



Product  
Information



# CopiOs<sup>®</sup>

Pericardium Membrane



# CopiOs Pericardium Membrane

## Why Bone Augmentation is Needed?

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.<sup>1</sup>

## What Does Bone Augmentation Entail?

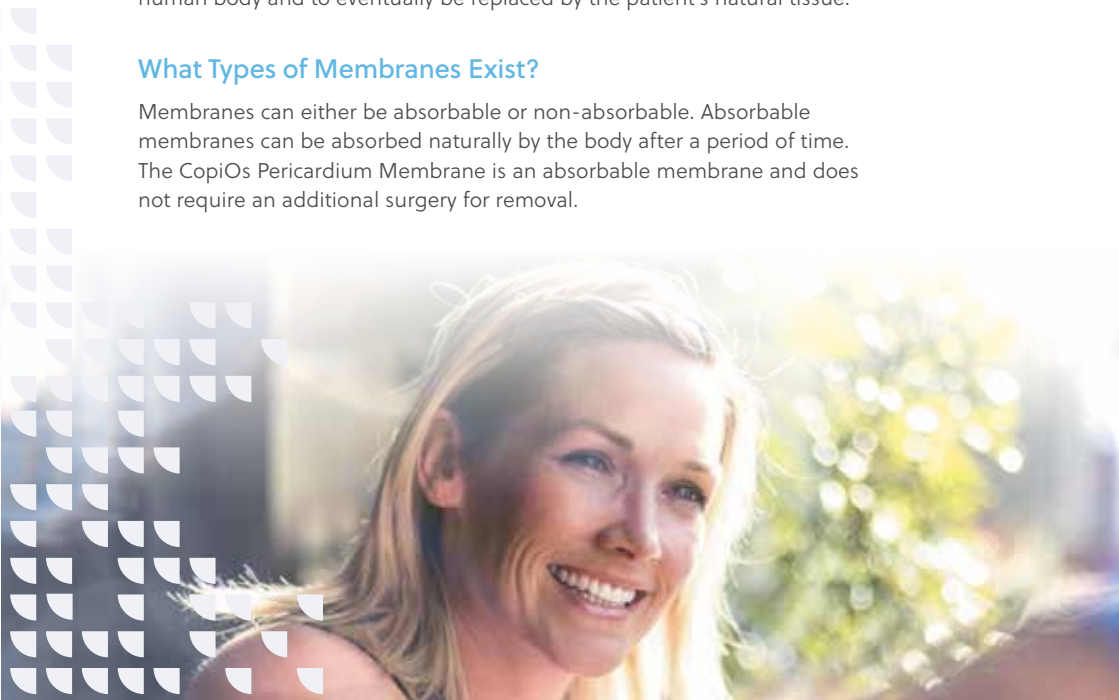
The surgical site is numbed locally. In the region requiring bone reconstruction, a small opening is created. A bone replacement material is placed into the opened receptor site. The bone replacement material is then stabilized with a protective covering, such as CopiOs Pericardium Membrane and closed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

## What Are CopiOs Pericardium Membranes?

CopiOs Pericardium Membranes are protective barrier membranes, comprised of natural occurring tissue produced from bovine (cow) pericardium. The membrane is designed to be fully absorbed by the human body and to eventually be replaced by the patient's natural tissue.<sup>2</sup>

## What Types of Membranes Exist?

Membranes can either be absorbable or non-absorbable. Absorbable membranes can be absorbed naturally by the body after a period of time. The CopiOs Pericardium Membrane is an absorbable membrane and does not require an additional surgery for removal.



## What Happens to CopiOs Pericardium Membrane in the Body?

The CopiOs Pericardium Membrane is absorbed naturally by the body.<sup>2</sup>

## How Do I Know It Is Safe?

The CopiOs Pericardium Membrane is a natural occurring tissue that has been treated through the proprietary, Tutoplast® Sterilization Process in compliance with strict procedures for consistency and quality. This process ensures high standard for safety and quality. The result is a safe, biocompatible membrane. However, transmission of diseases by biological materials cannot be ruled out with absolute certainty.

ZimVie 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 Pericardium Membranes are medical devices that comply with European Regulations for CE Certification.<sup>2</sup>

## Are There Any Side Effects Caused by CopiOs Pericardium Membranes?

While no specific side effects are known, patients may experience local reactions to CopiOs Pericardium Membranes.<sup>2</sup> No interactions for CopiOs Pericardium Membranes are known.<sup>2</sup>

## What Has to Be Considered?

CopiOs Pericardium Membranes should not be applied in any of the following events:<sup>2</sup>

- Known hypersensitivity to bovine collagen

A benefit-risk assessment for each individual patient shall be undertaken by the dentist/ surgeon in case of:

- 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
- Exclusive contact with surfaces preventing cell migration into the membrane or which do not offer sufficient capillarisation

The use of CopiOs Pericardium Membranes to cover grafted sites may be the best solution despite the presence of some of the circumstances listed above.

### References

1. Elgali I, Omar O, Dahlin C, Thomsen P. Guided bone regeneration: materials and biological mechanisms revisited. *Eur J Oral Sci* (2017) 125:315-337.
2. CopiOs Pericardium Membrane Instructions for use (IFU).

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

For more information, visit [ZimVie.eu](http://ZimVie.eu)

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The IFU for CopiOs Pericardium Membrane is solely provided in digital form via [eifu.tutogen.com](http://eifu.tutogen.com). Internet capable device with a PDF-viewer is required to display the Instructions for Use.

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