



# CopiOs<sup>®</sup> Cancellous Particulate Xenograft Bone Augmentation Material

Product Information



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## Why Do I Need Bone Augmentation?

Bone augmentation is most often used to prepare a site for dental implants that are needed to replace a missing tooth or teeth. Bone in an area where teeth have been lost naturally shrinks or resorbs over time, both in height and width. As a result, new bone must be grafted to create a secure site for placing implants and to achieve aesthetic results. Bone grafting can also be used to save teeth that have experienced bone loss.

## What Does Bone Augmentation Entail?

The surgical site is numbed locally. In the region requiring bone reconstruction, a small opening is created. A bone replacement material such as CopiOs Cancellous Particulate Xenograft is placed into the opened receptor site. The bone replacement material is then stabilized with a protective covering (a so-called membrane) and closed for the duration of the healing phase.<sup>1</sup>

## What Is CopiOs Cancellous Particulate Xenograft?

CopiOs Cancellous Particulate Xenograft is a bone grafting product obtained from bovine (cow) bone and used in a variety of indications to rebuild oral bone, including jaw augmentation, filling defects, and tooth extraction sites.<sup>2</sup> The particles are designed to provide a structure for the ingrowth of natural bone to replace what has been lost due to a variety of reasons.<sup>2</sup>

## What Types of Bone Grafts Exist?

Bone can be taken from another site in the patient's body and inserted at the required site. Because this method of bone grafting often results in post-surgical pain and discomfort at the donor site, bone grafts are commercially available to avoid this surgical step. Commercially-available bone grafts originate from human donors or animal bone, like CopiOs Cancellous Particulate Xenograft, or are synthetically manufactured.



## What Happens to CopiOs Cancellous Particulate Xenograft in the Body?

The CopiOs Cancellous Particulate Xenograft is remodeled naturally by the body and replaced by the body's own bone after a period of time.<sup>2</sup>

## How Do I Know It Is Safe?

CopiOs Cancellous Particulate Xenograft is sterile and biocompatible. It is processed through the Tutoplast<sup>®</sup> Tissue Sterilization Process in compliance with strict procedures for consistency and quality. These processes ensure a high standard for safety and quality. More than 6 million implants have been sterilized through the Tutoplast Process with zero confirmed incidence of implant-associated infection.<sup>3</sup> However, transmission of diseases by biological materials cannot be ruled out with absolute certainty.<sup>2</sup>

Zimmer Biomet Dental is committed to offering products with the highest possible quality and safety standards. For this reason, an independent Notified Body reviews and approves the manufacturer per standard processes. CopiOs Cancellous Particulate Xenografts are medical devices that comply with European Regulations for CE Certification.<sup>2</sup>

## Are There Any Side Effects Caused by CopiOs Cancellous Particulate Xenograft?

While no specific side effects are known, patients may experience incompatibility reactions to implanted materials. No interactions between CopiOs Cancellous Particulate Xenograft and medicinal products or medical devices are known.<sup>2</sup>

## What Has to Be Considered?

The use of CopiOs Cancellous Particulate Xenograft should be limited in patients with the following diseases or findings:<sup>2</sup>

- Known hypersensitivity to bovine collagen or bovine trabecular bone
- Disorders or diseases carrying an unacceptable increase in postoperative risk
- Disorders or conditions which inhibit healing due to poor vascularisation, like heart disease, diabetes or smoking
- Active or latent infection in the area of the graft

The use of CopiOs Cancellous Particulate Xenograft to fill bone defects may be a solution despite the presence of some of the circumstances listed above.<sup>2</sup>

## References

1. Elgali, I., et al., Guided bone regeneration: materials and biological mechanisms revisited. Eur J Oral Sci, 2017. 125(5): p. 315-337.
2. CopiOs Cancellous Particulate Xenograft Instructions for use (IFU).
3. Data on file with the manufacturer.

Please note that while this brochure is designed to address some of the frequently asked questions about CopiOs Cancellous Particulate Xenograft individual factors may limit product use in certain indications. Please read instructions for use for more information.



Contact us at 1-800-342-5454 or visit  
[zimmerbiometdental.com](http://zimmerbiometdental.com)

Zimmer Biomet Dental  
Global Headquarters  
4555 Riverside Drive  
Palm Beach Gardens, FL 33410  
Tel: +1-561-776-6700  
Fax: +1-561-776-1272

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