

SYNPOR[®] POROUS POLYETHYLENE IMPLANTS

For craniofacial and orbital augmentation and reconstruction

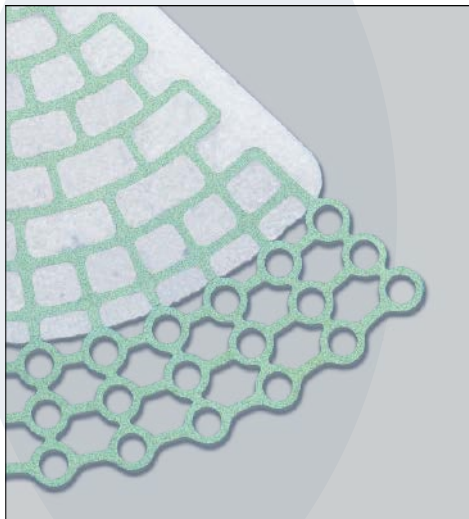
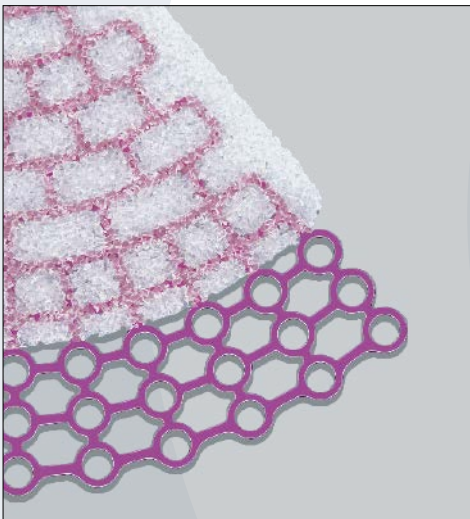


TABLE OF CONTENTS

INTRODUCTION	SYNPOR Porous Polyethylene Implants	2
	Indications and Contraindications	3
	SYNPOR Implant Sheets	4
	SYNPOR Implant Titanium Reinforced Fan Plates	5
<hr/>		
SURGICAL TECHNIQUE	Handling	6
	Sizing	7
	Contouring	8
	Stabilizing	9
	Additional Warnings and Precautions	10
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PRODUCT INFORMATION	SYNPOR Implants	11

SYNPOR POROUS POLYETHYLENE IMPLANTS

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, wire, or suture

Clinical applications

Orbital augmentation and reconstruction

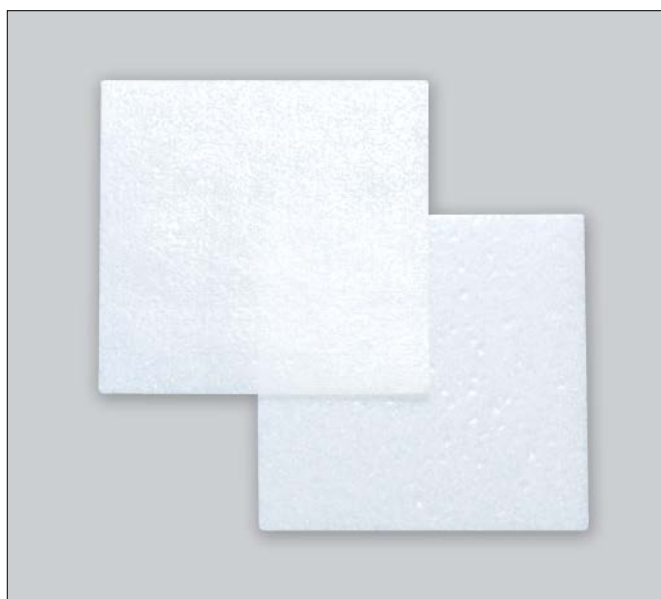
- Orbital floor/wall
- Orbital rim
- Enophthalmos

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.^{2,3} In addition, SYNPOR Implants have passed ISO standard tests for biocompatibility.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

1. Yaremchuk MJ. Facial Skeletal Reconstruction Using Porous Polyethylene Implants. *Plastic Reconstr Surg.* 2003; 111(6):1818-27.
2. ASTM F648, Standard Specification for Ultra-High-Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants.
3. ASTM F755, Standard Specification for Selection of Porous Polyethylene for Use in Surgical Implants.
4. ISO 10993, Biological Evaluation of Medical Devices.

SYNPOR IMPLANT SHEETS

SYNPOR Implant Sheets

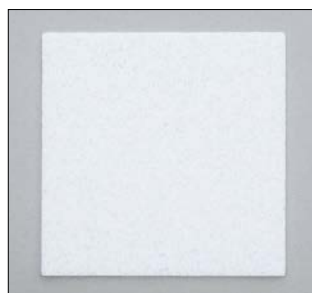
Engineered to maintain an open, interconnected porosity throughout the implant to support tissue ingrowth.

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 Square Sheet



SYNPOR Implant Smooth Square Sheet



SYNPOR Implant Orbital Floor Plate



SYNPOR Implant Fan Plate

SYNPOR IMPLANT TITANIUM REINFORCED FAN PLATES

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.



SYNPOR Implant Titanium Reinforced Fan Plate



SYNPOR Implant Titanium Reinforced Fan Plate, with exposed fixation holes



SYNPOR Implant Smooth Titanium Reinforced Fan Plate



SYNPOR Implant Smooth Titanium Reinforced Fan Plate, with exposed fixation holes

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.**
- **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.**



SIZING

2

Sizing

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

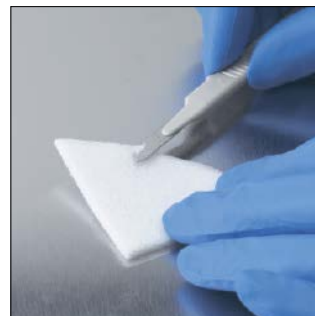
Thicker implants may be adapted to the surgical site using bone cutters or cutting burrs to achieve the desired shape. If the implant is burred, reestablish the open pore structure by shaving the outer surface with a scalpel.

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

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.



STABILIZING

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.



ADDITIONAL WARNINGS AND PRECAUTIONS

- **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.**

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

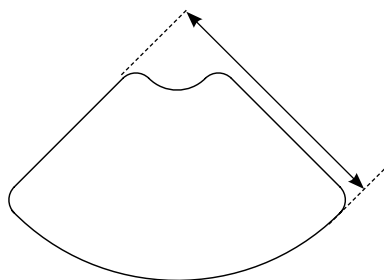
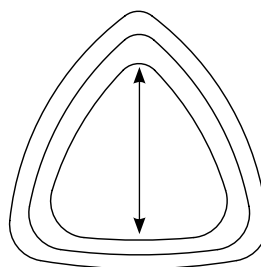
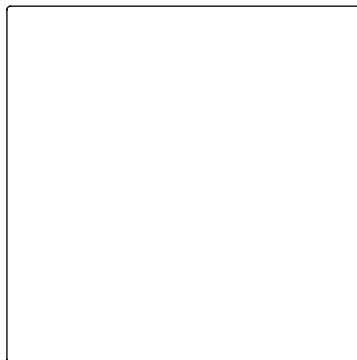
- 08.510.640S 24 mm, 0.8 mm thick
- 08.510.641S 30 mm, 0.8 mm thick
- 08.510.642S 35 mm, 0.8 mm thick

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

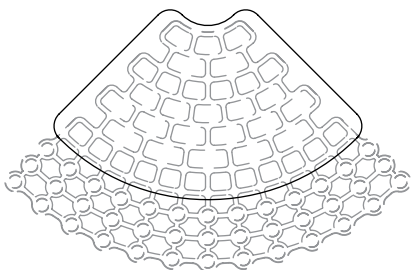
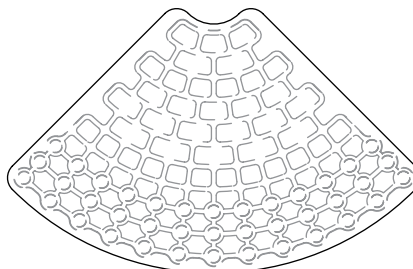
08.520.121S 0.8 mm thick (purple)

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)



Note: For additional information, please refer to the package insert or www.e-ifu.com.

For detailed cleaning and sterilization instructions, please refer to www.depuy-synthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

Limited Warranty and Disclaimer: DePuy Synthes 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.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this technique guide may not have been licensed in accordance with Canadian law and may not be for sale in Canada.

Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.



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Note: For recognized manufacturer, refer to the product label.

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