Instructions for Use
INSIGHT™ Lateral Access System

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

Not all products are currently available in all markets.

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Instructions for Use

INSIGHT™ Lateral Access System

Devices in scope:

03.816.001	03.816.120	03.816.800
03.816.002	03.816.130	03.816.801
03.816.003	03.816.140	03.816.806
03.816.004	03.816.150	03.816.810
03.816.010	03.816.160	03.816.816
03.816.011	03.816.170	03.816.000
03.816.012	03.816.180	03.816.411
03.816.013	03.816.280	03.816.412
03.816.014	03.816.290	03.816.413
03.816.015	03.816.300	03.816.414
03.816.016	03.816.310	03.816.415
03.816.019	03.816.320	03.816.416
03.816.020	03.816.330	03.816.420
03.816.025	03.816.340	03.816.421
03.816.030	03.816.350	03.816.422
03.816.033	03.816.360	03.816.423
03.816.036	03.816.370	03.816.424
03.816.037	03.816.380	03.816.444
03.816.040	03.816.700	03.816.445
03.816.050	03.816.701	03.816.446
03.816.060	03.816.702	03.816.602
03.816.070	03.816.703	03.816.610
03.816.080	03.816.704	03.816.616
03.816.090	03.816.705	03.816.620S
03.816.100	03.816.706	03.816.621
03.816.110	03.816.709	03.816.803

The INSIGHT Lateral Access System is a modular system designed to support the minimally invasive approach to the spine.

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
Polyetheretherketone (PEEK), Silicone (Polymer), Aluminium, Stainless Steel, Aluminium Alloy, Polypropylene, Glass fiber, PPSU and Titanium alloys.

Intended Use
The INSIGHT Lateral Access 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 light system is intended to illuminate the surgical site in minimally invasive surgeries. It is intended to be used with access systems containing corresponding interfaces such as the INSIGHT Lateral Access System and an appropriate light source (max. 300 Watt Xenon illuminator).

Indications/Contraindications
In case the INSIGHT Lateral Access System is 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. The product is 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 does not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the instructions for use and, the surgical procedures, if applicable, and /or the Synthes "Important Information" brochure as appropriate.

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).

Sterile Device

Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.


Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.


Do not resterilize

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single Use Device


Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical 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, re-use 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.

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 occurring during usage of the light system.
- Care should be taken in the handling of sharp devices. Incorrect handling might cause injury to patient and/or user.
- A thorough education and a comprehensive understanding of the respective anatomy as well as practical experience in performing the lateral approach to the thoracolumbar spine is a prerequisite for use of this system.
- Patient Positioning and Exposure: Ensure that the rotation of the strong arm or universal arm is securely locked by the table clamp.
- In addition, lateral and anteroposterior (AP) fluoroscopy should be utilized to place the neuromonitoring probe/Kirschner Wire through the psoas and into the annulus of the desired intervertebral disc space.
- Ensure the neuromonitoring probe or Kirschner Wire remains securely in position until the retractor is in place by having it sufficiently anchored in the disc space.
- Use fluoroscopy (lateral and AP) to determine location of dilators. Also ensure that dilators rest firmly against the vertebral body wall in order to determine skin depth. Keep downward pressure on the dilators until the strong arm or universal arm has been fixed to the retractor.
- During second stimulation probe placement in dilator groove, do not stimulate against any instruments in the surgical field.
- During retraction, do not place any accessories before retraction.
- It is not recommended to make adjustments to the operating room table once the retractor has been stabilized with the strong arm.
- In order to reduce tissue creep:
  - Retractor blades must be in zero position.
  - The retractor blades should be placed against the disc space and/or the vertebral endplates.
- Use fluoroscopic images to determine the position of the retractor. Identify presence of osteophytes. Do not apply excessive force when inserting retractor.
- Do not maneuver operating room table after fixing the retractor with the strong arm or universal arm system as this may lead to movement of the retractor in the surgical field.
- The retractor should not be placed either too anterior or too posterior to reduce the risk of damage to adjacent structures. Always retract under direct visual control.

– Care should be taken to avoid the segmental vasculature of the vertebral body when placing the bone screw.
– Remember to remove the bone screw(s) before repositioning or removing the retractor.
– During blade angulation, avoid retraction or angulation of the blades to the extent that the segmental vessels are exposed, or tissue is over retracted.
– To angle the blades, only turn the screwdriver finger tight to avoid applying excessive force on the retracted tissue.
– Check position under fluoroscopy (AP and lateral) before and while advancing (AP) the disc anchor into the intervertebral disc in order to confirm that its trajectory does not lead to bone or adjacent (anterior or posterior) structure damage. Always confirm the absence of nerves before inserting the disc anchor.
– Do not retract the third blade holder once the disc anchor is in place. As the disc anchor component is permanently attached to the respective blade, it must be cleaned according to its specific handling guidelines.
– If the rigid arm is attached to the retractor body and the disc anchor is deployed, do not use the retract function.
– As major vessels are close by, make sure the fourth blade tip does not compromise vital organs.
– Use the scoop with the blade extension and/or winglet to retract soft tissue. This is to reduce the risk of soft tissue damage due to compression by the blade extension and winglet.
– Do not reposition the retractor or perform further retraction after accessories are placed.
– When inserting and removing subsequent instruments (curettes, trials etc.) ensure that they do not conflict with the retractor blades or accessories, noting that manipulation (including accessory removal) may be required to avoid conflict.
– Retractor removal: Before the retractor can be removed, all accessories (blade extensions and winglets) have to be removed, the disc anchor has to be retracted and the retractor must be placed in the zero position.

Warnings and Precautions related to Reusable Light (03.816.700)
– Do not bend reusable light.
– Do not apply pressure on the light using a sharp object.
– Do not use higher wattage than indicated for reusable light (300W).
– Do not place the light-transmitting end on skin or soft tissue.
– Do not embed the reusable light in soft tissue.
– Exchange reusable light if it collects fluid inside, appears broken or damaged.
– Depending on light source, temperature of Reusable Light (03.816.700) and Adapter (optional, 03.816.709) may exceed 43 °C. Therefore, avoid contact to user and patient with these parts for longer duration.
– Do not touch the open end of the Reusable Light or optical fiber cable. The emitted intense light energy can lead to burns. Avoid longer contact between metal parts and tissue during surgeries. To prevent burns, never place the open end of a connected optical fiber cable on the patient or near the patient. Allow for cooling before disassembly.
– Never place the Light or the open end of a connected optical fiber cable near flammable materials such as textiles (curtains) or near cotton swabs or pads that have been soaked with flammable fluids (e.g. disinfectants). The heat generated by the intense light emission can ignite these materials.
– The reusable light should only be used with the associated light cables.
– When in operation, the lamp emits strong UV/IR radiation. Never look directly into the highly intense light since this could cause severe injuries to the eyes.
– Regardless of the condition and output of the light source and the light cable, combinations can occur which lead to excessive heat development at the light source end of the light cable and which can damage the light cable. In this case contact the manufacturer.
– Never leave the light system unattended when light is being transmitted from a light source.
– The light instruments containing fiber optics should not be ultrasonically cleaned.

Warnings and Precautions related to Bifurcated Light Cable (03.816.705) and Light Cable (03.816.706)
– Do not bend fiber optic cables under a radius of 5 cm.
– Do not apply pressure on the light cable using a sharp object.
– Exchange cable if it collects fluid inside, appears broken or damaged.
– Do not modify the light cable or adapters. The light cable is designed to provide an optimal light output level when delivered.
– Avoid damaging the fiber surfaces at the ends of the light cable as this will reduce the light output level.
– Do not use higher wattage than indicated for the light cables (300W).
– Never leave the light cable unattended when light is being transmitted from a light source.
– Regardless of the condition and output of the light source and the light cable, combinations can occur which lead to excessive heat development at the light source end of the light cable and which can damage the light cable. In this case contact the manufacturer.
– When connected to a light source, do not place the light cable end into the surgical field. Danger of over-heating! (>43 °C)
– Do not embed the light cable in soft tissue.
– In case of conspicuous mechanical damage (e.g. silicone hose is damaged), the light cable must not be used since sterility can no longer be ensured.
– Do not touch the open end of the cable. The emitted intense light energy can lead to burns. Avoid longer contact between metal parts and tissue during surgeries. To prevent burns, never place the open end of a connected optical fiber cable on the patient or near the patient. Allow for cooling before disassembly.
– Never place the open end of a connected optical fiber cable near flammable materials such as textiles (curtains) or near cotton swabs or pads that have been soaked with flammable fluids (e.g. disinfectants). The heat generated by the intense light emission can ignite these materials.
– When in operation, the lamp emits strong UV/IR radiation. Never look directly into the highly intense light since this could cause severe injuries to the eyes.
– The light instruments containing fiber optics should not be ultrasonically cleaned.

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.
– The Reusable Light for INSIGHT Lateral Access System is a glass fiber optic device intended for lighting into deep surgical sites. The Reusable Light is intended for use with a max. 300 Watt Xenon illuminator, using a 3.6 mm fiber optic cable (or smaller) and the corresponding adaptor to the light machine. The Reusable Light fits with a female ACMI connector.
– The Reusable Light is connected to an adapter for a light cable (03.816.709). The Reusable Light has a male ACMI interface.
– 03.816.705 and 03.816.706 are combined with 03.816.709 to connect to the light devices and 03.816.701; 03.816.702; 03.816.703; 03.816.704 to connect to the corresponding light source.
– When connecting the light cable to the light devices ensure that the cross sections of the glass fibers are the same for both components; otherwise an unwanted (excessive) heating of the coupling points may result.

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".

Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices 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.

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.

For 03.816.700, 03.816.705 and 03.816.706, Synthes recommends steam sterilization in fractionated vacuum at 132 °C for 4 minutes.

Do not clean the Reusable Light in an ultrasonic bath (03.816.700).

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

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