Instructions for Use
MatrixRIB

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

Not all products are currently available in all markets.

EC REP

Authorised Representative

DePuy Ireland UC
Loughbeg
Ringaskiddy
Co. Cork Ireland

Manuals are subject to change;
the most current version of each
manual is always available online.
Printed on: Aug 14, 2020

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

 SE_481917 AL 03/2020

Instructions for Use

MatrixRIB

Art. Nr.	04.501.018.05
04.501.069	04.501.020.01
04.501.068S	04.501.020.01S
04.501.068	04.501.020.05
04.501.042.05	04.501.022.01
04.501.042.01S	04.501.022.01S
04.501.042.01	04.501.026.05
04.501.040.05	04.501.026.01S
04.501.040.01S	04.501.026.01
04.501.040.01	04.501.024.05
04.501.030.05	04.501.022.05
04.501.030.01S	04.501.024.01
04.501.030.01	04.501.024.01S
04.501.028.05	04.501.208.01
04.501.028.01S	04.501.208.01S
04.501.028.01	04.501.209.01
04.501.018.01	04.501.209.01S
04.501.016.05	04.501.210.01
04.501.016.01S	04.501.210.01S
04.501.016.01	04.501.211.01
04.501.012S	04.501.211.01S
04.501.012	04.501.212.01
04.501.011S	04.501.212.01S
04.501.004S	04.501.213.01
04.501.004	04.501.213.01S
04.501.104S	04.501.214.01
04.501.104	04.501.214.01S
04.501.103S	04.501.215.01
04.501.103	04.501.215.01S
04.501.097S	04.501.216.01
04.501.097	04.501.216.01S
04.501.096S	04.501.217.01
04.501.096	04.501.217.01S
04.501.095S	04.501.218.01
04.501.095	04.501.218.01S
04.501.094S	04.501.219.01
04.501.094	04.501.219.01S
04.501.093S	04.501.220.01
04.501.093	04.501.220.01S
04.501.069S	04.501.250.01
04.501.011	04.501.250.01S
04.501.010S	04.501.252.01
04.501.010	04.501.252.01S
04.501.009S	
04.501.009	03.501.718
04.501.008S	03.501.719
04.501.008	
04.501.007S	03.501.750
04.501.007	03.503.071
04.501.006S	03.503.072
04.501.006	
04.501.005S	03.501.065
04.501.005	03.501.074
04.501.003S	03.501.715
04.501.003	
04.501.002S	03.501.030
04.501.001	03.501.031
04.501.001S	03.501.071
04.501.002	03.501.708
04.501.018.01S	03.501.709

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

The Synthes MatrixRIB Fixation System consists of pre-contoured locking plates, straight plates, sternal plates, intramedullary splints and locking and non-locking screws for the fixation and stabilization of ribs and sternum.
All implants are single packed.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Device(s)	Material(s)	Standard(s)
Pre-contoured and Straight Plates, Screws	TAN (Ti-6Al-7Nb)	ISO 5832-11
Sternal Plates	Titanium (TiCP)	ISO 5832-2
Instruments	Stainless Steel	ISO 5832-1

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
– Rib-to-sternum fixation

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.

Patient Target Group
The Synthes MatrixRIB Fixation System is indicated for use in skeletally mature patients with normal or osteoporotic bone.

Intended User
This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device. All personnel handling the device should be fully aware of the IFU, the surgical procedures, if applicable, and /or the Synthes "Important Information" brochure as appropriate.
Implantation is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the device is suitable for the pathology/condition indicated and that the operation is carried out properly.

Expected Clinical Benefits
Expected clinical benefits of internal fixation devices such as MatrixRIB Fixation System when used according to instructions for use and recommended technique are,
- Stabilize bone segment and facilitate healing
- Restore anatomical relationship and function

Performance Characteristics of the Device
Synthes has established the performance and safety of the MatrixRIB Fixation System and that it represents state of the art medical devices for fixation and stabilization of rib and sternum fractures, fusions and osteotomies of normal and osteoporotic bone, and reconstructions of the chest wall, when used according to their instructions for use and labeling.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
- Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction
- Infection
- Damage to Vital Organs or Surrounding Structures
- Neurovascular Damage
- Spinal Cord Compression and/or Contusion
- Peripheral Nerve Compression and/or Contusion
- Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis.
- Soft Tissue Damage
- Soft Tissue Irritation
- Malunion/Non-union
- Pain or Discomfort
- Injury to User
- Symptoms resulting from Implant Migration, Loosening or Breakage

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.

Do not use when packaging is damaged

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

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
Re-use or clinical 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.

Warnings and Precautions

Warnings

General Warnings

- The MatrixRIB Fixation System is not intended for use as a permanent implant for bridging gaps after chest wall resections.
- 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.

Warnings for Alternative Techniques Instructions

- Do not use self-drilling screws in 2.8 mm MatrixRIB Plates or in a 90° approach, which may result in misalignment of the screw during insertion resulting in higher insertion torque, debris formation, and/or inadequate screw locking.
- Improper screw length selection may lead to increased risk of screw protrusion or suboptimal cortex engagement. It's recommended to measure the thickness of each rib as it may vary between ribs.

Self-Drilling Screws for 1.5 mm MatrixRIB Plates & Self-Drilling Screws for Intramedullary Splints:
- If the tip of the screw does not engage the inner cortex of the rib, the risk of screw pullout may be increased.
- If the tip of the screw extends too far beyond the inner cortex, the risk of injury to underlying tissues may be increased.

Warnings for Chest Wall Defect Repair Instructions

Chest Wall Reconstruction, including Spanning Gaps:
- 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.

Precautions

Precautions for Surgical Technique Instructions

Plating Rib
- While exposing the rib, avoid significant muscle division to preserve as much respiratory function as possible.
- During rib thickness determination, take care to avoid damaging the nerve and vessel bundle at the inferior border of the rib.
- During plate selection and cutting, 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 of the implant.
- When positioning the plate, 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.
- If confirming rib thickness, do not extend the tip of the depth gauge too far beyond the posterior cortex of the rib.
- When inserting the screw, it 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.
- Use a minimum of three screws on each side of the fracture to properly secure the plate.

– 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
– While exposing the rib, avoid significant muscle division to preserve as much respiratory function as possible.
– Additionally, it is recommended to minimize the dissection of the soft tissue on the lateral side of the fracture.
– During rib thickness determination, take care to avoid damaging the nerve and vessel bundle at the inferior border of the rib.
– When preparing splint insertion hole, 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.
– Also 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.
– When inserting splint, 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.
– When drilling screw hole, do not drill any deeper than necessary, to avoid the risk of pneumothorax.
– If confirming rib thickness, do not extend the tip of the depth gauge too far beyond the posterior cortex of the rib.
– When inserting the screw, it 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.

Plating Sternum
– While exposing the fracture/osteotomy site on sternum, avoid significant muscle division to preserve as much respiratory function as possible.
– When placing forceps to approximate sternum to a desired position, 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.
– 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.
– 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.
– 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).
– For In-Plane countering:
  – Do not contour the straight sternal plates, 2.8 mm thick, beyond the 20° limit In-Plane at a single location.
  – The Sternal T plates and Sternal I plates, 2.8 mm thick, are not intended to be contoured In-Plane.
– For Out-of-Plane countering, do not contour the sternal T- and I-plates beyond the 30° limit Out-of-Plane at a single location.
– 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.
– If confirming sternal thickness, do not extend the tip of the depth gauge too far beyond the posterior cortex of the sternum.
– When inserting the screw, it 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.
– Self-drilling screws for plating the rib should not be used with sternal plates. There are no self-drilling screws available for the 2.8 mm MatrixRIB sternal plates.
– If non-locking screws are not replaced with locking screws, the likelihood of implant loosening/migration may be increased.
– When placing the remaining screws, use a minimum of three screws on each side of the fracture, to properly secure the plate.
– 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.

Precautions for Alternative Techniques Instructions

Self-Drilling Screws Technique for 1.5 mm MatrixRIB Plates
– When measuring bone thickness and positioning the plate, it is recommended to insert the forceps from the superior border of the rib to avoid damaging the nerve and vessel bundle at the inferior border of the rib.
– Improper alignment of the screw guide with the plate may result in off-axis insertion of the screw resulting in inadequate locking of the screw, and/or screw head sitting proud above the plate.
– Improper engagement of the screwdriver blade with the screw and/or overtightening of the screw during insertion may deform, strip or break the screw, which may make further tightening or eventual removal more difficult, and the screwdriver blade may deform or slip out of the screwhead drive recess.
– The non-locking screws are for temporary fixation and will need to be replaced with locking screws before closure.
– After implant placement is complete, discard any fragments or modified parts in an approved sharps container, in accordance with hospital procedures.
– Irrigate and apply suction for removal of debris potentially generated during implantation.

Self-Drilling Screws for Intramedullary Splints
– When positioning the screw guide on splint, improper alignment of the screw guide with the splint may result in off-axis insertion of the screw, resulting in inadequate locking of screw, and/or screw head protrusion above the splint.
– Improper engagement of the screwdriver blade with the screw and/or overtightening of the screw during insertion may deform, strip or break the screw, which may make further tightening or eventual removal more difficult, and the screwdriver blade may deform or slip out of the screwhead drive recess.
– After implant placement is complete, discard any fragments or modified parts in an approved sharps container, in accordance with hospital procedures.
– Irrigate and apply suction for removal of debris potentially generated during implantation.

Precautions for MIPO Instructions

Caliper Forceps
– Be careful not to pinch hand or gloves, or injure yourself when using the caliper forceps to measure rib thickness.
– If the caliper forceps are clamped too tightly during measurement, the caliper forceps may flex, resulting in a rib thickness measurement that is smaller than the actual thickness of the rib.
– Take care to avoid damaging the nerve and vessel bundle at the inferior border of the rib.

MatrixRIB Trocar Instruments
– 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.
– When inserting the screw, it 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
– 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
– 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.

– When inserting the screw, it 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.

Precautions for Chest Wall Defect Repair Instructions

Chest Wall Reconstruction, including Spanning Gaps
– When determining rib/sternal thickness, take care to avoid damaging the nerve and vessel bundle at the inferior border of the rib.
– When selecting and cutting plate, 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.
– If contouring 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 stress which may become the focal point for eventual breakage of the implant.
– When positioning plate, 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.
– If confirming rib/sternal thickness, do not extend the tip of the depth gauge too far beyond the posterior cortex of the rib.
– When inserting the screw, it 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
– When releasing deformed section of chest wall, 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).
– When positioning and fixing plates, 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.

Combination of Medical Devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance Environment
Torque, Displacement and Image Artifacts according to ASTM F 2213-17, ASTM F 2052-15 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
Non-Sterile Device
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".

Sterile Device
Store sterile devices 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. Remove products from the package in an aseptic manner.

Implant Removal
1. Preoperative Planning
   To ensure that the appropriate instruments are available for screw removal, the surgeon should have the following information before implant removal:
   – Implant type
   – Time of implantation
   – Material
   – Any visible damage to the implant (e.g., broken plate)
2. Before removing screws, clean the screw recess. Free the screw recess from ingrown bone and tissue to ensure the screwdriver can be fully inserted. Check the condition and geometry of the recess of the exposed screwhead.
3. To remove locking screws, ensure screwdriver blade is fully seated into the screwhead by applying some downward pressure on the screwdriver.
4. Slowly, turn the screwdriver counterclockwise until the screw unlocks from the plate. Then, fully remove the screw.

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Clinical Processing 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" are available on the website.

Disposal
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.
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

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