Patient Information Leaflet

Dental Barrier Membrane (DBM) creos™ xenoprotect

- Read this leaflet carefully because it contains important information for you
- Keep this leaflet. You may need to read it again.
- Ask your dentist if you need more information or advice.
- You must contact your dentist if any of the side effect describe further below worsen or do not improve.

This Patient Information Leaflet includes important information for you to consider and discuss with your healthcare provider prior to treatment with creos™ xenoprotect, including the benefits and risks of the treatment and any precautions which should be taken.

What is creos™ xenoprotect?
Your healthcare provider determined a need for a bone augmentation by bone substitute as part of your dental treatment. creos™ xenoprotect is a membrane that is used to cover and protect the bone substitute material during the healing phase. It is composed of highly purified natural protein collagen sourced from porcine tissues (pigs).

Why is a membrane needed?
It has been clinically proven that better bone formation is achieved when the bone substitute material is covered with a membrane. Since gum tissues grow faster than new bone can form, the membrane protects the bone substitute material from the faster growing soft tissue. This ensures that, beneath the membrane, the defect can heal undisturbed.

Does the membrane have to be removed in a second surgery?
No. After a few months, the collagen membrane is completely absorbed by the body. A second operation to remove the membrane is therefore not needed.

creos™ xenoprotect consists of tissue of animal origin. How safe and biocompatible is it?
Starting materials for the production of creos™ xenoprotect are harvested in EU certified facilities under strict veterinary controls from veterinary certified animals that are declared fit for human consumption. The biocompatibility of creos™ xenoprotect has been demonstrated through testing and is due to the utilization of effective purification and processing methods during manufacturing. It complies with all relevant regulations ensuring its safety and effectiveness.

When shall creos™ xenoprotect not be used?
The following are contraindications for creos™ xenoprotect:

- The use of creos™ xenoprotect without bone substitute material is not indicated.
- creos™ xenoprotect should not be used in infected areas. An active infection of the implant site may lead to an increased biodegradation of creos™ xenoprotect which may lead to an early loss of its barrier function.
- Adverse reactions during the use of porcine-derived collagen membranes during bone augmentation procedures have not been observed. However, allergic reactions cannot be totally excluded. The use of creos™ xenoprotect in patients with known sensitivity to porcine-derived materials and collagen is not recommended.

Where are precautions necessary?
In patients with constrained healing capacity (e.g. due to metabolic disorders, cancer treatments, heavy smoking) creos™ xenoprotect should be used with special caution and closer patient monitoring during post-operative care.

How do I attend my wound?
A bacterial inflammation of the gum and jawbone is one of the rare complications that can occur after creos™ xenoprotect treatment. The good news is that by maintaining good oral hygiene, you can generally prevent it by yourself!
Providing good preventive care is, therefore, the best thing you can do to take care of your wound.
In the first few days after surgery, you must protect the sensitive wound, so your dentist may have recommended to not brush the area with the new implant and may have instead suggested a rinsing regime which may also include an antiseptic mouthwash such as containing chlorhexidine.
To further encourage good healing during the first few days you should also avoid spicy foods as well as coffee, black tea, and alcohol, and allow your food to cool prior to eating. Furthermore, smoking is not recommended during the first days after surgery.
Depending on the surgical protocol that was chosen by your dentist to be best suitable for you, eating and brushing recommendations may vary.

Are there any undesirable side effects possible?
In case of soft tissue wound dehiscence (unwanted divergence of the wound edges), an increase in biodegradation of creos™ xenoprotect may occur, which could result in an earlier loss of the barrier function.
Other possible side effects are probably not related to creos™ xenoprotect itself but may occur with any surgery, like infection, wound swelling, bleeding, local inflammation, bone loss, or pain.

Please seek medical advice if you experience any of the forementioned symptoms.

Magnetic Resonance Imaging (MRI) with creos™ xenoprotect
Since creos™ xenoprotect does not contain any metallic components, there is no impairment of creos™ xenoprotect during an MRI scan.

For a patient in the European Union and in countries with an identical regulatory regime:

If, during the use of this device or as a result of its use, a serious incident has occurred in relation to creos™ xenoprotect, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Phone: +49 2407 56440
Email: vigilance@matricel.com

Australian patients may also report a serious incident to the Therapeutic Goods Administration at this link:
https://www.tga.gov.au/reporting-problems

This information sheet is available for download at:

http://www.matricel.com

Manufacturer

Matricel GmbH
Kaiserstrasse 100
52134 Herzogenrath
Germany
www.matricel.com

Distributor

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Västra Hamngatan 1
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Implant Card

Dental Barrier Membrane (DBM) creos™ xenoprotect

Together with this Patient Information Leaflet you have received an Implant Card (or will receive from your healthcare provider soon after the treatment).
This card, similar to a business card, contains all relevant information related to your individual creos™ xenoprotect.
You can keep this card in your wallet to always have that information with you.

	Patient Name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer of the dental barrier membrane.
	A website of the manufacturer where patients can get more information about the implant.
MD	Device Name - This symbol is used to indicate the device name.
LOT	Lot Number - This is the manufacturer‘s unique lot number of your implant.
	Use-by Date - This is the date after which the medical device may no longer be used.
UDI	Unique device identification (UDI) in automatic identification and data capture (AIDC) format. Manufacturer‘s information coded in here in a digitally readable format.
UDI-DI	A human readable format of the UDI information.
	Contains biological material of animal origin.