Patient Information VIVOSORB®

What is VIVOSORB® Used For

Vivosorb® is indicated for use as a temporary protective sheet to separate opposing soft tissues where applicable in patients undergoing surgery, thereby minimizing tissue attachment.

Product Description

Vivosorb® is composed of a bioresorbable copolyester poly(DL-lactide-ε-caprolactone) sheet. Vivosorb® can be applied to temporarily separate opposing soft tissues.
Vivosorb® elicits a minimal acute inflammatory reaction of the surrounding tissue, which is followed by gradual encapsulation of the material by fibrous tissue. Degradation of the sheet occurs through hydrolysis leading to gradual reduction of molecular weight. The sheet remains its initial mechanical properties up to at least 8-10 weeks, whereafter rapid loss of mechanical strength and gradual mass loss occur. The final degradation products, lactic acid and ω-hydroxy hexanoic acid, are resorbed, metabolized and excreted by the body. The material is resorbed within approximately 16 months. Expected device lifetime is 24 months if stored between -18°C and 8°C.

VIVOSORB® is available in 2 sizes:

Catalogue #	Type (Dimensions cm)
FS01-006/20	Vivosorb 2x3
FS01-035/20	Vivosorb 5x7

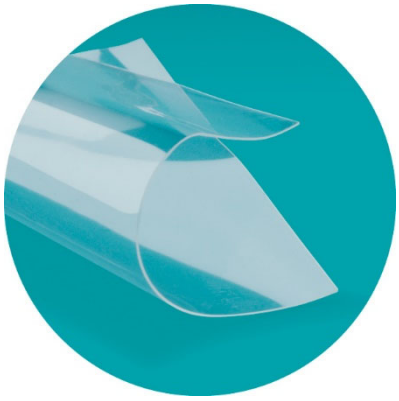

Figure 1 VIVOSORB®

Components

DL-Lactide monomer
L-Lactide monomer
Ɛ-Caprolactone monomer
Tin(II*)* 2-ethylhexanoate

When VIVOSORB® Should Not be Used

There are no contra-indications.

Precaution

Despite extensive testing of the product, adverse effects may occur as with any product and surgery. Any adverse outcomes potentially attributable to VIVOSORB® must be reported promptly to your doctor. You should also report it to Polyganics at +31 50 5886598 or directly to the Therapeutic Goods Administration at this link: https://www.tga.gov.au/reporting-problems

Adverse Effects

Procedures requiring implantation of a Vivosorb® sheet should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during the procedure.
Adverse events associated with the use of a Vivosorb® sheet may include but are not limited to:

- Failure to provide adequate support for appropriate healing;
- Transitory local irritation;
- Infection;
- Allergy;
- Delayed wound healing

Seek medical advice if you experience any of these symptoms.

MRI Information

VIVOSORB® is non-conducting and non-magnetic and poses no risk in the Magnetic Resonance Imaging (MRI) environment.

Usage

The product is for single patient use only. The cutting to the correct size in each procedure if needed is determined by the judgment of the clinician.
No specific instructions for use are applicable for the patient, besides the surgery specific instructions provided by the hospital to the patient.

Record Keeping

It is important that you keep a record of your implant. You will be sent a small card similar to a credit card that you can keep in your wallet which will have the details of your implant printed on it.

Manufacturer

Legal Manufacturer and Manufacturing Facility
Polyganics Innovations BV
Blauwborgje 32
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Phone (worldwide): +31 (0)50 5886588
This information sheet is available for download at:
https://polyganics.com/media/downloads/

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