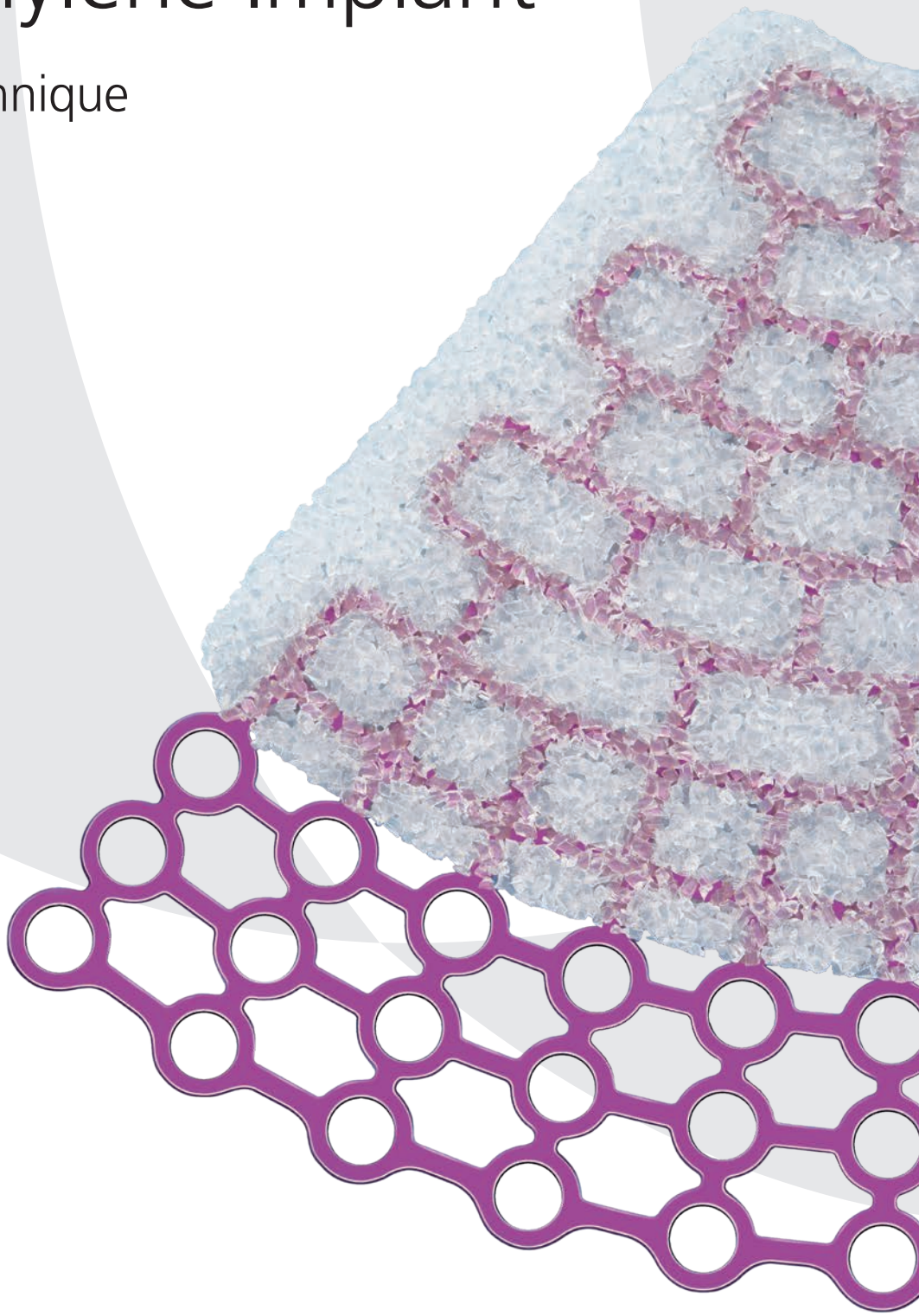
SynPOR™ Porous Polyethylene Implant

Surgical Technique



DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

AO approved by AO Technical Commission

Image intensifier control

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 DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy 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

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.

SynPOR implants are for craniofacial reconstruction and augmentation. The implant's porous structure promotes tissue ingrowth.

- Porous structure supports tissue in growth
- Implants have a thin layer of solid polyethylene on the superior surface and porous polyethylene on the inferior surface.
- Nonabsorbable Polymer
- Semi-rigid material
- Contourable
- Implants may be fixated with screws, tacks, wire or suture

Material
SynPOR implants are made from ultra-high molecular weight polyethylene (UHMWPE). Several SynPOR designs incorporate titanium mesh constructed from commercially pure titanium.

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.

Intended Use, Indications and Contraindications can be found in the corresponding system Instructions For Use.

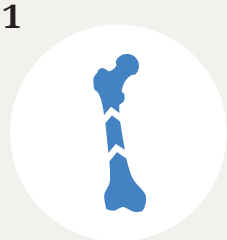
MRI Information on Torque, Displacement, Image Artifacts and Radio Frequency (RF)-induced heating can be found in the corresponding system Instructions for Use.

The AO Principles of Fracture Management

Mission
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

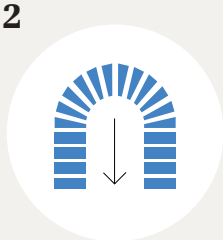
AO Principles [1,2]

1



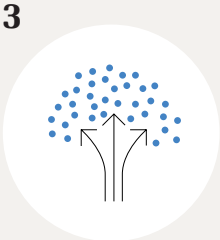
Fracture reduction and fixation to restore anatomical relationships.

2



Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4

Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

[1] Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991
[2] Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

Product Options

SynPOR Sheets
Implants have an open interconnected porosity to support tissue ingrowth.

SynPOR Smooth Sheets
Implants have a thin layer of solid polyethylene on the superior surface and porous polyethylene on the inferior surface.

- Radiolucency reduces interference with diagnostic imaging
- Implants are provided in a variety of shapes and thicknesses with access to definitive contouring
- 50 mm × 50 mm sheets available

For smooth implants, place the smooth side of the implant toward the soft tissue.


SynPOR Sheet


SynPOR Smooth Sheet

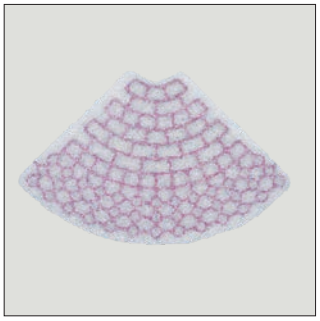

SynPOR Orbital Floor Plate

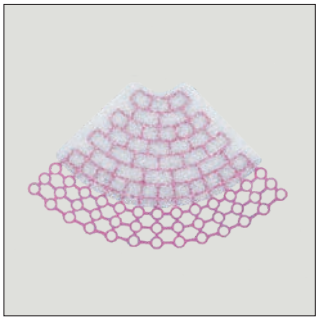

SynPOR Fan Plate

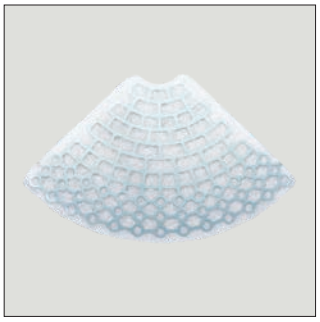
SynPOR Titanium Orbital Floor Mesh Plate
The fan-shaped orbital floor plate is embedded in porous sheets.

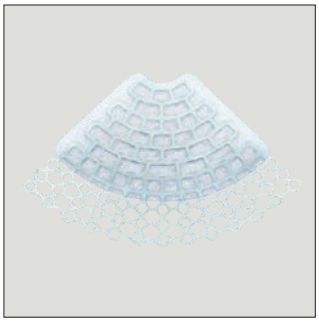
SynPOR Smooth Titanium Orbital Floor Mesh Plate
The fan shaped orbital floor plate is embedded in a porous and smooth sheet.

- Ti Mesh provides radiographic visibility
- Available with Ti Mesh partially exposed or completely covered
- Anatomical shape and radial mesh available
- Fixation hole positions allow for screw placement
- Available in 2 thicknesses: 0.8 mm and 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

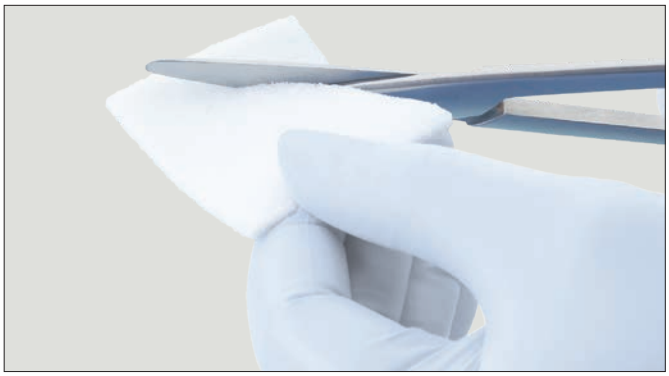
SynPOR implants should not be removed from their packaging until time of implantation.

The implants should be handled with clean, powder-free gloves to reduce the risk of contamination.

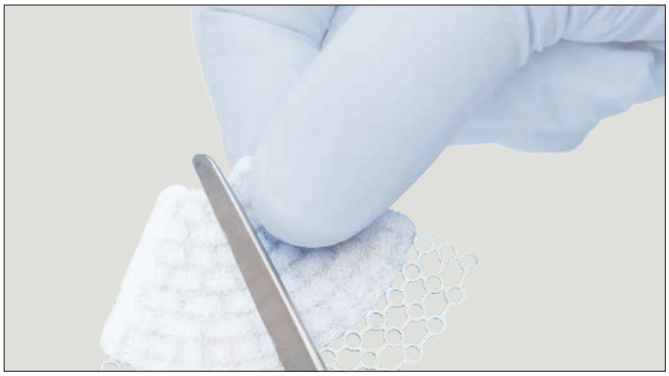
Do not place implants on surgical drapes, surgical clothing or any other material that may contaminate the implants with lint or other particulate matter. Implants may be placed in sterile saline to prevent contamination.

Sizing

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



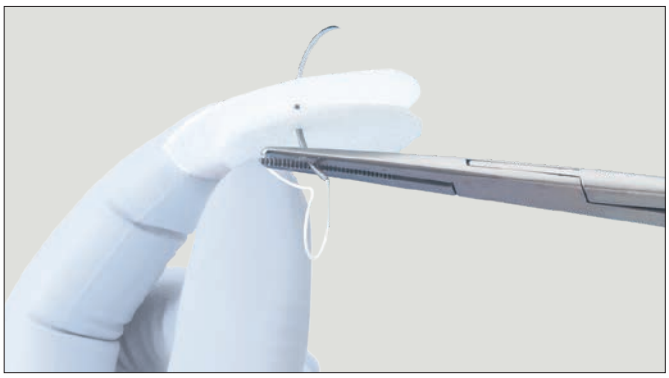
Do not use electrosurgical devices to cut or modify the implants.



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.



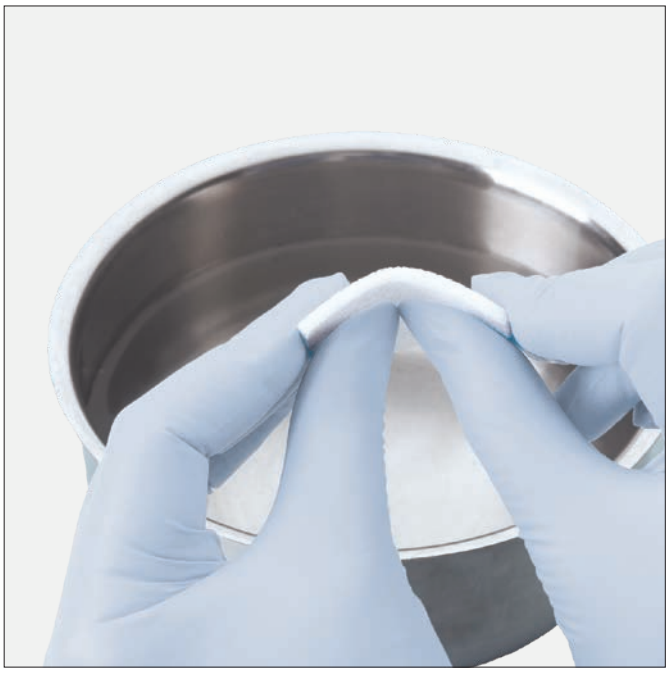
Contouring

SynPOR Implants can be contoured by submerging in heated, sterile saline (at least 70 °C +/– 5 °C) 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.



Implant Fixation

Implants may be stabilized with rigid fixation screws, wire or suture.

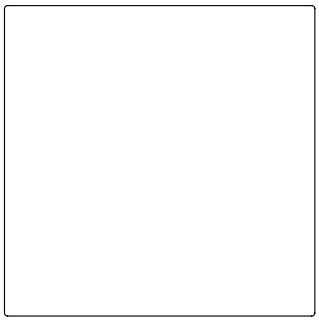
When using rigid fixation, the screws should be fully inserted to compress the implant to the bone, which aids to reduce screw profile. The edges of the implant could be feathered, to aid in a smooth transition from the implant to the patients natural contour. Final Modifications can be made in situ.

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

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

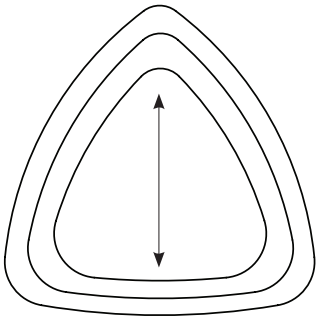


SynPOR Smooth Sheet, sterile

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

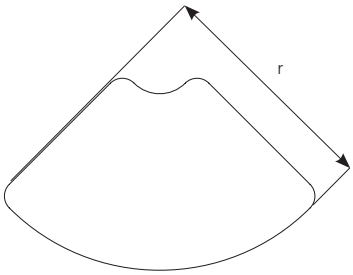


SynPOR Smooth Orbital Floor Plate, sterile

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

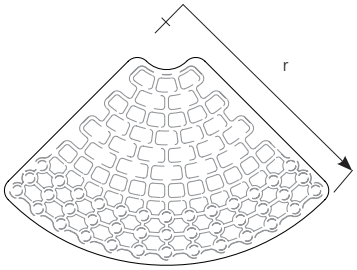


SynPOR Smooth Fan Plate, sterile

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

SynPOR Titanium Reinforced Fan Plate, sterile

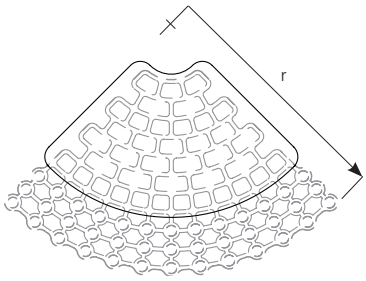
Art. No.	Radius (mm)	Thickness (mm)
08.520.120S	44.6	0.8
08.520.121S	43.6	0.8 with exposed fixation holes
08.520.130S	44.6	1.5
08.520.131S	43.6	1.5 with exposed fixation holes



SynPOR/SynPOR Smooth Titanium Orbital Floor Mesh Plate

SynPOR Smooth Titanium Reinforced Fan 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	43.6	1.5 with exposed fixation holes



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

SynPOR porous polyethylene implants are provided sterile and pyrogen free, for single-patient use. Do not resterilize.

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Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

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www.depuysynthes.com/ifu

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