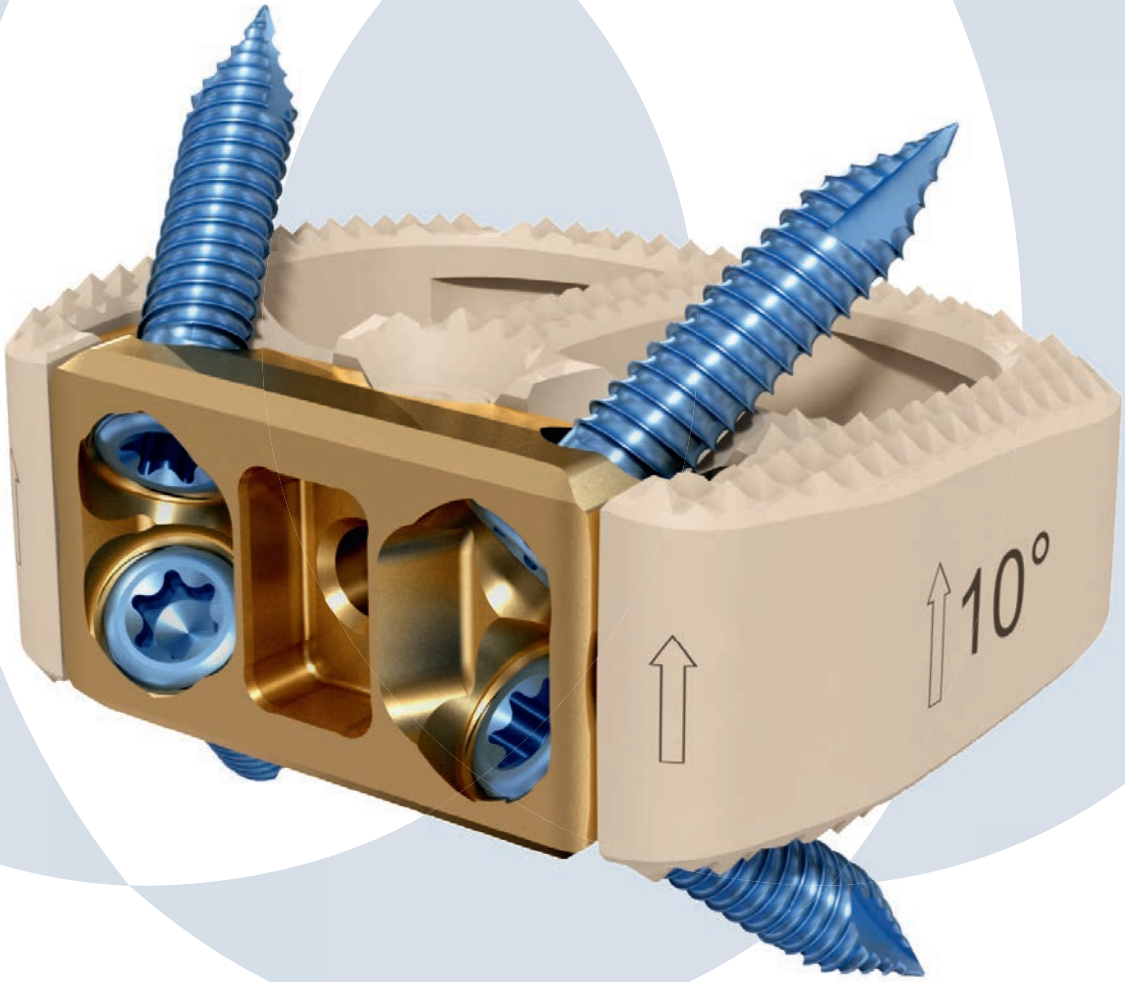
DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

SYNFIX® EVOLUTION SECURED SPACER SYSTEM

Instruments and implants for stand-alone anterior lumbar interbody fusion



Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

Image intensifier control

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

Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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Fine tip screw option for sclerotic bone

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Self-tapping double lead titanium alloy screw for rapid insertion

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Enhances graft retention

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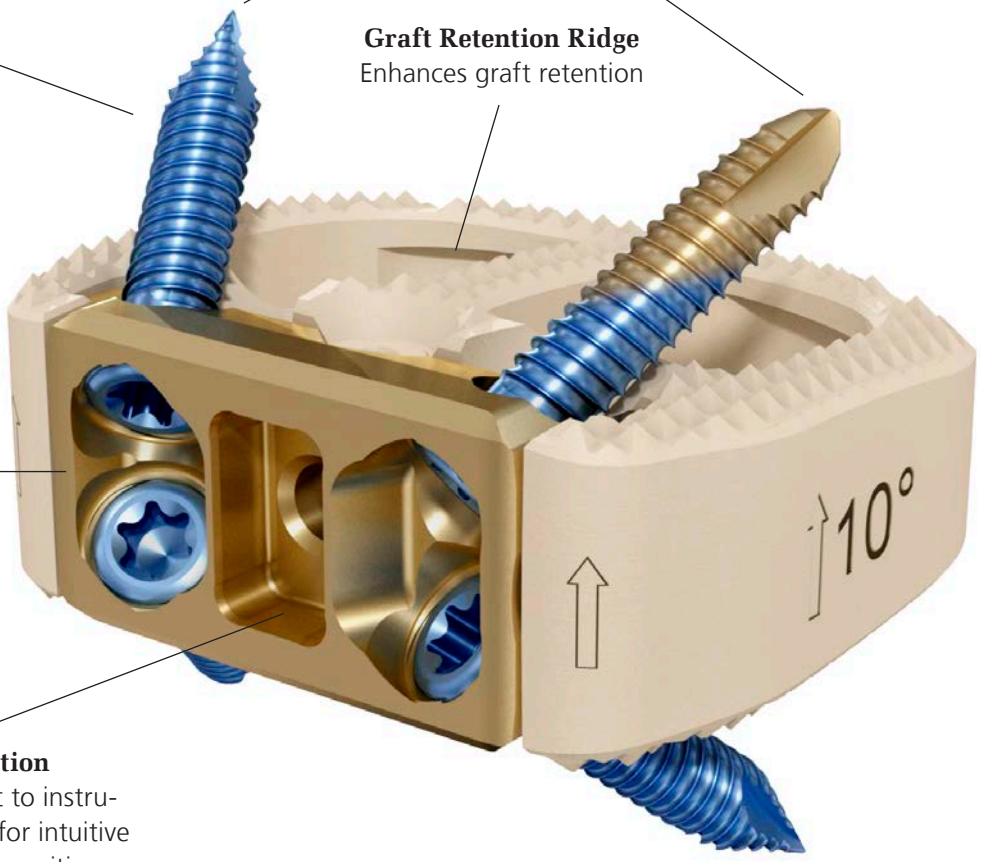
Zero profile plate design with angular stable locking screws



Keyed Connection
Secures implant to instrument interface for intuitive connection and positive tactile feedback

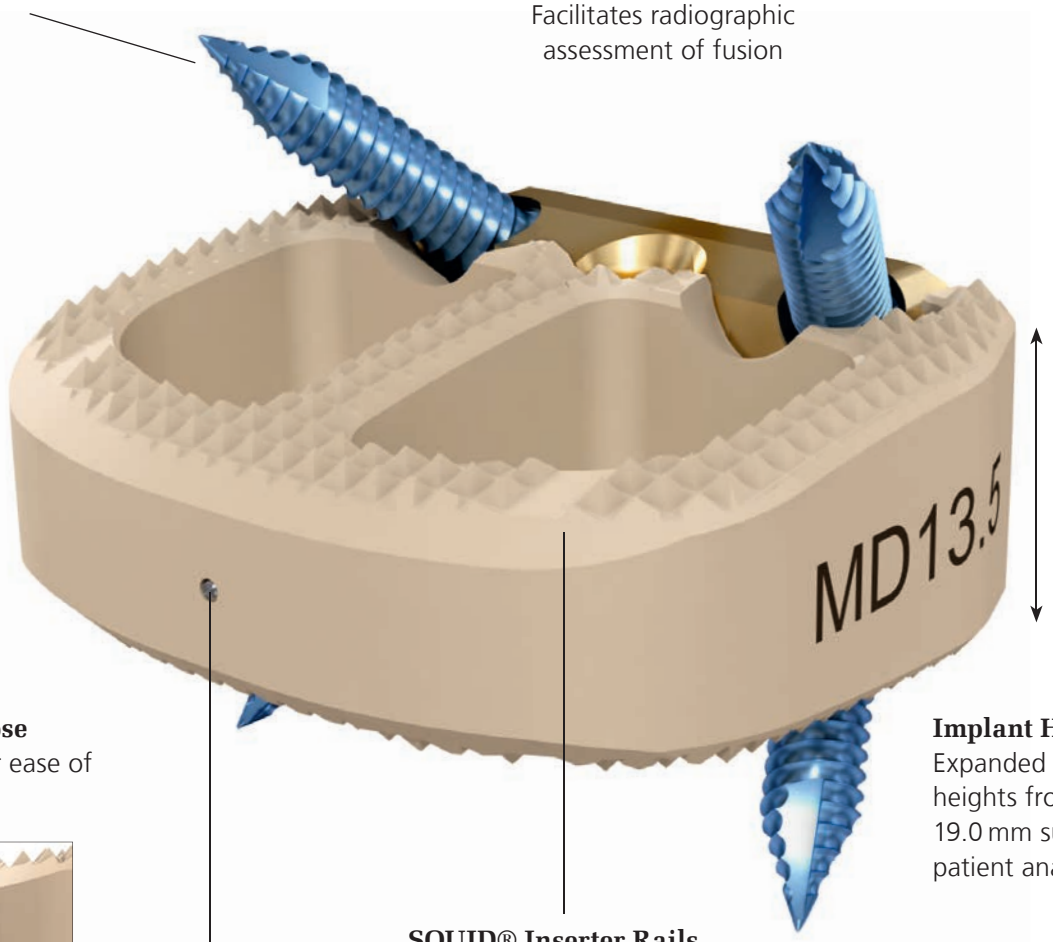
Anatomic Convexity*
Distinct cranial and caudal convexities accommodate variances in endplate anatomies

Lordotic Angulation
4 angulations 6°-10°-14°-18° support sagittal alignment restoration

* except for symmetric 6° implant

Large Graft Lumen
To maximize graft volume

PEEK Cage
Facilitates radiographic assessment of fusion



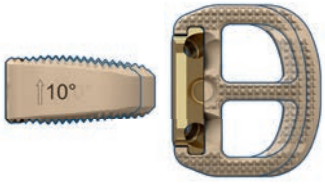
Bullet Nose
Allows for ease of insertion

Implant Heights
Expanded range of implant heights from 10.5 mm to 19.0 mm support individual patient anatomy

SQUID® Inserter Rails
Interface for Evolution SQUID™ Inserter/Distractor option

Radiographic Marker
Tantalum x-ray marker indicates the actual posterior edge of the implant

Deep Footprint Option
Deeper footprint option provides 3 mm additional depth in the AP direction to accommodate varied anatomies



INSTRUMENTS

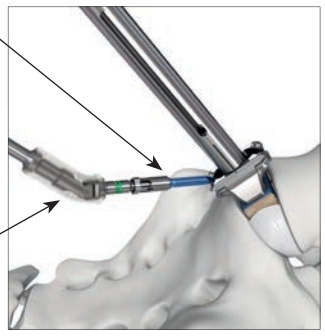
Ratchet Torque Limiting Handle
Ratchet for enhanced ergonomics during screw insertion, combined with torque limiting function for final tightening.

Single Instrument for Implant Insertion
Reduces number of instrument passes

Detachable Holder
Removable implant holder allows for increased visibility during screw insertion

Soft Tissue Retractor
Protects and retracts soft tissue

Thread Lock Sleeve
Locks screw to screwdriver and disengages automatically when inserting screw through the aiming device



Protection Sleeve
Separates soft tissue from the rotating U-joint to prevent soft tissue uptake

Aiming Device*
4-hole aiming device allows for insertion of all screws without an additional rotation step

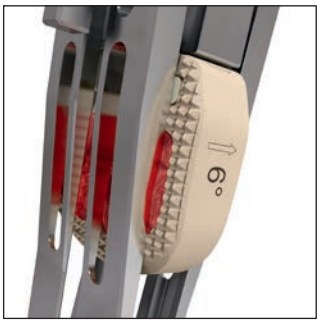
* except for SYNFIX Evolution Aiming Device 17 mm and 19 mm

SQUID® INSERTER/DISTRACTOR OPTION

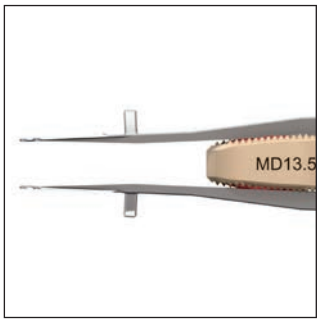
Controlled Distraction
Distracts and inserts in one simple step, without impaction

Positioning Options
Allows positioning of the implant from 0 mm to + 6 mm proud to the anterior aspect of the vertebral body

Rails
Provide guidance during implant insertion



Thin Blades
Reduce risk of over distraction during implant insertion

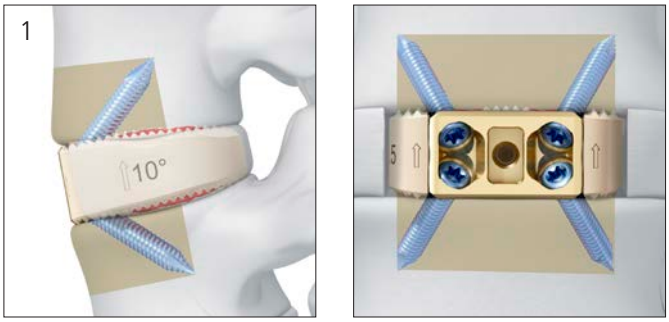


BACKGROUND OF SYNFIX EVOLUTION IMPLANT

The SYNFIX® Evolution Implant, a stand-alone anterior lumbar interbody fusion (ALIF) implant, employs the SYNFIX Implant technology which has been used clinically in the SYNFIX® LR Implant since 2004.

The SYNFIX Implant technology is a zero-profile construct that includes four diverging locking screws. This design negates, in most circumstances, the need for additional fixation.

1



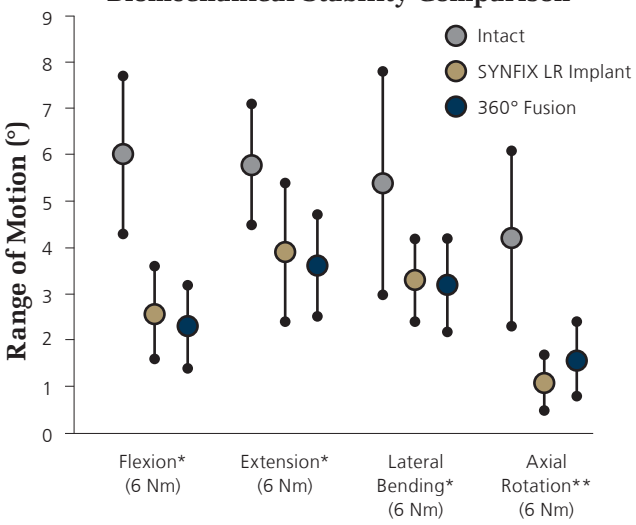
Biomechanical stability

The SYNFIX LR Implant is equivalent to a cage with pedicle screws in flexion, extension, lateral bending and superior in axial rotation (2).[1] The superior stability of the SYNFIX LR Implant is shown compared to other stand-alone ALIF implants.[2,3#]

Biomechanical stability is delivered through:

- An integrated titanium plate with four diverging locking screws that form a fixed-angle construct. This creates a wedge of bone designed as an anchor to potentially prevent fixation failure (1).
- A non-rigid connection between locking plate and PEEK cage allowing for load sharing[2]
- PEEK cage with elastic modulus similar to cortical bone
- Self-tapping cortical threads

2



* SYNFIX LR Implant is statistically equivalent to 360° fusion
** SYNFIX LR Implant is statistically superior in axial rotation to a spacer with pedicle screws

Clinical experience

The SYNFIX LR Implant has been shown to be as effective as 360° fusion in achieving fusion in the management of discogenic back pain over one and two levels.[4,5]

1 Cain et al (2005)
2 Schleicher et al (2008)
3 Freeman et al (2016)
4 Ardern et al (2008)
5 Siepe et al (2015)

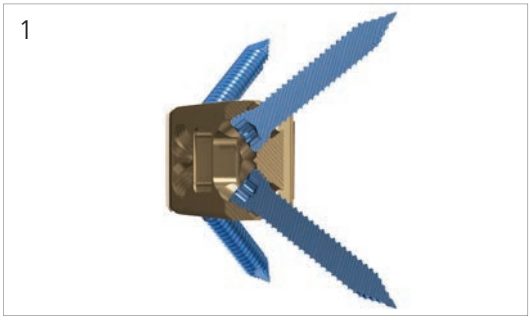
Biomechanical test results may not necessarily be indicative of clinical performance.

SYNFIX EVOLUTION SYSTEM BENEFITS

Biomechanical stability
The SYNFIX Evolution Implant has been designed to preserve the biomechanical stability of the SYNFIX LR Implant by delivering:

- An integrated titanium plate with four diverging locking screws that form a fixed-angle construct. This creates a wedge of bone designed as an anchor to potentially prevent fixation failure (1).
- A non-rigid connection between locking plate and PEEK cage allowing for load sharing[2]
- PEEK cage with elastic modulus similar to cortical bone
- Self-tapping cortical threads

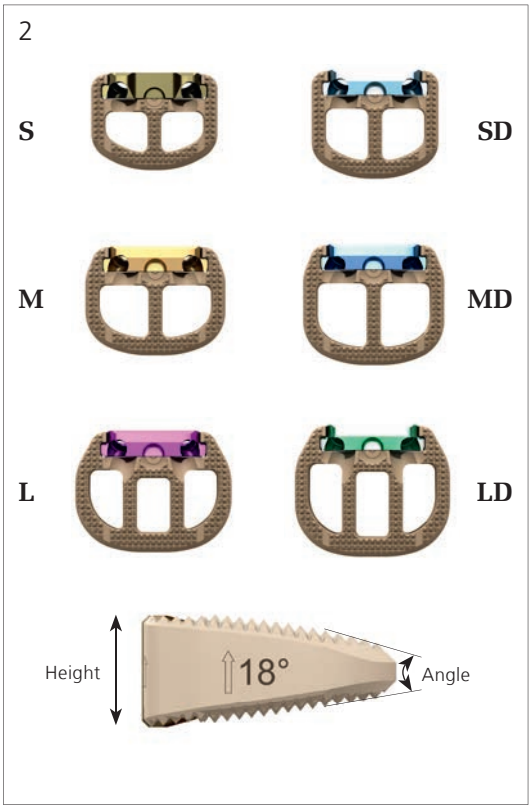
1



Comprehensive implant portfolio
126 implants to support an optimal fit and fill of disc space and restoration of sagittal alignment (2):

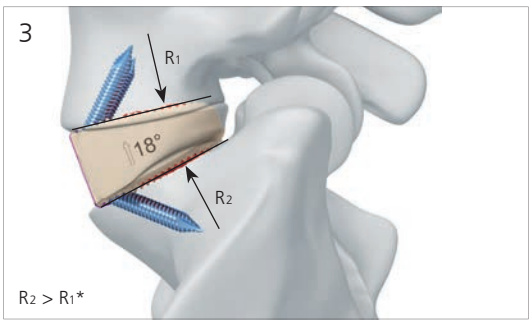
- 6 footprints
- 6 heights
- 4 angles

2



Anatomic convexity of the cage design. Greater superior convexity for optimal fit to lumbar and lumbosacral end-plates (3).

3



*except for symmetric 6° implant

Optimized lumen design to maximize graft volume (1)

1

Designed to increase procedural efficiencies

- **Double lead screw thread** for rapid screw insertion (2)

2

- **Protection sleeve** avoids soft tissue wrap-up in U-joint (3a)
- **Thread lock sleeve** locks screw to screwdriver and disengages automatically when inserting screw through the aiming device (3b)

3

- **Reduced number of instrumentation steps:**
  - One instrument for cage and screw insertion (4)
  - Bullet nose of the PEEK cage allows for ease of insertion (5)

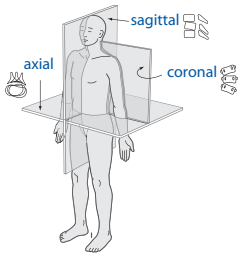
4

5

AO SPINE PRINCIPLES

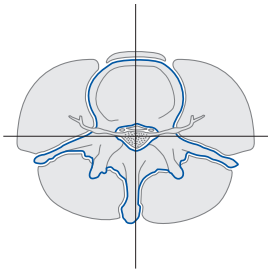
The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.[1,2]

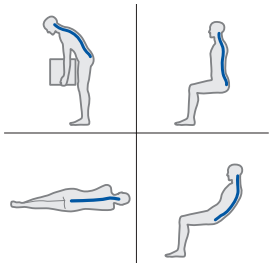
Stability
Stabilization to achieve a specific therapeutic outcome



Alignment
Balancing the spine in three dimensions

Biology
Etiology, pathogenesis, neural protection, and tissue healing





Function
Preservations and restoration of function to prevent disability

1 Aebi et al (1998)
2 Aebi et al (2007)

INDICATIONS AND CONTRAINDICATIONS

Intended Use
SYNFIX Evolution Secured Spacer System is an implant and instrument system for stand-alone anterior lumbar interbody fusion (ALIF) for skeletally mature patients. It is intended to replace lumbar interbody discs and to fuse adjacent vertebral bodies at vertebral levels L1-S1 following anterior lumbar discectomy for stabilization of the lumbar spine.

Indications
Lumbar and lumbosacral pathologies which may require anterior segmental arthrodesis, including:
- Localized symptomatic degenerative disc disease
- Revision surgery for failed decompression syndrome
- Pseudoarthrosis

Contraindications
- Spinal fractures
- Spinal tumor
- Osteoporosis
- Infection

Contraindications for stand-alone application
- Spondylolisthesis
- Severe segmental instability

PREPARATION

Required Sets	
01.835.004	SYNFIX Evolution Set, Complete
Optional Anterior Instrument Sets	
01.600.100	PROPREP Set
01.824.002	Tool Set for Posterior Release
01.825.007	Evolution SQUID, Set
Optional Access Sets	
187.310	SynFrame Basic System in Vario Case
187.316	SynFrame Soft Tissue Retractors in Vario Case, Stainless Steel
187.322	SynFrame Bone Levers in Vario Case, Stainless Steel
01.609.102	Set SynFrame RL, lumbar

Have the required sets readily available prior to the surgery.

Have all necessary imaging readily available to plan construct type, implant placement, incision approach and to identify individual patient anatomy.

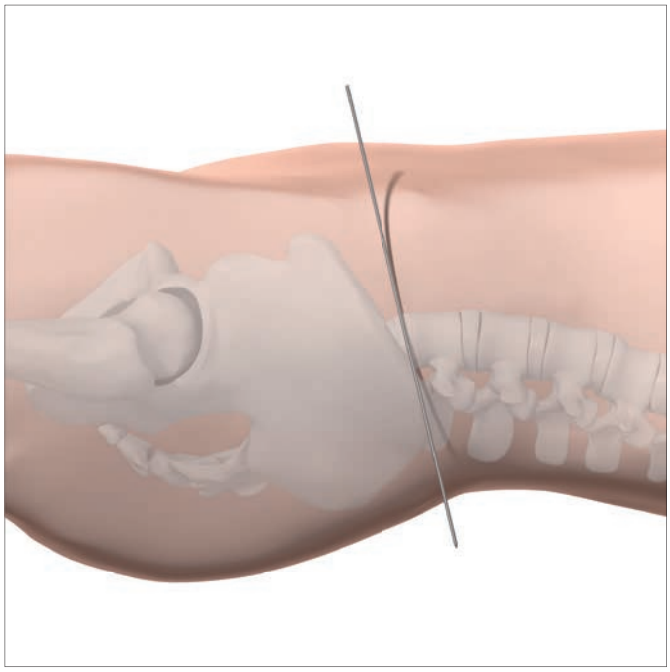
ACCESS AND EXPOSURE

1
Patient positioning

For an anterior approach to the lower lumbar levels, position the patient in a slight Trendelenburg position.

2
Anterior access and approach

Recommended Sets	
187.310	SynFrame Basic System in Vario Case
187.316	SynFrame Soft Tissue Retractors in Vario Case, Stainless Steel
187.322	SynFrame Bone Levers in Vario Case, Stainless Steel
01.609.102	Set SynFrame RL, lumbar



The surgical approach depends on the level to be treated.

Locate the correct operative level and incision site by taking a lateral fluoroscopic view while holding a straight metal instrument on the side of the patient. This ensures that the incision and exposure will allow direct access to the operative level and enable screw insertion.

It is recommended to expose the operative level through a standard retroperitoneal approach. However, other approaches may be indicated based on the patient's anatomy and pathology.

3
Exposure

Expose the operative level such that there is sufficient space on either side of the vertebral midline equal to half the width of the SYNFIX Evolution Implant.

The locking screws of the SYNFIX Evolution Implant must be inserted from a direct anterior direction.

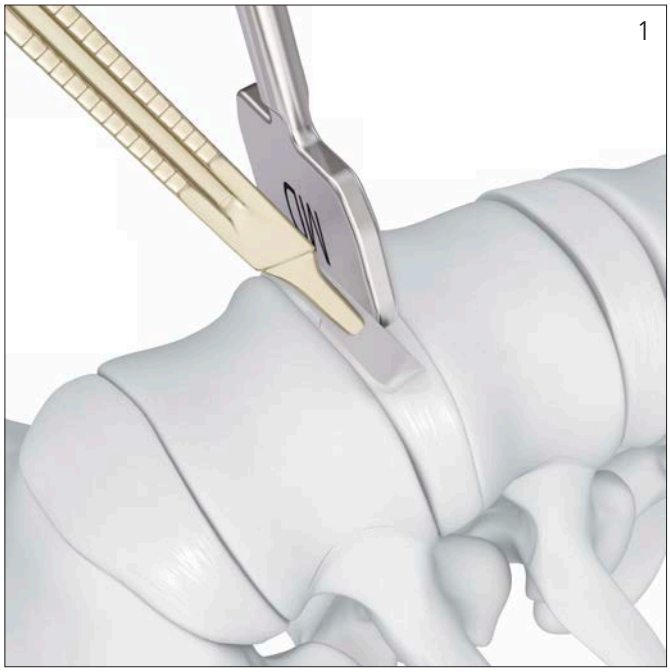
DISCECTOMY

1
Cut anterior window

Optional Instruments	
03.815.010	SYNFIX Evolution Trial, for Footprint small and small deep
03.815.011	SYNFIX Evolution Trial, for Footprint medium and medium deep
03.815.012	SYNFIX Evolution Trial, for Footprint large and large deep

Create an annulotomy centered on the midline and wide enough to accommodate the SYNFIX Evolution Implant. Optionally, a footprint trial (1) or trial implant (see pages 16 and 73) may be used as a template to indicate the width of the annular window.

Note: **Retain as much of the anterolateral, lateral and posterior annulus as possible in order to provide the necessary stability of the instrumented segment.**


1

2
Prepare disc space

Remove disc material through an incision in the annulus fibrosus. Excise the disc material and remove the cartilaginous endplates to expose the underlying bony vertebral endplates.

Adequate preparation of the endplates without compromising the structural integrity is important to enable the access of an appropriate vascular supply to the bone graft to enable fusion.

Once the endplates have been prepared, complete additional surgical procedures.

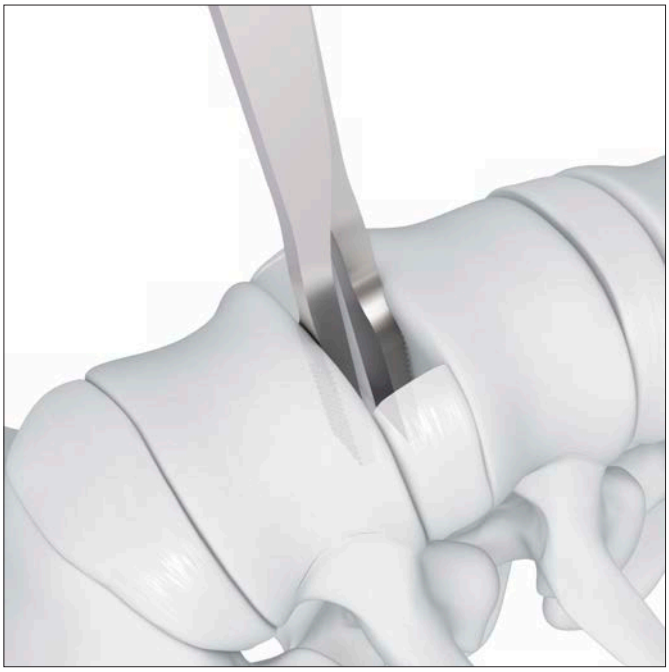
Precautions:
- **It is essential that the nucleus and the inner annulus are removed to prevent displacement of disc material into the spinal canal during implant insertion and interference with bone in-growth.**
- **Overly aggressive preparation can weaken the endplates by removing bone under the cartilaginous layers. Removal of the entire endplate can cause subsidence and lead to loss of segmental stability.**

2

DISTRACTION AND SEGMENT MOBILIZATION

1
Mobilize segment

Instruments	
SFW550R	Prodisc-L Spreader
SFW650R	Prodisc-L Spreader Forceps, curved
Optional Instruments	
01.824.002	Tool Set for Posterior Release



Under fluoroscopic control, insert the vertebral body spreader to the posterior margin of the vertebral bodies to gradually remobilize the motion segment.

Placement of the tips to the posterior margin will minimize the risk of endplate fracture. Place the spreader on one side to facilitate the discectomy on the contralateral side, and then repeat for the other side.

Distract the intervertebral space with the vertebral body spreader in such a way to restore the height of the disc and to enable access to the posterior aspect of the disc space.

Distraction of the segment is essential for restoration of disc height, opening of the neural foramina and indirect decompression of the canal. Achieving appropriate fit, fill and distraction of the disc space will also enhance the initial stability of the SYNFIX Evolution implant.

Note: **The height of the spreader is 6 mm (3 mm per side) when collapsed.**

Precautions:
- **In order to minimize the risk of endplate fracture, it is essential that the tips of the spreader are placed to the posterior margin of the vertebral body. In order to ensure this, image intensifier control is advised during insertion of the spreader.**
- **It is important not to over distract the segment to prevent injury of ligamentous and neural structures.**

TRIALING

1
Optional: Trial for footprint size

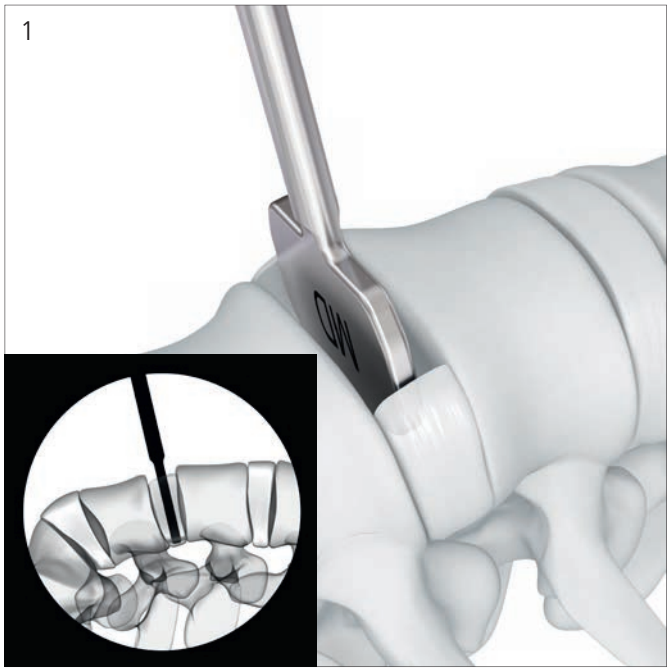
Optional Instruments	
03.815.010	SYNFIX Evolution Trial, for Footprint small and small deep
03.815.011	SYNFIX Evolution Trial, for Footprint medium and medium deep
03.815.012	SYNFIX Evolution Trial, for Footprint large and large deep

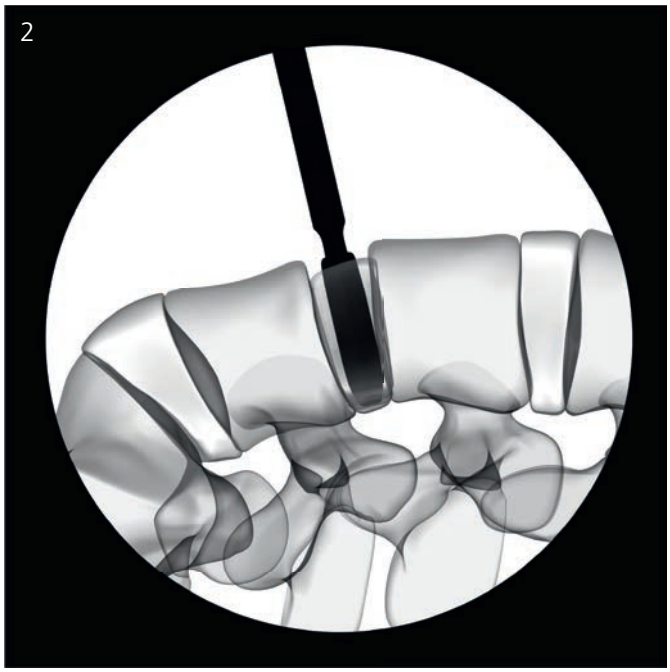
Choose an appropriately sized footprint trial and slide the footprint trial into the disc space (1).

AP and lateral fluoroscopy can be used to confirm correct footprint choice.

Note: **The footprint trial can be rotated slightly in the disc space to make the anterior margin more visible on fluoroscopy (2).**

Precaution: **Carefully assess the position of the anterolateral edges of the footprint trial to ensure they reside within the periphery of the vertebral body.**

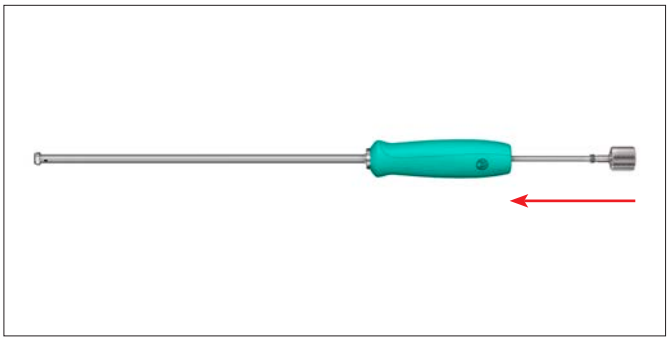




2
Assemble Trial Implant Holder

Instruments	
03.835.100	SYNFIX Evolution Trial Implant Holder
03.825.002	SynCage Evolution Spindle

Thread the spindle into the cannulated shaft of the trial implant holder.



3
Connect Trial Implant to Trial Implant Holder

Instruments

03.835.XXX	SYNFIX Evolution Trial Implant*

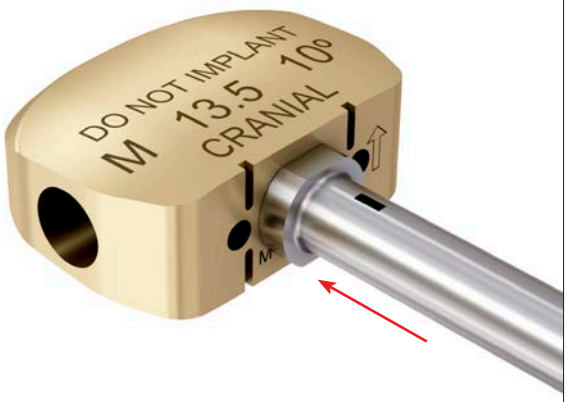
Select the trial implant corresponding to the footprint size determined by the footprint trialing. Select the height and angle corresponding to that considered appropriate based on preoperative planning, the anatomical features evident after disc clearance and endplate preparation, and the requirements in order to restore normal spinal alignment and disc height.

Mount the chosen SYNFIX Evolution Trial Implant on the trial implant holder. Secure it by fully tightening the knurled knob on the back of the trial implant holder.

Note: **The Trial Implant height is 0.8 mm undersized in comparison to the implant (2). This corresponds to half the implant teeth height on each side.**

Warning: **The diamond-shaped surface of the trial implant holder interface should reside inside of the Trial Implant interface.**

1



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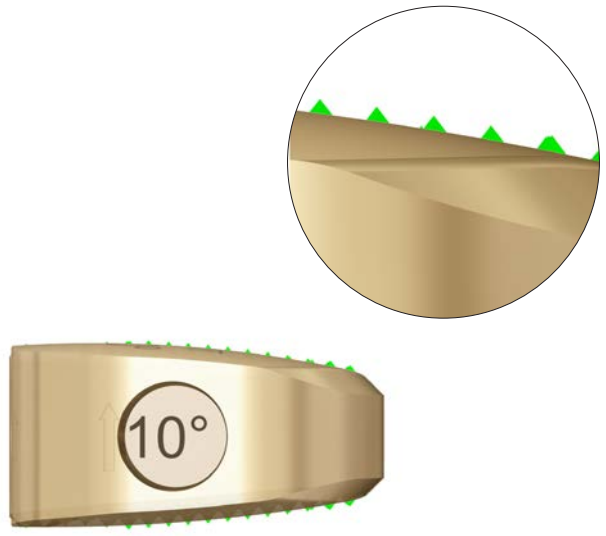


* see page 78 for available options

4
Insert Trial Implant

Optional Instruments

SFW691R	Prodisc-L Combined Hammer

Insert the Trial Implant into the disc space.

The anterior slots on the trial implant indicate the entry points of the locking screws in the anterior aspect of the adjacent vertebrae (1).

Controlled light hammering on the trial implant holder may be required to position the trial implant between the vertebral bodies to the desired depth.

If a tight fit is not achieved, repeat the process using incrementally larger trial implants or one with a different angle to best fit the anatomical features of the disc space.

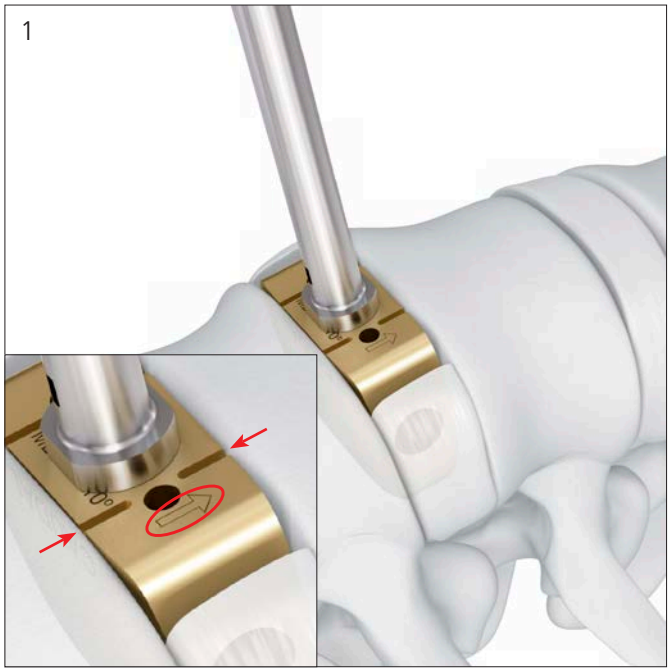
If the trial spacer is too large, preventing insertion with an appropriate amount of force, repeat using an incrementally smaller trial spacer or different angle.

Use fluoroscopy during trial insertion and to confirm final position and fit of the trial implant (2).

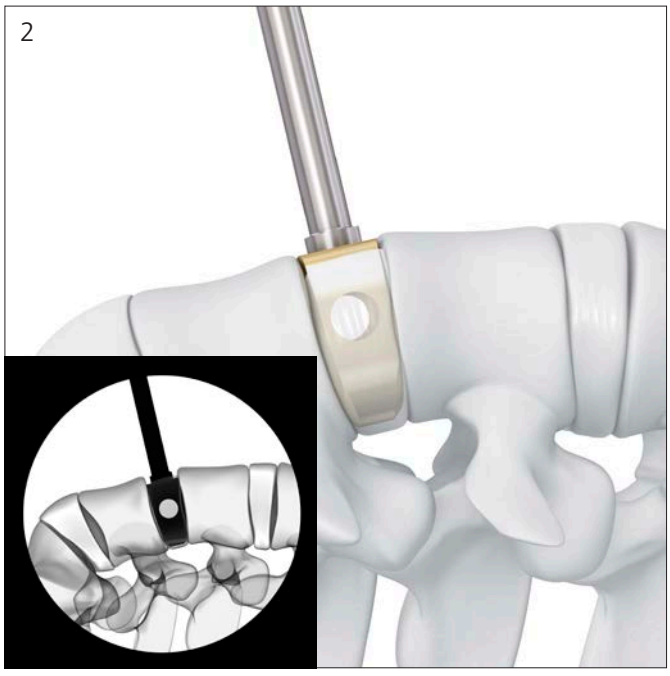
Precautions:

- **Do not leave the trial implant in the disc space.**
- **Insufficient disc space preparation may compromise vascular supply to the bone graft.**
- **Be aware of soft tissue or blood vessels that may be in the pathway of the trial spacer or cause possible interference with retractor blades.**
- **Ensure the arrow on the trial implant is pointing cranially before insertion, as the SYNFIX Evolution trial implants and implants are asymmetrical (1).**

1



2



5

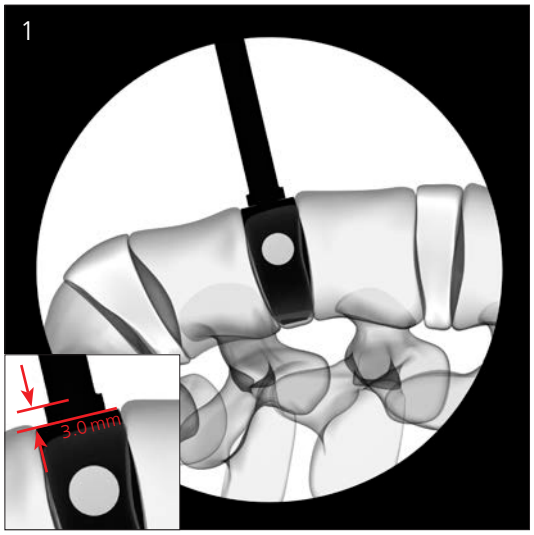
Assess anterior-posterior depth

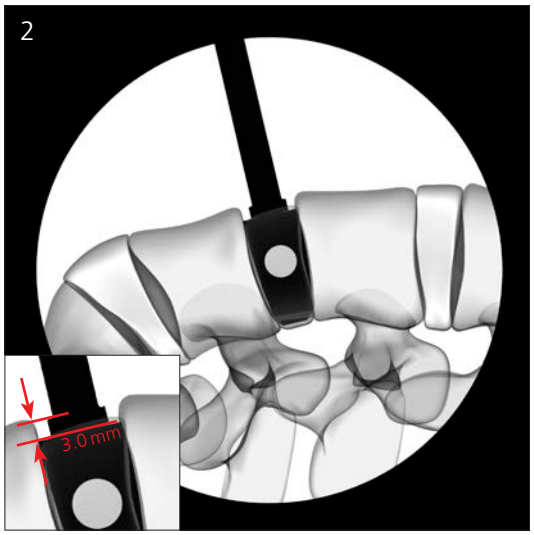
The trial spacer holder has a flange adjacent to its connection with the trial. When attached to the standard trial spacers, the flange represents the anterior aspect of a deep implant (1). The additional 3.0 mm depth enables assessment of the appropriate implant to be used, standard or deep, based on the fluoroscopic evaluation and direct visualization of the trial in the disc space (2).

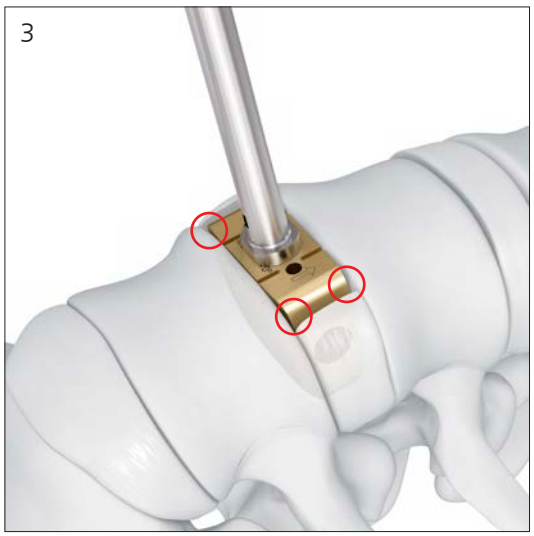
Note: **The deep implants and trial implants of a corresponding footprint (S/SD, M/MD, L/LD) are 3.0 mm deeper in AP direction but have the same width, anterior and posterior height.**

Precautions:

- **Carefully assess the position of the anterolateral edges of the trial implant to ensure they reside within the periphery of the vertebral body (3).**
- **If a deep implant spacer is needed, ensure the trial spacer holder flange is sufficiently recessed to make sure the deep implant will sit completely in the disc space when inserted (2).**







IMPLANT PREPARATION

1
Select implant

Select the SYNFIX Evolution Implant that corresponds to the footprint, height and angle chosen using the trial implant in the previous steps.

To facilitate selection of the implant, the trial implants are labelled with the height, lordotic angle and footprint of the implant. In addition, the trial implants and integrated locking plates are color-coded to match height.

For more information about the implant options, see pages 65 to 72 in this surgical technique.

2
Pack SYNFIX Evolution Implant

Instruments	
03.835.050	SYNFIX Evolution, Packing Block for Implants
03.815.023	Evolution Graft Packing Tamp, round
03.815.024	Evolution Graft Packing Tamp, oval

Insert the SYNFIX Evolution Implant into the appropriate mold in the packing station.

Fill the SYNFIX Evolution Implant in the packing station with the graft material until it protrudes from its cavities in order to ensure optimal contact with the vertebral endplates. Do not use excessive force to compress or impact the graft into the implant as this may interfere with vascular integration and bone healing.

Use a graft packing tamp to firmly pack the graft material into the implant cavities.

Notes:
- **The packing station combines the corresponding standard and deep footprints in one mold.**
- **The table on pages 65–70 lists the approximate graft volume of the SYNFIX Evolution Implants depending on footprint, height and angle.**

Precaution: **Avoid damage to the SYNFIX Evolution Implant during graft material packing.**

IMPLANT INSERTION

1
Assemble aiming device

Instruments	
03.835.001	SYNFIX Evolution Aiming Device, 10.5 mm and 12 mm
03.835.002	SYNFIX Evolution Aiming Device, 13.5 mm and 15 mm
03.835.003	SYNFIX Evolution Aiming Device, 17 mm and 19 mm
03.835.006	Coupling Screw for SYNFIX Evolution Aiming Device
03.835.004	SYNFIX Evolution Aiming Device Holder
03.835.005	Coupling for Aiming Device Holder SYNFIX Evolution

Choose the aiming device corresponding to the implant height. The heights 10.5/12 mm, 13.5/15 mm and 17/19 mm are combined in one aiming device each (1).

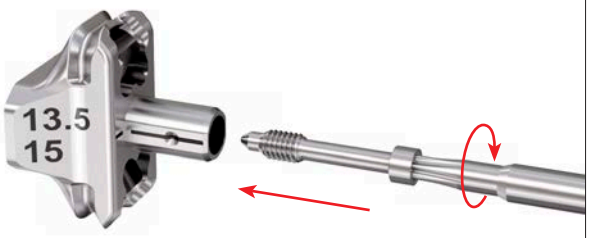
Fully engage the coupling screw in the aiming device with the coupling (2).

Assemble the aiming device holder according to the disassembly and assembly instructions (see page 57).

Note: The 17/19 mm aiming device is a 2 hole aiming device and needs to be rotated during screw insertion (section "Screw Insertion", step 7, page 46).

1

2

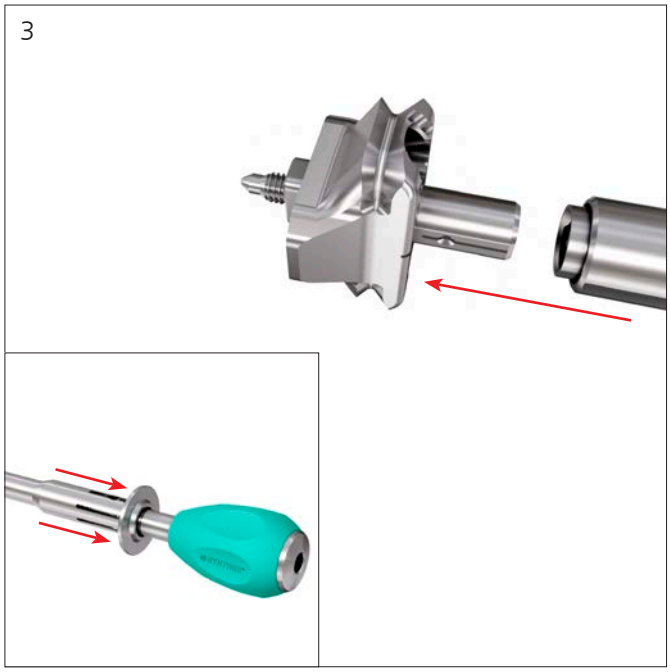


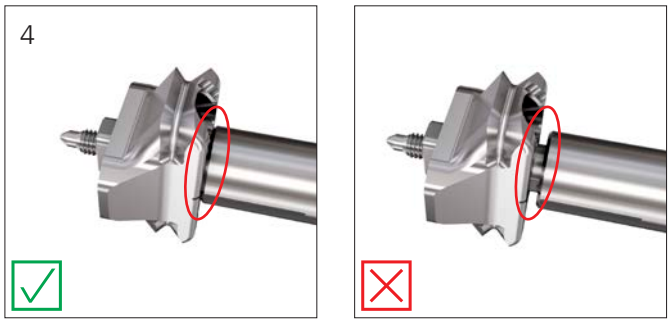
Attach the aiming device holder to the aiming device by pulling the outer shaft on the aiming device holder towards the handle and engage the aiming device (3). Align the vertical black lines on the aiming device holder and the aiming device. Release the outer shaft to lock the assembly.

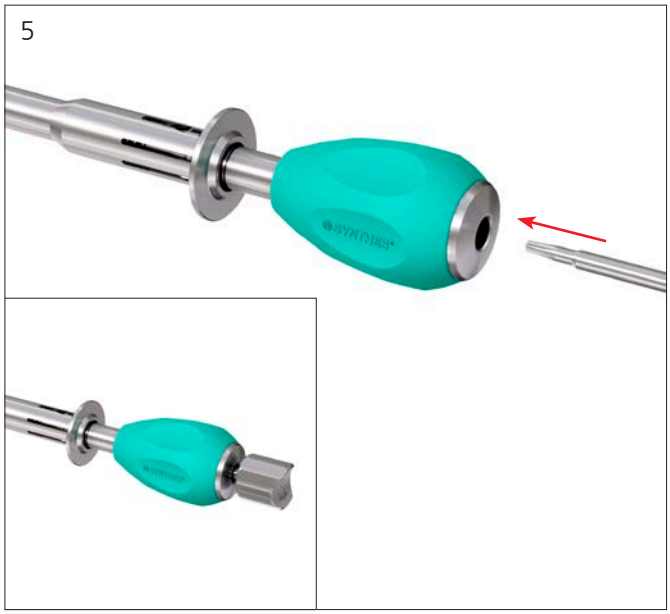
Insert the coupling into the aiming device holder (5).

Note: **Ensure the aiming device holder is fully seated on the aiming device (4).**

Warning: **Do not use awl or screwdriver without appropriate aiming device.**







OPTION A: USING AIMING DEVICE

1

Attach implant to aiming device

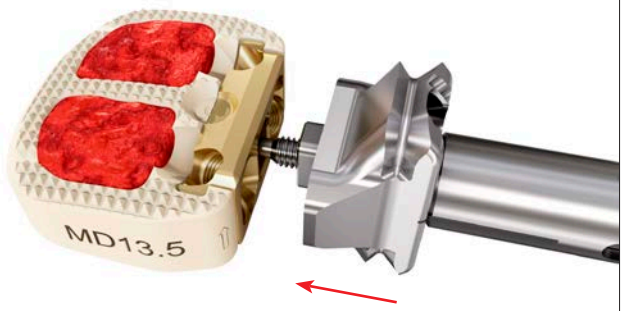
Dock the keyed connection interface of the assembled aiming device into the corresponding docking feature on the implant (1). After the aiming device has been positioned, secure it by turning the coupling clockwise to tighten the coupling screw (2).

Remove the coupling from aiming device before impacting the implant into the disc space (3).

Precautions:

- **Ensure the aiming device matches the implant size.**
- **The aiming device should fit tight against the plate.**
- **Ensure the aiming device/implant connection is secure.**

1



2

3

2
Insert implant

Optional Instrument

SFW691R	Prodisc-L Combined Hammer

Confirm the aiming device/implant connection is locked into position.

The arrow on the SYNFIX Evolution Implant has to point cranially to ensure appropriate fit within the disc space. Insert the SYNFIX Evolution Implant into the disc space (1).

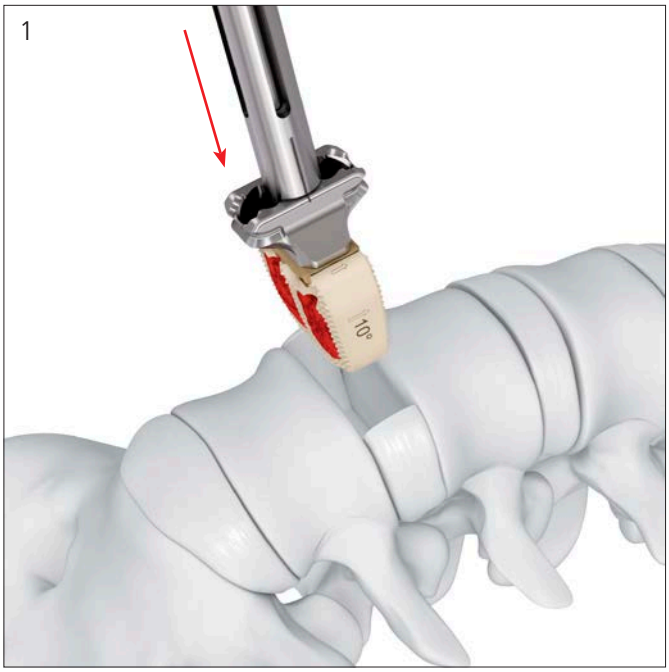
Controlled and light hammering on the aiming device holder may be required to advance the SYNFIX Evolution Implant into the intervertebral disc space.

Use fluoroscopic imaging during implant insertion to assess implant positioning.

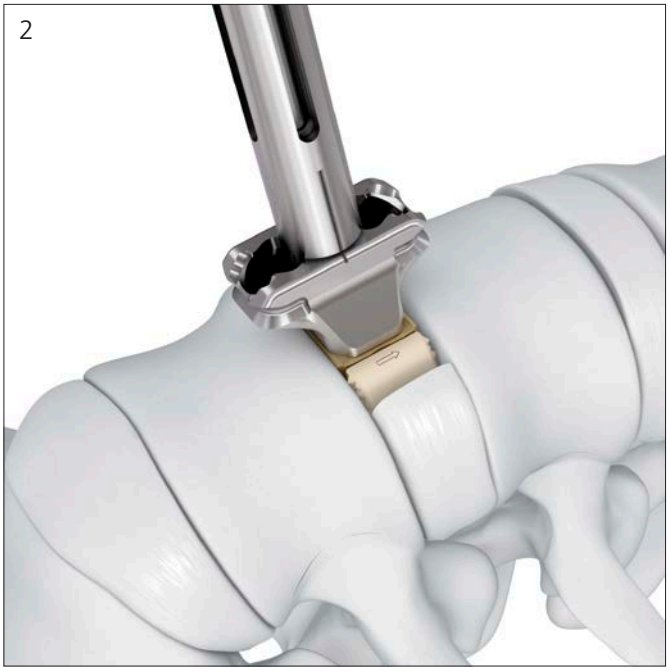
The SYNFIX Evolution Implant should fit firmly with a tight press-fit between the endplates.

Precautions:
- **Ensure that the SYNFIX Evolution Implant is inserted with the arrow pointing cranially as the implant is asymmetrical.**
- **Remove the Coupling prior to hammering to avoid damaging the coupling screw.**
- **Do not insert the implant too deep to avoid bone damage to the anterior rim caused by the aiming device (2). Excessive impaction can cause damage to the anterior aspect of the vertebrae.**

1



2



3
Verify placement

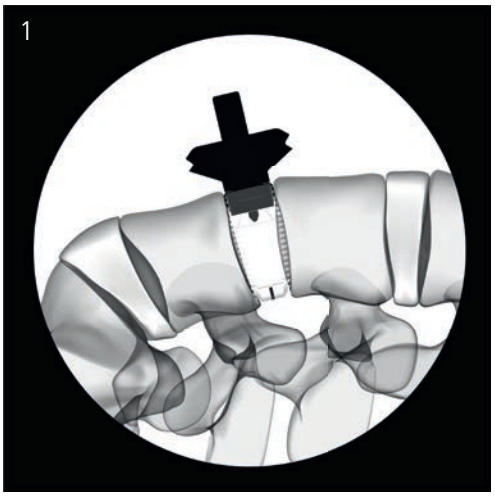
The optimal position for the SYNFIX Evolution Implant is centered within the periphery of the vertebral body and having achieved appropriate fit and fill of the disc space.

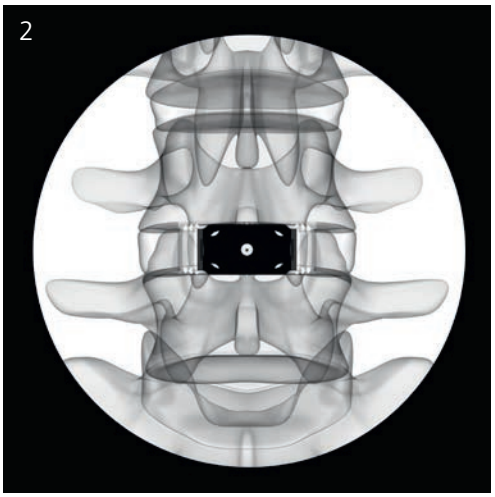
- Verify the location of the SYNFIX Evolution Implant relative to the vertebral bodies in the AP (2) and lateral directions (1) under fluoroscopy.

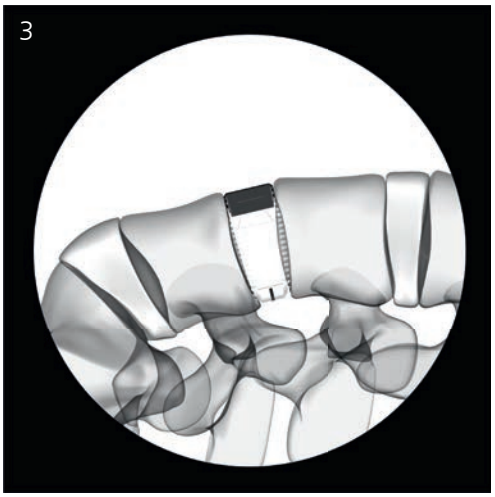
Optionally the aiming device can be removed during fluoroscopy to improve the visualization of the anterior aspect of the implant (2), (3).

The titanium plate and single posterior tantalum x-ray marker incorporated into the implant are designed to allow accurate intraoperative radiographic assessment of the position of the implant.

The x-ray marker is parallel to endplates and flush with the posterior wall of the SYNFIX Evolution Implant.







4
Optional: Final positioning

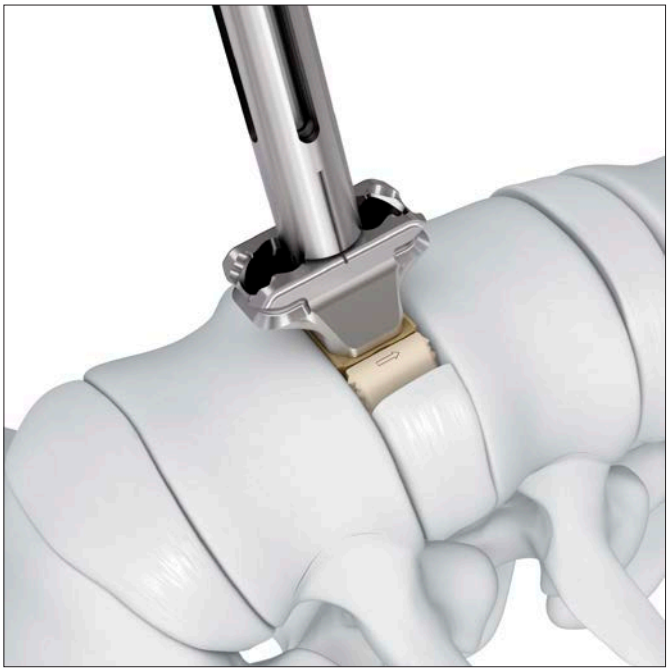
Optional Instrument	
SFW691R	Prodisc-L Combined Hammer

In case the SYNFIX Evolution Implant needs to be repositioned use the attached aiming device to manually manipulate the implant position.

Controlled and light hammering on the aiming device holder may be required to reposition the implant.

- Use fluoroscopic control during the repositioning of the implant.

Precaution: **Remove the coupling prior to hammering to avoid damaging the coupling screw.**



OPTION B: USING SQUID® INSERTER/DISTRACTOR

1

Assemble Evolution SQUID™ Inserter/Distractor and select Push Block

Instruments	
03.815.030	Evolution SQUID, Synthes Quick Inserter and Distractor
03.835.035	Evolution SQUID, Push Block for SYNFIX Evolution, Flush, 0 mm
03.835.036	Evolution SQUID, Push Block for SYNFIX Evolution, Proud, 3 mm
03.835.037	Evolution SQUID, Push Block for SYNFIX Evolution, Proud, 6 mm
03.815.029	Evolution SQUID, Assembly/Disassembly Tool
03.825.106	T-Handle, with Hexagonal Coupling, for Posterior Release Tool and Evolution SQUID

Assemble the Evolution SQUID™ Inserter/Distractor according to the disassembly and assembly instruction; see page 62 in this surgical technique.

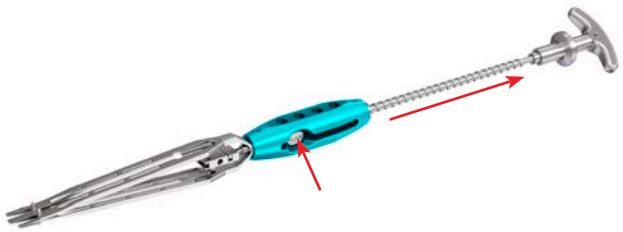
Release the spindle of the Evolution SQUID Inserter/Distractor by pushing the "release" button on the grip and slide the pusher block fully back (1). Lock the spindle by pushing the "engage" button and slide a push block into the pusher block coupling until it is fully seated (2).

Notes:

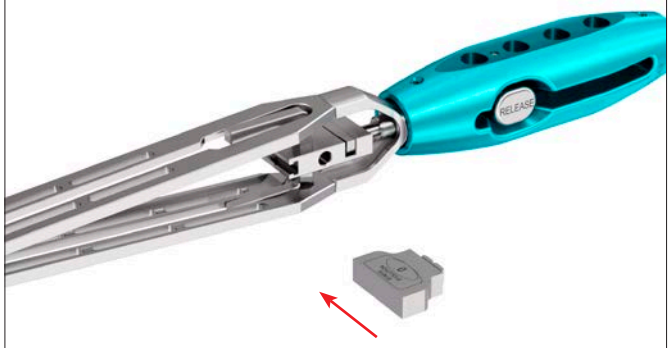
- **For the 19 mm SYNFIX Evolution Implant, first perform step 2 on the next page, then slide the push block into the pusher block.**
- **With the proud push blocks the implant is anteriorly protruding from the anterior rim of the vertebral body and can be fully seated using the aiming device.**

Warning: Ensure the SYNFIX Evolution push blocks are used. Do not use the black engraved SYNCAGE Evolution push blocks (03.815.035–37).

1



2



2

Mount SYNFIX Evolution Implant

Insert the SYNFIX Evolution Implant in between the paddles of the Evolution SQUID Inserter/Distractor so that the grooves of the SYNFIX Evolution Implant connect to the rails of the blades (1). Turn the T-handle of the Evolution SQUID Inserter/Distractor clockwise to advance the pushing block until it contacts the SYNFIX Evolution Implant (2). The SYNFIX Evolution Implant is now held securely in place and is ready for insertion.

Notes:

- **Mounting of the 19 mm SYNFIX Evolution Implant can only be performed prior to installing the push block (see previous step).**
- **The tip of the paddles will be inserted into the disc space up to the depth-stops on the paddles. To allow full insertion, the tip must be fully closed.**
- **The image on the push block depicts the protrusion of the SYNFIX Evolution Implant from the disc space.**

1

2

3
Insert Implant

Insert the tip of the Evolution SQUID Inserter/Distractor into the disc space until the depth-stops on the paddles touch the anterior rim of the vertebral body. The tip of the Evolution SQUID Inserter/Distractor is 25 mm deep and 28 mm wide. To ensure that the SYNFIX Evolution Implant is inserted symmetrically into the disc space, the central opening of the Evolution SQUID Inserter/Distractor paddles should be aligned with the anterior midline of the vertebral bodies.

Actuate SQUID Inserter/Distractor to distract the disc space as the implant is inserted.

Precaution: **Ensure that the Evolution SQUID Inserter/Distractor is inserted with the arrow on the SYNFIX Evolution Implant pointing cranially, as the implant is asymmetrical.**

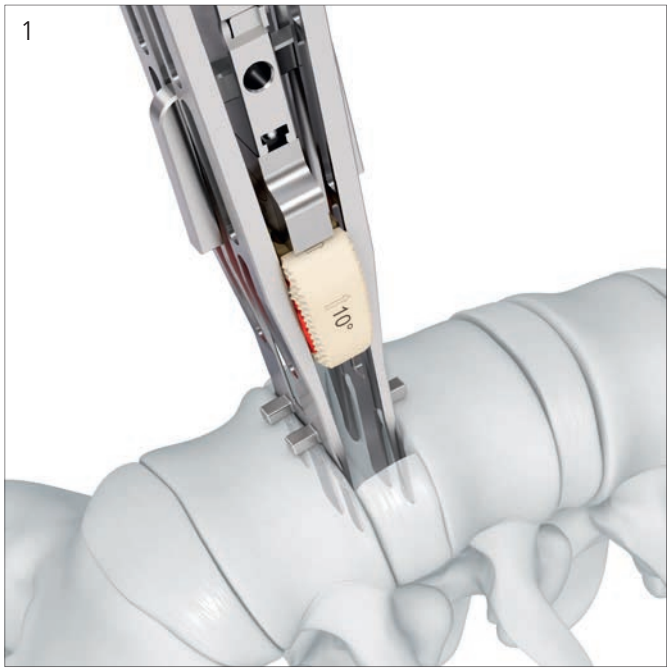
With the spindle engaged, turn the T-handle on the Evolution SQUID Inserter/Distractor to advance the implant down the paddles and into the disc space (1). The force required to turn the T-handle will increase as the SYNFIX Evolution Implant advances down the paddles and the Evolution SQUID Inserter/Distractor elevates the disc space. Under fluoroscopic control continue turning the T-handle until the SYNFIX Evolution Implant is fully ejected and released from the Evolution SQUID Inserter/Distractor (2). An audible click, as the paddles close, confirms that the SYNFIX Evolution Implant is seated and the Evolution SQUID Inserter/Distractor is fully ejected and released. Depending on the size of the vertebrae, the anterior edge of the SYNFIX Evolution Implant will usually be positioned +/– 1 mm to the amount listed on the chosen push block.

Note: **The Evolution SQUID Inserter/Distractor can only be used for an anterior approach.**

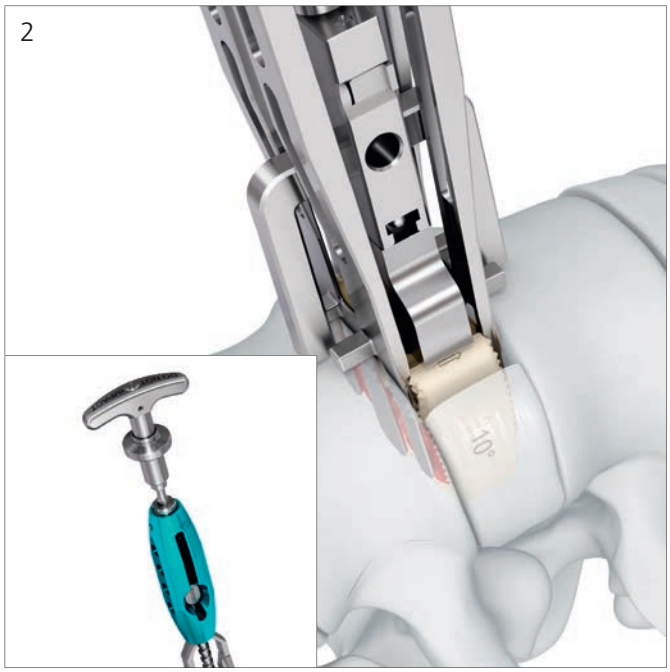
Precautions:

- **The implant, as well as the SQUID Inserter/Distractor stop, are moving towards the vertebral body. Be aware of soft tissue and blood vessels that may be in the pathway of the implant and the SQUID Inserter/Distractor stop, as they may be pushed against the vertebral bodies or interfere with retractor blades. Non-observance can lead to injuries of adjacent structures.**
- **It is important to refrain from using an implant that is too tall for the disc space to prevent over distraction of the segment and prevent injury of the ligamentous, neural structures and/or vertebral endplates.**
- **Use fluoroscopy to confirm the position of Evolution SQUID Inserter/Distractor and the SYNFIX Evolution Implant, restoration of disc and foraminal height, and overall alignment.**

1



2



4

Remove SQUID Inserter/Distractor

When the SYNFIX Evolution Implant is correctly positioned carefully remove the Evolution SQUID Inserter/Distractor.

Precaution: **Be aware of soft tissue or blood vessels that may be in the pathway of the Evolution SQUID Inserter/Distractor or cause possible interference with retractor blades.**

5
Attach Aiming Device

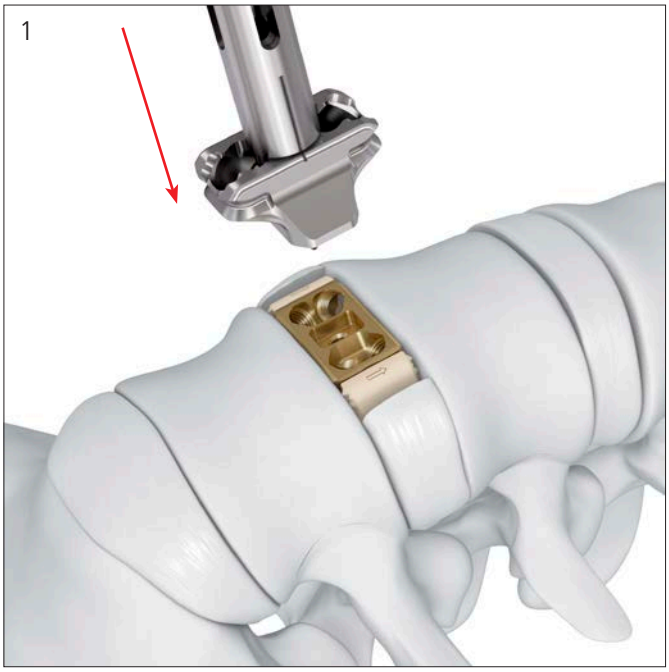
Insert the assembled aiming device (see page 25) into the exposure.

Dock the keyed connection interface of the aiming device into the corresponding docking feature on the implant (1).

After the aiming device has been positioned, secure it by turning the coupling clockwise to tighten the coupling screw.

Remove the coupling from aiming device (2).

Notes:
- **The Aiming Device should fit tight against the plate.**
- **Ensure the aiming device/implant connection is secure.**
- **Ensure the aiming device matches the implant size.**



6
Verify placement

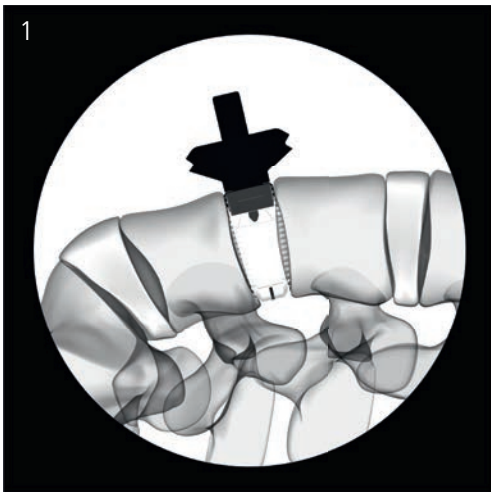
The optimal position for the SYNFIX Evolution Implant is centered within the periphery of the vertebral body and having achieved appropriate fit and fill of the disc space.

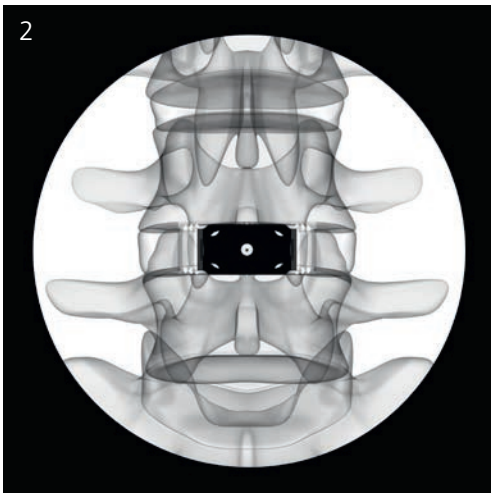
- Verify the location of the SYNFIX Evolution Implant relative to the vertebral bodies in the AP (2) and lateral directions (1) under fluoroscopy.

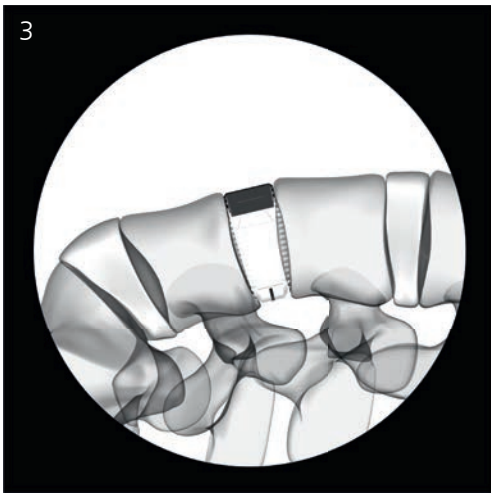
Optionally the aiming device can be removed during fluoroscopy to improve the visualization of the anterior aspect of the implant (2), (3).

The titanium plate and single posterior tantalum x-ray marker incorporated into the implant are designed to allow accurate intraoperative radiographic assessment of the position of the implant.

The x-ray marker is parallel to endplates and flush with the posterior wall of the SYNFIX Evolution Implant.







7
Optional: Final positioning

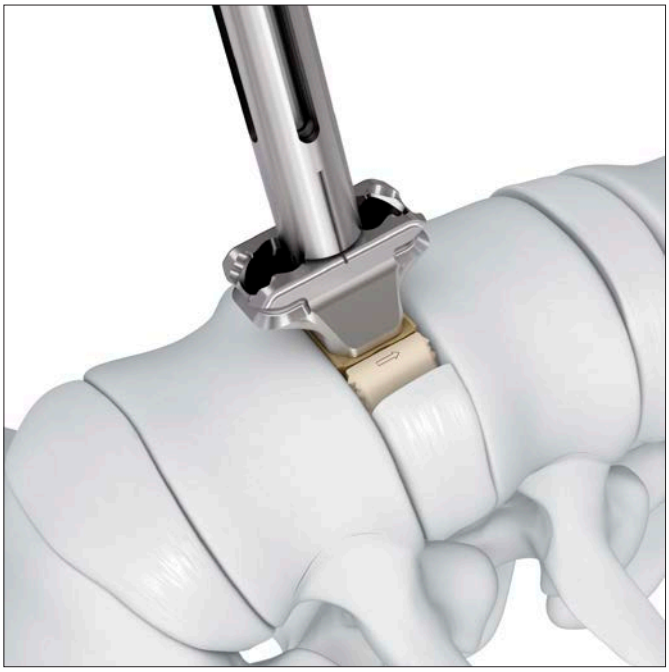
Optional Instrument	
SFW691R	Prodisc-L Combined Hammer

In case the SYNFIX Evolution Implant needs to be repositioned, use the attached aiming device to manually manipulate the implant position.

Controlled and light hammering on the aiming device holder may be required to reposition the implant.

- Use fluoroscopic control during the repositioning of the implant.

Precaution: **Remove the coupling before hammering to avoid damage of the coupling screw.**



SCREW INSERTION

1
Assemble Awl and Screwdrivers

Instruments	
03.835.032	SYNFIX Evolution Awl
03.835.010	SYNFIX Evolution Screwdriver
03.835.009S	SYNFIX Evolution Thread Lock Sleeve, sterile
388.396	Handle with Quick Coupling, small
Optional Instruments	
03.688.505	Handle with Ratchet Wrench for Quick Coupling, small
03.835.013	SYNFIX Evolution Screwdriver, without Thread Lock Sleeve
03.835.015	SYNFIX Evolution Screwdriver, straight, without Thread Lock Sleeve
03.632.204	Torque-limiting Handle, 3 Nm
03.835.043	Torque-limiting Handle, straight with Ratchet Wrench, 3 Nm

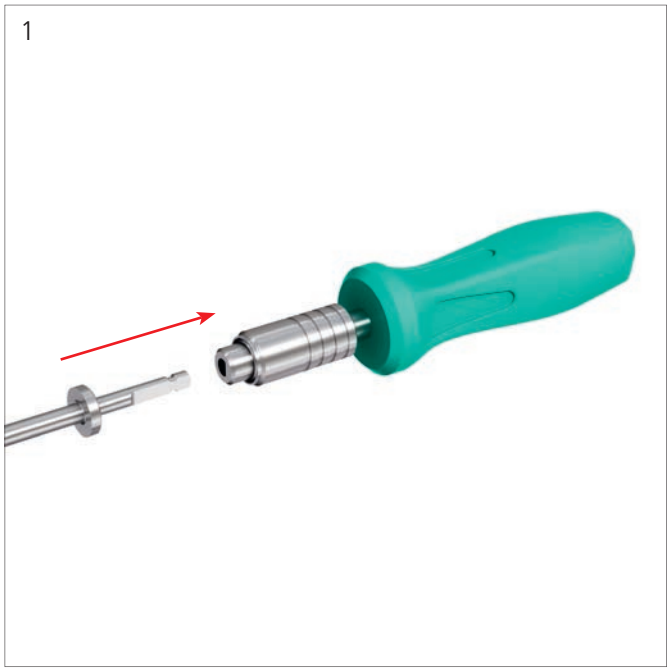
Attach a handle to the AO coupling of the awl (1).

Next, attach a handle to the AO coupling of the SYNFIX Evolution Screwdriver. Then thread the thread lock sleeve all the way down on the screwdriver tip.

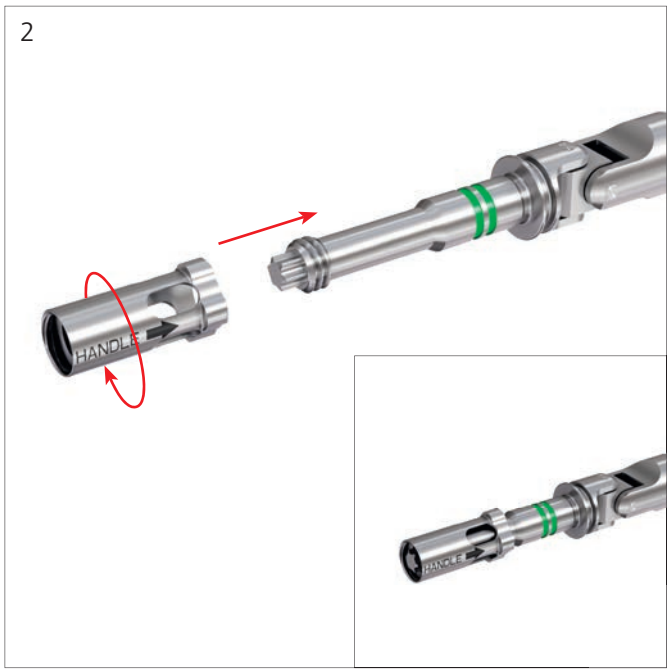
Ensure the arrow on the sleeve is pointing towards the screwdriver handle (2).

Precaution: **The thread lock sleeve is single use. Do not re-sterilize and re-use.**

1



2



Optional:

- **Upon surgeon preference, an optional ratchet handle (03.688.505), a screwdriver without thread lock sleeve (03.835.013) or a straight screwdriver (03.835.015) can be assembled.**
- **Upon surgeon preference, the screw insertion and the final tightening can be combined in one step by assembling the torque limiting handle (03.632.204 or 03.835.043) to the SYNFIX Evolution Screwdriver.**

2
Optional: Assemble Protection Sleeve

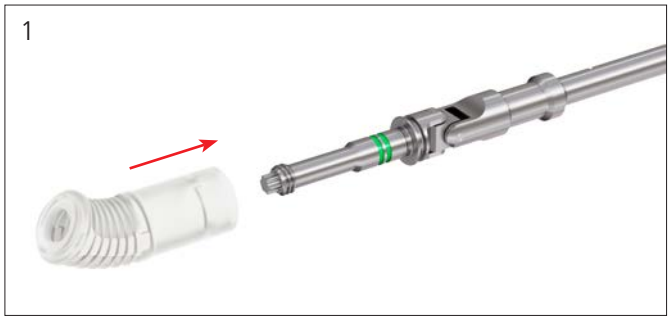
Instrument	
03.835.012S	SYNFIX Evolution Protection Sleeve for Screwdriver and Awl, pack of 3 units, sterile

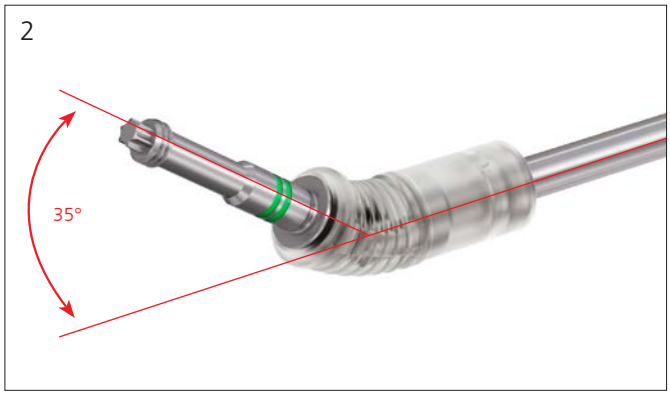
The protection sleeve can be assembled to all jointed SYNFIX Evolution instruments and is designed to prevent soft tissue uptake into the universal joint.

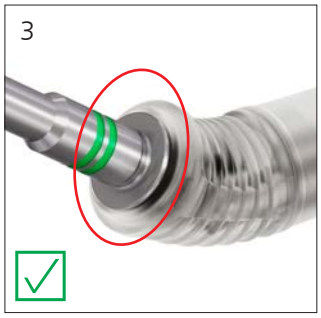
Slide the protection sleeve, with the arrow pointing to the handle end of the instrument, over the distal end of the instrument towards the joint (1). Carefully seat the protection sleeve in the corresponding grooves (3).

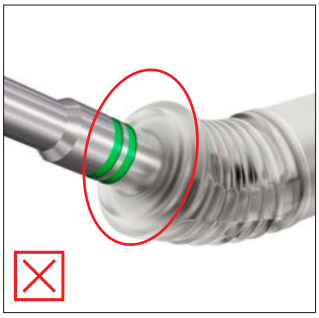
Notes:
- **The protection sleeve has a pre-angulation of 35° to facilitate insertion into the aiming device and provides additional positional memory of the joint (2).**
- **Verify the sleeve is correctly oriented and seated on the instrument (3).**

Precautions:
- **Carefully slide the protection sleeve in a straight manner over the awl tip to avoid damage to the protection sleeve. Take care to avoid injury from the sharp point of the awl.**
- **The protection sleeve is single use. Do not re-sterilize and re-use.**





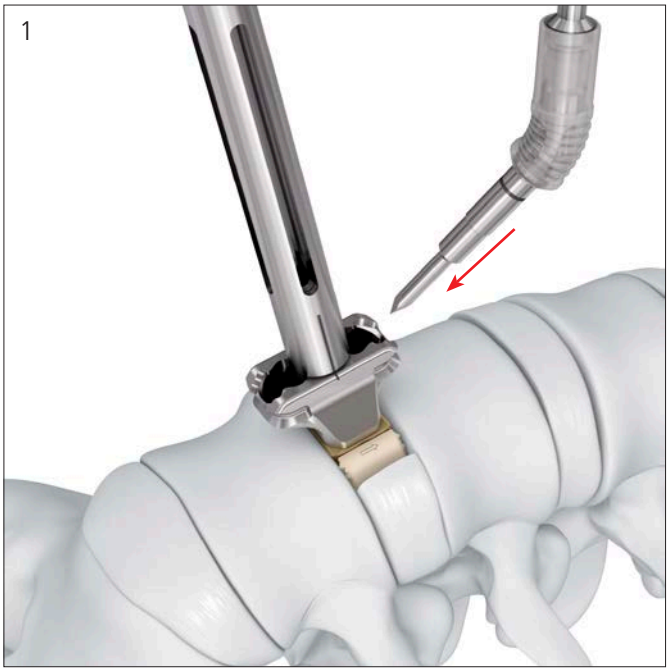




3
Create Pilot Hole

Optional Instruments	
03.835.060	SYNFIX Evolution Soft Tissue Retractor
03.802.038	Tweezers for SynFix-LR

Insert the awl into the aiming device. Create a pilot hole in the vertebral body for screw insertion by applying pressure on the handle of the awl with rotational motions (1).

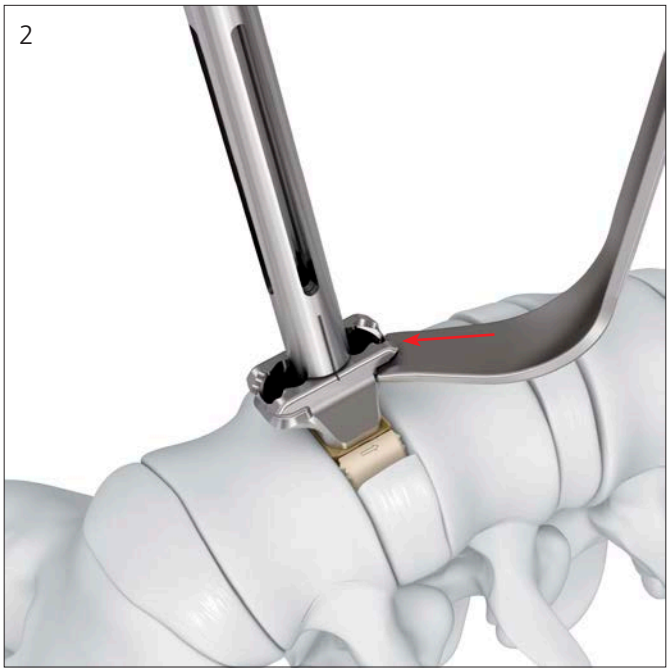


The soft tissue retractor can be used for additional tissue retraction and protection after the first screw has been inserted. Anchor the retractor in the corresponding groove on the selected aiming device for optimal tissue retraction (2).

If required, the holding instrument may be used to control the tip of the awl and to avoid injury to the surrounding soft tissues or vessels.

The holding instrument may also be used for removal of the awl, to avoid damaging adjacent structures.

After the first pilot hole continue with insertion of the first screw to stabilize the implant before preparing any other holes.


2

Notes:

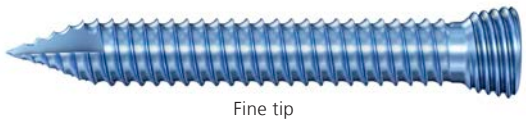
- **It is recommended to start screw insertion with the easiest screws to insert (e.g. S1 screws for L5/S1).**
- **It is not necessary to impact or completely rotate the awl to break the cortex. Rotational motions clockwise and counter-clockwise are typically sufficient.**
- **The purchase length of all screws exceeds the penetration depth of the awl.**

Precautions:

- **Before using the soft tissue retractor, it is recommended to insert one screw to prevent implant migration.**
- **Do not impact on awl during pilot hole creation to avoid damaging the awl joint or handle connection.**
- **Always use an aiming device to guide the awl during pilot hole creation.**

4
Select Screw

Implants	
04.835.120.02S	SYNFIX Evolution Locking Screw, with fine tip, 20 mm, pack of 2 units, sterile
04.835.125.02S	SYNFIX Evolution Locking Screw, with fine tip, 25 mm, pack of 2 units, sterile
04.835.130.02S	SYNFIX Evolution Locking Screw, with fine tip, 30 mm, pack of 2 units, sterile
04.835.220.02S	SYNFIX Evolution Locking Screw, 20 mm, pack of 2 units, sterile
04.835.225.02S	SYNFIX Evolution Locking Screw, 25 mm, pack of 2 units, sterile
04.835.230.02S	SYNFIX Evolution Locking Screw, 30 mm, pack of 2 units, sterile


Fine tip


Blunt tip

Select an appropriate screw type and length based on patient anatomy and clinical requirements.

For a two-level procedure, proper consideration should be given to the screw length on the common vertebral body to prevent screw interference.

Notes:
- **Fine tip screws support penetration of sclerotic bone.**
- **It is recommended to use the longest screw length possible depending on patient anatomy and safe usage.**

Warning: Do not use SYNFIX LR screws in combination with SYNFIX Evolution or SYNFIX Evolution screws in combination with SYNFIX LR. The systems are distinct and not backwards compatible.

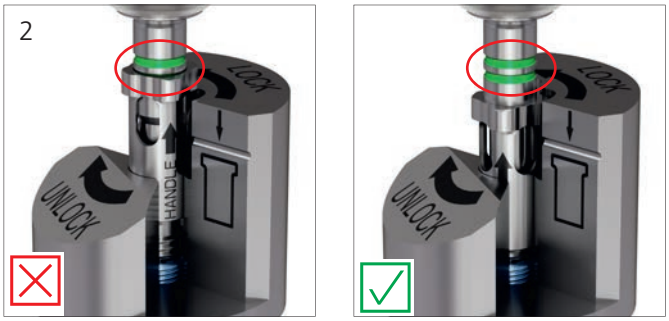
5
Load Screw to Screwdriver

Instrument	
03.835.049	Loading Station for Screws for SYNFIX Evolution

Securely position the screw loading station on any flat surface or hold it in one hand while loading a screw.

Place a screw in the screw loading station with the tip down (1).

Engage the screwdriver in the screw recess and ensure the thread lock sleeve is fully seated in the screw loading station (2). It may be necessary to push the sleeve down so it is in contact with the screw.



Load the screw two-finger tight by turning the screwdriver counter-clockwise until the screw is loaded and the sleeve is fully seated on the screw head (3).

Pull the screwdriver with the loaded screw out of the screw loading station.

Precautions:

- **Do not over tighten the screw in the thread lock sleeve to avoid damage to the thread lock sleeve.**
- **Do not load the screw without the screw loading station as this might cause damage and inhibit proper function of the thread lock sleeve.**

6
Insert and tighten screws

Instrument	
03.835.043	Torque-limiting Handle, straight with Ratchet Wrench, 3 Nm

Optional Instruments	
03.835.060	SYNFIX Evolution Soft Tissue Retractor
03.802.038	Tweezers for SynFix-LR
03.632.204	Torque-limiting Handle, 3 Nm

The soft tissue retractor can be used to facilitate screw insertion along the screw trajectory and for additional tissue retraction and protection. Anchor the retractor in the corresponding groove on the selected aiming device for optimal tissue retraction.

Insert the loaded screw through the aiming device and into the pilot hole created by the awl (1). Use fluoroscopic imaging during screw insertion to assess positioning.

The holding instrument may be used to control the screwdriver while inserting into or removing from the aiming device.

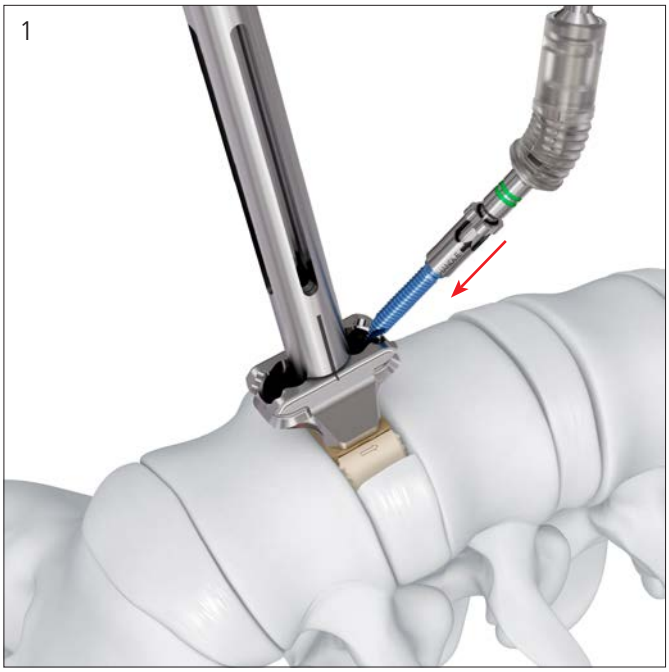
As soon as both green rings are visible in the windows on the thread lock sleeve and a firm end point is noted, the screw is fully inserted (2).

Note: **A constant force along the screw axis should be applied during entire screw insertion.**

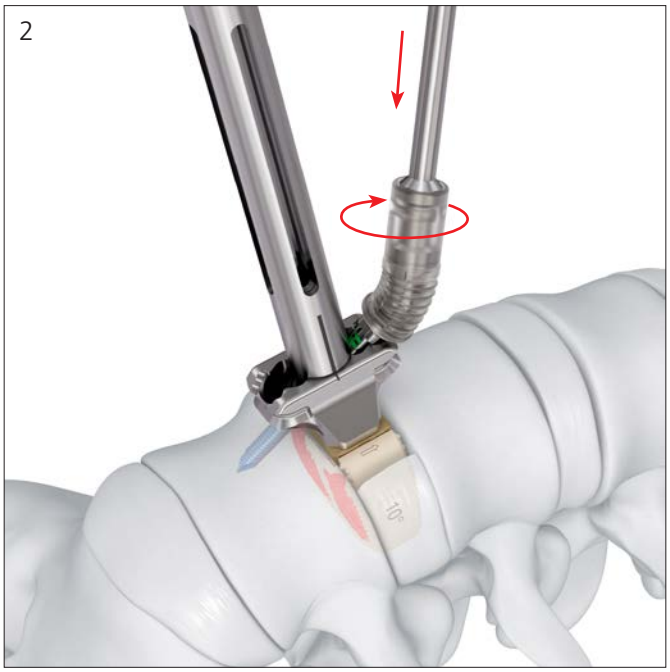
Precaution: **Before using the soft tissue retractor, it is recommended to insert one screw to prevent implant migration.**

Warnings:
- **Use only the handles provided with this set.**
- **Screw insertion must be done through a SYNFIX Evolution aiming device to ensure proper locking of the screw to the plate.**

1



2



Attach the torque limiting handle to the screwdriver. Tighten again until there is a tactile release which indicates that the required torque has been applied (1).

To ensure appropriate locking it is important that the angle of the u-joint does not cross over the aiming device holder during final tightening (2). Reduce the angulation of the U-joint by retracting tissue with the soft tissue retractor (3).

Verify screw position under fluoroscopy.

Optionally the aiming device holder can be removed after the first screw is inserted and tightened to facilitate screw insertion.

Repeat steps 3 to 6 for the remaining 3 screws.
If a 17/19 mm implant is being used, the aiming device must be rotated after the second screw is inserted (see step 7, page 46).

Notes:

- **If screw insertion is blocked or difficult, verify that the previously placed screws are advanced far enough and are not blocking the current screw and that a screw has not been inserted in that hole already.**
- **For final tightening, it is suggested to use the straight screwdriver if access allows or straighten the angled screwdriver as far as possible (2).**

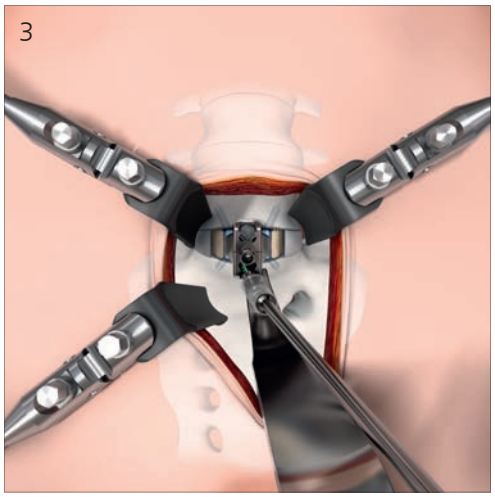
Precautions:

- **Four (4) screws should always be used for every SYNFIX Evolution Implant construct.**
- **The four locking screws should be inserted sequentially.**
- **Avoid excessive tightening of the screws to prevent damage to screwdriver tip and joint.**
- **When dealing with sclerotic bone, ensure the screws are fully locked to the locking plate.**

1

2

3



7
Optional: Rotate 17/19 mm Aiming Device

Instrument	
03.835.003	SYNFIX Evolution Aiming Device, 17 mm and 19 mm

For implant heights 17 and 19 mm, the aiming device needs to be rotated after the first 2 screws are inserted.

First, re-attach the aiming device holder to the aiming device. Pull the outer shaft of the aiming device holder towards the handle, and then attach to the aiming device. Release the outer shaft of the aiming device holder.

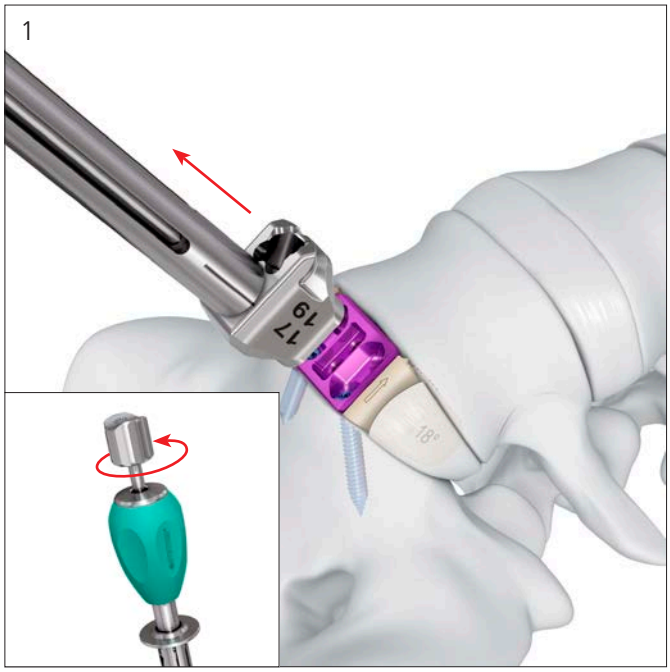
Insert the coupling in the aiming device holder and disengage the coupling screw from the implant by turning the coupling counter-clockwise.

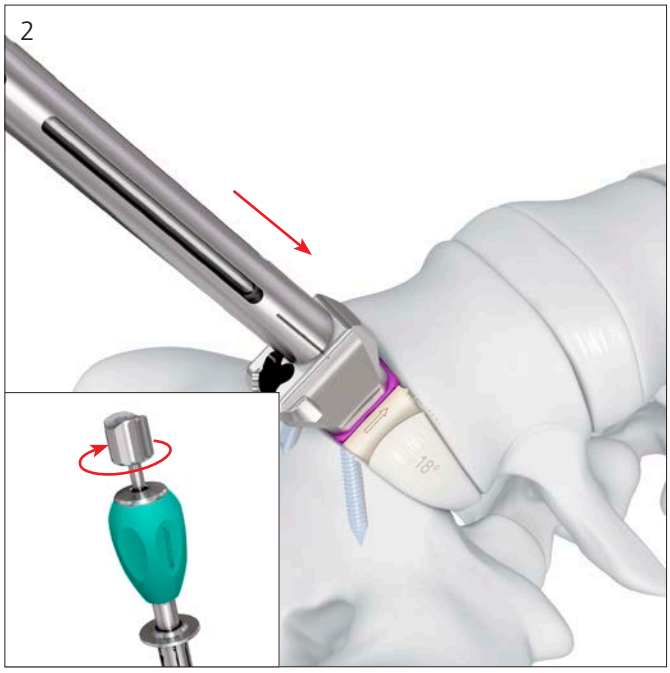
Remove the aiming device from the implant (1), rotate it 180° degrees and reattach it to the implant.

Dock the keyed connection interface of the assembled aiming device into the corresponding docking feature on the implant (2). After the aiming device has been positioned, secure it by turning the coupling clockwise to tighten the coupling screw.

Remove the coupling from aiming device.

Repeat steps 3–6 on pages 40–45 in this surgical technique to insert the remaining 2 screws.





8

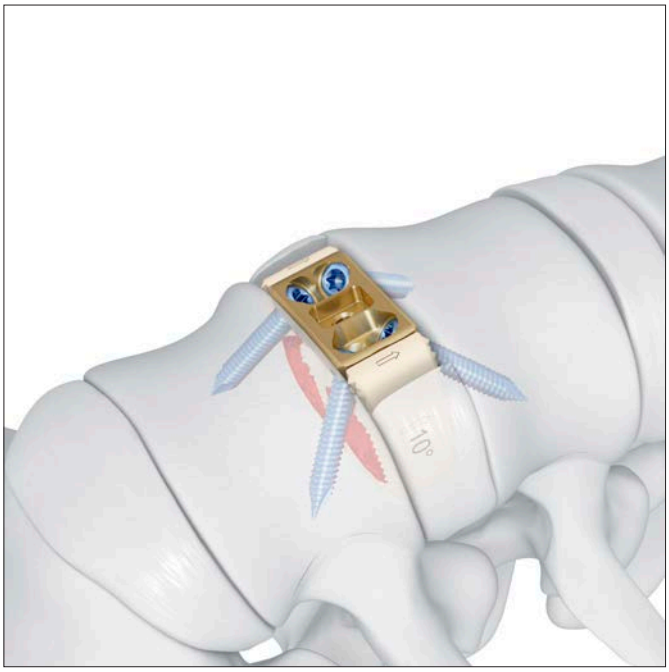
Remove Instruments

First, re-attach the aiming device holder to the aiming device. Pull the outer shaft of the aiming device holder towards the handle and then attach to the aiming device. Release the outer shaft of the aiming device holder.

Insert the coupling in the aiming device holder and disengage the coupling screw from the implant by turning the coupling counter-clockwise.

Remove the aiming device from the implant.

Note: **If the aiming device is difficult to remove, verify that all screws are fully seated and not blocking the aiming device during removal.**



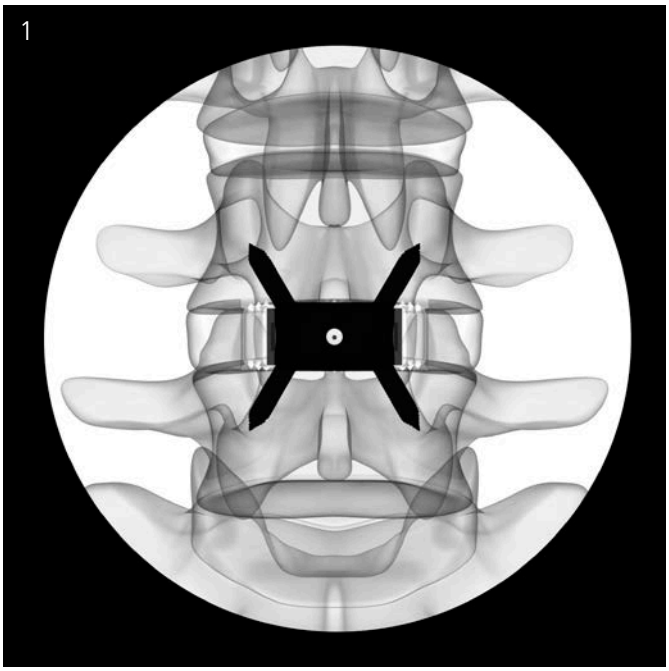
9
Verify implant positioning

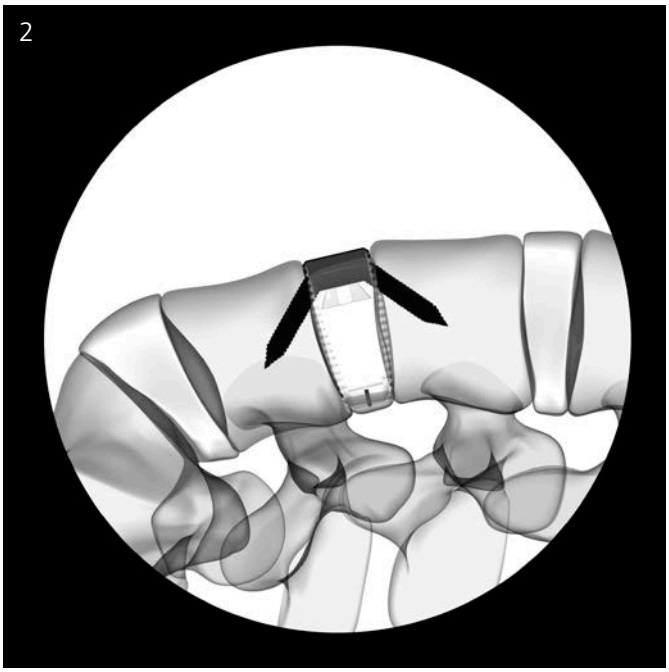
The optimal position for the SYNFIX Evolution Implant is centered within the periphery of the vertebral body and achieving appropriate fit and fill of the disc space.

Verify the location of the SYNFIX Evolution Implant relative to the vertebral bodies in the AP (1) and lateral (2) directions under fluoroscopy.

The titanium plate and single posterior tantalum x-ray marker incorporated into the implant are designed to allow accurate intraoperative radiographic assessment of the position of the implant.

The x-ray marker is parallel to endplates and is flush against the posterior wall of the SYNFIX Evolution Implant.





SCREW REMOVAL

1
Assemble aiming device

Instruments	
03.835.001	SYNFIX Evolution Aiming Device, 10.5 mm and 12 mm
03.835.002	SYNFIX Evolution Aiming Device, 13.5 mm and 15 mm
03.835.003	SYNFIX Evolution Aiming Device, 17 mm and 19 mm
03.835.006	Coupling Screw for SYNFIX Evolution Aiming Device
03.835.004	SYNFIX Evolution Aiming Device Holder
03.835.005	Coupling for Aiming Device Holder SYNFIX Evolution

Choose the aiming device corresponding to the implant height. Each aiming device combines 2 heights.

See implant description table on pages 65–70 for correlation between implant height and plate color.

Assemble the aiming device holder according to the disassembly and assembly instructions (see page 57).

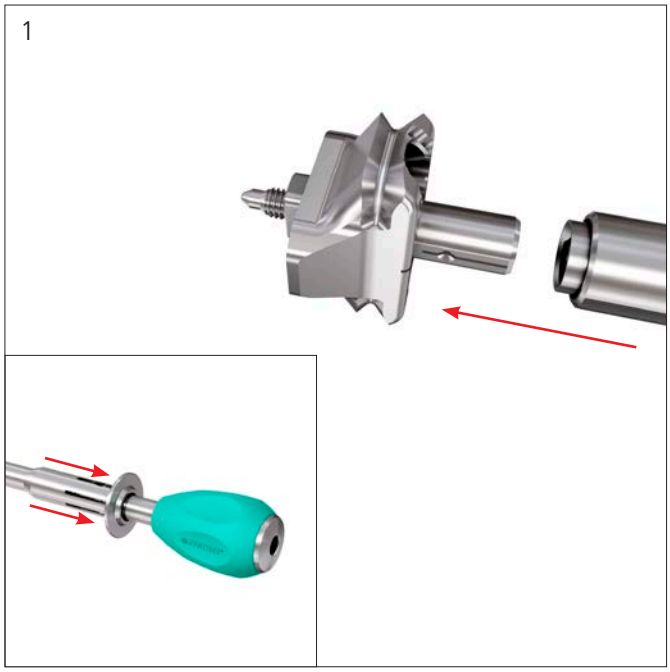
Fully engage the coupling screw in the aiming device with the coupling.

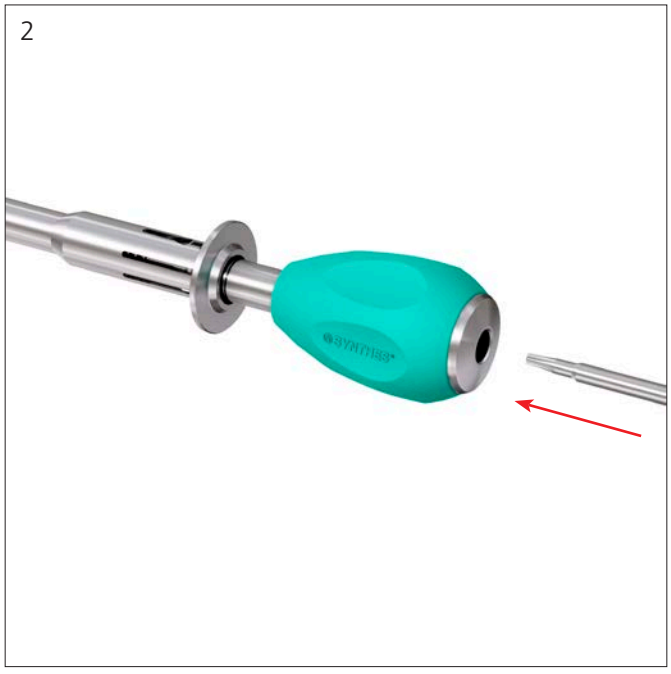
Attach the aiming device holder to the aiming device by pulling the outer shaft on the aiming device holder towards the handle and then engage the aiming device (1). Align the vertical black lines on the aiming device holder and the aiming device. Release the outer shaft to lock the assembly.

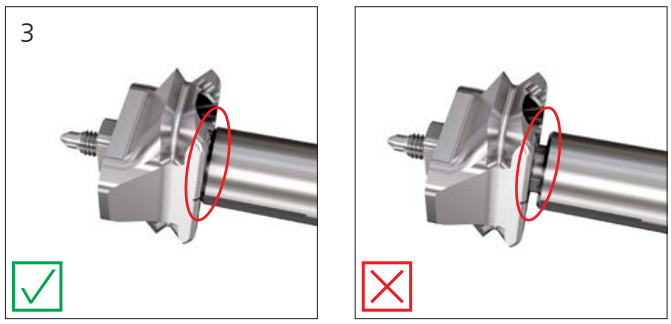
Insert the coupling in the aiming device holder (2).

Note: **Ensure the aiming device holder is fully seated on the aiming device (3).**

Warning: **Do not use the screwdriver without appropriate aiming device.**







2
Attach Aiming Device

Insert the assembled aiming device into the operative site.

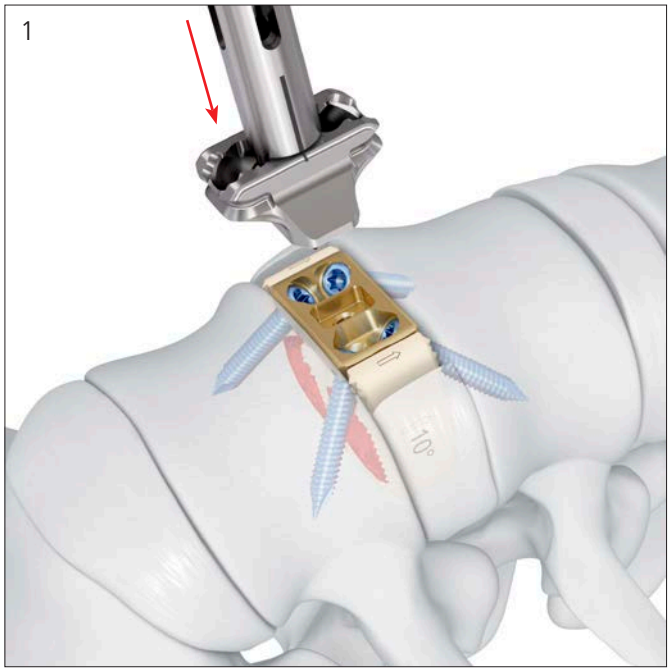
Dock the keyed connection interface of the aiming device into the corresponding docking feature on the implant (1).

After the aiming device has been positioned, secure it by turning the coupling clockwise to tighten the coupling screw.

Remove the coupling from aiming device (2).

Notes:
- **The aiming device should fit tight against the plate.**
- **Ensure the aiming device/implant connection is secure.**

1



2

3
Remove screws

Instruments	
03.835.013	SYNFIX Evolution Screwdriver, without Thread Lock Sleeve
388.396	Handle with Quick Coupling, small
Optional instruments	
03.835.015	SYNFIX Evolution Screwdriver, straight, without Thread Lock Sleeve
03.835.060	SYNFIX Evolution Soft Tissue Retractor
03.835.012S	SYNFIX Evolution Protection Sleeve for Screwdriver and Awl, pack of 3 units, sterile
03.802.038	Tweezers for SynFix-LR

Assemble the screwdriver without thread lock sleeve according to step 1 and optionally step 2 of section "Screw Insertion" from this surgical technique (see page 37).

Depending on the access, the straight screwdriver may be used.

The soft tissue retractor can be used for additional tissue retraction and protection with the angled screwdriver. Anchor the retractor in the corresponding groove on the selected aiming device for optimal tissue retraction.

Insert the screwdriver in the aiming device and engage it in the screw recess (1).

The holding instrument may be used to control the screwdriver while inserting into or removing from the aiming device.

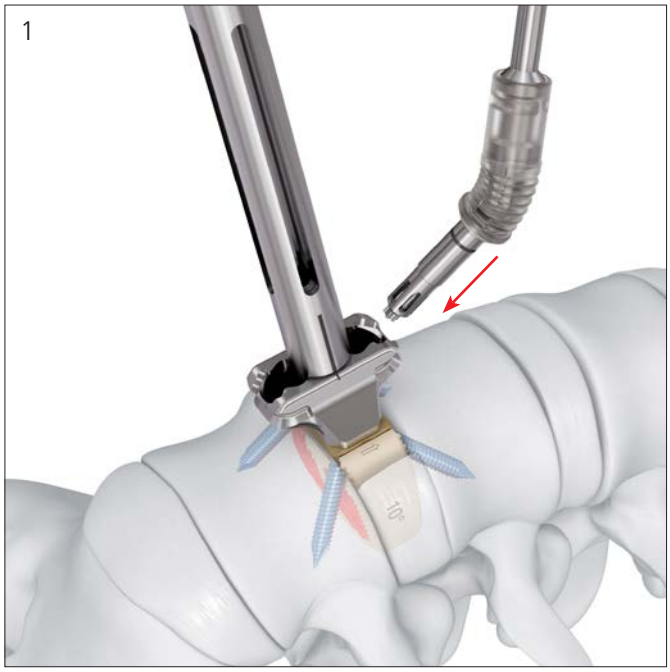
Turn the screwdriver counter-clockwise to unlock the screw and remove the screw (2).

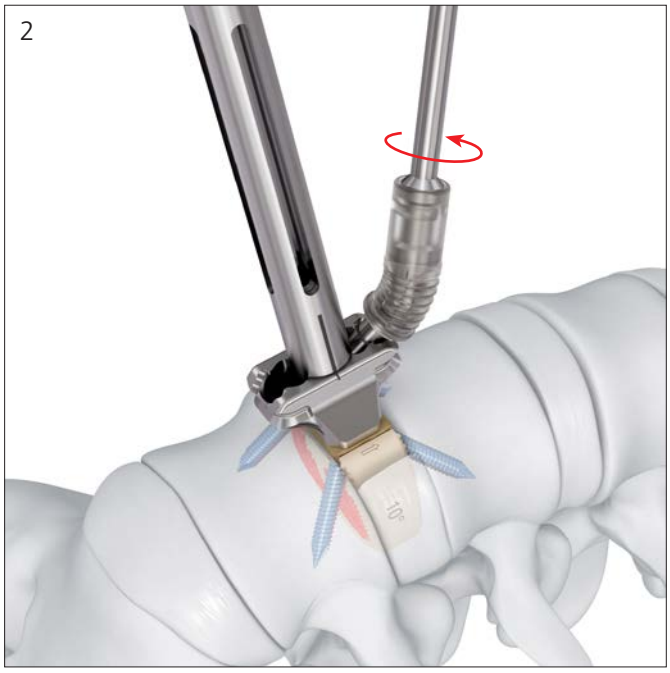
Optionally remove the Aiming Device Holder for better visibility and access.

Repeat this step to remove the remaining 3 screws.

Verify under fluoroscopy that all screws are removed

Note: **Do not use the angled screwdriver with thread lock sleeve for screw removal.**





4
Remove Aiming Device

If necessary, first re-attach the aiming device holder to the aiming device. Pull the outer shaft of the aiming device holder towards the handle and then attach to the aiming device. Release the outer shaft of the aiming device holder.

Insert the coupling in the aiming device holder and disengage the coupling screw from the implant by turning the coupling counter-clockwise.

Remove the aiming device from the implant.

Note: **If the aiming device is difficult to remove, verify that all screws are removed and are not blocking the aiming device during removal.**

CAGE REMOVAL

The standard solution for cage removal is reattaching the aiming device holder to the cage and then removing the cage from the disc space. The removal tool option below is to be used in case reattaching of the aiming device holder to the cage is not possible.

1
Assemble Screwdriver and Removal Tool

Instruments	
03.835.070	SYNFIX Evolution, Removal Tool for Implants, 10.5 mm and 12 mm
03.835.071	SYNFIX Evolution, Removal Tool for Implants, 13.5 mm and 15 mm
03.835.072	SYNFIX Evolution, Removal Tool for Implants, 17 mm and 19 mm
388.396	Handle with Quick Coupling, small
03.835.015	SYNFIX Evolution Screwdriver, straight, without Thread Lock Sleeve
03.835.100	SYNFIX Evolution Trial Implant Holder
03.825.002	SynCage Evolution Spindle
Optional instrument	
03.835.013	SYNFIX Evolution Screwdriver, without Thread Lock Sleeve

Assemble the screwdriver by attaching the handle to the straight screwdriver shaft.

Choose the implant removal tool corresponding to the implant height. Each Removal Tool combines 2 heights (1).

1

Engage the interlocking screw one full turn in the implant removal instrument (2).

Assemble the trial implant holder by threading the spindle into the cannulated shaft of the trial implant holder. Mount the trial implant holder on the removal tool (3).

Note: **In case the access does not allow usage of the straight screwdriver, use the angled screwdriver.**

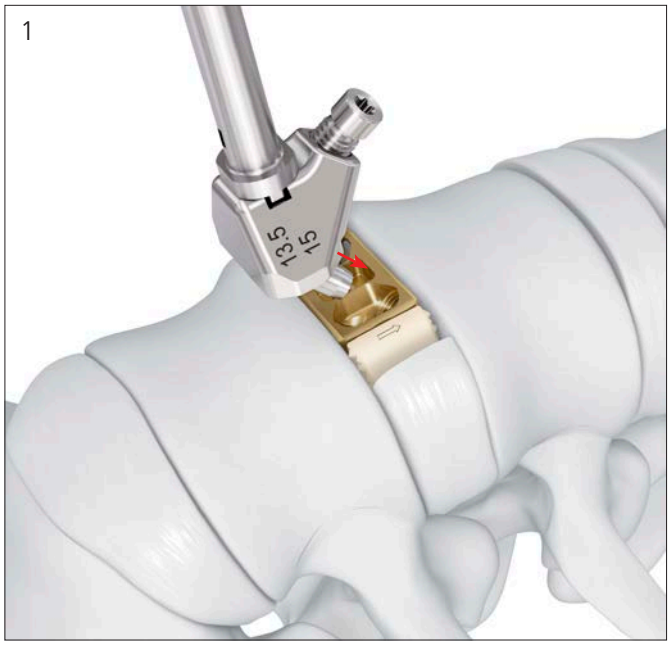
Warning: **The diamond-shape surface of the trial implant holder interface should reside inside of the removal tool interface.**

2
Attach Removal Tool to Implant

Optional instrument

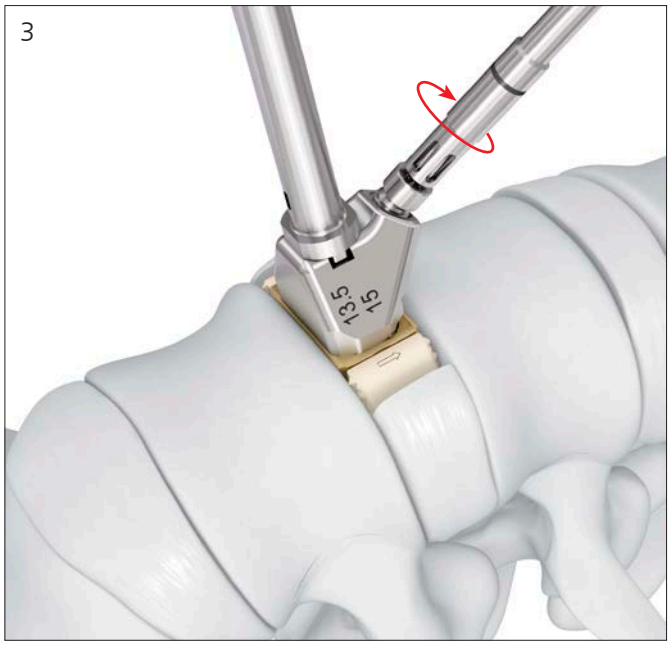
03.802.038	Tweezers for SynFix-LR

Insert the removal tool and guide the dowel pin into a corresponding screw hole on the implant (1). Align the removal tool with the implant and ensure the interlocking screw trajectory aligns with the screw hole in the implant (2).



Fully engage the interlocking screw with the screwdriver to secure the removal tool to the implant (3).

The holding instrument may be used to control the screwdriver while inserting into or removing from the removal tool.



3
Remove Implant

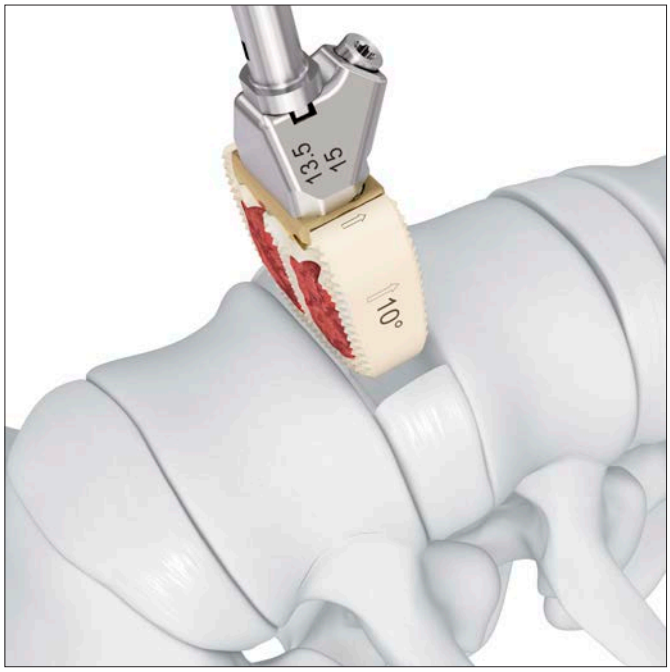
Optional Instrument

SFW691R	Prodisc-L Combined Hammer

Completely separate the endplate fusion areas prior to implant removal. An osteotome may be required to mobilize the implant if bone healing and integration has commenced.

Carefully remove the SYNFIX Evolution Implant from disc space by pulling on the trial implant holder.

Controlled, light hammering with a slotted mallet may be required to remove the implant from the disc space.



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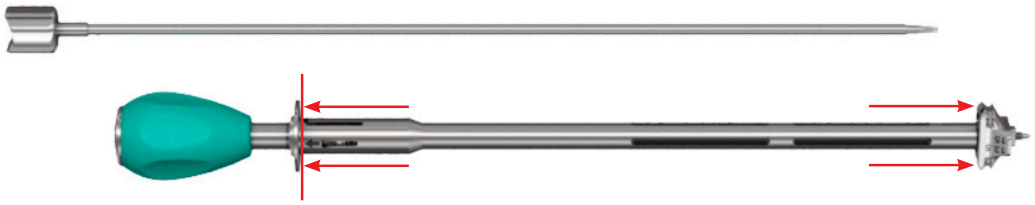

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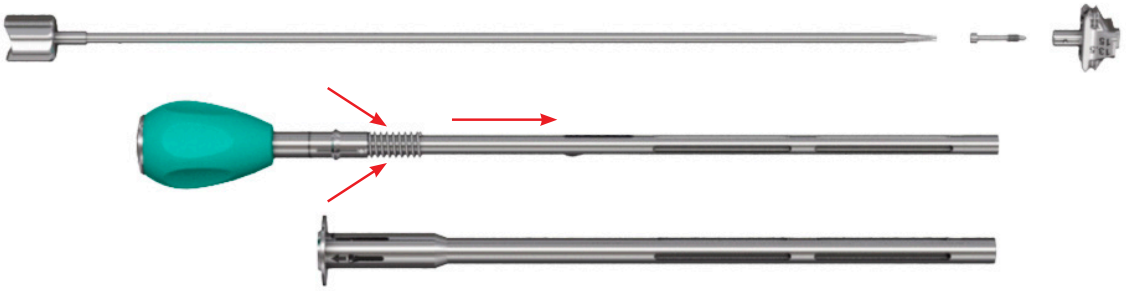

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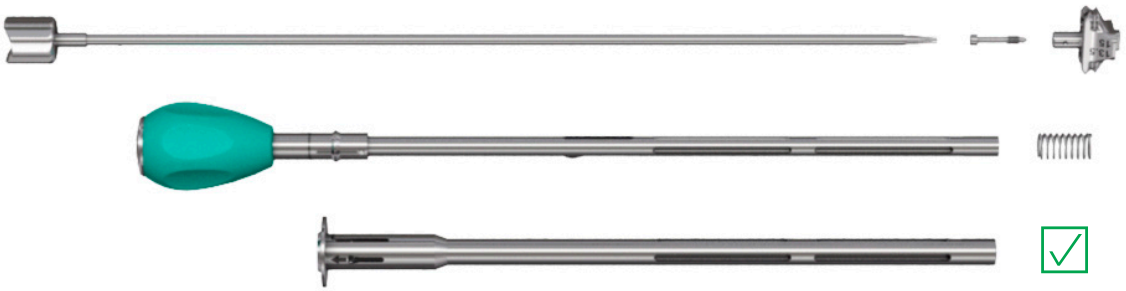

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STERILE

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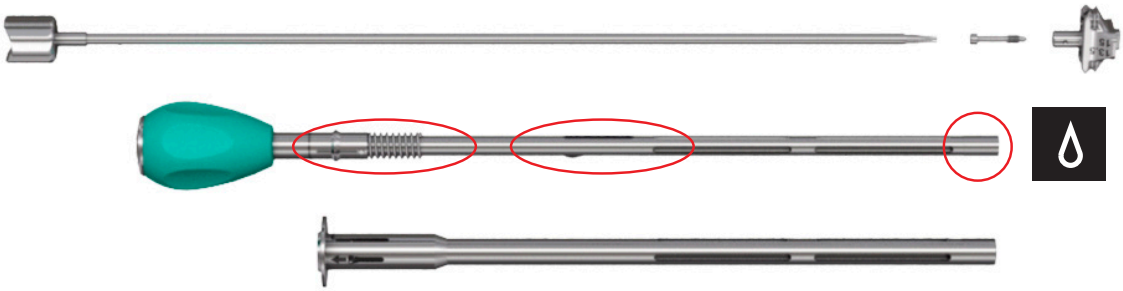
2



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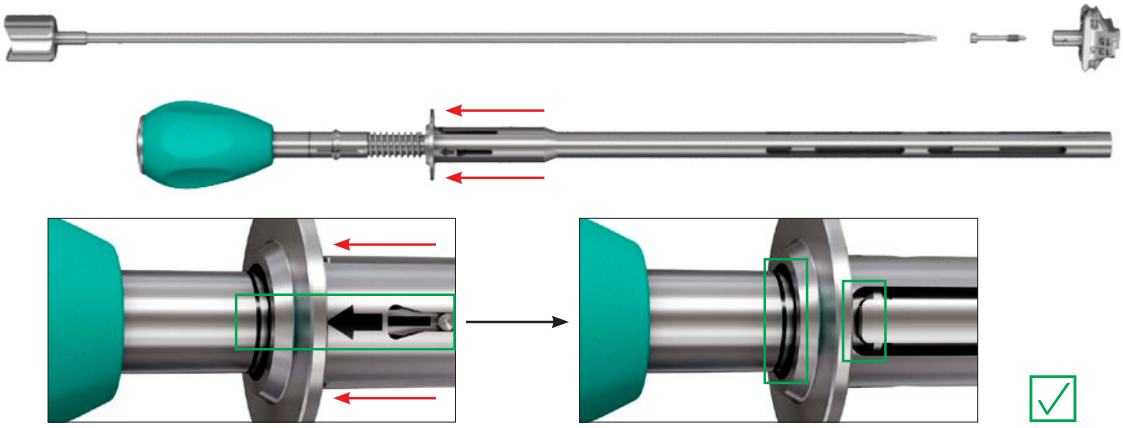

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OK
STERILE

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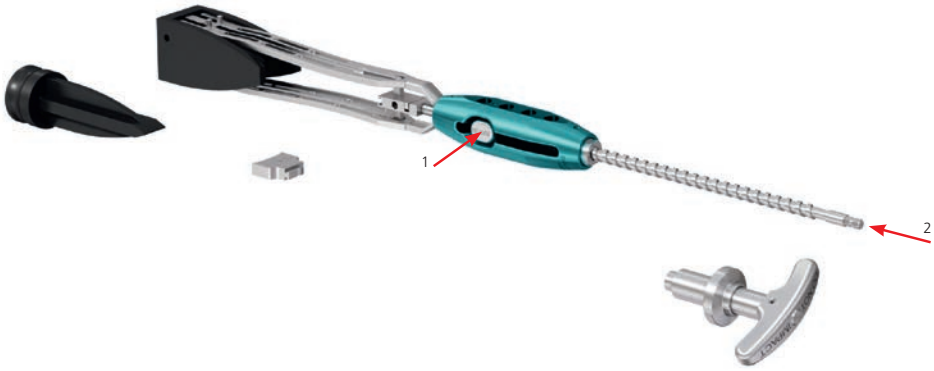
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03.815.030
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03.815.036 03.835.036
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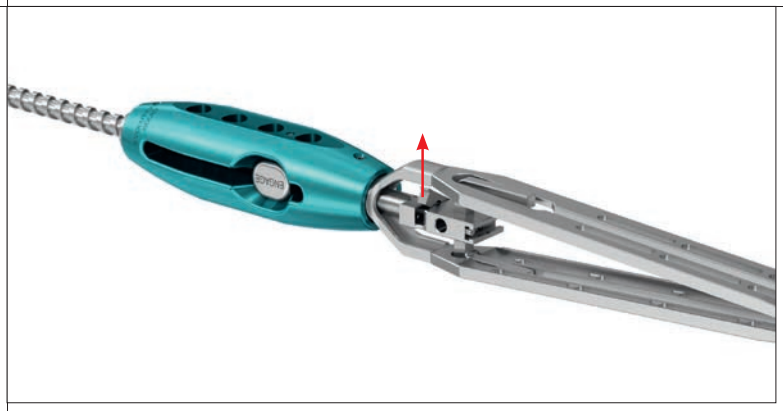


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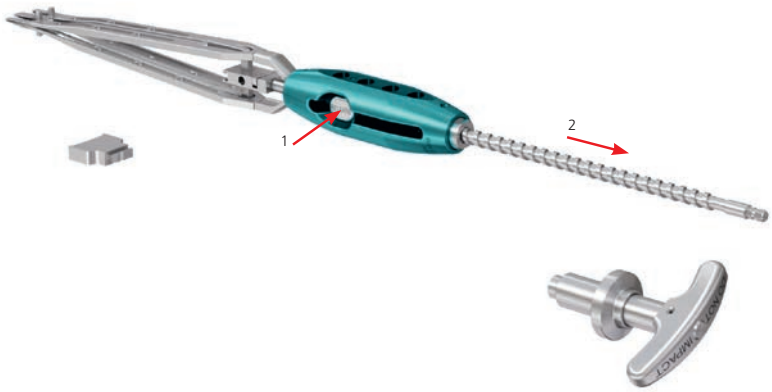
4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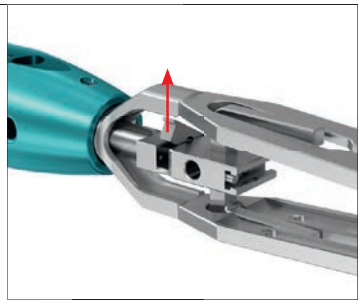

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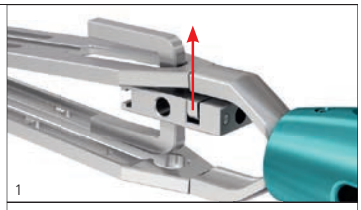
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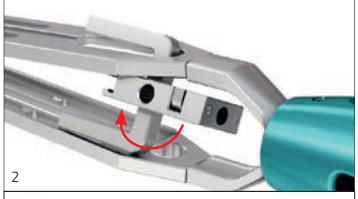
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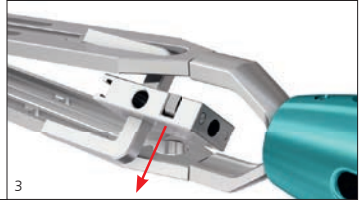
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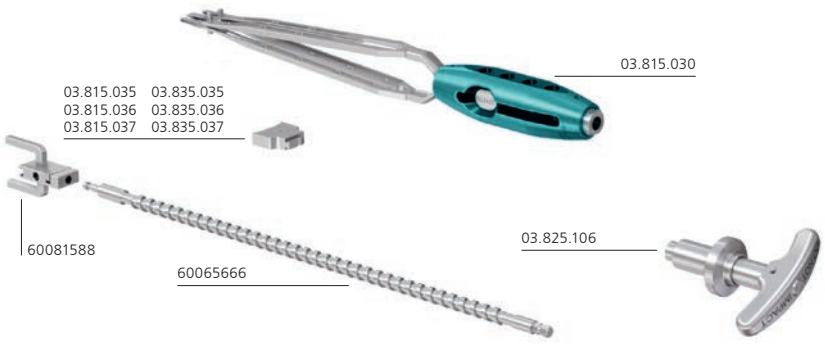
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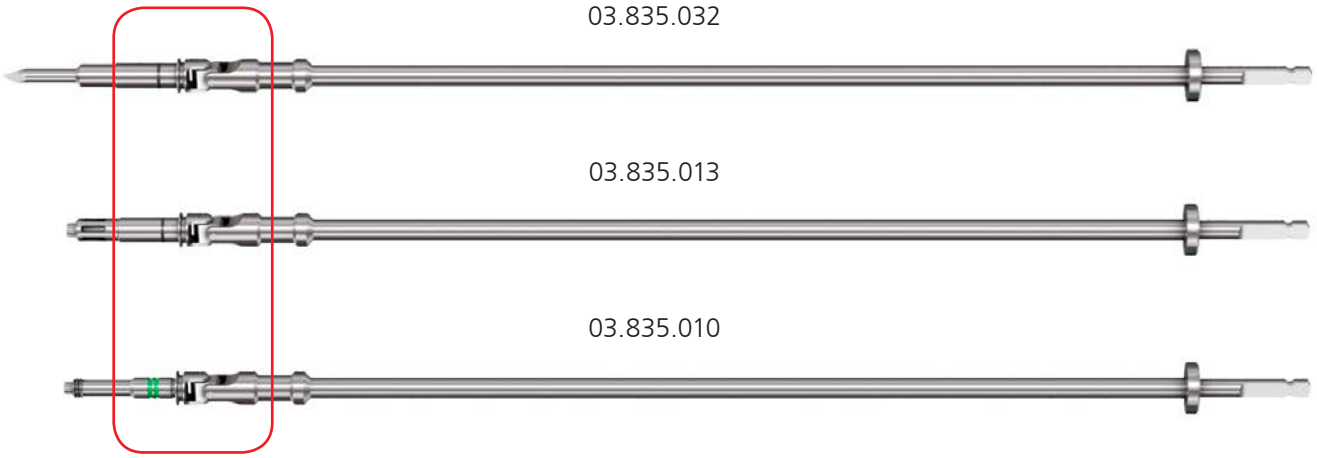
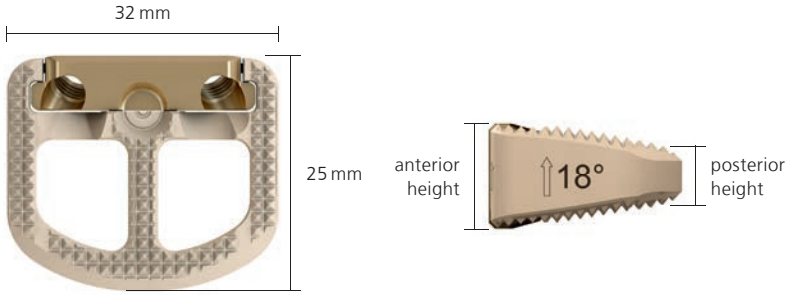
MAINTENANCE U-JOINT INSTRUMENTS

It is suggested to lubricate the U-joints of the awl and screwdrivers prior to sterilization to extend the U-joint's life time.



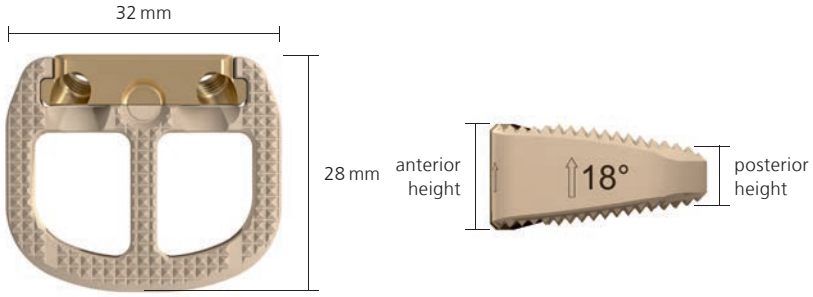
CAGES

SYNFIX Evolution Spacer, small



Article Number	Angle	Anterior Height (mm)	Posterior Height (mm)	Color of Implant Plate/ Trial implants	Cage Filling Volume (cc)
08.815.101S	6°	10.5	8.7	light green	2.1
08.815.102S	6°	12.0	10.2	blue	2.4
08.815.103S	6°	13.5	11.7	gold	2.7
08.815.104S	6°	15.0	13.2	dark blue	3.0
08.815.105S	6°	17.0	15.2	purple	3.5
08.815.106S	6°	19.0	17.2	green	3.9
08.815.111S	10°	10.5	6.9	light green	1.9
08.815.112S	10°	12.0	8.4	blue	2.2
08.815.113S	10°	13.5	9.9	gold	2.5
08.815.114S	10°	15.0	11.4	dark blue	2.8
08.815.115S	10°	17.0	13.4	purple	3.2
08.815.116S	10°	19.0	15.4	green	3.6
08.815.122S	14°	12.0	6.7	blue	1.9
08.815.123S	14°	13.5	8.2	gold	2.2
08.815.124S	14°	15.0	9.7	dark blue	2.5
08.815.125S	14°	17.0	11.7	purple	2.9
08.815.126S	14°	19.0	13.7	green	3.4
08.815.163S	18°	13.5	6.4	gold	2.0
08.815.164S	18°	15.0	7.9	dark blue	2.3
08.815.165S	18°	17.0	9.9	purple	2.7
08.815.166S	18°	19.0	11.9	green	3.1

SYNFIX Evolution Spacer, small, deep



Article Number	Angle	Anterior Height (mm)	Posterior Height (mm)	Color of Implant Plate/ Trial implants	Cage Filling Volume (cc)
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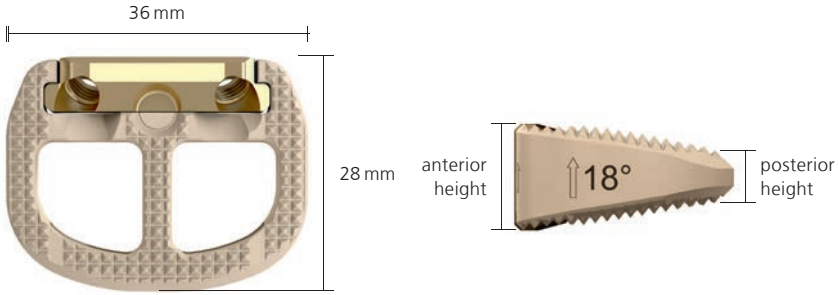
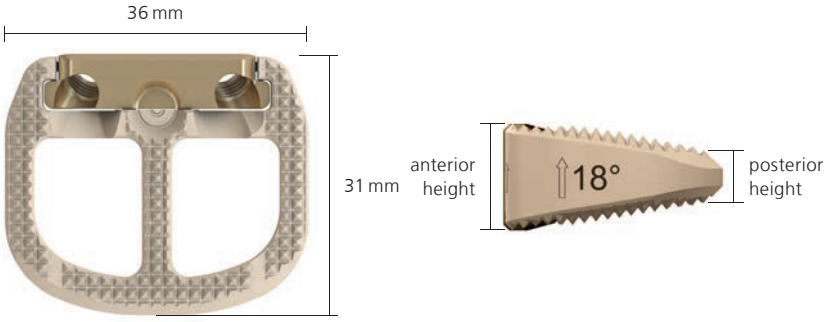
08.815.132S	6°	12.0	10.2	blue	3.3
08.815.133S	6°	13.5	11.7	gold	3.7
08.815.134S	6°	15.0	13.2	dark blue	4.1
08.815.135S	6°	17.0	15.2	purple	4.7
08.815.136S	6°	19.0	17.2	green	5.2
08.815.141S	10°	10.5	6.9	light green	2.6
08.815.142S	10°	12.0	8.4	blue	3.0
08.815.143S	10°	13.5	9.9	gold	3.4
08.815.144S	10°	15.0	11.4	dark blue	3.8
08.815.145S	10°	17.0	13.4	purple	4.3
08.815.146S	10°	19.0	15.4	green	4.9
08.815.152S	14°	12.0	6.7	blue	2.6
08.815.153S	14°	13.5	8.2	gold	3.1
08.815.154S	14°	15.0	9.7	dark blue	3.5
08.815.155S	14°	17.0	11.7	purple	4.0
08.815.156S	14°	19.0	13.7	green	4.5
08.815.173S	18°	13.5	6.4	gold	2.7
08.815.174S	18°	15.0	7.9	dark blue	3.1
08.815.175S	18°	17.0	9.9	purple	3.7
08.815.176S	18°	19.0	11.9	green	4.2

SYNFIX Evolution Spacer, medium



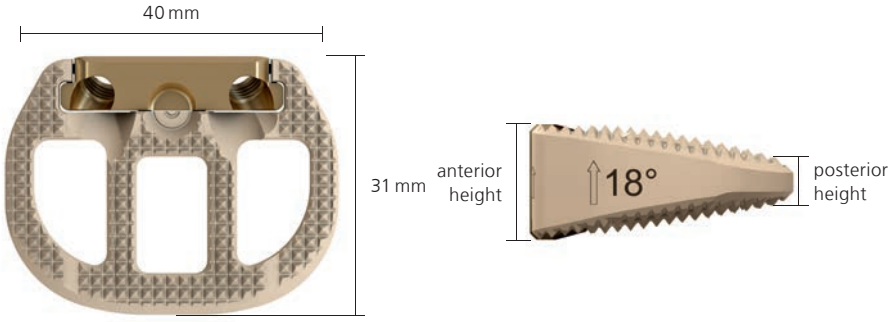
Article Number	Angle	Anterior Height (mm)	Posterior Height (mm)	Color of Implant Plate/ Trial implants	Cage Filling Volume (cc)
08.815.201S	6°	10.5	8.4	light green	3.3
08.815.202S	6°	12.0	9.9	blue	3.8
08.815.203S	6°	13.5	11.4	gold	4.3
08.815.204S	6°	15.0	12.9	dark blue	4.7
08.815.205S	6°	17.0	14.9	purple	5.4
08.815.206S	6°	19.0	16.9	green	6.0
08.815.211S	10°	10.5	6.4	light green	2.8
08.815.212S	10°	12.0	7.9	blue	3.3
08.815.213S	10°	13.5	9.4	gold	3.8
08.815.214S	10°	15.0	10.9	dark blue	4.3
08.815.215S	10°	17.0	12.9	purple	4.9
08.815.216S	10°	19.0	14.9	green	5.5
08.815.222S	14°	12.0	5.9	blue	2.9
08.815.223S	14°	13.5	7.4	gold	3.4
08.815.224S	14°	15.0	8.9	dark blue	3.8
08.815.225S	14°	17.0	10.9	purple	4.5
08.815.226S	14°	19.0	12.9	green	5.1
08.815.263S	18°	13.5	5.4	gold	3.0
08.815.264S	18°	15.0	6.9	dark blue	3.4
08.815.265S	18°	17.0	8.9	purple	4.1
08.815.266S	18°	19.0	10.9	green	4.7

SYNFIX Evolution Spacer, medium, deep



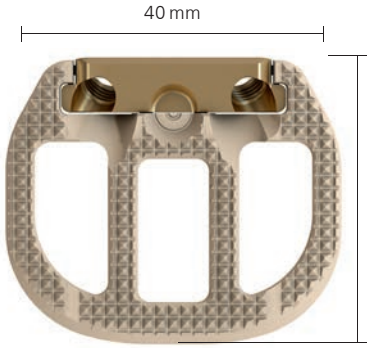
Article Number	Angle	Anterior Height (mm)	Posterior Height (mm)	Color of Implant Plate/ Trial implants	Cage Filling Volume (cc)
08.815.231S	6°	10.5	8.4	light green	4.3
08.815.232S	6°	12.0	9.9	blue	4.9
08.815.233S	6°	13.5	11.4	gold	5.5
08.815.234S	6°	15.0	12.9	dark blue	6.1
08.815.235S	6°	17.0	14.9	purple	6.8
08.815.236S	6°	19.0	16.9	green	7.6
08.815.241S	10°	10.5	6.4	light green	3.7
08.815.242S	10°	12.0	7.9	blue	4.3
08.815.243S	10°	13.5	9.4	gold	4.9
08.815.244S	10°	15.0	10.9	dark blue	5.5
08.815.245S	10°	17.0	12.9	purple	6.3
08.815.246S	10°	19.0	14.9	green	7.0
08.815.252S	14°	12.0	6.0	blue	3.8
08.815.253S	14°	13.5	7.5	gold	4.3
08.815.254S	14°	15.0	9.0	dark blue	4.9
08.815.255S	14°	17.0	11.0	purple	5.7
08.815.256S	14°	19.0	13.0	green	6.5
08.815.273S	18°	13.5	5.5	gold	3.8
08.815.274S	18°	15.0	7.0	dark blue	4.4
08.815.275S	18°	17.0	9.0	purple	5.2
08.815.276S	18°	19.0	11.0	green	6.0

SYNFIX Evolution Spacer, large



Article Number	Angle	Anterior Height (mm)	Posterior Height (mm)	Color of Implant Plate/ Trial implants	Cage Filling Volume (cc)
08.815.301S	6°	10.5	8.1	light green	3.9
08.815.302S	6°	12.0	9.6	blue	4.4
08.815.303S	6°	13.5	11.1	gold	5.0
08.815.304S	6°	15.0	12.6	dark blue	5.6
08.815.305S	6°	17.0	14.6	purple	6.3
08.815.306S	6°	19.0	16.6	green	7.1
08.815.311S	10°	10.5	5.9	light green	3.2
08.815.312S	10°	12.0	7.4	blue	3.8
08.815.313S	10°	13.5	8.9	gold	4.4
08.815.314S	10°	15.0	10.4	dark blue	4.9
08.815.315S	10°	17.0	12.4	purple	5.7
08.815.316S	10°	19.0	14.4	green	6.4
08.815.322S	14°	12.0	5.2	blue	3.3
08.815.323S	14°	13.5	6.7	gold	3.8
08.815.324S	14°	15.0	8.2	dark blue	4.4
08.815.325S	14°	17.0	10.2	purple	5.1
08.815.326S	14°	19.0	12.2	green	5.9
08.815.363S	18°	13.5	4.5	gold	3.3
08.815.364S	18°	15.0	6.0	dark blue	3.9
08.815.365S	18°	17.0	8.0	purple	4.6
08.815.366S	18°	19.0	10.0	green	5.4

SYNFIX Evolution Spacer, large, deep



Article Number	Angle	Anterior Height (mm)	Posterior Height (mm)	Color of Implant Plate/ Trial implants	Cage Filling Volume (cc)
08.815.331S	6°	10.5	8.1	light green	4.9
08.815.332S	6°	12.0	9.6	blue	5.6
08.815.333S	6°	13.5	11.1	gold	6.3
08.815.334S	6°	15.0	12.6	dark blue	7.0
08.815.335S	6°	17.0	14.6	purple	7.9
08.815.336S	6°	19.0	16.6	green	8.8
08.815.341S	10°	10.5	5.9	light green	4.1
08.815.342S	10°	12.0	7.4	blue	4.8
08.815.343S	10°	13.5	8.9	gold	5.5
08.815.344S	10°	15.0	10.4	dark blue	6.2
08.815.345S	10°	17.0	12.4	purple	7.1
08.815.346S	10°	19.0	14.4	green	8.0
08.815.352S	14°	12.0	5.4	blue	4.2
08.815.353S	14°	13.5	6.9	gold	4.8
08.815.354S	14°	15.0	8.4	dark blue	5.5
08.815.355S	14°	17.0	10.4	purple	6.4
08.815.356S	14°	19.0	12.4	green	7.3
08.815.373S	18°	13.5	4.7	gold	4.2
08.815.374S	18°	15.0	6.2	dark blue	4.9
08.815.375S	18°	17.0	8.2	purple	5.8
08.815.376S	18°	19.0	10.2	green	6.7

SCREWS

SYNFIX Evolution Locking Screw, with fine tip

- Self-tapping, double lead design
- Titanium alloy (Ti-6Al-7Nb)
- ∅ 4 mm Diameter
- Designed to support penetration of dense sclerotic bone
- 2 units per package

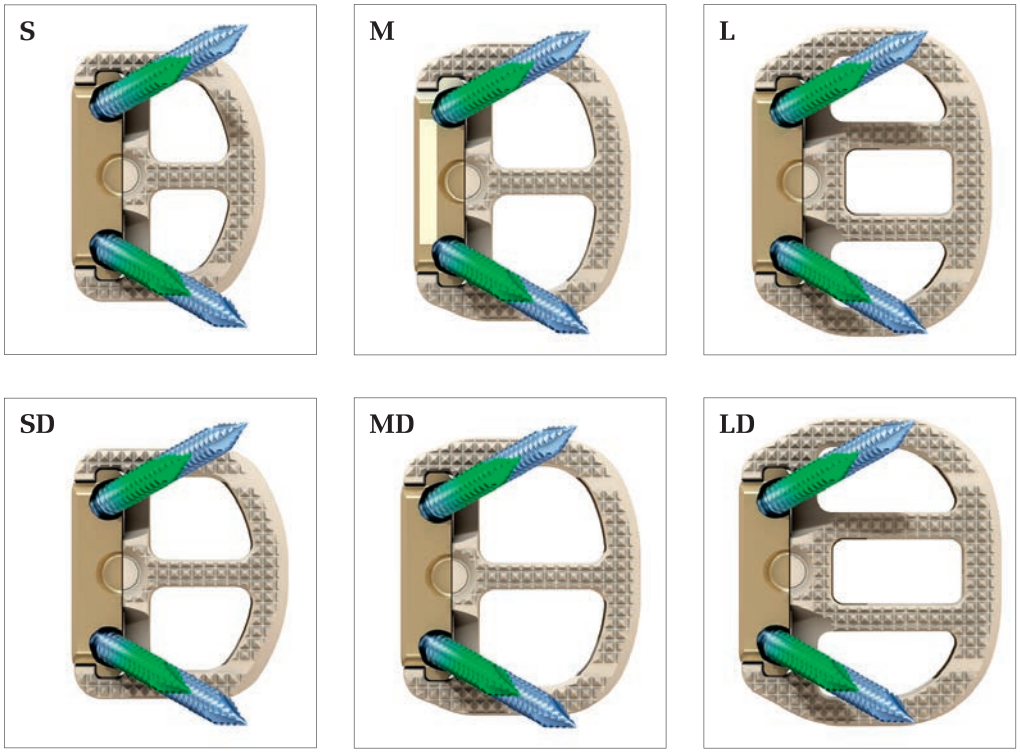
Article Nr	Description
04.835.120.02S	SYNFIX Evolution Locking Screw, with fine tip, 20 mm, pack of 2 units, sterile
04.835.125.02S	SYNFIX Evolution Locking Screw, with fine tip, 25 mm, pack of 2 units, sterile
04.835.130.02S	SYNFIX Evolution Locking Screw, with fine tip, 30 mm, pack of 2 units, sterile

SYNFIX Evolution Locking Screws, with blunt tip

- Self-tapping, double lead design
- Titanium alloy (Ti-6Al-7Nb)
- ∅ 4 mm Diameter
- 2 units per package

Article Nr	Description
04.835.220.02S	SYNFIX Evolution Locking Screw, 20 mm, pack of 2 units, sterile
04.835.225.02S	SYNFIX Evolution Locking Screw, 25 mm, pack of 2 units, sterile
04.835.230.02S	SYNFIX Evolution Locking Screw, 30 mm, pack of 2 units, sterile

Axial view of shortest and longest screw length for all prints



TRIALS

Standard Trials

Article Number	Description
03.835.101–106	SYNFIX Evolution Trial Implant, small, height 10.5–19 mm, 6°
03.835.111–116	SYNFIX Evolution Trial Implant, small, height 10.5–19 mm, 10°
03.835.122–126	SYNFIX Evolution Trial Implant, small, height 12–19 mm, 14°
03.835.163–166	SYNFIX Evolution Trial Implant, small, height 13.5–19 mm, 18°

03.835.201–206	SYNFIX Evolution Trial Implant, medium, height 10.5–19 mm, 6°
03.835.211–216	SYNFIX Evolution Trial Implant, medium, height 10.5–19 mm, 10°
03.835.222–226	SYNFIX Evolution Trial Implant, medium, height 12–19 mm, 14°
03.835.263–266	SYNFIX Evolution Trial Implant, medium, height 13.5–19 mm, 18°

03.835.301–306	SYNFIX Evolution Trial Implant, large, height 10.5–19 mm, 6°
03.835.311–316	SYNFIX Evolution Trial Implant, large, height 10.5–19 mm, 10°
03.835.322–326	SYNFIX Evolution Trial Implant, large, height 12–19 mm, 14°
03.835.363–366	SYNFIX Evolution Trial Implant, large, height 13.5–19 mm, 18°

Deep Trials (optional)

Article Number	Description
03.835.131–136	SYNFIX Evolution Trial Implant, small, deep, height 10.5–19 mm, 6°
03.835.141–146	SYNFIX Evolution Trial Implant, small, deep, height 10.5–19 mm, 10°
03.835.152–156	SYNFIX Evolution Trial Implant, small, deep, height 12–19 mm, 14°
03.835.173–176	SYNFIX Evolution Trial Implant, small, deep, height 13.5–19 mm, 18°

03.835.231–236	SYNFIX Evolution Trial Implant, medium, deep, height 10.5–19 mm, 6°
03.835.241–246	SYNFIX Evolution Trial Implant, medium, deep, height 10.5–19 mm, 10°
03.835.252–256	SYNFIX Evolution Trial Implant, medium, deep, height 12–19 mm, 14°
03.835.273–276	SYNFIX Evolution Trial Implant, medium, deep, height 13.5–19 mm, 18°

03.835.331–336	SYNFIX Evolution Trial Implant, large, deep, height 10.5–19 mm, 6°
03.835.341–346	SYNFIX Evolution Trial Implant, large, deep, height 10.5–19 mm, 10°
03.835.352–356	SYNFIX Evolution Trial Implant, large, deep, height 12–19 mm, 14°
03.835.373–376	SYNFIX Evolution Trial Implant, large, deep, height 13.5–19 mm, 18°

STANDARD

03.835.100	SYNFIX Evolution Trial Implant Holder	
03.825.002	SynCage Evolution Spindle	
03.815.023	Evolution Graft Packing Tamp, round	
03.815.024	Evolution Graft Packing Tamp, oval	
03.815.010	SYNFIX Evolution Trial, for Footprint small and small deep	
03.815.011	SYNFIX Evolution Trial, for Footprint medium and medium deep	
03.815.012	SYNFIX Evolution Trial, for Footprint large and large deep	
03.835.001	SYNFIX Evolution Aiming Device, 10.5 mm and 12 mm	
03.835.002	SYNFIX Evolution Aiming Device, 13.5 mm and 15 mm	
03.835.003	SYNFIX Evolution Aiming Device, 17 mm and 19 mm	

03.835.004	SYNFIX Evolution Aiming Device Holder	
03.835.005	Coupling for Aiming Device Holder SYNFIX Evolution	
03.835.006	Coupling Screw for SYNFIX Evolution Aiming Device	
03.835.009S	SYNFIX Evolution Thread Lock Sleeve, sterile	
03.835.010	SYNFIX Evolution Screwdriver	
03.835.013	SYNFIX Evolution Screwdriver, without Thread Lock Sleeve	
03.835.015	SYNFIX Evolution Screwdriver, straight, without Thread Lock Sleeve	
03.835.012S	SYNFIX Evolution Protection Sleeve for Screwdriver and Awl, pack of 3 units, sterile	

388.396	Handle with Quick Coupling, small	
03.688.505	Handle with Ratchet Wrench for Quick Coupling, small	
03.632.204	Torque-limiting Handle, 3 Nm	
03.835.043	Torque-limiting Handle, straight with Ratchet Wrench, 3 Nm	
03.835.032	SYNFIX Evolution Awl	
03.835.049	Loading Station for Screws for SYNFIX Evolution	
03.835.050	SYNFIX Evolution, Packing Block for Implants	
03.835.060	SYNFIX Evolution Soft Tissue Retractor	

03.835.070	SYNFIX Evolution, Removal Tool for Implants, 10.5 mm and 12 mm	
03.835.071	SYNFIX Evolution, Removal Tool for Implants, 13.5 mm and 15 mm	
03.835.072	SYNFIX Evolution, Removal Tool for Implants, 17 mm and 19 mm	
03.802.038	Tweezers for SynFix-LR	
SFW550R	Prodisc-L Spreader	
SFW650R	Prodisc-L Spreader Forceps, curved	
SFW691R	Prodisc-L Combined Hammer	

EVOLUTION SQUID INSERTER/DISTRACTOR

Modular Tray

68.825.005	Vario Case for Evolution SQUID

Instruments

03.815.030	Evolution SQUID, Synthes Quick Inserter and Distractor	
03.825.106	T-Handle, with Hexagonal Coupling, for Posterior Release Tool and Evolution SQUID	
03.835.035	Evolution SQUID, Push Block for SYNFIX Evolution, Flush, 0 mm	
03.835.036	Evolution SQUID, Push Block for SYNFIX Evolution, Proud, 3 mm	
03.835.037	Evolution SQUID, Push Block for SYNFIX Evolution, Proud, 6 mm	
03.815.029	Evolution SQUID, Assembly/Disassembly Tool	

SYNFIX EVOLUTION SET, COMPLETE (01.835.004)

Outer Vario Cases

689.510	Vario Case, Framing, size 1/1, height 88 mm
689.511	Vario Case, Framing, size 1/1, height 126 mm
689.514	Vario Case, Framing, size 1/2, height 67 mm
689.515	Vario Case, Framing, size 1/2, height 88 mm
689.516	Vario Case, Framing, size 1/2, height 126 mm
689.507	Lid (Stainless Steel), size 1/1, for Vario Case
689.537	Lid (Stainless Steel), size 1/2, for Vario Case

Modular Tray

68.835.001	Tray, for Instruments for Trial Implants and Implant Preparation, for SYNFIX Evolution, with Lid, without Contents

Instruments

03.835.100	SYNFIX Evolution Trial Implant Holder
03.825.002	SynCage Evolution Spindle
03.815.023	Evolution Graft Packing Tamp, round
03.815.024	Evolution Graft Packing Tamp, oval
03.815.010	SYNFIX Evolution Trial, for Footprint small and small deep
03.815.011	SYNFIX Evolution Trial, for Footprint medium and medium deep
03.815.012	SYNFIX Evolution Trial, for Footprint large and large deep
03.835.050	SYNFIX Evolution, Packing Block for Implants

03.835.070	SYNFIX Evolution, Removal Tool for Implants, 10.5 mm and 12 mm
03.835.071	SYNFIX Evolution, Removal Tool for Implants, 13.5 mm and 15 mm
03.835.072	SYNFIX Evolution, Removal Tool for Implants, 17 mm and 19 mm

Modular Tray

68.835.002	Tray, for Instruments for Implant Insertion, for SYNFIX Evolution, with Lid, without Contents

Instruments

03.835.001	SYNFIX Evolution Aiming Device, 10.5 mm and 12 mm
03.835.002	SYNFIX Evolution Aiming Device, 13.5 mm and 15 mm
03.835.003	SYNFIX Evolution Aiming Device, 17 mm and 19 mm
03.835.004	SYNFIX Evolution Aiming Device Holder
03.835.005	Coupling for Aiming Device Holder SYNFIX Evolution
03.835.006	Coupling Screw for SYNFIX Evolution Aiming Device
03.835.060	SYNFIX Evolution Soft Tissue Retractor

Modular Tray

68.835.003	Tray, f/Instruments, f/Screw Insertion f/ SYNFIX Evolution, w/Lid, w/o Contents

Instruments

03.835.010	SYNFIX Evolution Screwdriver
03.835.013	SYNFIX Evolution Screwdriver, without Thread Lock Sleeve
03.835.015	SYNFIX Evolution Screwdriver, straight, without Thread Lock Sleeve
03.688.505	Handle with Ratchet Wrench for Quick Coupling, small
388.396	Handle with Quick Coupling, small
03.835.032	SYNFIX Evolution Awl
03.835.049	Loading Station for Screws for SYNFIX Evolution
03.802.038	Tweezers for SynFix-LR
03.632.204	Torque-limiting Handle, 3 Nm
03.835.043	Torque-limiting Handle, straight with Ratchet Wrench, 3 Nm

Modular Tray

68.835.004	Tray, for General Instruments, for SYNFIX Evolution, with Lid, without Contents

Instruments

SFW550R	Prodisc-L Spreader
SFW650R	Prodisc-L Spreader Forceps, curved
SFW691R	Prodisc-L Combined Hammer

Modular Trays for Trials

68.835.005	Tray, for Trial Implants small, for SYNFIX Evolution, with Lid, without Contents
68.835.006	Tray, for Trial Implants small, deep, for SYNFIX Evolution, with Lid, without Contents
68.835.007	Tray, for Trial Implants medium, for SYNFIX Evolution, with Lid, without Contents
68.835.008	Tray, for Trial Implants medium, deep, for SYNFIX Evolution, with Lid, without Contents
68.835.009	Tray, for Trial Implants large, for SYNFIX Evolution, with Lid, without Contents
68.835.010	Tray, for Trial Implants large, deep, for SYNFIX Evolution, with Lid, without Contents

Trials
See page 73.

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