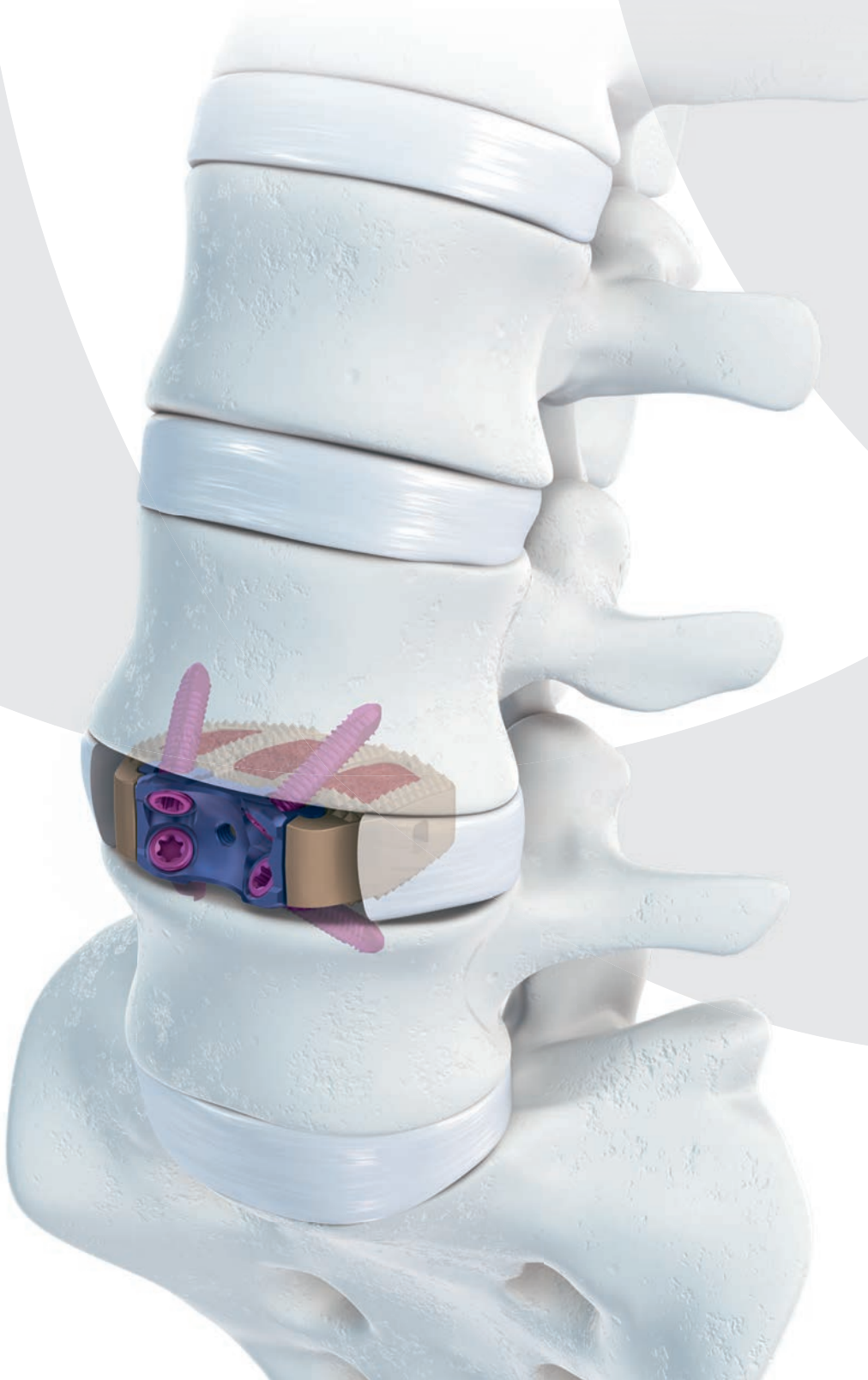
Instruments and implants for stand-alone anterior lumbar interbody fusion (ALIF)

SynFix-LR System

Surgical Technique



DePuy Synthes

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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.depuysynthes.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.depuysynthes.com/hcp/reprocessing-care-maintenance

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SynFix-LR Implants

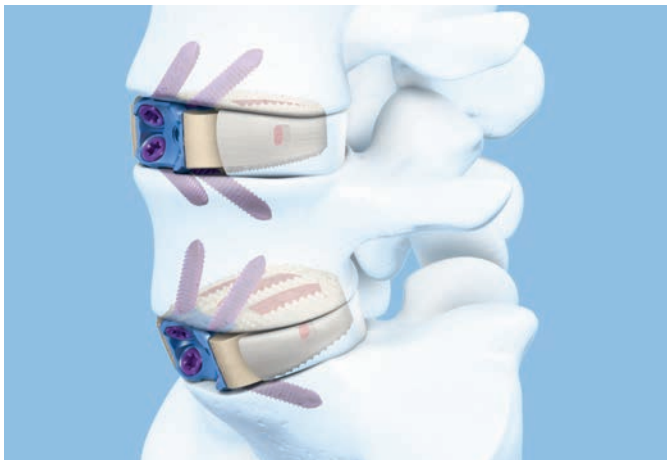
The SynFix-LR implant is a stand-alone ALIF device that incorporates the benefits of an anterior fixation plate and a radiolucent interbody spacer. The design creates a zero profile construct and includes four locking screws that is designed to provide anterior fixation and stability.

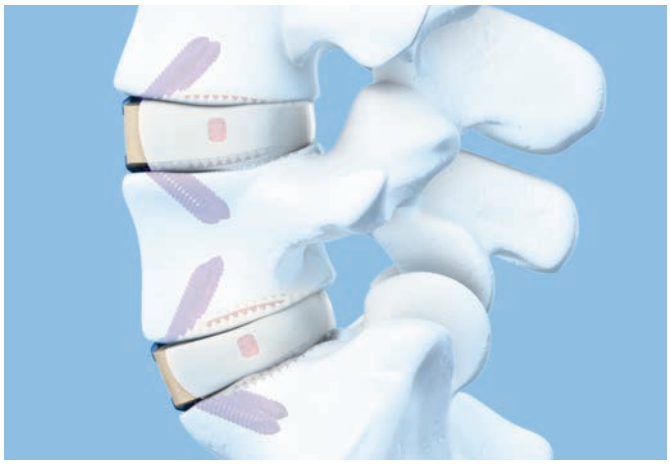
Stand-alone ALIF

- Biomechanically equivalent to a spacer with pedicle screws.[1]*
- PEEK spacer is designed to provide modulus of elasticity similar to cortical bone.
- Titanium plate with locking screws is designed to provide stable fixation.

Zero-profile construct

- Spacer and fixation plate fit completely within the disc space.



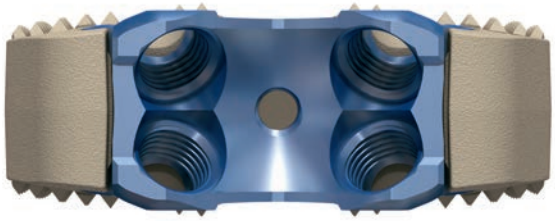


[1] See Cain et al. 2005

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

Anatomic shape

- The SynFix-LR is convex to match the anatomy of the disc space.
- Two footprints and two angles are offered to accommodate individual patient anatomy.

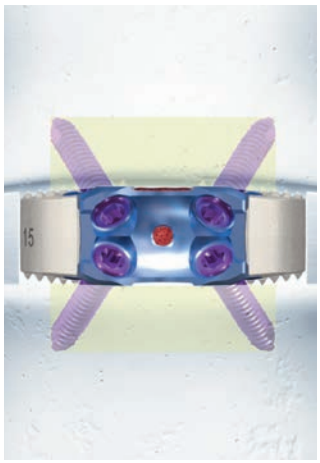


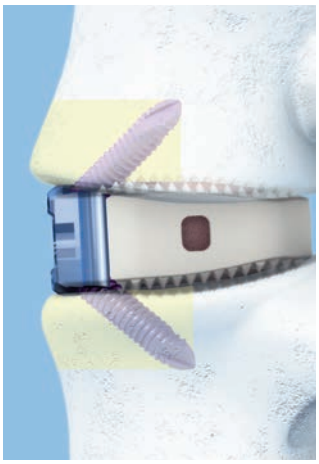
Titanium plate material:
Titanium alloy (TiAl6Nb7)

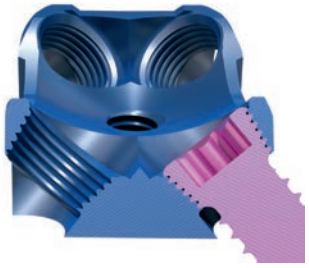
PEEK spacer material:
PEEK (polyetheretherketone)

Screw and plate fixation

- One-step conical locking mechanism is designed to ensure screws securely lock to plate and eliminates the need for a blocking plate.
- Locking screws is designed to provide stability and load transfer near the cortex of the vertebral body.
- Four locking screws diverge to form a fixed-angle construct that creates a wedge of bone (highlighted in yellow) for fixation.
- Self-tapping cortical threads allow largest possible core diameter for enhanced fixation.







Double-lead locking threads mate with threaded portion of plate

Titanium screw material:
Titanium alloy (TiAl6Nb7)

SynFix-LR System. Instruments and implants for stand-alone anterior lumbar interbody fusion (ALIF).

Instruments for insertion of the implant

Option A:

Quick inserter (SQUID)
The SynFix SQUID inserts in one simple step, without impaction.

Option B:

Implant holder and distractor
For the insertion of the implant while distraction is maintained.

Instruments for insertion of the screws

Standard instruments option A:

Awl with cardan joint
Penetrates the cortical rim for subsequent screw insertion.

Tweezers
For guiding awl and screwdriver into the aiming device.

Aiming device holder with implant coupling
For insertion of the aiming device. Easily removable to facilitate access for screw insertion.

Aiming device
Designed for precise positioning of the locking head screws.

Screwdriver with cardan joint

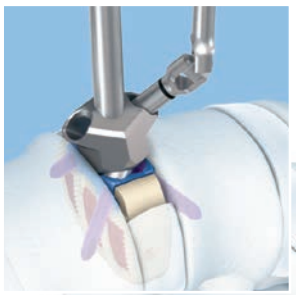
Opening of the cortical bone for screw insertion

Mini-open instruments option B:

Aiming device mini-open with fixed handle
Designed for precise positioning of the locking screws.

Awl for SynFix-LR mini-open
Penetrates the cortical rim for subsequent screw insertion.

Screwdriver for SynFix-LR mini-open with cardan joint

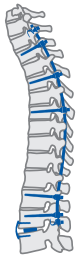


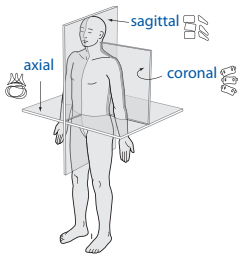
Opening of the cortical bone for screw insertion

AO Principles

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

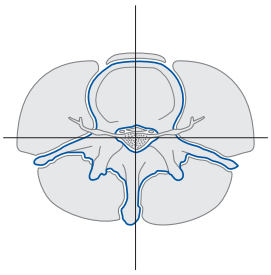
Stability
Stabilization to achieve a specific therapeutic outcome

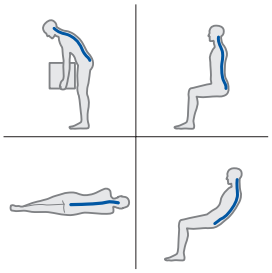




Alignment
Balancing the spine in three dimensions

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

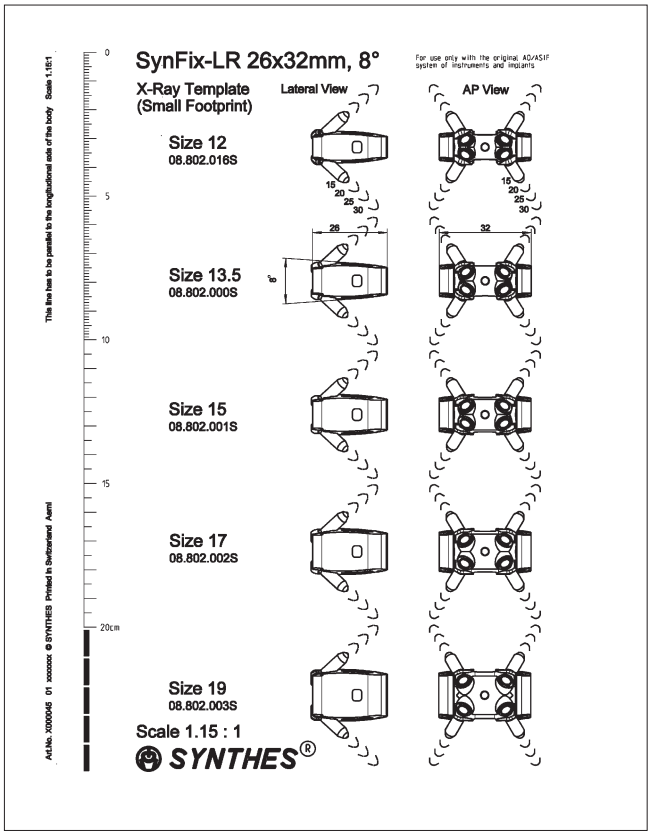
Indications
Lumbar and lumbosacral pathologies which may require anterior segmental arthrodesis, including:
- Localised symptomatic degenerative disc disease
- Revision surgery for failed decompression syndrome
- Pseudoarthrosis

Contraindications
- Spinal fractures
- Spinal tumor
- Osteoporosis
- Infection

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

1. Preoperative planning

Instruments	
X000045	X-ray Template for SynFix-LR, 26 × 32 mm, 8°
X000046	X-ray Template for SynFix-LR, 26 × 32 mm, 12°
X000047	X-ray Template for SynFix-LR, 30 × 38 mm, 8°
X000048	X-ray Template for SynFix-LR, 30 × 38 mm, 12°



Determine the approximate implant size by comparing the SynFix-LR X-ray template with a lateral radiograph of the patient's adjacent intervertebral discs.

Notes:

- **The height indicated on the template is approximately 1 mm lower than that of the actual spacer to account for penetration of the teeth into the vertebral endplate.**
- **It is recommended to select the maximum implant size, to enhance the stability of the segment through tension in the longitudinal ligaments.**

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

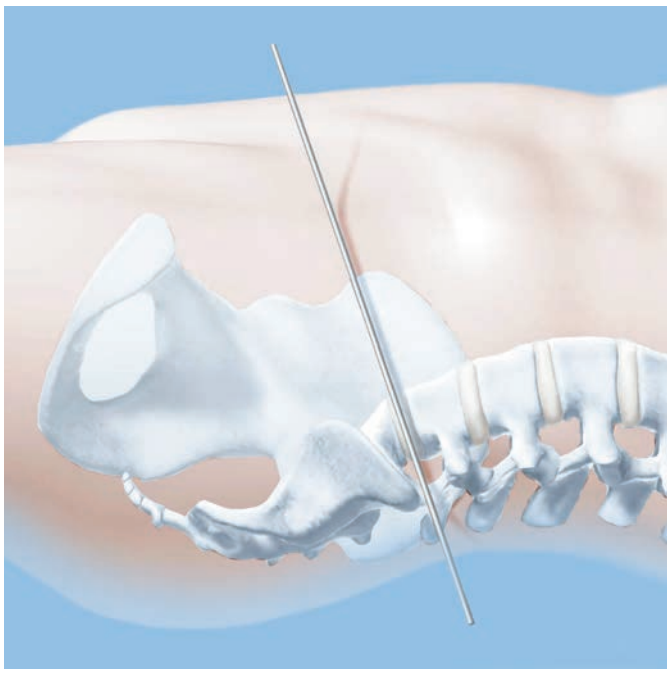
Recommended set	
01.609.102	Set SynFrame RL, lumbar
187.310	SynFrame Basic System in Vario Case

The surgical approach depends on the level to be treated.

Locate the correct operative disc level and incision location by taking a lateral fluoroscopic view while holding a straight metal instrument at the side of the patient. This ensures that the incision and exposure will allow direct visualization into the disc space.

Expose the operative disc level through a standard retroperitoneal approach. A mini-open retroperitoneal approach can be used if SynFix mini-open instruments will be used (see page 47).

Note: **If a retraction system such as the SynFrame is used, pay attention to the positioning of soft tissue or Hohmann retractors as they may interfere with the screw insertion.**



3. Exposure

The locking head screws of the SynFix-LR must be inserted from a direct anterior approach. Expose the intervertebral disc such that there is sufficient space on either side of the vertebral midline, equal to half the width of the SynFix-LR. This enables the insertion of the implant without interference from adjacent soft tissue structures (major vessels, peritoneum etc.).

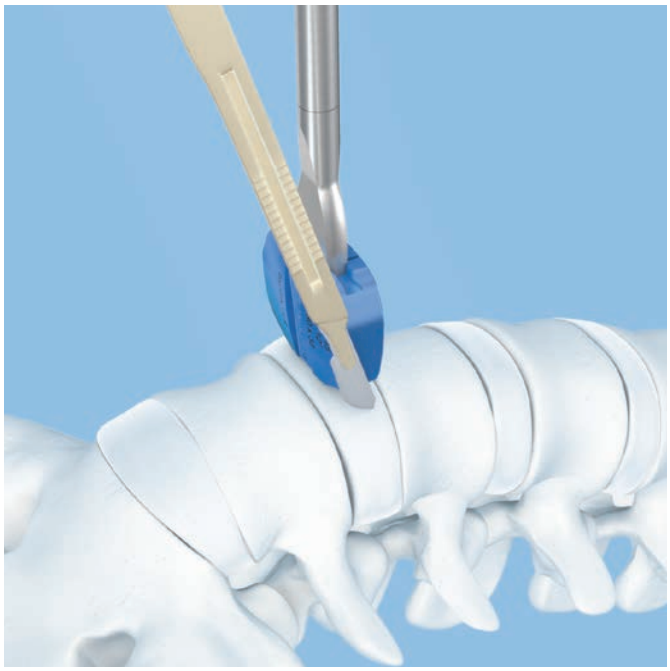
Once the spacer has been inserted, visualization of the entire anterior fixation plate is necessary for insertion of the locking head screws.

1. Cut anterior window

Cut a rectangular window the width of the SynFix-LR into the anterior longitudinal ligament and annulus fibrosus.

A trial implant (see page 42) may be used as a template to indicate the width of the window.

Retain as much of the antero-lateral, lateral and posterior annulus as possible in order to provide the necessary stability of the instrumented segment.



2. Prepare disc space

Recommended set	
01.600.100	Proprep Set

Excise the disc material and remove the cartilaginous endplates to expose the underlying bony vertebral endplates.

Adequate clearance of the endplates is important to enable the provision of a vascular supply to the bone graft. Excessive clearance or use of a rasp may, however, weaken the endplate and result in subsidence of the spacer.

Once the endplates have been prepared, complete eventual additional surgical procedures (i.e. removal of a disc fragment from the spinal canal).

Notes:

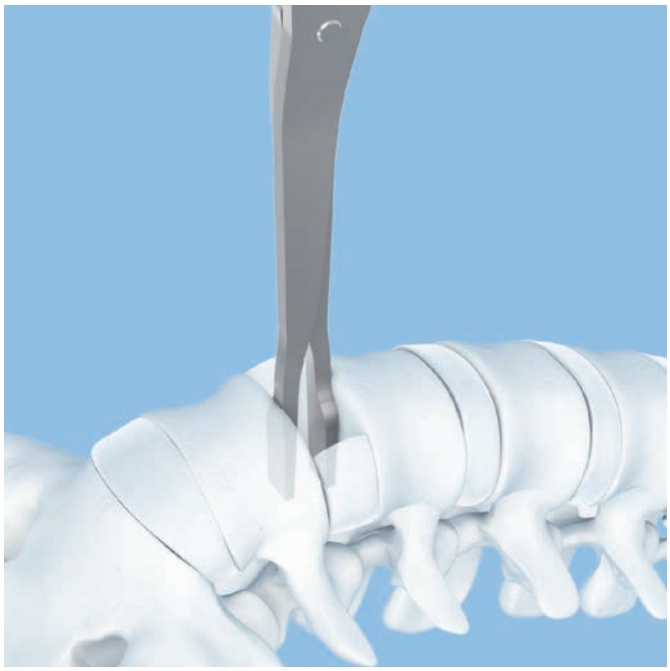
- **It is essential that the nucleus and the inner annulus are removed to prevent displacement of disc material into the spinal canal during spacer insertion and interference with bone in-growth.**
- **Excessive removal of subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.**

3. Distract segment

Instrument	
SFW650R	Prodisc-L Spreader Forceps, curved
Optional instrument	
SFW550R	Prodisc-L Spreader

To reduce risk of injury during placement, verify spreader position with the help of an intraoperative lateral X-ray.

Distraction of the segment is essential for restoration of disc height, opening of the neural foramina and initial stability of the SynFix-LR.

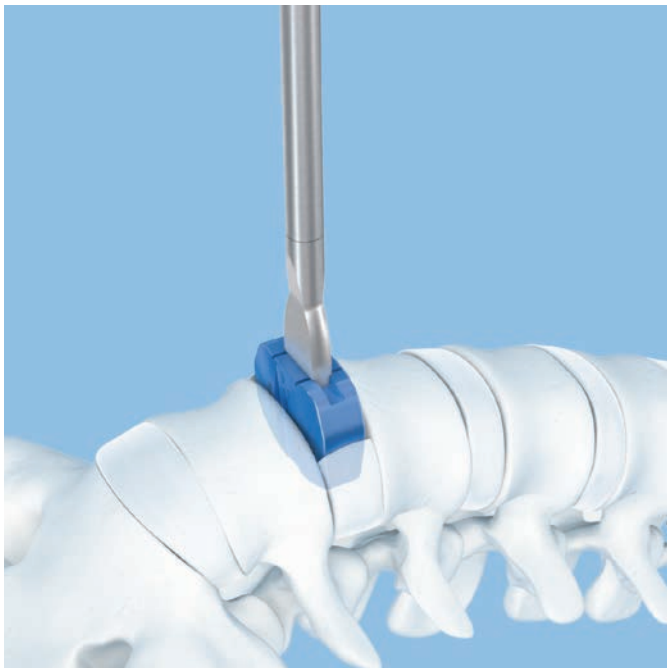


4. Trial for implant size

Instruments	
03.802.000 – 03.802.019	SynFix-LR Trial Implants
397.034	Handle for SynCage Trial Implants, straight
Optional instrument	
397.113	Distractor, anterior, for SynCage-LR

Select the trial implant that corresponds with the SynFix-LR size determined during the preoperative planning. Attach it to the handle for trial implants. The handle must be tightened firmly to prevent loosening of the trial implant.

Note: **Trials /Implants are color coded according to their size (height).**

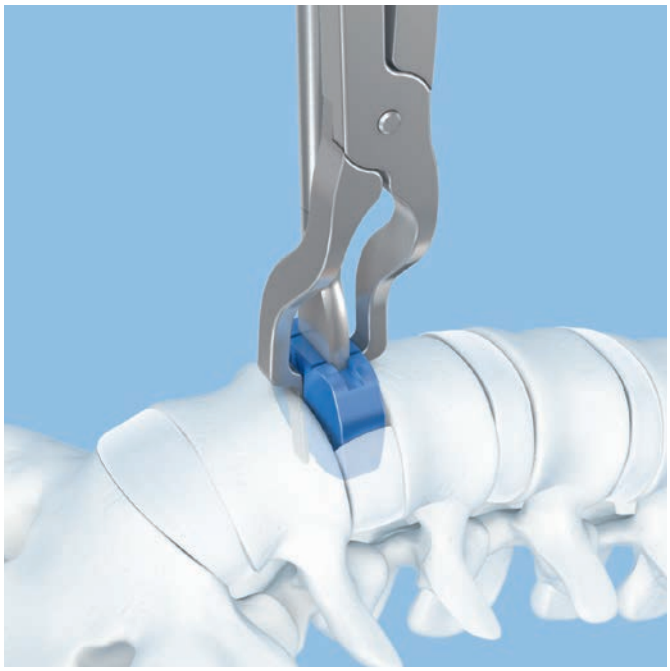


Controlled and light hammering on the handle for trial implants may be required to advance the trial implant into the disc space. If a tight fit is not achieved, repeat the process using larger trial implants. If the trial implant cannot be inserted, repeat using smaller trial implants.

Alternatively, a distractor may be used to assist with guiding the trial implant into the disc space. To ensure that the implant is inserted symmetrically into the disc space, the central line on the distractor blades should be aligned with the anterior midline of the vertebral bodies. Slide the trial implant between the distractor blades into the disc space.

With the segment fully distracted, the trial implant (and final implant) must fit firmly with a tight press-fit between the endplates so that the disc height is not lost once the distractor is removed.

The image intensifier may be used to check the position of the trial implant, restoration of disc and foraminal height and overall alignment before selecting the final SynFix-LR implant size.



Notes:

- **Markings on the trial implant indicate the entry points of the locking screws in the anterior aspect of the adjacent vertebrae.**
- **The distractor must be firmly held in place to prevent its ejection from the disc space and possible injury to adjacent structures.**
- **After impacting the trial spacer handle, it may be necessary to retighten the handle.**

Markings indicate the entry points of the locking screws

Selection and Packing of Implant

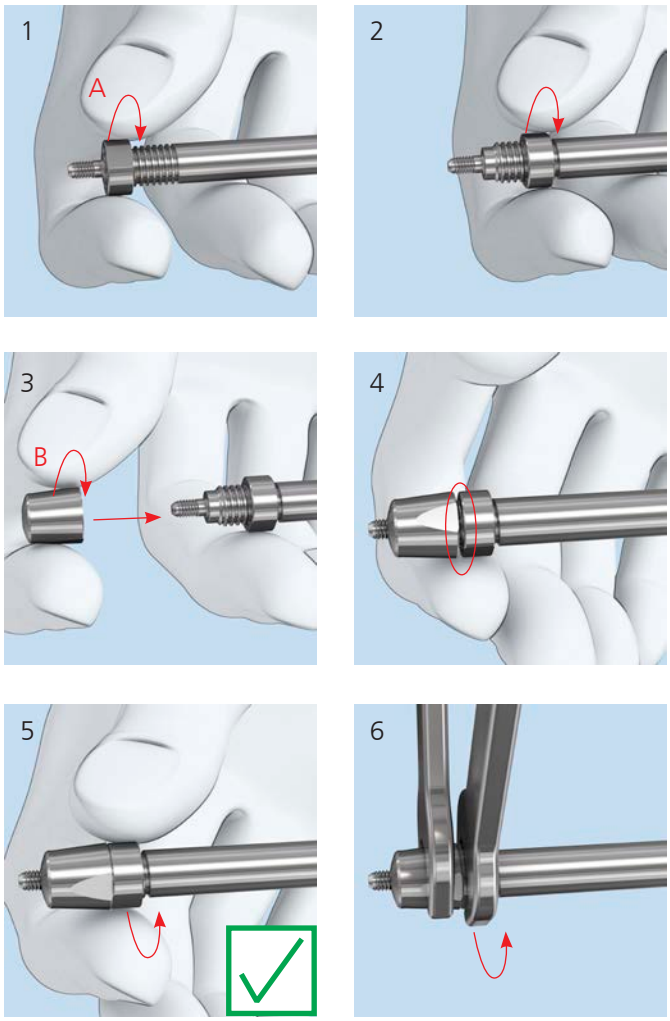
1. Implant Holder Assembly

Instrument	
03.802.039	Implant Holder for SynFix-LR

Before loading the SynFix-LR implant, ensure the implant holder is correctly assembled.

Screw the bolt (A) all the way down on the threaded portion of the holder (1, 2). Then screw the superior cap (B) all the way down (3). A gap will be apparent between the bolt and the cap (4), turn the bolt until this gap disappears (5).

Use the two wrenches to simultaneously hold the cap and counter-torque the bolt (6).



2. Select implant size

Instruments	
03.802.039	Implant Holder for SynFix-LR
E5211-3	Wrench Epoca, width across 10

Precaution: **Ensure the implant holder is correctly assembled and the cap and the bolt are counter-torqued using the two wrenches (see step 1 "Implant Holder Assembly" page 15 or "Disassembly and Assembly Instructions" pages 51-52).**

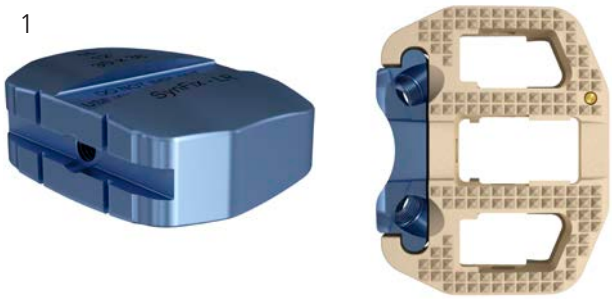
Select the final SynFix-LR implant corresponding to the trial implant size (1).

To facilitate selection of the final implant, trial implants are laser etched with the nominal height, lordotic angle and footprint of the implant. Trial implants, aiming guides and fixation plates are color-coded (see page 40).

Attach the selected implant two-finger tight to the implant holder (2).

Precaution: **Do not over-tighten the implant holder to the implant. Make sure the implant holder and the implant are aligned to each other and that no cross-threading occurs (3).**

1



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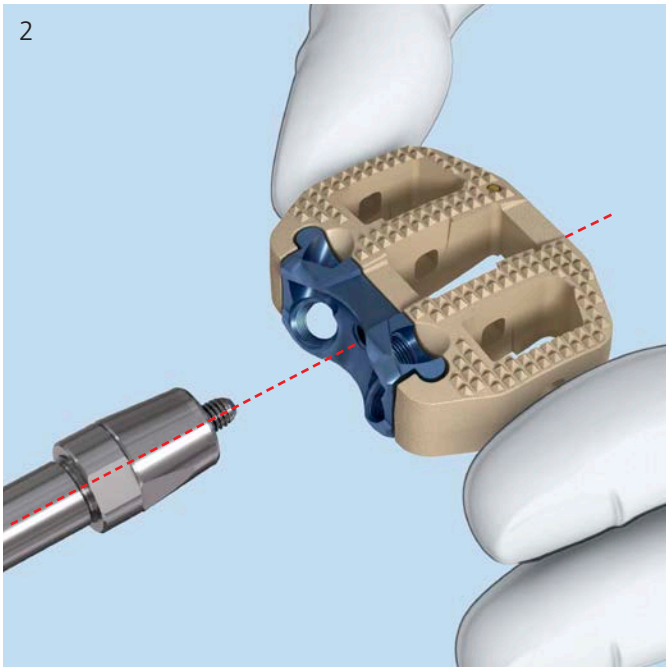

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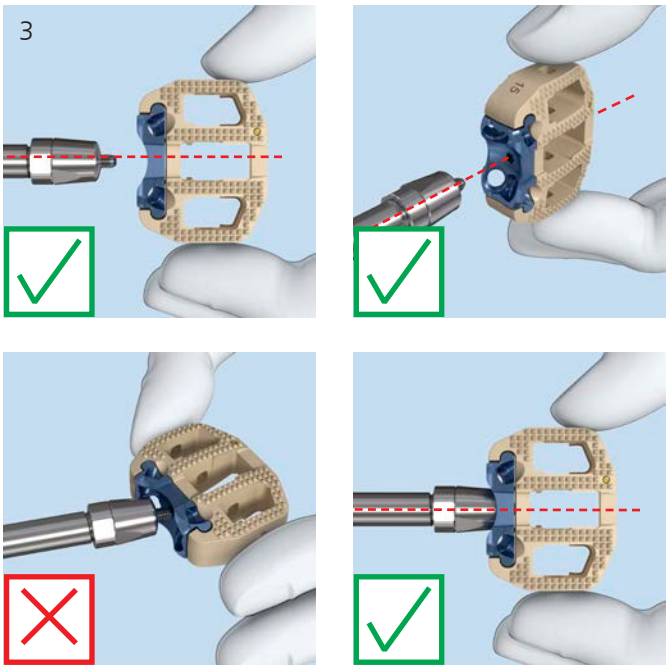
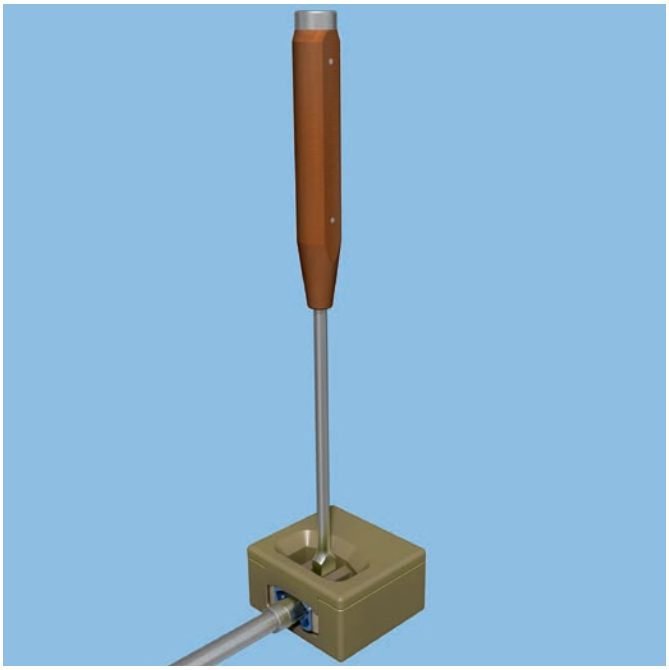


3. Pack implant with bone graft or bone substitution

Instruments	
03.802.041	Packing Block for SynFix-LR, 26 × 32 mm
03.802.042	Packing Block for SynFix-LR, 30 × 38 mm
389.288	Cancellous Bone Impactor, for Travios and Plivios, 8 × 2.5 mm
394.585	Cancellous Bone Impactor, 5.5 × 8.5 mm



After attaching the SynFix-LR to the implant holder, insert it into the appropriate packing block.

It is important to fill the spacer until the filling material protrudes from its perforations in order to ensure enhanced contact with the vertebral endplates.

Use a cancellous bone impactor to firmly pack the filling material into the implant cavities.

Notes:

- **The implant holder must be firmly attached to the fixation plate in order to avoid damage to either the implant holder or the plate.**
- **For more information about the filling material chronOS see page 48.**

Implant Insertion
Option A: SQUID

Instrument

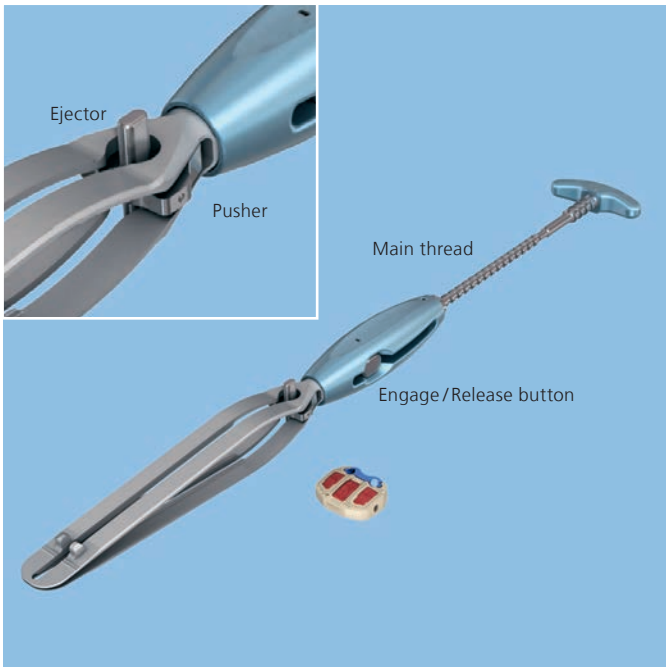
03.802.121	SQUID for SynFix-LR

1. Load the implant

Detach the implant from the implant holder.

Release the main thread of the SQUID by pushing the release button on the grip and slide the pusher fully back.

Place the instrument flat on the table to load the implant.

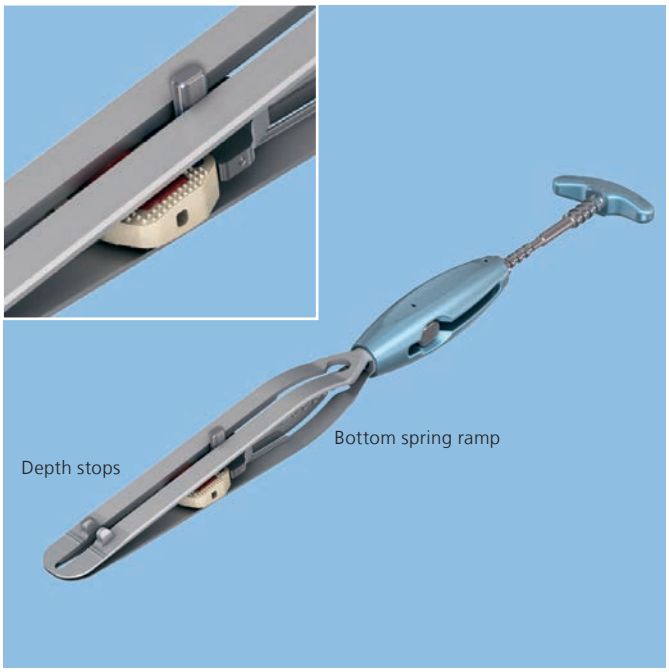


Place the implant onto the bottom spring ramp. Holding both sides of the implant, engage the grooves with the spring ramp guides and gently slide the implant forward until the implant is held without sliding back.

Slide the pusher up to the implant and engage the main thread by pressing the “engage” button.

The implant is now held securely in place and is ready for insertion.

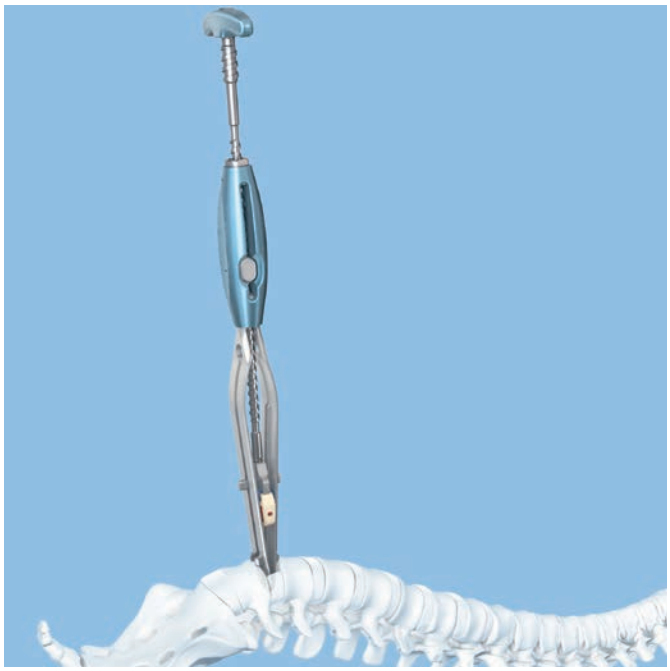
Note: **The tips of the inserter will be inserted into the disc space up to the depth stops on the spring ramps; to allow full insertion, the tips must not be spread apart.**



2. Insert the implant

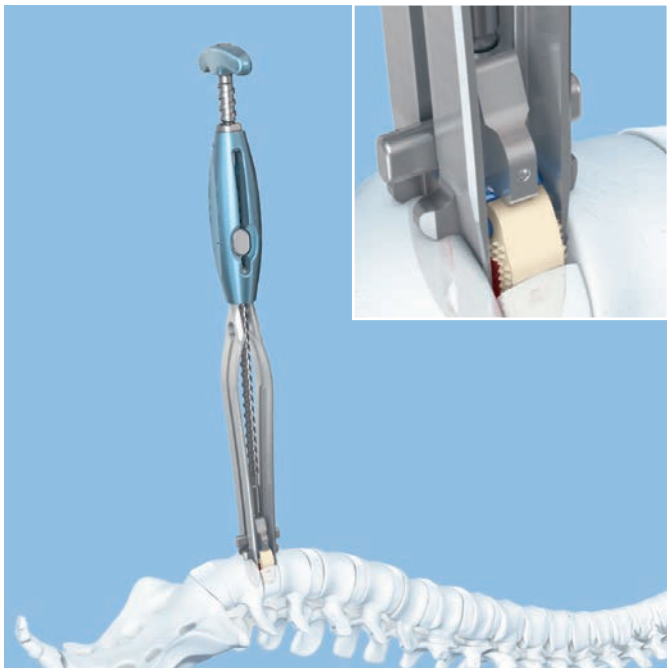
Place the tips of the instrument into the disc space so that the depth stops on the spring ramps touch the anterior rim of the vertebral body. The tips of the instrument are 26 mm deep and 30 mm wide. To ensure that the implant is inserted symmetrically into the disc space, the central line between the SQUID blades should be aligned with the anterior midline of the vertebral bodies.

With the main thread engaged, turn the T-handle on the SQUID to advance the implant down the spring ramps and into the disc space. The force required to turn the T-handle will increase as the implant advances down the spring ramps and the instrument elevates the disc space.



Continue turning the T-handle until the implant is fully ejected and released from the SQUID. An audible click, as the spring ramps spring back, confirms that the implant is seated and the instrument is fully ejected and released.

Note: **The pusher will be moving toward the vertebral body. Be aware of soft tissue and blood vessels that may be in the path of the pusher and ejector as they move toward and push against the vertebral bodies.**



3. Remove instruments

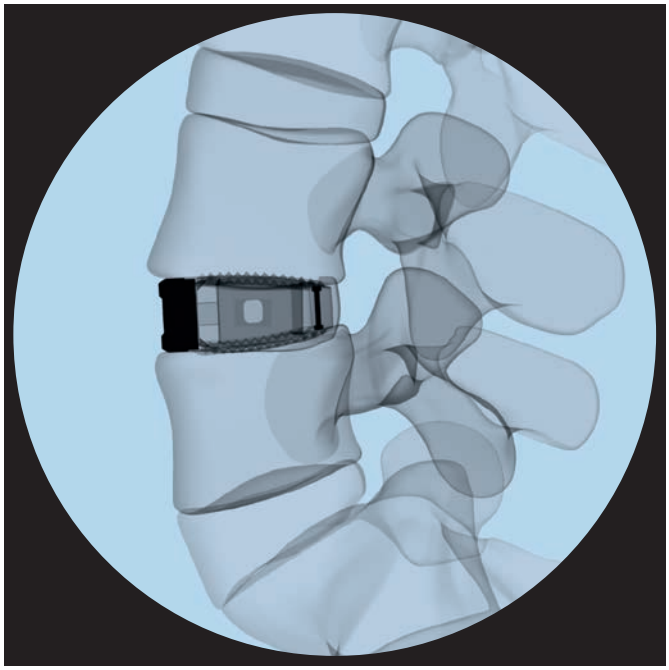
When the implant is correctly positioned, carefully remove the SQUID to reduce possible injury to adjacent structures.

Depending on the size of the vertebrae, the anterior edge of the implant will usually be 1 mm–3 mm recessed relative to the anterior aspect of the adjacent vertebrae.

4. Verify final implant position

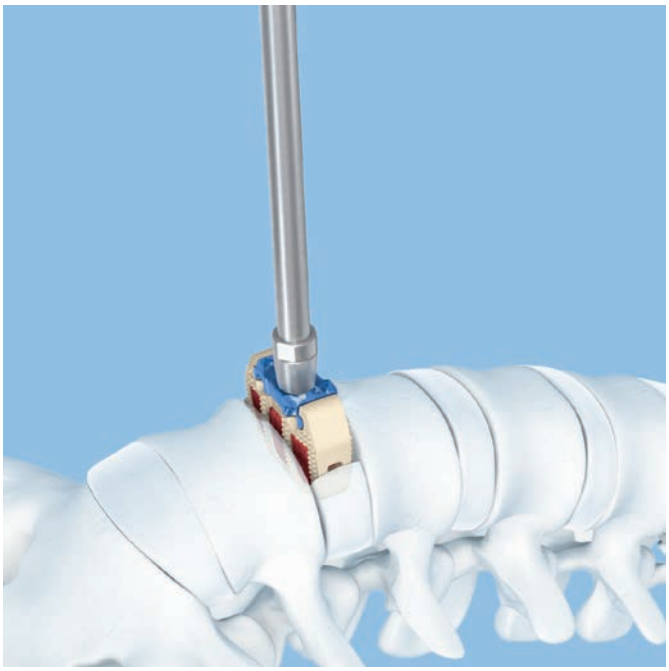
Verify final implant position with the help of an intraoperative lateral X-ray.

The titanium fixation plate and single posterior X-ray marker incorporated into the implant allow accurate intraoperative radiographic assessment of the position of the implant. The posterior X-ray marker is located approximately 3 mm from the posterior wall of the spacer.



Implant Insertion
Option B: Implant Holder

Instrument	
03.802.039	Implant Holder for SynFix-LR
Optional instrument	
397.113	Distractor, anterior, for SynCage-LR



1. Insert the implant

Insert the implant into the disc space.

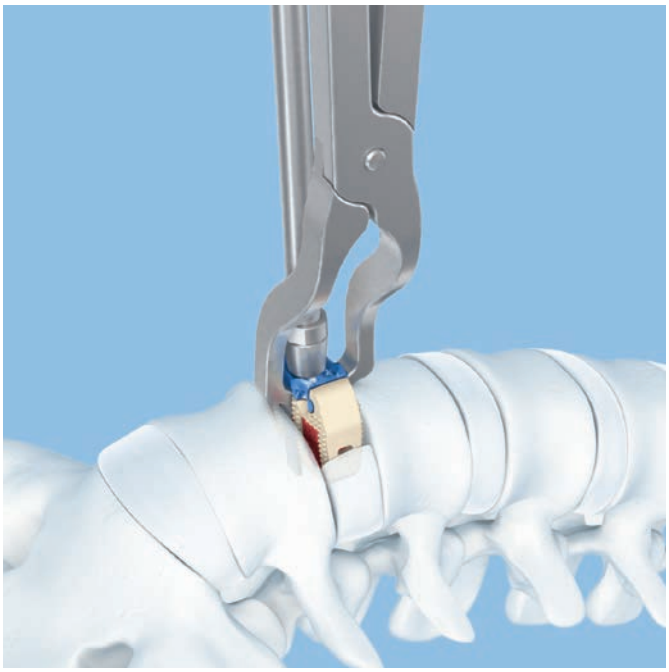
Precaution: **Ensure the implant holder remains tightened to the implant during the entire implant insertion procedure.**

Controlled and light hammering on the implant holder may be required to advance the implant into the disc space. The implant must fit firmly with a tight press-fit between the endplates.

Alternatively, a distractor can be used to assist with guiding the implant into the disc space. To ensure that the implant is inserted symmetrically into the disc space, the central line on the distractor blades should be aligned with the anterior midline of the vertebral bodies.

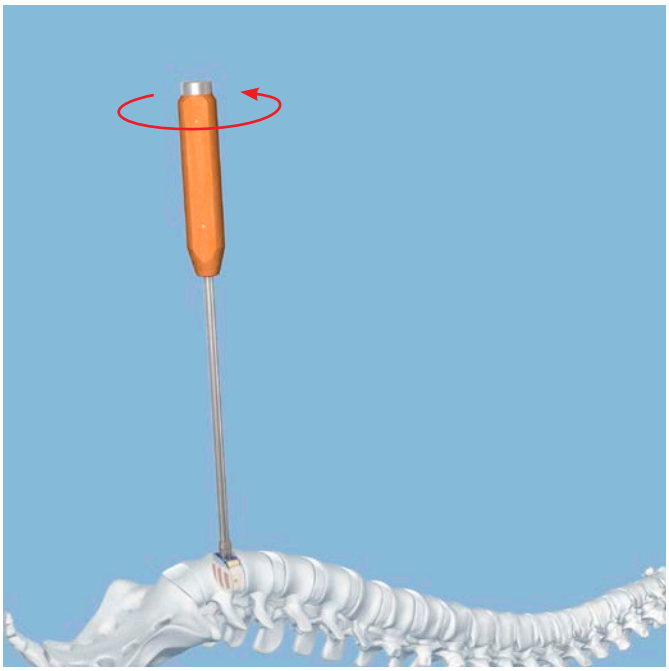
Slide the implant between the distractor blades and into the disc space.

The image intensifier may be used to check the implant position, restoration of disc and foraminal height, and overall alignment.



Note: **The distractor must be firmly held in place to prevent its ejection from the disc space and possible injury to adjacent structures.**

2. Remove instruments



When the implant is correctly positioned, if the optional distractor was used, loosen the locking nut on the distractor handle and release the distraction.
Gently remove the distractor while the implant holder holds the implant in position.
After the distractor is removed, ensure a secure fit by lightly hammering on the implant holder.

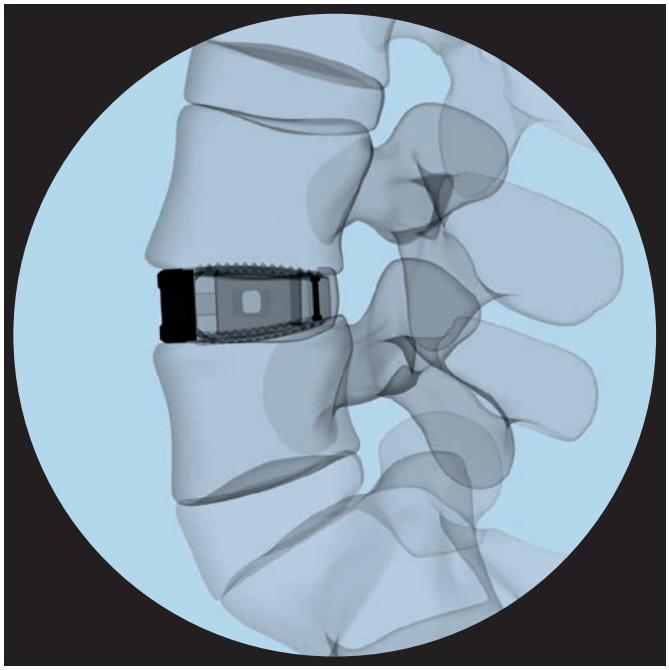
Precaution: **Ensure the implant holder remains tightened to the implant during the entire implant insertion procedure.**

Remove the implant holder by rotating the handle counterclockwise. The implant should now be in its optimal position.

Precaution: **If increased resistance is encountered during detachment, remove the implant holder with the implant attached. In case of a jammed connection between implant and implant holder detach the implant holder from the implant using one wrench to hold the cap while detaching the implant. Restart the implant insertion procedure with step 1 "Implant Holder Assembly" on page 15.**

Depending on the size of the vertebrae, the anterior edge of the implant will usually be 1 mm–3 mm recessed relative to the anterior aspect of the adjacent vertebrae.

3. Verify final implant position

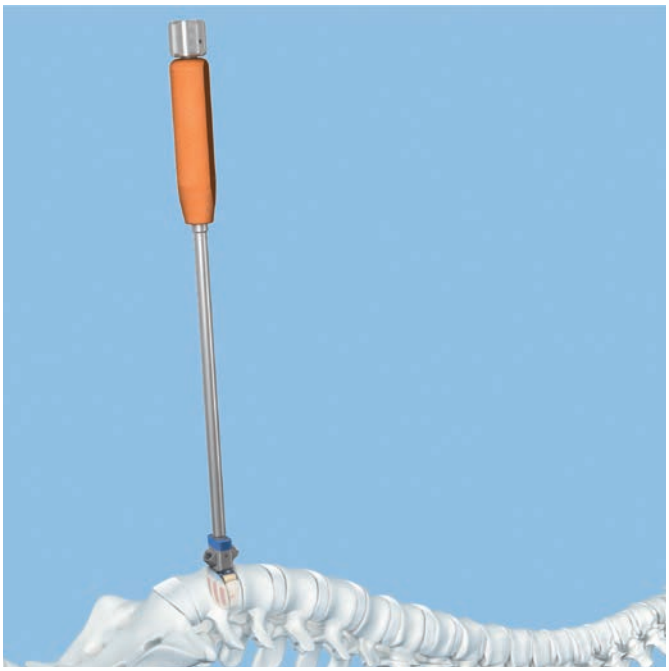


Verify final implant position with the help of an intraoperative lateral X-ray.

The titanium fixation plate and single posterior X-ray marker incorporated into the implant allow accurate intraoperative radiographic assessment of the position of the implant. The posterior X-ray marker is located approximately 3 mm from the posterior wall of the spacer.

Screw Insertion
Option A: Standard Instruments

Important: **All standard instruments have brown, phenolic handles.**



1. Mount aiming device

Instrument	
03.802.031	Holder for Aiming Device for SynFix-LR

The aiming devices are color-coded to correspond with the implant height and color.

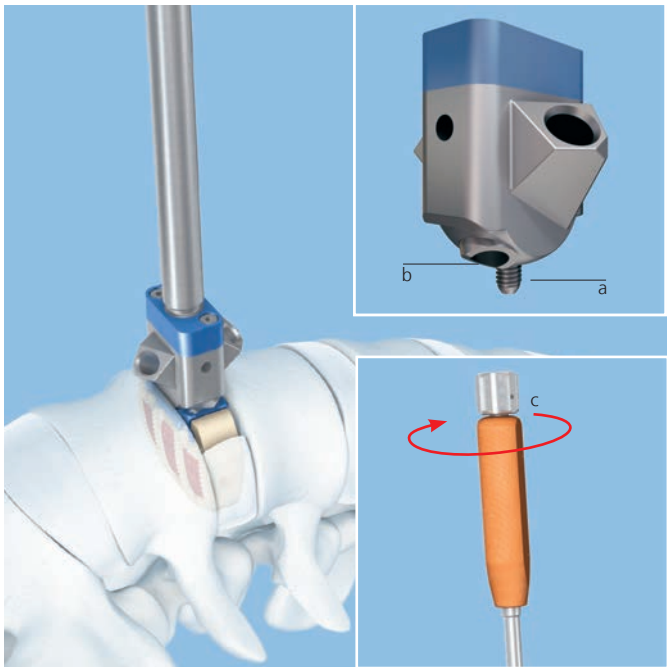
The aiming device ensures appropriate alignment, fit and engagement of the locking screws into the fixation plate and the vertebrae.

Aiming device	Corresponding implant size	Color code
03.802.020	12 mm	light blue
03.802.032	13.5 mm	gold
03.802.036	15 mm	blue
03.802.033	17 mm	purple
03.802.034	19 mm	green

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

Optional: The modified aiming device for SynFix-LR allows working through a smaller incision compared to the aiming device mentioned above (see also page 46).

Modified aiming device	Corresponding implant size	Color code
03.802.242	12 mm	light blue
03.802.243	13.5 mm	gold
03.802.245	15 mm	blue
03.802.247	17 mm	purple
03.802.249	19 mm	green



Choose the corresponding aiming device and attach the aiming device holder.

Insert the aiming device.

Position the aiming device so that the threaded pin (a) fits into the central hole of the fixation plate and the lateral positioning pin (b) aligns with one of the the plate holes for the fixation screw.

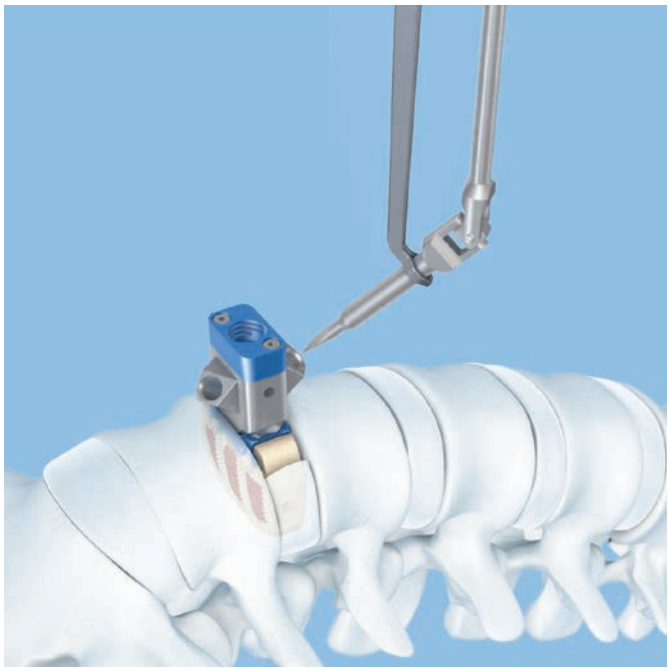
When the aiming device has been positioned, secure it by tightening the nut (c) on top of the aiming device holder.

Precaution: **If the aiming device cannot be secured to the implant, remove the implant and replace it with a new implant (continue with section "Implant Removal", p. 38).**

Notes:
- **The aiming device should fit snugly against the plate. Do not overtighten.**
- **As the guiding distance of the modified aiming device is shorter than the guiding distance of the standard aiming device, take care to maintain alignment of the awl and screwdriver (see page 46).**

2. Create pilot hole

Instruments	
03.802.035	Awl ∅ 3.2 mm for SynFix-LR
03.802.038	Tweezers for SynFix-LR
Optional instrument	
03.802.400	Soft Tissue Retractor, curved, for SynFix-LR



For better visualization of the operative site, the holder for aiming device can be removed, leaving only the aiming device attached to the fixation plate.

Insert the awl into the aiming device. Prepare the vertebral body for screw insertion by applying pressure on the handle of the awl with rotational motions. Tweezers should be used to ensure directional control of the awl tip and to reduce injury to the surrounding soft tissues or vessels.

Insert the first screw before preparing any other holes.

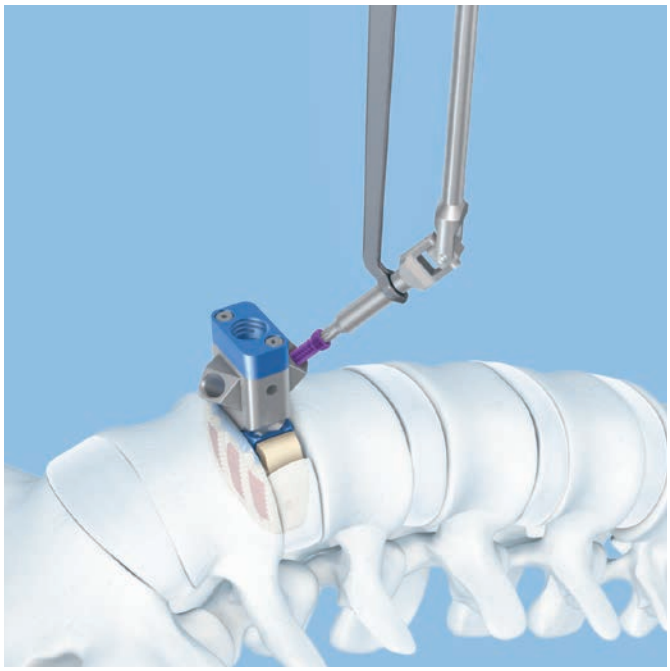
Notes:

- **The tweezers can also be used to remove the awl in order to avoid damaging adjacent structures.**
- **Using the soft tissue retractor with the aiming device helps to protect soft tissue.**
- **It is not necessary to completely rotate the awl to break the cortex, clockwise and counterclockwise rotational motions are sufficient.**
- **Awl depth is approximately 15 mm, equivalent to the purchase length of a 20 mm screw (see page 41).**

3. Insert and tighten first screw

Instruments	
03.802.037	Screwdriver for SynFix-LR
03.802.038	Tweezers for SynFix-LR

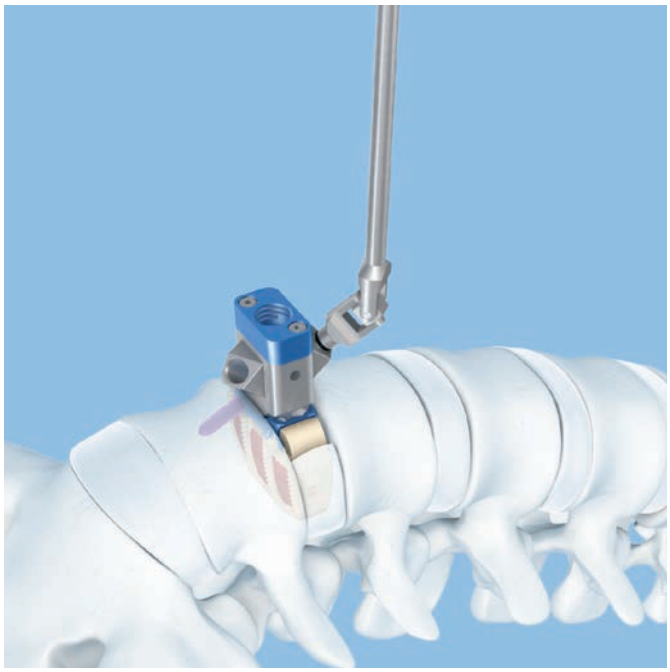
Select the appropriate screw length (20 mm screws are recommended for use in most cases). Screw length should be selected to penetrate completely through the cortical bone. For a two-level procedure, proper consideration should be given to the screw length on the common vertebral body to prevent screw interference. The tweezers allow control of the screw during insertion to reduce damage to the surrounding soft tissue or vessels.



Insert the self-tapping screw through the aiming device and into the pilot hole created by the awl. As soon as the ring marked on the screwdriver meets the entry point of the aiming device, the locking position of the screw within the fixation plate has been approximately reached.

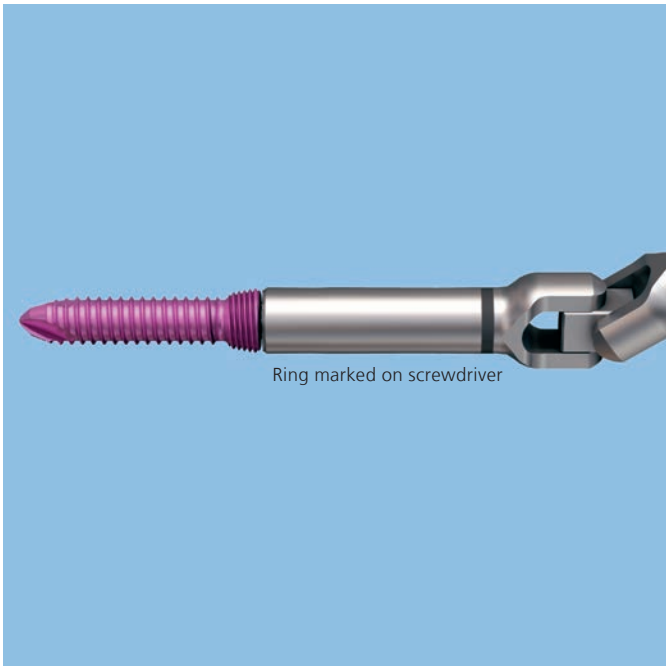
Tighten the screw firmly.

Warning: **Excessive torque can damage or break the instruments or implant.**



Notes:

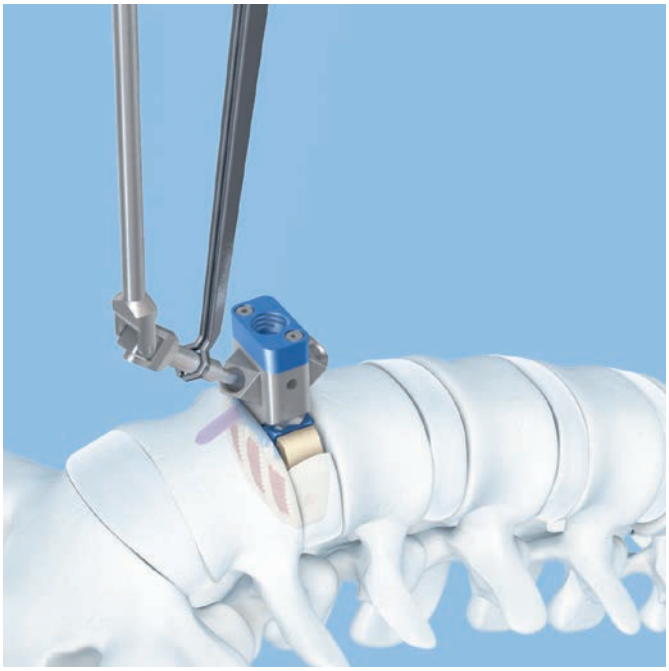
- **It is important that the four locking screws be inserted sequentially, and that awl and screw insertion be done through a SynFix-LR aiming device to ensure the proper locking of the screw to the plate.**
- **The tweezers can also be used for removal of the screwdriver to reduce damage to the adjacent structures.**
- **Using the soft tissue retractor with the aiming device helps to protect soft tissue.**


Ring marked on screwdriver

4. Insert second screw

Instruments	
03.802.035	Awl ∅ 3.2 mm for SynFix-LR
03.802.037	Screwdriver for SynFix-LR
03.802.038	Tweezers for SynFix-LR

Following steps 2 through 3, use the awl with the second opening in the aiming device in order to insert the second screw. Insert the second screw with the screwdriver. Use the tweezers, to ensure directional control.



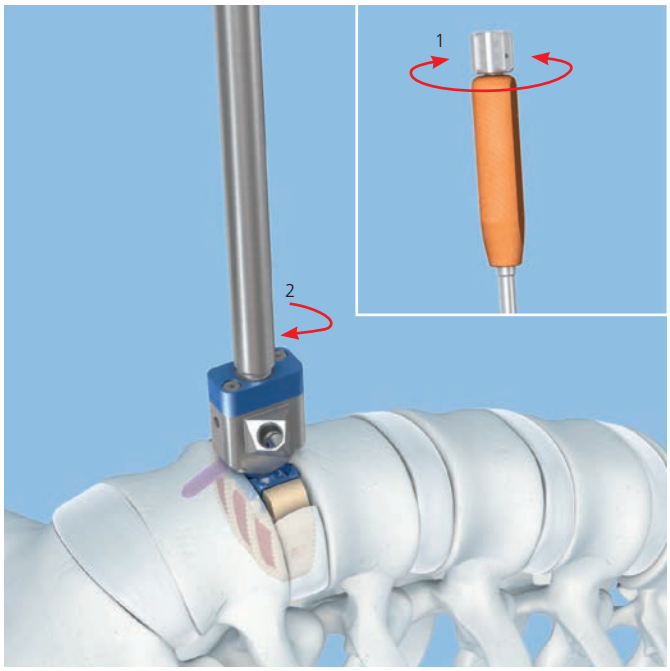
5. Rotate aiming device

Instrument	
03.802.031	Holder for Aiming Device for SynFix-LR

If the holder for the aiming device has been removed, reattach it to the aiming device before rotation.

Loosen the aiming device by turning the nut (1) counter-clockwise four to five times. The aiming device can be rotated 180°, without disengaging it completely from the fixation plate (2).

Relock the aiming device by turning the nut (1) clockwise.



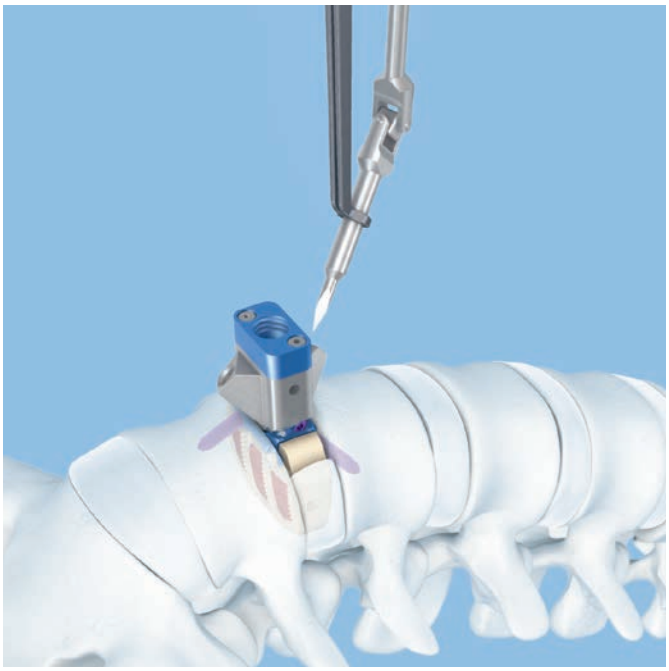
Notes:

- **If the aiming device is difficult to rotate, verify that the screws are advanced far enough and are not blocking the aiming device during rotation.**
- **Rotating the aiming device clockwise will ensure that the aiming device handle does not loosen unintentionally.**
- **The aiming device should fit snugly against the plate. Do not overtighten.**

6. Insert third and fourth screws

For insertion of the third and fourth screws, repeat steps 2 through 4.

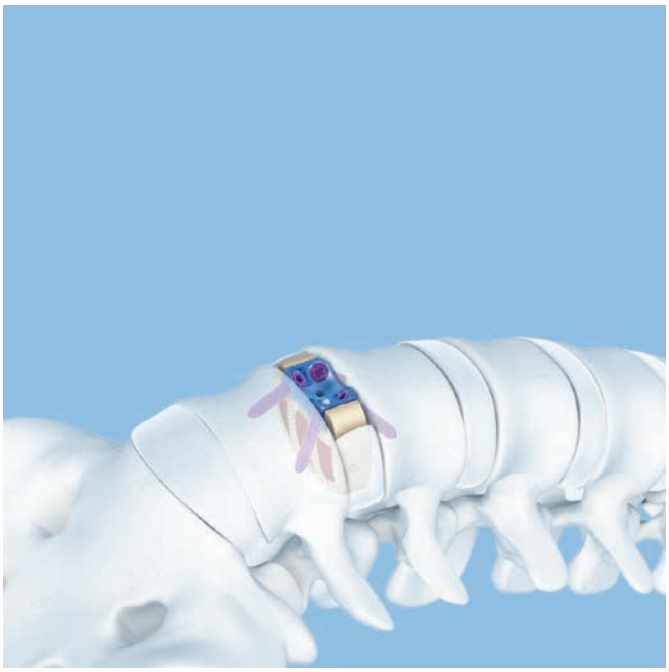
Notes:
- **Four (4) screws should always be used for every SynFix-LR construct.**
- **If less than four screws are inserted, a supplemental fixation is mandatory.**



7. Remove instruments

When the implant is secured, remove the aiming device by turning the nut on top of the aiming device holder.

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



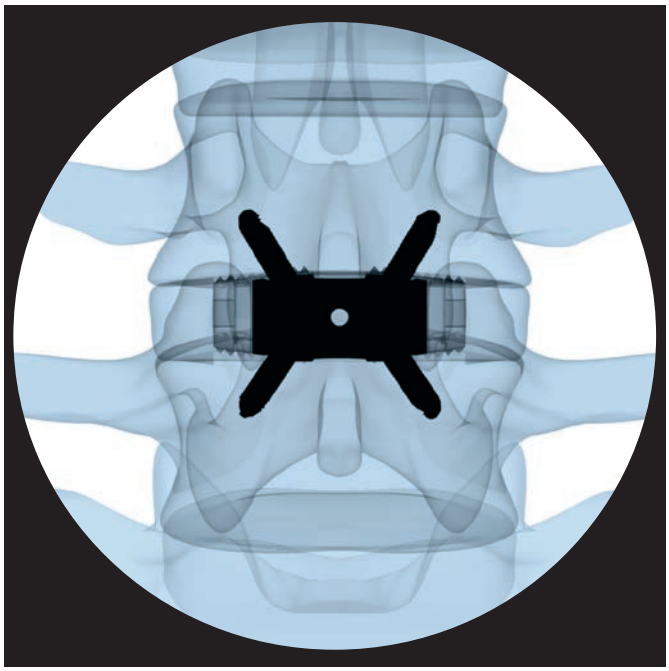
8. Verify placement

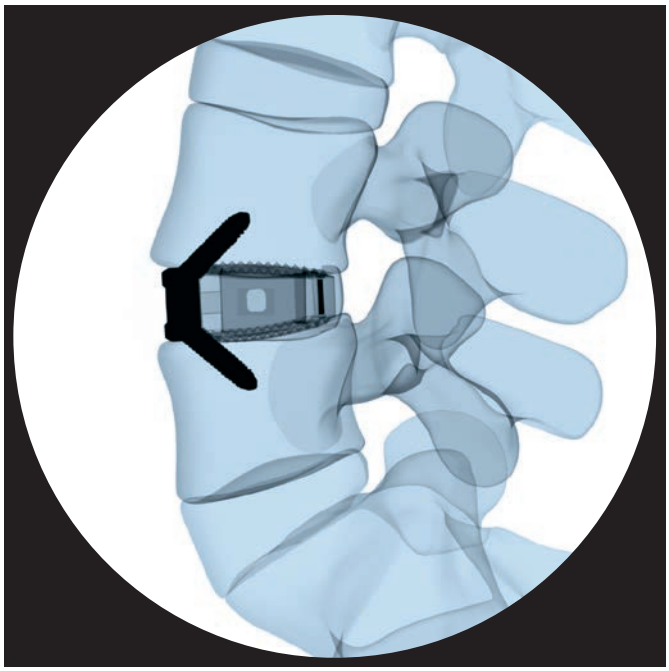
The SynFix-LR implant is positioned optimally when the implant is completely within the confines of the vertebral bodies.

Depending on the size of the vertebrae, the anterior edge of the SynFix-LR will usually be 1 mm–3 mm behind the anterior edge of the adjacent vertebrae.

The location of the implant relative to the vertebral bodies in the AP and lateral directions can be verified using an image intensifier.

The titanium fixation plate and single posterior X-ray marker incorporated into the implant design allow accurate intraoperative radiographic assessment of the implant's position.





Screw Insertion
Option B: Mini-Open Instruments

Important: **All mini-open instruments have green, silicone handles.**

Implant coupling

Fixed-handle aiming device

1. Mount aiming device

Instrument	
03.802.200	Coupling for Mini-Open Aiming Device, with fixed handle, for SynFix-LR

The aiming device is designed to ensure color-coded to correspond with the implant height and the plate color.

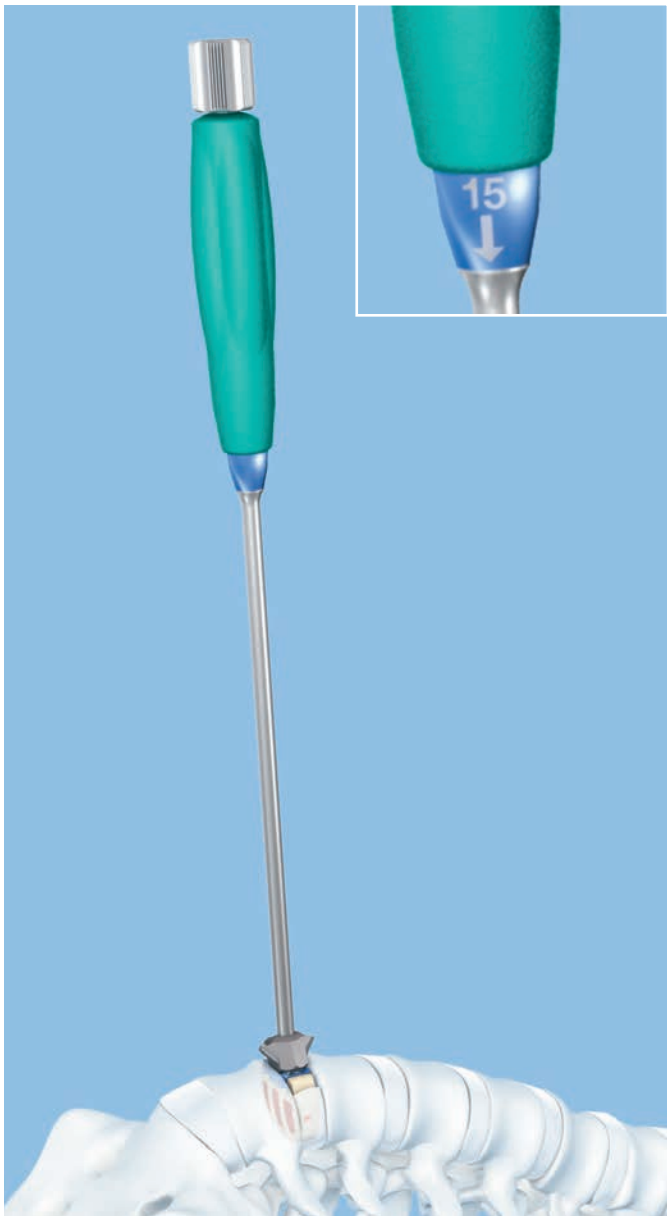
Fixed handle aiming device	Corresponding implant size	Color code
03.802.202	12 mm	light blue
03.802.203	13.5 mm	gold
03.802.205	15 mm	blue
03.802.207	17 mm	purple
03.802.209	19 mm	green

The aiming device is designed to ensure appropriate alignment, fit and engagement of the locking screws into the fixation plate and the vertebrae.

Choose the corresponding aiming device and attach the implant coupling.

Insert the aiming device.

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

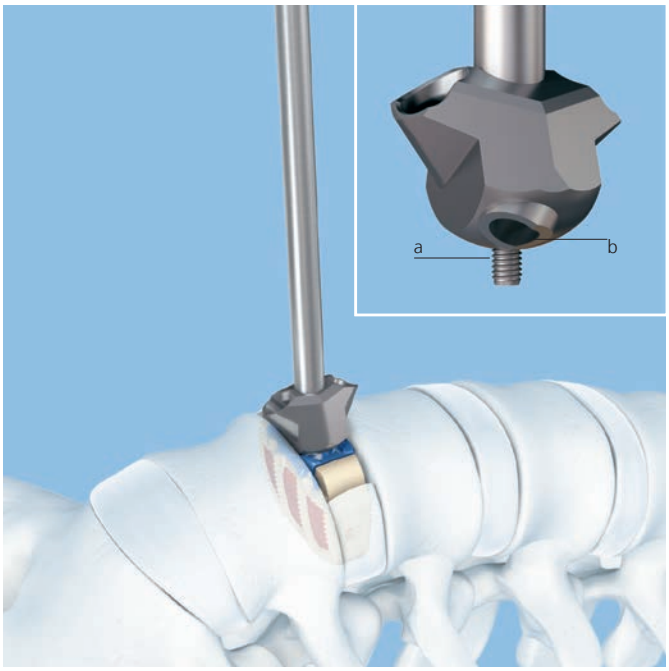


Position the aiming device so the threaded pin (a) fits into the central hole of the fixation plate and the lateral positioning pin (b) aligns with one of the plate holes for the fixation screw.

Arrows located just below the handle indicate caudal and cranial orientation of the aiming device. When the aiming device has been positioned, secure it by tightening the implant coupling top of the fixed handle aiming device.

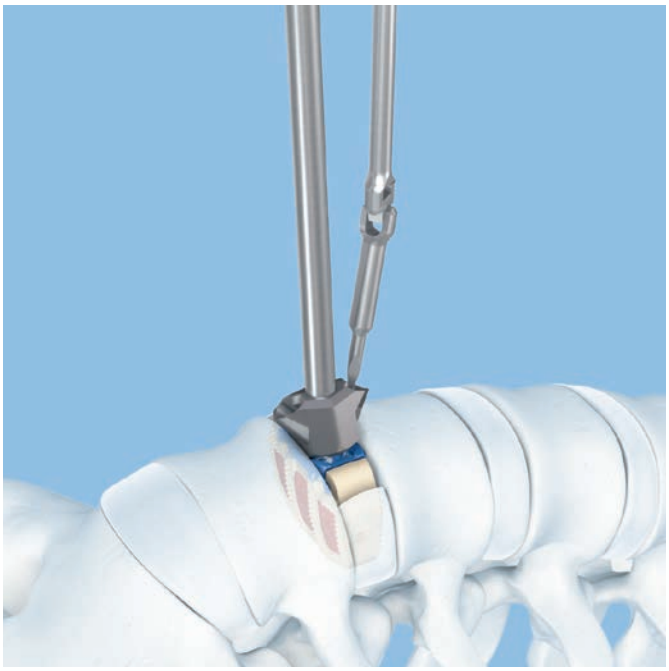
Precaution: **If the aiming device cannot be secured to the implant, remove the implant and replace it with a new implant (continue with section "Implant Removal", p. 38).**

Note: **The aiming device should fit snugly against the plate. Do not overtighten.**



2. Create pilot hole

Instrument	
03.802.230	Awl ∅ 3.2 mm for SynFix-LR Mini-Open
Optional instruments	
03.802.038	Tweezers for SynFix-LR
03.802.400	Soft Tissue Retractor, curved, for SynFix-LR



Insert the awl into the aiming device. Prepare the vertebral body for screw insertion by applying pressure on the handle of the awl with rotational motions.

Insert the first screw before preparing any other holes.

Notes:

- **It is not necessary to completely rotate the awl to break the cortex, rotational motions clockwise and counterclockwise are sufficient.**
- **The awl for SynFix-LR mini-open features a tip with positional memory. There is no need to use tweezers to control the tip while inserting into the aiming device; however, the tweezers can be used as an option.**
- **Awl depth is approximately 10 mm, equivalent to the purchase length of a 15 mm screw.**
- **Using the soft tissue retractor with the aiming device helps to protect soft tissue.**

3. Insert and tighten first screw

Instruments	
03.802.431/.331	Screwdriver Shaft for SynFix-LR Mini Open, with tapered Tip
388.396	Handle with Quick Coupling, small
Optional instruments	
03.802.038	Tweezers for SynFix-LR
03.802.400	Soft Tissue Retractor, curved, for Synfix-LR

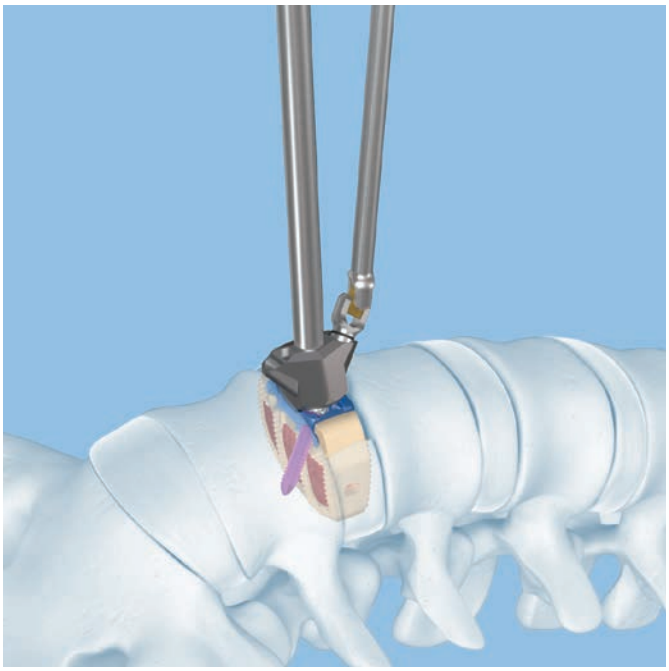
To insert the self tapping screw through the aiming device and into the pilot hole created by the awl, only use the screwdriver shaft for SynFix-LR mini-open (03.802.431/.331) with the small handle (388.396). Screw length should be selected to penetrate completely through the cortical bone. For a two-level procedure, proper consideration should be given to the screw length on the common vertebral body to prevent screw interference.

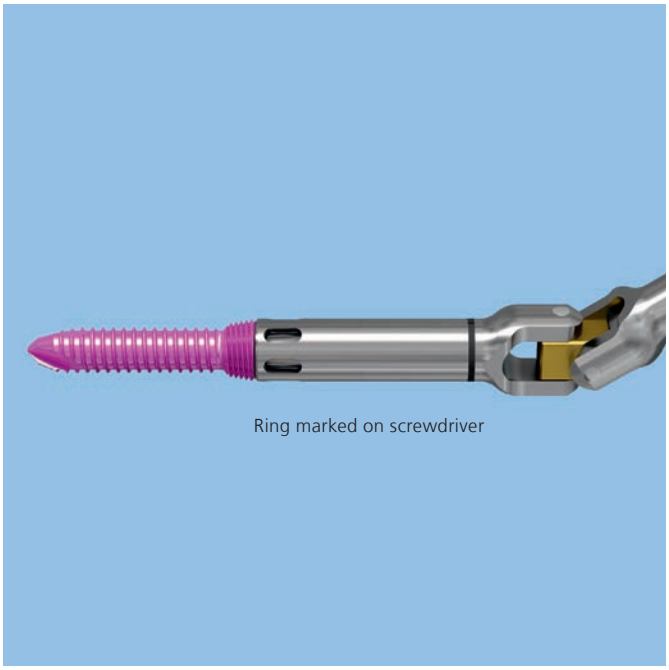
Insert the self-tapping screw through the aiming device and into the pilot hole created by the awl. As soon as the ring mark on the screwdriver passes the entry point of the aiming device, the locking position of the screw within the fixation plate is approximately reached.

Tighten the screw firmly.

Warning: **Excessive torque can damage or break the instruments or implant.**

Notes:
- **It is important that the four locking screws be inserted sequentially, and that awl and screw insertion be done through a SynFix-LR aiming device to ensure proper locking of the screw to the plate.**
- **The screwdriver shaft for SynFix-LR mini-open (03.802.431/.331) must only be used with the small silicone handle (388.396) mentioned above.**
- **The screwdriver for SynFix-LR mini-open features a tip with positional memory. There is no need to use tweezers to control the tip while inserting or removing the driver from the aiming device; however, the tweezers can be used as an option.**
- **Using the soft tissue retractor with the aiming device helps to protect soft tissue.**



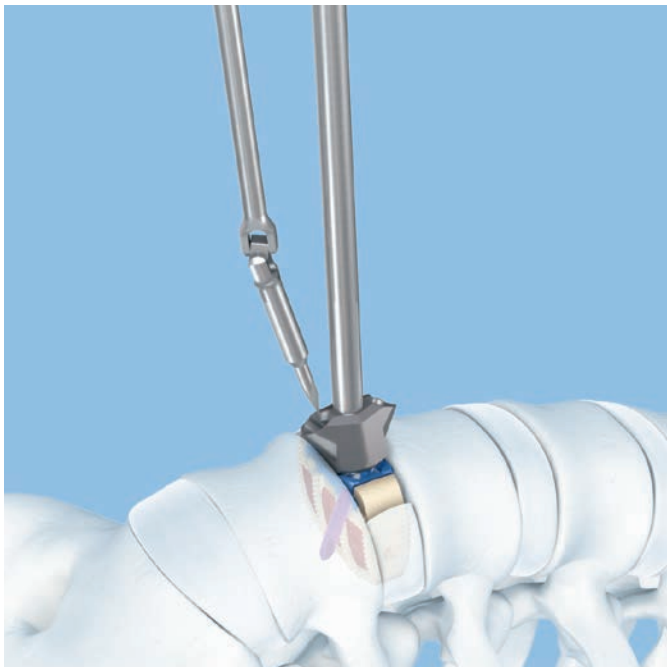


Ring marked on screwdriver

4. Insert second screw

Instruments	
03.802.230	Awl ∅ 3.2 mm for SynFix-LR Mini Open
03.802.431/.331	Screwdriver Shaft for SynFix-LR Mini Open, with tapered Tip
388.396	Handle with Quick Coupling, small

Following steps 2 through 3, use the awl with the second opening in the aiming device in order to insert the second screw. Insert the second screw with the screwdriver.



5. Rotate aiming device

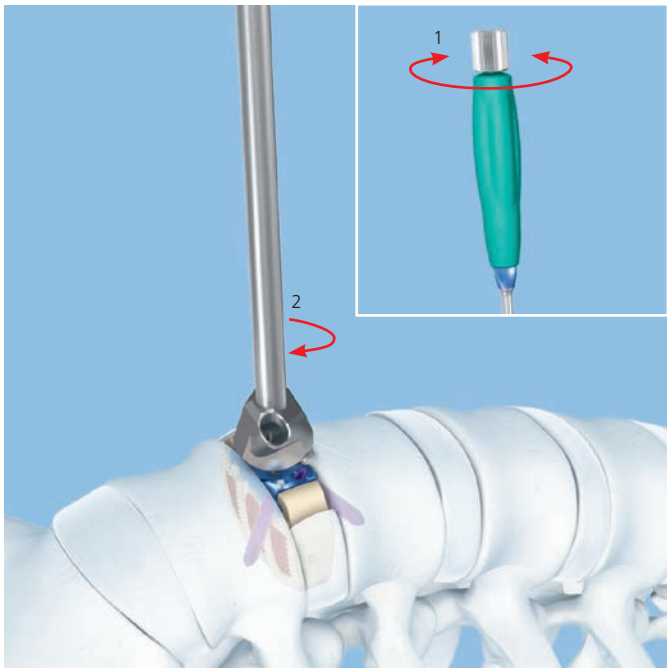
Loosen the aiming device by turning the nut (1) counter-clockwise four to five turns. The aiming device can be rotated 180° without disengaging completely from the fixation plate (2).

Arrows located just below the handle indicate caudal andcranial orientation of the aiming device.

Relock the aiming device by turning the nut (1) clock-wise.

Notes:

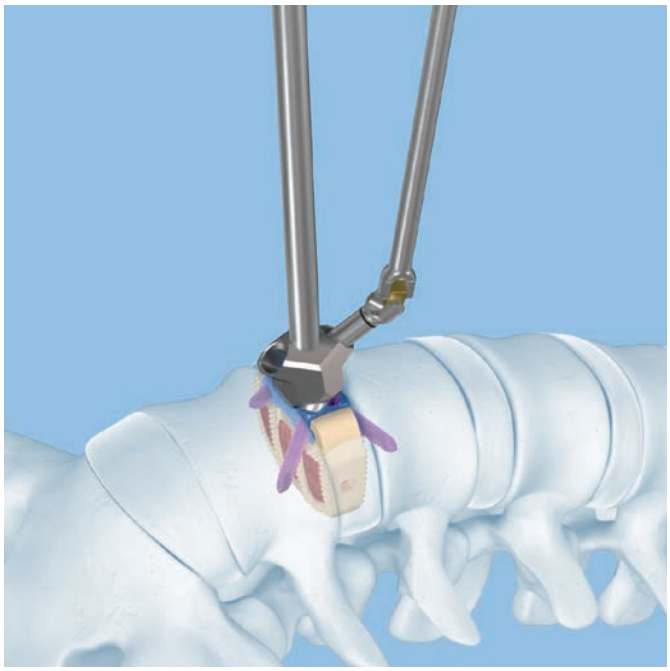
- **If the aiming device is difficult to rotate, verify that the screws are advanced far enough and are not blocking the aiming device during rotation.**
- **The fixed-handle aiming device can be rotated in either direction.**
- **The aiming device should fit snugly against the plate. Do not overtighten.**



6. Insert third and fourth screws

For insertion of the third and fourth screws, repeat steps 2 through 4.

Notes:
- **Four (4) screws should always be used for every SynFix-LR construct.**
- **If less than four screws are inserted, a supplemental fixation is mandatory.**



7. Remove instruments

When the implant is secured, remove the aiming device by turning the nut on top of the fixed handle aiming device.

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

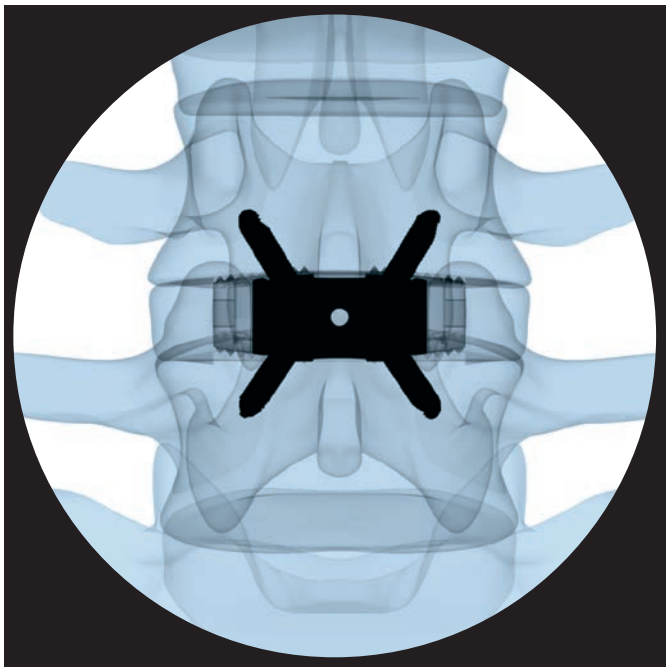
8. Verify placement

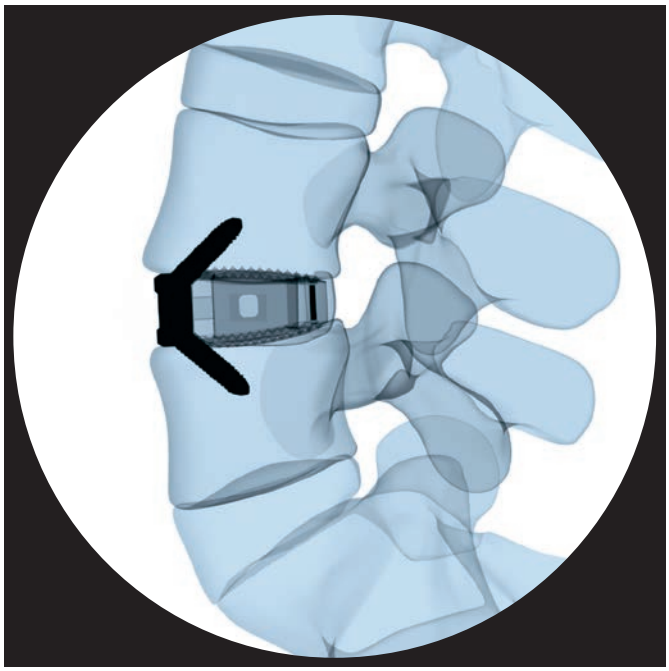
The SynFix-LR implant is positioned optimally when the implant is completely within the confines of the vertebral bodies.

Depending on the size of the vertebrae, the anterior edge of the SynFix-LR will usually be 1 mm–3 mm behind the anterior edge of the adjacent vertebrae.

The location of the implant relative to the vertebral bodies in the AP and lateral directions can be verified using an image intensifier.

The titanium fixation plate and single posterior X-ray marker incorporated into the implant design allow accurate intra-operative radiographic assessment of the implant's position.





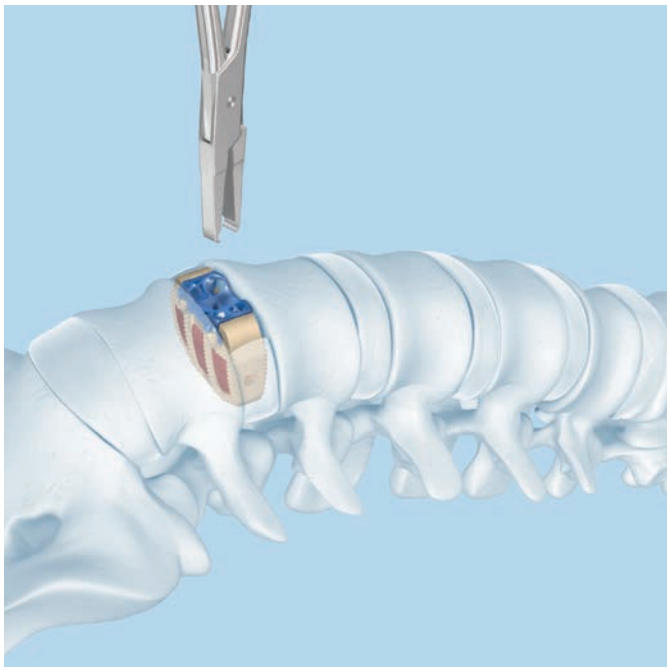
Implant Removal

1. Approach the Implant

Instrument	
388.407	Holding Forceps for Rods ∅ 3.5 mm, length 181 mm

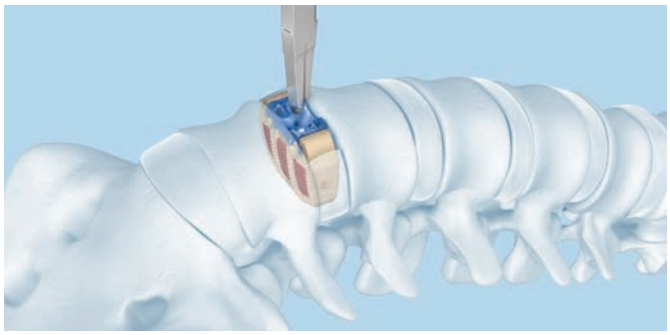
Make sure to remove all screws prior to usage of holding forceps.
In case the implant needs to be removed out of the intervertebral disc space, the holding forceps 388.407 can be used alternatively to the implant holder 03.802.039.
Check all four available bridges of the SynFix-LR implant prior removal. Choose a bridge that provides ease of access.
Approach the implant with the holding forceps in opened condition.

Note: **In case the accessibility of the bridge is limited due to bony structures, remove them with appropriate instrumentation.**



2. Connect Forceps to Implant

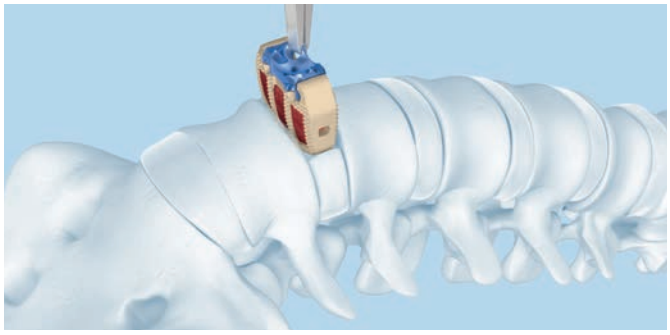
Grab the bridge with the holding forceps and lock it by scrunching the levers of the forceps.



3. Remove Implant

Apply a gentle extraction force to the holding forceps to remove the implant. Ensure after removal of the implant that all components were removed out of the intervertebral disc space.

Note: **Reuse of implant is not recommended due to possible damage to the conical thread of the plate after extraction.**



Postoperative management

Patients can usually be mobilized once they regain muscular control of their trunk on the same day or one day after surgery. As no supplementary posterior fixation is required, surgical morbidity and post-operative discomfort are likely to be reduced. Patients may be inclined to increase activities quite rapidly. However, patients should be cautioned against activities that place unreasonable stress on the lower back until solid bony union has been achieved.

Excessive physical activity and trauma may result in failure, with subsidence of the implant and/or the development of a non-union. Loss of fixation may also occur if excessive activity and motion is attempted prior to restoration of good lumbar trunk and abdominal muscle control and function.

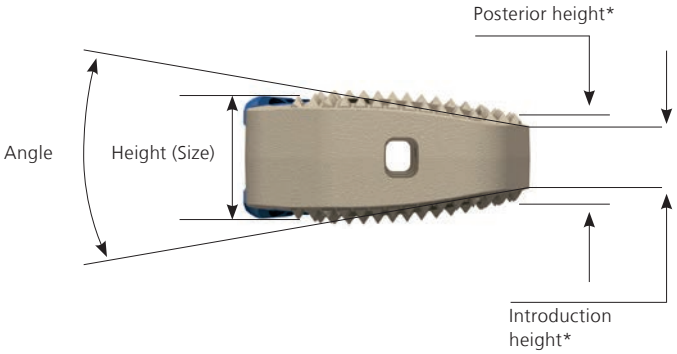
SynFix-LR Implants

Supplied sterile and preassembled (spacer with anterior fixation plate).

Plate components and trial components are color coded.

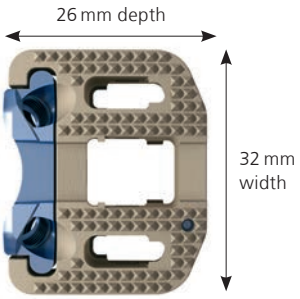
Spacer component: PEEK (polyetheretherketone)
Plate component: Titanium alloy (TiAl6Nb7)

* Posterior height is measured from the top of the most posterior teeth. Introduction height is approximately 1.8 mm less than the posterior height.



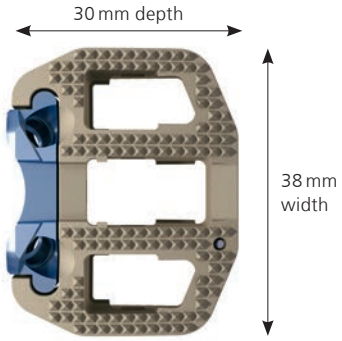
26 mm depth × 32 mm width

Implant	Lordotic angle	Height	Posterior height*	Color code
08.802.016S	8°	12 mm	9 mm	light blue
08.802.000S		13.5 mm	10.5 mm	gold
08.802.001S		15 mm	12 mm	blue
08.802.002S		17 mm	14 mm	purple
08.802.003S		19 mm	16 mm	green
08.802.017S	12°	12 mm	8 mm	light blue
08.802.004S		13.5 mm	9 mm	gold
08.802.005S		15 mm	11 mm	blue
08.802.006S		17 mm	12.5 mm	purple
08.802.007S		19 mm	14.5 mm	green



30 mm depth × 38 mm width

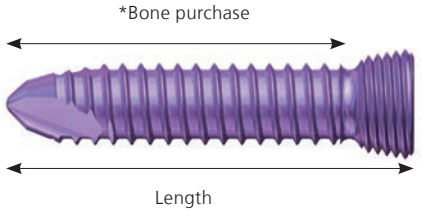
Implant	Lordotic angle	Height	Posterior height*	Color code
08.802.018S	8°	12 mm	9 mm	light blue
08.802.008S		13.5 mm	10 mm	gold
08.802.009S		15 mm	11.5 mm	blue
08.802.010S		17 mm	13.5 mm	purple
08.802.011S		19 mm	15.5 mm	green
08.802.019S	12°	12 mm	7 mm	light blue
08.802.012S		13.5 mm	8.5 mm	gold
08.802.013S		15 mm	10 mm	blue
08.802.014S		17 mm	12 mm	purple
08.802.015S		19 mm	14 mm	green



SynFix-LR Screws

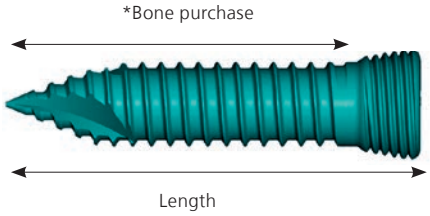
4.0 mm locking implant screws
Self-tapping
Titanium Alloy (TiAl6Nb7)

Screw purchase*	Length	Bone
04.802.200	15 mm	10 mm
04.802.201	20 mm	15 mm
04.802.202	25 mm	20 mm
04.802.203	30 mm	25 mm



4.0 mm locking implant screws fine tip
Self-tapping
Titanium Alloy (TiAl6Nb7)

Screw fine tip purchase*	Length	Bone
04.802.210	15 mm	10 mm
04.802.211	20 mm	15 mm
04.802.212	25 mm	20 mm
04.802.213	30 mm	25 mm



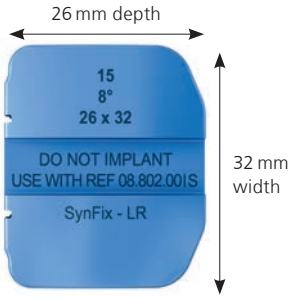
Fine tip screws are more pointed and therefore easier to use in dense sclerotic bone.

SynFix-LR Trial Implants

Trial implants
Color coded by size (same color as the SynFix-LR implant plate component).

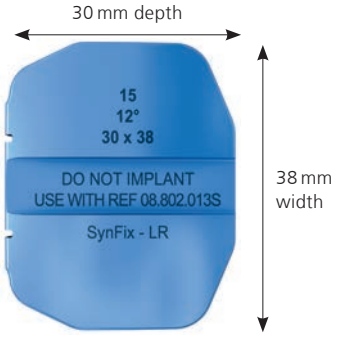
26 mm depth × 32 mm width

Implant	Lordotic angle	Height	Color code
03.802.016	8°	12 mm	light blue
03.802.000		13.5 mm	gold
03.802.001		15 mm	blue
03.802.002		17 mm	purple
03.802.003		19 mm	green
03.802.017	12°	12 mm	light blue
03.802.004		13.5 mm	gold
03.802.005		15 mm	blue
03.802.006		17 mm	purple
03.802.007		19 mm	green

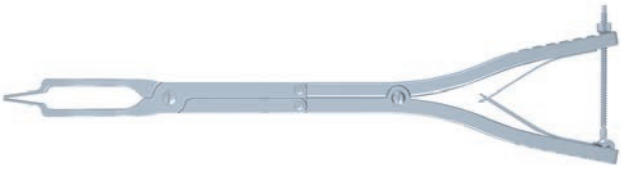


30 mm depth × 38 mm width

Implant	Lordotic angle	Height	Color code
03.802.018	8°	12 mm	light blue
03.802.008		13.5 mm	gold
03.802.009		15 mm	blue
03.802.010		17 mm	purple
03.802.011		19 mm	green
03.802.019	12°	12 mm	light blue
03.802.012		13.5 mm	gold
03.802.013		15 mm	blue
03.802.014		17 mm	purple
03.802.015		19 mm	green



SynFix-LR Instruments

397.034	Handle for SynCage Trial Implants, straight	
397.113	Distractor, anterior, for SynCage-LR	
389.288	Cancellous Bone Impactor for Travios and Plivios, 8 × 2.5 mm	
394.585	Cancellous Bone Impactor, 5.5 × 8.5 mm	
03.802.041	Packing Block for SynFix-LR, 26 × 32 mm	
03.802.042	Packing Block for SynFix-LR, 30 × 38 mm	
03.802.031	Holder for Aiming Device for SynFix-LR	
03.802.035	Awl ∅ 3.2 mm for SynFix-LR	

03.802.037	Screwdriver for SynFix-LR	
03.802.038	Tweezers for SynFix-LR	
03.802.039	Implant Holder for SynFix-LR	
388.311	Screwdriver T15, length 300 mm	
388.407	Holding Forceps for Rods ∅ 3.5 mm, length 181 mm	
SFW650R	Prodisc-L Spreader Forceps, curved	
SFW550R	Prodisc-L Spreader	

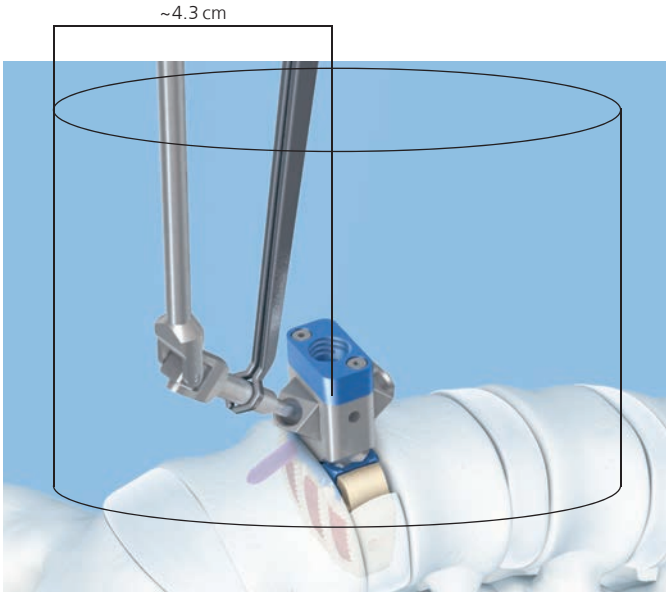
E5211-3	Wrench Epoca, width across 10 mm	
03.802.121	SQUID for SynFix-LR	
03.802.200	Coupling for Mini-Open Aiming Device, with fixed handle, for SynFix-LR	
03.802.400	Soft Tissue Retractor, curved, for SynFix-LR	
03.802.230	Awl ∅ 3.2 mm for SynFix-LR Mini Open	
03.802.431	Screwdriver Shaft for SynFix-LR Mini Open, with tapered Tip	
388.396	Handle with Quick Coupling, small	

SynFix-LR Aiming Devices

Standard aiming device (required exposure 8–10 cm)

03.802.020	Aiming Device for SynFix-LR, 12 mm, light blue
03.802.032	Aiming Device for SynFix-LR, 13.5 mm, gold
03.802.036	Aiming Device for SynFix-LR, 15 mm, blue
03.802.033	Aiming Device for SynFix-LR, 17 mm, purple
03.802.034	Aiming Device for SynFix-LR, 19 mm, green

If a standard aiming device is used, a radius of ~4.3 cm is required. This device is designed to enable good guidance of the awl and the screwdriver while allowing secure insertion of all screws.

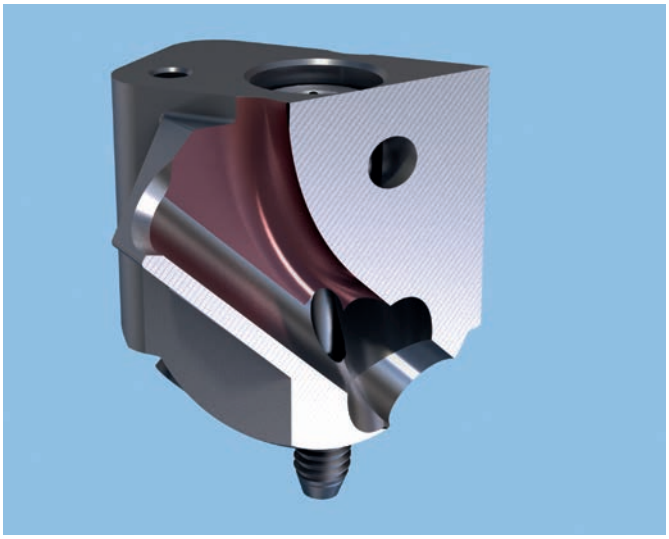


Modified aiming device (required exposure 7–9 cm)

Optional:

03.802.242	Aiming Device, modified, for SynFix-LR, 12 mm, light blue
03.802.243	Aiming Device, modified, for SynFix-LR, 13.5 mm, gold
03.802.245	Aiming Device, modified, for SynFix-LR, 15 mm, blue
03.802.247	Aiming Device, modified, for SynFix-LR, 17 mm, purple
03.802.249	Aiming Device, modified, for SynFix-LR, 19 mm, green

The modified aiming device has a relief that allows the awl to be inserted more toward the center, similar to the mini-open instruments. The red shaded area indicates the change made to the standard aiming device.

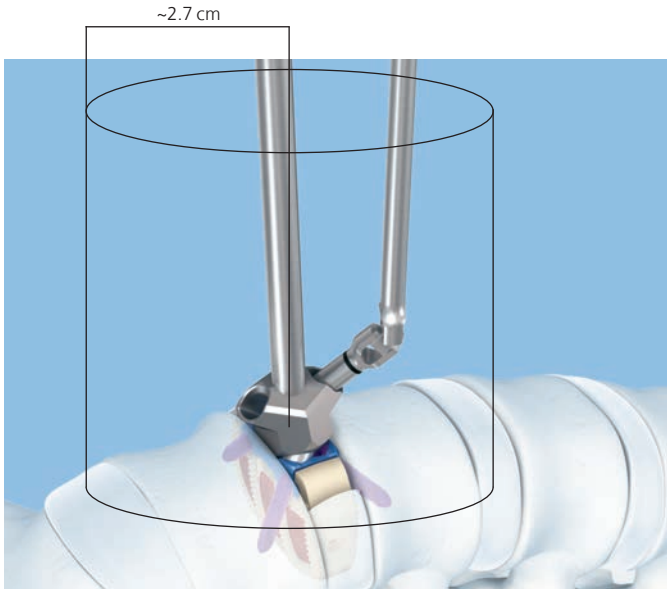


Guidance is established just before the awl penetrates the cortex.

Aiming device mini-open with fixed handle (required exposure 5–7 cm)

03.802.202	Aiming Device Mini-Open, with fixed handle, for SynFix-LR, 12 mm
03.802.203	Aiming Device Mini-Open, with fixed handle, for SynFix-LR, 13.5 mm
03.802.205	Aiming Device Mini-Open, with fixed handle, for SynFix-LR, 15 mm
03.802.207	Aiming Device Mini-Open, with fixed handle, for SynFix-LR, 17 mm
03.802.209	Aiming Device Mini-Open, with fixed handle, for SynFix-LR, 19 mm

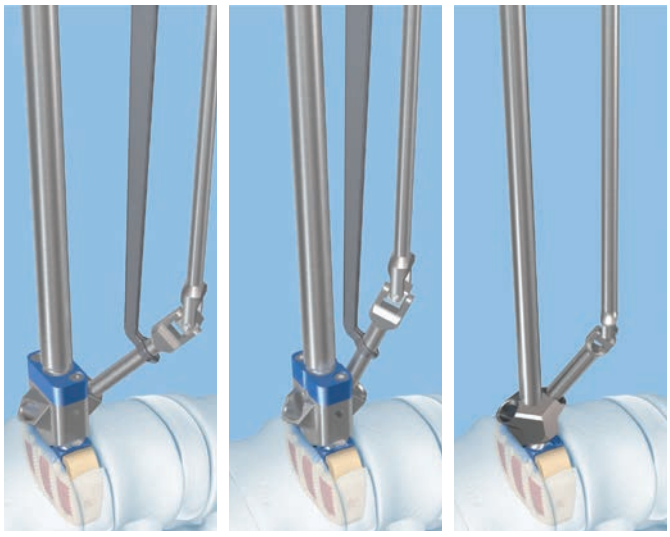
If an aiming device mini-open with fixed handle is used, a radius of ~2.7 cm is required. It is designed to enable good guidance of the awl and the screwdriver while allowing secure insertion of all screws.



Trade-off between guidance and exposure

There is a trade-off between guidance and exposure. The standard aiming device offers the best guidance but also requires a larger exposure. The aiming device mini-open requires a smaller exposure, but the guidance is decreased.

Compared to the standard aiming device, the modified aiming device allows less angulation when inserting the awl or the screwdriver. During the insertion of the instrument, less space is needed.



Standard aiming device | Modified aiming device | Aiming device mini-open

Filling Material

Synthetic cancellous bone graft substitute: chronOS Bone Void Filler
chronOS Bone Void Filler is a bone graft substitute consisting of pure ß-tricalcium phosphate. Its compressive strength is similar to that of cancellous bone once it has been incorporated and remodeled.[1] Based on literature, the use of ß-tricalcium phosphate in the spinal column is a valuable alternative to allografts and autografts, even when larger amounts are required.[2,3]

Resorbable
It is being replaced in the human body by host bone in 6 to 18 months; depending on the indication and the patient's conditions.[2,4-6]

Osteoconductive
Interconnected macropores of defined size (100–500 µm) facilitate bone formation throughout the entire implant. Interconnected micropores (<10 µm) allow a supply of nutrients.[1,7]

Osteoinductive with bone marrow
The combination of chronOS Bone Void Filler with bone marrow accelerates and enhances osteointegration.[4,5]

Synthetic
Having a synthetic origin, chronOS Bone Void Filler offers the advantage of uniform quality and availability.

[1] Gazdag et al. 1995
[2] Muschik et al. 2001
[3] Knop et al. 2006
[4] Stoll et al. 2004
[5] Becker et al. 2006
[6] Wheeler et al. 2005
[7] Lu et al. 1999

chronOS Granules Bone Void Filler

Article No.	∅ mm	Content (mL)
710.000S	0.5–0.7	0.5
710.001S	0.7–1.4	0.5
710.002S	0.7–1.4	1.0
710.003S	0.7–1.4	2.5
710.011S	1.4–2.8	2.5
710.014S	1.4–2.8	5.0
710.019S	1.4–2.8	10.0
710.021S	1.4–2.8	20.0
710.024S	2.8–5.6	2.5
710.025S	2.8–5.6	5.0
710.026S	2.8–5.6	10.0
710.027S	2.8–5.6	20.0

Synthetic cancellous bone graft substitute: chronOS Putty

chronOS Putty is a synthetic, porous, resorbable and biocompatible bone graft substitute consisting of chronOS Granules Bone Void Filler and sodium hyaluronate of non-animal origin. The synthetic sodium hyaluronate used in chronOS Putty provides improved handling properties and confers positional stability to the product during handling and use.

Mixing chronOS Putty with bone marrow or blood introduces blood cells, growth factors and, in the case of bone marrow, osteoprogenitor cells. Autologous bone marrow features an improved osteogenic potential.[5,8] Perfusion of the β-TCP component of chronOS Putty with bone marrow aspirate has shown clear remodeling of chronOS Bone Void Filler into new host bone 12 weeks postoperatively.[4,5]

chronOS Putty for Spine

Article number	Product name	Liquid to add
710.801S	chronOS Putty, 1.0cc	0.80 ± 0.25 ml
710.802S	chronOS Putty, 2.5cc	2.00 ± 0.5 ml
710.803S	chronOS Putty, 5.0cc	4.00 ± 0.5 ml
710.804S	chronOS Putty, 10.0cc	8.00 ± 0.5 ml

[8] Block 2005

Additional Recommended Sets

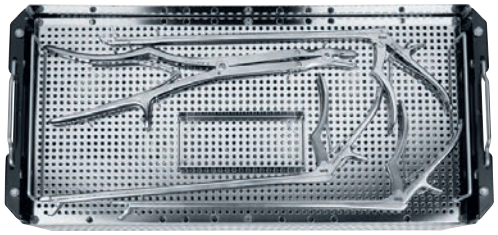
Sets	
01.609.102	SynFrame RL, lumbar
187.310	SynFrame Basic System in Vario Case

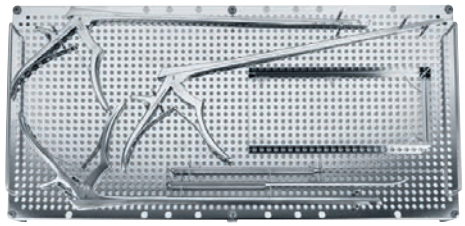
SynFrame Basic System is a surgical approach and retraction system. It consists of a basic system (basic construction) and modules that are specially designed for the respective requirements and needs of various indications and/or approach techniques. The SynFrame basic system is always constructed in the same sequence following the same principles. The SynFrame RL Lumbar is a supplementary module for the access and retraction system SynFrame. It contains radiolucent soft tissue and muscle retractors and semi transparent bone levers for minimally invasive surgery.

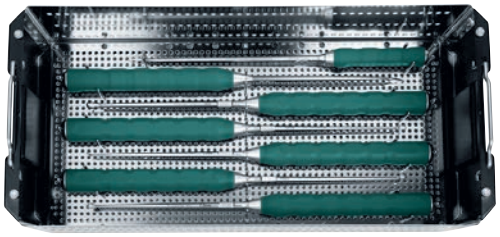
Set	
01.600.100	Proprep Set

A clearly arranged set for intervertebral disc preparation and vertebral body resection for lumbar surgery with an anterior approach.

- Compact but comprehensive: contains all instruments required for intervertebral disc preparation and vertebral body resection.
- Designed to simplify the entire anterior discectomy and corpectomy thanks to angled instruments with which even the posterolateral regions of the intervertebral discs can be reached.
- Designed for use in extensively collapsed segments as the instruments have a low profile.
- The instrument length is designed for anterior surgery and for patients with a high BMI.
- Enhanced instrument control thanks to silicone handles that can be gripped with two hands.







Disassembly Instruction

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Assembly Instruction

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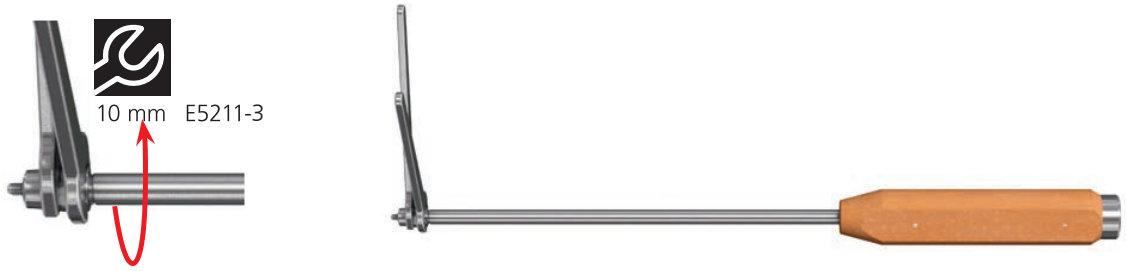

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