Instructions for Use
MatrixRIB

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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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)

Part(s)	Material(s):	Standard(s):
Precontoured, Straight Plates;	TAN (Ti-6Al-7Nb)	ISO 5832-11
Screws	TAN (Ti-6Al-7Nb)	ISO 5832-11
Sternal Plates (T, I, straight)	Titanium (TiCP)	ISO 5832-2

Intended use
The Synthes MatrixRIB Fixation System is intended for the fixation and stabilization of rib and sternum fractures, fusions, and osteotomies of normal and osteoporotic bone and reconstructions of the chest wall.
Pre-contoured Synthes MatrixRIB plates (04.501.001–04.501.008) are intended for:
– Rib fracture fixations, osteotomies and reconstruction
Synthes MatrixRIB straight plates (04.501.096, 04.501.097) are intended for:
– Rib fracture fixations, osteotomies and reconstruction
– Rib-to-sternum fixation
– Transverse sternum reconstruction
– Transverse plating across the sternum (rib-to-rib fixation)
The Synthes MatrixRIB pre-contoured and straight plates are intended for temporary reconstruction, if they are used as implant spanning gaps after resection of ribs and/or sternum.
Synthes MatrixRIB sternal plates (04.501.068, 04.501.069, 04.501.093, 04.501.094, 04.501.095, 04.501.103, 04.501.104) are intended for:
– Sternum fracture fixations and osteotomies
The Synthes MatrixRIB intramedullary splints (04.501.010, 04.501.011, 04.501.012) and the universal plate (04.501.009) are intended for rib fracture fixations and osteotomies.

Indications
The Synthes MatrixRIB Fixation System is indicated for use in skeletally mature patients with normal or osteoporotic bone.
Pre-contoured Synthes MatrixRIB plates (04.501.001–04.501.008) are indicated for the fixation, stabilization and reconstruction of:
– Rib fractures, fusions, osteotomies, and/or resections, including spanning gaps and/or defects
– Pectus Excavatum, Pectus Carinatum, and other chest wall deformities
Synthes MatrixRIB straight plates (04.501.096, 04.501.097) are indicated for the fixation, stabilization and reconstruction of:
– Rib and sternum fractures, fusions, osteotomies, and/or resections, including spanning gaps and/or defects
– Pectus Excavatum, Pectus Carinatum, and other chest wall deformities
Synthes MatrixRIB sternal plates, 2.8 mm thickness, (04.501.068, 04.501.069, 04.501.093, 04.501.094, 04.501.095, 04.501.103, 04.501.104) are indicated for the fixation, stabilization and reconstruction of:
– Sternum fractures, fusions, and/or osteotomies
– Pectus Excavatum, Pectus Carinatum, and other chest wall deformities

The Synthes MatrixRIB intramedullary splints (04.501.010, 04.501.011, 04.501.012) and the universal plate (04.501.009) are indicated for the fixation and stabilization of ribs.

Important: The Synthes MatrixRIB pre-contoured and straight plates are not indicated for use as permanent implants 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

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 problems result 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, 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:
For chest wall reconstruction including spanning gaps:
– Plate breakage
– Pneumothorax
– Loss of chest wall stability
– Herniation
– Postoperative dehiscence
– Seroma
– Bone Necrosis and partial skin necrosis
For chest wall deformities:
– Residual or recurrent chest wall deformities
– Pleural effusions
– Seroma
– Hematoma

Warnings
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, load-bearing, 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.
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 the associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.
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

Plating Rib
Avoid significant muscle division to preserve as much respiratory function as possible.
Take care to avoid damaging the nerve and vessel bundle at the inferior border of the rib.

Use a minimum of three screws on each side of the fracture, to properly secure the plate.
If contouring is necessary, 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.
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.
Do not drill any deeper than necessary, to avoid the risk of pneumothorax.
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.
Do not extend the tip of the depth gauge too far beyond the posterior cortex 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.
In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or osteotomy. DePuy Synthes recommends at least three screws per plate per fracture side when repairing osteotomies and fractures with this system. Additional fixation is recommended to ensure stability of large fractures and osteotomies.
The non-locking screws are for temporary fixation and will need to be replaced with locking screws before closure.
If non-locking screws are not replaced with locking screws, the likelihood of implant loosening/migration may be increased.
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.

Splint Insertion
Avoid significant muscle division to preserve as much respiratory function as possible.
It is recommended to minimize the dissection of the soft tissue on the lateral side of the fracture.
Take care to avoid damaging the nerve and vessel bundle at the inferior border of the rib.
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.
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.
To prevent additional 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.
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.
The screw should be placed bicortically. The tip of the screw should not extend too far beyond the posterior cortex to avoid deeper injury.
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.

Sternal plating
Avoid significant muscle division to preserve as much respiratory function as possible.
When placing forceps, care should be taken to avoid the intercostal and mammary vessels and nerves.
Avoid direct contact of stainless steel wires with titanium implants to prevent galvanic corrosion.
The 2.8 mm MatrixRIB Sternal Plates are not intended to be cut.
Use a minimum of three screws on each side of the fracture, to properly secure the plate.
Incorrect orientation of the plate, where the etched surface contacts the sternal bone, may result in the inability to lock the screws to the plate, resulting in inadequate fixation.
If contouring is necessary, 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.
Use of the incorrect instrumentation for bending may weaken the plate and lead to premature plate failure (e.g. breakage).
Do not contour the straight sternal plates beyond the 20° limit in-plane at a single location.
The Sternal T plates and Sternal I plates are not intended to be contoured in-plane.
Do not contour the sternal T- and I-plates beyond the 30° limit out-of-plane at a single location.
Incorrect orientation of the plate, where the etched surface contacts the sternal bone, may result in the inability to lock the screws to the plate, resulting in inadequate fixation.
Irrigate during drilling to avoid thermal damage to the bone.
Do not drill any deeper than necessary, to avoid the risk of injury to underlying organs or soft tissue.
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.
Do not extend the tip of the depth gauge too far beyond the posterior cortex of the sternum.
The screw should be placed bicortically. The tip of the screw should not extend too far beyond the posterior cortex to avoid deeper injury.
In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or osteotomy. DePuy Synthes recommends at least three screws per plate per fracture side when repairing osteotomies and fractures with this system. Additional fixation is recommended to ensure stability of large fractures and osteotomies.
The non-locking screws are for temporary fixation and will need to be replaced with locking screws before closure.
If non-locking screws are not replaced with locking screws, the likelihood of implant loosening/migration may be increased.
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.

MatrixRIB Trocar Instruments Instructions
Do not drill any deeper than necessary, to avoid the risk of pneumothorax.
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 placed bicortically. The tip of the screw should not extend too far beyond the posterior cortex to avoid deeper injury.
In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or osteotomy. DePuy Synthes recommends at least three screws per plate per fracture side when repairing osteotomies and fractures with this system. Additional fixation is recommended to ensure stability of large fractures and osteotomies.
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.

Threaded Reduction Tool Instructions
The Threaded Reduction Tool 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 Threaded Reduction Tool contacts the top surface of the drill guide. Continuing to power after contacting the top surface of the drill guide may cause the Threaded Reduction Tool threads to strip in the bone.
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.

90° Screwdriver for MatrixRIB System Instructions
Do not drill any deeper than necessary, to avoid the risk of pneumothorax.
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 placed bicortically. The tip of the screw should not extend too far beyond the posterior cortex to avoid deeper injury.
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.

Chest Wall Reconstruction, including Spanning Gaps Instructions
Take care to avoid damaging the nerve and vessel bundle at the inferior border of the rib.
In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or osteotomy. DePuy Synthes recommends at least three screws per plate per fracture side when repairing osteotomies and fractures with this system. Additional fixation is recommended to ensure stability of large fractures and osteotomies.
Avoid excessive and reverse bending as it may weaken the plate and lead to premature implant failure.
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.
Do not drill any deeper than necessary, to avoid the risk of pneumothorax.

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.
Do not extend the tip of the depth gauge too far beyond the posterior cortex 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.
In order to determine the appropriate amount of fixation for stability, the surgeon should consider the size and shape of the fracture or osteotomy. DePuy Synthes recommends at least three screws per plate per fracture side when repairing osteotomies and fractures with this system. Additional fixation is recommended to ensure stability of large fractures and osteotomies.
The non-locking screws are for temporary fixation and will need to be replaced with locking screws before closure.
If non-locking screws are not replaced with locking screws, the likelihood of implant loosening/migration may be increased.
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.
Use a minimum of three plates for fixation in sternal reconstruction.

Chest Wall Deformity Repair
Avoid significant muscle division to preserve as much respiratory function as possible.
If contouring is necessary, avoid sharp bends, reverse bends, or bending the implant at a screw hole. Avoid notching or scratching the implant. These factors may become the focal point for eventual breakage.
Use of the incorrect instrumentation for bending may weaken the plate and lead to premature plate failure (e.g. breakage).
Do not bend the plate beyond what is required to match the anatomy.
Use a minimum of three screws on each side of the fracture to properly secure the plate.

Warning
Chest Wall Reconstruction, including Spanning Gaps Instructions
When implants are used to bridge gaps after chest wall resections, there is potential risk for herniation and adhesion of the underlying organs/soft tissue.

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

Magnetic Resonance Imaging (MRI)
Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07
Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 5.4 T/m. The largest image artifact extended approximately 35 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a single Siemens Prisma 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a
Non-clinical electromagnetic and thermal simulations of worst case scenario lead to temperature rises of 21.7 °C (1.5 T) and 12.4 °C (3 T) under MRI conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 15 minutes).

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 MRI scanning for perceived temperature and/or pain sensations.
– Patients with impaired thermoregulation or temperature sensation should be excluded from MRI scanning procedures.
– Generally, it is recommended to use an MRI 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.

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

Position Patient
Plating Rib
1. Expose Rib
2. Determine rib thickness
   If an existing access into the intercostal space is available for measuring the rib thickness, it is recommended to insert the caliper tip using the existing access.
3. Approximate broken rib segments
4. Cut and contour plate template (optional)
5. Select and cut plate (optional)
   Position the precontoured plate with the marking toward the sternum. A universal plate is available for use in place of a precontoured plate. Straight plates are available for use in place of a precontoured plate.
6. Contour plate (optional)
7. Position plate
8. Drill
   The MatrixRIB Trocar Instruments may be used for drilling
   The 90° Screwdriver for MatrixRIB System may be used for drilling.
9. Confirm rib thickness (optional)
   When using the cannula, the 03.503.085 depth gauge must be used.
10. Select and insert screw
    The MatrixRIB Trocar Instruments may be used for screw insertion.
    The 90° Screwdriver for MatrixRIB System may be used for screw insertion.
11. Drill and place remaining screws

Splint Insertion
1. Expose fractured rib
2. Determine rib thickness
   If an existing access into the intercostal space is available for measuring the rib thickness, it is recommended to insert the caliper tip using the existing access.
3. Prepare splint insertion hole
   It is recommended to insert the hook near the superior edge of the rib, and to drill an entry hole in the upper 2/3 of the rib.
   The small plate holding forceps can be used to hold the drill guide against the rib during drilling.
   The splint driver may be threaded into the drill guide to act as a handle, as needed.
4. Select splint
   If the small template fits snugly, use the 3 mm wide splint.
   If the medium template fits snugly, use the 4 mm wide splint.
   If the medium template fits loosely, use the 5 mm wide splint.
   Use the mallet to assist insertion of the splint template, if needed.
5. Insert splint
6. Drill screw hole
   Plate holding forceps may be used to hold splint head flush to bone during drilling.
7. Confirm rib thickness (optional)
8. Select and insert screw

Plating Sternum
1. Expose fracture/osteotomy site on sternum
2. Determine sternal thickness
3. Approximate sternum to desired position
   Sternum can also be temporarily reduced with stainless steel surgical wire, if desired.
4. Select Plate
5. Contour plates (optional)
   Bending template can be used to assist in contouring of plate.
6. Position Plate
7. Drill
   The Trocar Instrumentation for MatrixRIB Fixation System may be used for drilling.
8. Confirm sternal thickness (optional)
9. Select and insert screw
   The Trocar Instrumentation for MatrixRIB Fixation System may be used for screw insertion.
10. Drill and place remaining screws
11. Insert remaining plates (optional)
12. Post-operative Considerations

MatrixRIB Trocar Instruments Instructions
1. Insert cannula
   The cannula can be used with or without the universal trocar handle.
2. Drill
   Retraction forceps may be used to retract soft tissue.
3. Select and insert screw

Threaded Reduction Tool Instructions

1. Thread drill guide to plate
2. Insert Threaded Reduction Tool through drill guide
3. Remove the power source
4. Reduce bone to plate

The Threaded Reduction Tool is designed to allow later placement of a 2.9 mm MatrixRIB locking screw in the same hole – after removal of the Threaded Reduction Tool.

90° Screwdriver for MatrixRIB System Instructions

1. Drilling with 90° Screwdriver
   Ensure the head of the drill guide is seated flat on top of the plate to ensure proper engagement.
   90° Screwdriver may stall during drilling if drill bit is misaligned with the drill guide.
2. Insert screw

Chest Wall Reconstruction, including Spanning Gaps Instructions

1. Expose surgical site
2. Determine rib/sternal thickness
3. Cut and contour bending template (optional)
4. Select and cut plate (optional)
   Position the precontoured plate with the etching toward the sternum.
5. Contour plate (optional)
6. Position plate
7. Drill
   The MatrixRIB Trocar Instruments may be used for drilling. The 90° Screwdriver for MatrixRIB System may be used for drilling.
8. Confirm rib/sternal thickness (optional)
   When using the cannula, the 03.503.085 depth gauge must be used.
9. Select and insert screw
   The MatrixRIB Trocar Instruments may be used for screw insertion.
   The 90° Screwdriver for MatrixRIB System may be used for screw insertion.
10. Drill and place remaining screws
11. Insert remaining plates (optional)
12. Post-operative Consideration

Deformity Repair

1. Expose surgical site
2. Release deformed sections of chest wall
   The perichondrium should be preserved.
   Several wedge osteotomies on a rib may be required for full anatomical repositioning.
   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.
   Minimally invasive instrumentation is available for percutaneous approach.
3. Realign the anterior chest wall into desired anatomic position
4. Position and fixate plate(s)
   The number, type, and orientation of plates is based on individual patient anatomy, severity of deformity, and surgeon preference
5. Post-operative Consideration

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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