Instructions for Use
Titanium Sternal Fixation System

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

Titanium Sternal Fixation System
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques Titanium Sternal Fixation System (036.000.009) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The Synthes Titanium Sternal Fixation System provides stable internal fixation of the sternum following a sternotomy or fracture of the sternum.
Different titanium plates according to the anatomical structures and patient's need are available:
– Sternal body plates for minimal dissection
– Star-shaped and H-shaped locking plates for fixation of the manubrium
– Titanium sternal locking straight plate without pin for transverse fractures
– Straight locking plates for a stable sternal rib-to-rib fixation

Implant(s):	**Material(s):**	**Standard(s):**
Plates:	CpTi (Grade 4)	ISO 5832-2–2012
Emergency Release Pin:	TAN	ISO 582-11–1994
Selfdrilling Screws:	TAN	ISO 582-11–1994
Selftapping Screws:	CpTi (Grade 4)	ISO 5832-2–2012

Intended use
Fixation of sternal halves

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 Sternal Locking Plate 2.4, straight, without emergency release pin is contraindicated for use in cardiac patients due to the potential delay if emergent re-entry is required.

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 include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, neurological impairments, etc.), thrombosis, embolism, infection 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 hyperreactions, 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.

Device Specific Adverse Events
Device specific adverse events include but are not limited to:
Screw Loosening/pull out, Plate breakage, Explantation, Pain, Seroma, Hematoma, Dehiscence, Infection, Mediastinitis, Deep Sternal Wound Infection.

Warnings
These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.
Be aware that implants are not as strong as native bone. Implants subjected to substantial loads may fail.

Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

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.

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
A sternal bone specimen should be sent to pathology to assess for osteomyelitis.
Antibiotic treatment should be based on the identification of pathogens from bone cultures at the time of bone biopsy or debridement. Bone cultures are obtained first, then suspected pathogens are covered by initiation of a parenteral antimicrobial treatment.
Avoid direct contact of stainless steel wires with titanium implants to avoid galvanic corrosion.
Use a minimum of four screws per side/per plate for sternal osteotomies with this system.
Select a plate with sufficient length to allow for a minimum of four screws on each side.
Use bending screws for severe bends to prevent plate hole deformation while contouring the plate. Bending screws may be left in place if they cannot be removed. However, DePuy Synthes recommends the use of at least four screws per side/per plate for sternal osteotomies with this system.
Avoid excessive and reverse bending as it may weaken the plate and lead to premature implant failure.
In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or osteotomy.
Recognize that the thickness of the adjacent ribs may be less than the sternal edge.
For sternal screws, drill bicortically.
For rib screws, drill bicortically wherever possible.
Do not drill any deeper than determined in step 4 to avoid the risk of pneumothorax.
Do not drill in the region above the internal mammary arteries.
Irrigate during drilling to avoid thermal damage to the bone.
Drilling speed should never exceed 1800 rpm. Higher speeds can result in thermal necrosis of the bone and increased hole diameter and may lead to unstable fixation.
The screw should be no longer than necessary to engage the posterior cortex, to avoid deeper injury. The tip of the screw should not extend more than 0.5 mm beyond the posterior cortex to avoid the risk of pneumothorax.
Avoid over-bending of the flat prong (>25°), as this can lead to breakage or inability to remove the pin for emergency reentry.
For primary closure, if one plate is used in combination with stainless steel surgical wires, at least four wires should be used for closure of a full sternotomy. If two plates are used in combination with stainless steel wires, a minimum of two wires should be used.
Avoid direct contact of stainless steel wires with titanium implants to prevent galvanic corrosion.
After implant placement is complete, discard any fragments or modified parts in an approved sharps container.
Irrigate and apply suction for removal of debris potentially generated during implantation and/or explantation.
The self-drilling locking screw should be inserted perpendicular to the plate and the screw axis should be aligned with the thread axis of the plate hole.
The self-drilling locking screw should be no longer than necessary to engage the posterior cortex, to avoid deeper injury. The tip of the screw should not extend more than 0.5 mm beyond the posterior cortex. In the area of the ribs, predrilling may facilitate the determination of the appropriate screw length.
Recognize that the thickness of the adjacent ribs may be less than the sternal edge.
Screw lengths 14 mm and longer should not be used in the area of the ribs.
For sternal screws, insert bicortically. For rib screws, insert bicortically whenever possible.
Do not insert screws any deeper than necessary, to avoid the risk of pneumothorax.
Do not insert screws in the region above the internal mammary arteries.
After surgery, routinely perform a chest x-ray to exclude the possibility of a pneumothorax.
Discard the pins. Pins must not be reused.
Bend the flat prong on the pin medially 20°–25°, to reduce the chance of pin migration.

Magnetic Resonance Environment
Non-clinical testing has demonstrated the DePuy Synthes Titanium Sternal Fixation System can be safely scanned in an MR system meeting the following conditions:
– S-tatic magnetic field of 1.5 Tesla or 3.0 Tesla transmit quadrature-driven coil only
– Maximum spatial field gradient of 2,000 gauss/cm (20 T/m) for 1.5 T or 3.0 T
– Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1W/kg in 1.5T systems and 2W/kg in 3.0T systems
– Maximum 15 minutes of continuous scanning

Under the scan conditions defined above, the DePuy Synthes Titanium Sternal Fixation System devices are expected to produce the maximum temperatures of 6.0 °C in 1.5 Tesla systems or 6.1 °C in 3.0 Tesla systems.

In non-clinical testing, the image artifact caused by the device extends approximately 35 mm from the edge of the device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Precautions
The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:
– It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
– Patients with impaired thermo regulation or temperature sensation should be excluded from MR scanning procedures.
– Generally it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
– Using the ventilation system may further contribute to reduce temperature increase in the body.
– It is recommended that the device be kept as far away from the coil wall as possible.

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Special Operating Instructions
1. Position Patient
2. Debride (for secondary closure of the sternum)
3. Expose ribs laterally, if necessary
4. Determine sternal edge thickness
5. Reduce sternum
   Sternum can also be reduced with stainless steel surgical wire, if desired.
6. Cut and contour bending template
7. Select and Size Plate
   All steps of preparation and implantation of the Sternal Locking Plate have to be done, whenever possible, with the assembled plate. Do not disassemble the plate by pulling out the Emergency Release Pin.
8. Contour Plate
   Be careful not to deform the pin section of the plate halves while contouring. If this portion of the plate is bent, the plate could break or the emergency release pin could become stuck in the plate.
   The smaller sternal body plates can be bent with universal bending pliers.
9. Position plate
10. Drill
    The alternative technique with self-drilling screws can be used.
11. Select and insert first self-tapping screw
    Screw length can be determined using the screw length indicator on the module. Optionally available Lag Tool (03.501.056) can be used to achieve plate to bone reduction. Please see Lag Tool reference guide (036.001.400) for more details.
12. Drill and place remaining screws
13. Insert remaining plates
14. Manubrium plate (optional)
15. Closure and postoperative considerations
    Do not pull or lift the patient by the arms for 6 weeks. Do not raise arms higher than 90° at shoulder level.

Alternative Technique with Self-Drilling Screws
1. Determine sternal edge thickness and position plate
2. Select and insert first screw
   Screw length can be determined using the screw length indicator on the module. Optionally available Lag Tool (03.501.056) can be used to achieve plate to bone reduction. Please see Lag Tool reference guide (036.001.400) for more details.
3. Place remaining screws

Emergency Reentry
1. Remove emergency release pin
   Plate and screw removal is necessary for reentry with the Sternal Locking Plate 2.4, straight, without emergency release pin or if sternal bony fusion has occured. To facilitate plate and screw removal, the Synthes Universal Screw Removal Set 01.505.300 may be used.
2. Insert emergency release pin

Troubleshooting Implant Removal
To facilitate plate and screw removal, the Synthes Universal Screw Removal Set 01.505.300 may be used.

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable 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://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel. +41 61 965 61 11
www.jnjmedicaldevices.com