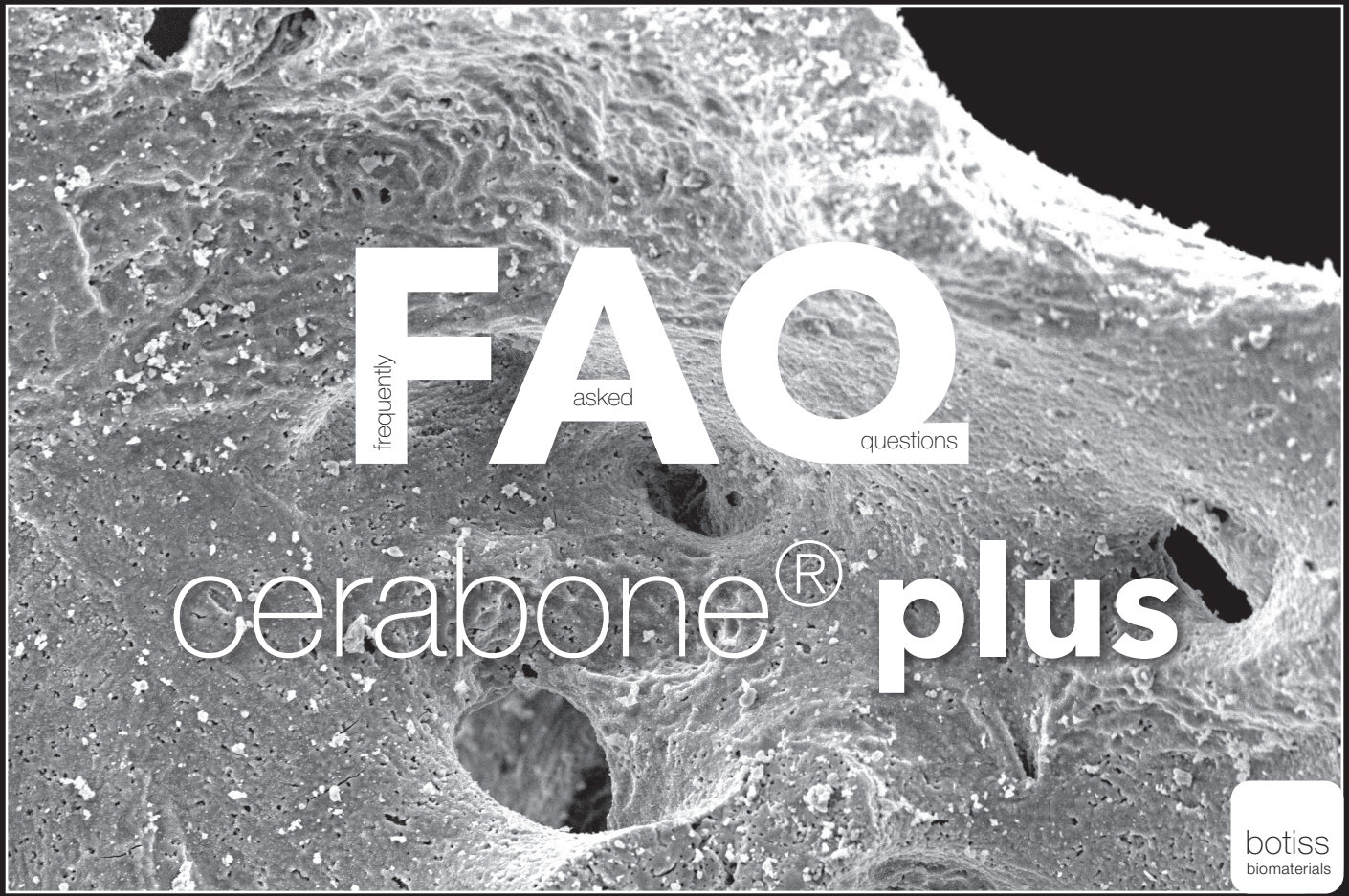

frequently
FAQ
asked
questions
cerabone® plus
botiss
biomaterials

1. What is cerabone® plus?

cerabone® plus is a combination of cerabone® granules and sodium hyaluronate, which is a water-soluble salt form of hyaluronic acid. Thanks to the pronounced liquid binding capacities of hyaluronate, cerabone® plus, upon hydration, forms a malleable material that enables both easy uptake and delivery to the site of application.

cerabone® plus provides a handling alternative by combining the established bone grafting material cerabone® with the well-known properties of hyaluronic acid.

2. How is cerabone® plus provided?

cerabone® plus is provided as small or large cerabone® granules mixed with hyaluronate in a blister for convenient hydration.

Specifications of cerabone® plus

Art.-No.	**Particle size**	**Volume**
1810	0.5 – 1.0 mm	0.5 ml
1811	0.5 – 1.0 mm	1.0 ml
1820	1.0 – 2.0 mm	0.5 ml
1821	1.0 – 2.0 mm	1.0 ml

3. What is hyaluronic acid?

Hyaluronic acid is a large organic polymer (polysaccharide) widely distributed throughout the human body as one major component of the extracellular matrix of many tissues such as skin, muscles, tendon, periodontal soft tissues and alveolar bone.

Hyaluronic acid has structural and space-occupying functions and plays a major role in the body's tissue repair processes.

Properties and functions:

- Stimulates early wound healing[1]
- Stimulates proliferation of fibroblasts[2]
- Stimulates collagen production[3]
- Promotes blood vessel formation[4]
- Has immunomodulatory functions[5]
- Is biocompatible and biodegradable
- Has exceptional liquid binding capacity

4. Where does the hyaluronic acid of cerabone® plus originate from?

The hyaluronic acid used for cerabone® plus is manufactured biotechnologically by bacterial fermentation.

5. What is the benefit of cerabone® plus compared to other particulate bone grafting materials?

cerabone® plus provides application comfort by allowing both easy uptake and delivery to the site of application as a malleable bone graft is formed upon hydration. Mixed with sterile saline, the hyaluronic acid binds and retains the liquid, forming a viscous solution that holds the cerabone® granules together, allowing for precise particle application.

Properties and advantages:

- Malleable following hydration
- Efficient defect filling and time-saving application
- Excellent adaptation to the augmentation area
- Easy defect contouring
- Minimized displacement of single granules during application

6. How is cerabone® plus applied?

cerabone® plus is provided dry and must be hydrated before use.

Following opening of the blister, the indicated amount of liquid (see table below or Instructions For Use) has to be added and must be thoroughly mixed with the bone graft until a connected mass with malleable texture is formed. Mixing can conveniently be performed in the provided blister.

When working with autologous bone, harvested bone chips can be added to cerabone® plus before hydration is performed. In this case, the amount of liquid to be added may vary.

Hydration Protocol

Art.-No.	Volume	Hydration with saline
1810	0.5 ml	approx. 0.25 ml
1811	1.0 ml	approx. 0.5 ml

7. Can I use
patient blood for hydration?

Hydration can also be performed with patient blood.
However, the exact amount of blood to be added has not been evaluated yet.
(see also question below)

8. What should I pay attention to during the application?

To obtain the malleable texture and sticky consistency of cerabone® plus, which is crucial for the stability of the bone graft at the defect site, **proper hydration and mixing with the liquid according to the hydration protocol should be performed.**

If it is not possible to measure the liquid volume for hydration, a careful dropwise addition of the liquid and mixing with the product is recommended. Adding less or more than the specified amount of liquid may prevent formation of the described texture or cause its loss. For optimal adaptation of cerabone® plus to the bone and stability at the augmentation area, excess liquid should be removed from the defect site prior to the application.

9. Do I have to cover cerabone® plus with a membrane after application?

Yes. Thorough fixation with a barrier membrane supports the stabilization of the bone grafting material at the application site. Moreover, in order to prevent ingrowth of soft tissue and to allow for undisturbed healing, the augmentation area should be covered with a barrier membrane according to the principles of GBR.

10. What happens with cerabone® plus after application?

The hyaluronic acid in cerabone® plus is completely resorbed by enzymatic degradation within the first weeks following implantation[6]. The cerabone® granules in cerabone® plus provide an osteoconductive scaffold for bone forming cells promoting osseous regeneration. As the cerabone® granules are only superficially resorbed, they provide long-term volume stability of the grafted site.

11. What are the indications of cerabone® plus?

In general, cerabone® plus can be used in all situations where a particulate bone grafting material is indicated. However, it performs optimally when bleeding at the defect site can be controlled, as in the case of well visible defects, e.g. in lateral augmentation. Very much liquid at the augmentation site may reduce the stability of the bone graft after application. Particularly in sinus floor- or socket augmentation, when profuse bleeding occurs, the use of cerabone® granules should be preferred over cerabone® plus, due to their pronounced hydrophilicity.

IMPLANTOLOGY, PERIODONTOLOGY, ORAL AND CMF SURGERY

- Horizontal and vertical augmentation
- Peri-implant defects
- Periodontal intrabony defects
- Socket and ridge preservation
- Sinus lift
- Furcation defects (class I and II)

12. Could a patient's inflammatory reaction (swelling, redness) be caused by an allergic reaction against the hyaluronic acid in cerabone® plus?

The safety and high biocompatibility of hyaluronic acid has been demonstrated by its use for more than 50 years in various clinical applications, e.g. aesthetic dermatology, ophthalmology and chronic diseases like osteoarthritis and rheumatoid arthritis. For cerabone® plus, the used hyaluronic acid is produced biotechnologically by bacterial fermentation, thus excluding potential adverse reactions against animal derived materials. However, intolerance symptoms and allergic reactions to hyaluronic acid may occur in extremely rare cases and therefore cannot be ruled out completely. In case of suspected allergy against hyaluronic acid, cerabone® plus should not be applied.

13. Are there comparable products to cerabone® plus on the dental market?

Currently, two synthetic bone grafting materials (pure ß-TCPs) are available on the dental market delivered with sodium hyaluronate. One of them is a paste-like material, while the other one may provide comparable handling characteristics (malleability) like cerabone® plus. However, cerabone® plus is currently the only available bovine bone substitute material combined with hyaluronate. Given the unique properties of cerabone®, cerabone® plus is the first bone grafting material on the dental market combining long-term volume stability with the proven properties of hyaluronic acid.

Literature:

1. King SR, Hickerson WL, Proctor KG. Beneficial actions of exogenous hyaluronic acid on wound healing. Surgery. 1991 Jan;109(1):76-84.

2. Greco, R.M., Iocono, J.A. and Ehrlich, H.P. (1998), Hyaluronic acid stimulates human fibroblast proliferation within a collagen matrix. J. Cell. Physiol., 177: 465-473.

3. Rooney, P., Wang, M., Kumar, P., Kumar, S. Angiogenic oligosaccharides of hyaluronan enhance the production of collagens by endothelial cells. Journal of Cell Science 1993 105: 213-218.

4. Sattar A, Rooney P, Kumar S, Pye D, West DC, Scott I, Ledger P. Application of angiogenic oligosaccharides of hyaluronan increases blood vessel numbers in rat skin. J Invest Dermatol. 1994 Oct;103(4):576-9.

5. Stern R, Asari AA, Sugahara KN. Hyaluronan fragments: an information-rich system. Eur J Cell Biol. 2006 Aug;85(8):699-715.

6. Pröhl A, Batinic M, Alkildani S, Hahn M, Radenkovic M, Najman S, Jung O, Barbeck M. In Vivo Analysis of the Biocompatibility and Bone Healing Capacity of a novel bone grafting material based on Xenogeneic Bone Substitute combined with Hyaluronic Acid. (Manuscript submitted)