Instructions for Use
MatrixRIB Fixation System

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

MatrixRIB Fixation System
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques MatrixRIB Fixation System (036.000.280) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The Synthes MatrixRIB Fixation System consists of precontoured locking plates, straight plates, sternal plates, locking screws, and intramedullary splints for the fixation and stabilization of ribs.

Material(s)

Material(s):	Standard(s):
TAN (Ti-6Al-7Nb)	ISO 582-11

Intended use
The MatrixRIB Fixation System is intended for the fixation and stabilization of rib fractures, fusions, and osteotomies of normal and osteoporotic ribs, and reconstructions of the chest wall and sternum.
The MatrixRIB Fixation System is intended for temporary reconstruction, if it is used as implant spanning gaps after resection of ribs and/or sternum.

Indications
The MatrixRIB Fixation System is indicated for use in skeletally mature patients with normal or osteoporotic bone for the fixation, stabilization, and reconstruction of:
– fractures, fusions, osteotomies, and/or resections of the ribs and sternum, including spanning gaps and/or defects
– Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

Important: The MatrixRIB Fixation System is not indicated for use as a permanent implant for bridging gaps after chest wall resections.

Contraindications
The MatrixRIB Fixation System is contraindicated for:
– The fixation of the sternum in acute cardiac patients, due to the potential delay if emergent re-entry is required
– Screw attachment or fixation to the clavicle or spine
– Use in patients with latent or active infection, with sepsis, or who are unwilling or incapable of following postoperative care instructions

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
   – An incorrect reading on the calliper/depth gauge leads to a selection of a too long drill bit or screw, resulting in a Pneumothorax
   – The selection of a too long drill bit or screw results in a Pneumothorax
2. Post-operative
   A Re- operation may be required in cases of:
   2.1 Non-Union
   – Excessive reverse plate bending leads to premature implant breakage, resulting in non bone healing
   – An improper reduction of the rib fracture leads to premature implant breakage, resulting in non bone healing
   – 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 or screw results in a weaker construct, resulting in non bone healing
   – Drilling with higher drill speeds than 1800 RPM may lead to increased hole diameters resulting in unstable fixation
   – Usage of less than three screws on each fracture side may result in a weaker construct, resulting in non bone healing
   2.2 Loss of chest wall stability
   – Premature plate failure due to prolonged thoracic dynamic stresses
   2.3 Herniation
   – Using the devices for bridging gaps, there is the risk of adhesion and/or herniation of underlying organs to the implant(s) resulting in pneumothorax or reoperation
   2.4 Residual chest wall deformities due to improper alignment or patient's underlying physiology/ pathology
   2.5 Bone Necrosis
   – Drilling without irrigation leads to thermal damage to the bone
   – Drilling with higher drill speeds than 1800 RPM may lead to thermal necrosis of the bone

Sterile device

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
Approach:
Avoid significant muscle division to preserve as much respiratory function as possible. The serratus anterior muscle insertions on the chest wall are generally the only muscle fibers that are divided for anterolateral injuries.
It is recommended to minimize the dissection of the soft tissue on the lateral side of the fracture.
Determination of Rib Thickness:
Take care to avoid damaging the nerve and vessel bundle at the inferior border of the rib.
If an existing access into the intercostal space is available for determining the rib thickness, it is recommended to insert the calliper tip using the existing access.
Drilling:
Do not drill any deeper than necessary, to avoid the risk of pneumothorax.

Do not extend the tip of the depth gauge too far beyond the posterior cortex of the rib.

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.
Plate Fixation:
Use a minimum of three screws on each side of the fracture, to properly secure the plate.
Avoid sharp bends, reverse bends, or bending the implant at a screw hole. Avoid notching or scratching the implant. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.
It is recommended to insert the forceps from the superior border of the rib to avoid damaging the nerve and vessel bundle located at the inferior border of the rib.

The screw should be placed bicortically. The tip of the screw should not extend too far beyond the posterior cortex to avoid deeper injury. The screw length indicator on the module can be used to select the appropriate screws.
The non-locking screws are for temporary fixation and will need to be replaced with locking screws before closure.

Splint Fixation:
If the drill guide without handle is used, ensure the tapered end, labeled "Fracture", is aligned with the fracture to ensure the hole is approximately 30 mm from the fracture line. Ensure the lateral fracture segment is at least 5 cm long to accommodate the insertion length of the splint before drilling.
To prevent additonal injuries to the rib, spine and/or underlying organs:
Avoid any steep angle during splint insertion to prevent damage of the posterior cortex of the rib.
Do not insert the splint head further once it is seated in the insertion hole.
Sternal Plating:
Do not extend the tip of the depth gauge too far beyond the posterior cortex of the sternum.
When placing forceps, care should be taken to avoid intercostal vessels and nerves.
Use a minimum of three plates in the sternal body for sternal reconstruction.
Avoid direct contact of stainless steel wires with titanium implants to prevent galvanic corrosion.
Chest wall reconstruction:
Use a minimum of three screws on the rib/sternum on either side of the osteotomy to properly secure the plate.

Threaded Reduction Tool (TRT):
The Threaded reduction tool (TRT) has a maximum insertion length of 15 mm. To avoid injuries, limit the insertion depth according to the patient's rib thickness. Stop insertion before the TRT contacts the top surface of the drill guide. Continuing to power after contacting the top surface of the drill guide may cause the TRT threads to strip in the bone.

Warnings
Medical devices containing stainless steel may elicit allergic reactions in patients with hypersensitivity to nickel.

These devices can break intraoperatively 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.

Metallic internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bone as these devices are not designed to withstand the unsupported stress of full weight-bearing, loadbearing, or gap spanning which may result in fatigue failure of the device. Additionally, using the device for spanning gaps in patients that put extreme strain on the implant (e.g. overweight or non-compliant) may further contribute to premature device failure.
The surgeon should consider additional surgical methods to reduce the potential for adhesion and/or herniation when implants are used to bridge gaps after chest wall resections.

Combination of medical devices
Drill bits are combined with power tools.

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
General:
Removal of the periosteum is not required.
Optionally, non locking screws are available to ensure the plates sits flush with the bone. These non locking screws are for temporary fixation and will need to be replaced with a locking screw before closure.
Plating rib:
Determine rib thickness.
Add 2 mm to the rib thickness to allow for the plate thickness.
Splint insertion:
Add 1 mm to the rib thickness to allow for the splint thickness.
Sternal plating:
Add 2mm to the thickness of the sternal edge to account for the plate thickness.
Chest wall reconstruction:
Consider additional surgical methods to reduce the potential for adhesion and/or herniation when implants are used to bridge gaps after chest wall resections.
Deformity repair:
Division of the xiphoid process, bilateral subperichondrial dissection of the cartilage, osteotomy of the anterior sternal cortex and retrosternal dissection may help facilitate to release the tension required to elevate the sternum into the desired anatomic position.
Number, type and orientation of plates are based on individual patient's anatomy, severity of deformity and surgeon preference.

Post-operative considerations:
Sternal plating and chest wall reconstruction:
Avoid pulling or lifting the patient by the arms for 6 weeks.
Avoid raising arms higher than 90° at shoulder level.
Deformity repair:
Avoid pulling or lifting the patient by the arms for 6 weeks.
Avoid raising arms higher than 90° at shoulder level.
Avoid contact sports and other activities for which there is the potential for a high-velocity impact.

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


Expiration date


Do not use when packaging is damaged

Notified body


Caution, see instructions for use

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