb F	20 x 30 mm	bilayer Matrix for GTR&GBR
25	Hypro-Sorb F	30 x 40 mm	bilayer Matrix for GTR&GBR

Hypro-Sorb F is a sterile medical device class III , ISO and CE certified

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Hypro-sorb X,Z



Atelocollagen Conus for alveolar ridge preservation and haemostasis

General information

Hypro-Sorb X is the concept of extensive experience and intensive research cooperation of Hypro Otrokovice s.r.o and Bioimplon GmbH scientific team . Hypro-Sorb X / Z are sterile pure atelocollagen type I of bovine origin , non-cross linked , purified and chemically modificated utilizing the atelopeptidation proprietary technology of Hypro Otrokovice s.r.o (registered patent No.276891). the material is sterile , biocompatible, apyrogenic, non-immunogenic, supports the healing processes and preserving the alveolar ridge after tooth extraction.



Hypro-Sorb X



Hypro-Sorb Z

Physiologic Activity

Atelocollagen is a very effective haemostatic agent. Hypro-Sorb X / Z has a specific activity to thrombocytes and releases clotting factors, which together with plasma binding factors promote fibrinogenesis and inhibits the collagenolytic activity of wound excretions, support of granulation and epithelisation, promotes soft tissue healing and accelerates woven bone formation after tooth extraction . Hypro-Sorb X / Z potent release activity of growth factors (TGF and PDGF) from the highly concentrated thrombocytes. TGF and PDGF are natural peptides responsible for triggering of cell proliferation and bone regeneration. Hypro-sorb X / Z as a pure atelocollagen is a very potent thrombocytes aggregator that after its degradation , two main functions accelerate, the one is the well documented haemostatic activity and the second is the release of growth peptide of the thrombocytes content. research results show that with the help of barrier function of the three dimensional conus form of Hypro-sorb X / Z it is possible to prevent penetration of epithelial cells into the bone defect and thus allow for gradual growth and reconstruction of the bone tissue of the alveolar ridge.

Storage conditions & Shelf life;

Hypro-Sorb X/Z to be stored in a dry place at temperatures between -25°C/-13°F to +50°C/+122°F. It needs to avoid direct sun light.

Hypro-sorb X / Z Properties

- Natural crystalline atelocollagen type I free of telopeptide.
- The especially designed Ø6 x 20 x Ø 10 mm conus presents an excellent atelo-collagen type I three-dimensional matrix for bone formation after tooth extraction
- Accelerated soft tissue healing
- Highest degree of tissue biocompatibility.

potent hemostatic property,bioresorbed within 2-4 weeks

long Shelf life time, safe and sterile for 5 Years

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Indications

- Closure of extraction sites
- Alveolar ridge preservation
- Control of bleeding in extraction sockets or biopsy sites

Handling instructions

- Cleansing the tooth extraction site.
- Placing the Hypro-sorb X into the bleeding cavity of the extraction socket.
- Suturing the flaps to help keeping the Hypro-sorb X in place.
- In case of larger defects, it is recommended to cover the conus with a fleece

Cat. No.	Product Name	Size	Description
14	Hypro-Sorb X	Ø6mm x 20 mm x Ø 10mm	conus ,hemostat&regenerative
31	Hypro-Sorb Z	Ø3mm x 15 mm x Ø 6mm	conus ,hemostat&regenerative

Hypro-Sorb X / Z is a sterile medical device class III , ISO and CE certified

Hypro-sorb R



Atelo-collagen haemostatics are fastest in achieving haemostasis and reducing blood loss.

Hypro-Sorb R is the most effective Haemostatic material , it is a pure native crystalline atelo-collagen Type I . biocompatible ,non-immunogenic , telopeptide free collagen , the source of the collagen is the bovine achilles tendon .

Hypro-Sorb R products portfolio includes different forms and extended selection of product sizes that has been especially concepted and processed in order to meet different and wide range of clinical indications . All Hypro-Sorb R forms & sizes are composed of the same bovine,pure crystalline atelo-collagen type I that has been especially concepted for haemostatic indications .it activates a cascade of native coagulation factors in blood in an entirely natural manner. Hypro-Sorb R has specific activity on thrombocytes and releases clotting factors, which together with plasma binding factors promote fibrinogenesis.The quick haemostatic effect of atelo-collagen is well known and induced by the adhesion of platelets to the collagen fibrils. As a consequence, platelets aggregate and release coagulation factors by degranulation what initiates the coagulation cascade resulting in haemostasis.

Different forms and sizes of Hypro-Sorb R



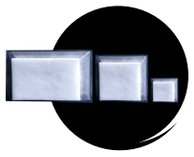
fleece 20x25x4mm



fleece 10x10x10mm



fleece pack 6 pcs



fleece sizes ,large

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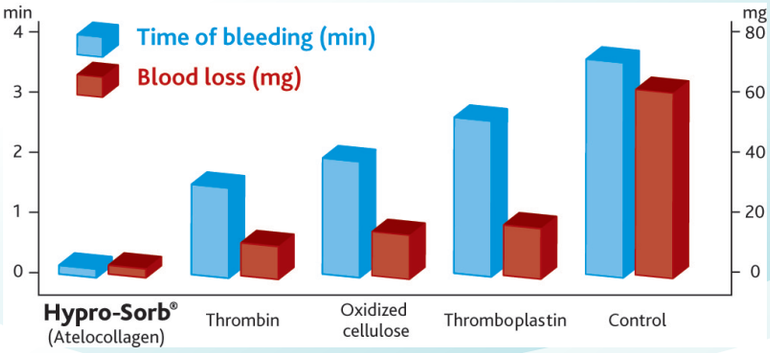
advantages of atelocollagen haemostatics

- Atelocollagen has a very efficient local haemostasis
- Hypro-Sorb has a specific activity to thrombocytes and releases clotting factors
- Strong adhesive properties in liquid environment
- Absorbable by enzymatic reaction
- Inflammatory reaction is either very mild or not present.
- Can be easily applied and removed if necessary
- Atelocollagen implants retain their compactness and effectiveness for 2-4 weeks
- Atelocollagen inhibits serine proteinase, therefore, it has a mild bacteriostatic effect.
- Hypro-Sorb R haemostatics do not support microbial growth and can be used in Infected wounds or in medically compromised patients
- Long Shelf life time, safe and sterile for 5 Years

Hypro-Sorb R products portfolio with different forms and extended selection of sizes has been especially concepted and processed in order to meet excellently wide range of clinical indications

Clinical Indication; Haemostasis in

1. Surgery, general, Orthopedic, Spinal, OBGN,
2. dentistry ,Perio ,oral and Maxillofacial surgery
3. traumatology
4. Burns 1st and 2nd degree
5. complicated wounds ,Decubitus



comparison of hemostasis time

available hemostatic sizes

Cat. No	Product Name	Size & pieces in pack	Description
3	Hypro-Sorb R	20 x 25x4 mm, 6 pcs	hemostatic fleece
6	Hypro-Sorb R	10 x 10 x 10 mm, 10 pcs	hemostatic sponge,cube
12	Hypro-Sorb R	65 x 55x4 mm , 1 pc	hemostatic sponge
1	Hypro-Sorb R	65 x 110x4 mm , 1 pc	hemostatic sponge
13	Hypro-Sorb R	50 x 50 x 4 mm , 1 pc	hemostatic fleece

Hypro-Sorb R is a sterile medical device class III , ISO and CE certified

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The products fulfill the following regulation requirements;

DIR 93/42/EEC:2007 Council Directive concerning medical devices
DIR 2003/32/EC Commission Directive on medical devices manufactured utilizing tissues of animal origin
CSN EN ISO 14971:2009 Medical devices - Application of risk management on medical devices
CSN EN ISO 22442:2008 Medical devices utilizing animal tissues and their derivatives
CSN EN ISO 10993-1:2010 Biological evaluation of medical devices - Evaluation and testing
CSN EN ISO 10993-5:2010 Biological evaluation of medical devices - Tests for in vitro cytotoxicity
CSN EN ISO 10993-6:2009 Biological evaluation of medical devices - Tests for local effects after implantation
CSN EN ISO 10993-10:2011 Biological evaluation of medical devices - Tests for irritation and skin sensitization
CSN EN ISO 11137:2012 Sterilization of health care products - Sterilization by radiation

Hypro-Sorb & Hypro-Oss CERTIFICATIONS ;

• EC Certificate No. 13 0049 QS/NB attesting that the products are manufactured under conditions meeting the requirements of the quality system in accordance with Annex II, Sections 3.3. and 5, of the Directive 93/42/EEC, Notified Body No.1023.

• EC Design-Examination Certificate No. 13 0050 CN/NB certifying that the products comply with the essential requirements specified in Article 4 of Annex II to Council Directive 93/42/EEC,Notified Body No.1023 .

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