Instructions for Use
Sternal ZipFix

This instruction for use is not intended for distribution in the USA.

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

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Instructions for Use

Sternal ZipFix
Please read these instructions for use, the DePuy Synthes brochure "Important Information" and the corresponding surgical techniques Sternal ZipFix System (036.001.285) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The Sternal ZipFix device is made up of a "zip tie"-like final implant body and an application needle.

Material(s)

Material(s):	Standard(s):
PEEK Optima	ASTM F 2026-14
Stainless Steel 301	ISO 7153-1:1991/Amd 1:1999

Intended use
Fixation of sternal halves.

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

Contraindications
Patients under 12 years of age.

General adverse events
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common may include but not limited to:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, and allergy/hypersensitivity reactions.
It is important to consider the risks of these events are possibly associated with general surgical procedure and hospitalization but not always directly device related.
DePuy Synthes has undertaken all necessary steps to ensure that residual risks in using ZipFix system are reduced as far as possible by applying the available state-of-the-art techniques in designing and manufacturing the medical devices to ensure safe usage. Based on the overall medical benefits and the equivalence of ZipFix to predicate surgical systems with a proven clinical history, DePuy Synthes concludes that the patient benefits of the ZipFix surgical system outweigh the possible risks when used according to its intended use.

Device specific events
Device specific adverse events include but not limited to:
Bone loosening, infection, damage to vital organs or surrounding structures, adverse tissue reaction, pain, dehiscence and soft tissue damage.

Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

Do not resterilize

Products supplied in a sterile condition are labeled "STERILE" (see "Interpretation of symbols"). Remove products from the package in an aseptic manner. The manufacturer cannot guarantee sterility if the package seal is broken or if the package is improperly opened, and assumes no liability in such instances

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and / or lead to device failure which may result in patient injury, illness or death.
Furthermore, re-use or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions
Do not resterilize ZipFix implants.
The ZipFix with attached ferromagnetic needle cannot be placed in the vicinity of a Magnetic Resonance (MR) scanner, anywhere in the MR procedure room, or used in an interventional MR imaging procedure.
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.
Make sure to remove the needle from the implant body before proceeding to insert the next implant.
Handle the implant carefully, especially the needle, to avoid damaging critical structures, soft tissue and/or hand gloves.
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.
Use 5 ZipFix, one per intercostal space, to achieve stable fixation in a full midline sternotomy.
Secure the locking mechanism in the intercostal space to minimize implant profile.
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.
- Ensure that the implant body is not twisted while passing the cut end through the locking head.
- ZipFix should only be inserted once into the locking head.
- 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 locking head of the implant is free of soft tissue and/or surgical material that could prevent locking of the implant.
The application instrument has a mechanism to prevent overtensioning of the ZipFix implant. Do not apply additional force (e.g. using application instrument as a lever) 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" in Surgical Technique (036.001.285) 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.
Ensure that the implant body follows the bony anatomy of the sternum.
If intercostal space is not suitable for ZipFix implants, use alternative methods for closure.
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.
Do not cut the implant until all implants have been fully tensioned since implants cannot be tensioned once cut.
Standard sternal precautions are recommended for 6 weeks after surgery, including:
- Patient should not lift more than 4.5 kg (10 lbs).
- 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.

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.

General 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.

Warnings
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.

General Warnings
The use of ZipFix implants is only appropriate with a midline sternotomy.
Cannot be used in location of transverse fracture.
Do not use ZipFix transsternally. This 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.
Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

Magnetic Resonance (MR) environment
MR safe after removing stainless steel needle. The medical device(s) 08.501.001.01S, 08.501.001.05S, 08.501.001.20S is (are) MR safe according to ASTM F 2052-14, ASTM F 2213-06(11), ASTM F 2182-11a.
Precaution: The ZipFix with attached ferromagnetic needle cannot be placed in the vicinity of a MR scanner, anywhere in the MR procedure room, or used in an interventional MR imaging procedure.

Special operating instructions
1. Insert Sternal ZipFix implant
   Using a needle holder, pass the ZipFix through the intercostal space and around the sternal halves.
2. Remove Sternal ZipFix needle
   Cut needle off the ZipFix below the notch, using the cable cutter.
3. Insert remaining Sternal ZipFix implants and remove needles
   Insert the remaining ZipFix and remove needles as described in Steps 1 and 2.
   ZipFix can be used with plates and/or wires or where ZipFix insertion is inhibited by patient anatomy.
4. Reduce sternal halves
   Reduce the sternal halves by using reduction forceps on both the superior and inferior aspects or by securing the ZipFix as in Step 5.
5. Secure Sternal ZipFix implants
   Pass the cut end through the locking head and tighten manually.
   Repeat for the remaining ZipFix.
   Remove forceps, if used.
6. Tension Sternal ZipFix implants
   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.
   If required, the ZipFix can be tensioned again to achieve the desired stability.
7. Cut and remove excess material
   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.
8. Confirm integrity of final construct
   Confirm the integrity of the sternum.
9. Postoperative considerations
   Standard sternal precautions are recommended for 6 weeks after surgery, including:
   – Patient should not lift more than 4.5 kg (10 lbs).
   – 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.

Implant removal
1. Cut Sternal ZipFix implants
   Cut all ZipFix with the cable cutter.
2. Remove Sternal ZipFix implants
   Carefully remove the ZipFix by pulling on the implant body.

Reprocessing, Care and Maintenance of DePuy Synthes Instruments
Detailed instructions for reprocessing re-usable devices, instrument trays and cases are described in the DePuy Synthes brochure “Important Information”. Assembly and disassembly instructions of instruments “Dismantling multipart instruments” can be downloaded from http://www.synthes.com/reprocessing

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