

# Patient Explanation Sheet

## Increasing Bone with Bio-Oss®/Bio-Gide®

**This explanation sheet describes the material characteristics of Bio Oss® and Bio-Gide®. It should be read together with other information you receive from your dentist for your planned treatment. It will assist you in giving your informed consent to the treatment.**

### Why is an Explanation Necessary?

There are numerous materials that are currently available for increasing bone. Your dentist must inform you about the alternative treatment methods and the materials that are available.

Bio-Oss® Bone Replacement Material

#### 1. What are the reasons for using Bio-Oss®?

In your particular case, you do not have enough of your own bone available for the dentist to be able to stabilize a tooth or to securely anchor a dental implant. Bio-Oss® will be used to increase your own bone, thus providing the dentist with an adequate amount for the procedure that you require.

#### 2. What is Bio-Oss®?

Bio-Oss® is a bone replacement material that is used to increase the body's own bone. Bio-Oss® is composed of the hard, mineral portion of natural bone and has a structure very similar to that of human bone. It is therefore well accepted by human bone tissue and serves as a guide rail for the new bone growth.

The starting material is carefully inspected bovine bone that has undergone treatment with patented processes for purification and sterilisation. Included amongst these processes is the treatment of Bio-Oss® at high temperature for more than 15 hours, after which it is highly purified and finally sterilised.

In certain procedures, Bio-Oss® COLLAGEN is used for regenerating bone. This product is the same as the Bio-Oss® described above, but has highly purified natural collagen fibres added to it. The collagen is obtained from pigs.

#### 3 What is the function of Bio-Oss®?

Bio-Oss® is a solid scaffold which serves as a guide rail to allow new bone to grow. This scaffolding material enables and facilitates bone formation in the area where the operation is performed. It is inserted into the operation area in the form of grains and small blocks. Your own bone slowly grows into the Bio-Oss® material, which at a later time is gradually broken down by the body.

#### 4. Are there alternatives?

As an alternative to Bio-Oss®, one can use the body's own bone, which is taken from a different location, for example, the chin or the hip. However, this procedure requires

additional anaesthesia. Once the bone sample is removed from its original site it is then inserted into the operation area. In this procedure, the following must be considered:

- There is now a second area of operation, which may be associated with additional pain or loss of sensitivity.
- It is possible that the amount of the newly gathered bone will not be adequate for the intended purposes.

### **Bio-Gide® Collagen Membrane**

#### **1. What is Bio-Gide®?**

Bio-Gide® is a membrane made of collagen that is generally used to cover the bone replacement material.

#### **2. What is the function of Bio-Gide®?**

It has been proved that better healing rates are achieved when the Bio-Oss® particles are covered with a membrane (Bio-Gide®). Because the tissues of the gum grow more rapidly than the new bone, the membrane protects the Bio-Oss® particles from this faster growing connective tissue. This ensures that the underlying bone can heal in an undisturbed fashion.

#### **3. What is Bio-Gide® made from?**

Bio-Gide® is composed of highly purified natural collagen obtained from pigs.

#### **4. Does the Bio-Gide® membrane have to be removed in a second procedure?**

No. The collagen membrane becomes completely broken down by the body; hence a further operation to remove it is unnecessary.

#### **5. Are there any independent quality controls?**

The manufacturing processes of Bio-Oss® and Bio-Gide® are subject to a Quality Assurance System based on international guidelines (ISO 9001/EN 46001). These processes are checked once every year by acknowledged, independent testing institutes and international authorities.

Bio-Oss® and Bio-Gide® are medical devices that satisfy the safety standard and conditions required by European Union (CE- Certification) and US Food and Drug Administration (FDA).

#### **6. Do side effects occur?**

As with almost all natural and artificial materials incompatibility and allergic reactions are possible and can never be fully excluded. However, because of the high degree of product purity such reactions have been linked to a few mild individual cases. If you experience any reactions tell your dentist or doctor.

**The products, Bio-Oss® and Bio-Gide® have been explained to me in terms I can understand and agree to treatment with Bio-Oss® and Bio-Gide®.**



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