





[Image intensifier control

This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product is highly recommended.

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to www.synthes.com/reprocessing

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INSIGHT LATERAL ACCESS SYSTEM

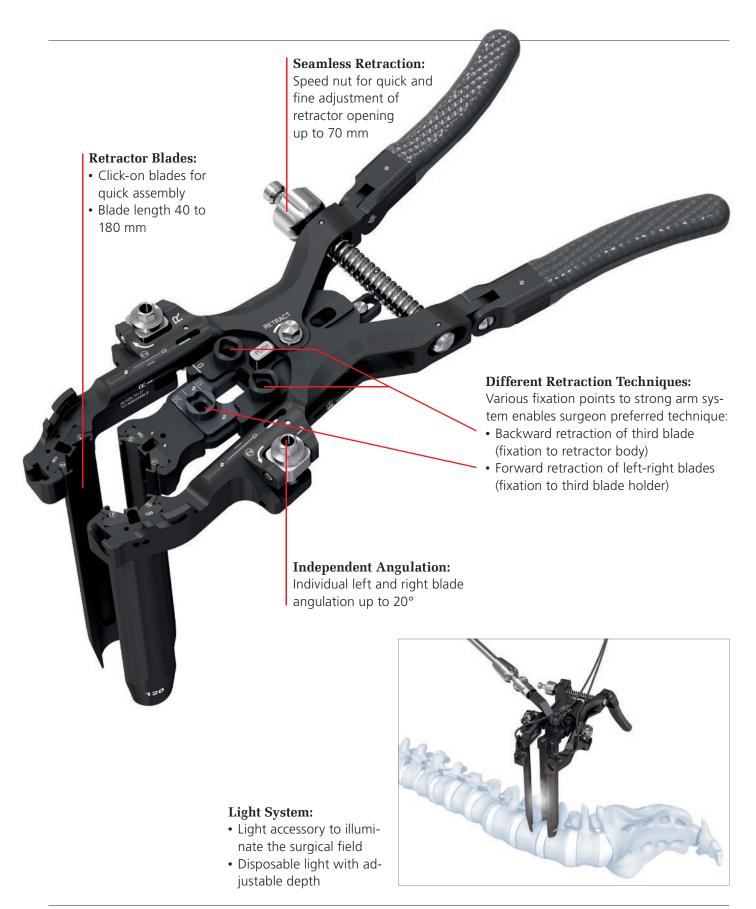
The INSIGHT Lateral Access System is a comprehensive modular system designed to support the minimal invasive approach to the spine.



X-Ray Visibility:

- Key parts are semi radiolucent (aluminum) for fluoroscopic visualization
- Radiolucent carbon fiber handles to avoid interference during anterior/ posterior fluoroscopy





DESCRIPTION OF RETRACTOR PARTS



AO PRINCIPLES

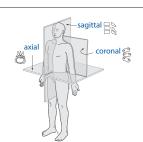
The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum:

Stability – Alignment – Biology – Function.

Stability

Stabilization to achieve a specific therapeutic outcome



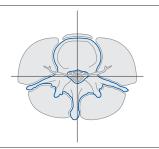


Alignment

Balancing the spine in three dimensions

Biology

Etiology, pathogenesis, neural protection, and tissue healing





Function

Preservations and restoration of function to prevent disability

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INDICATIONS AND CONTRAINDICATIONS

Intended Purpose

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.

Indications and Contraindications

In case the INSIGHT Lateral Access System is used in combination with implants or instruments, please refer to the respective technique guides for indications and contraindications and additional surgical steps.

PREPARATION

1 Patient Positioning

Instruments	
03.662.0285	Electrode Kit for Neuromonitoring
03.809.942	Table Clamp for Universal Arm
03.816.800 or	Strong Arm
03.809.941	Universal Arm

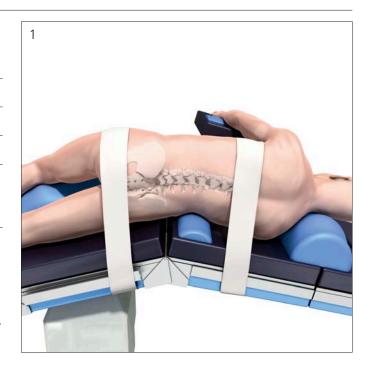
For the lateral approach, the patient is placed and taped in the lateral decubitus position as illustrated (1).

Note: Ensure that the position of the operative level is perpendicular to the floor for easier orientation of fluoroscopy and approach by confirming:

- In lateral fluoroscopy, the endplates are parallel with superimposed pedicles.
- In A/P fluoroscopy, the endplates are parallel, the pedicles reside in the cranial portion of the vertebral body and the spinous process is equidistant to both pedicles.

For further information, please refer to the dedicated implant technique guides. If neuromonitoring is being used, refer to the respective neuromonitoring technique guide.

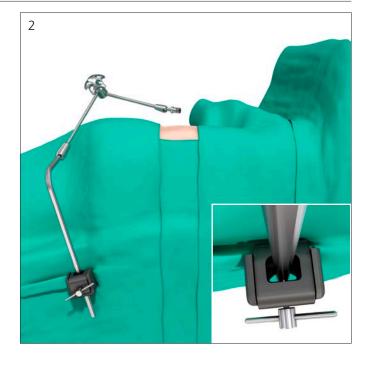
Precaution: A thorough education and a comprehensive understanding of the respective anatomy as well as practical experience in performing the lateral approach to the thoracolumbar spine is a prerequisite for use of this system.



2 Set Up Strong Arm System

Install table clamp onto the preferred side of the operating table by loosening it and attaching it onto the table rail. Insert the strong arm or universal arm with flat side facing away from the table (2). Secure table clamp by tightening it.

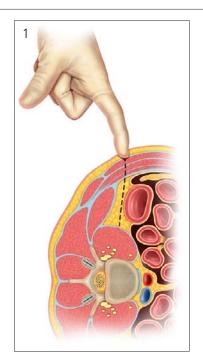
Precaution: Ensure that the rotation of the strong arm or universal arm is securely locked by the table clamp.

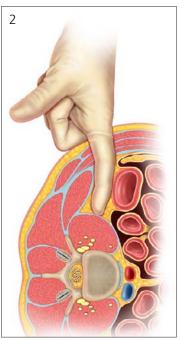


ACCESS UND EXPOSURE

1 Approach the Spine

- Locate and mark the correct operative level and associated incision site under lateral fluoroscopy and make a skin incision. Incision should be large enough to accommodate the retractor and subsequent retraction. Retract the subcutaneous tissue and bluntly dissect through the abdominal muscle layers and incise the transversalis fascia to enter the retroperitoneal space (1). Move the peritoneum anterior with forefinger and continue with blunt dissection to gently palpate down to the psoas by following the anterior border of the quadratus lumborum (2).
- Before puncturing the psoas, fluoroscopy is recommended to ensure targeting the area of interest of the affected disc space. The anterior third of the psoas muscle is the most likely safe zone for avoiding the neural elements of the lumbar plexus.¹





¹ Takatomo Moro, MD, Shin-ichi Kikuchi, MD, PhD, Shin-ichi Konno, MD, PhD and Hiroyuki Yaginuma, MD, PhD: "An Anatomic Study of the Lumbar Plexus with Respect to Retroperitoneal Endoscopic Surgery.", Spine 2003; Volume 28, Number 5, pp 423–428.

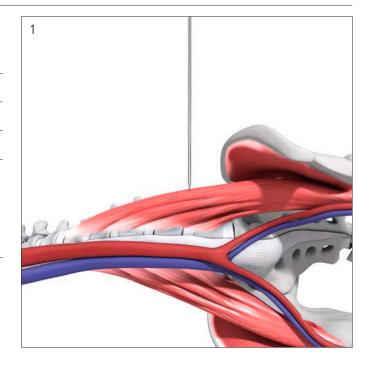
2 Neuromonitoring

Instruments	
03.662.0275	Neuromonitoring Stimulation Probe
03.662.0285	Electrode Kit for Neuromonitoring
03.662.029	Handle for Neuromonitoring Stimulation Probe
or	
02.809.002	Kirschner Wire \varnothing 3.0 mm with blunt tip, length 285 mm, Stainless Steel

In order to avoid neural structures it is recommended to use triggered EMG neuromonitoring (detection of motoric nerves). Additionally use direct visual control (detection of sensoric nerves).

Note: With the eccentric dilation technique the retractor will be positioned a maximum of 8 mm off-center.

Map out a safe corridor through the psoas muscle to the operating level by stimulating with the neuromonitoring probe (1). Once achieved, continue to perform a blunt dissection of the psoas muscle under direct visual control.

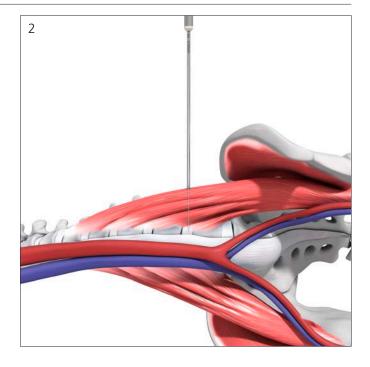


Precaution: In addition, lateral and AP fluoroscopy should be utilized to place the neuromonitoring probe/k-wire through the psoas and into the annulus of the desired intervertebral disc space (2).

In case no neuromonitoring is used, the 3.0 mm Kirschner wire can be utilized.

Precaution: 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.

For further information, please refer to the dedicated implant technique guides and to the respective neuromonitoring technique guide.



3 Insert Dilators

-	
Instruments	
03.816.806	Dilator, ∅ 6 mm, eccentric, small, for INSIGHT Lateral Access System
03.816.810	Dilator, \varnothing 10 mm, eccentric, medium, for INSIGHT Lateral Access System
03.816.816	Dilator, ∅ 16 mm, eccentric, large, for INSIGHT Lateral Access System
03.662.027S or	Neuromonitoring Stimulation Probe
02.809.002	Kirschner Wire \varnothing 3.0 mm with blunt tip, length 285 mm, Stainless Steel



The eccentric dilators allow for dilation away from any sensitive structures (e.g. posterior nerves). Slide the small dilator (rounded tip first) over the neuromonitoring probe or Kirschner wire in the orientation of preferred direction of dilation. Continue with the remaining two dilators with the groove for the stimulation probe facing the preferred direction of dilation (midline or eccentric (1)).

Precaution: 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 an accurate skin depth measurement. Keep downward pressure on the dilators until the strong arm or universal arm has been fixed to the retractor.

A second stimulation probe can be placed in the dilator groove in order to check on surrounding nerve structures (2). By turning the outermost dilator with a second probe in place, surrounding tissue can be monitored for presence of motoric nervous structures (3).

Precaution: Do not stimulate against any instruments in the surgical field.

Determine the appropriate retractor blade length from the markings on the dilators and round up to the next available blade length.

Note: When determining the blade length, consider the surrounding anatomy (iliac crest, ribs etc).

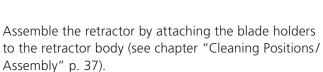




RETRACTION

1 Preparation

Retractor Body
Screwdriver, for INSIGHT Lateral Access System
Blade Holder, left, for No. 03.816.001
Blade Holder, right, for No. 03.816.001
Third Blade Holder, for No. 03.816.001
Blade, length 40–180 mm (in 10 mm increments)



Open the retractor by compressing the handles and turning the speed nut (1) and attach the appropriate blades ((2) top loading click-on connection).

If a disc anchor will be used, a disc anchor blade of corresponding length should be attached to the third blade holder (see chapter "Accessories, Additional Stability" instruction p. 28).

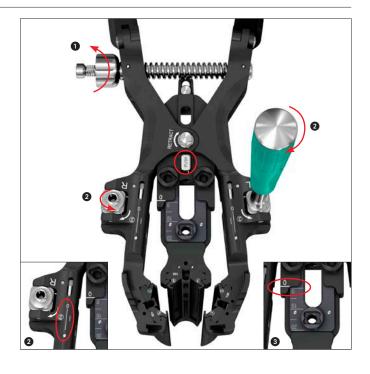
Note: The disc anchor blade can only be attached to the third blade holder.





Place Retractor In Zero Position:

Close the retractor by releasing speed nut (①). Return angulation of left and right blades to the zero position by turning the angulation nuts with the Screwdriver for INSIGHT Lateral Access System accordingly (②). Set the third blade to zero position by pushing the PUSH button and/or turning the RETRACT nut in the appropriate direction at the same time (③) until the "O" on the third blade aligns with the "O" on the retractor body.



Attach Connector

Instruments	
03.816.801	Connector, for Strong Arm No. 03.816.800
03.816.010	Screwdriver, for INSIGHT Lateral Access System
Optional	
03.816.019	Wrench, for INSIGHT Lateral Access System

Attach connector to the respective point on the retractor (A or B, see next page) and tighten with the Screwdriver or wrench depending on tightening preference (1). The connector can only be attached in the illustrated positions and orientations (from the left and right side) to avoid subsequent conflict with angulation mechanism.

For the role of the different attachment options, see next page.



Forward/Backward Retraction Options

Retract Forward

If forward retraction is desired **(A)**, attach the connector to the **third blade holder** connection point.

Subsequent clockwise rotation of the RETRACT nut results in forward retraction of the retractor body (with left and right blade holders) relative to the fixed third blade holder.

Α

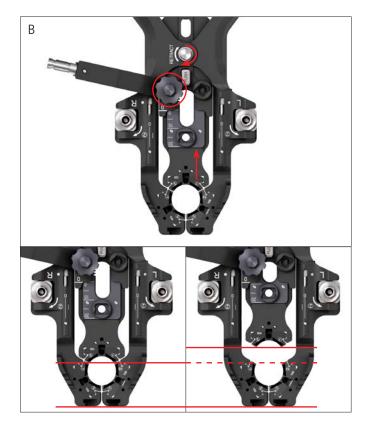
or

Retract Backward

If backward retraction is desired **(B)**, attach the connector to either one of the attachment points on the **retractor body**.

Subsequent clockwise rotation of the RETRACT nut results in backward retraction of the third blade holder relative to a fixed retractor body (with left and right blade holder).

Precaution: Do not place any accessories before retraction.

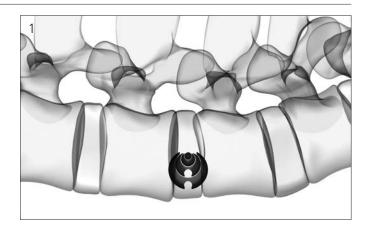


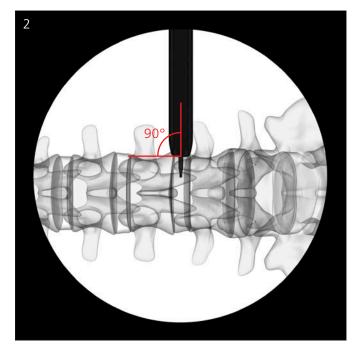
2 Slide Retractor Over the Dilators

Use fluoroscopic imaging to determine the position of the dilators (1). Slide the retractor with the blades and connector attached over the dilators.

Note: The handles of the retractor can be placed either anterior or posterior depending on surgeons preference.

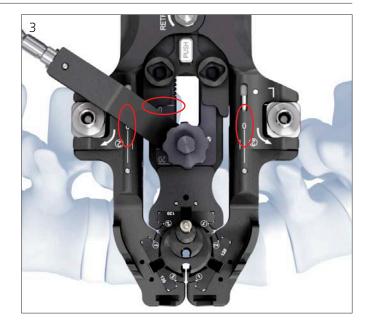
Use fluoroscopic imaging to determine the position of the retractor. Retractor blades should rest against the disc space and/or vertebral endplates in a perpendicular orientation to the disc space (2). Maintain the dilators and retractor in place until the strong arm or universal arm has been fixed to the retractor.





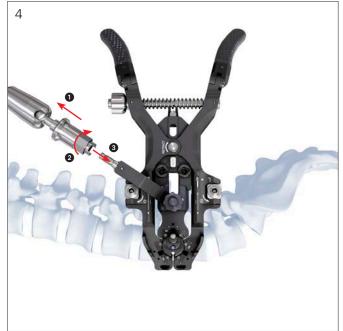
Precaution: In order to minimize tissue creep:

- Retractor blades must be in zero position (3)
- The retractor blades should be placed against the disc space and/or the vertebral endplates.
- Precaution: Use fluoroscopic images to determine the position of the retractor. Identify presence of osteophytes. Do not apply excessive force when inserting retractor.



Attach Retractor to Strong Arm or Universal Arm Attach connector to strong arm or universal arm (1,2,3) and tighten the stabilizing system by turning the knob on the arm (4).

Precaution: Do not maneuver operating-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.

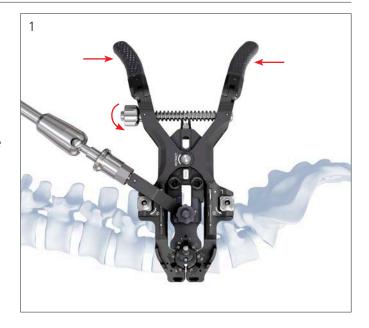


3

Retract Lateral

Open the retractor in the cranial-caudal direction to the desired position by compressing the handles and turning the speed nut (1). Use fluoroscopic images to determine the position of the retractor. Remove the dilators. Use caution when removing the dilators so as not to dislodge the probe/Kirschner wire from the disc space.

Note: Leave the stimulation neuromonitoring probe/ Kirschner wire in place for orientation while opening the retractor.



4 Retract Forward/Backward

Instrument	
03.816.010	Screwdriver, for INSIGHT Lateral Access System

To perform either forward or backward retraction (see A and B in chapter "Forward/Backward Retraction Options" instruction p. 17), turn the RETRACT nut clockwise with the screwdriver (1). Use fluoroscopic imaging during retraction to determine and confirm the position.

Precaution: The retractor should not be placed either too anterior or too posterior to minimize the risk of damage to adjacent structures. Always retract under direct visual control.



Release Forward/Backward Retraction

To release the forward or backward retraction, push the button with corresponding laser etching PUSH (2) while turning the RETRACT nut counterclockwise using the screwdriver (3).





5 Blade Angulation

Instrument	
03.816.010	Screwdriver, for INSIGHT Lateral Access System

If additional exposure of the surgical site is needed or if

the exposure needs to be centralised around the neuro-monitoring probe/Kirschner wire, use the screwdriver to independently angle the right or left blade and turn it in the direction of the arrow etched on the retractor (1).

Use fluoroscopic imaging during change of angulation to determine the position of the blades. In order to reduce the angulation, turn the screwdriver in the other direction.

Remove the neuromonitoring probe/Kirschner wire.

Precaution: Avoid retraction or angulation of the blades to the extent that the segmental vessels are exposed or tissue is over retracted.

Precaution: To angle the blades, only turn the screw-driver finger-tight to avoid applying excessive force on the retracted tissue.

For further information, please refer to the dedicated implant technique guide for the subsequent procedure.



6

Subsequent Levels

Remove the retractor (see chapter "Removal" p. 32). Repeat patient positioning and neuromonitoring steps for subsequent levels.

Note: Patient position may need to be adjusted (through table adjustment) in order to perform subsequent levels (see chapter "Patient Positioning", described on p. 7).

ACCESSORIES

Light System

Instruments	
03.816.080- 03.816.180	Blade, length 80–180 mm (in 10 mm increments)
03.816.700	Reusable Light, for INSIGHT Lateral Access System
03.816.705	Bifurcated Light Cable, for No. 03.816.700
03.816.709 or	Adapter, for Light and Cable
03.816.7105	Disposable Light, for INSIGHT Lateral Access System, sterile
03.816.706	Light Cable, for No. 03.816.710S
03.816.709	Adapter, for Light and Cable
Optional	
03.816.701	Wolf Adapter, for Light Source
03.816.702	Storz Adapter, for Light Source
03.816.703	Olympus Adapter, for Light Source
03.816.704	ACMI Adapter, for Light Source

Screw the appropriate light source adapter (Wolf, Storz, Olympus or ACMI) onto the appropriate light cable and screw the light adapter(s) to the other end(s) of the cable.



Disposalble Light



Slide the reusable light (1) or disposable light (2) into the light slots. Secure light underneath the provided hooks. Connect the light cable to the light source. Turn on the light source.

Precautions and Warnings

- Do not bend fiber optic cables/lights under a radius of 5 cm.
- Do not apply pressure on the light cable/lights using a sharp object.
- Exchange reusable light/cables if it collects fluid inside, appears broken or damaged.
- 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 and reusable light (300 W).
- Depending on light source, temperature of the light, cables and/or adapters may exceed 43°C. Therefore avoid contact to user, patient, temperature-sensitive objects and flammable materials such as textiles (curtains) or near cotton swabs or pads that have been soaked with flammable fluids with these parts.
- The reusable light/disposable light should only be used with the associated light cables.
- Never leave the light system unattended when light is being transmitted from a light source.
- 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.





Additional Stability

Instruments	
03.816.280– 03.816.380	Disc Anchor Blades, length 80 mm–180 mm (10 mm increments)
03.816.012	Instrument for Disc Anchor Blade
03.816.013	Inner Shaft, for Instrument for Disc Anchor Blade
03.816.014	Turning Knob, for Instrument for Disc Anchor Blade
03.816.015	Push Button, for Instrument for Disc Anchor Blade

Attach the appropriate disc anchor blade on the third blade holder instead of a common blade. Assemble the instrument for disc anchor blade (see chapter "Cleaning Positions/Assembly" p. 44).

When inserting the assembled instrument into the disc anchor blade, ensure that it is in the disengaged position (with the arrows at the distal end pointing together) (1). Slide the instrument down the groove and push down until the disc anchor rests in the desired position (2).

Precaution: 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.





To retract the disc anchor, slide the instrument (in the disengaged position) (1) down the groove until it sits on the disc anchor component (3).

Rotate the turning knob to the engaged position (counter-clockwise) to engage the disc anchor component (4). Retract the disc anchor component by pulling up the instrument (5). Disengage the instrument by turning the knob to the disengaged position (clockwise) (6).

Precaution: 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 (see chapter "Cleaning Positions/Assembly" p. 41).



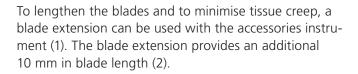






Additional Retraction

Instruments	
03.816.030	Accessories Instrument
03.816.033	Blade Extension
03.816.036	Winglet, right
03.816.037	Winglet, left
03.816.080 – 03.816.180	Blade, length 80–180 mm (in 10 mm increments)
03.816.025	Scoop, for INSIGHT Lateral Access System

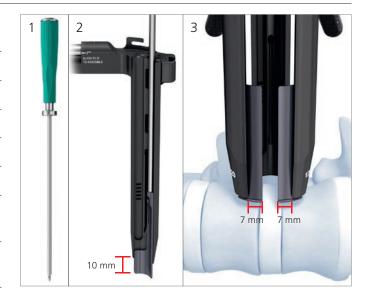


To minimise lateral tissue creep, winglets can be used. Each winglet provides an additional 7 mm in blade width (3).

Screw the accessory fully onto the accessories instrument.

The groove number on the blade corresponds to numbers **1**/**2** on back of the accessory (4).

Precaution: Use the scoop with the blade extension and/or winglet to retract soft tissue. This is to minimize the risk of soft tissue damage due to compression by the blade extension and winglet.





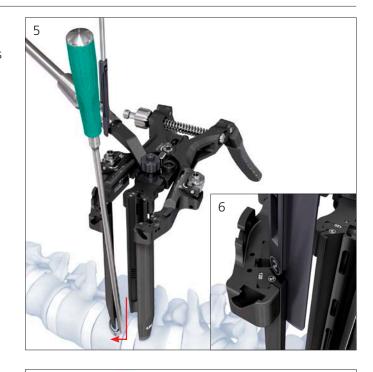




The scoop is used to retract soft tissue.

Glide the scoop down on the concave side of the blades to the site of tissue creep. Push the soft tissue behind the blade (5).

Then slide the accessory down the respective accessory groove (6).



Turn the handle of the scoop counterclockwise (7) into the retractor opening until it no longer resides behind the blade and can be removed.

Unscrew the accessories instrument from the extension.

Precaution: Do not reposition the retractor or perform further retraction after accessories are placed.

Precaution: 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.



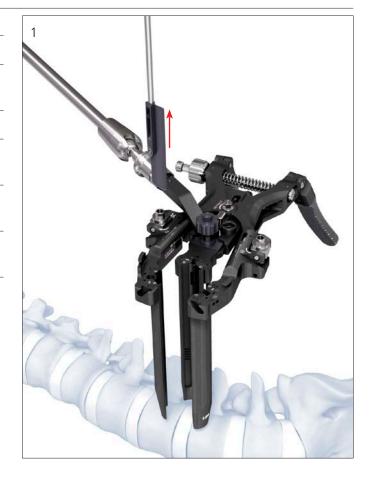
REMOVAL

Instruments	
03.816.030	Accessories Instrument
03.816.010	Screwdriver, for INSIGHT Lateral Access System
03.816.012	Instrument for Disc Anchor Blade
03.816.013	Inner Shaft, for Instrument for Disc Anchor Blade
03.816.014	Turning Knob, for Instrument for Disc Anchor Blade
03.816.015	Push Button, for Instrument for Disc Anchor Blade

Switch off the light source and remove the light.

Then remove/retract all remaining accessories/disc anchor component with the corresponding instruments (1).

Precaution: Before the retractor can be removed, all accessories (blade extensions and winglets) have to be removed (1), the disc anchor has to be retracted and the retractor must be placed in the zero position.



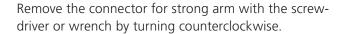
The retractor has to be placed in the zero position as follows (2):

- Close the left and right blades by loosening the speed nut on the retractor body (1).
- Turn the angulation nuts on the left and right blade holder with the screwdriver to bring the blades back into the zero position (2). Turn in the opposite direction of the etched arrows.
- Push the button etched with "PUSH" while turning the RETRACT nut counterclockwise (3) to bring the third blade holder into its original zero position.
- Loosen the strong arm by turning the knob on it counterclockwise and detach connector from strong arm or universal arm.
- Remove the retractor from the surgical field.



Removal After Surgery

Instruments	
03.816.011	Blade Removal Tool
03.816.016	Sleeve, for Blade Removal Tool No. 03.816.011
03.816.010	Screwdriver, for INSIGHT Lateral Access System
Optional	
03.816.019	Wrench, for INSIGHT Lateral Access System



For cleaning, reprocessing and storage, disassemble the blades from the retractor using the blade removal tool. Assemble the sleeve for blade removal tool onto the blade removal tool (see chapter "Cleaning Positions/ Assembly" p. 40) ensuring that the sleeve is fully pulled back.

Engage the assembled blade removal tool into the blade – blade holder connection (1).

Advance the sleeve for the blade removal tool until the blade is engaged (2).

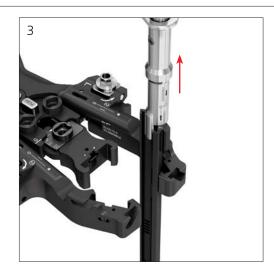
Alternatively, the flat spring can be compressed by hand without the sleeve.





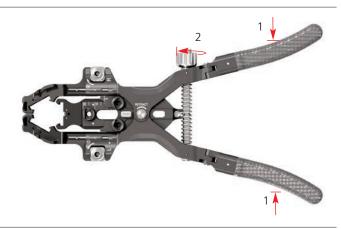
Pull the blade out (3). Retract the sleeve for the blade removal tool in order to release the blade.

Disassemble the blade holders from the retractor body according to the disassembling instructions (see chapter "Cleaning Positions/Assembly" illustrated on the next page).









2

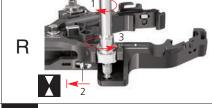




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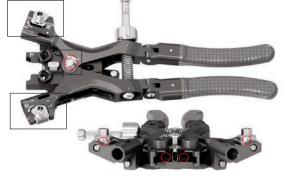






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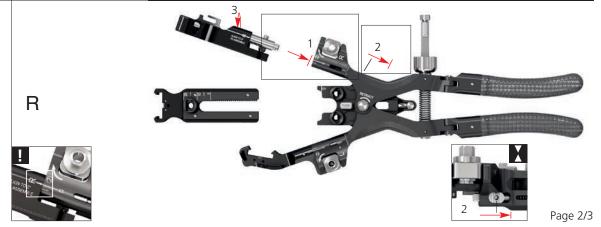


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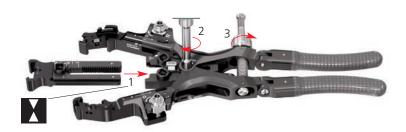




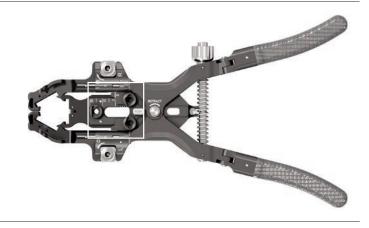




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3























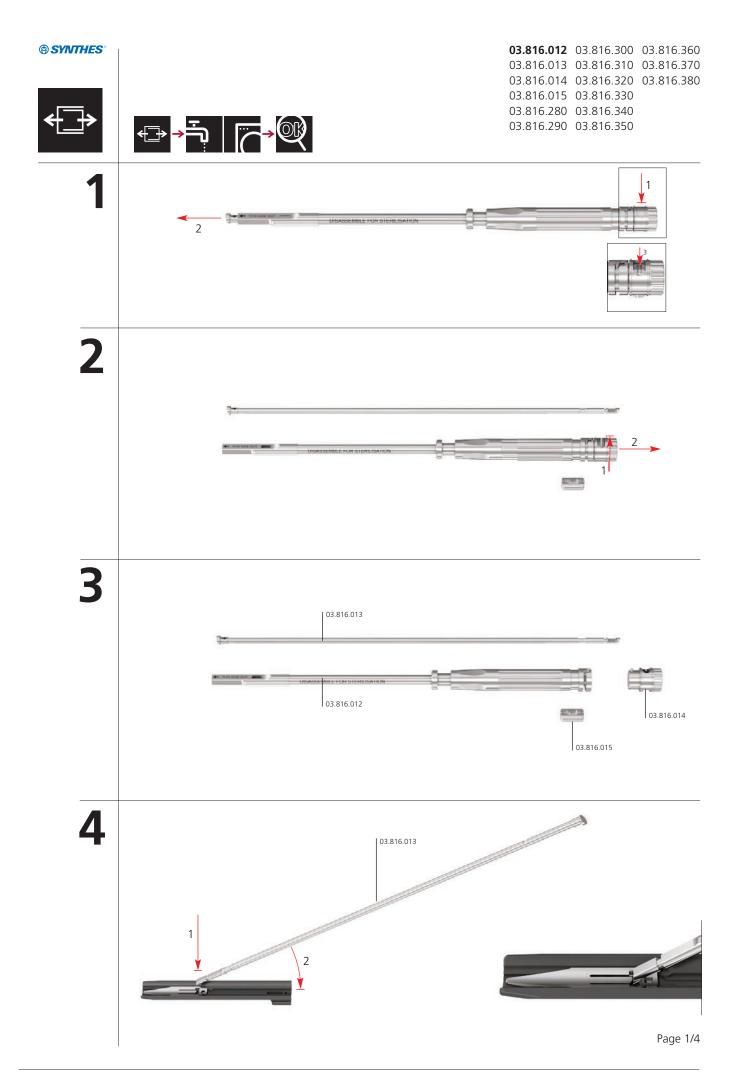
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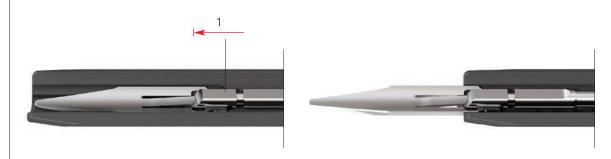
SYNTHES



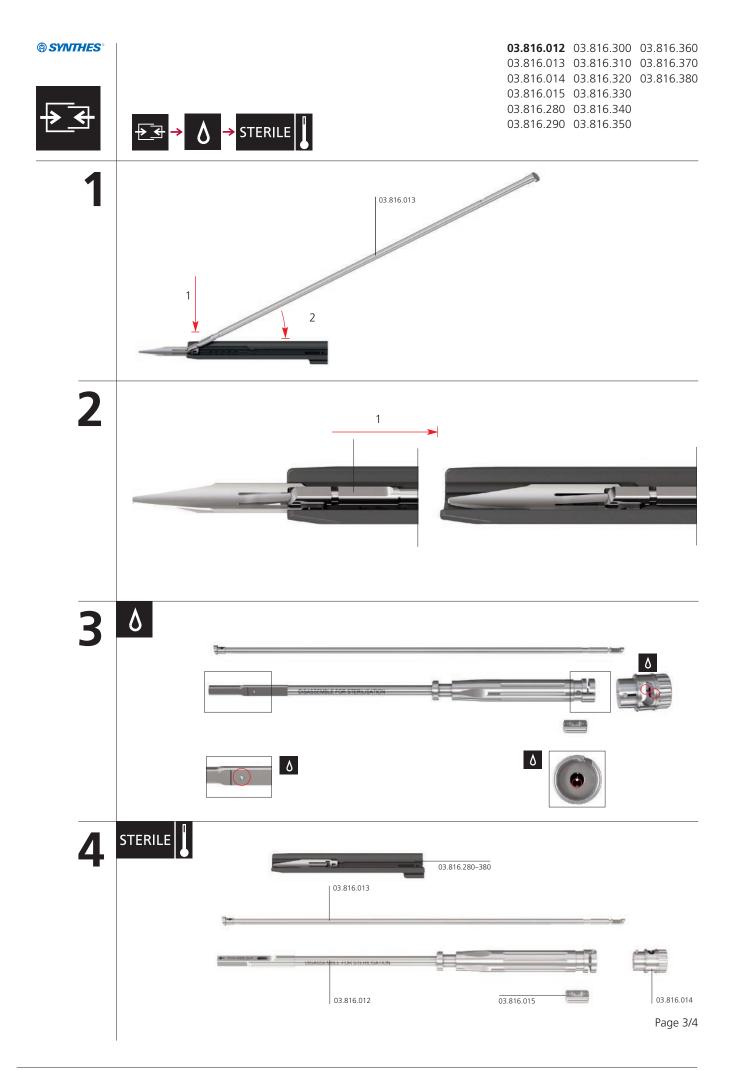


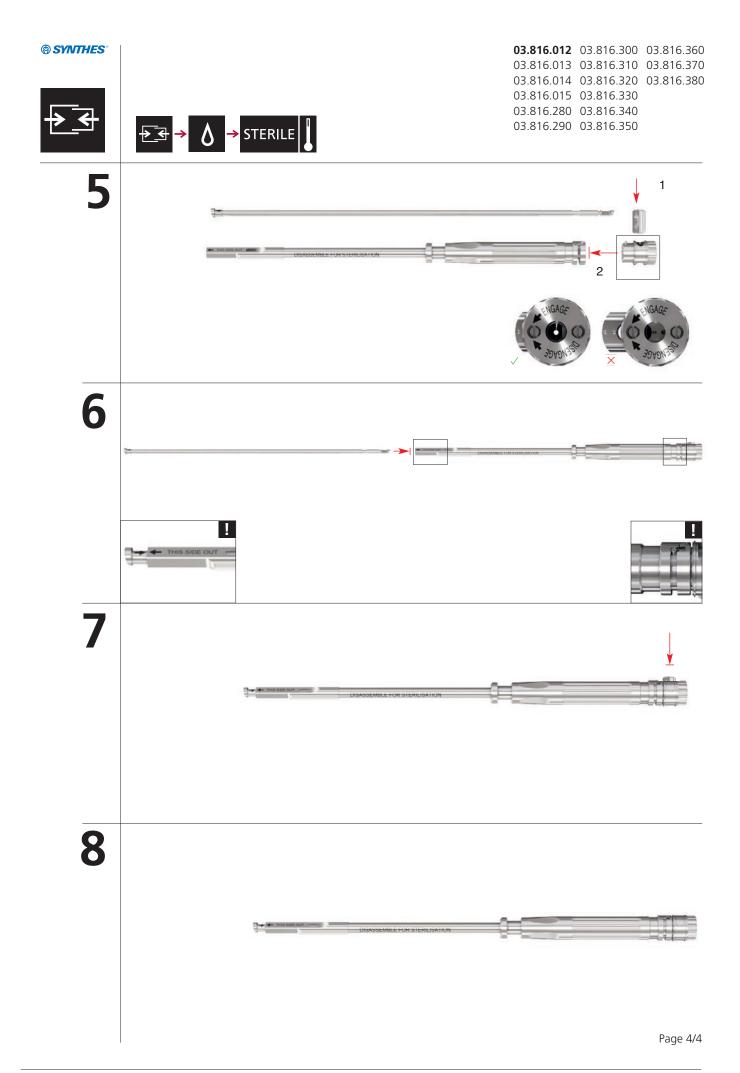
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03.816.280 03.816.340 03.816.290 03.816.350









INSTRUMENTS

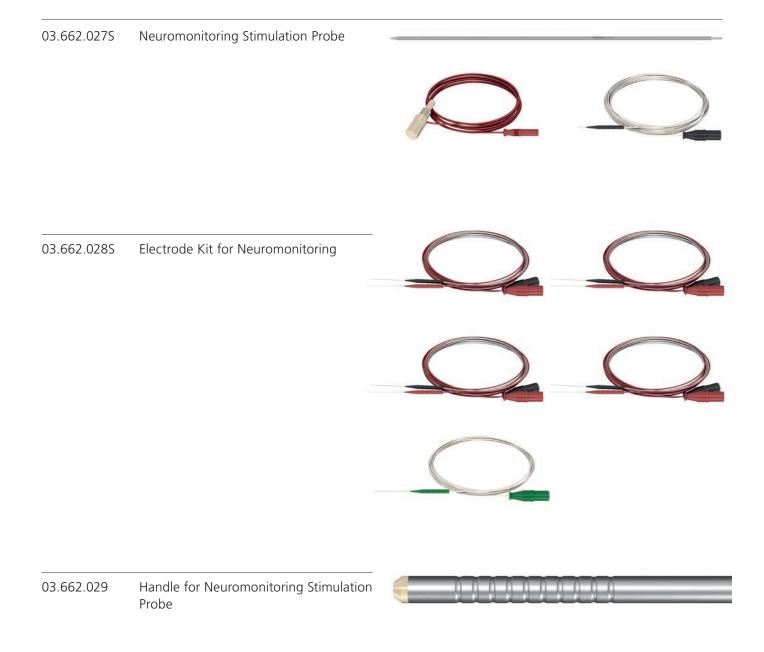
03.809.941 Universal Arm 03.809.942 Table Clamp for Universal Arm Retractor Body 03.816.001 03.816.002 Blade Holder, left, for No. 03.816.001 03.816.003 Blade Holder, right, for No. 03.816.001 03.816.004 Third Blade Holder, for No. 03.816.001

03.816.010	Screwdriver, for INSIGHT Lateral Access System	3-5 VIVINES"
03.816.011	Blade Removal Tool	
03.816.016	Sleeve, for Blade Removal Tool No. 03.816.011	ASSENDLE DELICOLUBLE
03.816.012	Instrument for Disc Anchor Blade	
03.816.013	Inner Shaft, for Instrument for Disc Anchor Blade	
03.816.014	Turning Knob, for Instrument for Disc Anchor Blade	
03.816.015	Push Button, for Instrument for Disc Anchor Blade	
03.816.019	Wrench, for INSIGHT Lateral Access System	
03.816.020	Holder, for INSIGHT Lateral Access System	
03.816.025	Scoop, for INSIGHT Lateral Access System	
03.816.030	Accessories Instrument	

03.816.033	Blade Extension	
03.816.036	Winglet, right	
03.816.037	Winglet, left	
03.816.800	Strong Arm	
03.816.801	Connector, for Strong Arm No. 03.816.800	
03.816.806	Dilator, ∅ 6 mm, eccentric, small, for INSIGHT Lateral Access System	=
03.816.810	Dilator, ∅ 10 mm, eccentric, medium, for INSIGHT Lateral Access System	i≋ i iŝ i iŝ i iŝ I iŝ I ANTERIOR
03.816.816	Dilator, \emptyset 16 mm, eccentric, large, for INSIGHT Lateral Access System	IS I IS I IS I IS ANTERIOR
03.816.040- 03.816.090	Blade, length 40 mm–90 mm (10 mm increments)	S
03.816.100- 03.816.180	Blade, length 100 mm–180 mm (10 mm increments)	- 12°

03.816.280– 03.816.380	Disc Anchor Blade for Third Blade Holder, length 80 mm–180 mm (10 mm increments)	
03.816.700	Reusable Light, for INSIGHT Lateral Access System	
03.816.701	Wolf Adapter, for Light Source	
03.816.702	Storz Adapter, for Light Source	
03.816.703	Olympus Adapter, for Light Source	
03.816.704	ACMI Adapter, for Light Source	
03.816.705	Bifurcated Light Cable, for No. 03.816.700	
03.816.706	Light Cable, for No. 03.816.710S	
03.816.709	Adapter, for Light and Cable	
03.816.710S	Disposable Light, for INSIGHT Lateral Access System, sterile	

INSTRUMENTS FOR NEUROMONITORING



TRAYS AND VARIO CASES

The trays with the instruments for the INSIGHT Lateral Access System can be assembled to the needs of the surgeon. They can be stored in Vario Cases with corresponding height.

68.809.040 (without) instruments	Tray, for Retractor and Dilators, for INSIGHT Lateral Access System
68.809.041 (without instruments)	Tray, for Blades and Scoop, for INSIGHT Lateral Access System
68.809.042 (without instruments)	Tray, for Accessories and Blades, length 40–90 mm, for INSIGHT Lateral Access System
68.809.043 (without instruments)	Tray, for Disc Anchor Blades, for INSIGHT Lateral Access System
68.809.044 (without instruments)	Tray, for Lighting Instruments, for INSIGHT Lateral Access System
689.510	Vario Case, Framing, size 1/1, height 88 mm
689.511	Vario Case, Framing, size 1/1, height 126 mm
689.507	Lid (Stainless Steel), size 1/1, for Vario Case
68.809.048 (without instruments)	Vario Case for Strong Arm System, with Lid, without Contents

