For Fast and Stable Fixation of the Sternum

Sternal ZIPFIX® System

Surgical Technique

DePuy Synthes
PART OF THE JOHNSON & JOHNSON FAMILY OF COMPANIES
This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these instruments is highly recommended.

**Reprocessing, Care and Maintenance of Synthes Instruments**
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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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.

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

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
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.¹ ²

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

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

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

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

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Indications
Closure of the sternum following sternotomy to stabilize the sternum and promote fusion.

Contraindications
Patients under 12 years of age.

Warnings:
• Cannot be used in location of transverse fracture.
• 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.
• Using the system in pediatric patients older than 12 years of age may result in pain and/or implant protrusion which may require explantation.

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.
- Avoid clamping of implant in the area of the teeth or excessive bending/twisting of the implant, as this may lead to implant failure.
- Ensure that the needle is attached to the implant body before being inserted into the intercostal space.
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.

Notes:
- Needle can also be removed using a wire/pin cutter.
- Ensure sufficient length remains after cutting to facilitate closure of the ZIPFIX Implant.
3
Insert remaining Sternal ZIPFIX Implants and remove needles

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

The ZIPFIX Sternal System can be used with plates and/or wires or where ZIPFIX Implant insertion is inhibited by patient anatomy.

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

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

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<th>Instrument</th>
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<td>398.903 Sternal Reduction Forceps, angled, with ratchet lock</td>
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Optional instruments

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<th>Instrument</th>
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<td>398.902</td>
<td>Sternal Reduction Forceps</td>
</tr>
<tr>
<td>398.985</td>
<td>Reduction Forceps, large, with Points, ratchet lock, length 200 mm</td>
</tr>
</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.
5

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.
• 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.
• Ensure that the implant body is not twisted while passing the cut end through the locking head.
• ZIPFIX Implant should only be inserted once into the locking head.

Precautions:
• Ensure that the implant body follows the bony anatomy of the sternum.
• Secure the locking mechanism in the intercostal space to minimize implant profile.
• Make sure to remove the needle from the implant body before proceeding to insert the next implant.
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.

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 tensioned.
- 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.
- Do not cut the implant until all implants have been fully tensioned since implants cannot be tensioned once cut.

Note:
- The application instrument may not tension if the cutting lever is not in the locked position.
- If the instrument slips on the implant during tensioning, the instrument can be repositioned such that the teeth of the implant interface with the teeth of the instrument.
Remove excess material

**Instrument**

03.501.080 Application Instrument for Sternal ZIPFIX

**Optional Instrument**

391.905 Cable cutter, standard

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 DePuy Synthes Titanium Sternal Fixation System Surgical Technique for additional information.

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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.
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<thead>
<tr>
<th>Code</th>
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<tr>
<td>08.501.001.01S</td>
<td>Sternal ZIPFIX with Needle, PEEK, sterile, single pack</td>
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<td>08.501.001.05S</td>
<td>Sternal ZIPFIX with Needle, PEEK, sterile, pack of 5 units</td>
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<tr>
<td>08.501.001.20S</td>
<td>Sternal ZIPFIX with Needle, PEEK, sterile, pack of 20 units</td>
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<tr>
<td>Code</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>Screwdriver Shaft MatrixMANDIBLE, long, self-holding, for Hexagonal Coupling*</td>
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<tr>
<td>03.503.073</td>
<td>MatrixMANDIBLE Screwdriver, self-holding*</td>
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<tr>
<td>311.023</td>
<td>Ratcheting Screwdriver Handle, with Hexagonal Coupling*</td>
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*Also available.
Instruments

391.905  Cable Cutter, standard

398.905  Reduction Forceps with Points, ratchet lock, length 180 mm*

398.902  Sternal Reduction Forceps*

398.903  Sternal Reduction Forceps, angled, with ratchet lock

398.985  Reduction Forceps with Points, ratchet lock, length 180 mm*

*Also available.
## Sternal ZIPFIX Instrument Set (01.501.006)

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<tr>
<td>398.903</td>
<td>Sternal Reduction Forceps, angled, with ratchet lock, 2 ea</td>
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<tr>
<td>Code</td>
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<td>Sternal Reduction Forceps</td>
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<tr>
<td>398.985</td>
<td>Reduction Forceps with Points, ratchet lock, length 180 mm</td>
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<tr>
<td>399.980</td>
<td>Reduction Forceps, large, with Points, ratchet lock, length 200 mm</td>
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<tr>
<td>311.006</td>
<td>Handle, medium, with Hexagonal Coupling</td>
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<tr>
<td>311.007</td>
<td>Handle, large, with Hexagonal Coupling</td>
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<tr>
<td>311.023</td>
<td>Ratcheting Screwdriver Handle, with Hexagonal Coupling</td>
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<tr>
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<td>Screwdriver shaft MatrixMANDIBLE, long, self-holding, for Hexagonal Coupling</td>
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<td>MatrixMANDIBLE Screwdriver, self-holding</td>
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The Application Instrument for Sternal ZIPFIX must be lubricated prior to sterilization.

Apply oil directly to the areas indicated.

- 519.970 Synthes Special Oil, 40 ml
- 05.001.098 Synthes Maintenance Spray, 400 ml
- 05.001.095 Synthes Maintenance Oil, 40 ml, for EPD and APD