Instructions for Use
INSIGHT™ Retractor System and INSIGHT™ Tubular Retractor System

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

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each manual is always available online.
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

INSIGHT™ Retractor System and INSIGHT™ Tubular Retractor System

Devices in scope:

03.610.001	03.615.199	03.615.380
03.610.002	03.615.223	03.615.390
03.610.003	03.615.224	03.615.400
03.610.004	03.615.225	03.615.440
03.610.005	03.615.226	03.615.450
03.610.006	03.615.227	03.615.460
03.610.007	03.615.228	03.615.470
03.610.008	03.615.229	03.615.480
03.612.010	03.615.253	03.615.490
03.612.012	03.615.254	03.615.500
03.615.002	03.615.255	03.615.510
03.615.003	03.615.256	03.615.540
03.615.005	03.615.257	03.615.550
03.615.100	03.615.258	03.615.560
03.615.163	03.615.259	03.615.570
03.615.164	03.615.283	03.615.580
03.615.165	03.615.284	03.615.590
03.615.166	03.615.285	03.615.600
03.615.167	03.615.286	03.615.610
03.615.168	03.615.287	03.615.640
03.615.169	03.615.288	03.615.650
03.615.193	03.615.289	03.615.660
03.615.194	03.615.300	03.615.670
03.615.195	03.615.340	03.615.680
03.615.196	03.615.350	03.615.690
03.615.197	03.615.360	
03.615.198	03.615.370	

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials
Stainless Steel, Silicone Rubber, Aluminium Alloy.

Intended Use
The INSIGHT Retractor System is a surgical access system intended to provide a minimally invasive approach to the thoracolumbar spine. It is designed for needs of various indications and/or surgical techniques.

The INSIGHT Tubular Retractor System is a surgical access system intended to provide a minimally invasive approach to the thoracolumbar spine. It is designed for needs of various indications and/or surgical techniques.

Indications/Contraindications
In case the INSIGHT Retractor System and INSIGHT Tubular Retractor System are used in combination with implants or instruments, please refer to the respective instructions for use for indications and contraindications and additional surgical steps.

Patient Target Group
The patient target group is based upon the implant devices rather than the instruments. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient. Specific patient target group for the implants can be found in the respective implant instructions for use.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: adverse tissue reaction, allergy/hypersensitivity reaction, infection, damage to vital organs or surrounding structures, compression and/or contusion of neural structures, damage to adjacent bones, disc or soft tissue. Symptoms resulting from instrument malfunction, such as bending, fragmentation, loosening and/or breakage (whole or partial).

Warnings and Precautions
- 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.
- Care should be taken in the handling of sharp devices. Incorrect handling might cause injury to patient and/or user.
- Flex arm tension should be fully released after each use to prevent instrument damage and allow proper instrument sterilization.
- Carefully monitor the position of the dilator during dissection and placement to avoid injury to the nerve root and other deeper structures.
- Ensure the Kirschner wire remains securely in position throughout entire duration of procedure until adequate dilation has been achieved. The tip of the Kirschner wire should be monitored by fluoroscopy to ensure it does not slip off the bony structures (e.g. facet joint) and penetrate the dura or the nerve root.
- Ensure the Kirschner wire does not slip out before the retractor or tube is in place. The Kirschner wires are long enough to be held in place by hand during soft tissue dilation.
- If it is not possible to expand the retractor, make sure the skin and fascia cut is large enough and if not, enlargement may be necessary. Make sure the switch is in the locked position.
- Use fluoroscopic imaging to determine the position of the retractor.
- Do not use excessive force to toe the blades.
- If it is not possible to toe the blade, make sure the skin and fascia incision is large enough and if not, enlargement may be necessary.

For more information, please refer to the Synthes brochure "Important Information".

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 Unsafe: These devices are MR unsafe according to ASTM F 2052, ASTM F 2213, ASTM F 2182.

Treatment before Device is Used
Non-Sterile Device:
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Disposal
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

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Instructions for Use:
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