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

Stand-alone ALIF
- Biomechanically equivalent to a spacer with pedicle screws
- PEEK spacer provides modulus of elasticity similar to cortical bone
- Titanium plate with locking screws provides stable fixation

Zero-profile construct
- Spacer and plate fit completely within the disc space

Anatomic shape
- The SynFix-LR is convex to match the anatomy of the disc space
- Two footprints and two lordotic angles are offered to accommodate individual patients

Screw and plate fixation
- One-step conical locking mechanism ensures screws securely lock to plate and eliminates need for blocking plate
- Locking screws 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 maximum fixation

Simple instrumentation
Once disc preparation and implant trialing are complete, only four simple instruments are needed to insert the SynFix-LR.

SynFix Quick Inserter/Distractor (SQUID)
Inserts and distracts in one simple step, without impaction.

Fixed-handle aiming device
For precise positioning of the locking screws.

Low-profile awl
Penetrates the cortical bone for screw insertion.

Low-profile driver
Provides precise insertion of locking screws.
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.\(^2\) They are:

- Anatomic reduction
- Stable internal fixation
- Preservation of blood supply
- Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.\(^3\)

**AO Principles as Applied to the Spine\(^4\)**

**Anatomic alignment**
Restoration of normal spinal alignment to improve the biomechanics of the spine.

**Stable internal fixation**
Stabilization of the spinal segment to promote bony fusion.

**Preservation of blood supply**
Creation of an optimal environment for fusion.

**Early, active mobilization**
Minimization of damage to the spinal vasculature, dura, and neural elements, which may contribute to pain reduction and improved function for the patient.

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3. Ibid.

Indications and Contraindications

Indications
The Synthes SynFix-LR is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the SynFix-LR can be packed with autograft.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of nonoperative treatment.

Contraindications
Use of the Synthes SynFix-LR is contraindicated when:
– There is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials (PEEK, titanium, aluminum and/or niobium).
– Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
– Where patient anatomy or pathology prevents insertion of all four locking head screws.
Preoperative Planning

**Optional technique**

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>X000045*</td>
<td>SynFix-LR Preoperative Planner, 26 x 32 mm, 8°</td>
</tr>
<tr>
<td>X000046*</td>
<td>SynFix-LR Preoperative Planner, 26 x 32 mm, 12°</td>
</tr>
<tr>
<td>X000047*</td>
<td>SynFix-LR Preoperative Planner, 30 x 38 mm, 8°</td>
</tr>
<tr>
<td>X000048*</td>
<td>SynFix-LR Preoperative Planner, 30 x 38 mm, 8°</td>
</tr>
</tbody>
</table>

Determine the approximate implant size by comparing the SynFix-LR preoperative planner 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 optimize the stability of the segment through tension in the longitudinal ligaments.

* Also available
Preparation

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

Anterior access and approach

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 with the SynFix mini-open instruments.

Exposure

The locking screws of the SynFix-LR system must be inserted from a direct anterior approach. Expose the segment to produce sufficient space on either side of the vertebral midline, equal to half the width of the implant. This allows insertion of the implant, without interference from adjacent soft tissue structures. (Two implant widths are available, 32 mm and 38 mm.)

Note: When the spacer has been inserted, visualization of the entire anterior plate is necessary for insertion of the locking screws. Give proper consideration to the exposure so instrumentation can be used as depicted on the following pages.
1 Discectomy and endplate preparation

Optional instrument

PDL114* Vertebral Body Spreader, angled

Create an annulotomy centered on the midline and wide enough to accommodate the SynFix-LR implant. A trial spacer may be used as a template to indicate the width of the annular window required.

Perform a thorough discectomy, ensuring the posterolateral corners are freed of disc material.

Remove the cartilaginous endplates to bleeding bone, taking care to not compromise the integrity of the bony endplates. If additional disc space distraction or remobilization is necessary, the spreader is available in the ProDisc-L Instrument Set.

**Note:** 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.

For a safe placement, verify spreader position with the help of an intraoperative lateral x-ray.

*Also available*
2

Trial for implant size

Instruments

03.802.000 – SynFix-LR Trial Implants
03.802.019

389.151 Handle, for Trial Spacers

Optional instrument

397.113 Distractor, for SynFix-LR

PDL102 Slotted Mallet

Select the trial implant with the appropriate footprint and lordotic angle (see page 33). Firmly attach it to the trial spacer handle.

A distractor may be used to assist with guiding the trial spacer 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.

Controlled, light hammering on the trial spacer handle may be required to advance the trial spacer into the disc space.

**Important:** After impacting the trial spacer handle, it may be necessary to retighten the handle.
2. Trial for implant size continued

If a tight fit is not achieved, repeat the process using incrementally larger trial spacers. Conversely, if the trial spacer cannot be inserted, repeat using incrementally smaller trial spacers.

With the segment fully distracted, the trial spacer must fit firmly in the disc space.

When rocking the trial spacer handle in a cranial to caudal direction, no toggling of the trial spacer should be evident.

**Note:** Do not move the trial spacer handle laterally during removal. It is recommended that the slotted mallet be used to remove the handle if necessary.

X-ray 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 spacer 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.

Select the maximum size, to optimize the stability of the segment.

---

### 3
**Select implant size**

Select the SynFix-LR implant corresponding to the final trial spacer size and attach it to the implant holder.

To facilitate selection of the implant, trial spacers are laser etched with the height, lordotic angle and footprint of the implant. Trial spacers, aiming guides and plates are color-coded by height.

---

### 4
**Pack implant with autograft**

#### Instruments

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.041</td>
<td>Packing Block, for 26 mm depth x 32 mm width SynFix-LR</td>
</tr>
<tr>
<td>03.802.042</td>
<td>Packing Block, for 30 mm depth x 38 mm width SynFix-LR</td>
</tr>
<tr>
<td>389.288</td>
<td>Cancellous Bone Impactor, 8 mm x 2.5 mm</td>
</tr>
<tr>
<td>394.585</td>
<td>Cancellous Bone Impactor, 5.5 mm x 8.5 mm</td>
</tr>
</tbody>
</table>

Insert the SynFix implant into the appropriate packing block.

Use a cancellous bone impactor to firmly pack the autograft material into the implant cavities.
5

**Insert Implant**

**Option A: Using SQUID**

**Instrument**

| 03.802.121 | SynFix-LR Synthes Quick Inserter/Distractor (SQUID) |

Release the main thread 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 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.
Place the tips of the instrument into the disc space so 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.

**Important:** The pusher will be moving toward the vertebral body and the ejector is proud above the spring ramps and stops. 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.

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 distracts the disc space.

Continue turning the T-handle until the instrument is fully ejected and released. An audible click as the ramps spring back to meet each other confirms that the implant is seated and the instrument is fully ejected and released.

**Note:** The titanium 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 2 mm from the posterior wall of the spacer.
5. Insert implant continued

Option B: Using implant holder

**Instrument**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.039</td>
<td>Implant Holder, for SynFix-LR</td>
</tr>
</tbody>
</table>

**Optional instrument**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>397.113</td>
<td>Distractor, for SynFix-LR</td>
</tr>
</tbody>
</table>

Attach the implant holder to the SynFix-LR implant. The implant holder must be attached firmly to the plate to avoid damage to the implant holder or the plate.

**Important:** Do not cross thread the implant holder into the implant. To prevent cross threading, ensure that the implant holder is perpendicular to the implant during engagement.

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.

Hold the distractor firmly in place during implant insertion.

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

**Notes:** The titanium 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 2 mm from the posterior wall of the spacer.

If it is necessary to remove the implant once it is positioned, see page 30 for implant removal procedure.
Remove instruments
When the implant is correctly positioned, if an optional distractor was used, loosen the locking nut on the distractor handle and release the distraction.

Gently remove the distractor while the implant holder maintains the implant position.

After the distractor is removed, ensure a secure fit by lightly hammering on the implant holder.

Remove the implant holder by rotating the handle counter-clockwise.

The implant should now be in its optimal position.

Depending on the size of the vertebrae, the anterior edge of the implant will usually be flush to three-millimeters-recessed relative to the anterior aspect of the adjacent vertebrae.

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

Optional instrument

03.802.400 Handheld Retractor, curved, for SynFix-LR

The curved retractor can be used for additional tissue protection with both the mini-open and standard instrument sets. Anchor the retractor under the selected aiming device for optimal tissue retraction. For additional information about the aiming device, see pages 17 and 24.

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

The retractor is not designed to withstand excessive forces.
Insert Screws Using Mini-Open Instruments

Screws can be inserted using either mini-open instruments or standard instruments (see pages 24–30 for Steps 6b–14b).

6a

Mount aiming device

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.200</td>
<td>SynFix Mini-Open Implant Coupling</td>
</tr>
</tbody>
</table>

**Mini-Open Fixed-Handle Aiming Devices**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.202</td>
<td>For 12 mm SynFix (light blue)</td>
</tr>
<tr>
<td>03.802.203</td>
<td>For 13.5 mm SynFix (gold)</td>
</tr>
<tr>
<td>03.802.205</td>
<td>For 15 mm SynFix (blue)</td>
</tr>
<tr>
<td>03.802.207</td>
<td>For 17 mm SynFix (purple)</td>
</tr>
<tr>
<td>03.802.209</td>
<td>For 19 mm SynFix (green)</td>
</tr>
</tbody>
</table>

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

The aiming device ensures appropriate alignment of the screws and engagement of the locking heads into the plate.

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

Choose the appropriate aiming device and insert the implant coupling.

Insert the aiming device into exposure. The arrows located just below the handle indicate caudal and cranial orientation of the aiming device.

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

When the aiming device has been positioned, secure it by tightening the implant coupling knob on the top of the fixed-handle aiming device.

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

**Notes:**
It is not necessary to impact or completely rotate the awl to break the cortex. Rotational motions clockwise and counterclockwise are sufficient.

The guiding forceps can be used as an option to control the tip while inserting into the aiming device.

The awl penetration is approximately 10 mm, equivalent to the purchase length of a 15 mm screw.

Insert the first screw before preparing any other holes.
**8a Insert first screw**

**Instruments**

- 03.802.431 Tapered U-Joint Driver for SynFix Mini-Open
- 03.802.038 Screw Holding Instrument, for SynFix-LR (guiding forceps)
- 388.396 Handle, with quick coupling, small

**Optional Instrument**

- 03.802.030 Screwdriver Shaft, T15

Select the appropriate screw length. Screw length should be selected to penetrate completely through the cortical bone. For a two-level procedure, proper consideration should be given to the length of screw in the common vertebral body to prevent screw interference. Use the guiding forceps to control the screw while inserting into or removing from the aiming device.

**Important:** The small handle with quick coupling is required when using the SynFix mini-open driver or the T15 screwdriver shaft. You must not use any other handle with either of these shafts.

The mini-open instruments can accommodate up to a 25 mm length screw. For a 30 mm screw, use the standard instruments (see pages 24–30 for Steps 6b–14b).

Insert the self-tapping screw through the aiming device and into the pilot hole created by the awl.

**Important:** Four (4) screws should always be used for every SynFix-LR construct.

The four locking screws should be inserted sequentially. Awl and screw insertion should be done through a SynFix-LR aiming device, to ensure the proper locking of the screw to the plate.
Tighten first screw

**Instruments**

- 03.802.431 Tapered U-Joint Driver for SynFix Mini-open
- 03.802.038 Screw Holding Instrument, for SynFix-LR (guiding forceps)
- 388.396 Handle, with quick coupling, small

Tighten the screw firmly.

As soon as the ring marked on the screwdriver meets the entry point of the aiming device, the screw is locked to the plate and should not be advanced further.

**Warning:** Excessive torque can damage or break the instruments or implant. Use four fingers for final tightening.

**Notes:**

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

The guiding forceps can also be used for removal of the screwdriver to avoid damaging adjacent structures.
10a
Insert second screw

Instruments

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>03.802.038</td>
<td>Screw Holding Instrument, for SynFix-LR (guiding forceps)</td>
</tr>
<tr>
<td>03.802.230</td>
<td>Low-Profile U-Joint Awl, for SynFix Mini-Open</td>
</tr>
<tr>
<td>03.802.431</td>
<td>Tapered U-Joint Driver for SynFix Mini-open</td>
</tr>
<tr>
<td>388.396</td>
<td>Handle, with quick coupling, small</td>
</tr>
</tbody>
</table>

Insert the second screw through the second opening in the aiming device, following Steps 7a through 9a.

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

The guiding forceps can also be used for removal of the screwdriver to avoid damaging adjacent structures.

11a
Rotate aiming device

Loosen the aiming device by turning the implant coupling counterclockwise four to five turns. The aiming device can be rotated 180° without disengaging completely from the plate.

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

Relock the aiming device by turning the implant coupling clockwise.

Notes:
The fixed-handle aiming device can be rotated in either direction.

The aiming device should fit snugly against the plate, do not overtighten.
12a

Insert third and fourth screws

For insertion of the third and fourth screws, repeat Steps 7a through 10a.

**Note:** Four (4) screws should always be used for every SynFix-LR construct.

13a

Remove instruments

When the plate is secured, remove the aiming device by turning the implant coupling on top of the handle.
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 implant will usually be flush to three-millimeters-recessed, relative to the anterior aspect of the adjacent vertebrae.

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

The titanium 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 approximately 2 mm from the posterior edge of the implant.
For inserting screws using mini-open instruments (Steps 6a–14a), see pages 17–23.

6b

Mount aiming device

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.031</td>
<td>Aiming Device Holder, for SynFix-LR</td>
</tr>
<tr>
<td>03.802.020</td>
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</tr>
<tr>
<td>03.802.032</td>
<td>13.5 mm (gold)</td>
</tr>
<tr>
<td>03.802.036</td>
<td>15 mm (blue)</td>
</tr>
<tr>
<td>03.802.033</td>
<td>17 mm (purple)</td>
</tr>
<tr>
<td>03.802.034</td>
<td>19 mm (green)</td>
</tr>
</tbody>
</table>

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

The aiming device ensures appropriate alignment of the screws and engagement of the locking heads into the plate.

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

Choose the appropriate aiming device and insert the implant coupling.

Insert the aiming device into exposure.

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

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

**Note:** The aiming device should fit snugly against the plate, do not overtighten.
Insert Screws Using Standard Instruments

### 7b

**Open cortex**

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.035</td>
<td>Cortex Opener, for SynFix-LR (awl)</td>
</tr>
<tr>
<td>03.802.038</td>
<td>Screw Holding Instrument, for SynFix-LR (guiding forceps)</td>
</tr>
</tbody>
</table>

For better visualization of the operative site, the aiming device holder can be removed, leaving the aiming device attached to the 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. Guiding forceps should be used to ensure directional control of the awl tip.

**Notes:**

Use the guiding forceps to control the tip of the awl and to avoid injury to the surrounding soft tissues or vessels.

The guiding forceps can also be used for removal of the awl, to avoid damaging adjacent structures.

It is not necessary to impact or completely rotate the awl to break the cortex. Rotational motions clockwise and counterclockwise are sufficient.

The awl penetration is approximately 10 mm, equivalent to the purchase length of a 15 mm screw.

Insert the first screw before preparing any other holes.
Insert first screw

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.037</td>
<td>Screwdriver, for SynFix-LR</td>
</tr>
<tr>
<td>03.802.038</td>
<td>Screw Holding Instrument, for SynFix-LR (guiding forceps)</td>
</tr>
</tbody>
</table>

**Optional Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.030</td>
<td>Screwdriver Shaft, T15</td>
</tr>
<tr>
<td>388.396</td>
<td>Handle, with quick coupling, small</td>
</tr>
</tbody>
</table>

Select the appropriate screw length. Screw length should be selected to penetrate completely through the cortical bone. For a two-level procedure, proper consideration should be given to the length of screw in the common vertebral body to prevent screw interference.

Insert the self-tapping screws with the screwdriver and the guiding forceps, through the aiming device and into the pilot hole created by the awl.

**Important:** The small handle with quick coupling is required when using the T15 screwdriver shaft. You must not use any other handle with this shaft.

Four (4) screws should always be used for every SynFix-LR construct.

The four locking screws should be inserted sequentially. Awl and screw insertion should be done through a SynFix-LR aiming device to ensure the proper locking of the screw to the plate.

**Notes:**

The guiding forceps allow control of the screw during insertion, to avoid damage to the surrounding soft tissue or vessels.

The guiding forceps can also be used for removal of the screwdriver to avoid damaging adjacent structures.
Tighten the first screw

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.037</td>
<td>Screwdriver, for SynFix-LR</td>
</tr>
<tr>
<td>03.802.038</td>
<td>Screw Holding Instrument, for SynFix-LR (guiding forceps)</td>
</tr>
</tbody>
</table>

Tighten the screw firmly.

As soon as the ring marked on the screwdriver meets the entry point of the aiming device, the screw is locked to the plate and should not be advanced further.

**Warning:** Excessive torque can damage or break the instruments or implant. Use four fingers for final tightening.

**Notes:**

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

The guiding forceps can also be used for removal of the screwdriver to avoid damaging adjacent structures.
### 10b
**Insert second screw**

**Instruments**

- 03.802.035 Cortex Opener, for SynFix-LR (awl)
- 03.802.037 Screwdriver, for SynFix-LR
- 03.802.038 Screw Holding Instrument, for SynFix-LR (guiding forceps)

Insert the second screw following Steps 7b through 9b through the second opening in the aiming device. Use the guiding forceps, to ensure directional control.

**Notes:**

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

The guiding forceps can also be used for removal of the screwdriver to avoid damaging adjacent structures.

---

### 11b
**Rotate aiming device**

**Instrument**

- 03.802.031 Aiming Device Holder, for SynFix-LR

If the aiming device handle was removed, reattach it to the aiming device before rotation.

Loosen the aiming device by turning the nut (1) counterclockwise four to five turns. The aiming device can be rotated 180°, without disengaging it completely from the plate.

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

**Notes:**

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.
12b

Insert third and fourth screws

For insertion of the third and fourth screws, repeat Steps 7b through 10b.

**Note:** Four (4) screws should always be used for every SynFix-LR construct.

---

13b

Remove instruments

When the plate is secured, remove the aiming device by turning the nut on top of the aiming device holder.
**14b**

**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 implant will usually be flush to three-millimeters-recessed, relative to the anterior aspect of the adjacent vertebrae.

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

The titanium 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 approximately 2 mm from the posterior edge of the implant.
Implant Removal Procedure

Instrument

388.407  Holding Forceps

The holding forceps can be used to retrieve the SynFix-LR implant. Once the implant is removed, it may not be reused.

If cross threading occurs while engaging the implant holder with the SynFix-LR implant, the threaded end of the implant holder may fragment in the central hole of the plate. If this occurs, the threaded fragment must be removed.

Connect forceps to implant
Engage the SynFix-LR implant with the forceps at one of the four screw holes.

Remove implant
Apply a gentle extraction force to the forceps to remove the implant. After removal of the implant, ensure that all components are removed from the intervertebral disc space.
**SynFix-LR Implants**

- Supplied sterile and preassembled (spacer with anterior plate)
- Plate components are color-coded by height
- Cage component: PEEK (polyetheretherketone)
- Plate component: titanium alloy (Ti-6Al-7Nb)

---

### 26 mm x 32 mm

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Lordotic angle</th>
<th>Height (mm)</th>
<th>Posterior Height (mm)</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.802.016S</td>
<td>8°</td>
<td>12</td>
<td>9</td>
<td>Light Blue</td>
</tr>
<tr>
<td>08.802.000S</td>
<td>8°</td>
<td>13.5</td>
<td>10.5</td>
<td>Gold</td>
</tr>
<tr>
<td>08.802.001S</td>
<td>8°</td>
<td>15</td>
<td>12</td>
<td>Blue</td>
</tr>
<tr>
<td>08.802.002S</td>
<td>8°</td>
<td>17</td>
<td>14</td>
<td>Purple</td>
</tr>
<tr>
<td>08.802.003S</td>
<td>8°</td>
<td>19</td>
<td>16</td>
<td>Green</td>
</tr>
<tr>
<td>08.802.017S</td>
<td>12°</td>
<td>12</td>
<td>7.5</td>
<td>Light Blue</td>
</tr>
<tr>
<td>08.802.004S</td>
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<td>13.5</td>
<td>9</td>
<td>Gold</td>
</tr>
<tr>
<td>08.802.005S</td>
<td>12°</td>
<td>15</td>
<td>10.5</td>
<td>Blue</td>
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<td>08.802.006S</td>
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<td>08.802.007S</td>
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</table>

### 30 mm x 38 mm

<table>
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<tr>
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<th>Lordotic angle</th>
<th>Height (mm)</th>
<th>Posterior Height (mm)</th>
<th>Color</th>
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<tbody>
<tr>
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<td>08.802.008S</td>
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</tr>
<tr>
<td>08.802.009S</td>
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<td>15</td>
<td>11.5</td>
<td>Blue</td>
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<tr>
<td>08.802.010S</td>
<td>8°</td>
<td>17</td>
<td>13.5</td>
<td>Purple</td>
</tr>
<tr>
<td>08.802.011S</td>
<td>8°</td>
<td>19</td>
<td>15.5</td>
<td>Green</td>
</tr>
<tr>
<td>08.802.019S</td>
<td>12°</td>
<td>12</td>
<td>7</td>
<td>Light Blue</td>
</tr>
<tr>
<td>08.802.012S</td>
<td>12°</td>
<td>13.5</td>
<td>8.5</td>
<td>Gold</td>
</tr>
<tr>
<td>08.802.013S</td>
<td>12°</td>
<td>15</td>
<td>10</td>
<td>Blue</td>
</tr>
<tr>
<td>08.802.014S</td>
<td>12°</td>
<td>17</td>
<td>12</td>
<td>Purple</td>
</tr>
<tr>
<td>08.802.015S</td>
<td>12°</td>
<td>19</td>
<td>14</td>
<td>Green</td>
</tr>
</tbody>
</table>

*Posterior height is measured from the top of the most posterior teeth. Total combined height of teeth is 1.8 mm.*
4.0 mm Titanium Locking Screws
– Self-tapping
– Titanium alloy (Ti-6Al-7Nb)

<table>
<thead>
<tr>
<th>Length (mm)</th>
<th>Bone Purchase (mm)</th>
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</thead>
<tbody>
<tr>
<td>04.802.200</td>
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<tr>
<td>04.802.201</td>
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<tr>
<td>04.802.202</td>
<td>25</td>
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<tr>
<td>04.802.203</td>
<td>30</td>
</tr>
</tbody>
</table>

**Bone purchase is approximately 5 mm less than length.**

4.0 mm Titanium Locking Screws, fine tip
– Self-tapping
– Titanium alloy (Ti-6Al-7Nb)
– Designed to more easily penetrate dense sclerotic bone

<table>
<thead>
<tr>
<th>Length (mm)</th>
<th>Bone Purchase (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.802.210</td>
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</tr>
<tr>
<td>04.802.211</td>
<td>20</td>
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<tr>
<td>04.802.212</td>
<td>25</td>
</tr>
<tr>
<td>04.802.213</td>
<td>30</td>
</tr>
</tbody>
</table>
SynFix-LR Trial Implants
– Color-coded by height
– Color corresponds to the SynFix-LR implant plate component

<table>
<thead>
<tr>
<th>26 mm x 32 mm</th>
<th>30 mm x 38 mm</th>
<th>Lordotic angle</th>
<th>Height (mm)</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.016</td>
<td>03.802.018</td>
<td>8°</td>
<td>12</td>
<td>Light Blue</td>
</tr>
<tr>
<td>03.802.000</td>
<td>03.802.008</td>
<td>8°</td>
<td>13.5</td>
<td>Gold</td>
</tr>
<tr>
<td>03.802.001</td>
<td>03.802.009</td>
<td>8°</td>
<td>15</td>
<td>Blue</td>
</tr>
<tr>
<td>03.802.002</td>
<td>03.802.010</td>
<td>8°</td>
<td>17</td>
<td>Purple</td>
</tr>
<tr>
<td>03.802.003</td>
<td>03.802.011</td>
<td>8°</td>
<td>19</td>
<td>Green</td>
</tr>
<tr>
<td>03.802.017</td>
<td>03.802.019</td>
<td>12°</td>
<td>12</td>
<td>Light Blue</td>
</tr>
<tr>
<td>03.802.004</td>
<td>03.802.012</td>
<td>12°</td>
<td>13.5</td>
<td>Gold</td>
</tr>
<tr>
<td>03.802.005</td>
<td>03.802.013</td>
<td>12°</td>
<td>15</td>
<td>Blue</td>
</tr>
<tr>
<td>03.802.006</td>
<td>03.802.014</td>
<td>12°</td>
<td>17</td>
<td>Purple</td>
</tr>
<tr>
<td>03.802.007</td>
<td>03.802.015</td>
<td>12°</td>
<td>19</td>
<td>Green</td>
</tr>
</tbody>
</table>
**SynFix-LR Aiming Devices**

### Standard Aiming Device (required exposure 8–10 cm)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.020</td>
<td>Aiming Device, 12 mm, for SynFix-LR (light blue)</td>
</tr>
<tr>
<td>03.802.032</td>
<td>Aiming Device, 13.5 mm, for SynFix-LR (gold)</td>
</tr>
<tr>
<td>03.802.036</td>
<td>Aiming Device, 15 mm, for SynFix-LR (blue)</td>
</tr>
<tr>
<td>03.802.033</td>
<td>Aiming Device, 17 mm, for SynFix-LR (purple)</td>
</tr>
<tr>
<td>03.802.034</td>
<td>Aiming Device, 19 mm, for SynFix-LR (green)</td>
</tr>
</tbody>
</table>

If a standard aiming device is used, a radius of approximately 4.3 cm is required. It enables guidance of the awl and the screwdriver while ensuring the secure insertion of all screws.

### Modified Aiming Device (required exposure 7–9 cm)

Also Available:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.242</td>
<td>12 mm Aiming Device Modified Guide Opening, for SynFix-LR (light blue)</td>
</tr>
<tr>
<td>03.802.243</td>
<td>13.5 mm Aiming Device Modified Guide Opening, for SynFix-LR (gold)</td>
</tr>
<tr>
<td>03.802.245</td>
<td>15 mm Aiming Device Modified Guide Opening, for SynFix-LR (blue)</td>
</tr>
<tr>
<td>03.802.247</td>
<td>17 mm Aiming Device Modified Guide Opening, for SynFix-LR (purple)</td>
</tr>
<tr>
<td>03.802.249</td>
<td>19 mm Aiming Device Modified Guide Opening, for SynFix-LR (green)</td>
</tr>
</tbody>
</table>

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

Guidance is established just before the awl penetrates the cortex.
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 mini-open device requires a smaller exposure, but offers minimal guidance. The modified aiming device offers slightly less guidance than the standard aiming device, but allows for a smaller incision.
### Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.802.030</td>
<td>Screwdriver Shaft, T15</td>
<td><img src="image1" alt="Image" /></td>
</tr>
<tr>
<td>03.802.031</td>
<td>Aiming Device Holder, for SynFix-LR</td>
<td><img src="image2" alt="Image" /></td>
</tr>
<tr>
<td>03.802.035</td>
<td>Cortex Opener, for SynFix-LR</td>
<td><img src="image3" alt="Image" /></td>
</tr>
<tr>
<td>03.802.037</td>
<td>Screwdriver, for SynFix-LR</td>
<td><img src="image4" alt="Image" /></td>
</tr>
<tr>
<td>03.802.038</td>
<td>Screw Holding Instrument, for SynFix-LR</td>
<td><img src="image5" alt="Image" /></td>
</tr>
<tr>
<td>03.802.039</td>
<td>Implant Holder, for SynFix-LR</td>
<td><img src="image6" alt="Image" /></td>
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For use with Distractor (397.113)
<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>03.802.041</td>
<td>Packing Block, for 26 mm depth x 32 mm width SynFix-LR</td>
</tr>
<tr>
<td>03.802.042</td>
<td>Packing Block, for 30 mm depth x 38 mm width SynFix-LR</td>
</tr>
<tr>
<td>03.802.121</td>
<td>SynFix-LR Synthes Quick Inserter/Distractor (SQUID)</td>
</tr>
<tr>
<td>03.802.200</td>
<td>SynFix Mini-Open Implant Coupling</td>
</tr>
<tr>
<td>03.802.230</td>
<td>Low Profile U-Joint Awl, for SynFix Mini-Open</td>
</tr>
<tr>
<td>03.802.431</td>
<td>Tapered U-Joint Driver, for SynFix Mini-Open</td>
</tr>
</tbody>
</table>
Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>388.396</td>
<td>Handle, with quick coupling, small</td>
</tr>
<tr>
<td>388.407</td>
<td>Holding Forceps</td>
</tr>
<tr>
<td>389.151</td>
<td>Handle, for Trial Spacers</td>
</tr>
<tr>
<td>389.288</td>
<td>Cancellous Bone Impactor, 8 mm x 2.5 mm</td>
</tr>
<tr>
<td>394.585</td>
<td>Cancellous Bone Impactor, 5.5 mm x 8.5 mm</td>
</tr>
<tr>
<td>397.113</td>
<td>Distractor, for SynFix-LR</td>
</tr>
</tbody>
</table>
## SynFix-LR Standard Instrument Set (01.802.110)

### Graphic Case
- **60.802.110**  
  Graphic Case, for SynFix-LR Standard Instruments

### Instruments
- **03.802.030**  
  Screwdriver Shaft, T15
- **03.802.031**  
  Aiming Device Holder, for SynFix-LR
- **03.802.032**  
  Aiming Devices, for SynFix-LR
- **03.802.030**  
  12 mm
- **03.802.032**  
  13.5 mm
- **03.802.036**  
  15 mm
- **03.802.033**  
  17 mm
- **03.802.034**  
  19 mm
- **03.802.035**  
  Cortex Opener, for SynFix-LR
- **03.802.037**  
  Screwdriver, for SynFix-LR
- **03.802.038**  
  Screw Holding Instrument, for SynFix-LR
- **03.802.039**  
  Implant Holder, for SynFix-LR
- **03.802.041**  
  Packing Block, for 26 mm depth x 32 mm width SynFix-LR
- **03.802.042**  
  Packing Block, for 30 mm depth x 38 mm width SynFix-LR
- **388.396**  
  Handle, with quick coupling, small
- **389.288**  
  Cancellous Bone Impactor, 8 mm x 2.5 mm
- **394.585**  
  Cancellous Bone Impactor, 5.5 mm x 8.5 mm
- **397.113**  
  Distractor, for SynFix-LR

### Also Available
- **60.802.240**  
  Module for SynFix-LR Aiming Devices
- **60.802.241**  
  Aiming Devices, Modified Guide Opening, for SynFix-LR
- **03.802.242**  
  12 mm
- **03.802.243**  
  13.5 mm
- **03.802.245**  
  15 mm
- **03.802.247**  
  17 mm
- **03.802.249**  
  19 mm

---

Note: For additional information, please refer to package insert.
For detailed cleaning and sterilization instructions, please refer to [http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm](http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm) or to the below listed inserts, which will be included in the shipping container:
- Processing Synthes Reusable Medical Devices— Instruments, Instrument Trays and Graphic Cases— DJ1305
- Processing Non-sterile Synthes Implants— DJ1304
## SynFix-LR Mini-Open Instrument Set (01.802.120)

### Graphic Case

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>60.802.120</td>
<td>Graphic Case, for SynFix Mini-Open Instruments</td>
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</table>

### Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>03.802.121</td>
<td>SynFix-LR Synthes Quick Inserter/Distractor (SQUID)</td>
</tr>
<tr>
<td>03.802.200</td>
<td>SynFix Mini-Open Implant Coupling, 2 ea.</td>
</tr>
<tr>
<td></td>
<td>Mini-Open Fixed Handle Aiming Devices, for SynFix</td>
</tr>
<tr>
<td>03.802.202</td>
<td>12 mm</td>
</tr>
<tr>
<td>03.802.203</td>
<td>13.5 mm</td>
</tr>
<tr>
<td>03.802.205</td>
<td>15 mm</td>
</tr>
<tr>
<td>03.802.207</td>
<td>17 mm</td>
</tr>
<tr>
<td>03.802.209</td>
<td>19 mm</td>
</tr>
<tr>
<td>03.802.230</td>
<td>Low Profile U-Joint Awl, for SynFix Mini-Open</td>
</tr>
<tr>
<td>03.802.431</td>
<td>Tapered U-Joint Driver for SynFix Mini-Open</td>
</tr>
<tr>
<td>388.396</td>
<td>Handle, with quick coupling, small</td>
</tr>
<tr>
<td>388.407</td>
<td>Holding Forceps</td>
</tr>
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</table>

### Also Available

<table>
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<tr>
<td>PDL114</td>
<td>Vertebral Body Spreader, angled</td>
</tr>
<tr>
<td>03.802.400</td>
<td>Hand-Held Retractor Curved, for SynFix-LR</td>
</tr>
</tbody>
</table>
SynFix-LR Trial Spacer and Screw Set (01.802.130)

Graphic Case
60.802.130  Graphic Case, for SynFix-LR Trial Spacers and Screws

Instruments
03.802.000  SynFix-LR Trial Implants
03.802.019*  Screwdriver Shaft, T15
389.151  Handle, for Trial Spacers, 2 ea.

Implants
4.0 mm Titanium Locking Screws, for SynFix-LR
04.802.200  15 mm, 5 ea.
04.802.201  20 mm, 10 ea.
04.802.202  25 mm, 10 ea.
04.802.203  30 mm, 5 ea.

4.0 mm Titanium Locking Screws, Fine Tip
for SynFix-LR
04.802.210  15 mm, 5 ea.
04.802.211  20 mm, 8 ea.
04.802.212  25 mm, 8 ea.
04.802.213  30 mm, 5 ea.

*For full listing, see page 33
Carry Case
60.802.101 Carry Case, for SynFix-LR Implants

Implants

SynFix-LR, 8°, 26 mm depth x 32 mm width, sterile
08.802.016S 12 mm height, 2 ea.
08.802.000S 13.5 mm height, 2 ea.
08.802.001S 15 mm height, 2 ea.
08.802.002S 17 mm height
08.802.003S 19 mm height

SynFix-LR, 12°, 26 mm depth x 32 mm width, sterile
08.802.017S 12 mm height, 2 ea.
08.802.004S 13.5 mm height, 2 ea.
08.802.005S 15 mm height, 2 ea.
08.802.006S 17 mm height
08.802.007S 19 mm height

SynFix-LR, 8°, 30 mm depth x 38 mm width, sterile
08.802.018S 12 mm height
08.802.008S 13.5 mm height, 2 ea.
08.802.009S 15 mm height, 2 ea.
08.802.010S 17 mm height
08.802.011S 19 mm height

SynFix-LR, 12°, 30 mm depth x 38 mm width, sterile
08.802.019S 12 mm height
08.802.012S 13.5 mm height, 2 ea.
08.802.013S 15 mm height, 2 ea.
08.802.014S 17 mm height
08.802.015S 19 mm height
## SynFix-LR System (01.802.100)

**Consists of Sets:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>01.802.110</td>
<td>SynFix-LR Standard Instrument Set</td>
</tr>
<tr>
<td>01.802.120</td>
<td>SynFix-LR Mini-Open Instrument Set</td>
</tr>
<tr>
<td>01.802.130</td>
<td>SynFix-LR Trial Spacer and Screw Set</td>
</tr>
<tr>
<td>01.802.102</td>
<td>SynFix-LR Implant Set</td>
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</tbody>
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