Instructions for Use
Titanium Sternal Fixation System

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

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

Material(s)

Material(s):	Standard(s):
CpTi (Grade 4)	ISO 5832-2
TAN	ISO 582-11

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 primary closure of the sternum.

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.
1. Pre- or Intra-operative
A significant delay of surgery may be necessary in cases of:
1.1. Incorrect Handling
– Excessive reverse bending leads to plate breakage while contouring, requiring the usage of a new plate
– Severe bending of the plate without bending screws leads to plate hole deformation, requiring the usage of a new plate
– An incorrect reading on the calliper/depth gauge leads to a selection of a too long drill bit, resulting in a Pneumothorax
– The selection of a too long drill bit length results in a Pneumothorax
2. Post-operative
A Re-operation may be required in cases of:
2.1. Non-Union and/or Infection
– An inadequate number of used plates or plates plus additional fixation (wires) leads to premature implant breakage, resulting in non bone healing
– An inadequate number of used plates or plates plus additional fixation (wires) leads to postoperative bone fractures, resulting in non bone healing
– An incorrect bend of the emergency release pin results in migration of the pin.
– An incorrect reading on the calliper/depth gauge leads to selection of a too short drill bit or screw, resulting in a weaker construct with risk for non bone healing
– The selection of a too short drill bit length or screw results in a weaker construct, resulting in non bone healing
– An off-axis insertion of self drilling screws causes a weaker construct, resulting in non bone healing
– The usage of dissimilar metals in contact when plates are used in combination with Stainless Steel wires leads to galvanic corrosion of the implants, resulting in non bone healing
– Failure to follow recommended post-operative considerations could lead to breakage of the implants, resulting in non bone healing

2.2 Bone Necrosis
– Drilling without irrigation leads to thermal damage to the bone.
A significant delay during Emergency Re-entry may happen in cases of:
– Deformation of the pin section of the plate while contouring leads to difficulties or inability of pin removal, resulting in the need for complete implant removal
– Over bending of the Emergency Release Pin leads to difficulties or inability of pin removal, resulting in the need for complete implant removal

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
Avoid direct contact of stainless steel wires with titanium implants to avoid galvanic corrosion.

If one plate is used in combination with stainless steel surgical wires, at least four wires should be used in the sternal body 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.

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.

Use bending screws for severe bends to prevent plate whole deformation while contouring the plate.

Avoid reverse bends as it may weaken the plate and lead to premature implant failure.

Avoid over-bending of the flat prong of the Emergency Release Pin (>25°), as this can lead to breakage or inability to remove the pin for emergency re-entry.

Do not drill any deeper than necessary, 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.

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, pre-drilling 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 medial screws, insert bicortically. For lateral 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.

Magnetic Resonance environment
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
– Heating or migration of the device
– Artifacts on MR images

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
Determine sternal edge thickness
Using the depth gauge, determine the thickness of the sternal edges adjacent to each rib where a plate may be placed.
Add 3 mm to the thickness of the sternal edge to account for the plate thickness and to determine the appropriate length drill bit with stop.
Reduce sternum
Reduce the sternum using reduction forceps on both the superior and inferior aspects of the sternum.
When placing the forceps, care should be taken to avoid the intercostal and mammary vessels and nerves. Note: Sternum can also be reduced with stainless steel surgical wire, if desired.
Select plate
Select the appropriate length titanium sternal locking plate. Center the release pin on the sternum with sufficient plate length on each side to allow a minimum of four locking screws on each side.
Contour plate
Orient the plate so that the titanium emergency release pin is parallel to the midline of the sternum. The closed end of the emergency release pin should be oriented cranially. If the emergency release pin interferes with the bending tool, it can be temporarily removed.
Drill (for self tapping screws)
Insert the 1.5 mm threaded drill guide into the plate to ensure the locking screw will be aligned with the plate hole. For the sternum, use the drill bit with stop of the proper length as determined. Recognize that the thickness of the adjacent ribs may be less than the sternal edge.
Select and insert self tapping screws
Select the proper locking screw. The screw should be no longer than necessary to engage the posterior cortex, to avoid deeper injury.
Select and insert self drilling screws
Select the proper length sternal self drilling locking screw based on sternal edge thickness determination. Add 3 mm to the thickness of the sternal edge to account for the plate thickness.
Check Emergency Release Pin
After the plate has been fixated to the sternum/ribs, it is important to verify that the prong is bent medially to prevent migration of the pin.
Manubrium plate (optional)
A plate can be placed on the manubrium for extra support,if needed.
Removal of Implant/ Emergency Re-entry
Remove the emergency release pins from the plates and discard the pins. Pins must not be reused.
Separate the two plate halves to open the sternum.
Plate and screw removal is necessary for re-entry with the Sternal Locking Plate 2.4, straight, without emergency release pin or if sternal bony fusion has occurred.
To reclose the sternum, a forceps or reduction instrument may be used. Remove any soft tissue that could prevent them from interdigitating properly. Once the plate halves are coupled, insert a new titanium emergency release pin. The closed end of the emergency release pin should be oriented cranially with the sloped bend oriented anteriorly. Bend the flat prong on the pin medially 20°–25°, to reduce the chance of pin migration.
For sterile procedure kits:
After determination of the sternal thickness, choose the appropriate sterile kit. Since the bone thickness may vary, additional screws lengths are optionally available in the instrumentation set or single packed sterile.
Do not pull or lift the patient by the arms for 6 weeks. Do not raise arms higher than 90° at shoulder level.

Troubleshooting
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 Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from http://www.synthes.com/reprocessing

Reference Number

Lot or batch number


Manufacturer


Manufacturing date


Do not use when packaging is damaged

Notified body


Caution, see instructions for use

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