SU-POR®
Surgical Implant

CE 0120 Patient-Specific Surgical Implant

STERILE EO ② STERILE IMPLANT, FOR SINGLE USE ONLY

PORIFEROUS, LLC
535 Pine Road Suite 206
Newnan, GA 30263-7640, USA
1-678-683-3855 | 1-877-631-1954 | Fax 1-770-683-7459

Sterility guaranteed unless Inner packaging is opened, damaged, or wet.
Caution : Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Tel: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299

⚠ Product Information MR

DESCRIPTION

SU-POR® Patient- Specific Surgical Implants are manufactured of porous high-density polyethylene, a biomaterial that is readily modified and shaped to suit the functional and anatomical requirements of the patient. The interconnecting pores of the Porous HDPE material permits fibrovascular ingrowth into the implant. The implant will not show through overlying tissue due to its light color. In virto and in vivo biocompatibility studies have shown SU-POR Patient-Specific Surgical Implants to be free from any observable systemic or cytotoxic effects. Porous HDPE Surgical Implants are provided STERILE. The SU-POR Patient-Specific Surgical Implants are MR Safe and pose no known hazards in all magnetic resonance imaging environments. SU-POR Patient-Specific Surgical Implants are not made with natural rubber latex.

INDICATIONS

SU-POR Patient-Specific Surgical Implants in customized shapes are intended for non-weight-bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma. SU-POR Patient-Specific Surgical Implants are also intended for the augmentation or restoration of contour in the craniomaxillifacial skeleton.

CONTRAINDICATIONS

1. Active infection.
2. In areas where there are prolonged, significant, compressive stresses.
3. Foreign body sensitivity. Where material sensitivity is suspected, appropriate testing should be made to rule out this possibility prior to implantation.
4. Patients who are unwilling or unable to follow postoperative instructions due to accompanying conditions (mental or physical).
5. Limitations in blood supply and/or systemic disorders that may slow healing and increase the possibility of infection and/or rejection of the implants.
6. Use in tissue that has been compromised by cancer therapies.
7. Inadequate coverage with healthy tissue.
8. Any degenerative disease process that would adversely affect proper placement of the implants.
9. Procedures in which a non-sterile environment exists, such as sinuses.
10. Use in weight bearing area such as the temporal mandible joint.

POSSIBLE ADVERSE EFFECTS

1. Vascular changes.
2. Allergic reaction to the implant.
3. Deformation or fracture of the implant.
4. Surgical trauma related nerve damage.
5. Pain, discomfort, and /or abnormal sensation due to presence of the implant.
6. Superficial and/or deep infection.
7. Loosening or migration of the implant.

WARNINGS

1. SU-POR Patient-Specific Surgical Implants must never be re-used or re-sterilized. Re-use may increase the risk of infection.
2. Sufficient patient instruction is a crucial factor in the success of the surgical procedure. Post-operative follow-up and care are essential. The patient must be made aware that excessive physical activity or load bearing may cause implant migration, loosening, deformation, or fracture. The patient must be informed of the risks of using the implants, including possible adverse effects.
3. The success of any implant is dependent upon careful handling and proper surgical technique. When shaping and contouring the implant, sharp edges should be avoided to minimize trauma to the surrounding tissue.
4. The implant must never be shaped by use of intense heat producing devices such as electrosurgical devices, heated knives, or lasers.
5. Because of the porous nature of the implant material, there is an increased possibility of contamination. Therefore, it is most important, when handling and preparing porous polyethylene implants that the highest level of aseptic care be used. Do not store, place, or carve the implant on surfaces which may contaminate it with lint or other particulate matter such as: surgical drapes or cloth.
6. The surgeon must be thoroughly familiar with the implants, the method of application, the instrumentation, and the surgical procedure.
7. These implants are not designed for applications with weight or load bearing requirements.
8. Responsibility for completion of technical training, appropriate patient selection, and choice and placement of the implants is at the discretion of the physician.

INSTRUCTIONS FOR USE

This document is in no way intended to be a comprehensive manual of surgical techniques. Surgeons should utilize their surgical training, clinical experience, and applicable surgical techniques to determine appropriate surgical procedures. Experienced surgical judgment should be utilized in the selection and use of SU-POR implants.

The success of an implant is dependent upon surgical technique. The incision should be made such that the closure does not occur directly over the implant whenever possible. The implant shape may be modified with the techniques outlined in the following sections.

SHAPING THE IMPLANT

SU-POR Patient-Specific Surgical Implants are provided in a customized anatomical shape, which may be modified by the surgeon to produce the desired results. The material may be carved using scalpel, burr, or cut with scissors, care should be taken to smooth the edges of the implant where it transitions to bone. Trim any poorly attached implant material from the edges. After carving and sculpting is complete, wash the implant with sterile saline to remove any loose particles from its surface and edges. To help the shaping process, the implant can be submerged in a hot, sterile saline bath (82° - 100°C, 180° - 212°F). Having been heated the implant will be more flexible allowing for modification to the shape. If the implant cools and becomes difficult to bend, it should be returned to the hot saline. Once the desired shape is obtained, the implant should be held in that shape and allowed to cool. A cold, sterile bath can be used to accelerate the cooling process. Repeat the above steps if further molding is required.

PLACING THE IMPLANT

As a prophylactic measure, the implants should be rinsed in a sterile antibiotic solution prior to implantation. Surgeons should remove all carved debris from the surgical site with care.
A sufficient tissue pocket should be prepared to ensure that tissue is not pulled taut over the implant. Incisions located exactly over the implant site should be avoided. If the potential for the implant to move before tissue ingrowth exists, fixation can be accomplished with sutures, surgical fixation screws, or K-wire. Fixation screws should be tightened until they are flush with the surface of the implant. Multiple pieces of implant material can be stacked and joined by suturing. A cutting needle can easily penetrate the surface of the implant enabling the surgeon to re-suspend tissue or muscle by attaching it to the implant. For implants placed using the intraoral route, a rubber dam or impervious plastic film should be used to isolate the incision to reduce the risk of contaminating the implant.

WARRANTY
All products are warranted to be free from defects in material and workmanship. No warranty is made for any purpose other than in the product specifications and labeling.

Additional information pertaining to specific devices or issues may be obtained from Poriferous, LLC.

Labeling Symbols

	Keep Dry
	Do not use if Packaging is Damaged
MR	MR Safe
	Do Not Resterilize
DIM	Dimensions
CAT #	Catalog Number

PORIFEROUS