Synpor Synthes Porous Polyethylene Implant

Surgical Technique
This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

**Processing, Reprocessing, Care and Maintenance**

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
# Table of Contents

## Introduction
- SynPOR 2
  - Clinical Applications 3
  - Indications and Contraindications 4
  - Precautions and Warnings 4
  - Magnetic Resonance (MR) Environment 5
  - Product Options 6

## Surgical Technique
- Handling 7
- Sizing 8
- Contouring 9
- Implant Fixation 10

## Product Information
- Implants 11
Synpor
Synthes Porous Polyethylene Implants

Overview
SynPOR implants are made 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 implants¹.

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 fixed with screws, tacks, wire or suture

Material
SynPOR implants are made from ultra-high molecular weight polyethylene (UHMWPE), which has a long history of use as a surgical implant and meets the requirements of ASTM standard². In addition, SynPOR implants have passed ISO standard tests for biocompatibility³. Several SynPOR designs also incorporate titanium mesh constructed from commercially pure titanium⁴.

³ ISO 10993, Biological Evaluation of Medical Devices.
Clinical Applications

Indications and Contraindications

Clinical Applications

Orbital augmentation and reconstruction:
• Orbital floor/wall
• Orbital rim
• Enophthalmos
• Lower eyelid retraction

Facial augmentation:
• Malar
• Genioplasty
• Mandibular: angle/body/ramus

Indications and contraindications

Indications
SynPOR Implants are indicated for orbital augmentation/reconstruction or facial augmentation of bony contours in non-load bearing applications only.

Contraindications
SynPOR Implants should not be used in the following circumstances:
• The presence of active or latent infections
• Inadequate coverage of healthy, vascularized tissue
• 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
• Load bearing and unstable applications
Precautions and Warnings

Precautions:
• Excessive and repetitive contouring of the implant increases the risk of implant breakage.
• In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or augmentation area.
• Do not attempt to re-sterilize the unused contents of an opened pack. Re-sterilizing of SynPOR implants can result in product not being sterile, and/or not meeting performance specifications.
• Do not use if there is loss of sterility of the device.
• Do not place or contour the implant on any surface that could transfer contaminants to the implant.
• Do not place or carve 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.
• Do not use electrosurgical devices to cut or modify the implants.

Warnings:
• Using SynPOR implants in skeletally immature patients is not recommended. The natural course of bone growth in these patients may result in malalignment of the implant. However, the treating physician should weigh the benefits of the application of the SynPOR implants against the potential risk for the patient.
• Improper selection, placement, positioning and fixation of the implant can cause a subsequent undesirable result.
• 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.
• Porous materials are particularly at risk for contamination by foreign materials and particulate matter, including glove powder, lint from draping materials, and cleaning agents. All efforts should be made to limit handling of the implants.

The product should be used with caution in patients with the following conditions:
• Patients with poor wound healing
• Patients with poor bone quality

In these cases the treating physician should weigh the benefits of the application of the SynPOR implants against the potential risk for the patient.
Magnetic Resonance (MR) Environment

**Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-14 and ASTM F2119-07**

Non-clinical testing of a worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 5.4 T/m. The largest image artifact extended approximately 20 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a single Siemens Prisma 3 T MRI system.

**Radio Frequency (RF) – induced heating according to ASTM F2182-11a**

Non-clinical electromagnetic and thermal simulations of a worst case scenario lead to temperature rises of 9.3 °C (1.5 T) and 6.0 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

**Precautions:** The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermo regulation or temperature sensation should be excluded from MR scanning procedures.
- Generally it is recommended to use an MRI system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further limit temperature increase in the body.
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 allow for quick implantation in a variety of sites with minimal manipulation required
- 50 mm × 50 mm sheets for custom shaping
- Multiple thicknesses to meet clinical needs

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 Orbital Floor Mesh Plate
The fan-shaped orbital floor plate is embedded in porous sheets.

SynPOR Smooth Titanium Orbital Floor Mesh Plate
The fan-shaped 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 and 1.5 mm
Handling

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

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

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 and/or scalpel to the desired shape.

**Do not use electrosurgical 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. If employing a cutting burr, 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 (at least 70° +/- 5 °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 contour. Cold, sterile saline can accelerate the cooling process.

Implants may be reheated as necessary to achieve the final form desired.
Implants may be stabilized with rigid fixation screws, wire or suture, if desired.

When using rigid fixation, the screws should be fully inserted to compress the implant to the bone and minimize screw profile.

Final modifications can be made in situ. Feathering the edges of the implant will help create a smooth transition and minimize palpability.

Take care to remove all carved debris from the surgical site.
### SynPOR Sheet, sterile

<table>
<thead>
<tr>
<th>Art. No.</th>
<th>Dimension (mm)</th>
<th>Thickness (mm)</th>
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</thead>
<tbody>
<tr>
<td>08.510.110S</td>
<td>50×50</td>
<td>0.45</td>
</tr>
<tr>
<td>08.510.120S</td>
<td>50×50</td>
<td>0.8</td>
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<tr>
<td>08.510.130S</td>
<td>50×50</td>
<td>1.5</td>
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<tr>
<td>08.510.140S</td>
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<td>3.0</td>
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### SynPOR Smooth Sheet, sterile

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<tbody>
<tr>
<td>08.510.220S</td>
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<td>0.8</td>
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### SynPOR Orbital Floor Plate, sterile

<table>
<thead>
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<th>Art. No.</th>
<th>Dimension (mm)</th>
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<tbody>
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<tr>
<td>08.510.543S</td>
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<td>1.5</td>
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<tr>
<td>08.510.544S</td>
<td>30×30</td>
<td>1.5</td>
</tr>
<tr>
<td>08.510.545S</td>
<td>35×35</td>
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<tbody>
<tr>
<td>08.510.640S</td>
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<tr>
<td>08.510.641S</td>
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<td>0.8</td>
</tr>
<tr>
<td>08.510.642S</td>
<td>35×35</td>
<td>0.8</td>
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### SynPOR Fan Plate, sterile

<table>
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<tr>
<th>Art. No.</th>
<th>Radius (mm)</th>
<th>Thickness (mm)</th>
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<tbody>
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<td>08.510.546S</td>
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<tr>
<td>08.510.547S</td>
<td>35</td>
<td>1.5</td>
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</tbody>
</table>

### SynPOR Smooth Fan Plate, sterile

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<tbody>
<tr>
<td>08.510.646S</td>
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<td>0.8</td>
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</table>
**SynPOR Titanium Reinforced Fan Plate, sterile**

<table>
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<th>Thickness (mm)</th>
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<tbody>
<tr>
<td>08.520.120S</td>
<td>44.6</td>
<td>0.8</td>
</tr>
<tr>
<td>08.520.121S</td>
<td>43.6</td>
<td>0.8 with exposed fixation holes</td>
</tr>
<tr>
<td>08.520.130S</td>
<td>44.6</td>
<td>1.5</td>
</tr>
<tr>
<td>08.520.131S</td>
<td>43.6</td>
<td>1.5 with exposed fixation holes</td>
</tr>
</tbody>
</table>

**SynPOR Smooth Titanium Reinforced Fan Plate, sterile**

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</tr>
<tr>
<td>08.520.221S</td>
<td>43.6</td>
<td>0.8 with exposed fixation holes</td>
</tr>
<tr>
<td>08.520.230S</td>
<td>44.6</td>
<td>1.5</td>
</tr>
<tr>
<td>08.520.231S</td>
<td>43.6</td>
<td>1.5 with exposed fixation holes</td>
</tr>
</tbody>
</table>

SynPOR porous polyethylene implants are provided sterile and pyrogen free, for single-patient use. Do not resterilize.
Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

All surgical techniques are available as PDF files at www.depuysynthes.com/ifu