For Fast and Stable Fixation of the Sternum

Sternal ZIPFIX® System

Surgical Technique
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**MR Information**
The Sternal ZIPFIX System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the Sternal ZIPFIX System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
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 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)

Precaution: The ZIPFIX Implant 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.

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

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
Multiple Closure Options
**Construct strength comparison***

Dynamic Test¹

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

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

![Graph showing construct strength comparison](image)

**Fatigue load***

Dynamic Test²

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

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

![Graph showing fatigue load](image)

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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.

*Mechanical test data on file at DePuy Synthes. Mechanical test results may not necessarily be indicative of clinical performance.

†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.

Cut-through test*
Yield load in “poor-quality bone” until cut through

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

The ZIPFIX Implant 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 DePuy Synthes. Mechanical test results may not necessarily be indicative of clinical performance.
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.\(^4,5\)

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

**Stable fixation**
Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

**Early, active mobilization**
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

**Preservation of blood supply**
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.
INDICATIONS

**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

**Warnings:**
- Cannot be used in location of transverse fracture.
- Using the system in pediatric patients may result in pain and/or implant protrusion, which may require explantation.
- Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.
- The use of ZIPFIX Implants is only appropriate with a midline sternotomy.
- Do not use ZIPFIX Implants transternally. The system is for intercostal space application only.

**Precautions:**
- Do not damage the implant teeth and locking head by manipulating with instruments.
- Irrigate thoroughly in order to remove any debris generated during implant implantation or removal.
- Surgeon to instruct patient about postoperative care.
- Do not re-sterilize ZIPFIX Implants.
- Ensure that the locking head of the implant is free of soft tissue and/or surgical material that could prevent locking of the implant.
- Handle implants carefully, especially needles, to avoid damaging critical structures, soft tissue and/or hand gloves.
1

Insert Sternal ZIPFIX Implant

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

Precautions:
- 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 Implant needle

Instrument
391.905 Cable Cutter, standard

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

Precautions:
• 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 Implant and remove needles as described in Steps 1 and 2.

**Precaution:** Use 5 ZIPFIX Implants, one per intercostal space, to achieve stable fixation in a full midline sternotomy.

The ZIPFIX Sternal System can be used with plates and/or wires or where ZIPFIX Implant 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 Implants used in partial sternotomy is according to patient anatomy.

4
**Reduce sternal halves**

**Instrument**

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<thead>
<tr>
<th>Instrument Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>398.903</td>
<td>Sternal Reduction Forceps, angled, with teeth</td>
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</tbody>
</table>

**Optional instruments**

<table>
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<tr>
<th>Instrument Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>398.902</td>
<td>Sternal Reduction Forceps</td>
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<tr>
<td>398.985</td>
<td>Bone Reduction Forceps, large</td>
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</tbody>
</table>

Reduce the sternal halves by using reduction forceps on both the superior and inferior aspects or by securing the ZIPFIX Implant 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 Implants.

Remove forceps, if used.

Precautions:
To avoid damage to the locking head:
• Stainless steel needles must be removed before closing the ZIPFIX Implant.
• Make sure to remove the needle from the implant body before proceeding to insert the next implant.
• Prior to insertion of the cut end, ensure the ZIPFIX Implant 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.
• Secure the locking mechanism in the intercostal space to minimize implant profile.
• Ensure that the implant body is not twisted while passing the cut end through the locking head.
• Ensure that the implant body follows the bony anatomy of the sternum.
• ZIPFIX Implant should only be inserted once into the locking head.
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 Implant.

Tension remaining ZIPFIX Implants.

If required, the ZIPFIX Implant 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.

Precautions:
- 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 Implant 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.
- Tension the implant using only the application instrument until the sternum reduction is achieved and the implant is properly positioned.
- Do not tension the implant if the locking head is not sitting in the intercostal space.
- If intercostal space is not suitable for ZIPFIX Implants, use alternative methods for closure.

Note: The application instrument may not tension if the cutting lever is not in the locked position.
Remove excess material

**Instrument**

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<tr>
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<tr>
<td>391.905</td>
<td>Cable cutter, standard</td>
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</tbody>
</table>

Ensure the cutting lever is in the locked position.

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. Ensure that the implant is properly placed, that it does not cut through the bone and that the locking function is preserved to confirm the integrity of the final construct.

**Precautions:**

- 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.
- 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 Titanium Sternal Fixation System Surgical Technique for additional information.

9  Postoperative considerations

Precautions:
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 Implants with the cable cutter.

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

2 Remove Sternal ZIPFIX Implants

Carefully remove the ZIPFIX Implant by pulling on the implant body.

**Precautions:**
Avoid multiple cuts on the implant body so that the implant can be removed in one piece. If the implant is cut down to more than one piece ensure that all fragments are removed.
**Sternal ZIPFIX**

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<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>
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<tr>
<td>08.501.001.20S</td>
<td>Sternal ZIPFIX, with needle, 20-pack, sterile</td>
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<tr>
<td>03.501.080</td>
<td>Application Instrument, for Sternal ZIPFIX</td>
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<tr>
<td>03.503.072</td>
<td>MatrixMANDIBLE/THORAX Screwdriver Blade, self-retaining, long*</td>
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<tr>
<td>03.503.073</td>
<td>MatrixMANDIBLE/THORAX Screwdriver, fixed handle, self-retaining*</td>
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<tr>
<td>311.023</td>
<td>Ratcheting Screwdriver Handle*</td>
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*Also available.*
Instruments

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<td>391.905</td>
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<tr>
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*Also available.
### Graphic Case

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<td>68.501.001</td>
<td>Sternal ZIPFIX Graphic Case</td>
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<td>Sternal Reduction Forceps, angled, with teeth, 2 ea</td>
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For detailed cleaning and sterilization instructions, please refer to [www.synthes.com/cleaning-sterilization](http://www.synthes.com/cleaning-sterilization) or sterilization instructions, if provided.
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 Application Instrument for Sternal ZIPFIX must be lubricated prior to sterilization.

Apply oil directly to the areas indicated.

519.97 Special Autoclavable Oil
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