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Intersomatic Intervertebral Space Maintenance Device – PEEK

Instructions for Use

Fundamentals of Operation and Action

The Intersomatic Intervertebral Space Maintenance Device – PEEK is a device designed to the fixation of the vertebral column, suitable for the thoracic and lumbar zones. The product is an invasive implant for long-term use. The device is designed to be placed between two vertebral bodies, with rectangular-shape, made in PEEK in according with ASTM F2026 Standard (Standard Specification for Poly-ether-ether-ketone.).

The Intersomatic Intervertebral Space Maintenance Device – PEEK is a medical device developed to promote the fixation and stabilization of the vertebral bones in the vertebral column, presenting the suitable components for use in vertebral column surgeries, allowing the bone reconstruction and the perfect adjust of the implantable materials. Exclusive use in the hospitalar medical area. The Intersomatic Intervertebral Space Maintenance Device – PEEK is an implant that provides to the surgeon and for the pacient an alternative for the bone graft technique, while provides mechanical stablity.

The implant was designed in a rectangular shape to maintain the anatomy of the vertebral column, being necessary only one perforation for the implantation, reducing the surg ery duration and minimizing the infection risks to the pacient. The implant must be filled with graft material that works like an osteoinductive matrix for the bone cure. It's recommended the use of a Pedicular system for a better bone structure fixation.

Handling

The implants are packed individually in a double blister that is placed into an external box of stiff cardboard, identified with labels to protect it from shocks until the moment of use.

Component Specification: Sterilization package
Package – Double Blister Type
Product Composition:
Blister: Polyethilene Terephtalate - PET
Protective Foam: Expanded Polyethilene or EVA – Ethilene – Vinil Acetate
Sealant Paper: Surgical grade paper
The Validation report guarantees the quality and integrity of the packages

Verification of the package and superficial product state:

Check the integrity and characterize if the product must be disqualified in case of accidents in the handling or in the transport. The package must be without perforations, tears, and must contain the instructions for use inside the box. The package must be labeled. The product must not be used in case of any of this requirements are not present.

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The integrity of the product's package must be inspected before the implantation to assure the integrity of its sterility or to evaluate any other damage that may be caused by incorrect handling and transport. The product must by integrate, without risks, compression marks, cracks or structural deformations, and in these situations the product must not be used. If any non-conformity were detected in the packaging, label or Instructions for Use, please contact the manufacturer company or the European Authorized Representative to return the product. The company data is printed in the Instructions for Use.

Selection Criteria

The correctly choose of the shape, size and design of the implantable device for each patient is essential for the surgery success. The surgeon is the responsible for the choice for each patient. The excessive weight of the patient can be responsible for pressures and deformation over the implants that can accelerate the material fatigue and/or can produce a deformation or fail of the implants.

The size and the shape of the bone structure determine the size, the form and the type of implant. Once implanted, they will be exposed to loads and deformation. Those loads applied repeatedly should be considered by the surgeon in the choice of implant, its implantation and during the follow-up pos-surgery. The action of these loads could cause fatigue in the implant, leading to rupture of the material before the bone graft is totally consolidated.

Components

Intersomatic Intervertebral Space Maintenance Device – PEEK - 7,0 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 7,5 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 8,0 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 8,5 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 9,0 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 9,5 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 10 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 10,5 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 11,0 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 11,5 mm
Intersomatic Intervertebral Space Maintenance Device – PEEK - 12,0 mm

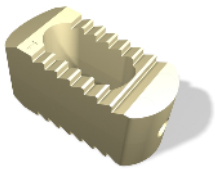

Figure 1: PEEK Device.

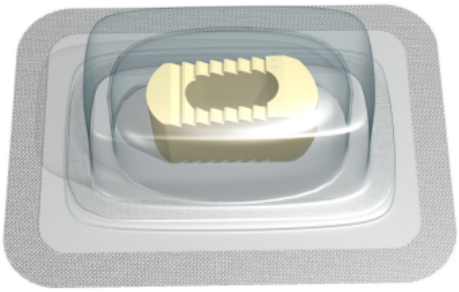

Figure 2: PEEK's Package.

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Advertence

The implant is commercialized in the sterile way. The method of sterilization used is the submission of the product in the presence of Ethylene Oxide (EO) in an appropriated chamber, previously validated, following the parameters and procedures established in the validation protocol – ISO 11135-1. The surgeon must warn the patient about the limitation over the implant and the risks about an overload created by the human body over the implant until the bone consolidation occur. It is recommended the follow-up of the status of the surgery to evaluate the success of the arthrodesis within 1 year after the implantation, to prevent a possible pseudo-arthrosis.

The standard ASTM F 2077 states the following:

"Since the main purpose of an intervertebral body fusion device assembly is fusion, the maximum runout force or moment is defined from a clinical standpoint. Since fusion should occur well within one year of implantation, the device should withstand normal intervertebral spinal loading until fusion occurs. If one uses a factor of safety of 2.5, the intervertebral fusion device assembly should withstand 2.5 years of loading, which corresponds to 5 million cycles" This ASTM analysis was based in Hedman et. al. studies about design and project of Disc Prosthesis. Font: Hedman, T. P., Kostuick, J. P., Fernie, G. R., Hellier, W. G., "Design of an Intervertebral Disc Prosthesis," *Spine*, Vol 16, No. 65, 1991, pp. S 256–260.

The device was subjected to mechanical loads assuring its safety for 2,5 years using a safety factor of 2.5. Therefore, the implant useful time (time which the implant will be subjected to mechanical loads in according with the ASTM F2077 standard) is 1 year. After this consolidation time, the implant will remain in place, however, it will not be subjected to mechanical loads anymore.

Points to be considered before the surgery:
The physical activities – excessive physical activities can lead the implant to failure.
The weight – a heavy patient can produce overload in the implants.
Alcoholism or mental problems – the patient could not respect the limits of the implants.
Degenerative diseases – can make the osteointegration slower or even stop it.
Foreign body sensibility – observe the biocompatibility of the implant's materials and the patient's bone tissue. The implants can cause pain, discomfort or weird sensations.
Implants must be used once – is not possible determine the fatigue stage of an implant already used.
The code number and lot number of each implant must be maintained.
If the osteointegration doesn't occur, the implant may fail.

Special care

Must be avoided abrasive instruments or products (abrasive sponge and metallic brush).
The integrity of the medical instruments and their functionalities should be verified before each surgery.

Contraindications

The contraindications must be considered by surgeon to take a decision. The choose of device must be carefully studied front the evaluation of patient. The situations below must be avoided to lead to a better chance of successfully results.

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Any abnormality that interfere the normal process of bone remodeling like: severe osteoporosis in the column, bone absorption, osteopenia, tumors, infections active in loco or certain metabolic disturbs that affect the osteogenesis.

Quality or quantity of bone tissue not enough to promote a rigid fixation of implant.
Previous infection historic.
Patient with systemic infection.
Inflammation in the bone site.

If the patient shows suspect or confirm an allergic or intolerance reaction against the material.
Presence of neural/vascular deficits or associated pathologies that after could be harm by the implant use.

Obesity. Weight excess could lead to a faster fail of the implant or his fixation. The patient must not have more than 120 kg (surgeon criterion).

Pregnancy. Patients with another medical, surgical or psychological condition that can interfere the benefits of the fixation surgery as: tumors, congenital anomalies, growth of sedimentation tax without reasons, increase of leucocytes or significant deviation in the differential counting of leucocytes.

Information to the Patients

The surgeon must discuss with the patient all physical and psychological limitations inherent to the use of implant, including the rehabilitation stage, physiotherapy and the use of orthopedic devices, according to medical prescription. The surgeon must warn about the risk of physical activities.

Patient with vigorous work or activities (lift weight, run, jump, or any excessive muscular work) that require a compressive resistance in the spine must be warned about the necessity of a substitution in future, to avoid the risks of fail. Smokers show a tendency of fail in the bone fusion and must be warned about this condition. Patient with degenerative disease in advanced stage can be susceptible to a smaller life time of the fixation system so this surgical technique is faced as a palliative technique.

The Tantalum is a non-ferromagnetic material non ferromagnetic and don't offers any restriction related to the environment or equipment (X-ray, computerized axial tomography and magnetic resonance).

Cautions in Case of Explanation
Preserve the adjacent tissues with minimal damages in the implants.
Radiologic Monitoring.
Clinical Historic of patient/implant.
Verify the functionality of the implant before the removal procedure.
Register the removal (X-ray, computerized axial tomography).
Microbiological study over the tissue around the implant is advised.
Sample of fluid and tissue for historic exam.
Identify of the removed implant properly.
Labeling of the implant for future identification.
The disposal procedure is described in the item Product Security/Disposal.

Product Clarification

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The PEEK Fixation is designed to orthopedic and traumatologic surgery, existing specifics methods for each case. The surgeon must choose the most appropriate device according to the disease and dimension after complete exams for each patient.

All cares and precautions must be reviewed before any procedure.

The domain and knowledge of all technique about manipulation and setting of implants is extremely important. They mustn't be modified, scratched or crooked because these situations can lead to a fracture or fail of implants.

All the support staff (instrument manager, nurse, etc) must be familiarized with the product, as well the procedures adopted.

Package and Storage

The implants are packed individually in a double blister that goes into an external box of stiff cardboard identified with labels to protect it from shocks until the moment of use.

The implants shall be stored in an environment with controlled temperature (limits: 15 to 40 ºC) as presented in label.

Figure 3: PEEK Packaged.

Figure 4: The card box.

Verifying before use:

The pack and label mustn't show any damage and the device must have its identification printed on his own body.

The device must be free of damages, without any mark or crack. The surface must be clean and polished.

The device must be handled with care. The device must be removed from the pack just at the time of surgery.

If the device has suffered a fall and is suspect to have suffered damage, the surgeon must send the device to OSTEOMED for evaluation.

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Traceability

All devices receive identification printed on their own body. This print contains information necessary to realize the traceability: trademark and lot number.

In the invoice, the lot number is registered with the customer data, emission date and description and quantity of product.

The invoice has a traceability report annexed. The fields Name and Code of distributor and the invoice number must be filled by the seller, and the others data must be filled by the customer. All fields must be filled.

The traceability report must be kept for at least 2 years after the sale date or expire date of the implant. Where necessary, the Osteomed can require this report back at any moment without any previous notice.

Product Safety

The Intersomatic Intervertebral Space Maintenance Device – PEEK is implant classified as class II b according to rule 8, therefore is a surgically invasive, long-term use and implantable device and is susceptible to bio-incompatibility, mechanical and sterilization problems, contamination, product information and traceability.

The decisions taken by Osteomed to prevent such risks are:

Bio-Incompatibility Risks:

All raw material used in the Intersomatic Intervertebral Space Maintenance Device – PEEK are available in medical literature, with good acceptance in the human body, with the absence of generation of chips that can cause allergies or poisoning the patient. Suppliers undergo evaluations according to the NPR 011 (Supplier Evaluation) to ensure that the properties are described as the properties of the material provided. This test is performed on receipt, which is performed according to the NPR 025 (Receive Control).

Mechanical Problems Risks:

Problems in the manufacturing process are minimized with the recruitment of qualified personnel and with training activities. In case of defective parts in the manufacturing process, they will be identified due to the 100% inspection. During the application of the device, the mechanical failures are controlled by instruction to clients on how to use the correct tools to avoid damage to instruments during the application of the device.

Sterilization Problems Risks:

The implants are sterilized by a previously validated company. All sterilization parameters are met.

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Product Information:

All relevant information about the device is printed in the handout that comes within the same packaging. During the process to packaging, every care is taken to ensure that all devices receive the brochures correct.

Traceability:

All devices receive laser engraving on your body, containing the batch number, the raw material and the company logo. The device goes with a variety of labels with their identification, which are distributed to all sectors involved, from marketing to its deployment.

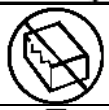
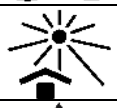
Disposal:

In case of discard, all devices must have their functional characteristic disenabled using a hammer, saw or pliers.

Those devices must be placed in plastic double bags, white, impermeable, identified as biohazard garbage. Verify your country legislation about its disposal regulations.

Symbols:

The symbols used in the label are in according with the EN 980:2008. Below are presented the definitions.

STERILE EO	Sterilized using ethylene oxide
	Do not use if package is damaged
	Do not reuse
	Consult instructions for use
	Keep away from sunlight
	Caution
EC REP	Authorised representative in the european community

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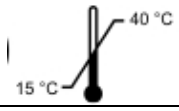
	Manufacturer
	Manufacture Date
	Use by
	Temperature Limitation

Sharp or pointed materials must be placed in waterproof container with cover.

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MS: 800719-1 / ANVISA Register n° 80071910022
Engineer Responsible: Engº Fernando Argenton Neto
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