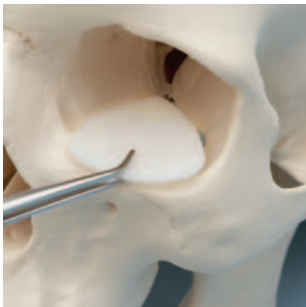
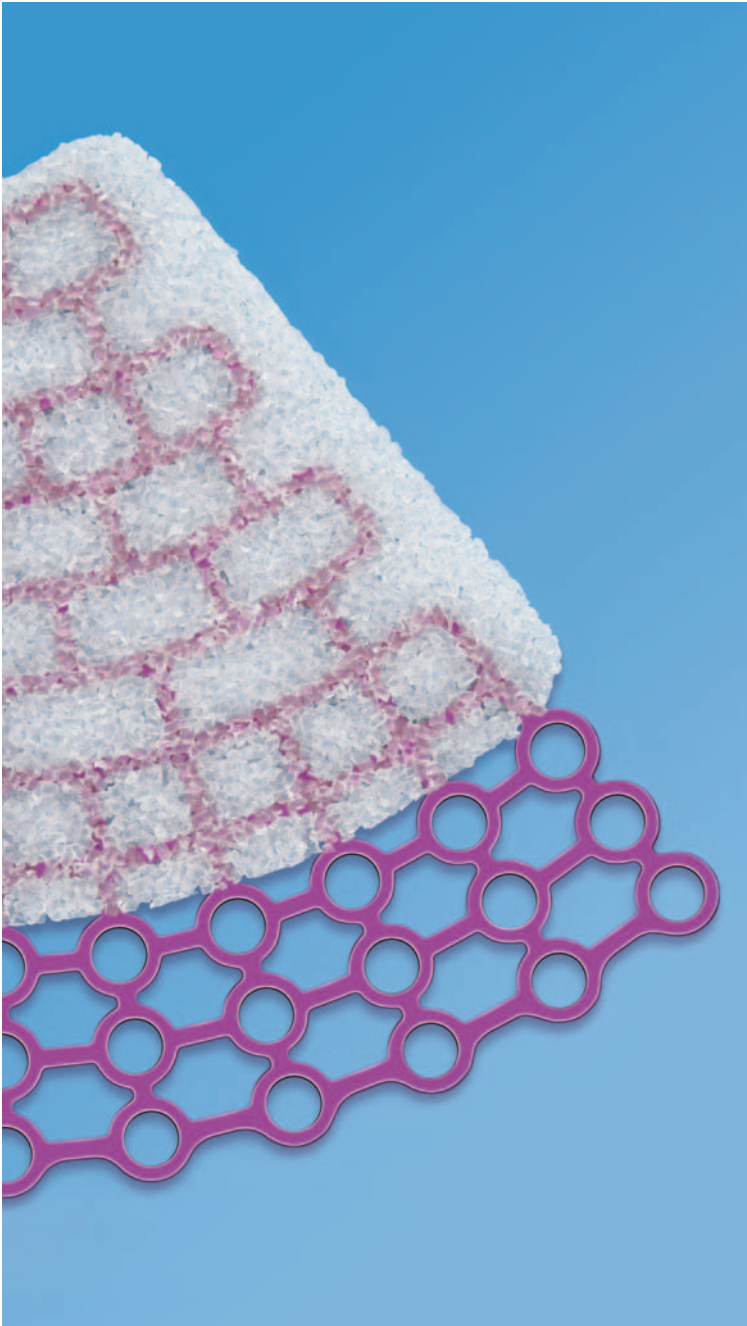


# SynPOR. Synthes porous polyethylene implants.

## Technique Guide





# Table of Contents

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Introduction	<b>SynPOR</b>	2
	<b>Clinical Applications</b>	3
	<b>Indications and Contraindications</b>	3
	<b>Product Options</b>	4
Surgical Technique	<b>Handling</b>	5
	<b>Sizing</b>	6
	<b>Contouring</b>	7
	<b>Implant Fixation</b>	8
Product Information	<b>Implants</b>	9

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 Image intensifier control

### **Warning**

This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

### **Reprocessing, Care and Maintenance of Synthes Instruments**

For general guidelines, function control and dismantling of multi-part instruments, please contact your local sales representative or refer to:  
[www.synthes.com/reprocessing](http://www.synthes.com/reprocessing)

# SynPOR. Synthes porous polyethylene implants.

## Overview

SynPOR implants are manufactured from an inert, nonabsorbable polymer formulated to contain a network of open and interconnecting pores approximately 100–250 µm in size. These interconnected pores allow fibrovascular tissue ingrowth and relative host incorporation, rather than host encapsulation observed with smooth-surface implants<sup>1</sup>.

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 material
- Semi-rigid material is strong yet flexible
- Contourable and easily shapeable
- Implants may be fixated with screws, tacks, wire or suture

## 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 the requirements of ASTM standard<sup>2</sup>. In addition, SynPOR implants have passed ISO standard tests for biocompatibility<sup>3</sup>. Several SynPOR designs also incorporate titanium mesh constructed from commercially pure titanium.



1. Yaremchuk, M.J., Facial skeletal reconstruction using porous polyethylene implants. *Plast Reconstr Surg*, 2003. 111(6): p. 1818-27
2. ASTM F648, Standard Specification for Ultra-High-Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants.
3. ISO 10993, Biological Evaluation of Medical Devices.

# Clinical Applications

## Indications and Contraindications

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### Clinical Applications

#### **Orbital augmentation and reconstruction:**

- Orbital floor/wall
- Orbital rim
- Enophthalmos
- Lower eyelid retraction

#### **Facial augmentation:**

- Malar
- Genioplasty
- Mandibular: angle/body/ramus

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### Indications

SynPOR Implants are intended for the augmentation or reconstruction of bony contours in the craniomaxillofacial skeleton in non-load bearing indications only.

### Contraindications

SynPOR Implants should not be used in the following circumstances:

- The presence of active or latent infections
- Systemic disorders and/or limitations in blood supply that may cause slow healing and increase the possibility of infection and/or rejection of the implants
- Tissue that has been compromised by cancer therapies
- Any degenerative disease process that would adversely affect proper placement of the implants
- Sinus procedures
- Cranioplasty procedures
- Dura repair or cases where the dura is damaged

SynPOR Implants are not indicated for use in load bearing and unstable indications unless used in conjunction with appropriate osteosynthesis fixation systems.

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

# Product Options

## SynPOR Sheets

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

## SynPOR Smooth Sheets

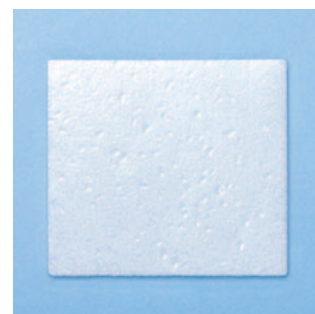
Implants have a thin layer of solid polyethylene on the superior surface to minimize tissue adhesion and porous polyethylene on the inferior surface to support tissue ingrowth.

- Radiolucency reduces interference with diagnostic imaging
- Anatomical shapes, proven through many years of clinical history, allow for quick implantation
- 50 mm×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.



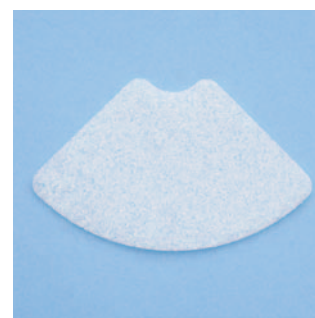
SynPOR Sheet



SynPOR Smooth Sheet



SynPOR Orbital Floor Plate



SynPOR Fan Plate

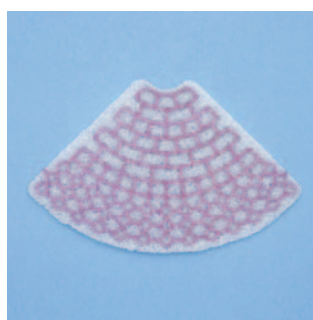
## SynPOR Titanium Orbital Floor Mesh Plate

The fan-shaped 1.3 mm orbital floor plate is embedded in porous sheets.

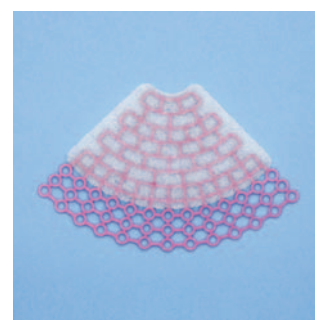
## SynPOR Smooth Titanium Orbital Floor Mesh Plate

The fan-shaped 1.3 mm orbital floor plate is embedded in a porous and a smooth sheet. 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 ingrowth.

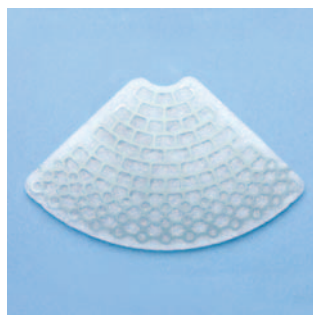
- Titanium mesh provides radiographic visibility
- Increased sheet strength and contour retention
- Available with titanium mesh partially exposed or completely covered for multiple fixation options
- Anatomical shape and radial titanium mesh design minimize cutting
- Polyethylene sheets reduce sharp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



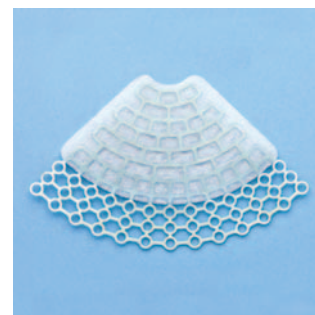
SynPOR Titanium Orbital Floor Mesh Plate



SynPOR Titanium Orbital Floor Mesh Plate, with exposed fixation holes



SynPOR Smooth Titanium Orbital Floor Mesh Plate



SynPOR Smooth Titanium Orbital Floor Mesh Plate, with exposed fixation holes

## Handling

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SynPOR implants should not be removed from their sterile packaging until time of implantation.

The implants should be handled with clean, powder-free gloves to prevent contamination.

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**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.

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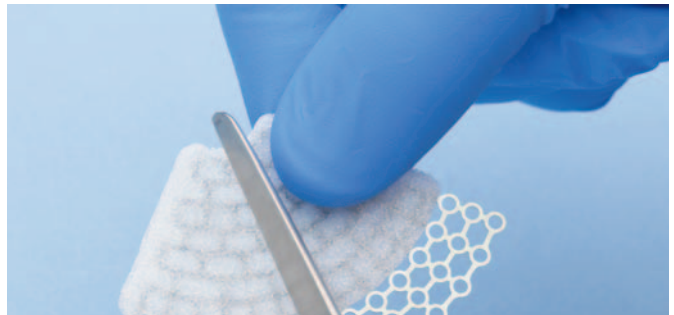


# Sizing

SynPOR implants can be easily cut and sculpted with scissors, mesh cutters and/or scalpel to the desired shape.



**Caution:** Do not use electro-surgical devices to cut or modify the implants.



## Thicker implants

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



## Multiple pieces

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

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





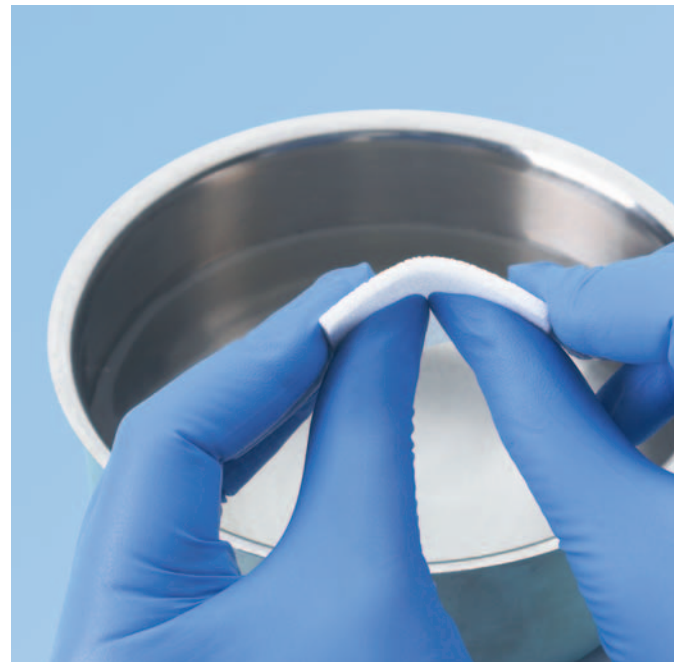
# Contouring

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

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

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

Reheat the implant as necessary to achieve the final form desired.



# Implant Fixation

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Stabilize the implant with screws, tacks, wire or suture as desired.

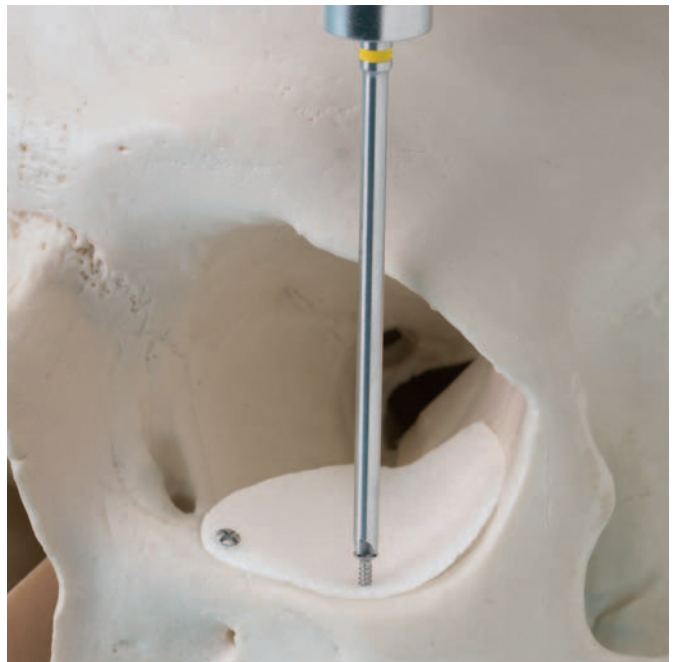
When using screws, tighten sufficiently to compress the implant to the bone and minimize screw profile.

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

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**Caution:** Take care to remove all carved debris from the surgical site.

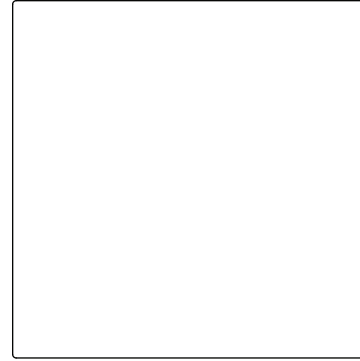
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# Implants

## SynPOR Sheet, sterile

Art. No.	Dimension (mm)	Thickness (mm)
08.510.110S	50×50	0.45
08.510.120S	50×50	0.8
08.510.130S	50×50	1.5
08.510.140S	50×50	3.0

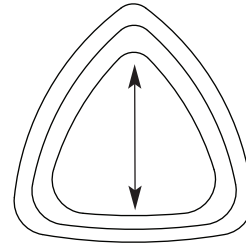


## SynPOR Smooth Sheet, sterile

Art. No.	Dimension (mm)	Thickness (mm)
08.510.220S	50×50	0.8

## SynPOR Orbital Floor Plate, sterile

Art. No.	Dimension (mm)	Thickness (mm)
08.510.540S	24×24	0.8
08.510.541S	30×30	0.8
08.510.542S	35×35	0.8
08.510.543S	24×24	1.5
08.510.544S	30×30	1.5
08.510.545S	35×35	1.5

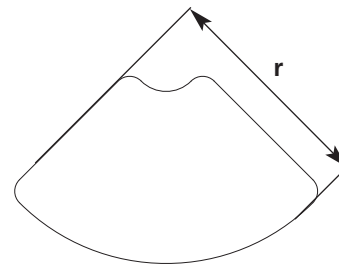


## SynPOR Smooth Orbital Floor Plate, sterile

Art. No.	Dimension (mm)	Thickness (mm)
08.510.640S	24×24	0.8
08.510.641S	30×30	0.8
08.510.642S	35×35	0.8

## SynPOR Fan Plate, sterile

Art. No.	Radius (mm)	Thickness (mm)
08.510.546S	35	0.8
08.510.547S	35	1.5

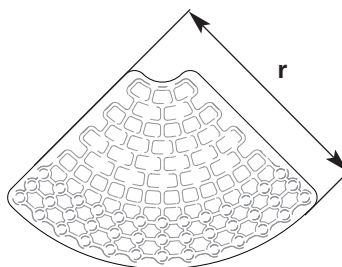


## SynPOR Smooth Fan Plate, sterile

Art. No.	Radius (mm)	Thickness (mm)
08.510.646S	35	0.8

**SynPOR Titanium Orbital Floor Mesh Plate, sterile**

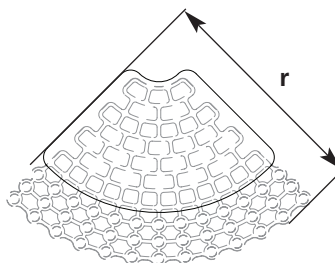
Art. No.	Radius (mm)	Thickness (mm)
08.520.120S	44.6	0.8
08.520.121S	43.6	0.8 with exposed fixation holes
08.520.130S	44.6	1.5
08.520.131S	43.6	1.5 with exposed fixation holes



SynPOR/SynPOR Smooth Titanium Orbital Floor Mesh Plate

**SynPOR Smooth Titanium Orbital Floor Mesh Plate, sterile**

Art. No.	Radius (mm)	Thickness (mm)
08.520.220S	44.6	0.8
08.520.221S	43.6	0.8 with exposed fixation holes
08.520.230S	44.6	1.5
08.520.231S	44.6	1.5 with exposed fixation holes



SynPOR/SynPOR Smooth Titanium Orbital Floor Mesh Plate , with exposed fixation holes

**Note:** SynPOR porous polyethylene implants are provided sterile and for single-patient use. Do not resterilize.











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