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.1

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, tacks, 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
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

Please see Directions for Use for complete indications, contraindications, warnings and precautions.

References
4. ISO 10993, Biological Evaluation of Medical Devices.
SynPOR Sheets
Engineered to maintain an open interconnected porosity throughout the implant to support tissue ingrowth.

SynPOR 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 Titanium Reinforced Fan Plates
Porous sheet embedded with the Synthes fan-shaped 1.3 mm titanium orbital floor plate.

SynPOR Smooth Titanium Reinforced Fan Plates
Porous sheet embedded with the Synthes fan-shaped 1.3 mm titanium orbital floor plate. SynPOR 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 in-growth

– 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.
Handling

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.
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 use electrosurgical devices to cut or modify the implants.
Contouring

3 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.
If desired, implants may be stabilized with screws, tacks, wire, or suture.

SynPOR 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.
### Product Information

**SynPOR 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

**SynPOR Smooth Square Sheets, sterile**
- 08.510.220S 50 mm x 50 mm, 0.8 mm thick

**SynPOR 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

**SynPOR 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

**SynPOR Fan Plates, sterile**
- 08.510.546S 35 mm radius, 0.8 mm thick
- 08.510.547S 35 mm radius, 1.5 mm thick

**SynPOR 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)