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.

For accompanying information, such as Surgical Techniques, please visit www.jnjmedtech.com/en-EMEA/product/accompanying-information or contact local customer support.

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; death, stroke; swelling, abnormal wound healing or scar formation; heterotopic ossification; functional impairment of the musculoskeletal system; paralysis (temporary or permanent); 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; adjacent segment degeneration; ongoing pain or neurological symptoms; damage to adjacent bones, discs, organs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; device or graft material displacement; 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. The operating surgeon must have knowledge of the device limitations, which are detailed in the contraindications as well as warnings and precautions listed below.
- Implantation is to take place as per 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.
- Warning: Special considerations should be taken with patients with known allergies or hypersensitivities to implant materials.

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
Loosen locking cap
- For this technique, always use the torque limiting handle to reduce risk of damage to the T25 screwdriver shaft.

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 Instruments.

MATRIX Spine System – Degenerative	
03.616.042	Retaining Sleeve, locking
03.616.043	Retaining Sleeve, locking, long
03.620.017	Compression Forceps, f/Lumbar Spine
03.620.018	Distraction Forceps, f/Lumbar Spine
03.620.019	Torque-limiting Handle, 10 Nm
03.620.061	T-Handle w/Ratchet Wrench & w/Torque Limiter
03.620.091	Socket, hexagonal 6.0 mm
03.632.000	Distraction Fork
03.632.001	Retaining Sleeve, standard, f/Matrix 5.5
03.632.002	Screwdriver Shaft Stardrive®, T25, standard
03.632.004	Screwdriver Stardrive®, w/T-Handle, standard
03.632.005	Screwdriver Stardrive®, T25, w/straight handle
03.632.006	Rod Pusher/Counter Torque, standard
03.632.007	Alignment Tool f/polyaxial Screw Head
03.632.009	Rod Persuader, standard, f/Matrix 5.5
03.632.010	Rocker Fork, small
03.632.011	Rocker Fork, footed
03.632.012	Rocker Fork, medium
03.632.017	Rod Bender w/Silicone Handle
03.632.025	Counter Torque f/Reduction Screws, f/Matrix 5.5
03.632.026	Rod Pusher/Counter Torque f/Reduction Screws
03.632.029	Holding Crown f/Reduction Screws
03.632.030	Tab Remover f/Reduction Screws
03.632.036	Retaining Sleeve, long, f/Matrix 5.5
03.632.037	Positioning Instrument f/Polyaxial Screw Heads
03.632.042	Rod Pusher/Counter Torque f/Reduction Screw
03.632.045	Removal Instrument f/Polyaxial Screw Heads
03.632.046	Reamer f/Pedicle Screws, f/Matrix
03.632.049	Counter Torque, standard, f/Matrix 5.5
03.632.050	Retaining Sleeve f/Transverse Connectors, Snap-on
03.632.052	Screwdriver Stardrive®, T15, short, f/Matrix
03.632.053	Length Indicator f/Transverse Connectors, Snap-on
03.632.055	Screwdriver Shaft Stardrive®, T15, standard
03.632.057	Pedicle Marker f/Matrix
03.632.058	Inserter f/Pedicle Marker
03.632.072	Screwdriver Shaft Stardrive®, T25, long
03.632.074	Screwdriver Stardrive®, T25, long, w/T-Handle
03.632.075	Screwdriver Stardrive®, T25, long, w/str. handle
03.632.076	Rod Pusher/Counter Torque, long, f/Matrix 5.5
03.632.079	Rod Introduction Pliers, long, f/Matrix 5.5
03.632.080	Handle, detachable, f/Matrix
03.632.081	Rod Holding Forceps f/Rods ∅ 5.5 mm
03.632.083	Distractor Tip, f/Bone Screws
03.632.084	Distractor Tip, f/Screw Heads
03.632.085	Retaining Sleeve, detachable, f/Matrix 5.5
03.632.087	Toothed Rack Retractor, f/Matrix
03.632.090	T-Handle w/Ratchet Wrench, w/Hex. Coupling 6.0 mm
03.632.091	Handle w/Ratchet Wrench, straight, w/Hex. Coupling
03.632.099	Counter Torque, long, f/Matrix 5.5
03.632.103	Tap f/Pedicle Screws ∅ 3.5 mm, L 180 mm
03.632.104	Tap f/Pedicle Screws ∅ 4.0 mm, L 180 mm
03.632.105	Tap f/Pedicle Screws ∅ 5.0 mm, L 180 mm
03.632.106	Tap f/Pedicle Screws ∅ 6.0 mm, L 180 mm
03.632.107	Tap f/Pedicle Screws ∅ 7.0 mm, L 180 mm
03.632.108	Tap f/Pedicle Screws ∅ 8.0 mm, L 180 mm
03.632.109	Tap f/Pedicle Screws ∅ 9.0 mm, L 180 mm
03.632.155	Tap f/Pedicle Screws ∅ 5.5 mm, L 180 mm
03.632.169	Rod Pusher f/Rods ∅ 5.5 / 6.0 mm, f/Matrix
03.632.202	Holding Forceps f/Rods ∅ 5.5 and ∅ 6.0 mm
03.632.204	Torque-limiting Handle, 3 Nm
03.632.400	Screwdriver Shaft Stardrive®, T25, standard
03.632.401	Screwdriver Shaft Stardrive®, T25, long
03.632.408	Reduction Instrument f/Spondylolisthesis, standard
03.632.409	Reduction Instrument f/Spondylolisthesis, long
03.636.008	T-Handle w/Hexagonal Coupling 6.0 mm
388.410	Spreader Forceps f/Pedicle Screws, L 330 mm
388.422	Compression Forceps, L 335 mm, f/Pedicle Screws

388.536	Pedicle Probe f/Screws ∅ 4.2 mm, L 240 mm
388.545	Feeler f/Screw Channel, straight
388.546	Feeler f/Screw Channel, curved
388.549	Feeler, straight, w/rounded tip
388.551	Pedicle Awl ∅ 3.0 mm, L 230 mm
388.654	Ratchet w/Handle
388.655	Pedicle Probe ∅ 3.7 mm, L 240 mm
388.656	Pedicle Awl ∅ 4.0 mm, L 255 mm
388.657	Pedicle Probe ∅ 3.8 mm, curved, L 290 mm
388.720	Bolt Cutter
388.750	USS Rod Cutting and Bending Device
388.906	Trial Rod ∅ 5.0 mm, L 150 mm
68.632.125	Loading Station f/Matrix 5.5

MATRIX Spine System – MIS

02.606.003	Kirschner Wire ∅ 1.6 mm w/o trocar tip, L 480 mm
03.600.030	Pedicle Awl ∅ 5.6 mm, cannulated
03.600.031	Pedicle Probe ∅ 5.0 mm, cannulated
03.600.032	Pedicle Awl ∅ 3.8 mm, cannulated
03.600.033	Pedicle Probe ∅ 3.5 mm, cannulated
03.606.021	Trocar Holder, f/No. 03.606.020
03.611.035	Extractor f/Set Screw ∅ 4.0 mm
03.611.059	Extender f/No. 03.611.035
03.616.003	Template f/Rod Length
03.616.035	Retraction Blade, percutaneous
03.616.036	Retraction Blade, mini-open
03.616.037	Retraction Blade, percutaneous, long
03.616.038	Retraction Blade, mini-open, long
03.616.039	Retraction Blade Removal Instrument
03.616.040	Retraction Blade Removal Instrument, long
03.616.042	Retaining Sleeve, locking
03.616.043	Retaining Sleeve, locking, long
03.616.044	Centering Sleeve f/Rod Holder, long
03.616.046	Dissector, blunt
03.616.047	Centering Sleeve f/Rod Holder
03.616.048	Rod Holder
03.616.050	Polyaxial Head Alignment Tool
03.616.051	Cap Guide, one-step
03.616.052	Cap Guide, one-step, long
03.616.053	Rod Forceps
03.616.054	Axial Reduction Instrument
03.616.055	Rod Pusher
03.616.056	Rod Persuader
03.616.057	Counter Torque
03.616.058	Distraction Instrument, mini-open
03.616.059	Compression Instrument, mini-open
03.616.062	Trocar f/cannulated Awl
03.616.063	Axial Reduction Instrument, long
03.616.069	Rod Holder, percutaneous, w/fixed angle
03.616.070	Handle f/Kirschner Wire ∅ 1.6 mm
03.616.071	In-situ Reattachment Tube
03.616.072	Retraction Blade Reattachment Tool
03.616.074	Dilator ∅ 1.8 mm / 10.0 mm
03.616.075	Protection Sleeve f/∅ 5.0 mm cannulated Tap
03.616.076	Protection Sleeve f/∅ 6.0 mm cannulated Tap
03.616.077	Protection Sleeve f/∅ 7.0 mm cannulated Tap
03.616.078	Protection Sleeve f/∅ 8.0 mm cannulated Tap
03.616.079	Protection Sleeve f/∅ 9.0 mm cannulated Tap
03.616.081	Tamp f/Nitinol Kirschner Wire
03.616.083	Knob f/Reduction Instruments, axial
03.620.061	T-Handle w/Ratchet Wrench & w/Torque Limiter
03.620.205	Tap, cannulated, f/Pedicle Screws ∅ 5.0 mm
03.620.206	Tap, cannulated, f/Pedicle Screws ∅ 6.0 mm
03.620.207	Tap, cannulated, f/Pedicle Screws ∅ 7.0 mm
03.620.208	Tap, cannulated, f/Pedicle Screws ∅ 8.0 mm
03.620.209	Tap, cannulated, f/Pedicle Screws ∅ 9.0 mm
03.627.029	Instrument Holder, radiolucent
03.631.521	Screw Length Indicator
03.632.001	Retaining Sleeve, standard, f/Matrix 5.5
03.632.003	Screwdriver Shaft, T25, cannulated, standard
03.632.017	Rod Bender w/Silicone Handle
03.632.036	Retaining Sleeve, long, f/Matrix 5.5
03.632.037	Positioning Instrument f/Polyaxial Screw Heads
03.632.042	Rod Pusher/Counter Torque f/Reduction Screw
03.632.073	Screwdriver Shaft, T25, cannulated, long
03.632.076	Rod Pusher/Counter Torque, long, f/Matrix 5.5
03.632.080	Handle, detachable, f/Matrix
03.632.090	T-Handle w/Ratchet Wrench, w/Hex. Coupling 6.0 mm
03.632.099	Counter Torque, long, f/Matrix 5.5
03.632.400	Screwdriver Shaft Stardrive®, T25, standard
03.632.401	Screwdriver Shaft Stardrive®, T25, long
04.616.500	Guide Wire, flexible
388.906	Trial Rod ∅ 5.0 mm, L 150 mm
68.632.125	Loading Station f/Matrix 5.5
SFW691R	Combined Hammer

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.

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 by visual inspection:

- Inspect the entire area of sterile barrier package including the sealing for completeness and uniformity.
- Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.

Do not use if the package is damaged or expire.

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

The MATRIX implants are intended for permanent implantation and are not intended for removal. Any decision to remove the devices must be made by the surgeon and the patient, taking into consideration the patient’s general medical condition and the potential risk to the patient of a second surgical procedure.

If one of the MATRIX implants must be removed, the following techniques are 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 multi-part instruments" are available on the website.

Special Operating Instructions
MATRIX Spine System – Degenerative
Prepare pedicles and determine screw lengths
– Locate pedicles and use the awl to perforate the cortex.
– Use the probe to open the pedicle canal. Using radiographic imaging, confirm pedicle location, orientation and depth by inserting the probe. When selecting the appropriate length screw, use the markings on the probe to determine the pedicle depth.
– All MATRIX pedicle screws are self-tapping; however, if tapping is preferred, use the appropriate tap and tap handle.

Assemble screwdriver
– Slide retaining sleeve on the screwdriver shaft and attach the ratchet handle.
– Pick up screw
– Choose the appropriate screw diameter and length based on pedicle probe feedback.
– 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.
– Verify the screw length with the template provided in the screw module.
– Set the ratchet to the neutral position before picking up a screw.

Insert screw
– Insert the screw. Hold the black part of the retaining sleeve during screw insertion.
– To disengage the retaining sleeve, rotate the green knob counterclockwise and remove the screwdriver.
– 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.
– If pedicle screws with separate polyaxial heads are used, then follow optional technique screw insertion with retaining sleeve, locking.

Select, cut, and bend rod
– Use the head alignment tool to rotate and align the screw heads.
– Use the trial rod to determine contour and length of the rod.
– Select pre-contoured rod, or use rod bender to form rod according to the template.
– The screw height must be adjusted to the rod. If necessary, adjust the screw height using a screwdriver without retaining sleeve.
– To restore polyaxiality of a screw head that has already been tightened, insert the alignment tool in the screw head and apply sufficient pressure to release the lock.
– When using connecting rods MATRIX can be connected to a qualified posterior spinal stabilization system; please refer to the corresponding instructions for use for information.

Insert rod
Reduce rod
Option A: Reduce rod with a rod pusher
– Connect detachable handle to the octagonal end of the rod pusher/counter torque.
– Advance rod into the screw head using the rod pusher/counter torque.

Option B: Reduce rod with a rocker fork
– Use a rocker fork to lever the rod into the head of the pedicle screw.

Reduction travels:
– Small rocker fork = 8.5 mm
– Medium rocker fork = 13.5 mm
– Footed rocker fork = 7.5 mm
– Use the footed MATRIX rocker fork to aid in reducing the rod into adjacent screw heads.

Option C: Reduce rod with a rod persuader
– Ensure that the ratchet handle is fully open. Place the rod persuader over the rod and onto the screw head. Press down firmly until the tips engage the head of the screw. Squeeze the handle to seat the rod into the head of the pedicle screw.
– Reduction travel: 15 mm
– The rod persuader can be used as counter torque for final tightening of the locking cap.

Option D: Reduce rod with a reduction instrument for spondylolisthesis
– To assemble the instrument, slide the inner tube through the outer tube. Insert the black nut and press down firmly until audible feedback. Push the inner tube up towards the black nut and turn the black nut clockwise until the black line is visible at the 30 line.
– Place the reduction instrument over the screw head. Press down firmly until the tips engage. Load the hexagonal socket into the ratchet handle and insert it into the top of the reduction instrument.
– Rotate the ratchet handle clockwise to reduce the rod into the screw head. Full reduction is achieved when the black line on the side of the instrument is visible at the 0 line.
– Remove the hexagonal socket to insert a locking cap through the instrument.
– To remove the instrument from the screw head, turn the palm handle counterclockwise until the line on the side of the instrument is visible at the 30 line.
– Reduction travel: 30 mm
– Parallel reduction can be achieved by the simultaneous use of two reduction instruments on the same vertebral body.
– The reduction instrument for spondylolisthesis can be used as counter torque for final tightening of the locking cap.

Insert 1-step locking cap
– Insert the tip of the screwdriver shaft into the T25 recess of the locking cap. Press down firmly. The screwdriver shaft is self-retaining.
– To ensure desired cap alignment, insert the locking cap through the rod pusher/counter torque. Thread the locking cap clockwise into the implant head.
– Apply a light torque to provisionally tighten the locking cap and maintain the desired rod position. Place the remaining caps and provisionally tighten.

Distract
– Finally tighten one locking cap completely to create a fixed point for distraction. Reverse the locking cap of the screw to be relocated a quarter of a turn.
– Use the distraction forceps to distract the construct. Once in the desired position, tighten the locking caps with the screwdriver.
– The holding forceps can be used as a temporary point of distraction when adjacent pedicle screws are too distant from each other.

Compress
– Finally tighten one locking cap completely to create a fixed point for distraction. Reverse the locking cap of the screw to be relocated a quarter of a turn.
– Use the compression forceps to compress the construct. Once in the desired position, tighten the locking caps with the screwdriver.
– The rod holding forceps can be used as a temporary point of compression when adjacent pedicle screws are too distant.

Perform final tightening
– Place the counter torque over the head of the screw. Attach the screwdriver shaft to the T-handle with torque limiter. Insert the instrument through the counter torque cannula into the drive recess of the locking cap. Ensuring that the polyaxial head is perpendicular to the rod, tighten until there is a tactile release. This indicates that the required 10 Nm of torque has been applied. Repeat for all locking caps.
– After initial final tightening of all screws, sequentially revisit all locking caps. Start at the caudal left screw of the construct and proceed clockwise to systematically repeat final tightening of all locking caps of the construct.
– Alternatively, the reduction instrument for spondylolisthesis and the rod persuader can be used as counter torque for final tightening of the locking cap.

Optional technique
Screw insertion with retaining sleeve, locking
Insert screw with retaining sleeve, locking
– To assemble the screwdriver and the retaining sleeve, depress the loading collar on the proximal end of the retaining sleeve.
– Then slide the sleeve toward the handle on the shaft until it stops.
– Release the loading collar and verify that the retaining sleeve is firmly attached to the screwdriver.
– Retract the green locking ring towards the handle.
– Place the screwdriver tip securely into the T25 star drive recess of the pedicle screw.

– When using a ratchet handle, make sure to set it to neutral setting.
– Rotate the grey knob of the retaining sleeve clockwise. Firmly tighten to secure the implant, using the handle as counter torque.
– Push the green locking ring toward the grey knob. If required, set the ratchet handle to the forward setting to insert the screw.
– To release the screw from the retaining sleeve, retract the grey locking ring towards the handle, rotate the silver knob counterclockwise and remove the screwdriver.
– Polyaxial screwheads need to remain free and mobile after insertion to allow alignment to the rod during locking cap insertion and final tightening.
– The mobility of the screw head cannot be assessed while the holding sleeve is attached.

Optional technique
Unassembled pedicle screw insertion
Insert unassembled pedicle screw
– Prepare the pedicle and insert the unassembled pedicle screws as recommended.
– Slide the reamer over the screwdriver shaft. Engage the tip of the screwdriver in the unassembled pedicle screw. Ream until the black line is visible on the shaft. This indicates that there is enough room for the implant head.

Assemble polyaxial head
– Insert the inner shaft of the positioning instrument into the handle and tighten in the clockwise direction. To pick up a screwhead, align the positioning instrument for polyaxial screw heads to the rod slot features on the polyaxial head implant and press down.
– Position the placement tool with the polyaxial head over the unassembled pedicle screw and press down. To ensure the polyaxial head is securely attached to the unassembled pedicle screw, gently lift on the placement tool and angulate the polyaxial head.
– To release the head placement tool, press the button located at the distal end of the instrument.
– If the polyaxial head does not successfully attach to the head of the unassembled pedicle screw, additional reaming or screw height adjustment may be required to ensure sufficient space exists to allow free mobility of the head.

Optional technique
Polyaxial head removal
– If required, the polyaxial head can be removed from the pedicle screw intraoperatively.
– 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.
– Ensure that the black line is visible on the inner shaft of the head removal tool.
– Press the tip of the head removal tool into the polyaxial head. A tactile feedback may be felt as the tip of the head removal tool mates with the collet of the polyaxial head. While holding the handle, thread the inner shaft clockwise until it stops. Lift to remove the head.
– To remove the implant head from the instrument, turn the ratchet counter-clockwise until the black line is visible. Pull the head off the instrument.
– The head removal tool can be used to remove the polyaxial head of both unassembled as well as preassembled screws.
– To remove the polyaxial reduction head, the tabs must first be broken off.

Optional technique
Reduction screws
– Reduction screws are available in preassembled form or as click-on versions for subsequent assembly.
– Follow the technique for preassembled polyaxial screw, or unassembled pedicle screw to insert screw.
– Pick up a locking cap from the screw module with a T25 screwdriver shaft. The screwdriver shaft is self-retaining.
– Place the rod pusher/counter torque for reduction screws over the screw head. Insert the locking cap through the counter torque. Turning the locking cap will reduce the rod into the screw head.
– To break off the reduction screw tabs, place the rod pusher/ counter torque for reduction screws with the handle over the screw head. Gently rock the tab removal tool medial then lateral to break the tab wall free from the polyaxial head.

Alternative technique for locking cap insertion
– The holding crown for reduction screws can be used instead of the counter torque to provide guidance for the locking cap insertion.

Optional technique
Adding transverse connectors
– Use the length indicator for transverse connectors to estimate the distance between the two rods. On the crossbar of the length indicator note the size of the appropriate transverse connector.
– The transverse connectors are marked with sizes 1–8, matching the figures on the length indicator. Select the appropriate transverse connector.
– The ends of the transverse connector can be clicked onto the rod to secure it at the desired point.
– Use the screwdriver and the torque limiting handle to secure the transverse connector to the rods. Use the retaining sleeve when tightening the setscrew. When tightening the setscrews a tactile release is felt.

Optional technique
Adding rod-to-rod connectors
– Choose the snap-on open parallel connector according to the rod diameters to be received. The diameters accepted are etched on both sides of the connector to ensure the correct rod size is attached to each opening.
– Attach the preferred connector to each rod. Mount the T15 screwdriver shaft to the 3 Nm torque-limiting handle and slide the retaining sleeve over the screwdriver shaft. To secure the connector to the rods, engage the T15 drive into each setscrew recess, slide the retractable retaining sleeve to the distal position. Tighten all the set screws until a tactile release is felt.
– If any part of the construct requires further adjustment, all set screws must be loosened to the point of resistance. Do not remove set screws from the assembly. After final adjustment, retighten the set screws.
– The retaining sleeve for transverse connector cannot be used when tightening parallel with two set screws.
– Refer to the torque-limiting handle package and labeling for the recommended calibration maintenance.

Optional technique
Distraction for posterior interbody fusion
– Slide detachable retaining sleeve over long T25 screwdriver. Slide the distractor tip over the screwdriver tip and press firmly into the detachable retaining sleeve.
– Insert the tip of the screwdriver shaft into the screw head. Make sure that the tip of the screwdriver is fully seated in the recess of the screw head. Turn the green knob clockwise.
– Insert two pedicle screws.
– To release the detachable retaining sleeve from the distractor tip, pull the green knob towards the handle. Remove the screwdriver and retaining sleeve and repeat the procedure for the second pedicle screw.
– Insert both posts of the distractor into the distractor tips. Lock the angular position of the rotatable distractor arm by turning the lever. Switch the rocker lever to the distraction position (D) and rotate the wing nut screw clockwise until the desired distraction is achieved.
– Perform discectomy and interbody fusion.
– Turn the rocker lever to neutral (N) to unlock the angular position and remove the distractor.
– Reattach the screwdriver/detachable retaining sleeve and turn the green knob counterclockwise.

Alternative distractor tips and techniques
– Three different distractor tips are available, which can be used in a variety of combinations.
– The distractor tip for screws can be used with pedicle, polyaxial, and polyaxial reduction screws. Parallel distraction can be performed.
– The distractor tip with screw heads can be used with polyaxial, polyaxial reduction, and monoaxial screws. They are attached to the polyaxial screw head after insertion of the pedicle screw. If firmly tightened the screw becomes monoaxial and parallel distraction can be performed. These tips are particularly suitable for cases where the tips for bone screws would cross over as a result of pronounced lordotic curvature of the spine.
– The distractor tip with hook end can be used with pedicle, polyaxial, and polyaxial reduction screws. Distraction can be performed.

Optional technique
Locking cap removal
Loosen locking cap
– To remove a locking cap, slide the counter torque with detachable handle over the screwhead. Place the ratchet of the torque limiting handle in the neutral position, engage a T25 screwdriver with the star drive recess of the locking cap and turn counter-clockwise.
– Locking caps are designed to lock the construct and reduce the chance of post-operative loosening and rod-push-through. Therefore, in certain cases, the loosening torque may be higher than 10 Nm. In such cases, use the following techniques to remove a locking cap.
– Sequentially turn clockwise and then immediately counter-clockwise. Turn until tactile or audible feed-back from the implant is experienced. Repeat the steps until the locking cap is loose.
– If after multiple attempts to loosen the locking cap the torque is still excessive, the following techniques should be used:

Option A: Counter torque on an adjacent screw
– Place the rod pusher/counter torque with detachable handle over an adjacent screw on the same rod (i.e. one level higher or lower). Simultaneously place the counter torque over the locking cap to be loosened and engage the screwdriver shaft and torque limiting handle with the star drive recess of the locking cap. Place the ratchet of the torque limiting handle in the neutral position and begin to sequentially turn clockwise and then immediately counter-clockwise. Turn until tactile or audible feedback from the implant is experienced. Repeat the steps until the locking cap is loose.

Option B: Apply a downward force to the rod
– Apply a downward force to the rod. Place the rod persuader on the screw and firmly squeeze the handles. Place the ratchet of the torque limiting handle in the neutral position. With the reduction load applied begin to sequentially turn clockwise and then immediately counter-clockwise. Turn until tactile or audible feedback from the implant is experienced. Repeat the steps until the locking cap is loose.

MATRIX Spine System – MIS Instrumentation
Preparation
Patient positioning
– Position the patient on a radiolucent OR table in the prone position. To obtain optimal visualization of the spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for AP, oblique and lateral views. Accurate visualization of the anatomic landmarks and fluoroscopic visualization of the pedicles are imperative for using the MATRIX MIS System. In the following sections, the use of AP and lateral fluoroscopy will be described.

Approach
Option A: Percutaneous approach
– The percutaneous approach facilitates blunt dissection of the muscles through small individual incisions, through which single implants are placed.
– Using fluoroscopy, locate and mark the lateral borders of each pedicle to receive a screw. These marks indicate where the individual incisions will be made. Each incision should have a sagittal orientation and should be approximately 15 mm in length, depending on patient anatomy and fluoroscopic location of the pedicles.
– After determining the appropriate locations, make each incision in the skin and the fascia where appropriate. The blunt dissector can be used to facilitate dissection of the tissue prior to subsequent insertion of pedicle preparation instruments.

Option B: Mini-open approach
– The mini-open approach allows an atraumatic blunt dissection of the muscles so that all instruments and implants are introduced through a common incision.
– Using fluoroscopy, locate and mark the lateral borders of the pedicles. This will indicate where the fascial incisions should be made. As a general guide, the incisions should be made 2 cm–4 cm lateral to the midline. This depends on patient anatomy and actual fluoroscopic location of the pedicles.

Lateral or bilateral skin and fascial incisions
– After determining the surgical trajectory, make an incision in the skin and the fascia of the appropriate size (approximately 30 mm for single-level procedures). Following incision of the fascia, locate the cleavage plane between the multifidus and longissimus muscle groups. Bluntly dissect between the multifidus and longissimus muscle planes down to the bony anatomy. Careful separation of the muscle planes can yield an avascular dissection. Ensure that adequate dissection is performed to accommodate further instrument and implant placement. The blunt dissector can be used to facilitate dissection of the tissue planes.

Midline skin incision
– Alternatively, a midline skin incision with lateral or bilateral fascial incisions can be applied.

Perforate cortex of pedicle with bone access needle
– Place the tip of the bone access needle at the entry point of the pedicle and align the bone access needle with the pedicle trajectory. If necessary, reinsert and realign the needle. Advance the bone access needle into the pedicle by tapping lightly with a mallet. Twist the handle one-quarter turn to detach the trocar from the bone access needle while ensuring the bone access needle remains in place.

Alternative technique
Perforate cortex of pedicle with cannulated awl
Assemble cannulated awl
– Unscrew the knob from the trocar holder and place it on a flat surface. Insert the large end of the trocar and seat it in the knob recess.
– Slide the holding sleeve over the trocar and tighten.
– When the trocar and trocar holding sleeve are assembled, the end of the trocar should be seated in the knob, making it flush with the knob.
– Select the cannulated awl that corresponds to the appropriate screw diameter.
– Insert the assembled trocar with holding sleeve into the palm handle of the cannulated awl and tighten.

Perforate cortex of pedicle with cannulated awl
– Use a cannulated awl with the trocar and trocar holder to perforate the cortex of the pedicle. While maintaining the awl's position within the pedicle, rotate the trocar assembly counterclockwise to remove it from the end of the awl.
– To reduce exposure to radiation to the staff, the pedicle awl can be attached to the radiolucent instrument holder.

Insert Kirschner Wire
– The Kirschner wires are long enough to be held in place by hand during pedicle preparation and soft tissue dilation.
– Insert the Kirschner wire into the end of the cannulated awl or bone access needle.
– Advance the Kirschner Wire, guided by fluoroscopy, to the appropriate depth. Kirschner Wire etch lines can be used as a depth reference.
– The Kirschner Wire can be advanced manually or with the handle for Kirschner Wire (see alternative technique using handle for Kirschner wire).
– Insert all Kirschner wires as required.

Alternative technique
Using the handle for Kirschner wire
– The handle for Kirschner wire is used to either advance or remove Kirschner wires during the procedure. The arrow on the tool indicates direction of Kirschner wire advancement or removal. To use the handle for Kirschner wire, depress the locking trigger and slip the tool over the Kirschner wire. Release the trigger to locate the tool at a position above the end of the cannulated awl or bone access needle. The distance between the tool and the cannulated awl or bone access needle equals the insertion depth of the Kirschner wire.
– Lightly mallet the impaction surface to advance the Kirschner wire.
– Stop impacting when the tool reaches the top of the cannulated awl or bone access needle.
– Insert all Kirschner wires as required.

Alternative technique
Using the flexible guide wire and tamp
– The flexible guide wires can easily be bent away from the area of work or for fluoroscopy. The tamp is used to either advance or remove the flexible guide wires.
– Insert the flexible guide wire through a bone access needle. Turn the knob of the tamp counterclockwise to open the locking feature and slip the tool over the guide wire.
– Rest the tip of the tool inside the luer lock port of the pedicle access cannula needle. Hold the knurled section of the tamp and turn the knob clockwise to tighten the tool on the guide wire.
– Avoid placing downward pressure on the tool while tightening to the guide wire.
– Lightly mallet the top of the tamp to advance the guide wire. Depth graduations in 5 mm increments are provided on the tip of the instrument to estimate depth of guide wire advancement.
– After each 15 mm of insertion, the tamp needs to be retracted to allow the guide wire to be further advanced. Turn the knob counterclockwise to open the locking feature, retract the tamp until the spring-loaded tip is fully extended and turn the knob clockwise to retighten.
– Stop impacting when the guide wire reaches the desired depth.
– The tamp can advance the guide wire 15 mm from the end of the bone access needle.
– To remove the tool, turn the knob counterclockwise to loosen and slide the tool off the guide wire. Insert all guide wires as required.
– For guide wire removal, insert the guide wire into the hole in the center of the knob. Turn the knurled portion of the tool clockwise to tighten the tool on the guide wire. Lightly mallet on the tool upwards to remove the guide wire.

Pedicle probe
– While maintaining the position of the Kirschner wire within the pedicle, remove the cannulated awl or bone access needle. Place the tip of the cannulated probe over the end of the Kirschner wire.
– To reduce exposure to radiation to the staff, the pedicle probe can be attached to the radiolucent instrument holder.

Tap pedicle (optional)
– Prepare a pathway for the dual core screws with the cannulated taps by penetrating the pedicle prior to screw insertion. To reduce trauma to surrounding soft tissues, protection sleeves cover the proximal tip of the tap. The protection sleeves are made of electrically insulating PEEK material. To lock the protection sleeve onto the cannulated tap shaft, align the arrows and push together. To unlock the protection sleeve, hold the knurled portion of the protection sleeve and advance the tap clockwise. Depth graduations are provided at both ends of the tap to estimate depth for proper implant sizing.

Screw Insertion
Determine screw length
– The correct length of the screw must be determined after the Kirschner wires have been placed and pedicles have been prepared.
– Insert the 10 mm dilator over the Kirschner wire until the tip reaches the pedicle entry point. The dilator is made of electrically insulating PEEK material.
– Determine the screw length by placing the screw length indicator on top of the dilator. Read off the screw length between the double lines of the Kirschner wire.

Polyaxial screw assembly (optional)
– In case an unassembled cannulated pedicle screw is used, the polyaxial head needs to be assembled prior to the attachment of the retraction blades and the insertion of screw assembly.
– To pick up a screw head, align the positioning instrument for polyaxial screw heads to the rod slot features on the polyaxial head implant and press down.
– Position the placement tool with the polyaxial head over the unassembled pedicle screw and press down. To ensure the polyaxial head is securely attached to the unassembled pedicle screw, gently lift up on the placement tool and angulate the polyaxial head.
– To release the head placement tool, press the button located at the distal end of the instrument.

Select retraction blades
- For the mini-open method, a single level construct will utilize only retraction blade, mini-open.
- For percutaneous method and multilevel constructs, use the retraction blade, percutaneous at all levels.
- Use the standard retraction blade for approaches up to 80 mm.
- Use the long retraction blade for any approach greater than 80 mm.
- Etch markings on the side of the dilator indicate tissue depth.

Attach retraction blade to pedicle screw
- Choose the appropriate screw. Check length and verify diameter of the pedicle awl/probe or tap (if used) and the selected screw correspond to each other.
- To connect a retraction blade, mini-open to the screw, hold the pedicle screw and the retraction blade in opposite hands, and align the slots. Pinch the retraction blade while pressing the retraction blade onto the pedicle screw until they snap together.
- To connect a percutaneous retraction blade to the screw, hold the blade whilst applying fingertip pressure to the starting point of the leaf spring. Press the retraction blade onto one side of the pedicle screw until they snap together.
- Snap a second retraction blade onto the opposite side of the pedicle screw.
- Check with a brief "push and pull" of the retraction blade/screw construct to ensure secure attachment of the blades.

Alternative technique
Using reattachment tool
- Choose the appropriate screw. Check length and verify diameter of the pedicle probe or tap (if used) and the selected screw correspond to each other.
- To connect a mini-open retraction blade, slide it up the shaft of the reattachment tool so that the window of the retraction blade matches up with the etch marks on the tool. The retraction blade will catch in the ring of the tool.
- To connect percutaneous retraction blades to the screw, load the first retraction blade onto one side of the reattachment tool. Load a second retraction blade, percutaneous onto the opposite side of the reattachment tool.
- Hold the pedicle screw and the loaded reattachment tool in opposite hands and align the slots. Press the reattachment tool onto the pedicle screw until the retraction blades snap on. The leaf springs of the retraction blades have to be fully engaged in the snap on feature.
- Check with a brief "push and pull" of the retraction blade/screw construct to ensure secure attachment of the blades.

Alternative technique
Attach retraction blade to pedicle screw seated in the screw module
- Choose the appropriate screw. Check length and verify diameter of the pedicle awl/probe or tap (if used) and the selected screws correspond to each other.
- Hold the retraction blade and press it onto the pedicle screw in the screw module until they snap together.
- Check with a brief "push and pull" of the retraction blade/screw construct to ensure secure attachment of the blades.

Load screw assembly to locking retaining sleeve
- To assemble the screwdriver and the retaining sleeve, depress the loading collar on the proximal end of the retaining sleeve.
- Then slide the sleeve toward the handle on the shaft until it stops.
- Release the loading collar and verify that the retaining sleeve is firmly attached to the screwdriver.
- Retract the green locking ring towards the handle.
- Load a retraction blade/MATRIX screw assembly onto the holding sleeve by inserting the tip of the driver through the retraction blade and into the screw head.
- When using a ratchet handle, make sure to set it to neutral setting. Rotate the grey knob of the retaining sleeve clockwise. Firmly tighten to secure the implant, using the handle as countertorque.
- Push the green locking ring toward the grey knob. If required, set the ratchet handle to the forward setting to insert the screw.
- To release the screw from the retaining sleeve, retract the green locking ring towards the handle, rotate the grey knob counterclockwise and remove the screwdriver.

Alternative technique
Using retaining sleeve
- Assemble the ratchet handle to a cannulated shaft.
- To assemble the polyaxial screwdriver, retract the green knob distally, then slide the sleeve toward the handle on the cannulated shaft until it stops.
- Load a retraction blade and pedicle screw onto the retaining sleeve by inserting the tip of the retaining sleeve through the retraction blade and into the polyaxial screw.
- Place the screwdriver tip securely into the T25 stardrive recess of the polyaxial pedicle screw and rotate the green knob of the retaining sleeve clockwise. Firmly tighten to secure the implant.
- Set the ratchet handle to the forward position to insert the screw. To release the sleeve, rotate the green knob counter-clockwise and remove the screwdriver.

Insert screw
- Match the screw axis to the Kirschner Wire axis by passing the retaining sleeve assembly over the Kirschner Wire until the tip of the screw reaches the pedicle entry point. Prior to advancing the screw, fluoroscopy should be used to ensure proper placement.
- Advance the screw into the pedicle by turning the ratchet handle clockwise.
- The black part of the retaining sleeve and the retraction blade below the green knob can be held during insertion to guide trajectory.
- Control the Kirschner Wire exiting the proximal end of the ratchet handle.
- Remove the Kirschner Wire once the tip of the screw enters the vertebral body. The handle for Kirschner Wire can be used.
- During insertion, use fluoroscopy to confirm screw trajectory and depth.
- The mobility of the screw head cannot be assessed while the retaining sleeve is attached.
- Detach the screwdriver and retaining sleeve by rotating the green knob on the retaining sleeve counterclockwise while holding the ratchet handle as countertorque.
- Remove the retaining sleeve and screwdriver.
- The retraction blade and polyaxial head should now pivot freely.
- Insert all remaining screws in the same manner.
- After insertion, use fluoroscopy to confirm final screw placement is correct.

Adjust screw height (optional)
- If the screw height needs to be adjusted, attach a ratchet handle to the T25 screwdriver shaft. Place the driver through the retraction blade(s) and into the T25 recess of the bone screw. Adjust screw height as needed.

Orient retraction blade
- Option A: For retraction blade, percutaneous visually assess retractor blade orientation after screw insertion is complete. Insert the alignment tool through the retraction blade and seat it in the polyaxial head.
- Rotate the retraction blade as needed to achieve proper orientation. The black lines should direct towards the sagittal plane.
- Use the alignment tool on the Percutaneous retraction blade to orient rod slots as needed.

Mobilize polyaxial heads (optional)
- If required insert the alignment tool through the retraction blade and seat it in the polyaxial head. If head is immobile turn screw one turn back by using the T25 screwdriver.
- Use the head alignment tool to confirm that the head is still mobile and free from the surrounding anatomy prior to inserting the rod.

Option B: For retraction blade, mini-open
- Visually assess retraction blades' orientation after screw insertion is complete. If required insert the alignment tool through the retraction blade and seat in the polyaxial head.
- Rotate the retraction blade as needed to achieve proper orientation. Arrows should point toward each other into the middle of the constructs.

Mobilize polyaxial heads (optional)
- Insert the alignment tool through the retraction blade and seat it in the polyaxial head. If head is immobile turn screw one turn back by using the T25 screwdriver.
- Use the head alignment tool to confirm that the head is still mobile and free from the surrounding anatomy prior to inserting the rod.

Rod introduction
Determine rod length
Option A: For percutaneous method
- For percutaneous and multi-level constructs the bending template can be used to determine the rod length at the skin level.
- Align the most caudal and cranial retraction blades such they are parallel. Hold the trial rod level with the proximal ends of the retraction blades. Read the distance between the outer edges of the retraction blades. Choose rod length to allow for 5 mm of rod projection over the screw head on each side of the construct.
- Additionally, the trial rod can be bent in the dedicated shape of the final rod.
- When choosing rod length, anticipate the effect of distraction or compression maneuvers.
- Nominal length of MIS rods does not include the length of the bullet nose and the rod attachment feature.

Option B: For mini-open method
- For a single level mini-open approach use the rod length template to determine the length of the rod.
- Insert the ball tips of the rod length template through the retraction blade until seated in the polyaxial heads.
- The scale on the top of the instrument indicates which MIS rod to select. After selecting the rod, verify the length chosen against the caliper scale to ensure proper selection.

Contour rod (optional)
- Contour the rod, as needed, before insertion.

Prepare rod introducer – attach centering sleeve
- Assemble the rod introducer prior to use in the wound. Use the centering sleeve length that corresponds to the retraction blade length.
- Snap the centering sleeve onto the rod introducer along the entire length. Slide the centering sleeve up the post toward the handle until it stops.
- The centering sleeve is removed by pushing off from the back side of the golden knob until it detaches.

Prepare rod introducer – load rod
- Pull the golden knob to open the capture mechanism. The red line near the handle indicates the mechanism is open.
- Place the machined end of the selected MIS rod onto the receiving features at the distal tip of the rod introducer.
- Squeeze the brake lever to close the capture mechanism. The red line must no longer be visible.
- Squeeze the brake lever to maintain the rod at a desired insertion angle. Ensure the rod is securely attached.
- The rod can be released if the rod introducer is in the open position and the rod is perpendicular to the shaft of the instrument.

Alternative technique for percutaneous method
Load rod using fixed angle rod holder
- For use with percutaneous retraction blades, the fixed angle rod holder can be used.
- Turn the green knob counterclockwise until it is in the fully unlocked position.
- Depress and hold the green knob to open the attachment mechanism.
- Place the proximal machined end of the selected MIS rod into the receiving feature of the distal tip of the rod holder.
- Release the green knob to fully capture the rod.
- Turn the green knob clockwise to lock the rod in place. Ensure the rod is securely attached.

Place rod
Option A: For percutaneous method/retraction blade
- The rod may be inserted from either cranial or caudal direction.
- Align the slots of the retraction blade prior to rod insertion.
- With the rod pointed down, insert the rod through the retraction blade. With the tip below the fascia and near the head of the screw, push the rod through the muscle toward the adjacent retraction blade.
- Verify rod placement through adjacent retraction blade by attempting to rotate the blade. If the retraction blade will not rotate, then the rod has been inserted correctly.
- Once the bullet nose of the rod is past the last adjacent retraction blade of the construct, push the heel of the rod introducer down into the head of the first MATRIX implant.
- Verify final rod position using lateral fluoroscopy. Once the rod is perpendicular to the introducer shaft, keep finger pressure on the brake lever.

Alternative technique for percutaneous method
Introduce rod using fixed angle rod holder
- For use with percutaneous retraction blades, the fixed angle rod holder can be used.
- Align the slots of the retraction blades prior to insertion.
- The rod may be inserted from either the cranial or caudal direction.
- With the rod pointed down, insert the rod through the retraction blades. With the tip below the fascia, push the rod through the muscle toward the adjacent retraction blades. In case of increased resistance, confirm that the rod has passed through or been placed below the fascia. The rod holder shaft should sit outside of the retraction blades.
- Once the bullet nose of the rod is past the last adjacent retraction blades of the construct, push the rod holder down and position the rod holder shaft on the outside of the retraction blades.
- Verify placement through adjacent retraction blades by attempting to rotate the retraction blades. If the retraction blades will not rotate, then the rod has passed through correctly.
- Verify final rod position using lateral fluoroscopy.

Option B: For mini-open method / retraction blade
- The rod may be inserted from either the cranial or caudal direction.
- Align the slots of the retraction blade prior to rod insertion.
- With the rod pointed down, position the bullet nose of the rod against the inside wall of the cranial or caudal retraction blade.
- The line on the post of the rod introducer indicates the centering sleeve is inserted completely.
- Slide the rod down until it passes through the window and slightly past the head of the MATRIX implant.
- Drag the heel of the rod introducer into the inside wall of the opposite retraction blade.
- Push the heel down into the head of the opposite MATRIX implant.
- Verify rod placement through adjacent retraction blade by attempting to rotate the blade. If the retraction blade will not rotate, then the rod has been inserted correctly.
- Verify final rod position using lateral fluoroscopy. Once the rod is perpendicular to the introducer shaft, keep finger pressure on the brake lever.

Alternative technique for mini-open method
Introduce rod using rod forceps
- Clasp the selected rod with the forceps.
- The rod may be inserted from either the cranial or caudal direction.
- The rod can pivot while attached to the rod forceps.
- With the rod pointed down, introduce the rod until it passes through the window of the first retraction blade.
- Pass the opposite end of the rod through the window of the opposite retraction blade.
- Push down on the forceps to seat the rod in the MATRIX implants.
- Do not remove the forceps until the rod is secured by a locking cap.
- Verify final rod position using lateral fluoroscopy.

Secure rod introducer
- The post of the rod introducer should be coaxial with the retraction blade.
- Slide the centering sleeve down the post and into the retraction blade until the black line is visible.
- Do not remove the rod introducer until the rod is secured by a locking cap.

Rod reduction and locking cap introduction
Load locking cap
- Properly orient and position the cap guide over the locking cap on the holding tray. Press down firmly to capture the locking cap. The locking cap will snap into the distal tip of the cap guide.

Insert locking cap
- Insert the loaded cap guide into the retraction blade with the black indicator facing the middle of the construct.
- Insert the screwdriver until it is seated in the locking cap. If persuasion is required refer to (optional) rod reduction.
- Seat the locking cap with a light downward pressure.
- Apply a light torque to provisionally tighten the locking cap and maintain the desired rod position. After rod position has been secured, detach the rod introducer. Place the remaining locking caps and provisionally tighten.
- Remove the driver or proceed to final tightening.
- Only attempt to tighten the locking cap if the black line of the cap guide is in line with the black line on the retraction blade. If these lines are not in line, proceed with the step "Rod reduction (optional)".

Rod reduction (optional)
- For persuasion up to 9 mm, use the rod persuader.
- For persuasion greater than 9 mm and up to 30 mm, use the axial reduction instrument.
- When the etch lines on the cap guide and the retraction blade are not aligned, rod persuasion is required.
- Attach the top fork of the persuader to the cap guide, then pivot down to engage the retraction blade.
- Squeeze the handle to persuade the rod. Once reduction has been achieved, the handle will remain in the reduced position. The rod introducer may be attached during reduction procedure.
- Proceed with cap insertion.

Using axial reduction instrument
- Ensure the PEEK knob is fully turned clockwise until it stops.
- Properly orient and position the axial reduction instrument tip over the locking cap on the holding tray. Press down firmly to capture the locking cap. The locking cap will snap into the distal tip of the axial reduction instrument.
- Turn the PEEK knob counterclockwise until it stops, and the 25 mm etch mark is fully visible. The reduction tip with locking cap will be fully retracted into the axial reduction instrument. Insert the axial reduction instrument into the retraction blade with the black etch on the reduction assembly facing the middle of the construct. Apply downward pressure. The axial reduction instrument tabs will snap into the window(s) of the retraction blades and the etch lines will match up.
- Turn the PEEK knob clockwise to reduce the rod. The etch markings on the threaded shaft will indicate how much reduction is still required. If needed, the axial reduction instrument Knob can be used for better grip. The counter torque handle can also be used to assist with turning the reduction knob. The rod introducer may be attached during reduction procedure.
- Confirm the rod placement within the polyaxial head.
- Once fully reduced, insert the screwdriver with attached 10 Nm torque limiting handle until it is seated in the locking cap. Slide the countertorque down the driver shaft and seat it in the proximal socket on the axial reducer.
- Adjust the orientation of the countertorque handle to be 90° to the rod orientation. Provisionally tighten the locking cap.
- Turn the PEEK knob counterclockwise until it fully stops. Depress the axial reducer tabs and pull upwards to remove. Proceed to final tightening.
- The reducer tip must be fully retracted before the tabs can be depressed for instrument removal.

Final tighten locking cap
– If using a rod persuader, it may be used as a countertorque.
– Insert the screwdriver until it is seated in the locking cap.
– If using the cap guide or the axial reduction instrument, slide the counter torque down the driver shaft and seat it in the proximal socket on the instruments. Adjust the orientation of the counter torque handle laterally or medially.
– Final tighten the locking cap with the 10 Nm torque limiting handle until there is a tactile release.
– If a locking cap needs to be loosened or removed after having been tightened to 10 Nm, use a counter torque and straight-tip screwdriver shaft with torque limiting handle.

Detach rod introducer
– Ensure the first locking cap is provisionally tightened prior to rod introducer detachment.
– Slide the centering sleeve up and out of the retraction blade.
– Pull the golden knob to open the capture mechanism on the rod introducer.
– The red line indicates the tool is ready to be detached from the rod.
– Remove the rod introducer from the retraction blade.
–

Alternative technique for percutaneous method
Detach fixed angle rod holder
– Prior to rod holder detachment ensure at least one locking cap has been finally tightened and all other locking caps have been provisionally tightened.
– Turn the green knob counterclockwise until it is in the fully unlocked position.
– While depressing the green knob to open the attachment mechanism, push the tip of the rod holder to the left.
– Remove the rod holder from the wound.

Sequential revisiting of locking caps
Revisit locking caps
– Before retraction blade removal, repeat the final tightening of all locking caps. Start at the caudal left screw of the construct and proceed clockwise to systematically repeat final tightening of all locking caps.

Compression and distraction (optional)
Compress mini-open construct
– At the level where compression is desired, final tighten the first locking cap. With the compressor foot retracted into the cannula shaft, insert the cannula of the compression instrument into the other retraction blade.
– Ensure correct alignment of the etching of the compression instrument and the retraction blade. If the lines cannot be aligned, check the reduction of the rod.
– Place the driver through the compression instrument cannula, and seat it onto the screw head. Reverse the provisionally tightened locking cap ¼ of a turn.
– With the k-bar in the unlocked position, lift the k-bar arm while moving toward the cannula of the compression instrument. Lower the arm and slide outward until the k-bar arm catches on the final tightened locked locking cap.
– Lock the k-bar and turn the knob to the desired compression. Perform compression under lateral fluoroscopy and ensure that the rod is properly aligned within the polyaxial head.
– Provisionally tighten the locking cap. Remove the compression instrument and final tighten the locking cap.

Alternative technique
Insertion of locking cap using the compression instrument
– Properly orient and position the compressor over the locking cap on the module for locking caps. Press down firmly to capture the locking cap. The locking cap will snap into the distal tip of the compressor.
– With the compressor foot retracted into the cannula shaft, insert the cannula of the compressor into the retraction blade. Place the driver through the compression instrument cannula, seat it into the socket of the untightened locking cap and provisionally tighten.

Distract mini-open construct
– At the level where distraction is desired, final tighten the first locking cap. With the distractor foot retracted into the cannula shaft, insert the cannula of the distraction instrument into the other retraction blade.
– Ensure correct alignment of the etching of the distraction instrument and the retraction blade. If the lines cannot be aligned, check the reduction of the rod.
– Place the driver through the distraction instrument cannula, and seat it onto the screw head. Reverse the provisionally tightened locking cap ¼ of a turn.
– Position the k-bar next to the adjacent implant.
– Set the rack to lock and turn the knob to distract.
– Perform distraction under fluoroscopy.
– Provisionally tighten the locking cap. Remove the distraction instrument and final tighten the locking cap.

Alternative technique
Insertion of locking cap using the distraction instrument
– Properly orient and position the distractor instrument over the locking cap on the module for locking caps. Press down firmly to capture the locking cap. The locking cap will snap into the distal tip of the distractor.
– With the distractor foot retracted into the cannula shaft, insert the cannula of the distractor into the retraction blade. Place the driver through the distractor instrument cannula, seat it into the socket of the untightened locking cap and provisionally tighten.

Locking cap loosening
Loosen locking cap (optional)
– 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.
– Locking caps are designed to lock the construct and resist postoperative loosening and rod push through. Therefore, in certain cases, the loosening torque may be higher than 10 Nm. In such cases, apply the following technique to loosen a locking cap.
– Place the torque handle in the neutral position and begin to sequentially tighten and then immediately loosen the locking cap. Turn until tactile or audible feedback from the implants is experienced. It is important to approach the torque limit of the handle, but not exceed through the limit. Repeat the tightening/loosening steps until the locking cap is loose. To ensure the screwdriver shaft is protected from damage, always use the 10 Nm torque limiting handle.

Retraction blade removal
Remove retraction blades
– Insert the retraction blade removal instrument with tabs facing the windows on the retraction blade. Apply light pressure until the tabs snap into the windows. Pull the remover with the attached retraction blade from the incision.

Retraction blade reattachment
In situ reattachment of retraction blades
– To reattach the retraction blade(s) onto a final tightened screw head, slide the selected retraction blade(s) up the shaft of the reattachment tool so that the window(s) of the retraction blades(s) match(es) up with the etch marks on the tool. The retraction blade end will catch in the ring of the tool.
– If tissue creep around the head of the screw is encountered, place the in-situ reattachment tube into the wound over the screw with the tightened locking cap. Orient the tube rod slot with the rod.
– The tube should be centered over the screw head.
– Place the reattachment tool into the tube, with retraction blade arrows pointing towards the center of the construct and seat the retraction blade(s) over the head. Apply downward pressure until the retraction blade(s) snap(s) on.
– The T25 screwdriver shaft can be placed through a loaded retraction blade reattachment tool to help guide the attachment tool to the screw.
– Remove the reattachment tool and in-situ reattachment tube.

MATRIX Sine System – Perforated
Preoperative planning
– Preoperative planning includes evaluation and assessment of the patient regarding the specifications of the bone cement used for augmenting MATRIX perforated screws.
– Imaging equipment must be used to determine correct implant dimensions in relation to the anatomy.
– The decision whether to augment MATRIX perforated screws can be taken intraoperatively, based on tactile feedback upon pedicle preparation and screw insertion. If screws are augmented, bilateral screw augmentation is recommended.

Approach
– This section includes supplementary instructions on handling Perforated MATRIX pedicle screws and the application of bone cement.
– Prior to augmentation follow the steps as described in the section “Special Operation Instructions” for screw placement (Kirschner wire handling, approach, prepare pedicles, insert screws, and assess proper screw placement).

Cement handling
Prepare cement
– Perforated screws are combined with VERTECEM V+ cement. 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.

Injection preparation
– Option a – simple adapter
– Option b – needle adapter kit
– Option c – guide sleeve and locking needle adapter

– Place the C-arm to monitor the extrusion of the cement into the vertebral body.
– Attach simple adapter onto the syringe.
– Additional image intensifier control in the AP projection is recommended.

Simple adapter
– Attach simple adapter onto the syringe.
– Connect the syringe with the adapter to the screw and press down firmly. Make sure the adapter is fully introduced into the screw recess.

Needle adapter kit
– Connect the needle adapter to the screw and press down firmly.
– Turning clockwise, attach the pre-filled syringe onto the Luer-Lock.

Guide sleeve and locking needle adapter
– Introduce the locking needle adapter into the guide sleeve, locking it in with a slight push and a clockwise turn.
– Turning clockwise, attach the pre-filled syringe onto the Luer-Lock.
– Ensure that the locking needle adapter is properly locked in.

Injection procedure
– Make sure that the syringes with the adapters are firmly connected with the pedicle screws to be augmented prior to cement application, depending on option a, b and c.
– Inject as much cement as required until it slowly starts to extrude from the perforations of the screw.
– Continue to add cement to each screw using continuous image intensifier control. A growing cloud pattern should form. If a spider web-like pattern forms, wait approximately 30 to 45 seconds or proceed with another screw and return to the present screw later.
– If more cement is needed or the injection pressure is too high, switch to the 1 ml syringes. Start again with the first screw.
– After injection is made using the locking needle adapter or the needle adapter, the cement in the adapter can be utilized using the corresponding plunger.
– Remove the syringe or plunger from the locking needle adapter and insert the cleaning stylet to create a recess for cement backflow. Confirm that the tip of the cleaning stylet protrudes through the tip of the adapter.
– Following augmentation continue with the steps as described in the section "Special Operation Instructions" (Place screw heads, attach construct, approach).

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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