STERNAL ZIPFIX®
SYSTEM

For fast and stable fixation of the sternum

SURGICAL TECHNIQUE
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STERNAL ZIPFIX SYSTEM
For fast and stable fixation of the sternum

The Sternal ZIPFIX System enables fast sternal closure with consistent tension along a sternotomy or fracture of the sternum.

The system primarily consists of PEEK (polyetheretherketone) implants and an application instrument.

- Flexible and easy to handle
- Excellent closure strength and stability
- Biocompatible, PEEK
- MR safe after removing stainless steel needle
**Sternal ZIPFIX System**

**Application instrument**
Multifunctional instrument to consistently tension and cut ZIPFIX implant.

1. Squeeze trigger to tension implant
2. Lift lever to cut implant
3. Mechanism to prevent over-tensioning of the implant

**Sternal ZIPFIX implant**
- Can be cut using wire/pin cutter for quick emergent re-entry
- Rounded edges for less soft tissue irritation
- Less risk of glove puncture than wires
- MR Safe after removing stainless steel needle (see device specific insert for full instructions)

**Removable stainless steel needle**
- Blunt, stainless steel needle for peristernal application

**Locking head**
- Self-locking for easy implant application
- Flat-locking feature for low profile

**Caution:** The ZIPFIX with attached ferromagnetic needle cannot be placed in the vicinity of an MR scanner, anywhere in the MR procedure room, or used in an interventional MRI procedure.
Multiple Closure Options
Construct strength comparison

Dynamic Test

Maximum load to reach 500,000 cycles (more than 3 weeks of bone healing)

The ZIPFIX construct demonstrates a higher resistance to fatigue failure compared to stainless steel wire.

Fatigue load

Dynamic Test

The ZIPFIX survives over 1 million cycles (more than 6 weeks of bone healing) at exaggerated loading.

The ZIPFIX survives a higher number of loading cycles at 300N than stainless steel wires.

1 Constructs loaded cyclically in tension in lateral direction. All tests were performed on stainless steel pins to simulate the sternum.

2 Implant loaded cyclically in tension in lateral direction. All tests were performed in polyoxymethylene (copolymer) blocks to simulate the sternum.

† The estimate for the amount of cycles at 300N represents fracture healing based on 14.1 breaths per minute. 300N represents the maximum load on a single implant during an aggressive cough.


* Mechanical test data on file at Synthes. Mechanical test results may not necessarily be indicative of clinical performance.
Cut-through test*
Yield load in “poor-quality bone” until cut through

The ZIPFIX provides increased resistance to implant cut-through in the sternum compared to stainless steel wire.

The ZIPFIX has larger implant-to-bone contact area compared to stainless steel wire to reduce risk of bone cut-through.

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3 Implants loaded in tension in lateral direction. All tests were performed in 12 mm thick polyurethane foam blocks of 10 lb/ft³.

* Mechanical test data on file at Synthes. Mechanical test results may not necessarily be indicative of clinical performance.
In 1958, the AO formulated 4 basic principles, which have become the guidelines for internal fixation. Those principles are:

**Anatomic reduction**
Fracture reduction and fixation to restore anatomical relationships.

**Stable fixation**
Stability by fixation, as the personality of the fracture and the injury requires.

**Preservation of blood supply**
Preservation of the blood supply to soft tissue and bone by careful handling.

**Early, active mobilization**
Early, active mobilization of the part and patient.

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**Indications**
Primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

**Contraindications**
The DePuy Synthes Sternal ZIPFIX implants are not intended for use in:
- Infection
- Patient conditions including limited blood supply, insufficient quantity or quality of bone
- Material sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
- Patients who are unwilling or incapable of following postoperative care instructions

**Warning:** Not for use in location of transverse fracture.

*Please refer to package insert for full list of warnings, precautions, and/or possible adverse events.*
1
Insert Sternal ZIPFIX implant

Using a needle holder, pass the ZIPFIX through the intercostal space and around the sternal halves.

Cautions:
• Take care to avoid injury to, or impingement upon, the internal mammary artery and intercostal vessel and nerve bundles.
• There may be a risk of bleeding when used transsternally.
• Transsternal application may be inhibited by hard bone.
• Avoid clamping of implant in the area of the teeth or excessive bending/twisting of the implant, as this may lead to implant failure.
Remove Sternal ZIPFIX needle

**Instrument**

| 391.905 | Cable Cutter, standard |

Cut needle off the ZIPFIX below the notch, using the cable cutter.

**Cautions:**
- Do not cut the implant directly at the notch.
- Removing the needle by bending or twisting will cause a deformed end that may damage the locking head during insertion. Always ensure that the implant end is cut and not deformed. If the implant is not cut, implant failure may occur.

**Note:** Needle can also be removed using a wire/pin cutter.
3

Insert remaining Sternal ZIPFIX implants and remove needles

Insert the remaining ZIPFIX and remove needles as described in Steps 1 and 2.

Use 5 ZIPFIX to achieve stable fixation in a full midline sternotomy. ZIPFIX can be used with plates and/or wires or where ZIPFIX insertion is inhibited by patient anatomy.

Notes:
• Stainless steel wires may be applied to the manubrium and xyphoid regions if desired.
• The number of ZIPFIX used in partial sternotomy is according to patient anatomy.

4

Reduce sternal halves

<table>
<thead>
<tr>
<th>Instrument</th>
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<tr>
<td>398.903</td>
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Optional instruments

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<td>398.902</td>
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<td>398.985</td>
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Reduce the sternal halves by using reduction forceps on both the superior and inferior aspects or by securing the ZIPFIX as in Step 5.

Note: The sternum can also be reduced with sternal wires.
Secure Sternal ZIPFIX implants

Pass the cut end through the locking head and tighten manually.

Repeat for the remaining ZIPFIX.

Remove forceps, if used.

Cautions:
To avoid damage to the locking head:
• Stainless steel needles must be removed before closing the ZIPFIX.
• Prior to insertion of the cut end, ensure the ZIPFIX is properly oriented such that the toothed surface contacts the sternum.
• Align the cut end with the locking head during insertion. Do not insert at an angle.
• Avoid excessive force when tightening implant. Do not use forceps to tighten implant. Damage resulting from excessive force or forceps may cause implant failure.

Notes:
• Secure the locking mechanism in the intercostal space to minimize implant profile.
6  

Tension Sternal ZIPFIX implants

Instrument

03.501.080 Application Instrument, for Sternal ZIPFIX

Ensure the cutting lever is in the locked position. The cutting lever is locked when the lever is snapped into the latch.

Insert the cut end of the implant into the front portion of the application instrument and slide the application instrument down to the locking head.

Squeeze the trigger to tension the ZIPFIX.

Tension remaining ZIPFIX.

If required, the ZIPFIX can be tensioned again to achieve the desired stability.

**Warning:** Do not cut the implant until all implants have been fully tensioned. Implants cannot be tensioned once cut. Do not cut implants under tension.

**Cautions:**

- The application instrument has a mechanism to prevent overtensioning of the ZIPFIX implant. Do not apply additional force to overtension the implant.
- Care should be taken to control ZIPFIX tension in patients with poor bone quality to prevent additional injuries.
- Refer to "Maintenance of Application Instrument" section (page 22) for proper care instructions for the application instrument. Failure to lubricate the application instrument may result in instrument failure.
- Ensure that the application instrument is placed perpendicular to and is touching the locking head during tensioning.

**Note:**

- The application instrument may not tension if the cutting lever is not in the locked position.
7

Remove excess material

**Instrument**

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>03.501.080</td>
<td>Application Instrument for Sternal ZIPFIX</td>
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**Optional Instrument**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>391.905</td>
<td>Cable cutter, standard Ensure the cutting lever is in the locked position.</td>
</tr>
</tbody>
</table>

Insert the cut end of the implant into the front portion of the application instrument and slide the application instrument down to the locking head.

Fully extend the lever to cut the implant.

Return the cutting lever to the locked position before cutting subsequent implants.

**Warning:** The tensioning trigger must be completely released before and during implant cutting. Cutting the implant while tensioning with the application instrument could compromise the implant lock and lead to implant failure. **Do not cut the implant under tension.**

**Note:** Ensure that the application instrument is placed perpendicular to and is touching the locking head during cutting to avoid sharp edges. The excess material can also be removed with a wire/pin cutter.

**Caution:** The Sternal ZipFix implant cannot be tensioned after it is cut.
8

Confirm integrity of final construct

Confirm the integrity of the sternum.

**Note:** A manubrium plate can be added if additional stability in the manubrium is desired. Refer to the *Synthes Titanium Sternal Fixation System Surgical Technique* for additional information.

9

Postoperative considerations

Standard sternal precautions are recommended for 6 weeks after surgery, including:

- Patient should not lift more than 10 lbs (4.5 kg).
- Patient should not raise arms greater than 90°.
- Patient should press a pillow against his/her chest in the event of a strong cough.
- Do not pull or lift the patient by the arms.
- Avoid trunk twisting.
1
Cut Sternal ZIPFIX implants

| Instrument          | 391.905   | Cable Cutter, standard |

Cut all ZIPFIX with the cable cutter.

Note: The ZIPFIX can also be cut with wire/pin cutters.

2
Remove Sternal ZIPFIX implants

Carefully remove the ZIPFIX by pulling on the implant body.
### Sternal ZIPFIX

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>08.501.001.01S</td>
<td>Sternal ZIPFIX, with needle, single pack, sterile</td>
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<tr>
<td>08.501.001.05S</td>
<td>Sternal ZIPFIX, with needle, 5-pack, sterile</td>
</tr>
<tr>
<td>08.501.001.20S</td>
<td>Sternal ZIPFIX, with needle, 20-pack, sterile</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>03.501.080</td>
<td>Application Instrument, for Sternal ZIPFIX</td>
</tr>
<tr>
<td>03.503.072</td>
<td>MatrixMANDIBLE/THORAX Screwdriver, Blade, self-retaining, long*</td>
</tr>
<tr>
<td>03.503.073</td>
<td>MatrixMANDIBLE/THORAX Screwdriver, fixed handle, self-retaining*</td>
</tr>
<tr>
<td>311.023</td>
<td>Ratcheting Screwdriver Handle*</td>
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*Also available.
## Instruments

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<tr>
<td>391.905</td>
<td><strong>Cable Cutter, standard</strong></td>
</tr>
<tr>
<td>398.902</td>
<td><strong>Sternal Reduction Forceps</strong></td>
</tr>
<tr>
<td>398.903</td>
<td><strong>Sternal Reduction Forceps, angled, with teeth</strong></td>
</tr>
<tr>
<td>398.985</td>
<td><strong>Bone Reduction Forceps, large</strong></td>
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*Also available.
For detailed cleaning and sterilization instructions, please refer to:
www.synthes.com/cleaning-sterilization
In Canada, the cleaning and sterilization instructions will be provided with
the Loaner shipments.

**Graphic Case**

- 68.501.001  Sternal ZIPFiX Graphic Case

**Instruments**

- 03.501.080  Application Instrument, for Sternal ZIPFiX
- 391.905  Cable Cutter, standard
- 398.903  Sternal Reduction Forceps, angled, with teeth, 2 ea
Also available

- 03.503.072 MatrixMANDIBLE/THORAX Screwdriver Blade, self-retaining, large
- 03.503.073 MatrixMANDIBLE/THORAX Screwdriver, fixed handle, self-retaining
- 311.023 Ratcheting Screwdriver Handle
- 398.902 Sternal Reduction Forceps
- 398.985 Bone Reduction Forceps, large

Titanium Sternal Locking Manubrium Plates, sterile

- 460.027S H-Plate, small, 8 holes
- 460.028S H-Plate, large, 8 holes
- 460.035S Star Plate, 6 holes
- 460.036S Star Plate, 12 holes

3.0 mm Titanium Sternal Locking Screws, self-drilling, sterile, single pack

- 04.501.110S 10 mm
- 04.501.112S 12 mm
- 04.501.114S 14 mm
- 04.501.116S 16 mm
- 04.501.118S 18 mm
- 04.501.120S 20 mm

- 460.171S Titanium Sternal Fixation Kit, Large H-Plate with 12 mm self-drilling screws, sterile
- 460.172S Titanium Sternal Fixation Kit, Large H-Plate with 14 mm self-drilling screws, sterile
The Sternal ZIPFix application instrument must be lubricated prior to sterilization.

Apply oil directly to the areas indicated.

519.97  Special Autoclavable Oil
Limited Warranty and Disclaimer: DePuy Synthes CMF products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.