bio implon GmbH
Biotech Innovation Pioneers

Patient Education Sheet

Innovative biomaterials for guided bone and tissue regeneration

Dear Patient,

You want to bite firmly again with all your teeth and regain your smile? Dental implants look like real teeth and feel just as it. However, it is necessary to have a sufficient bone structure for a successful implantation. For this reason our biomaterials Bioimplon Hypro-Oss® und Bioimplon Hypro-Sorb® are being applied. This education sheet will help to advise you with the characteristics of these products, especially the mode of action, their advantages and potential risks. Please read it prior to the personal discussion with your physician or dentist. This information sheet does not intend to replace the informative talk with your attending physician or dentist. It mainly refers to the material properties of Hypro-Oss® und Hypro-Sorb®.

Why is this Education Required?

Your dentist is obliged to inform you about the properties, i.e. the mode of action, advantages and risks of Hypro-Oss® and Hypro-Sorb®. Furthermore, he or she has to inform you about seriously considered alternatives in therapy. This information sheet is meant to support your physician or dentist in this purpose

Causes for Loss of Bone Substance

There exist many reasons for possible loss of bone material. Often, it is caused by an accident or an inflammatory affection of the peridontium due to bacterial plaque. Often, the jaw bone also degrades after the extraction of a tooth due to the absence of a mechanical load. A sufficient amount of bone material is a prerequisite for the long term preservation and stability of a dental implant. It is also a key requirement for an attractive aesthetic of teeth and gums.

When to use Bioimplon Hypro-Oss® and/or Bioimplon Hypro-Sorb® for Therapy?

Endogenous bone, which is essential to ensure permanent stability of your own teeth or a dental implant, is missing in one or more areas of your jaw. In order to augment endogenous bone substance, your physician or dentist intends to apply Bioimplon Hypro-Oss® and/or Bioimplon Hypro-Sorb®

How can Bone Tissue be Renewed?

Under appropriate conditions, endogenous bone is capable of self-renewal. In most cases, this buildup is mediated by a scaffold. Bioimplon Hypro-Oss® perfectly fits the requirements for this buildup, because it keeps the natural structure of a bone during the manufacturing process. Hypro-Oss® is applied in granules to the operation area. Here it will subsequently guide the growth of endogenous bone material. After an approximate period of six months this process is completed and vital bonetissue is regained. In order to enable an intact growth of the endogenous bone material, a protective barrier can be used in form of our Bioimplon Hypro-Sorb® membrane, which is applied surrounding the operation area. This prevents engraftment of soft tissue into the slower growing bone tissue. Furthermore, Hypro-Sorb® supports wound healing. Because its composition is completely biological, Hypro-Sorb® is absorbed by the human organism and does not need to be removed in a further procedure.

Some Information about Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb®

Bioimplon Hypro-Oss® was developed and patented by researchers of Bioimplon GmbH and Hypro s.r.o. This bone substitution material of bovine origin consists of 30% Atelo-Collagen Type I and 70% hydroxyapatite. It is manufactured by a specially designed technology of lyophilization, and is atelopeptidized and bio-compatible. Histological trials have shown that this material supports a rapid bone renewal of very high quality. Furthermore, the successful appliance of these materials has been proven thousandfold in practice. All Bioimplon Hypro-Sorb® products consist of 99,9% pure Atelo-Collagen Type I – a biocompatible, non-immunogenic collagen, free of telopeptides. The source of the Atelo-Collagen Type I is the bovine Achilles Tendon. Atelo-Collagen Type I is the most effective hemostatic product with bacteriostatic effect. The Bioimplon Hypro-Sorb® portfolio is the result of many years of experience and an intensive research cooperation between Bioimplon GmbH and Hypro s.r.o.

Alternative Options

In order to built up bone structures at a distinct area, there exist several alternative options to Bioimplon Hypro-Oss®. One of the alternatives is the appliance of autologous bone graft materials. Usually, practitioners prefer to gain autologous material from the patient´s chin or pelvis. This procedure automatically generates an additional operation area, which might be accompanied by painful complications. Also, sometimes the gained amount of the grafted bone material might not be sufficient. Of course, there are several other products of bone substitution material of animal or chemically synthesized origin with all different characteristics and properties in structure and biological compatibility.

Manufacturing Criteria

The selection of original material, as well as rigorous quality controls are consistent with highest safety standards and ensure the best tolerance for the patient.

- Accuracy in the selection of original material for the manufacturing of Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb®. We strictly process bone substance and collagen of audited companies
- Extensive test and documentarieson the state of health of the cattle used in our certification used in our certified manufacturing process.
- Very effective chemical and physical methods of purification
- Monitored manufaturing process and permanent controls by independent and governmental institutions
- Sterilization of the final products
- Documented quality management

Sovereign Quality Control

The manufacturing of Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb® is subject to a documented quality management consistent to international guidelines (ISO 9001 / EN 46001), which is audited annually by international authorities. Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb® are medical devices, which accomplish requirements of European health authorities (CE certification).

What is the Experience with Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb®?

Many thousands of patients have already been treated with Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb® worldwide. So far, exclusively positive feedback has been reported. Products of Bioimplon GmbH increase in popularity worldwide.

Side Effects

Because Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb® consist of natural collagen, in very rare cases allergic or inflammatory reactions cannot be excluded. Possible adverse reactions might be redness, swelling or itching. Intolerance can appear with any form of material, natural and/or synthetic.

Restrictions of Application

Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb® should not be applied to patients suffering from:

- Acute and chronic infection in the operation area (osteomyelitis)
- Metabolic diseas (non-adjusted diabetes, hyperparathyroidism, osteomalacia etc.)
- Severe disfunction of liver or kidney
- Therapies based on appliance of corticoids in strong dose

In some cases the application of Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb® can be also restricted due to individual cases of the patients, which cannot be attributed to the product itself (i.e. intake of bisphosphonates for the treatment of osteoporosis). Please talk to your applying physician or dentist before using Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb®

Pregnancy / Lactation

- No reliable studies concerning pregnant women have been performed
- There exist no solid data for the appliance of Bioimplon Hypro-Oss® and Hypro-Sorb® during lactation
- For safety reasons , Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb® should not be applied to pregnant females or during lactation

For Further Information

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Statement of Agreement

I was informed about the products Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb® in a comprehensible way. I understand the content of the education sheet and agree to the treatment with Bioimplon Hypro-Oss® and Bioimplon Hypro-Sorb®.

Patient´s Name

Date and Dentist´s Signature

Patient´s Date of Birth

Date and Assistance´s Signature

Patient´s Address

Stamp:

Date and Patient´s Singature

Remarks