Instructions for Use
STENOFIX™

This instruction for use is not intended for distribution in the USA.

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DePuy Synthes
COMPANIES OF Johnson&Johnson

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Instructions for Use

STENOFIX™
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material

Material:	Standard:
TAN	ISO 5832-11

Intended use
STENOFIX is intended for use as a space holder between the spinous processes for one or two lumbar motion segments. It controls the segmental extension and distracts the interspinous space. The intended effects on the posterior elements are:
– Preservation of the foraminal height
– Reduction of stress on the facet joints
– Reduction of pressure on the posterior annulus

It can be implanted at one or two lumbar levels from L1 to S1. For implantation at L5/S1, the presence of an S1-spinous process of adequate size is a prerequisite to fully support the implant.

Indications
STENOFIX is indicated for symptomatic moderate to severe lumbar spinal stenosis with or without concomitant low back pain.
STENOFIX is used after open or microsurgical decompressive surgery.

Contraindications
– Severe osteoporosis
– Morbid obesity (BMI >40)
– Conus/Cauda syndrome
– Fractures
– Spondylolysis/Isthmic spondylolisthesis
– Degenerative spondylolisthesis at index level of grade >1
– Scoliotic deformity at index level
– Kyphosis
– Acute or chronic systemic or localized spinal infections
– Laminectomy and facetectomye

Side effects
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common may include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, side effects associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones, discs, or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, partial displacement of the graft, vertebral angulation.

Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions
The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information".

Warnings
It is strongly advised that STENOFIX is implanted only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical techniques. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment
MR Conditional:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the STENOFIX system are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the STENOFIX implant will produce a temperature rise not greater than 5.3°C at a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.
MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the STENOFIX device.

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