

INSIGHT™

TUBULAR RETRACTOR SYSTEM

Surgical Technique

Tubular access system for the posterior thoracolumbar spine

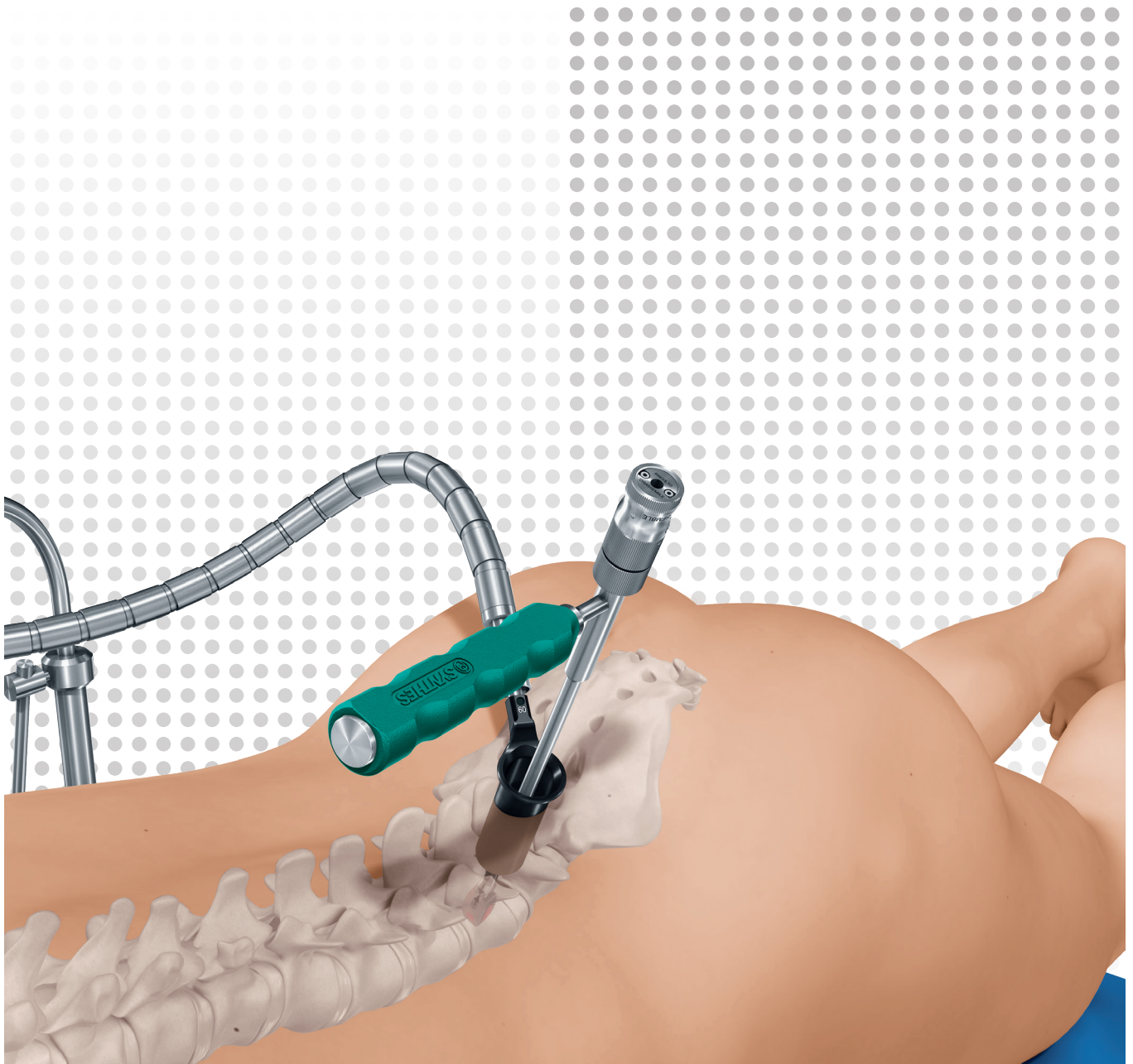



 Image Intensifier Control

 Warnings

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance>

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:

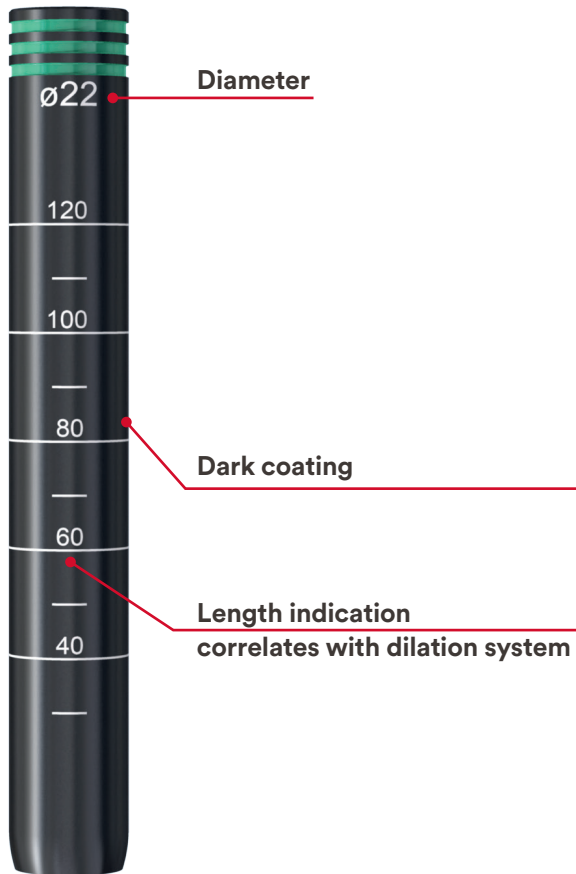
<http://emea.depuyssynthes.com/hcp/reprocessing-care-maintenance>

Table of Contents

Introduction	INSIGHT™ Tubular Retractor System	4
	AO Spine Principles	6
Surgical Technique	Preparation	7
	Surgical Technique	12
Indications and Contraindications		19
Bibliography		20

INSIGHT™ Tubular Retractor System

Dilator Ø 22 mm



Insight Tube Ø 22 mm, length 60 mm

Table fixation via Hudson Connector
Secure tube in desired position





Insert dilators

Insert Insight Tube

Use instruments through tube

AO Spine 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.^{1,2}

AO Principles

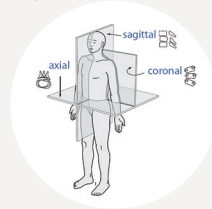
1.



Stability

Stabilization to achieve a specific therapeutic outcome.

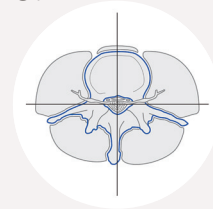
2.



Alignment

Balancing the spine in three dimensions.

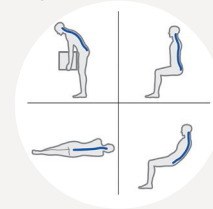
3.



Biology

Etiology, pathogenesis, neural protection, and tissue healing.

4.



Function

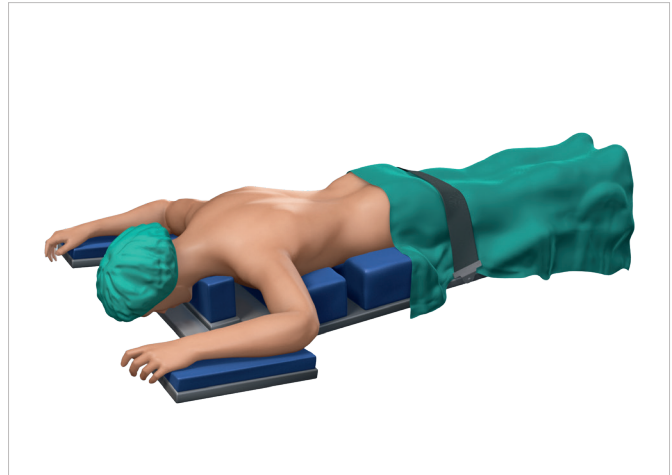
Preservations and restoration of function to prevent disability.

Preparation

1. Patient positioning

The patient is placed in a prone position. To facilitate intra-operative exposure of the posterior disc space, the spine can be flexed.

- If a fusion procedure is being performed ensure the spine is returned to the physiological position before inserting trials and implants.



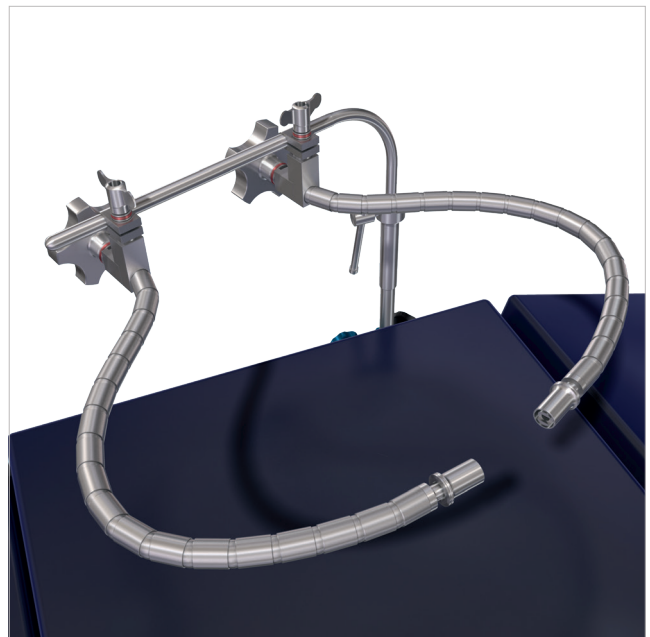
2. Set up MIS Support System

MIS Support System

387.346	SynFrame Holding Base, insulated, for OR Table, dark blue
387.343	SynFrame Guiding Tube, for Angled Rod No. 387.344, for Basic System
03.612.012	Flex Arm – SynFrame Connection
03.612.010	Flex Arm

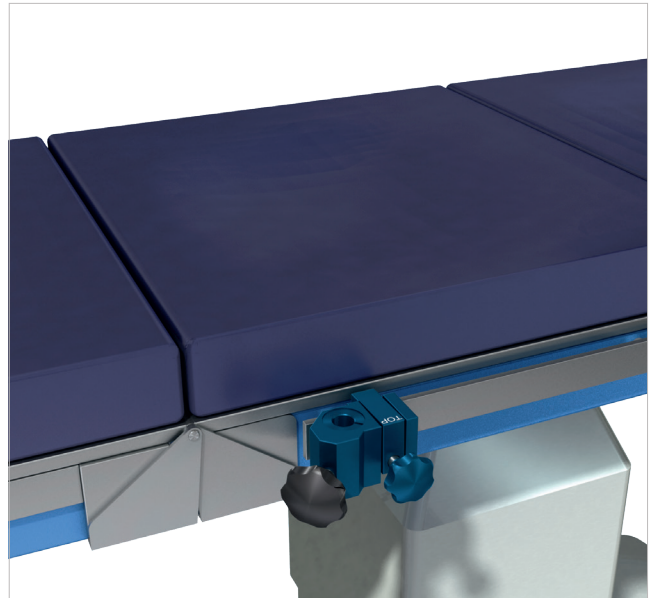
When working through a tubular access system, table mounting is very important. Therefore always use the INSIGHT Tubes in combination with the Synthes MIS support system which securely fixes the INSIGHT Tubes to the OR table.

- Two flex arms may be used simultaneously on the Flex Arm – SynFrame Connection for bilateral approaches.



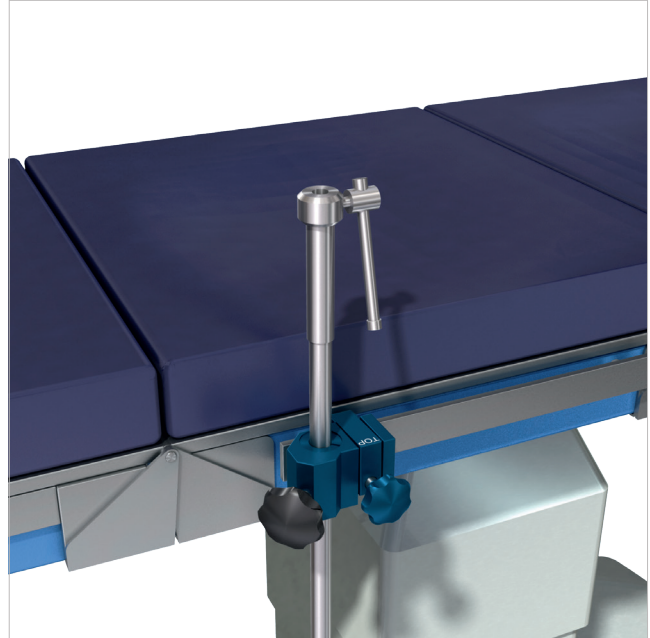
2a. Secure holding base

Install the holding base on the operative table by sliding in along a guide rail from the rail end. "TOP" must be visible on the clamp surface. Tighten the knob to secure it to the rail at the desired location.



2b. Insert guiding tube into holding base

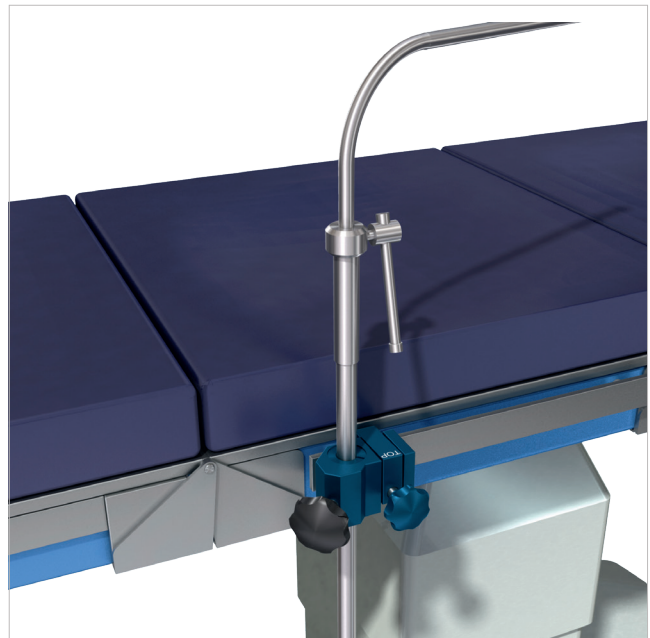
Insert a guiding tube into the holding base and lock it in place with the tightening knob.



2c. Insert flex arm bridge into guiding tube

Insert the tapered end of the flex arm bridge into the holding sleeve of the guiding tube until the desired shaft length is exposed.

Once the desired height is achieved, lock in place by using the clamp handle.



2d. Attach flex arm to flex arm bridge

Slide the flex arm clamp into the flex arm bridge. Turn the clamp knob clockwise to tighten the flex arm clamp.

- Two flex arms may be used simultaneously on one Flex Arm – SynFrame Connection.

▲ Precaution:

Flex arm tension should be fully released after each use to prevent instrument damage and allow proper instrument sterilization.



Surgical Technique

1. Approach the spine

Instruments

02.606.001	Kirschner Wire Ø 1.6 mm with trocar tip, length 480 mm, Stainless Steel
02.606.003	Kirschner Wire Ø 1.6 mm without trocar tip, length 480 mm, Stainless Steel

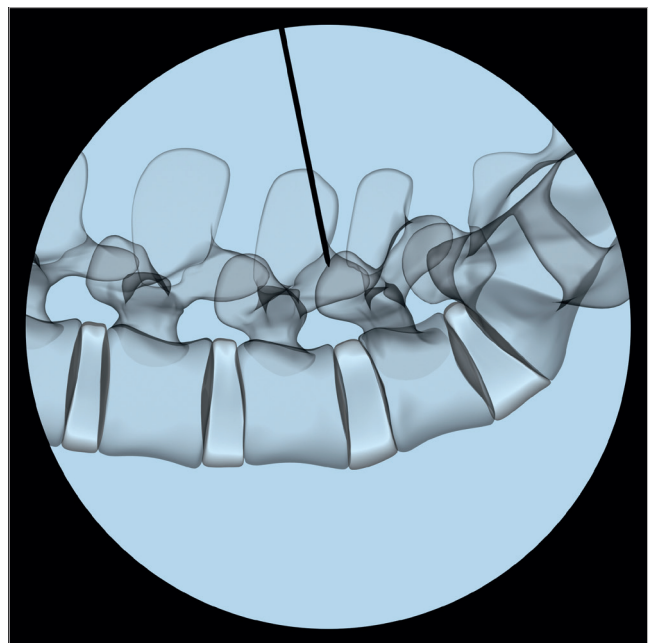
The mini-open approach uses paramedian incision made through the skin and fascia approximately 2–3 cm (for PLIF) or 3–4 cm (for TLIF) from the midline. This allows muscle splitting within the multifidus and longissimus cleavage plane.

- 1 Determine the location of the skin incision using anatomic landmarks or radiographic imaging. Create an incision. The incision length should match the respective tube diameter (Ø 16–28 mm), then cut through the subcutaneous tissue and make a fascial incision to the same length.

- 2 Position the Kirschner Wire in the incision and advance it carefully while controlling the position under fluoroscopy. Fix the Kirschner Wire in the bony structure where you plan to do the minimally invasive procedure.

- 3 **▲ Warning:**

Ensure the Kirschner Wires remain securely in position throughout the entire duration of the procedure. 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 dura or the nerve root.



2. Dilate incision

Instruments

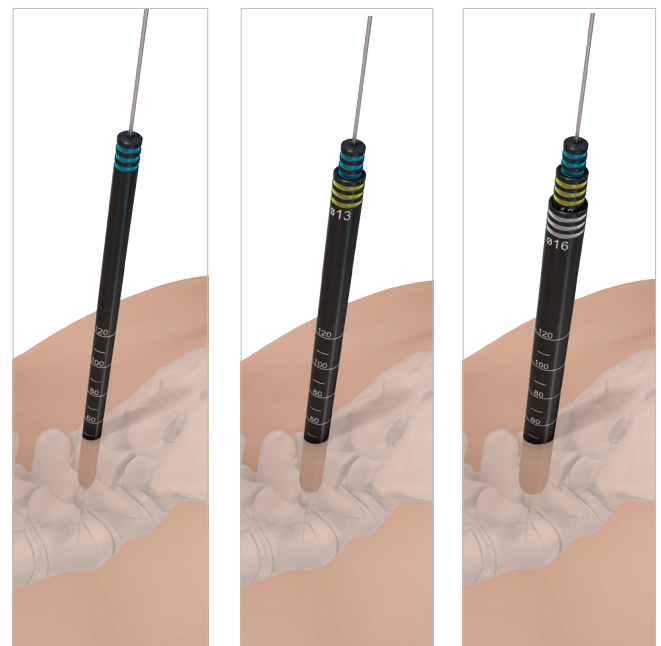
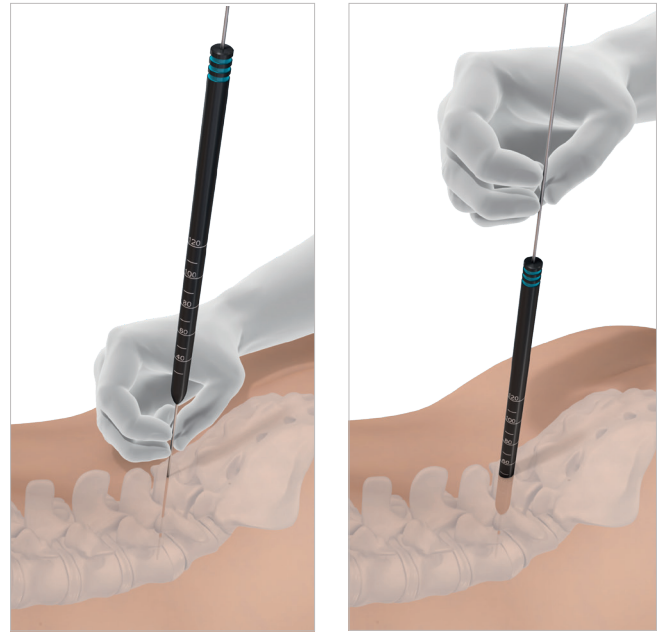
03.610.001	Dilator Ø 1.8/10.0 mm, cannulated, for Guide Wire Ø 1.6 mm
03.610.002	Dilator Ø 10.0/13.0 mm, for No. 03.610.001
03.610.003	Dilator Ø 13.0/16.0 mm, for No. 03.610.002
03.610.004	Dilator Ø 16.0/19.0 mm for No. 03.610.003
03.610.005	Dilator Ø 19.0/22.0 mm for No. 03.610.004
03.610.006	Dilator Ø 22.0/25.0 mm for No. 03.610.005
03.610.007	Dilator Ø 25.0/28.0 mm for No. 03.610.006

Insert the 1.8/10.0 mm dilator over the Kirschner Wire. Continue dilation placing the 10.0/13.0 mm dilator over the 1.8/10 mm dilator. Then place the 13.0/16.0 mm dilator over the 10.0/13.0 mm dilator.

If a larger diameter is required continue to dilate the incision by inserting dilator after dilator following the diameter sizes of the dilators.

▲ Warning:

Ensure the Kirschner Wire does not slip out before the tube is in place. The Kirschner Wires are long enough to be held in place by hand during soft tissue dilation.

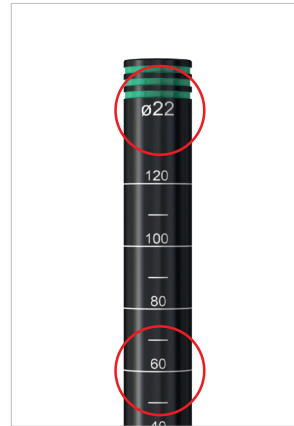


3. Choose Insight Tube

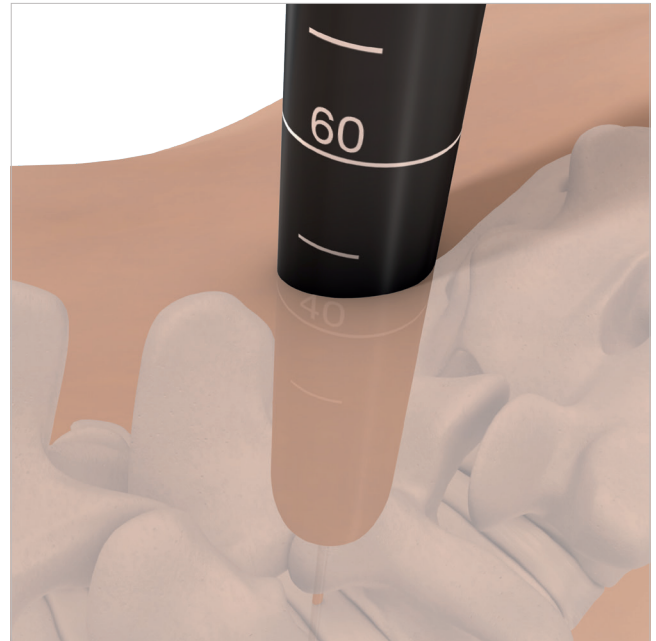
Instruments

03.615.163–169	MIS Access Tube, size 16 × 30 mm–16 × 90 mm
03.615.193–199	MIS Access Tube, size 19 × 30 mm–19 × 90 mm
03.615.223–229	MIS Access Tube, size 22 × 30 mm–22 × 90 mm
03.615.253–259	MIS Access Tube, size 25 × 30 mm–25 × 90 mm
03.615.283–289	MIS Access Tube, size 28 × 30 mm–28 × 90 mm

Etched markings on the dilators indicate the length of the appropriate tube. The soft tissue coverage can vary between 30 and 90 mm.



Choose the correct tube according to the last dilator. The etching of the dilator indicates the diameter of the tube and the etched ring marks indicate the length of the tube. Use the shortest allowable tube to access the posterior bony structures of the spine for less impact on instrument mobility.



4. Insert Insight Tube

The selected Insight Tube is inserted over the last dilator and pushed down.

Place the tube so that the Hudson connector is pointed away from the surgeon. This allows for a wide working area and better visibility.



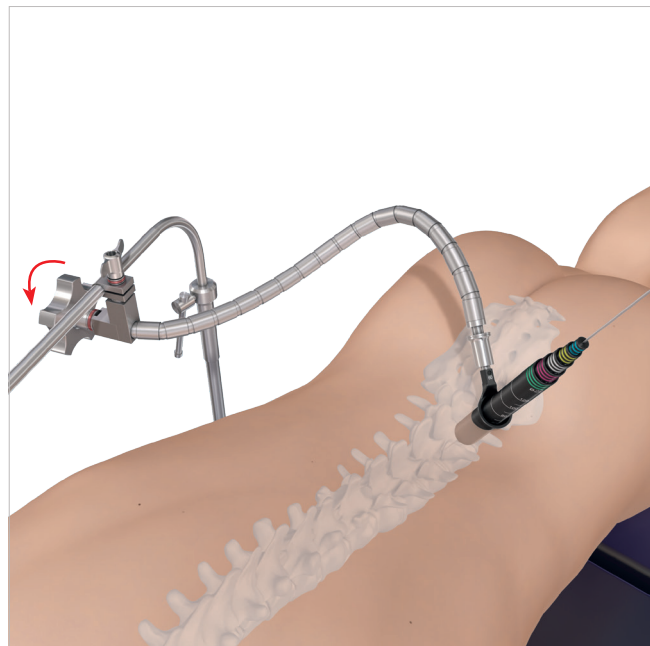
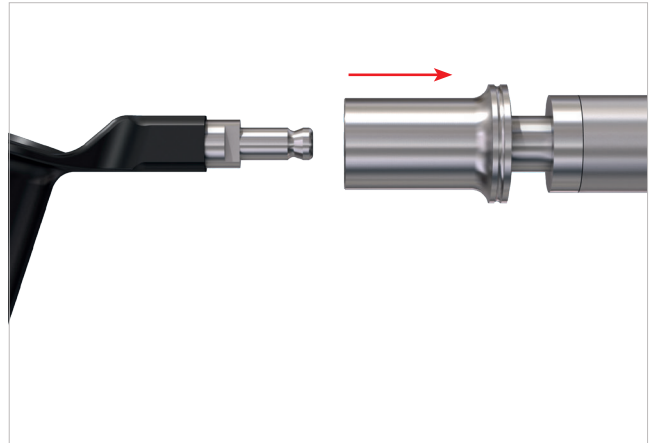
5. Connect Insight Tube to the flex arm

Connect the tube with the flex arm by pulling back the coupling on the flex arm and plug in the Hudson connector of the tube.

Position the tube in the desired working position and hold it in place.

Turn the tension knob on the flex arm until it is secured.

To reposition the tube, release the flex arm tension by turning the tension knob back. Place the tube in the desired position, then retighten the tension knob.

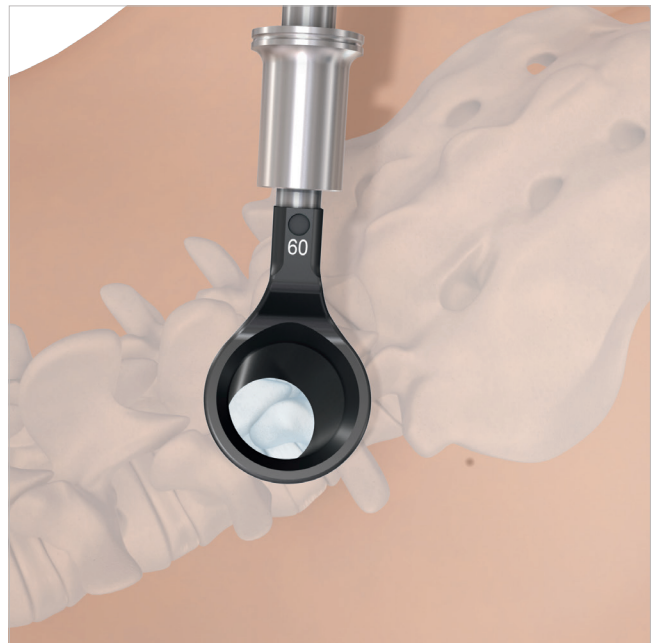
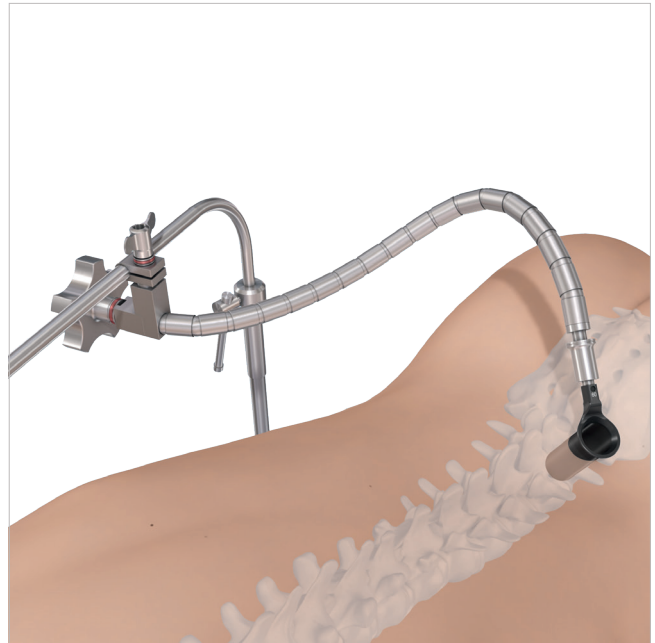


6. Remove Kirschner Wire and dilators

After securing the Insight Tube with the flex arm, the Kirschner Wire and dilators can be removed one after another.

Perform the procedure (laminectomy, discectomy, etc.) using instruments through the tube.

The rest of the surgical steps are described in the corresponding surgical techniques of the chosen system.



Indications and Contraindications

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu.

Bibliography

1. Aebi M, Arlet V, Webb JK (2007): AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.
2. Aebi M, Thalgott JS, Webb JK (1998): AO ASIF Principles in Spine Surgery. Berlin Heidelberg New York: Springer.

Not all products may currently be available in all markets.
This publication is not intended for distribution in the USA.
Surgical techniques are available as PDF files at www.depuySynthes.com/ifu



Manufactured or distributed by:

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland

Tel: +41 61 965 61 11

www.jnjmedicaldevices.com

Note: For recognized manufacturer, refer to the product label.