SYNPOR® POROUS POLYETHYLENE IMPLANTS

For craniofacial and orbital augmentation and reconstruction
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SYNPOR Implants are manufactured from an inert, nonabsorbable polymer formulated to contain a network of open and interconnecting pores approximately 100 µm–250 µm in size. These interconnected pores allow fibrovascular tissue ingrowth and relative host incorporation, rather than the host encapsulation observed with smooth-surface implants.

SYNPOR Implants are well-suited for craniofacial reconstruction and augmentation. The implant’s porous structure promotes tissue ingrowth and results in rapid integration and stabilization.

**Features**
- Porous structure supports tissue ingrowth
- Smooth implants have one barrier surface allowing tissue ingrowth on only one side
- Nonabsorbable and biocompatible material
- Semirigid material is strong yet flexible
- Contourable and easily shaped
- Implants may be fixated with screws, wire, or suture

**Clinical applications**

**Orbital augmentation and reconstruction**
- Orbital floor/wall
- Orbital rim
- Enophthalmos

**Cranial/skull base augmentation and reconstruction**
- Cranioplasty
- Calvarial bone graft donor sites
- Burr hole defects
- Sellar floor
- Pterion
- Mastoid

**Facial augmentation and reconstruction**
- Malar
- Genioplasty
- Mandibular: angle/body/ramus
Material
SYNPOR Implants are manufactured from ultra-high molecular weight polyethylene (UHMWPE), which has a long history of use as a surgical implant and meets ASTM standards.\textsuperscript{2,3} In addition, SYNPOR Implants have passed ISO standard tests for biocompatibility.\textsuperscript{4} Several SYNPOR Implant designs also incorporate titanium mesh constructed from commercially pure (CP) titanium.

Indications
SYNPOR Porous Polyethylene Implants are intended for use in non-load bearing applications in craniofacial reconstruction, cosmetic surgery, and repair of craniofacial trauma.

Contraindications
- Active or latent infection
- Inadequate coverage of healthy, vascularized tissue
- Full load-bearing applications
- Systemic disorders that cause poor wound healing or may lead to soft tissue deterioration over the implant

References
4. ISO 10993, Biological Evaluation of Medical Devices.
SYNPOR IMPLANT SHEETS

**SYNPOR Implant Sheets**
Engineered to maintain an open, interconnected porosity throughout the implant to support tissue ingrowth.

**SYNPOR Implant Smooth Sheets**
Implants have a thin layer of solid polyethylene on the superior surface to minimize tissue adhesion and porous polyethylene on the inferior surface to support tissue ingrowth.

- Radiolucency reduces interference with diagnostic imaging
- Anatomical shapes, proven through many years of clinical history, allow quick implantation and minimize trimming
- 50 mm x 50 mm sheets for custom shaping
- Multiple thicknesses to meet clinical needs

**Technique tip:** For smooth implants, place the smooth side of the implant toward the soft tissue to minimize adhesion and ensure motility of the globe.
SYNPOR Implant Titanium Reinforced Fan Plates
Porous sheet embedded with the DePuy Synthes CMF fan-shaped 1.3 mm titanium orbital floor plate.

SYNPOR Implant Smooth Titanium Reinforced Fan Plates
Porous sheet embedded with the DePuy Synthes CMF fan-shaped 1.3 mm titanium orbital floor plate. SYNPOR Implant Smooth Titanium Reinforced Fan Plates provide a barrier to minimize soft tissue adhesion on the superior surface and a porous surface on the reverse side to support tissue ingrowth

- Radiographic visibility
- Increased sheet strength and contour retention
- Available with titanium mesh partially exposed or completely covered for multiple fixation options
- Anatomical shape and radial titanium mesh design minimize cutting
- Polyethylene sheets reduce sharp titanium edges after cutting and facilitate insertion
- Fixation hole positions allow optimal screw placement
- Available in two thicknesses: 0.8 mm and 1.5 mm
- Compatible with 1.3 mm titanium screws

**Technique tip:** For smooth implants, place the smooth side of the implant toward the soft tissue to minimize adhesion and ensure motility of the globe.
1 Handling

SYNPOR Porous Polyethylene Implants are provided sterile and pyrogen-free, for single-patient use. Do not resterilize.

Do not remove SYNPOR Implants from their packaging until time of implantation.

Handle implants with clean, powder-free gloves to prevent contamination.

Caution

• Do not place implants on surgical drapes, surgical clothing, or any other material that may contaminate the implants with lint or other particulate matter. Implants may be placed in sterile saline to prevent contamination.
• Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged packages.
• DO NOT USE if there is loss of sterility of the device.
• The implants are intended for SINGLE use only.
2

Sizing

SYNPOR Implants can be easily cut and sculpted with scissors, mesh cutters, or a scalpel.

Thicker implants may be adapted to the surgical site using bone cutters or cutting burrs to achieve the desired shape. If the implant is burred, reestablish the open pore structure by shaving the outer surface with a scalpel.

Multiple pieces can be sutured together when thicker or larger implants are required.

After sizing the implant, rinse it in sterile saline solution to remove loose particles.

Caution

- Do not place or carve the implant on cloth or any other surface that may contaminate the implant with lint and other particulate matter.
- The implants are NOT to be modified by any electrosurgery device.
Contouring

SYNPOR Implants can be contoured by submerging in hot, sterile saline (over 70°C/160°F) for several minutes until the implant softens. Higher temperatures will improve the ability to contour the implant.

Remove the implant from the hot saline and contour to the desired shape. If there is too much resistance, return the implant to hot saline.

Allow the implant to cool completely to maintain the achieved shape. Cold, sterile saline can accelerate the cooling process.

Reheat the implant as needed to achieve the final form desired.
4 Stabilizing

If desired, implants may be stabilized with screws, wire, or suture.

SYNPOR Implant Titanium Reinforced Fan Plates are compatible with 1.3 mm titanium cortex screws.

When using screws, tighten them sufficiently to compress the implant to the bone and minimize the screw profile.

Make any final modifications in situ. Feather the edges of the implant to create a smooth transition and minimize palpability.

**Important:** Take care to remove all carved debris from the surgical site.
SYNPOR Porous Polyethylene Implants are not intended for full load-bearing applications unless used with traditional rigid fixation. The device can break or bend as a result of stress or activity, which could cause failure of the device or the treatment.

The surgeon is to be thoroughly familiar with the devices, the method of application, the instruments, and the surgical procedure. The surgeon must select a type or types of internal fixation appropriate for the treatment.

Improper selection, placement, positioning, and fixation of the devices can cause subsequent undesirable results.

Porous Polyethylene Implants should not be used in areas exposed to the outside environment.

The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the implant construct, which could require additional surgery and device removal.
SYNOPOR Square Sheets, sterile
08.510.110S  50 mm x 50 mm, 0.45 mm thick
08.510.120S  50 mm x 50 mm, 0.8 mm thick
08.510.130S  50 mm x 50 mm, 1.5 mm thick
08.510.140S  50 mm x 50 mm, 3.0 mm thick

SYNOPOR Smooth Square Sheets, sterile
08.510.220S  50 mm x 50 mm, 0.8 mm thick

SYNOPOR Orbital Floor Plates, sterile
08.510.540S  24 mm, 0.8 mm thick
08.510.541S  30 mm, 0.8 mm thick
08.510.542S  35 mm, 0.8 mm thick
08.510.543S  24 mm, 1.5 mm thick
08.510.544S  30 mm, 1.5 mm thick
08.510.545S  35 mm, 1.5 mm thick

SYNOPOR Smooth Orbital Floor Plates, sterile
08.510.640S  24 mm, 0.8 mm thick
08.510.641S  30 mm, 0.8 mm thick
08.510.642S  35 mm, 0.8 mm thick

SYNOPOR Fan Plates, sterile
08.510.546S  35 mm radius, 0.8 mm thick
08.510.547S  35 mm radius, 1.5 mm thick

SYNOPOR Smooth Fan Plates, sterile
08.510.646S  35 mm radius, 0.8 mm thick
**SYNPOR Titanium Reinforced Fan Plates, sterile**
- 08.520.120S 0.8 mm thick (purple)
- 08.520.130S 1.5 mm thick (teal)

**SYNPOR Smooth Titanium Reinforced Fan Plates, sterile**
- 08.520.220S 0.8 mm thick (purple)
- 08.520.230S 1.5 mm thick (teal)

**SYNPOR Titanium Reinforced Fan Plates, with exposed fixation holes, sterile**
- 08.520.121S 0.8 mm thick (purple)
- 08.520.131S 1.5 mm thick (teal)

**SYNPOR Smooth Titanium Reinforced Fan Plates, with exposed fixation holes, sterile**
- 08.520.221S 0.8 mm thick (purple)
- 08.520.231S 1.5 mm thick (teal)
Limited Warranty and Disclaimer: DePuy Synthes CMF products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

Rx Only

Not all products are currently available in all markets.