Patient information

for applying maxgraft® bonebuilder (patient matched allogenic/human bone implant)

Dear Patient,

your dentist recommends a ridge augmentation and suggests the use of a bone regeneration material. In dentistry, there are several techniques and materials available for this indication.

Due to the nature and dimension of the bone defect, your dentist has chosen to perform a block augmentation using **maxgraft® bonebuilder (patient matched allogenic/human bone implant)**.

Since the harvesting of autologous bone grafts requires an additional surgical procedure and possibly a second operating site, the risk of complications like infection and wound dehiscence increases significantly. Therefore, autologous bone grafts are applied less and less.

maxgraft® bonebuilder is produced from processed human donor bone tissue (allograft). Those allografts are safe, sterile and derived from cancellous bone of femoral heads from living donor patients from German, Austrian and Swiss hospitals.

maxgraft® bonebuilder is processed and distributed by Cells + Tissuebank Austria (C+TBA). C+TBA is a non-for-profit organization aiming to maintain continuity of the medical supply of allografts under pharmaceutical conditions. Cells + Tissuebank Austria is certified, audited and regulated by the Austrian health ministry in accordance to the regulating European Directives (EU 2004/23EC, 2006/17EC, 2006/86EC) and by the Austrian Tissue Safety Act.

The tissue is processed in compliance with highest quality standards under cleanroom conditions. Additional to prior testing of the donor material, the process includes important steps that efficiently inactivate potential viruses (e.g. HIV, hepatitis B and C, syphilis) and bacteria, such as repeated treatments with diethyl ether, peroxide and ethanol.

Due to the specific lyophilization and freeze-drying procedure allografts can be stored at room temperature and can easily be rehydrated.

The C+TBA process by which **maxgraft® bonebuilder** is produced ensures that all cellular components and particles which can cause an immune reaction are removed.

Processed human bone tissue (allograft), by experience, have always shown to be pressure resistant and advantageous to wound healing. Moreover, we maintain a three dimensional structure which only contains of bone mineral and collagen.

Therefore, your cellular system will identify **maxgraft® bonebuilder** as a bio-compatible growth matrix for new bone tissue. Your bone-forming cells can invade the growth matrix and form a stable connection between your own bone tissue and the allograft, resulting in long-term

stability of the **maxgraft® bonebuilder** block. Ultimately, the donor material is completely replaced by your own newly formed bone.

The safety of the process has been validated by independent institutes and considered absolutely reliable regarding inactivation of viruses (2010) and bacteria (2011). Efficiency of the final sterilization has been validated by the Austrian Health Ministry (AGES).

The Institute of Material Science at the Technical University of Vienna has confirmed optimal elasticity and pressure resistance of the processed allografts.

The osteoconductive and biomechanical properties of the C+TBA allografts support natural and controlled bone remodelling.

Doctor's declaration

*I informed the patient on the details regarding **maxgraft® bonebuilder** and answered all questions to the best of my knowledge.*

Doctor's signature Date

Patient's declaration

*I have read and understood everything. My Dentist informed me of the treatment with **maxgraft® bonebuilder**. I comprehend the content of the information and I consent to the treatment with **maxgraft® bonebuilder**.*

Patient's signature Date

Assistance declaration

I herewith confirm that the patient has been informed on maxgraft® bonebuilder as mentioned in this document.

Assistance signature Date