Instructions for Use
MATRIX Spine System

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

Not all products are currently available in all markets.

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

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Instructions for Use

MATRIX Spine System
The MATRIX Spine System is a posterior screw and hook fixation system designed for use in the thoracolumbar and sacral region of the spine. It is comprised of solid, cannulated and perforated pedicle screws as well as connectors, rods and locking caps needed to create spinal constructs.

The implants of the MATRIX Spine System are available in different types and sizes, allowing the system to be assembled as a spinal construct.

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.

Materials
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11
Titanium: TiCP (Commercially pure Titanium) according to ISO 5832-2
Cobalt-Chromium-Molybdenum Alloy: CoCrMo (Cobalt – 28% Chromium – 6% Molybdenum) according to ISO 5832-12
Nickel-Titanium Alloy: Nitinol (55% Nickel – 45% Titanium) ASTM F2063 (Transverse connector)

Intended Use
The MATRIX Spine System is intended for posterior fixation of the thoracolumbar and sacral spine (T1-S2) as an adjunct to fusion in skeletally mature patients.

Indications
– Degenerative spine disease
– Trauma
– Tumor
– Deformities
For MATRIX Perforated Screws: Diminished bone quality when used concurrently with Vertecem V+.

Contraindications
– In fractures and tumors with severe anterior vertebral body disruption, an additional anterior support or column reconstruction is required.
– Poor bone quality in which significant purchase cannot be established.

For MATRIX Perforated Screws: Diminished bone quality when used without Vertecem V+ cement.

For additional contraindications and potential risks related to Vertecem V+ please refer to the corresponding instructions for use for the Vertecem V+ system.

Patient Target Group
The MATRIX Spine System is intended for use in skeletally mature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that 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.

Expected Clinical Benefits
When the MATRIX Spine System is used as intended and according to the instructions for use and labeling, the device provides segmental stabilization as an adjunct to fusion, which is expected to provide relief of back and/or leg pain caused by indicated conditions and correct spinal deformity.

A summary of safety and clinical performance can be found at the following link (upon activation): https://ec.europa.eu/tools/eudamed

Performance Characteristics of the Device
The MATRIX Spine System is a posterior fixation device, designed to provide stability at the motion segment(s) prior to fusion.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis; embolism; infection; excessive bleeding; neural and vascular injury; swelling, abnormal wound healing or scar formation; functional impairment of the musculoskeletal system; complex regional pain syndrome (CRPS); allergy/hypersensitivity reactions; symptoms associated with implant or hardware prominence, implant breakage, loosening or migration; malunion, non-union or delayed union; decrease in bone density due to stress shielding; ongoing pain; damage to adjacent bones, organs, discs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; displacement of the graft; vertebral angulation.

Sterile Device

Sterilized using irradiation

Store sterile devices 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 or date of expiration has passed.


Do not resterilize

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

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, re-use 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
- It is strongly advised that the MATRIX Spine System is implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.
- Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

MATRIX Spine System – Degenerative
Prepare pedicles and insert screw
- When countersinking, care should be taken in reaming the most superior and inferior levels to protect the facet joints.
- Do not grasp the green knob during screw insertion as this will cause the retaining sleeve to disengage from the screw.

Select, cut and bend rod
- The USS rod cutting and bending device must be used to cut cobalt chromium rods.
- Do not reverse bend rods. Reverse bending may produce internal stresses, which may become the focal point for eventual breakage of the implant.

Insert rod
- When using a connecting rod, it is important not to position the transition taper within the head of a screw or hook.

Reduce rod
- If significant reduction forces are encountered, consider:
  - Adjusting the screw height
  - Checking the rod placement for tissue trapped between the rod and screw head.

Insert locking cap
- Confirm that the rod is fully aligned to the polyaxial head. Improper alignment of the rod with respect to the MATRIX implant heads could lead to construct loosening.
  Examples of misalignment:
  - The rod is sitting high in the polyaxial head.
  - The rod is not perpendicular to the polyaxial head.
  - A severe bend is positioned within the polyaxial head.

Distract and compress
- Ensure all locking caps are fully reduced and provisionally tightened. Failure to do so could potentially lead to a misalignment.
- Always fully seat the counter torque on the rod. The instrument must be perpendicular to the rod during tightening.

Perform final tightening
- Ensure all locking caps are fully reduced and provisionally tightened. Failure to do so could potentially lead to a misalignment.
- The handle of the counter torque must be oriented laterally or medially. Do not orient the handle of the counter torque in line with the rod. This action could cause misalignment of the rod with the implant.
- Final tightening of the locking caps should only be performed with a Synthes 10 Nm torque handle. MATRIX screw implants achieve performance standard only when tightened to the required 10 Nm tightening torque.
- Always fully seat the rod pusher/counter torque on the rod. The instrument must be perpendicular to the rod during final tightening.

Optional technique
Unassembled pedicle screw insertion
- Care should be taken in reaming the most superior and inferior levels to protect the facet joints.

Assemble polyaxial head
- Polyaxial screw heads can be removed a maximum of three times without removing the pedicle screw; a new head must be used for each assembly.

Adding rod-to-rod connectors
- Parallel connectors with one set screw should be used in pairs on each side of the construct. Connectors with two set screws can be used one per side of the construct.
- Care should be taken not to tighten the connector on a portion of the rod that has been contoured or deformed by a rod cutter.

Distraction for posterior interbody fusion
- Do not grasp the green knob during screw insertion as this will cause the retaining sleeve to disengage from the screw.

Locking cap removal
Option A: Counter torque on an adjacent screw
- For this technique, always use the torque limiting handle to reduce risk of damage to the T25 screwdriver shaft.
- Retighten the locking cap on which the counter torque was applied to 10 Nm.
- To loosen the last locking cap, replace the counter torque, consisting of rod pusher/counter torque and handle with a rod persuader.

Option B: Apply a downward force to the rod
- For this technique, always use the torque limiting handle to reduce risk of damage to the T25 screwdriver shaft.

MATRIX Spine System-MIS
Patient positioning and approach
Position the patient on a radiolucent operating room table in the prone position.
- Consider incision location with respect to final construct positioning to reduce soft tissue forces on the construct during assembly.

Pedicle preparation
Perforate cortex of pedicle
- Use fluoroscopy to monitor position of the awl during insertion.

Insert Kirschner wire
- Ensure the Kirschner wires remain securely in position throughout the entire duration of the procedure.
- Monitor the tip of the Kirschner wire under fluoroscopy to ensure it does not penetrate the anterior wall of the vertebral body.

Using the flexible guide wire and tamp
- Monitor the tip of the flexible guide wire under fluoroscopy to ensure it does not penetrate the anterior wall of the vertebral body.

Pedicle probe
- To prevent inadvertent advancement of the Kirschner wire, align the trajectory of the probe with the Kirschner wire and monitor the Kirschner wire position using fluoroscopy.
- To avoid glove damage, ensure that the exit point for the Kirschner wire is held free.

Tap pedicle
- To prevent the inadvertent advancement of the Kirschner wire, align the trajectory of the tap with the Kirschner wire and monitor the Kirschner wire position using fluoroscopy.
- To reduce trauma to the surrounding soft tissues, protection sleeves to cover the proximal tip of the tap must be used.

Screw insertion
Determine screw length
- To prevent inadvertent advancement of the Kirschner wire while inserting the dilator, monitor the Kirschner wire position using fluoroscopy.

Polyaxial screw assembly
- Do not use a screw head which was removed from a pedicle screw previously.
- Ensure that polyaxial head is securely attached to the unassembled pedicle screw by gently lifting the positioning instrument and angulate the polyaxial head.

Attach retraction blade to pedicle screw
- To avoid glove damage, do not hold the retraction blade near the bottom of the deflecting tab.

Load screw assembly to locking retaining sleeve
- Ensure when loading a screw, the ratchet handle is always in the neutral position.
- Ensure that the retraction blade is properly seated before engaging a screwdriver.

Insert screw
- Do not advance the screw into the pedicle until the screw axis is aligned with the Kirschner wire to prevent kinking or unintended advancement.
- Monitor the tip of the Kirschner wire under fluoroscopy to ensure it does not penetrate the anterior wall of the vertebral body.
- Do not grasp the green knob during insertion as it will cause the retaining sleeve to disengage from the screw.
- Ensure that the polyaxial screw head remains free to adapt its position and is not restricted by, or does not rest on, bony structures. If necessary, adjust the screw height and/or ream space for the screw head.

Rod introduction
Determine rod length
- Do not force open or distract the natural position of the retraction blade by expanding the tips of the template.

Contour rod
– Do not reverse bend rods. Reverse bending may produce internal stresses which may become the focal point for eventual breakage of the implants.
– The rod coupling can fit into the rod holder only in one direction. Make sure to consider the orientation of the rod coupling when contouring the rod.
– Do not bend the rod coupling to ensure correct attachment of the rod to the rod holder.
– Excessive rod contouring should be avoided to ensure proper alignment of the rod with respect to the polyaxial heads.

Place rod
For percutaneous method / retraction blade
– If significant reduction forces are encountered, consider:
  – Adjusting the screw height
  – Checking the rod placement for tissue trapped between the rod and screw head.

Alternative technique for percutaneous method:
Introduce rod using fixed angle rod holder
– Ensure the coupling at the end of the MIS rod is seated outside the screw head.
– If significant reduction forces are encountered, consider:
  – Adjusting the screw height
  – Checking the rod placement for tissue trapped between the rod and screw head.

Rod reduction and locking cap introduction
Insert locking cap
– Confirm with lateral fluoroscopy that the rod is fully aligned to the polyaxial head.
  Examples of misalignment:
  – The rod is sitting high in the polyaxial head.
  – The rod is not perpendicular to the polyaxial head.
  – A severe bend is positioned within the polyaxial head.
– The polyaxial head must align perpendicular to the rod. The use of curved rods might cause the instruments to cross each other. If necessary adjust position of instruments laterally and medially. Improper alignment of the rod with respect to the MATRIX polyaxial heads could lead to construct loosening.
– If significant reduction forces are encountered, consider:
  – Adjusting the screw height
  – Checking the rod placement for tissue trapped between the rod and screw head.

Rod reduction
– The polyaxial head must align perpendicular to the rod. The use of curved rods might cause the instruments to cross each other. If necessary adjust position of instruments laterally and medially.

Final tighten locking cap
– Ensure all locking caps are fully reduced and provisionally tightened. Failure to do so could potentially lead to a misalignment.
– Ensure that the polyaxial head is perpendicular to the rod. When using lordotically contoured rods it may be necessary to allow the retraction blades and inserted instruments to cross in the sagittal plane.
– The handle of the counter torque must be oriented laterally or medially. Do not orient the handle of the counter torque in line with the rod. This action could cause misalignment of the rod with the implant.
– Refer to the torque limiting handle instructions for use for the recommended calibration maintenance.
– Ensure the required torque of 10 Nm is applied to each locking cap by using the torque limiting handle.
– Never use a fixed or ratcheting T-handle screwdriver for this technique. If the torque limiting attachment is not used, breakage of the driver may occur and could potentially harm the patient.

Detach rod introducer
– Avoid rod displacement by excess lateral or medial tilting of the instrument.

Sequential revisiting of locking caps
– The counter torque must be placed on each implant requiring final tightening. If the counter torque is not used during final tightening, construct loosening may occur.
– Do not orientate the handle of the counter torque in line with the rod. This action could cause misalignment of the rod with the polyaxial heads.

Compression and distraction
Compress mini-open construct
– Ensure all locking caps are fully seated and provisionally tightened.
– Always fully seat the compressor instrument on the screw head. The cannula of the instrument must be perpendicular to the rod during tightening.

Distract mini-open construct
– Ensure all locking caps are fully seated and provisionally tightened.
– Always fully seat the distraction instrument on the screw head. The cannula of the instrument must be perpendicular to the rod during tightening.

Locking cap loosening
– Never use a fixed or ratcheting T-handle screwdriver for this technique. If the torque limiting attachment is not used, breakage of the driver may occur and could potentially harm the patient.

Retraction blade reattachment
– Do not impact the retraction blade reattachment tool.

MATRIX Spine System-Perforated
Preoperative planning
– The MATRIX Perforated Screws are combined with Vertecem V+. Handling knowledge of Vertecem V+ is required prior to augmentation of perforated screws. Please refer to the associated instructions for use for details on its use, precautions, warnings and side effects.
– Image intensifier control is mandatory while injecting cement.

Kirschner wire handling
– Ensure the Kirschner wires remain securely in position throughout the entire duration of the procedure. The tip of the Kirschner wire should be monitored by image intensifier to ensure it does not penetrate the anterior wall of the vertebral body and damages the vessels situated in front.
– To avoid glove damage, ensure that the exit point for the Kirschner wire is not blocked.

Open approach
Prepare pedicles, insert screws and assess proper screw placement
– The MATRIX Perforated Screw must enter in approximately 80% of the vertebral body.
– If the screws are too short, the bone cement might be injected too close to the pedicle. It is required that the screw perforations are located in the vertebral body, close to the anterior cortical wall. For this reason, 35 mm screws should be placed in the sacrum only.
– If the screws are too long, or placed bi-cortically, the anterior cortical wall may be penetrated, and cement leakage might occur.
– Do not grasp the green knob during insertion as it will cause the retaining sleeve to disengage from the screw.
– Thoroughly rotate the lateral arms of the guide sleeve clockwise to ensure that the distractor tip is fully engaged with the screw. For later augmentation only the locking needle adapter kit with luer-lock should be used with the guide sleeve for MATRIX Perforated Screw.
– In case of any perforation, special caution is required when bone cement is applied. Cement leakage and its related risks may compromise the physical condition of the patient.

Cement handling
Injection preparation (simple adapter)
– Care should be taken when exchanging the syringes as cement might be left in the Stardrive head of the screw. If simple adapter is used, only Vertecem V+ 2cc syringes should be used to inject cement in order to avoid disconnecting and reconnecting of the syringe.

Injection procedure
– Ensure that no cement leakage occurs outside the intended area. Immediately stop the injection if leakage occurs.
– Care should be taken when replacing of syringes is necessary, as cement can be left in the Stardrive of the screw.
– When using the simple adapter, do not remove or replace syringes immediately after injection. The longer the syringe remains connected to the screw, the lower the risk of undesired cement flow.
– The cement flow follows the path of least resistance. Therefore, it is mandatory, during the whole injection procedure, to maintain real-time image intensifier control in the lateral projection. In case of unexpected cloud forming patterns or if the cement is not clearly visible, the injection must be stopped immediately.
– Any cement remaining in the screw drive must be removed with the cleaning stylet while it is still soft (or has not hardened yet). This will ensure that future revision surgeries remain possible.
– Wait until the cement has cured before removing adapters and continuing with the instrumentation (about 15 minutes after last injection).
– Handling knowledge of Vertecem V+ is required prior to the augmentation of any screws, with particular emphasis being paid to “fill patterns” and “cement flow” within the vertebral body. Please refer to the associated instructions for use for details on its use, precautions, warnings and side effects.
– Avoid uncontrolled or excessive bone cement injection, as this may cause cement leakage with severe consequences such as tissue damage, paraplegia or fatal cardiac failure.
– A major risk from performing screw augmentation is cement leakage. Therefore all steps of the surgical procedure should be followed to minimize complications.
– If significant leakage occurs, the procedure has to be stopped. Return the patient to the ward and assess the patients’ neurological situation. In case of compromised neurological functions an emergency CT scan should be performed to assess the amount and location of the extravasation. If applicable, an open surgical decompression and cement removal may be performed as an emergency procedure.

– In order to minimize the risk of extravasation, it is strongly recommended to follow the surgical procedures, use a Kirschner wire for pedicle screw placement and use a high-quality C-arm in lateral position.
– If leaking outside the vertebra is recognized, the injection has to be stopped immediately. Wait for 45 seconds. Slowly continue with the injection. Due to faster curing in the vertebral body, the cement occludes the small vessels and the filling can be accomplished. Amounts of cement of approximately 0.2 ml are recognizable. If filling cannot be performed as described, stop the procedure.

Place screw heads
– Care should be taken in reaming the most superior and inferior levels to protect the facet joints.
– Before placing a polyaxial head onto the perforated screw, ensure that the cement has completely cured.
– Always use image intensifier control when placing polyaxial heads to ensure that the screw does not advance. If the screw advances, wait for the cement to cure.

Attach construct
– Distraction/compression might lead to loosening of the augmented screws resulting in construct failure.
– Prior to performing correction maneuvers ensure that the cement is fully hardened.

MIS approach
– The MATRIX Perforated Screw must enter in approximately 80% of the vertebral body.
– If the screws are too short, the bone cement might be injected too close to the pedicle. It is required that the screw perforations are located in the vertebral body, close to the anterior cortical wall. For this reason, 35 mm screws should be placed in the sacrum only.
– If the screws are too long, or placed bi-cortically, the anterior cortical wall may be penetrated, and cement leakage might occur.
– To avoid glove damage, do not hold the retraction blades near the bottom of the deflecting tab.
– Thoroughly rotate the lateral arms of the guide sleeve clockwise to ensure that the distractor tip is fully engaged with the screw.
– Wait until the cement has cured before removing adapters and continuing with the instrumentation (about 15 minutes after last injection).
– Prior to performing correction maneuvers ensure that the cement is fully hardened.
– Distraction/compression might lead to loosening of the augmented screws resulting in construct failure.
– Do not use the guide sleeve to remove the distractor tip.

For more information, please refer to the Synthes brochure “Important Information”.

Combination of Medical Devices
The MATRIX Spine System consists of bone screws, connectors, rods and locking caps. Please ensure that the matching diameter is used with the corresponding implants.

The bone screws are self-tapping and available in preassembled and modular (unassembled) options. In the modular option, the screw head is connected to a modular screw during the procedure. Screw heads are available in standard and reduction options (provides 15 mm rod reduction). MATRIX Perforated Screws are provided in the modular condition and can be used with or without cement.
For information related to Vertecem V+, please refer to the corresponding instructions for use for the Vertecem V+ system.

Bone screw types:

Solid
– Preassembled and modular (unassembled): ∅ 4.0 mm to ∅ 9.0 mm

Cannulated
– Preassembled: ∅ 5.0 mm to ∅ 9.0 mm
– Modular (unassembled): ∅ 5.0 mm to ∅ 8.0 mm

Perforated
– Modular (unassembled): ∅ 5.0 mm to ∅ 7.0 mm

The connectors are designed to facilitate the linking of devices within the MATRIX Spine System and other compatible spinal stabilization systems. These devices allow for construct extension (laterally or longitudinally), transitions to rods of different diameters (MATRIX devices all reflect a rod diameter of ∅ 5.5 mm), or transverse stabilization of a construct. All of the available MATRIX connectors utilize integrated locking screws.

– Snap-on transverse connector
– Rod connector
– Parallel connectors

The rods are designed to facilitate the longitudinal connection of devices within the MATRIX Spine System and other compatible spinal stabilization systems.
– Posterior curved and straight rods
– Straight and curved MIS rods
– Connecting rods

The locking cap is comprised of components which are utilized once bone screws have been implanted and appropriate rods have been selected for implantation. These components are used for retaining screws/rods in the desired construct assembly, effectively locking the screw to the rod.

The MATRIX Spine System is applied using associated MATRIX Spine Instrumentation.

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

Magnetic Resonance Environment
MR Conditional:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the MATRIX Spine System are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 15 minutes of scanning.

Based on non-clinical testing, MATRIX Spine implants will produce a temperature rise not greater than 5.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the MATRIX Spine devices.

Treatment before Device is Used
Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.
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.

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”.

Implant Removal
MATRIX Spine System – Degenerative and Perforated
If an implant has to be removed the following technique is recommended:
– Remove the snap-on transverse/parallel connectors if necessary. The set-screws on the transverse connectors that attach to the longitudinal rods can be removed with the T15 Stardrive screwdriver with the 3 Nm torque limiting handle.
– To remove a locking cap, slide the counter torque with detachable handle over the screw head. Place the ratchet of the torque limiting handle in the neutral position, engage a T25 screwdriver with the Stardrive recess of the locking cap and turn counter-clockwise.
– Remove the rod using the rod holding forceps.
– To remove the polyaxial head of a pedicle screw, remove any existing locking cap and the rod. Connect the inner shaft of the removal tool for polyaxial screw heads to the ratchet and insert into the handle of the removal tool. While holding the handle, thread the inner shaft clockwise until it stops. Lift to remove the head.
– To remove the pedicle screw, insert the screwdriver tip into the recess of the pedicle screw and rotate the green knob of the retaining sleeve clockwise until the tip of the sleeve is firmly attached to the pedicle screw. Remove the screw.

MATRIX Spine System – MIS
If the construct requires revision or removal, use a minimally invasive approach to gain access to the construct.
– Insert the rod pusher/counter torque, with detachable handle attached.
– If a locking cap needs to be loosened after tightened to 10 Nm, use a counter torque with detachable handle, MATRIX screwdriver shaft, and a 10 Nm torque limiting handle to loosen the locking cap.
– Remove the 10 Nm torque limiting ratchet handle with locking cap from the incision site. Use the rod forceps to recover the rod once the locking caps are removed.
– Once the rod has been recovered, use the ratchet T-handle driver construct to back out each pedicle screw.

Please note that precautions/warnings related to implant removal are listed in section "Warnings and Precautions".

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the 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.

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