

Facet Joint Fixation Device

Facet Wedge

Surgical Technique



 Image intensifier control

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.depuyshnthes.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.depuyshnthes.com/hcp/reprocessing-care-maintenance>

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* For Product Catalog contact your local DePuy Synthes representative

Introduction

Facet Wedge System*

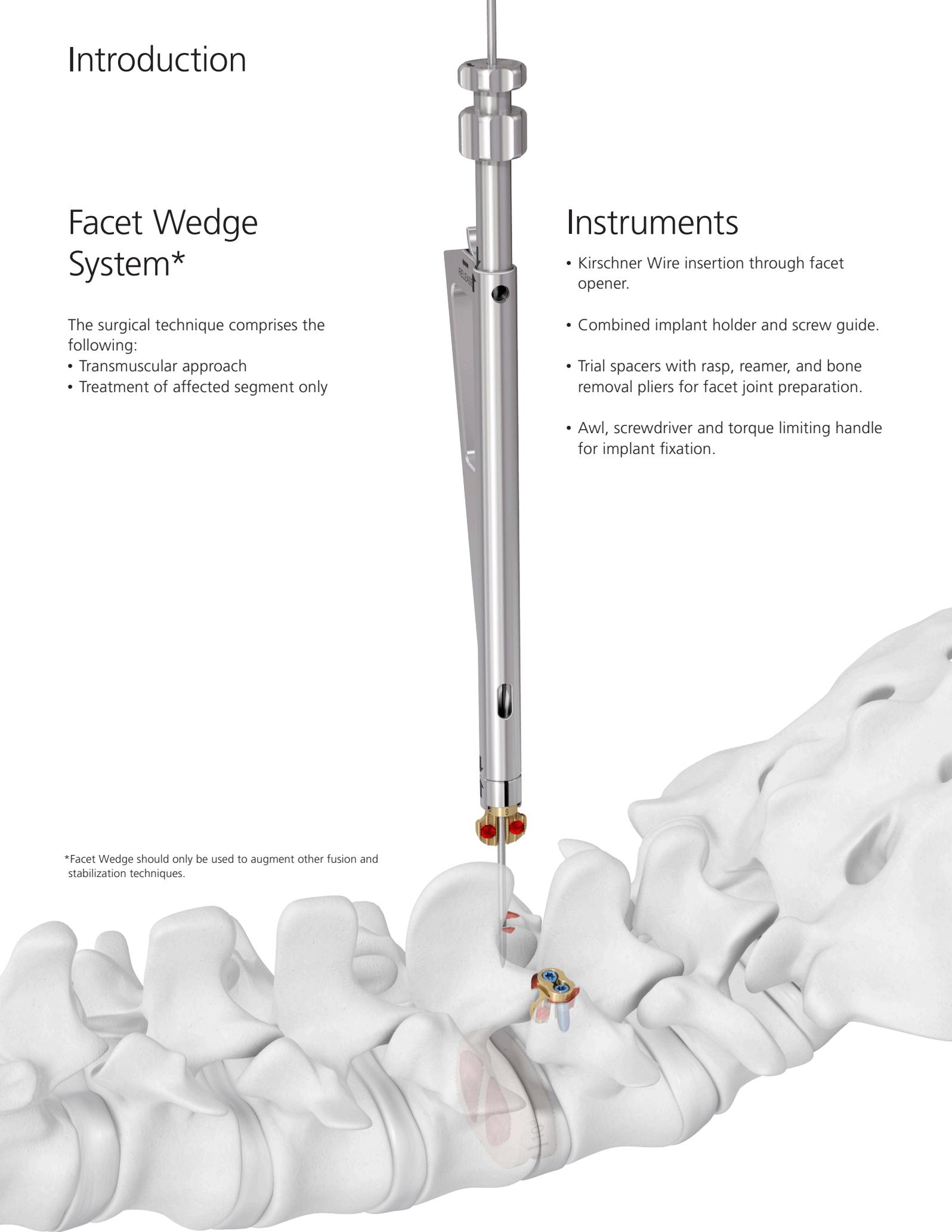
The surgical technique comprises the following:

- Transmuscular approach
- Treatment of affected segment only

Instruments

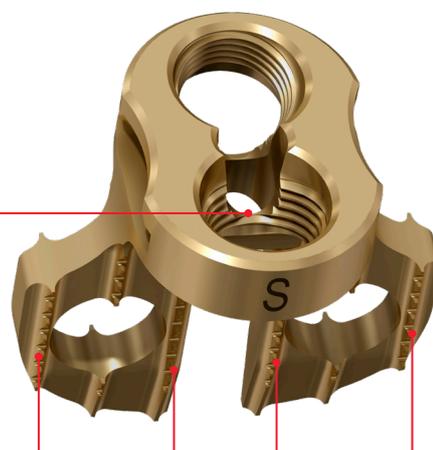
- Kirschner Wire insertion through facet opener.
- Combined implant holder and screw guide.
- Trial spacers with rasp, reamer, and bone removal pliers for facet joint preparation.
- Awl, screwdriver and torque limiting handle for implant fixation.

*Facet Wedge should only be used to augment other fusion and stabilization techniques.



Implant

Kirschner Wire hole



Rails

Generate contact between subchondral bone and implant

Implant shoulder

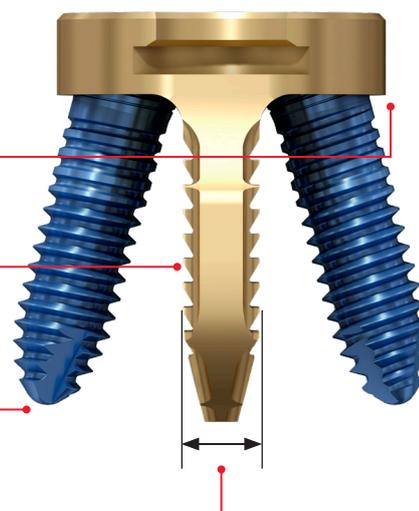
Teeth

Screws

Diverging locking screws for primary fixation

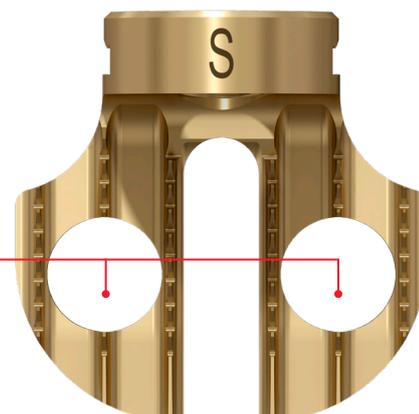
Sizes

Different implant sizes available



Perforations

Designed to pack implant with bone or bone graft substitute



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}

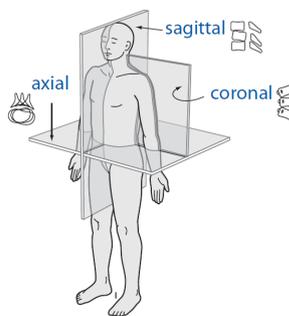
Stability

Stabilization to achieve a specific therapeutic outcome



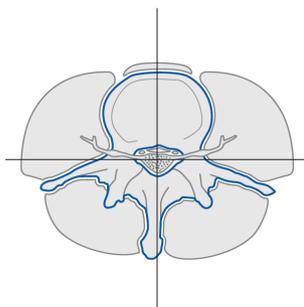
Alignment

Balancing the spine in three dimensions



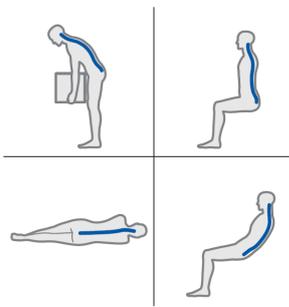
Biology

Etiology, pathogenesis, neural protection, and tissue healing



Function

Preservations and restoration of function to prevent disability



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Preoperative Planning and Preparation

Preoperative planning

The orientation of facet joints varies in the different spinal levels (1).

Use imaging techniques (MRI, CT) to visualize the operating level in a transverse view (2) to assess:

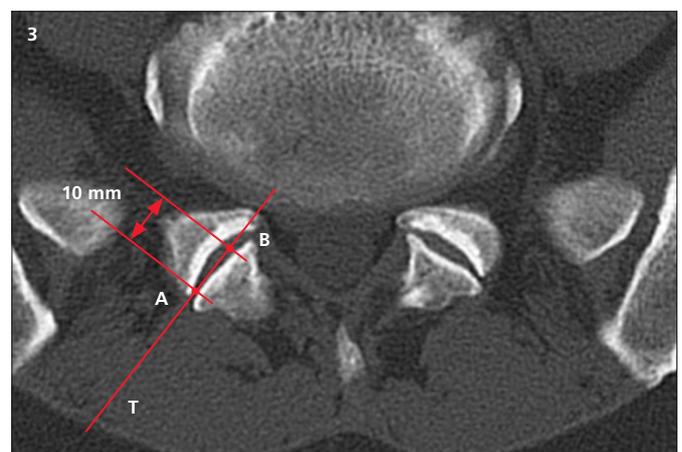
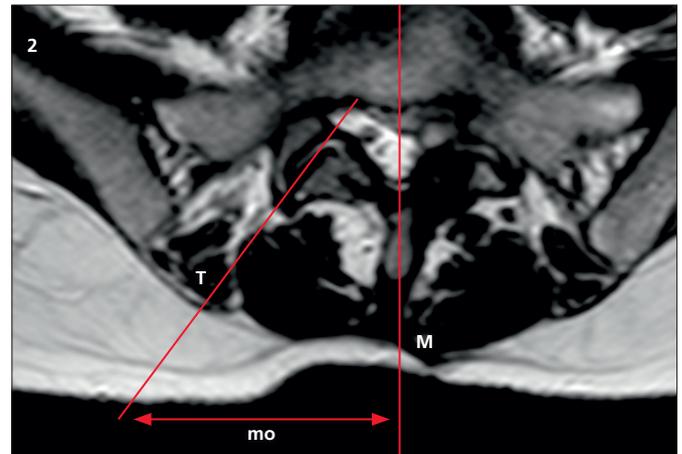
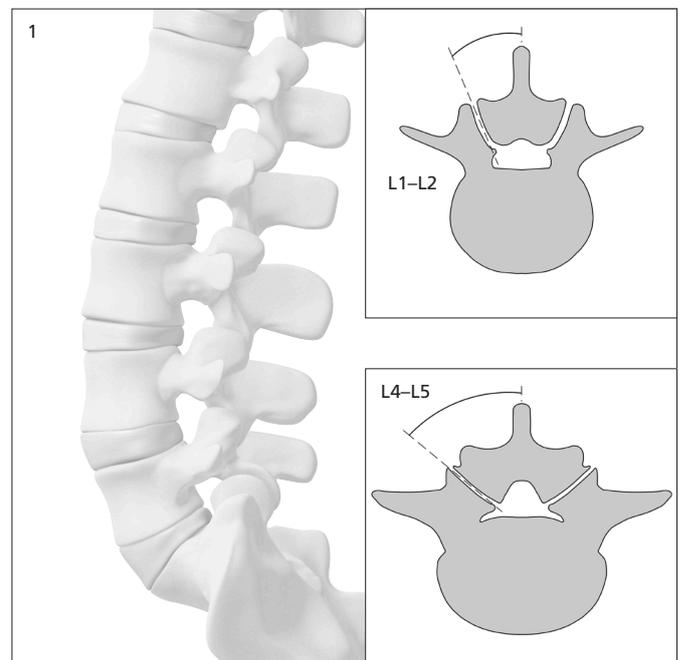
- facet joint orientation
- facet joint shape
- obstructive tissues (e.g. osteophytes, pelvis)

Keep this information readily available during surgical procedure to:

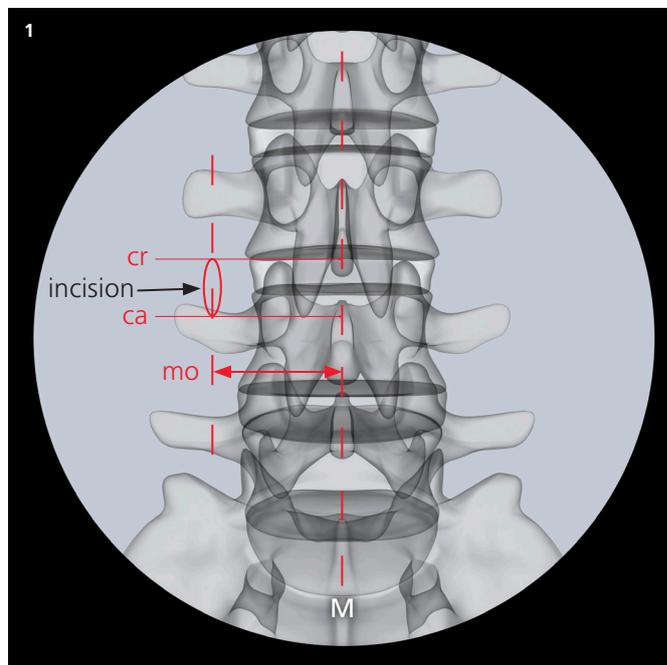
- select an appropriate approach
- identify incision location
- confirm trajectory of instruments and implants

To define the trajectory (T) of implants and instruments identify the facet joint entry (A) and the joint space in 10 mm depth (B) on axial CT or MRI scans (3). The 10 mm length corresponds to the implant length inserted into the facet joint.

Use the determined trajectory (T) to estimate the midline offset (mo) distance between the midline (M) and the trajectory (T) at the skin level.

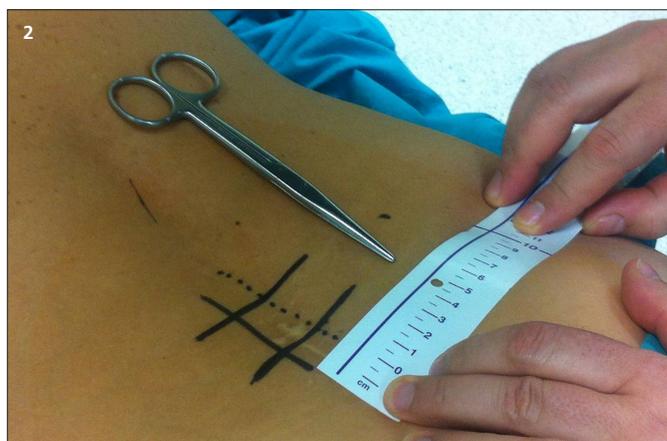


Identify on an anterior/posterior intraoperative image (1) the cranial (cr) and caudal (ca) boundary of the facet joint. Ensure that the superior endplate of the inferior vertebra is in line with the x-ray.



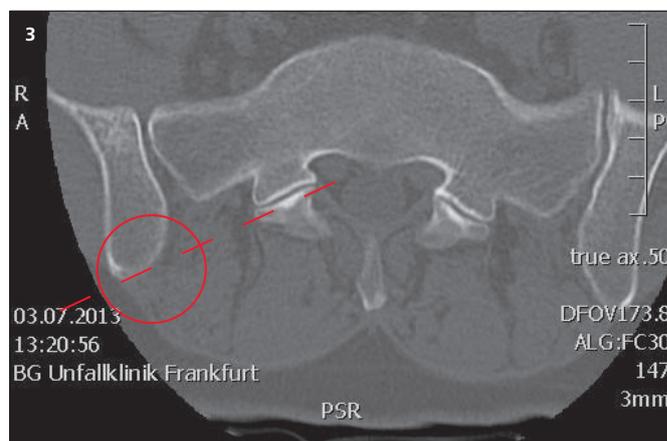
The location of the incision (1 and 2) is defined by the midline offset (mo) and the cranio-caudal boundary of the facet joint aligned parallel to midline (M).

Note: The incision length must be at least 19 mm.



Precaution: Be aware that not all patients can be treated with Facet Wedge. Patient specific anatomy needs to be considered e.g. if the facet joint orientation is in conflict with the iliac crest (3).

Depending on the indications and treated level there are different options of anterior column support that may be combined with Facet Wedge. Preoperative planning should be made accordingly.



Preparation

Required set

01.630.131 Facet Wedge Standard set (Tray 1 and 2)

Optional sets

01.612.100 MIS Support System

01.605.903 Set for MIS Posterior Instruments

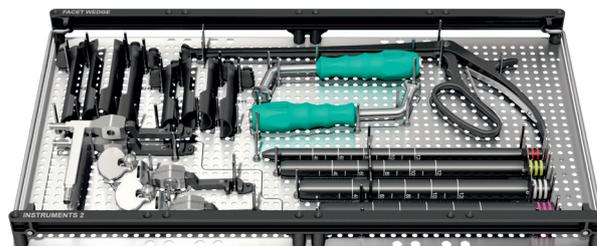
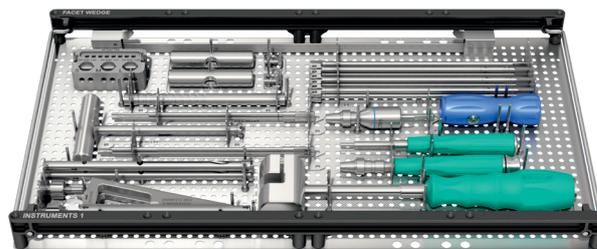
01.615.002 Insight Retractor Set, Standard Configuration

The standard set contains all required instruments and implants.

Optionally the retractor frame can be attached to a table fixation system e.g. MIS Support System 01.612.100.

Have all sets readily available prior to surgery.

Have all necessary imaging studies readily available to plan implant placement, trajectory of approach and identify individual patient anatomy (see page 5).



Patient Positioning

1. Position the patient

Position the patient on a radiolucent OR table in prone and natural alignment of the spine. To obtain optimal visualization of the spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for AP, oblique and lateral views.

- ⌚ Accurate visualization of the anatomic landmarks and fluoroscopic visualization of the facet joints are imperative for using the Facet Wedge System.

Precaution: The Facet Wedge offers no reduction possibilities.



Access and Exposure

1. Approach

Instruments

03.630.148	Dilator Ø 2.0/10.0 mm, for Kirschner Wire Ø 2.0 mm
03.610.002	Dilator Ø 10.0/13.0 mm, for 03.610.001
03.610.003	Dilator Ø 13.0/16.0 mm, for 03.610.002
03.610.004	Dilator Ø 16.0/19.0 mm, for 03.610.003
03.615.100	Retractor Frame, cranial caudal
03.615.003	Handle for Retractor
03.630.140– 03.630.143	Retractor Blade with Clearance, right/left, length 80/60 mm

- Ⓢ Lateral and/or AP (anterior/posterior) imaging is necessary to locate the correct operative level.

Use the preoperative planning (see page 5) to define incision location.

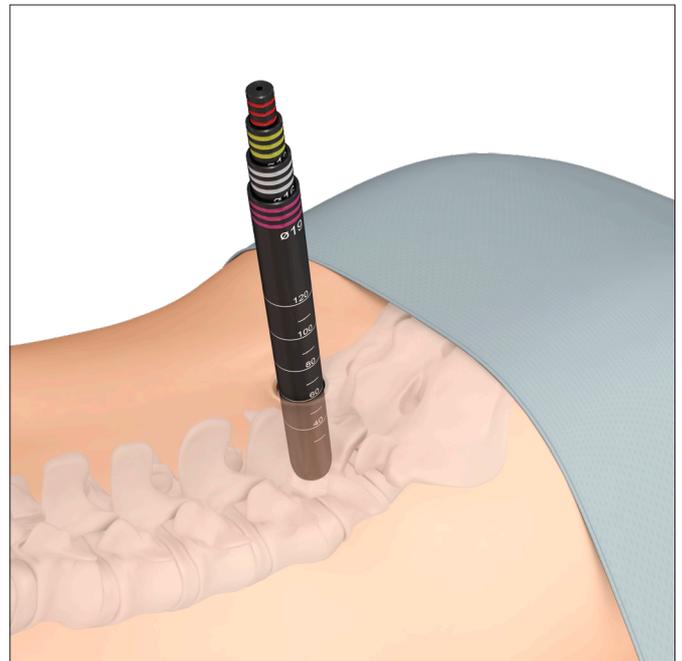
The incision length should be at least 19 mm (initial opening of retractor).

Separate the soft tissue and localize the facet joint.

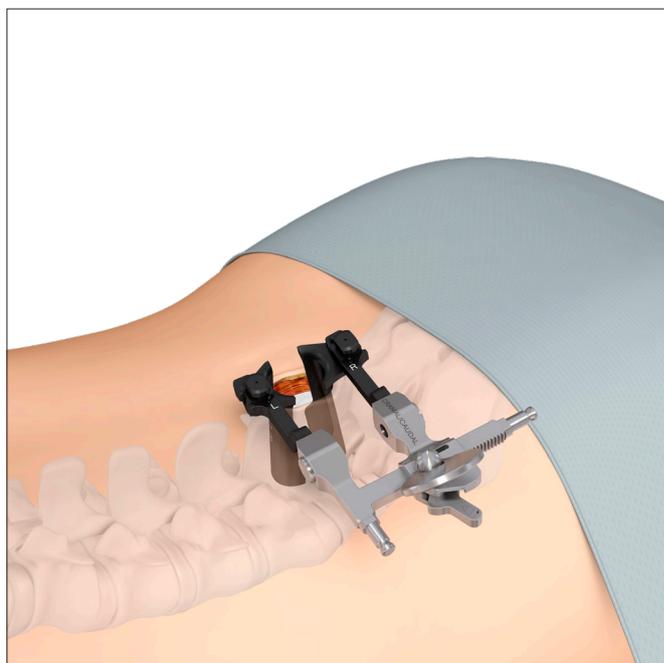
Dilate soft tissue by inserting the smallest diameter dilator.

Repeat with the next larger diameter dilator until required dilation Ø 19 mm is achieved.

Determine the appropriate retractor lengths (60 or 80 mm) of the blades from the depth indicators on the dilators (1).



Slide the retractor with the attached blades over the dilators until the blades contact the facet joint. Remove dilators.



Distract cranial/caudal and angle the blades sufficiently to obtain exposure of the facet joint.

Note: Refer to the **Insight Retractor Technique Guide** for further information on how to use the retractor.



2. Open capsula

Instrument

03.630.136 Bone Removal Pliers

Precaution: Visualize and prepare the facet joints including the removal of osteophytes to ensure the correct placement of the Facet Wedge implant.

Remove remaining soft tissue to visualize the facet joint capsula.

Open the capsula and visualize the joint entry.

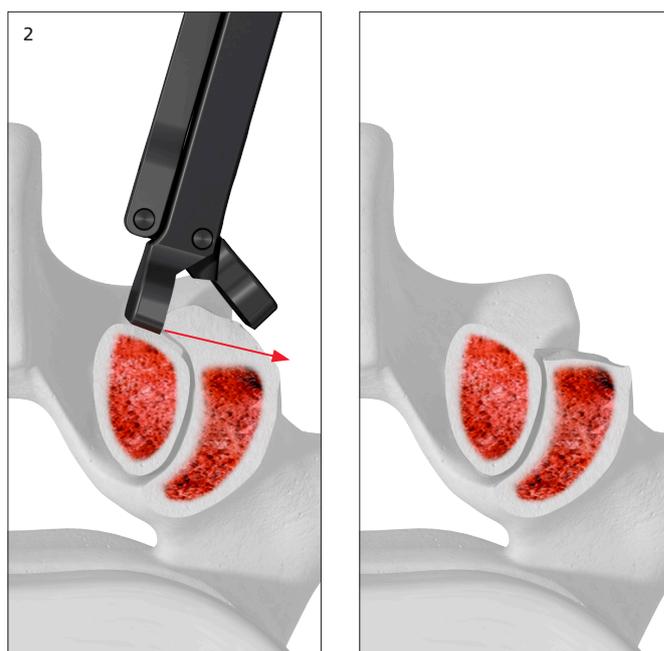


For better visualization of the technique step, the facet joint capsula is removed in the following illustrations.

If necessary, use the bone removal pliers to remove any osteophytes (1).

Place the fixed end of the bone removal pliers on the medial articular process and remove the osteophytes superficially from medial to lateral (2) to allow implant insertion into the facet joint.

Precaution: Avoid articular process weakening during osteophytes removal.



Kirschner Wire Insertion

1. Open facet joint

Instruments

03.630.139	Facet Opener, cannulated
03.630.133	T-handle, for Quick Coupling, cannulated

Precaution: Before inserting the Kirschner Wire use the facet opener to ensure proper insertion location.

Assemble the T-handle and connect the T-handle to the facet opener (see page 34).

Mobilization of the segment may be necessary to visually identify the facet joint entry.

Gently insert the facet opener with T-handle manually into the facet joint until the stop (1). Be aware of the central positioning and correct angulation.

Note: The T-handle orientation should match the facet plane orientation (1).

Precaution: Do not insert the facet opener beyond the stop (1).

Light movement of the facet opener may help to verify the correct placement in the joint.

Warning: Do not use the facet opener to distract the joint and/or to rasp the joint.



2. Kirschner Wire insertion

Instruments

03.630.139	Facet Opener, cannulated
03.630.133	T-handle, for Quick Coupling, cannulated
02.630.139	Kirschner Wire Ø 2.0 mm, tip with thread, length 320 mm
03.630.137	Tamp Ø 2.0 mm for Kirschner Wire, length 320 mm
03.630.138	Combined Hammer, Ø 2.0 mm, cannulated

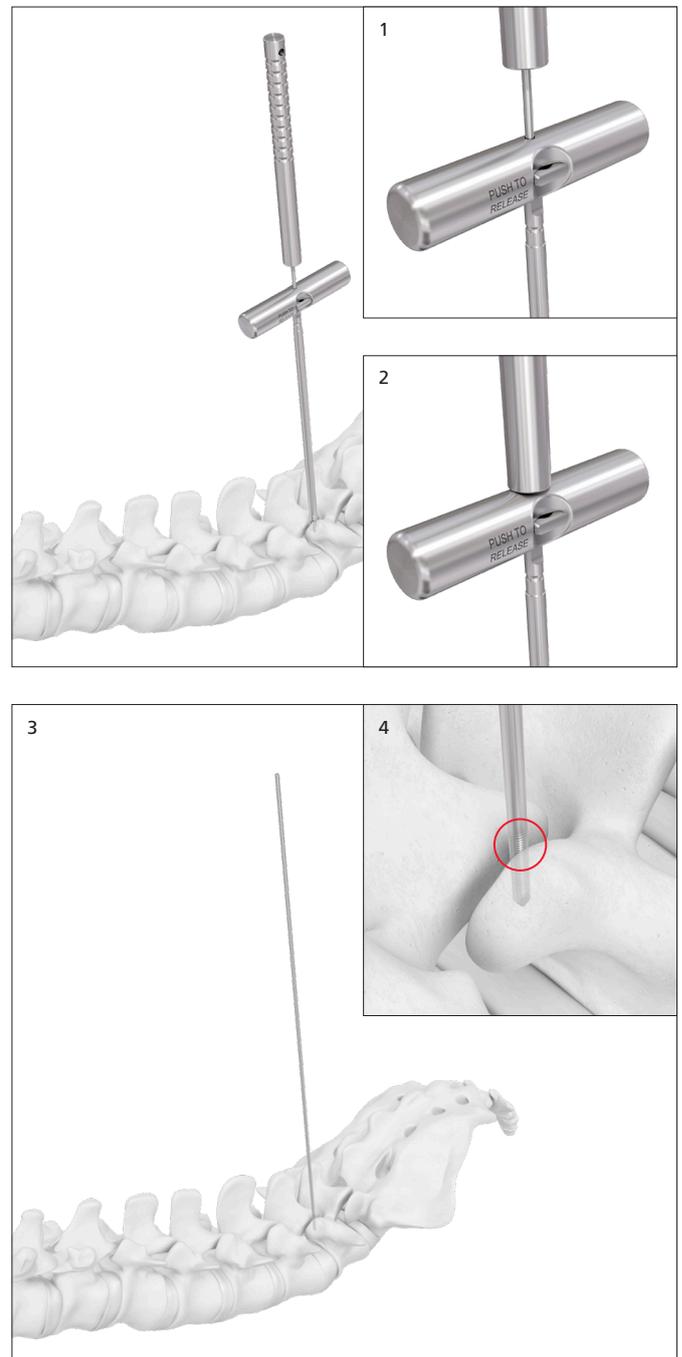
Precaution: Only use the Kirschner Wire from the Facet Wedge system.

Insert the Kirschner Wire into the cannula of the facet opener. Slide the tamp over the Kirschner Wire (1) and insert the Kirschner Wire until the tamp contacts the T-handle (2). Controlled and light hammering on the tamp may be required to advance the Kirschner Wire into the lateral articular process.

Remove the tamp and the facet opener (3).

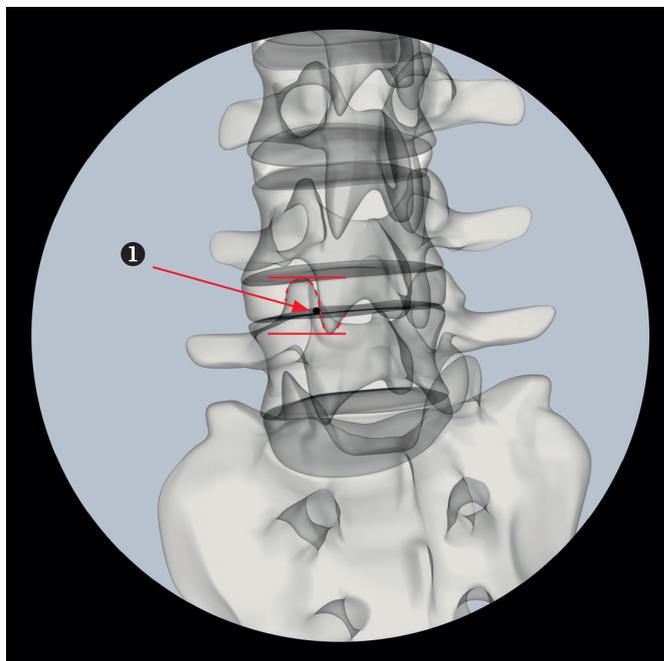
Notes:

- The threaded part can be used as visual reference to control the insertion depth (4).
- The Kirschner Wire has to be inserted with the tamp.
- The tamp controls the Kirschner Wire insertion depth. The Kirschner Wire is inserted 5 mm deeper than the implant/facet opener.

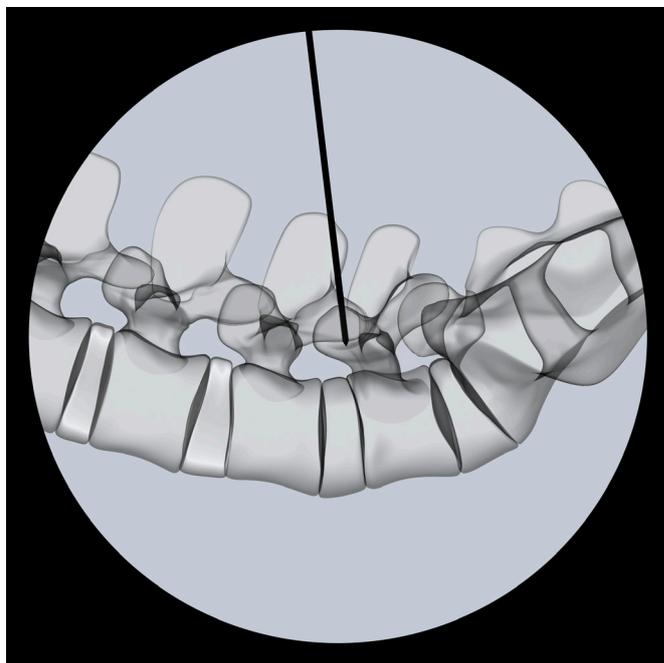


- ① Oblique imaging in line with the Kirschner Wire ① is recommended to confirm the central placement of the Kirschner Wire in the facet joint.

The Kirschner Wire should be equidistant from the cranial and caudal boundaries of the facet joint.



- ① Lateral imaging is necessary to adjust the Kirschner Wire orientation to be in line with the superior endplate of the inferior vertebra.



Facet Joint Preparation

1. Insert trial/rasp

Instruments

03.630.133	T-handle, for Quick Coupling, cannulated
03.630.130– 03.630.132	Facet Wedge Trial Implant with Rasp, small, medium, large, cannulated
03.630.138	Combined Hammer, Ø 2.0 mm, cannulated

Note: Use the trial/rasp to remove the superficial cartilaginous layers of the joint surfaces to prepare for fusion.

Connect the assembled T-handle to the small trial/rasp size (see page 34).

Slide the trial/rasp over the Kirschner Wire and insert the trial/rasp into the facet joint. Controlled and light hammering on the T-handle in the axis of the Kirschner Wire may be required to advance the trial/rasp until the stop (1).

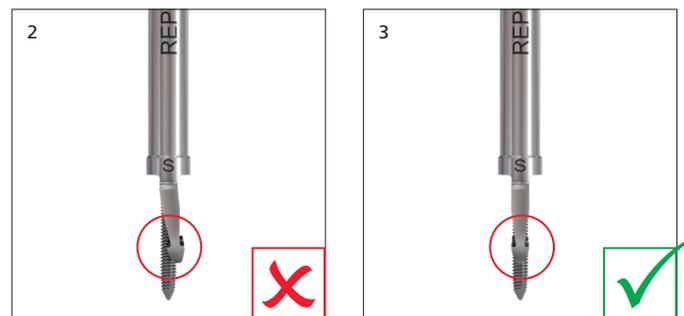
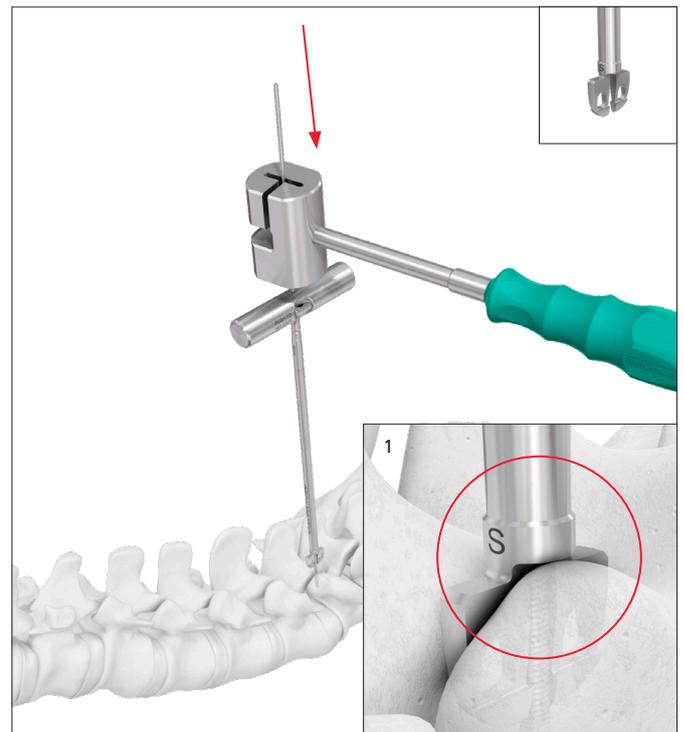
Warnings:

- Excessive hammering may lead to facet joint fracture.
- Make sure the Kirschner Wire is not pushed forward during trial/rasp insertion.

Note: The T-handle orientation should match the facet plane orientation.

Precautions:

- The trial/rasp shall not be inserted beyond the stop (1).
- Do not use the trial/rasp if the tip is bent (2). Check if the trial/rasp tip is bent by inserting the Kirschner Wire into the cannula of the trial/rasp and control axial alignment of the tip to the Kirschner Wire axis (3).



Make sure that the appropriate trial/rasp size is selected. If the trial/rasp is undersized, try the next larger size until the most secure press fit is achieved.

Precaution: The selection of a too large implant might lead to closing of the facet joint on the contralateral side.

2. Remove cartilage

Instruments

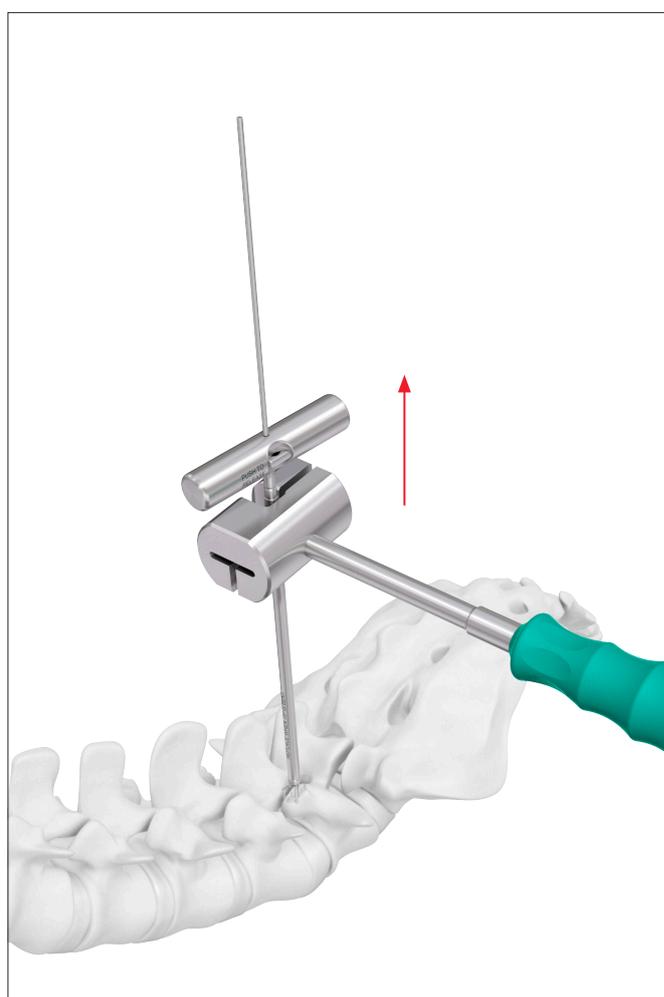
03.630.133	T-Handle, for Quick Coupling, cannulated
03.630.130– 03.630.132	Facet Wedge Trial Implant with Rasp, small, medium, large, cannulated
03.630.138	Combined Hammer, Ø 2.0 mm, cannulated

Retract the trial/rasp from the facet joint. Controlled and light hammering on the T-handle in the axis of the Kirschner Wire may be required to retract the trial/rasp. Repeat the trial/rasp insertion and retraction multiple times to achieve desired cartilage removal.

Note: Controlling the Kirschner Wire during instrument retraction is recommended to keep the Kirschner Wire in place.

Warning: Excessive removal of the subchondral bone may weaken the articular process and may result in pseudarthrosis, segmental instability or facet joint fracture.

Note: Only apply manipulations in line with the facet joint. Apply gentle force using the trial/rasp only.



3. Ream facet joint entry

Instrument

03.630.134 Reamer for Facet Wedge

After cartilage is removed, push the slider (1) and remove the T-handle (2).

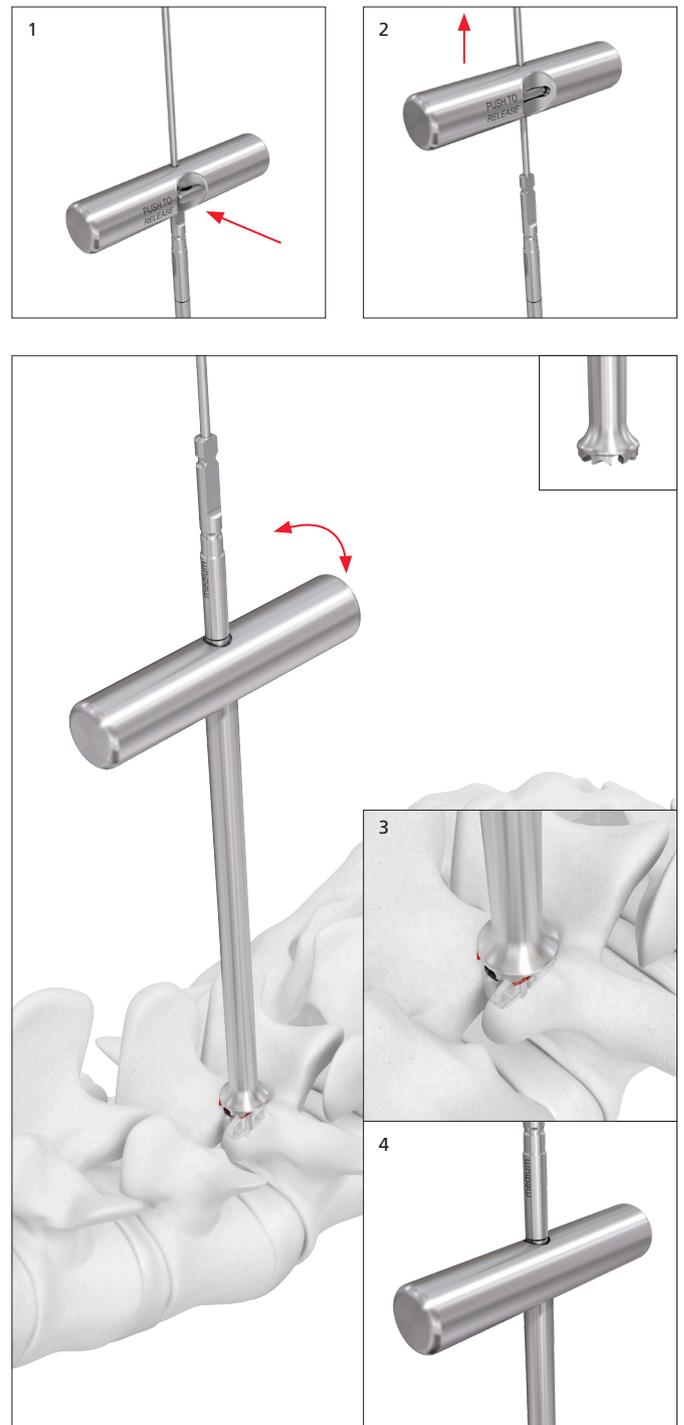
Insert the reamer over the trial/rasp. Push down and swivel the reamer to remove bone on the facet joint entry to create a flat surface for optimal implant seating (3).

Notes:

- A line indicates when the reamer has reached maximal depth (4).
- Make sure that an appropriate surface for implant fixation is created.

Note: Controlling the Kirschner Wire and trial/rasp during instrument retraction is recommended to keep the Kirschner Wire and trial/rasp in place.

After reaming is done, remove the reamer but keep the trial/rasp in situ.



Implant Insertion

1. Pack implant with bone or bone graft substitute

Instruments

03.630.146	Loading Station for Facet Wedge
03.630.147	Cancellous Bone Impactor for Facet Wedge

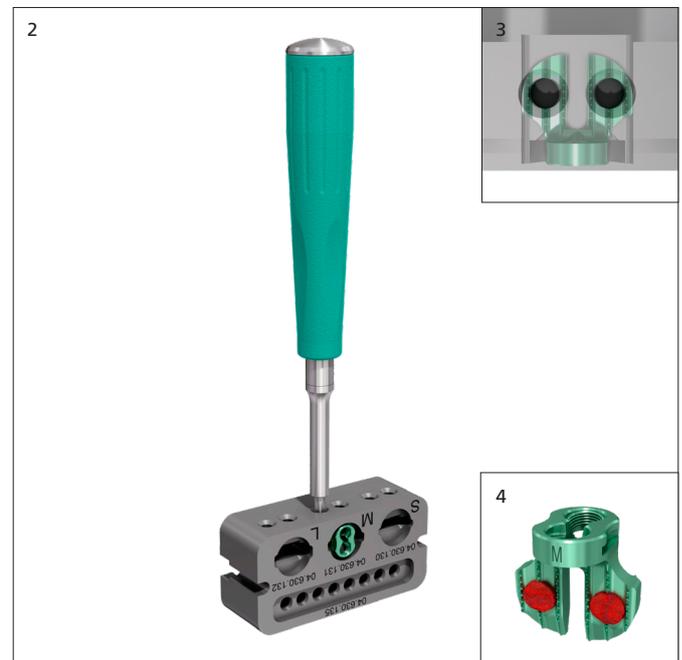
Select the Facet Wedge implant that corresponds to the trial/rasp size used in the previous step.

Insert the selected implant into the appropriate place in the loading station (1).

Turn the loading station on its side and use the cancellous bone impactor to firmly pack the bone or bone graft substitute into the implant perforations (2).

Make sure the implant is fully seated in the loading station to avoid implant damage during graft filling (3).

It is important to fill the implant until the bone or bone graft substitute protrudes from its perforations to ensure contact with the facet joint surfaces (4).



2. Connect implant holder to implant

Instruments

03.630.146 Loading Station for Facet Wedge

03.630.135 Implant Holder for Facet Wedge

To connect the implant holder to the implant turn the loading station upwards again.

Connect the shaft of the implant holder onto the implant (1).

Slide the screw guide over the inner shaft. Pull back the flat spring to allow the screw guide to fully slide down the inner shaft (2). If necessary, rotate the screw guide until the flat spring snaps into position (3).

Screw the cap onto the inner shaft (4).

Note: Make sure the arrows (3) are pointing to each other to lock the screw guide into position.



3. Remove trial/rasp

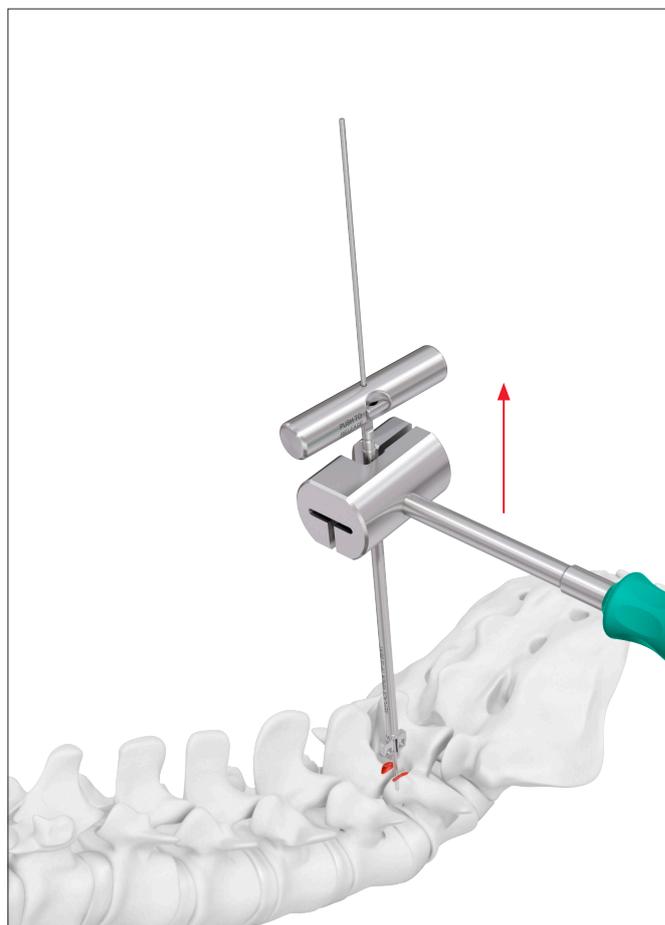
Instruments

03.630.133 T-handle, for Quick Coupling, cannulated

03.630.138 Combined Hammer, Ø 2.0 mm, cannulated

Connect the T-handle to the trial/rasp (see page 34) and remove the trial/rasp. Controlled and light hammering on the T-handle in the axis of the Kirschner Wire may be required to retract the trial/rasp.

Precaution: Controlling the Kirschner Wire while retracting the instrument is recommended to keep the Kirschner Wire in place.



4. Insert implant

Instruments

03.630.135	Implant Holder for Facet Wedge
03.630.138	Combined Hammer, Ø 2.0 mm, cannulated

Slide the implant holder with connected implant over the Kirschner Wire. Controlled and light hammering on the implant holder cap may be required to advance the implant into the facet joint.

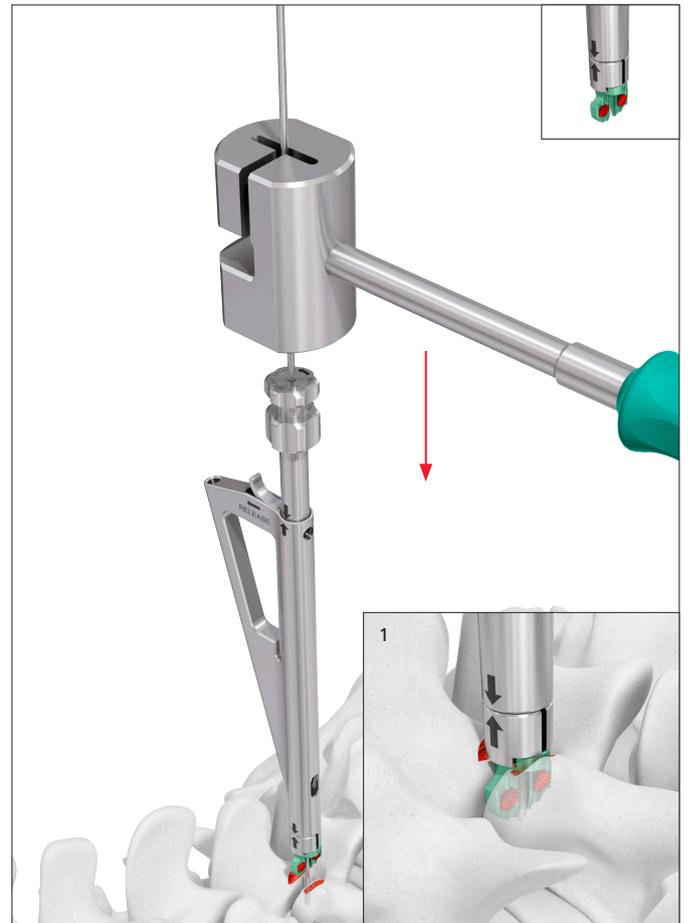
Make sure that the implant is fully inserted into the facet joint and the insertion stop contacts the reamed surface of the joint entry (1).

Warnings:

- Make sure the Kirschner Wire is not pushed forward during the implant insertion.
- When the implant has reached final depth excessive hammering may lead to facet joint fracture.

Precaution: Hammer on the top cap of the implant holder only.

- ⓘ Imaging for position verification may be required prior to screw insertion.



Screw Insertion

1. Remove Kirschner Wire

Before awling or screw insertion the Kirschner Wire must be removed. The use of a clamp may be necessary.

Notes:

- Holding the implant holder during Kirschner Wire removal may be necessary to keep the implant holder in place.
- Remove the Kirschner Wire inline with the implant holder



2. Awl

Instruments

03.630.144	Shaft for Awl, for No. 04.630.135S
03.647.903	Handle, small, with Quick Coupling

Connect the handle to the awl.

When the Kirschner Wire is removed the awl can be inserted into the screw guide.

Precaution: Always use the awl in combination with the implant holder.

Prepare the screw hole by awling until the shoulder of the awl shaft contacts the opening of the screw guide (1). Application of controlled and light pressure on the awl may be required to advance the awl.

When the final depth is reached, remove the awl.

Notes:

- Maintain the orientation of the implant holder while awling.
- While using the awl confirm that the screw will be placed in bone.



3. Loading screw

Instruments

03.630.146	Loading Station for Facet Wedge
03.630.145	Screwdriver Shaft T8, self-holding
03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm

Insert the screws into the appropriate place in the loading station.

Precaution: Always use the awl prior to screw insertion.

Assemble the torque limiter to the screwdriver shaft and handle (see page 34).

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

To load a screw onto the screwdriver with torque limiter, make sure the T8 coupling geometry is oriented to the screw interface and press the screwdriver onto the screw.



4. Insert first screw

Instruments

03.630.145	Screwdriver Shaft T8, self-holding
03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm

Precaution: Always use the screwdriver in combination with the implant holder.

Insert the screw into the screw guide and advance the screw until the etched line reaches the opening of the screw guide (1). The etched line indicates when the screw head has contact to the implant.

Tighten the screw to the recommended 1.2 Nm torque.

Note: Maintain the orientation of the implant holder during screw insertion.

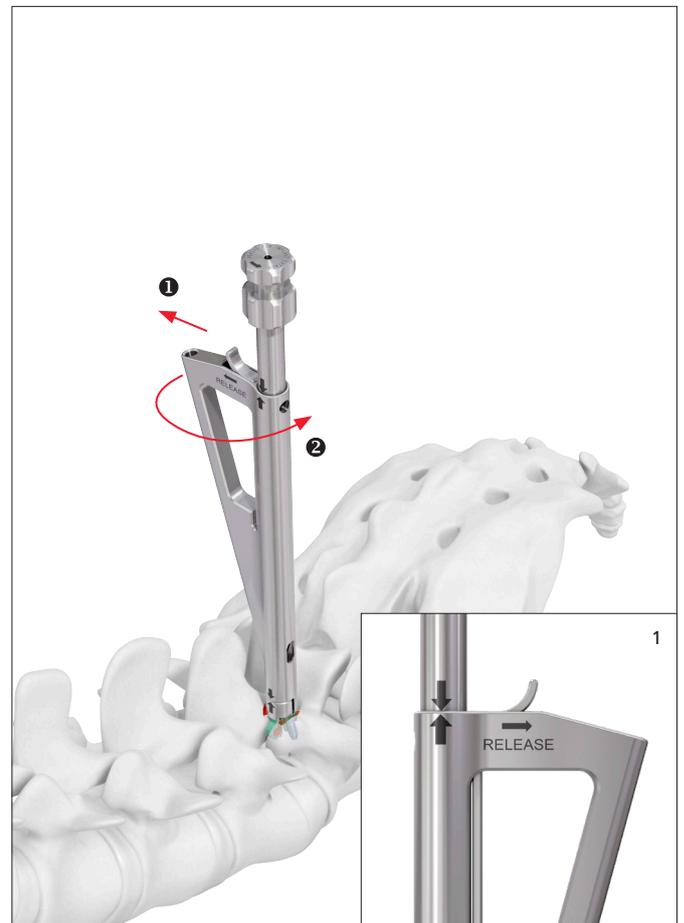


5. Flip screw guide

Pull back the flat spring ❶ and turn the screw guide 180°. Make sure the flat spring snaps into position ❷.

If the retracting blades inhibit direct rotation, it may be necessary to pull back the screw guide until it reaches the cap. Turn the screw guide 180° and slide it down until the flat spring snaps into position (1).

Note: Make sure the arrows are pointing to each other to lock the screw guide into position.



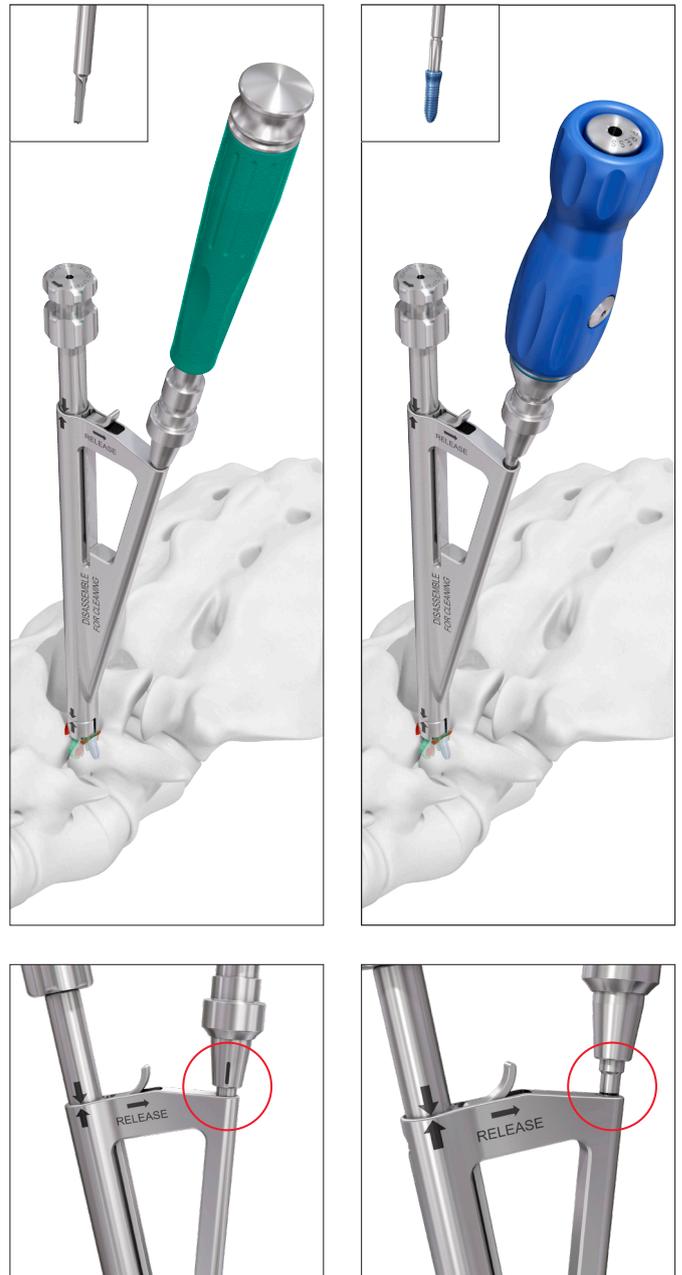
6. Awl and insert second screw

Instruments

03.630.146	Loading Station for Facet Wedge
03.630.144	Shaft for Awl, for No. 04.630.135S
03.647.903	Handle, small, with Quick Coupling
03.630.145	Screwdriver Shaft T8, self-holding
03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
03.110.005	Handle for Torque Limiter 0.4/0.8/1.2 Nm

Awl and insert the second screw as described for the first screw in steps 2–4.

Precaution: The Facet Wedge must be secured with two screws.



Implant Holder Removal

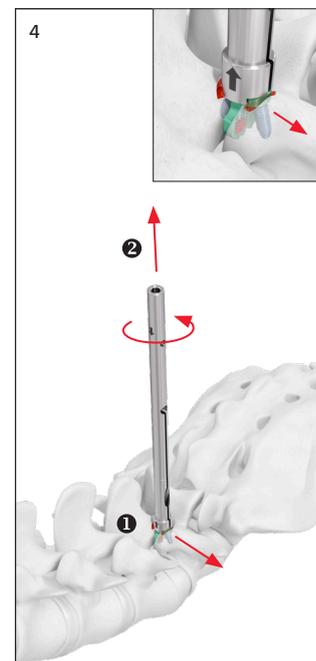
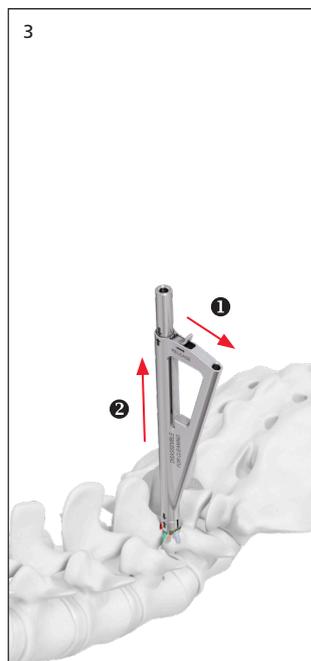
After both screws are inserted, remove the implant holder.

Unscrew the cap (1) and remove it from the inner shaft (2).

Pull back the flat spring and remove the screw guide from the inner shaft (3).

Disconnect the shaft of the implant holder from the implant by applying gentle medial or lateral pressure (4). If the shaft does not disconnect, apply additional rotation onto the shaft.

Note: Once the implant holder is removed visually confirm that the screws are fully seated in the implant.

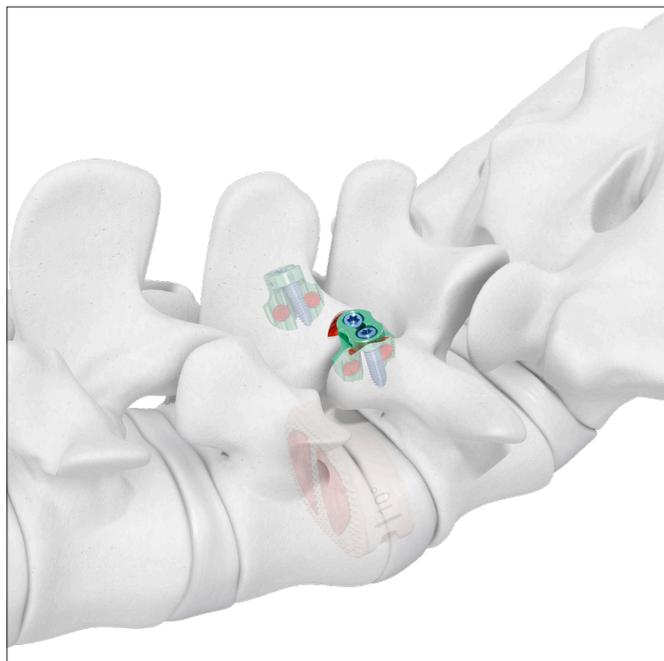


Construct Finalization

1. Implant insertion on contralateral side

To insert Facet Wedge on the contralateral side repeat the previously described steps:

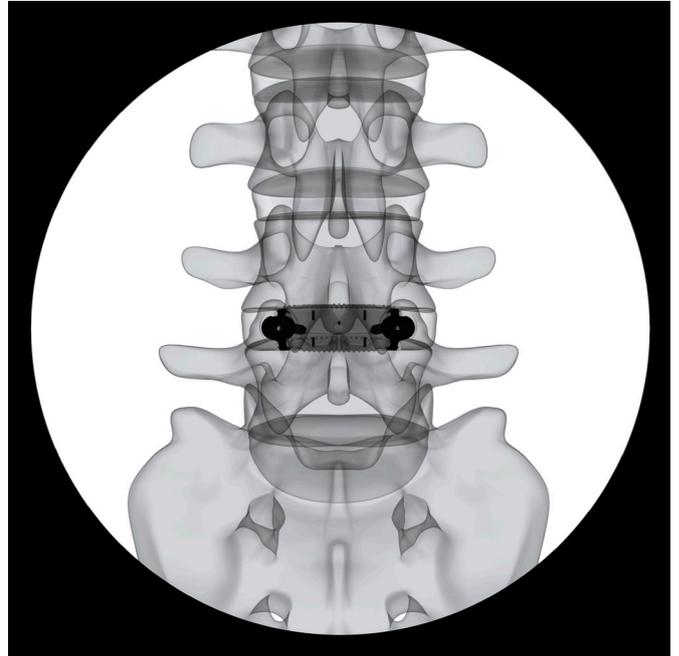
- Access and Exposure (page 9)
- Kirschner Wire Insertion (page 13)
- Facet Joint Preparation (page 16)
- Implant Insertion (page 19)
- Screw Insertion (page 23)
- Implant Holder Removal (page 29)



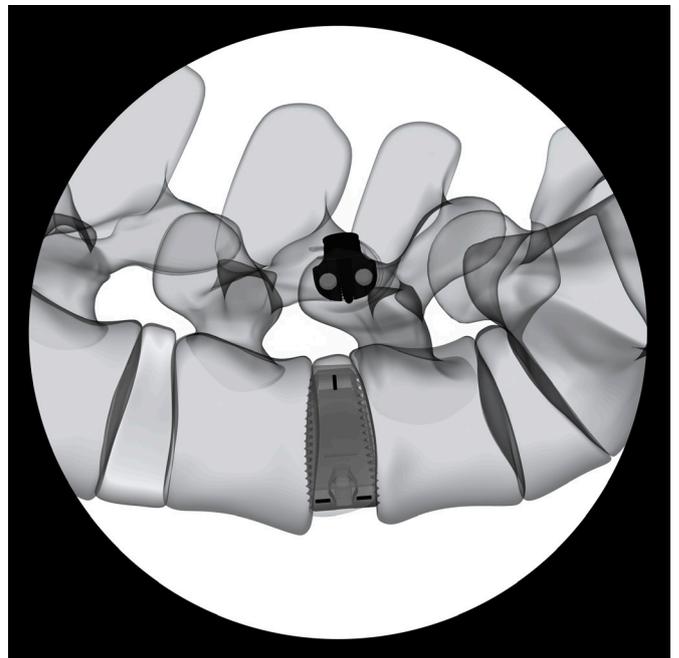
2. Control position

- ① Use imaging to verify the final position of both implants.

On an anterior/posterior image, both Facet Wedge implants should be positioned symmetrically to the left and right of the midline, approximately at the height of the cranial endplate of the inferior vertebra.



- ① On a lateral image, both Facet Wedge implants should be superimposed.



Implant Removal

If a Facet Wedge implant must be removed, the following technique is recommended.

1. Remove screws

Instruments

03.647.903	Handle, small, with Quick Coupling
03.630.145	Screwdriver Shaft T8, self-holding
03.630.135	Implant Holder for Facet Wedge

Connect the handle to the screwdriver shaft.

Connect implant holder to the implant as described on page 20.

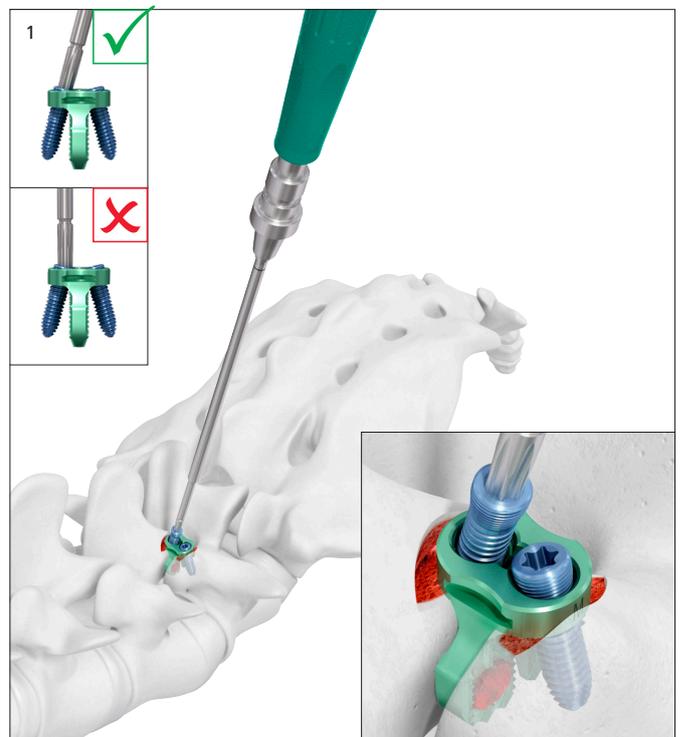
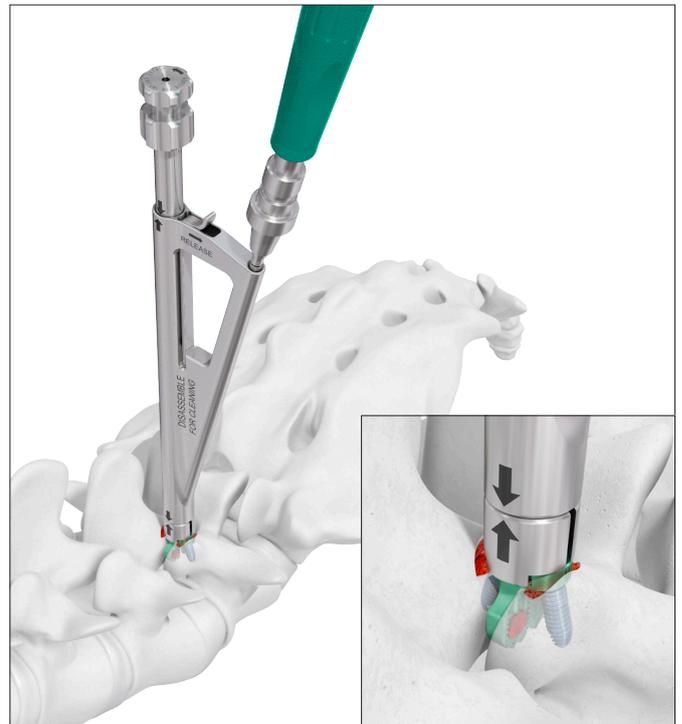
Loosen both screws a maximum of two turns with the screwdriver inserted in the screw guide. After loosening the first screw the screwdriver must be removed and the screw guide must be flipped as described on page 27.

Precaution: Screw loosening with the torque limiting handle may damage the torque limiting handle. Therefore always use the standard handle for screw loosening.

Remove the implant holder as described on page 29.

Remove both screws with the screwdriver. Tweezers may be necessary to remove the screws.

Note: The Screwdriver shaft must be in line with the screw axis when torque is applied (1).



2. Remove implant

Instruments

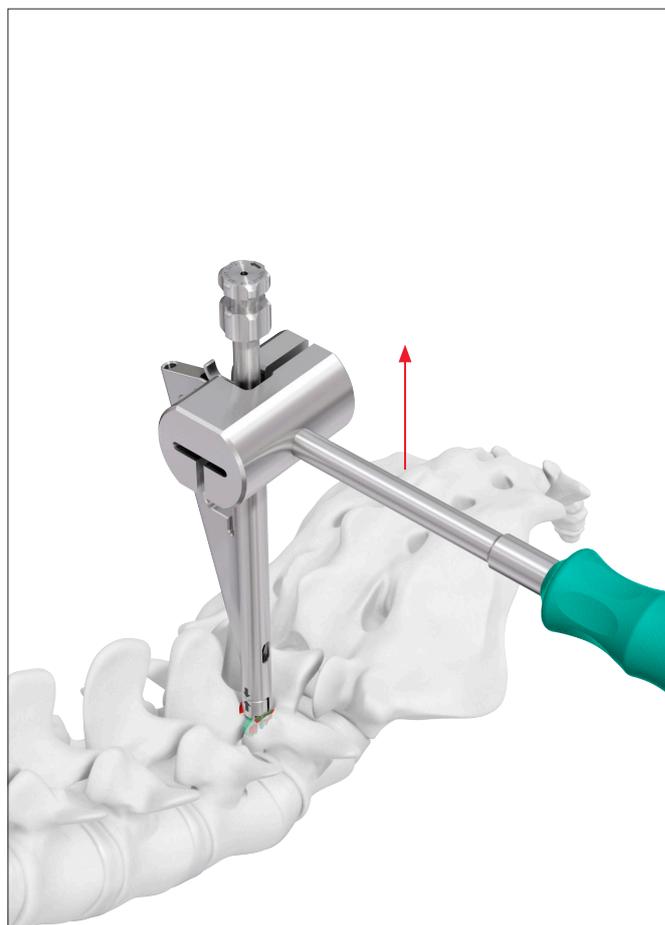
03.630.135 Implant Holder for Facet Wedge

03.630.138 Combined Hammer, Ø 2.0 mm, cannulated

Connect implant holder to the implant as described on page 20.

Note: Make sure the arrows are pointing to each other to control that the screw guide is locked into position.

Controlled and light hammering on the implant holder cap may be required to retract the implant.



Assembly Instructions

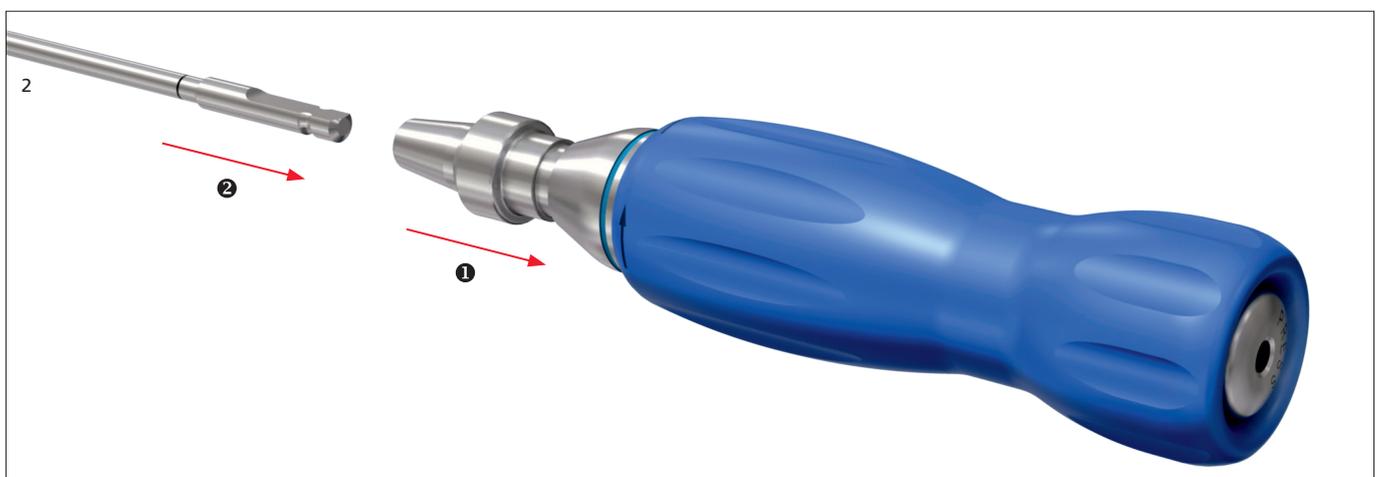
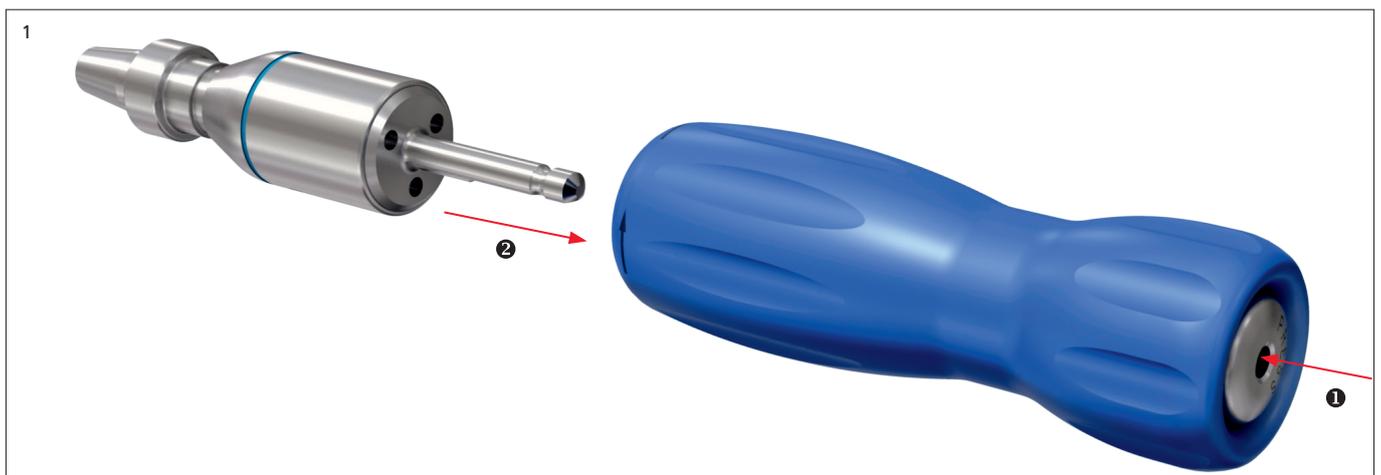
T-handle connection

03.630.133, 03.630.139, 03.630.130-132



Torque limiting handle connection

03.110.002, 03.110.005, 03.630.145



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

