Instructions for Use
Sternal ZipFix

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

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CMF
COMPANIES OF Johnson&Johnson

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Instructions for Use

Sternal ZipFix
Please read these instructions for use, the 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 "cable tie" like final implant body and an application needle.

Material(s)

Material(s):	Standard(s):
PEEK Optima	ASTM F 2026
Stainless Steel 301	ISO7153-1

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.

Side effects
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 include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hypersensitivity reactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.
Pre- or Intra-operative
A significant delay of surgery may be necessary in cases of:
Incorrect handling
Inadequate reprocessing of the application instrument can cause a malfunction of the device.
Premature removal of Sternal ZipFix excess material and/or before proper sternal reduction is achieved and/or before all implants are in place.
For transsternal application, the application of the implant could cause a larger hole in the sternal bone leading to excessive bleeding.
Incorrect application of the implant may result in a failure of the locking function due to
Pushing the needle through the locking head,
Twisting the implant during the application,
Incorrect insertion of the implant end into the locking head,
Incorrect needle removal without a cutting instrument.
Over-tensioning of the implant by angulating the instrument while tensioning could cause an intra-operative failure of the locking function of the implants.
The activation of the instruments cutting function whilst tensioning could cause an intra-operative failure of the locking function of the implants.
Too high stresses from tensioning of the implants in poor bone quality and/or off-midline sternotomies may result in transverse sternal fractures intra-operatively.
Allergy
Allergic reaction to the application needle may occur in patients with hypersensitivity to nickel.
MRI
Placement of the implants without removal of the ferromagnetic needle in the vicinity of a MR scanner and/or anywhere in the MR procedure room may cause an injury of the user or patient.
Others
Injury of vessels may occur, if the implant application is not done carefully.
Injury of user or patient through sharp edges and/or spikes, if the implant is not cut properly
Post-operative
A Re- operation may be required in cases of:
Failure to follow recommended post-operative precautions for the first 6 weeks postoperatively could lead to breakage or stretch of the implants
Failure to apply the recommended number of implants (minimum of 5 ZipFix or alternatives) for full midline sternotomy lead to postoperative breakage or stretch of the implants
Insufficient fixation of the Manubrium and/or Xyphoid with ZipFix or alternative fixation methods result in delayed or non-union of these anatomical areas.
Incorrect application of the implant may result in a failure of the locking function due to
pushing the needle through the locking head,
Twisting the implant during the application,
Incorrect insertion of the implant end into the locking head
Incorrect needle removal without a cutting instrument.
Over-tensioning of the implant by angulating the instrument while tensioning could cause a failure of the locking function of the implants post-operatively, requiring a re-operation.
The activation of the instruments cutting function whilst tensioning could cause a post-operative failure of the locking function of the implants.
Too high forces applied during implant tensioning may result in bone injury, stretch of implants and/or reduced blood supply.
Too high stresses from tensioning of the implants in poor bone quality and/or off-midline sternotomies may result in transverse sternal fractures post-operatively.
Too low forces applied during implant tensioning may result in a sternal non-union.
Usage of implants in patients with too tight intercostal spaces could cause post-operative pain.

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, reuse 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 take the implants into MR environment before the needle is removed.
- 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.
- Do not cut the implant directly at the junction between the needle and the implant.
- Do not remove the needle without the assistance of a cutter. Do not twist the implant to remove the needle.

- The implant teeth must face toward the sternum to ensure proper closure.
- Stainless steel needles must be removed before closing the Sternal ZipFix implants to avoid damage to the locking head.
- Take care to align the cut end with the locking head during insertion. Do not insert at an angle.
- Secure the locking mechanism in the intercostal space to minimize implant profile.
- Care should be taken to control implant tension in patients with poor bone quality as excessive tension in this patient population could induce transverse fractures.
- The Sternal ZipFix implant cannot be further tensioned after it is cut.

– The trigger must be released before and during cutting. Do not cut under tension, as it may result in premature implant failure.

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.
– Standard sternal precautions are recommended for six weeks after surgery, including:
– Do not lift more than 4.5 kg.
– Do not pull or lift the patient by the arms.
– Do not raise arms greater than 90 degrees.
– Avoid trunk twisting.
– Patient should press a pillow against chest in the event of a strong cough.

The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
The implant components applied (name, article number, lot number) must be documented in each patient's record.

Magnetic Resonance environment
MR Safe: 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 ASTM F 2213, ASTM F 2182

Special operating instructions
1. Insert Sternal ZipFix implant
   Using the attached needle, pass the implant through the intercostal space and around the sternal halves.
   A standard needle holder can be used to assist with insertion.
2. Remove Sternal ZipFix needle
   Use standard cutters to create a clean cut along the implant medial to the needle.
3. Insert remaining Sternal ZipFix implants and remove needles
   Insert the remaining Sternal ZipFix implants and remove needles as described in steps 1 and 2.
   It is recommended to use a minimum of five Sternal ZipFix implants to achieve stable fixation in a full midline sternotomy. ZipFix can be used with plates or wires according to surgeon preference.
4. Reduce sternal halves

Reduce the sternum using one of the following technique options.
– Using reduction forceps on both the superior and inferior aspects of the sternum followed by steps 5 and 6.
– Using Sternal ZipFix as per steps 5 and 6.
– Using stainless steel wires followed by steps 5 and 6.

5. Secure Sternal ZipFix implants
   Pass the cut end through the locking head and tighten manually.
6. Secure any remaining implants
   Secure and tighten any remaining Sternal ZipFix implants manually as described in step 5.
   Remove the forceps where applicable.
7. Tension Sternal ZipFix implant
   Ensure the cutting lever is in the locked position. Slide the application instrument over the loose end of the implant, down to the locking head. Squeeze the trigger to tension the implant. The implant should fit snuggly to the bone.
   Tension all Sternal ZipFix implants.
8. Confirm stability of closure
   Verify visually that the sternal halves are correctly approximated.
   Apply light pressure to the sternum to confirm the integrity of the closure.
9. Cut implants
   Ensure the cutting lever is in the locked position.
   Slide the application instrument over the loose end of the implant, down to the locking head.
   Fully extend the lever to cut the implant.
   Return the cutting lever to the locked position.
10. Confirm stability of final construct
    Confirm the stability of the fixation by applying light pressure to the sternum.

Removal of Implant/ Emergency Re-entry
1. Cut Sternal ZipFix implants
   Cut all Sternal ZipFix implants with the standard cutters distal to the locking head.
2. Remove Sternal ZipFix implants

Carefully remove the Sternal ZipFix implants by pulling on the implant body.
Closure and postoperative considerations
Standard sternal precautions are recommended for six weeks after surgery, including:
– Do not lift more than 4.5 kg.
– Do not pull or lift the patient by the arms.
– Do not raise arms greater than 90 degrees.
– Avoid trunk twisting.
– Patient should press a pillow against chest in the event of a strong cough.

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the 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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