Osteopore® PCL Scaffold Bone Filler

INSTRUCTIONS FOR USE

English

INTENDED USE / INDICATIONS

The Osteomesh®/Osteoplug®/Osteoplug®-C is a Bone Void Filler. It is intended for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects. It is also for use in the augmentation or restoration of bony contour in the craniofacial skeleton. The shape of the device conforms to the defect, thus maximizing direct contact with viable host bone. The device is made of polycaprolactone which will degrade and resorb fully in vivo by hydrolysis into which it is then metabolized by the body, over a period of 18-24 months. This device does not contain radioactive substances and is safe for use with MRI.

CONTRAINDICATIONS

1. Do not use in patients with conditions including: latent or active infections, systemic disorders which will hinder wound healing, or with insufficient quantity or quality of bone stock.
2. Do not use in contaminated surgical areas.
3. Do not use in patients with septic reactions.
4. Not indicated for load bearing anatomical sites.
5. Do not use in areas exposed to outside environment.

WARNINGS

1. Do not expose the scaffold to heat over 45°C.
2. Do not use if a package has been opened or damaged.
3. For single use only. Additional sterilization may alter device characteristics, e.g. advanced resorption.
4. Do not use if there is a loss of sterility.
5. Do not resterilize.
6. Do not expose to direct sunlight.
7. Excessive bending (>90 degree) of the device will cause scaffold rods to break down, thus rendering it unsuitable for implantation.
8. Disposal of devices that have been implanted but then removed from the patient are deemed contaminated and shall be disposed appropriately as biohazard waste as part of routine hospital practice.

POTENTIAL ADVERSE EFFECTS

1. Infections both deep and superficial.
2. Bending, loosening, rubbing and migration of the device can occur as a result of excessive activity, trauma or load bearing. (Osteomesh+ only)
3. Allergies and other reactions to scaffold materials.
4. Neurovascular injuries can occur in course of surgery.
5. Fracture and migration can occur due to excessive trauma or load bearing
6. Other possible adverse reactions with the mesh are those typically associated with any implantable prosthesis, including, but not limited to residual diplopia, persistent enophthalmos, ectropion, scleral show, implant extrusion and infraorbital hypesthesia. (Osteomesh+ only)

PRECAUTIONS

1. Patient must be warned that excessive stress or load on surgical site post-implantation will cause it to loosen or fracture.
2. Patient must be educated of the surgical risk and possible postoperative effects if due care and instructions are not followed.
3. External exposure should be avoided. (Osteomesh+ only)
4. The safety and effectiveness of adding any substances to the device is not known. These may change the setting time, strength, and reaction rate.
5. The safety and effectiveness of the material when used adjacent to non-viable bone is not known. If there is a need to re-operate in the area of the implant, the device should be removed.
6. The effect of the device on patients with sinus obliteration is not known. (Osteomesh+ only)

PREPARATION FOR USE

1. The device is provided in STERILE foil packaging.
2. Using aseptic technique, remove the device from foil packaging.
3. Place the device in the sterile field. It should only reside in sterile environment once removed from packaging.
4. If bone wax or gel foam is used, it should be removed from the bone interface prior to the administration of the material.

DIRECTIONS FOR USE

1. Prepare the implantation site using standard surgical techniques.

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2. Control of active bleeding should be achieved prior to implantation of the material.
3. Fixate the device in place according to the surgeon's professional clinical judgment and currently accepted surgical practices. Refer to the Osteomesh® and Osteoplug® Surgial Guide for detailed implantation instructions.
4. Affix the traceability label in the patient's medical record.

STORAGE INSTRUCTIONS

1. Store in cool dry place out of direct sunlight.
2. Prior to use inspect package for signs of tampering, damage or water contamination.
3. Do not leave the device in the car under direct sunlight even for short periods to prevent accidental melting of the device.

INFORMATION

EC REP	Obelis s.a. Bd., General Wahis 53 1030 Brussels, Belgium Tel: +32(0)2 732 59 54 Fax: +32(0)2 732 60 03		Keep Package Dry
	Osteopore International Pte Ltd, 2 Tukang Innovation Grove #09-06 JTC MedTech Hub, Singapore 618305 Tel: +65 6250 2817		Use by Expiration Date
	Do Not Reuse		Do Not Resterilize
STERILE R	Sterilized Using Irradiation	-10°C 30°C	Storage Temperature Limitation (-10°C to 30°C)
SN	Serial Number		Do Not Use If Package Is Damaged
	Keep Away From Sunlight		Consult Instructions For Use

DISCLAIMER OF WARRANTY

Although Osteomesh®/Osteoplug®/Osteoplug®-C (hereinafter referred to as "product") has been manufactured under carefully controlled conditions, Osteopore® has no control over the conditions under which the product is used. OSTEOPORE®, THEREFORE, DISCLAIMS ALL CONDITIONS, WARRANTIES, GUARANTEES, BOTH EXPRESSED AND IMPLIED (WHETHER STATUTORY OR OTHERWISE), WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OTHER THAN THOSE MANDATORY WARRANTIES OR GUARANTEES PROVIDED FOR BY LAW WHICH CANNOT LAWFULLY BE EXCLUDED. THE PRODUCT IS PROVIDED "AS IS" AND OSTEOPORE® SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES, OR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE, OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. No person has any authority to bind Osteopore® to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

Store at or below room temperature. Do not Expose Device to Temperature More than 45°C (116°F).