

SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF).

Technique guide



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 Image intensifier control

Warning

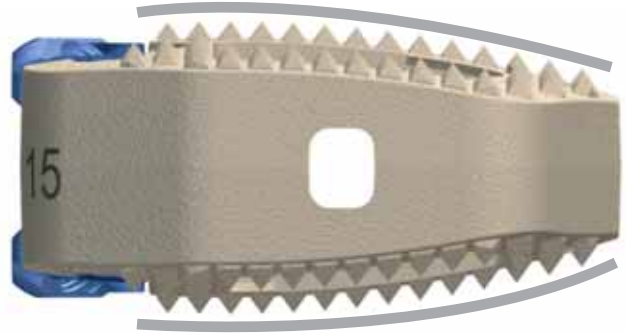
This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.

SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF).

Stand-alone ALIF implant

SynFix-LR acts as stand-alone implant for the treatment of degenerative disc disease.

The design of the SynFix-LR cage component is a further enhancement of the SynCage and SynCage-LR concept. The addition of an integrated fixation plate based on state-of-the-art fixation methods provides stable fixation, negating the need for additional anterior or posterior fixation in most circumstances.



Perfect anatomic shape – initial stability

- Cage component fits snugly into the natural concavity between two adjacent vertebral bodies

- Teeth on the superior and inferior implant surface provide initial stability of the implant

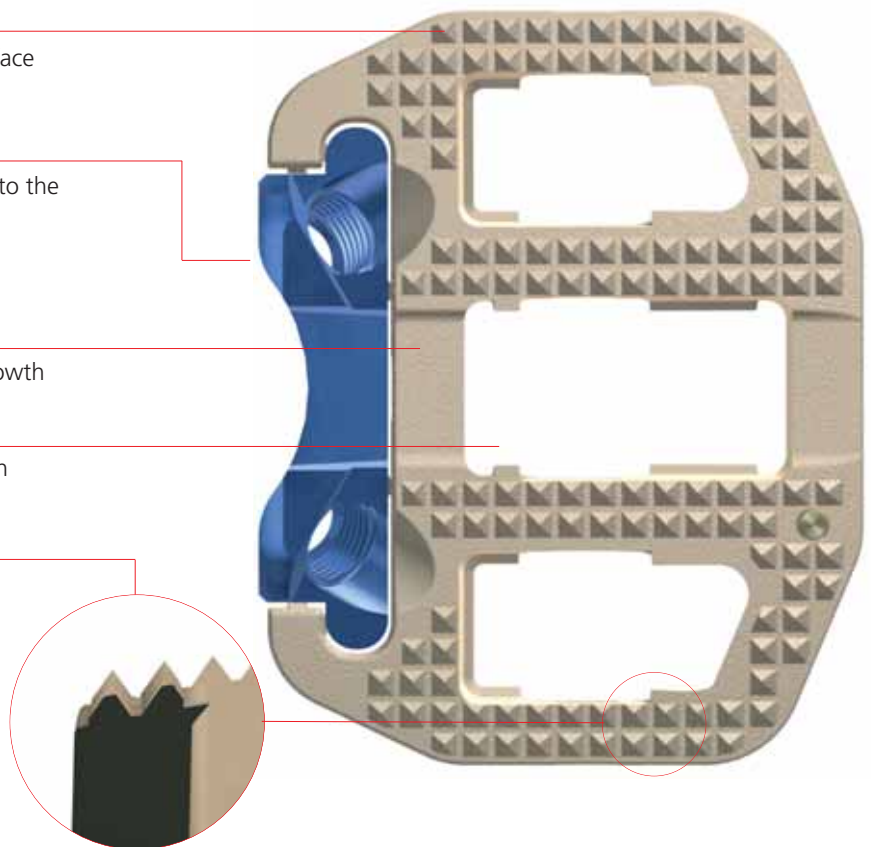
- The fixation plate and screws provide stability to the motion segment to facilitate bony healing

Enhanced fusion – secondary stability

- Roughened implant surface allows bony ongrowth

- Open implant structure promotes bone growth through the cage

- Beveled rims in the bone graft compartments act as additional anchors for ingrowing bone



Stable internal fixation – optimal stability

Biomechanical tests have demonstrated that the SynFix-LR offers comparable stability to that of a cage combined with posterior pedicle screw fixation in flexion, extension and lateral bending, and is superior in torsion.¹

- The integrated anterior fixation plate with locking head screws act as an anterior “tension band”
- Diverging screws provide purchase into the stronger peripheral bone near the anterior rim and peripheral wall of the vertebral bodies

Locking head screws

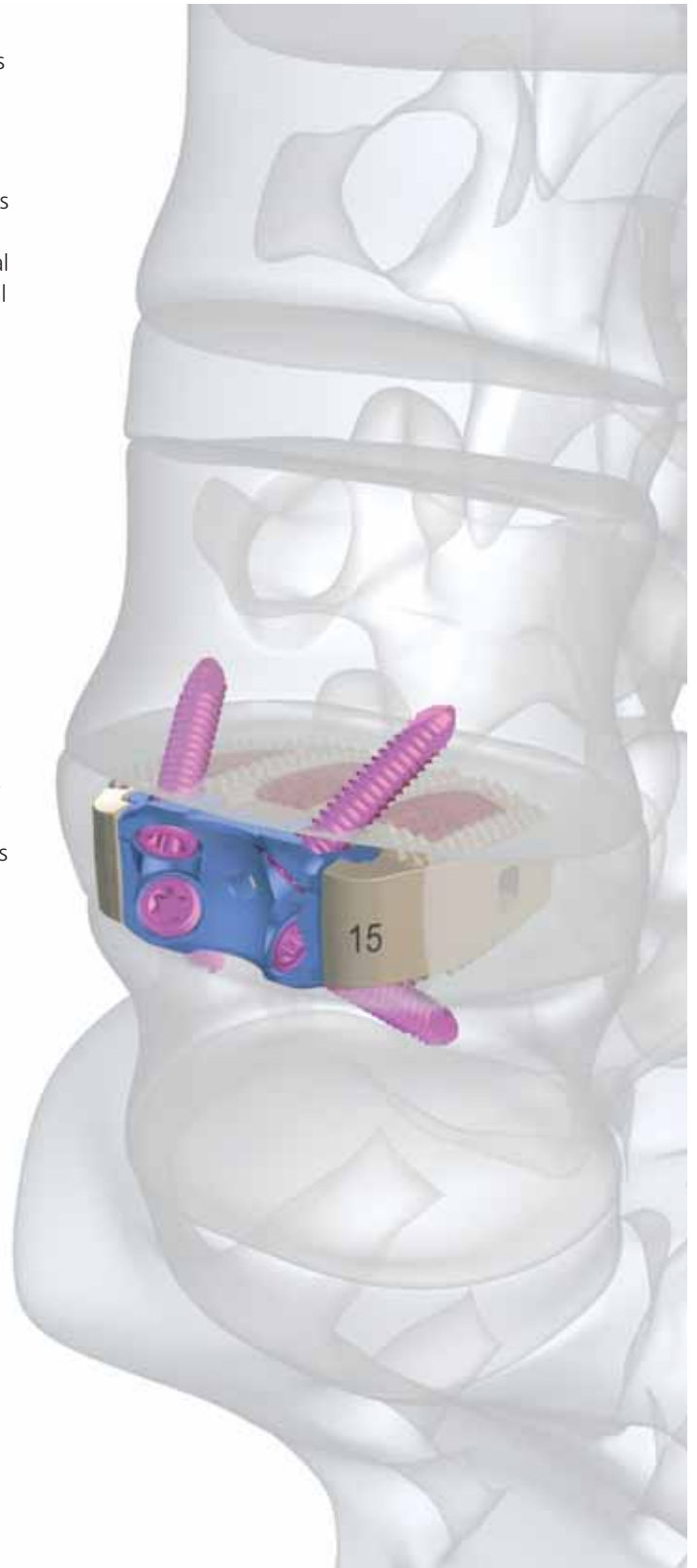
- Adapted from state-of-the-art fixation methods utilized in load-bearing trauma devices
- Self-tapping screw improves thread purchase
- Stardrive recess

Atraumatic, less invasive technique

- Single anterior approach allows restoration of disc height, lordotic angle and provides stable internal fixation
- Posterior muscular structures are preserved and surgical morbidity associated with 360° or posterior lumbar fusion surgery is eliminated
- SynFix-LR and its fixation does not extend beyond the confines of the intervertebral space, limiting the risk of damage to vessels and adjacent soft tissues

Superior biocompatibility

- Cage component is made out of pure medical grade PEEK Optima® (Polyetheretherketone)
- Peek Optima does not contain carbon fibres thereby reducing the risk of systematic uptake and local connective tissue formation

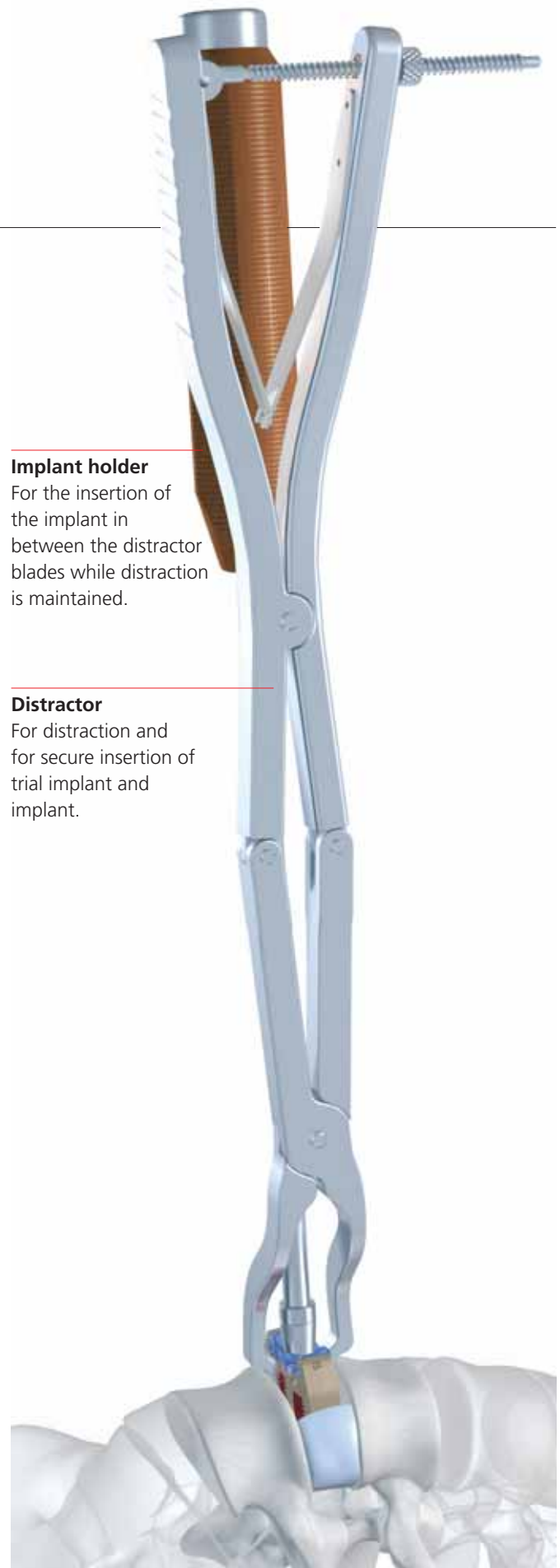


¹ Cain et al, 2005

SynFix-LR. Implant and instrumentation for stand alone anterior lumbar interbody fusion (ALIF).

Unique and simple instruments

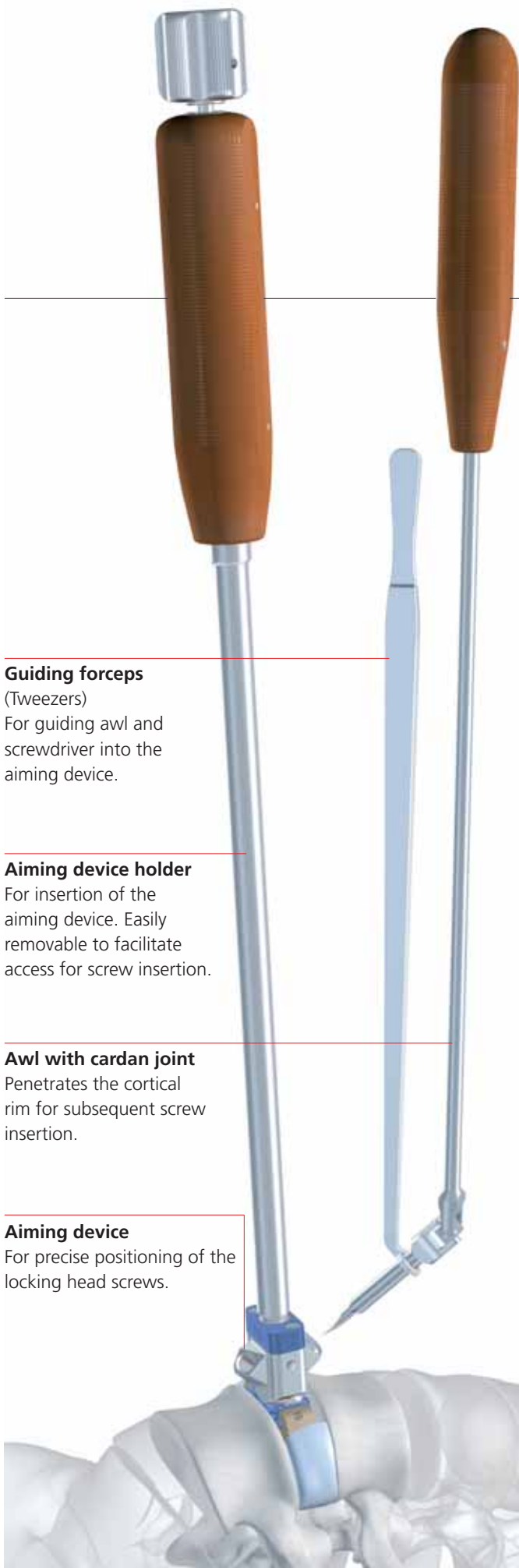
Specially designed instruments facilitate the insertion of locking head screws, overcoming potential problems with fixation at the lumbosacral junction.



Implant holder
For the insertion of the implant in between the distractor blades while distraction is maintained.

Distractor
For distraction and for secure insertion of trial implant and implant.

Insertion of the implant



Guiding forceps

(Tweezers)

For guiding awl and screwdriver into the aiming device.

Aiming device holder

For insertion of the aiming device. Easily removable to facilitate access for screw insertion.

Awl with cardan joint

Penetrates the cortical rim for subsequent screw insertion.

Aiming device

For precise positioning of the locking head screws.

Opening of the cortical bone for screw insertion



Self-retaining screwdriver with cardan joint

With ring marker to indicate the locking position of the screw within the titanium plate.

Insertion of the locking head screw

SynFix-LR is the Synthes implant and instrument system for stand-alone anterior lumbar interbody fusion (ALIF). The implant is designed in accordance with the AO/ASIF Principles for Spinal Interbody Fusion¹:

1. Provide adequate stability
2. Restore disc height
3. Restore lordosis
4. Maintain the integrity of the endplates
5. Provide an optimised fusion bed
6. Atraumatic technique

The integrated anterior fixation plate with locking head screws provides an anterior “tension band” and additional stability that allows its use as a stand-alone implant.

¹Aebi M, Thalgott JS, Webb JK (1998) AO ASIF Principles in Spine Surgery. Berlin: Springer

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 tumour
- Osteoporosis
- Infection

Contraindications for stand-alone application

- Spondylolisthesis
- Severe segmental instability

Implants

SynFix-LR

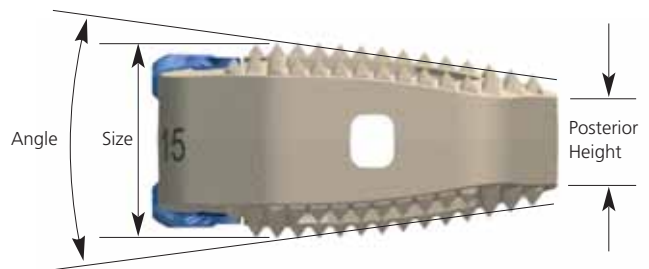
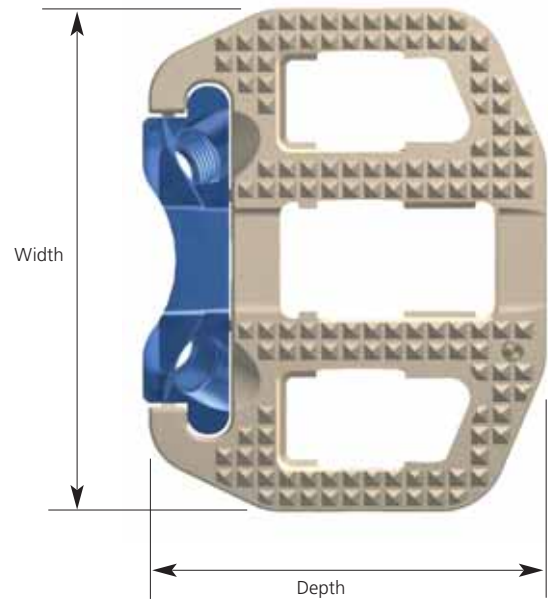
- Supplied sterile and pre-assembled (cage with anterior fixation plate)
- Plate components and trial implants are colour coded
- Cage component: PEEK Optima
- Plate component: Titanium Alloy (TAN)

Footprint 26 × 32 mm (depth × width)

Lordotic angle	Size	Posterior height	Implant	Colour code
8°	13.5 mm	7 mm	08.802.000S	gold
	15 mm	8.5 mm	08.802.001S	blue
	17 mm	10.5 mm	08.802.002S	purple
	19 mm	12.5 mm	08.802.003S	green
12°	13.5 mm	6 mm	08.802.004S	gold
	15 mm	7 mm	08.802.005S	blue
	17 mm	9 mm	08.802.006S	purple
	19 mm	11 mm	08.802.007S	green

Footprint 30 × 38 mm (depth × width)

8°	13.5 mm	6 mm	08.802.008S	gold
	15 mm	8 mm	08.802.009S	blue
	17 mm	10 mm	08.802.010S	purple
	19 mm	12 mm	08.802.011S	green
12°	13.5 mm	5.5 mm	08.802.012S	gold
	15 mm	7 mm	08.802.013S	blue
	17 mm	9 mm	08.802.014S	purple
	19 mm	11 mm	08.802.015S	green



Locking head screws

- Self-tapping
- Titanium Alloy (TAN)

Diameter	Length	Screw
4.0 mm	15 mm	04.802.200
4.0 mm	20 mm	04.802.201 (Recommended)
4.0 mm	25 mm	04.802.202
4.0 mm	30 mm	04.802.203



Trial implants

– Colour coded (same colour as the SynFix-LR plate component)

Footprint 26 × 32 mm (depth × width)

Lordotic angle	Size	Posterior height	Trial implant	Colour code
8°	13.5 mm	7 mm	08.802.000	gold
	15 mm	8.5 mm	08.802.001	blue
	17 mm	10.5 mm	08.802.002	purple
	19 mm	12.5 mm	08.802.003	green
12°	13.5 mm	6 mm	08.802.004	gold
	15 mm	7 mm	08.802.005	blue
	17 mm	9 mm	08.802.006	purple
	19 mm	11 mm	08.802.007	green

Footprint 30 × 38 mm (depth × width)

8°	13.5 mm	6 mm	08.802.008	gold
	15 mm	8 mm	08.802.009	blue
	17 mm	10 mm	08.802.010	purple
	19 mm	12 mm	08.802.011	green
12°	13.5 mm	5.5 mm	08.802.012	gold
	15 mm	7 mm	08.802.013	blue
	17 mm	9 mm	08.802.014	purple
	19 mm	11 mm	08.802.015	green



Distraction and insertion assembly

- Facilitates simultaneous distraction of the segment and insertion of the trial implants/final implants
- Reduces the force required for implant insertion
- Ergonomic
- Time-saving

Flexible instruments

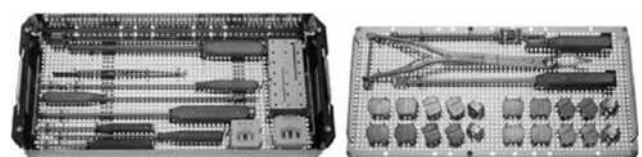
New instrumentation improves the accessibility of difficult insertion points for screws, e.g. screws inserted from a caudal to cranial direction at the lumbosacral level.



397.113	Distractor, anterior	
397.034	Handle for Trial Implants, straight	
03.802.031	Holder for Aiming Device for SynFix-LR	
03.802.032	Aiming Device for SynFix-LR, 13.5 mm	
03.802.036	Aiming Device for SynFix-LR, 15 mm	
03.802.033	Aiming Device for SynFix-LR, 17 mm	
03.802.034	Aiming Device for SynFix-LR, 19 mm	
03.802.035	Awl Ø 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	
03.802.041	Packing Block for SynFix-LR, 26 × 32 mm	
03.802.042	Packing Block for SynFix-LR, 30 × 38 mm	
394.585	Cancellous Bone Impactor, 7.0 × 8.5 mm	
389.288	Cancellous Bone Impactor, 8.0 × 2.5 mm	

Set

01.802.000	Instrument Set for SynFix-LR in Vario Case™
68.802.000	Vario Case™ for SynFix-LR, with Lid, without Contents



Preoperative planning

1

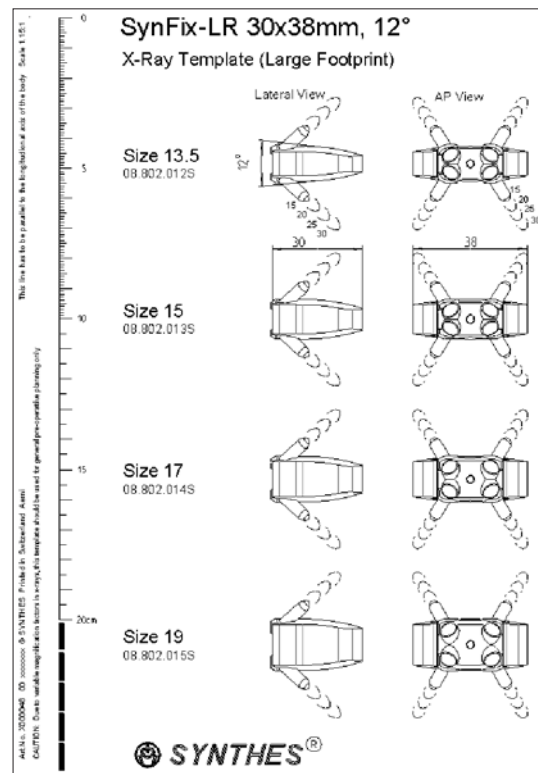
Preoperative planning

The surgical approach depends on the level to be treated, however direct anterior access is required for the insertion of the fixation screws.

Determine the approximate implant size by comparing the SynFix-LR radiograph template (X000045 – X000048) 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 cage to account for penetration of the teeth into the vertebral endplate.
- With the segment fully distracted, the SynFix-LR must fit firmly between the endplates before locking head screws are inserted. When rocking the implant holder backward and forward in a cephalad to caudal direction, no toggling of the implant should be evident.
- It is recommended to select the maximum implant size in order to optimize the stability of the segment through tension in the annulus fibrosus and longitudinal ligaments.



2

Patient positioning

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

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 cage has been inserted, visualisation of the entire anterior fixation plate is necessary for insertion of the locking head screws.

Surgical technique

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 9) 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.

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



2

Prepare disc space

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 cage.

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

Note: It is essential that all nuclear material and the inner annulus are removed to prevent displacement of disc material into the spinal canal during cage insertion and interference with bone in-growth.



3

Distract segment

Required instruments

Anterior Distractor	397.113
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Distraction of the segment is essential for restoration of disc height, opening of the neural foramina and initial stability of the SynFix-LR.

Distract the segment with the anterior distractor. To ensure that the SynFix-LR 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.

Compress the distractor handle to open the disc space.

Note: The distractor must be firmly held in place during distraction and insertion of the trial implant or implant to prevent its ejection from the disc space and possible injury to adjacent structures.



4

Trial for implant size

Required instruments

Trial implants (see page 9)	03.802.000-015
Handle for Trial Implants, straight	397.034

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.

Slide the trial implant between the distractor blades into the disc space. 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 incrementally larger trial implants. Conversely, if the trial implant cannot be inserted, repeat using incrementally smaller trial implants.

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

Note: Markings on the trial implant indicate the entry points of the locking screws in the anterior aspect of the adjacent vertebrae.

- ① The image intensifier may be used to check the position of the trial implant, restoration of disc and foraminal height and the overall alignment before selecting the final SynFix-LR implant size.



5

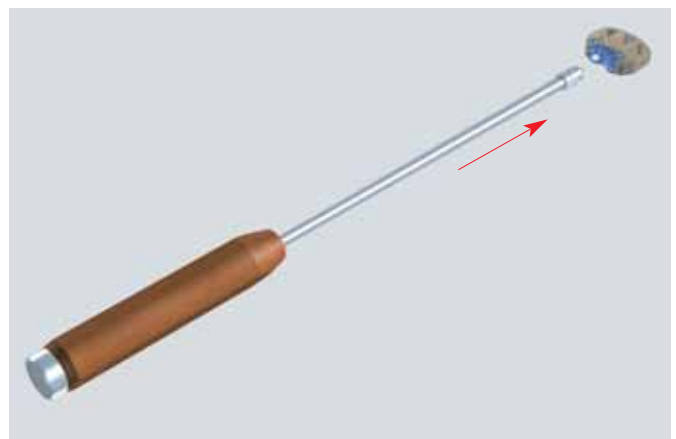
Select implant size

Required instruments

Implant Holder for SynFix-LR	03.802.039
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Corresponding to the trial implant size, select the final SynFix-LR implant and attach it to the implant holder.

To facilitate selection of the final implant, trial implants are laser etched with the nominal height of the cages, and both trial implants and fixation plates are colour coded.



6

Pack implant with bone graft

Required instruments

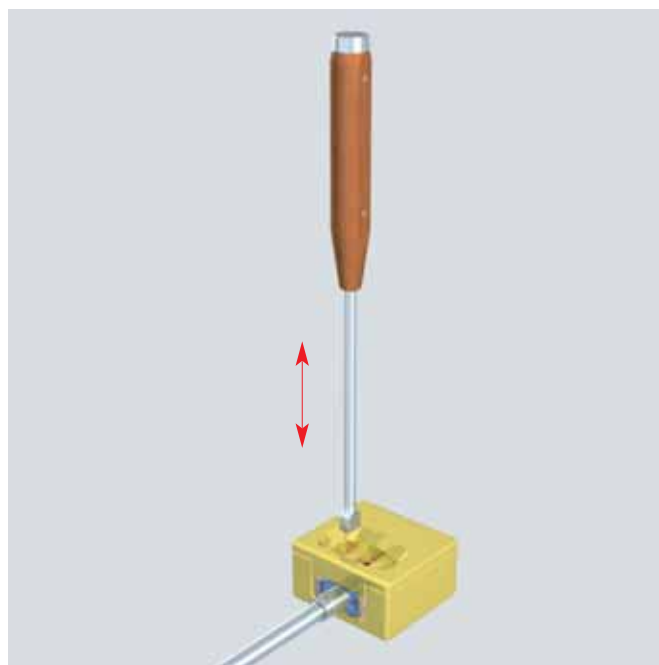
Packing Block for SynFix-LR, 26 × 32 mm	03.802.041
Packing Block for SynFix-LR, 30 × 38 mm	03.802.042
Cancellous Bone Impactor, 7.0 × 8.5 mm	394.585
Cancellous Bone Impactor, 8.0 × 2.5 mm	389.288

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

Note: The implant holder has to be attached firmly to the fixation plate in order to avoid damage either of the implant holder or the plate.

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

It is important to fill the cage until the graft protrudes from the perforations in the cage, to ensure optimal contact with the vertebral endplates.



7

Insert implant

Required instruments

Anterior Distractor	397.113
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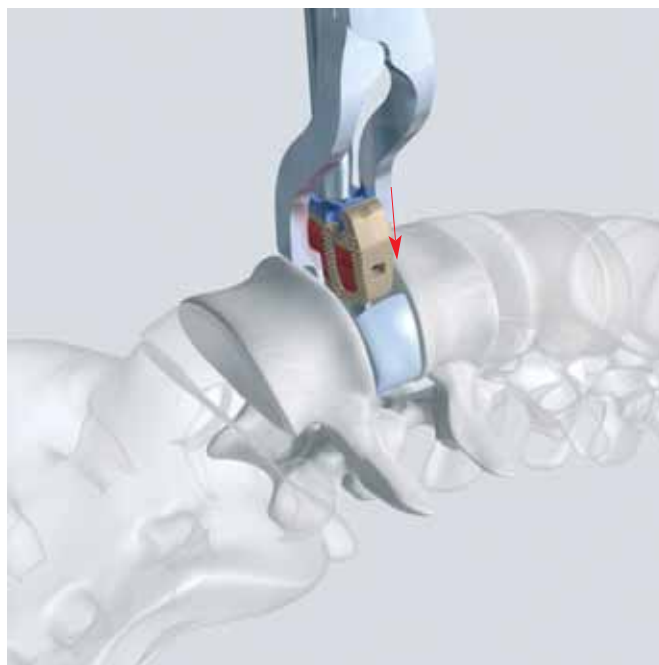
With the SynFix-LR ready for insertion, distract the segment again. Fix the distraction by tightening the locking nut on the distractor handle.

Slide the SynFix-LR between the distractor blades into the disc space.

Fully introduce the SynFix-LR into the disc space with light hammering.

Note: The distractor should be held firmly in place during implant insertion.

- Verify final implant position with the help of an intra-operative lateral X-ray. It is recommended to place the cage such that the screws subsequently will penetrate the endplates of the superior and inferior vertebral bodies close to the anterior rim.



8

Remove instruments

When the SynFix-LR is correctly positioned loosen the locking nut on the distractor handle and release the distraction.

Gently remove the distractor while the implant holder is holding the SynFix-LR in position.

After the distractor has been removed ensure a secure fit by lightly hammering on the implant holder.

Release the implant holder. The implant should now have its optimal position.

Note: All instruments must be removed carefully to avoid possible injury to adjacent structures.



9

Mount aiming device

Required instruments

Holder for Aiming Device for SynFix-LR	03.802.031
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The aiming devices are colour coded and correspond with the implant size and colour:

Aiming Device	Corresponding implant size	Colour code
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

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

Choose the corresponding aiming device and insert it using the aiming device holder.

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) fits with the plate hole for the fixation screw.

Once the aiming device has been positioned, fix it by tightening the nut (c) on top of the handle of the holder for aiming device.



10

Insert awl

Required instruments

Awl Ø 3.2mm for SynFix-LR	03.802.035
Tweezers for SynFix-LR	03.802.038

For better visualisation of the operative site it is recommended to remove the aiming device holder temporarily, leaving the aiming device attached to the fixation plate.

Insert the awl with the Tweezers for SynFix-LR, which ensures directional control. Prepare the cortical rim of the vertebral body for screw insertion by applying pressure on the handle of the awl in conjunction with rotational motions.

Notes:

- Use the tweezers to control the tip of the awl and to avoid injury to the surrounding abdominal viscera or vessels.
- The tweezers can also be used for removal of the awl in order to avoid damage of adjacent structures.



11

Insert first screw

Required instruments

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

According to the preoperative planning and intraoperative findings select the appropriate screw length (20 mm screws are recommended for use in most cases).

Insert the self-tapping screws with the self-retaining screwdriver and the tweezers.

Notes:

- The tweezers allow control of the screw during insertion. This avoids damage of the surrounding abdominal viscera or vessels. They are of particular value in lumbosacral instrumentations for screw insertion into the inferior endplate of the level L5.
- The tweezers can also be used for removal of the screwdriver in order to avoid damage of adjacent structures.



12

Tighten the 1st screw

Required instruments

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

Tighten the screw firmly. 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 is reached and the screw head engages the fixation plate correctly.

Note: It is difficult to remove the aiming device unless the locking head of the screw is properly seated in the fixation plate.



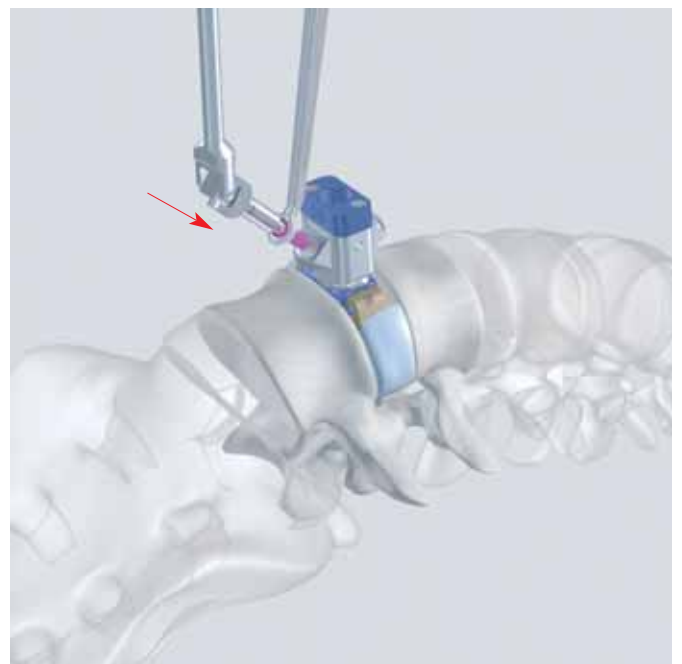
13

Insert 2nd screw

Required instruments

Awl \varnothing 3.2mm for SynFix-LR	03.802.035
Tweezers for SynFix-LR	03.802.038
Screwdriver for SynFix-LR	03.802.037

Insert the second screw following steps 10 to 12: Use the awl in conjunction with the tweezers through the second opening in the aiming device. Insert the second screw with the screwdriver and the tweezers.



14

Rotate aiming device

Required instruments

Holder for Aiming Device for SynFix-LR

03.802.031

Re-attach the aiming device holder to the aiming device before rotation.

Loosen the aiming device by turning the nut on top of the holder of the handle four to five turns (1). Now the aiming device can be rotated 180° without having to disengage it completely from the fixation plate (2).

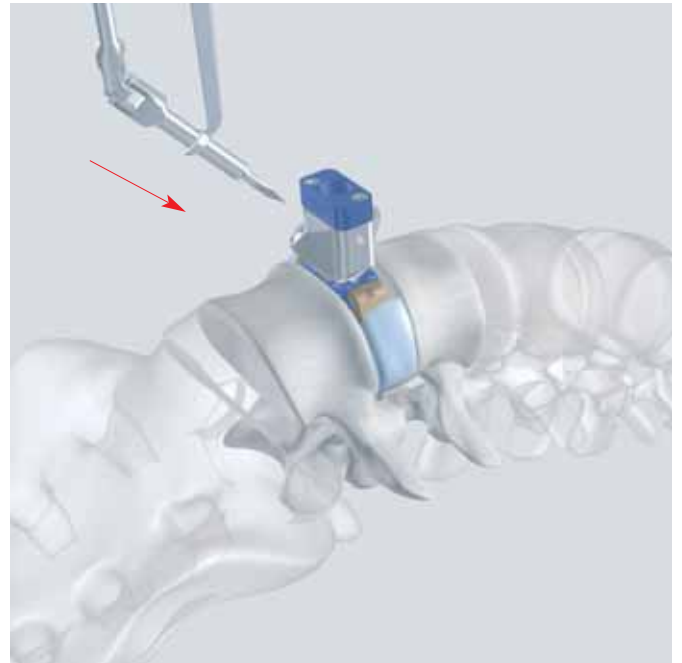
Re-lock the aiming device.



15

Insert 3rd and 4th screw

For insertion of the third and fourth screw, repeat steps 10 to 13.



16

Remove instruments

Once the fixation plate is secured, remove the aiming device by turning the nut on top of the aiming device holder.



17

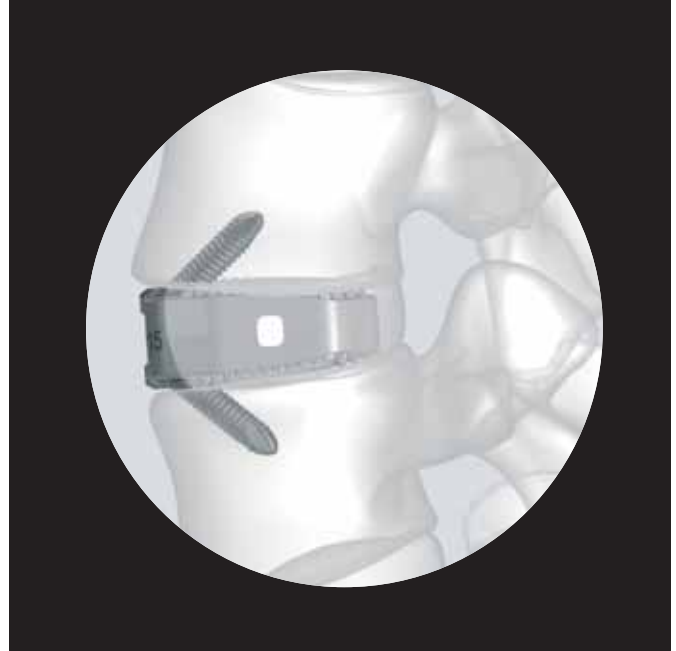
Verify placement

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

Depending on the size of the vertebrae, the anterior edge of the SynFix-LR will usually be one to three millimetres behind the anterior edge of the adjacent vertebrae.

- The location of the SynFix-LR relative to the vertebral bodies in the AP and lateral direction can be verified using an image intensifier.

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



Postoperative management

Notes and warnings

Postoperative management

The patients can usually be mobilised 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.

Notes and warnings

The following is a brief description of additional information on the SynFix-LR system. Please consult the package insert for further information.

- The SynFix-LR is provided sterile pre-packed.
- For sterilisation of the instruments remove all packaging and labelling and clean the products (e.g. with medical grade ethanol or in an ultrasound bath) and then sterilise them in a steam autoclave at a maximum temperature of 134°C (273°F).
- Use caution in handling the SynFix-LR. Damage to the surface finish and/or teeth can lead to fatigue failure or displacement of the SynFix-LR.
- It is essential that enough material is removed from the intervertebral disc to accommodate the SynFix-LR, otherwise disc material may be displaced posteriorly during insertion of the implant.
- The trial implants are not for implantation and must be removed before insertion of the SynFix-LR.
- The indications and contraindications for the use of the SynFix-LR are listed above.
- If it is not possible to insert and lock into position all four locking head screws, additional posterior fixation is recommended.
- Translaminar screws or transpedicular screw fixation might be indicated.

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Presented by

