Instructions for Use
In-Space

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DePuy Synthes
COMPANIES OF Johnson&Johnson

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Instructions for Use

In-Space
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:
PEEK	ASTM F 2026
TAV ELI	ASTM F 136

Intended use
In-Space is intended to stop the segmental extension and to distract the interspinous space at a symptomatic level between L1 to S1. In-Space acts as a space-holder and protects mainly the posterior elements by
– maintaining the foraminal height,
– opening up the area of the spinal canal,
– reducing stress on the facet joints and
– relieving pressure on the posterior annulus.

Indications
In-Space can be implanted at one or two levels from L1 to S1 for posterior approach (L1 to L5 for percutaneous approach). For implantation at L5/S1, the presence of a S1-spinous process of adequate size is a prerequisite to fully support the implant.

Based on the intended use, In-Space can be used for the following indications:
– Central, lateral and foraminal lumbar spinal stenosis with leg, buttock or groin pain, which can be relieved during flexion
– Soft disc protrusions with discogenic low back pain
– Facet syndrome due to facet osteoarthritis
– Degenerative spondylolisthesis up to grade I with hyperlordotic curve
– Degenerative Disc Disease (DDD) with retrolisthesis
– Interspinous pain arising from Baastrup syndrome ("kissing spines")

In-Space can also be used as a temporary implant in conditions which require a temporary unloading of the disc and/or facet joints.

Contraindications
– Severe Osteoporosis
– Conus/Cauda syndrome
– Severe structural spinal stenosis lacking a dynamic component
– Fractures
– Spondylolisis
– Degenerative spondylolisthesis at index level of grade > I according to Meyerding
– Scoliotic deformity at index level
– DDD with fixed retrolisthesis
– Sequestrated disc herniation
– Previous surgery at the operative level
– Spinous process and/or lamina dysplasia
– Infection
– Morbid obesity (BMI >40)

Potential risks
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, Complex regional pain syndrome (CRPS), allergy/hypersensitivity reactions, side effects associated with implant or hardware prominence, ongoing pain; damage to adjacent bones, discs, or soft tissue, osteolysis, subsidence, dural tear or spinal fluid leak; spinal cord compression and/or contusion, 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.

Do not resterilize

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 stability of the In-Space relies on the presence of the following structures:
– Supraspinous ligament
– Laminae
– Spinous processes
– Facet joints
Complete or significant removal of those structures may result in device migration.
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 In-Space 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. For additional information, please refer to the corresponding technique guide.

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 In-Space 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 In-Space implant will produce a temperature rise not greater than 4.1°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 In-Space device.

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