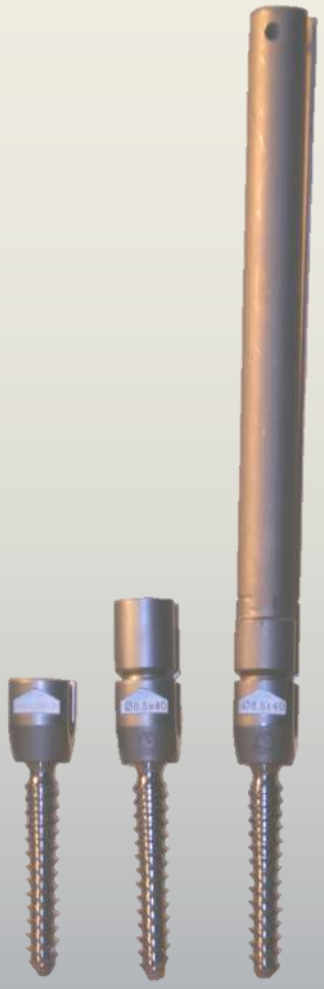


LANTERNA MEDICAL TECHNOLOGIES

SPINE SOLUTIONS SIMPLY DELIVERED

TRUSTED SOLUTIONS
OPTIMIZED RESOURCES
MAXIMIZED COST SAVINGS

SANTIS™ ¨HYBRID¨ PEDICLE SCREW SYSTEM

SURGICAL TECHNIQUE GUIDE

¨HYBRID¨ REFERS TO THE FACT THAT THE SYSTEM MAY BE USED TO PERFORM EITHER A MINIMALLY INVASIVE OR OPEN PROCEDURE

STM-1 VER. 15.03.18

SANTIS™ ¨HYBRID¨ PEDICLE SCREW SYSTEM

A LESS INVASIVE SURGICAL OPTION

The SANTIS™ 5.5mm Pedicle screw system is by intent a ¨HYBRID¨ pedicle screw system.
It is designed for implantation either by way of an open or percutaneous M.I.S. (Minimally Invasive Surgery) approach, or a combination of both during the same procedure.

Implants
SANTIS™ delivers:

- 3 Diameters: 5.5mm 6.5mm 7.5mm
- Color coded for easy identification
- Quick screw capture
- Modern design features
- Swiss quality and precision with excellent value

Instruments
SANTIS™ delivers:

- Secure, Precise Rod placement
- All in one instrument set
- Intuitive components for operating efficacy
- Simple, Secure, Controlled Reduction

SANTIS™ ··HYBRID·· PEDICLE SCREW SYSTEM

Minimal invasive spine surgery has several proposed advantages over traditional open techniques. Smaller incisions and minimal muscle resection, markedly decreases operating time, blood loss and postoperative pain.

The **SANTIS™** HYBRID Pedicle Screw System was created to offer a less invasive surgical option for pedicle screw placement. The system incorporates anatomically driven solutions such as self-tapping cannulated polyaxial screws and pre-lordosed rods. The instrumentation is ergonomically designed to allow for either a true percutaneous or Wiltse approach. The **SANTIS™** HYBRID Pedicle Screw System offers a simple, precise and effective solution to spinal fixation.

PREOPERATIVE PLANNING:

When using the **SANTIS™** HYBRID Pedicle Screw System, the patient should be positioned prone on a radiolucent table. Chest rolls may be used, but the knee-to-chest position should be avoided.

Using fluoroscopic imaging, it should be verified that the true views of both anterior-posterior (A/P) and lateral images of the spine (views which adequately delineate pedicle morphology and geometry) are obtainable. It is also recommended that preoperative planning be used to help determine a proper entry point and trajectory.

After identifying the pedicle entry point, a targeting needle and guide should be used to initiate the starting entry point. Adjustments to the entry angle and the trajectory should be made as often as needed with the assistance of fluoroscopic imaging until the proper position is attained.

This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warning.

1. Pedicle Targeting and Guide wire Placement

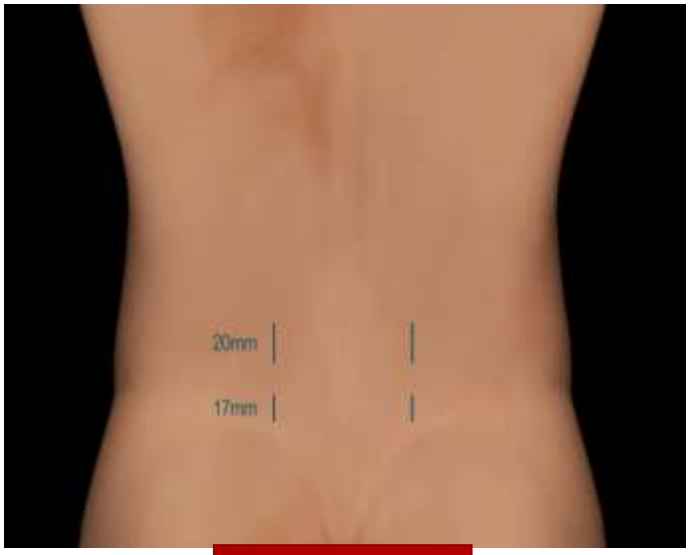


Figure 1

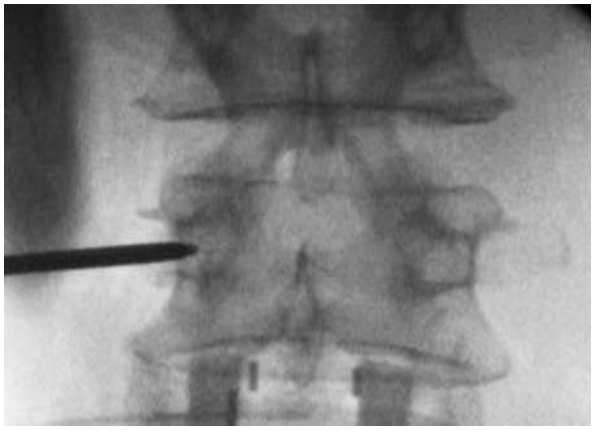


Figure 2

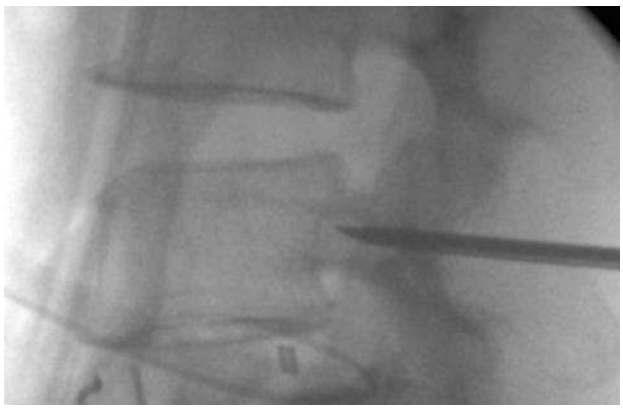


Figure 3

It is recommended that preoperative planning be used to help determine the proper entry point and trajectory as the starting point is not usually at the point directly over the pedicle.

Identify the operative levels using A/P and lateral fluoroscopy. Plan the entry point to target the pedicle from a transverse trajectory lateral to the facet.

Make an incision through the skin and fascia. The typical starting point is 3-4cm off the midline. ***Figure 1***

Insert the Targeting Needle down to the surface of the pedicle and dock the tip on the bony anatomy of the desired level and confirm placement with A/P fluoroscopy. Adjustments to the entry angle and the trajectory should be made until the proper position is attained. ***Figures 2 and 3***

Advance the Targeting Needle and Guide down through the pedicle. Once proper placement is confirmed, remove the inner stylet of the targeting needle.

Insert the Guidewire through the cannulated target needle sheath and advance the Guidewire just past the tip of the Targeting Guide. Use caution when advancing the Guidewire. Under fluoroscopy ensure the location of the Guidewire. Once the Guidewire is in place remove the Targeting needle and leave the Guidewire in place. ***Figure 4***

Figure 4

2. Tissue Dilation

CAUTION: Use fluoroscopy to monitor Guidewire position during this phase of the procedure

Figure 5

Prepare a pathway to the pedicle by sequentially using dilators 1,2 and 3. Once the Large Dilator is placed remove the inner Dilators. *Figures 5, 6*

Leave the Large Dilator and guidewire, in place to protect the soft tissue while tapping. *Figure 7*

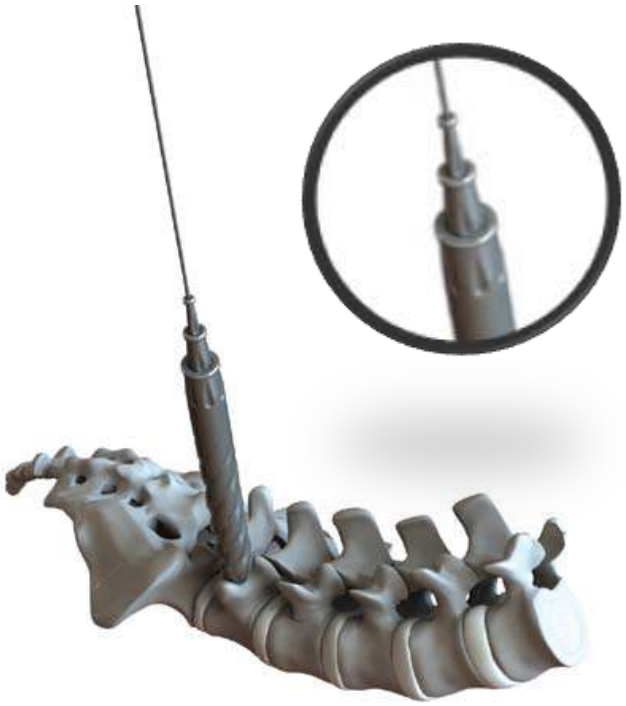


Figure 6

Figure 7

3. Tapping

SANTIS™ Screws are self Tapping. However, in the presence of sclerotic bone the tapping step will facilitate fast and easy screw insertion.
Your first option for pedicle preparation is a cannulated awl.
Advance the awl over the guide wire until the cortex of the pedicle is breached.
Figure 8
Using fluoroscopy, confirm the position of the awl.

The awl may then be removed while maintaining the position of the guide wire.
Figure 9

CAUTION: Use fluoroscopy to monitor Guidewire position during this phase of the procedure

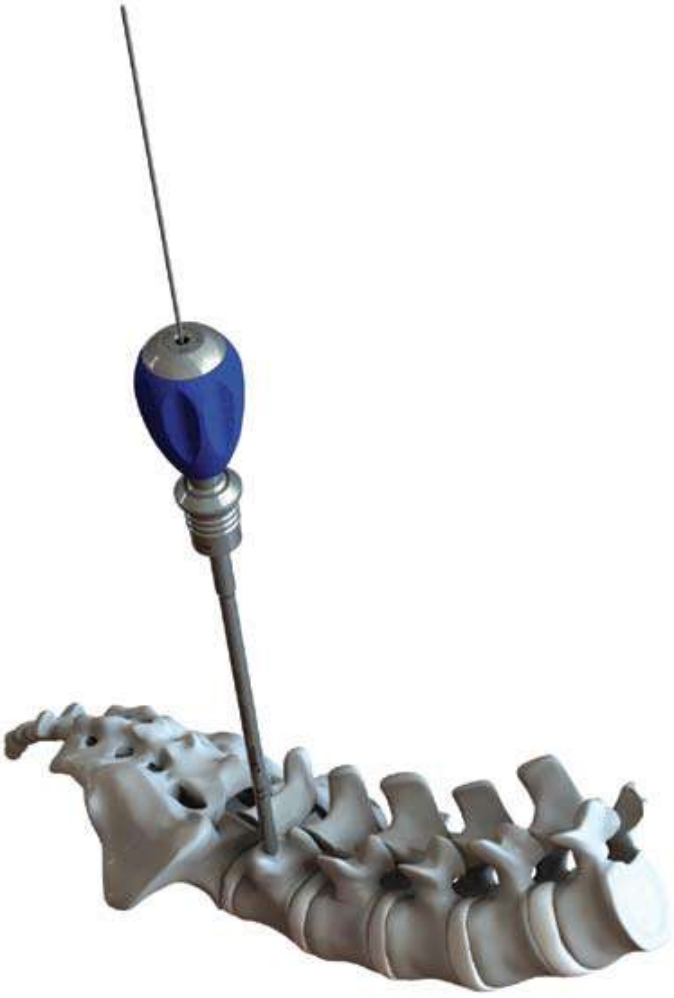


Figure 8

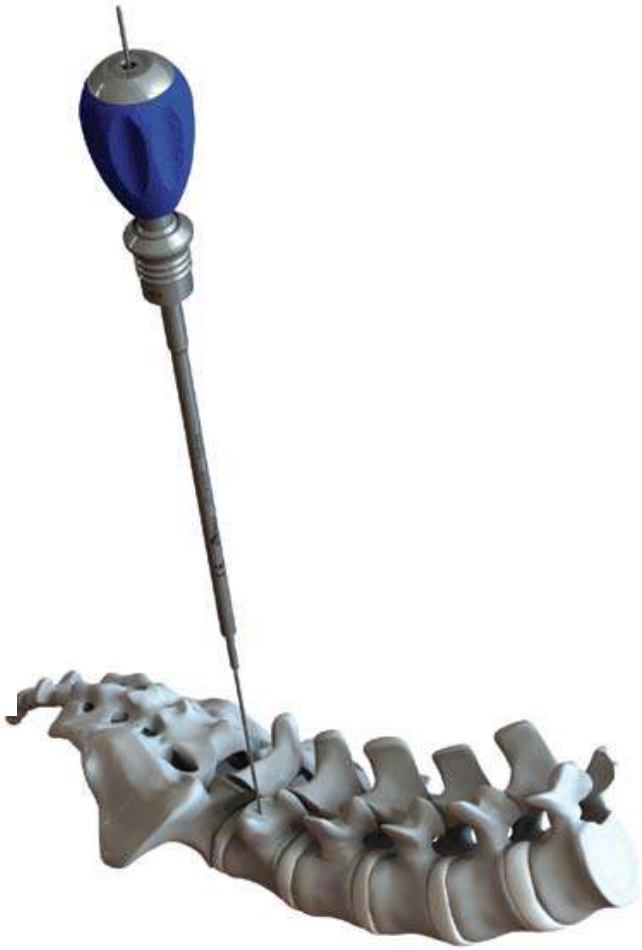


Figure 9

3. Tapping (Contd.)

SANTIS™ Screws are self Tapping. However, in the event of sclerotic bone this step will facilitate fast and easy screw insertion. It may also be used to determine screw length.

CAUTION: Use fluoroscopy to monitor Guidewire position during this phase of the procedure

Figure 10

Attach the appropriate Tap size to the preferred handle (axial or T). Place the tap over the Guidewire and through the Large Dilator to the surface of the pedicle. ***Figure 10***

The depth markers on the Tap shaft where the Tap shaft meets the top of the Large Dilator are used to monitor insertion. They can also be used to determine screw length. ***Figure 11***

Once desired depth has been achieved remove tap while **maintaining control of the guidewire.**

Load the EMG sleeve over dilator 3 and advance to bony anatomy. Depth can be verified by using fluoroscopy to locate the ring at the distal tip of the EMG sleeve. ***Figure 12***

REMOVE DILATOR 3

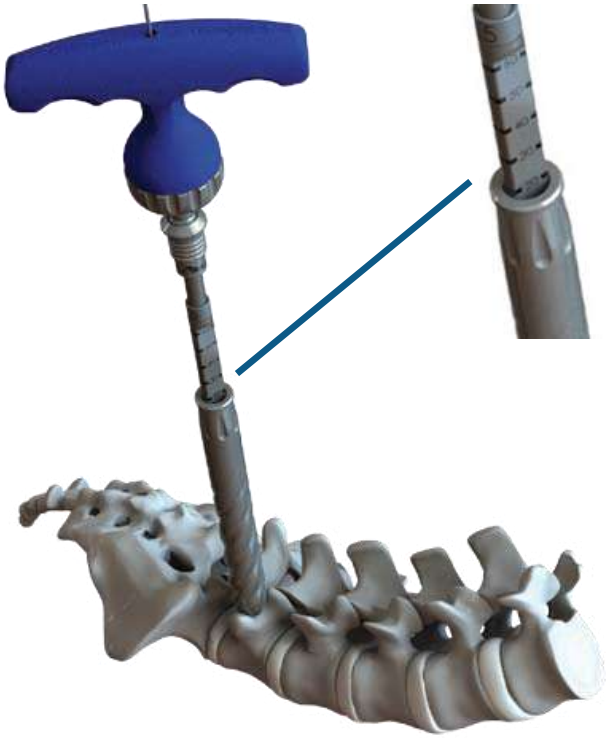


Figure 11

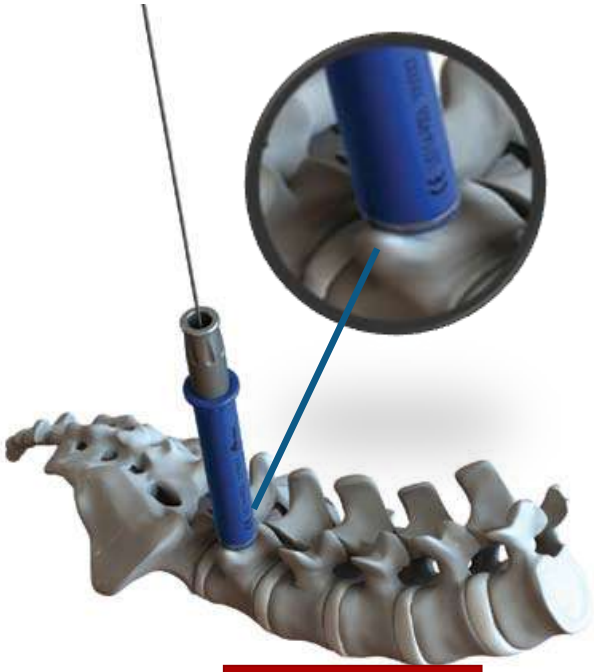


Figure 12

4. Screw Driver and Tower Assembly

Tower Assembly – Verify that the tower prongs are fully extended. ***Figure 13***

Advance the prongs over the screw head until the ***Blocker*** stops forward movement. Ensure that the pips are aligned with the grooves on the head of the screw. ***Figure 13b***

Use the collar to push the sleeve forward until the prongs are fully retracted into the tower and the screw head is fully captured. Turn the collar clockwise to fix the tower to the screw.
If needed, the Universal handle (MIS-7913) can be used to securely fix the tower. ***Figure 14***

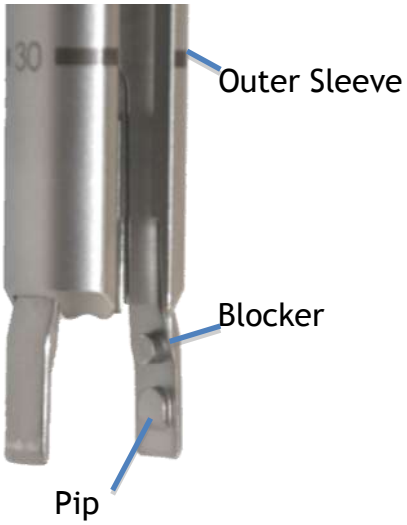


Figure 13

Figure 13b

Figure 14

4. Screw Driver and Tower Assembly (Contd.)

Figure 15

Screwdriver assembly:
Insert the screwdriver through tower and engage the tip of the screwdriver into the head of the pedicle screw. ***Figure 15***

Rotate the LARGE silver knob clockwise to lock the screwdriver to the tower. ***Figure 16***

Attach the preferred handle to the screwdriver.

Figure 16

4B. Screw Driver Assembly - Multi Purpose Screwdriver

Screwdriver assembly:
The Multi purpose screwdriver can be disassembled into 3 parts. This facilitates proper cleaning and sterilization:

Step 1: Insert screwdriver body into threaded shaft

Step 2: Apply Wing Nut: Stop at desired screw setting (Reduction or Standard Screw).
Figure 16a,b,c

Rotate the wing nut clockwise to lock the screwdriver to the screw.
Attach the preferred handle to the screwdriver.

N.B. The screwdriver body may be used as a freehand screwdriver

Figure 16a

Figure 16b

Figure 16c

5. Screw Insertion

Figure 17

Guide the Tower and Polyaxial Screwdriver assembly over the Guidewire and into the Pedicle. ***Figure 17***

Advance the Screw to the desired depth and verify placement under fluoroscopy. ***Figure 18***

After Screw placement remove the Guidewire and Screwdriver from the Tower.

To remove the Screwdriver Assembly from the Tower, turn the silver knob of the Polyaxial Screwdriver counter-clockwise and gently tug in an upward motion. ***Figure 18***

Repeat the steps above to place Screws at the adjacent or other levels. ***Figures 19 & 20***

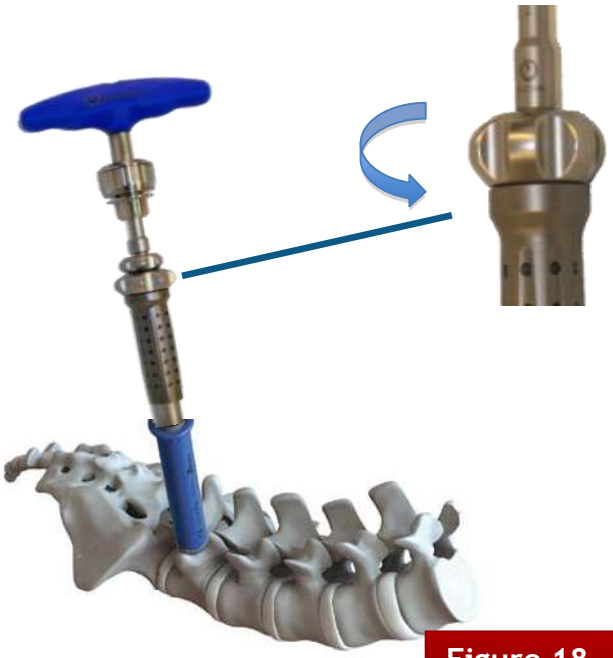


Figure 18

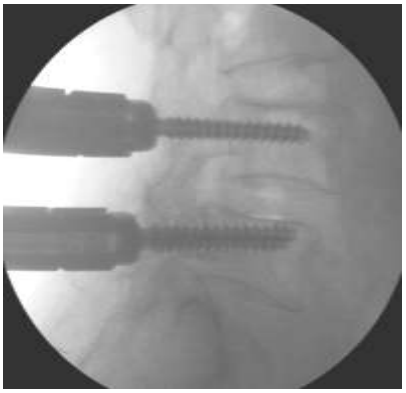


Figure 19

Figure 20

6. Rod Measurement

Align the towers and the Rod Gauge instrument will allow you to measure the exact length of the Rod needed. Assemble the Rod Gauge to the proximal end of the towers. ***Figure 21***

Based on the Screw positions the pointer will indicate the appropriate Rod length on the Gauge. Read rod measurement length from size marking on caliper, if the pointer falls between measurements the measurement should be rounded up to the next rod length. After determining the Rod length, remove the rod guage.

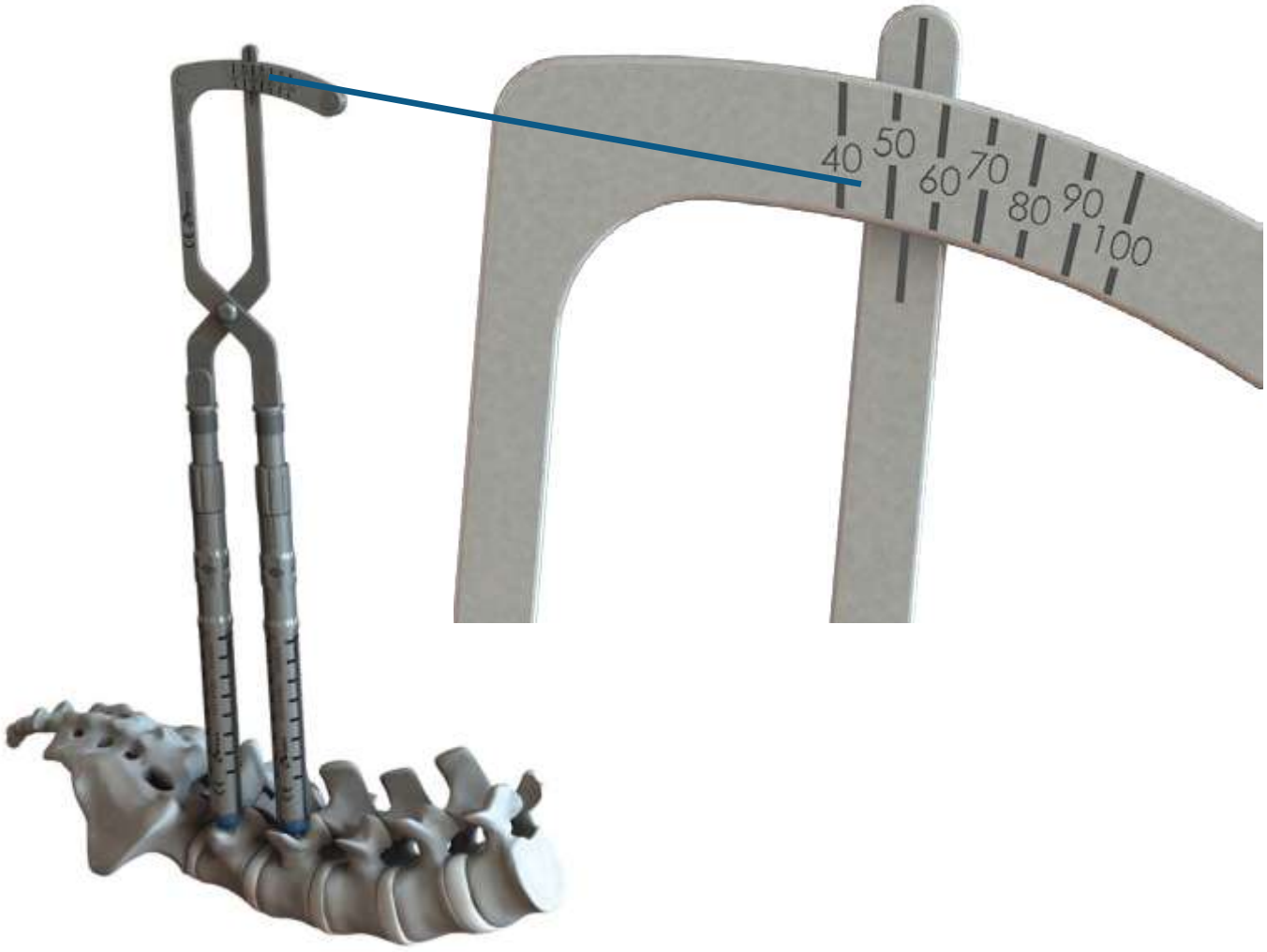


Figure 21

7. Tissue Preparation

To assist in rod placement, the Wanding Blade may be used to dissect interfering tissue. ***Figure 22***

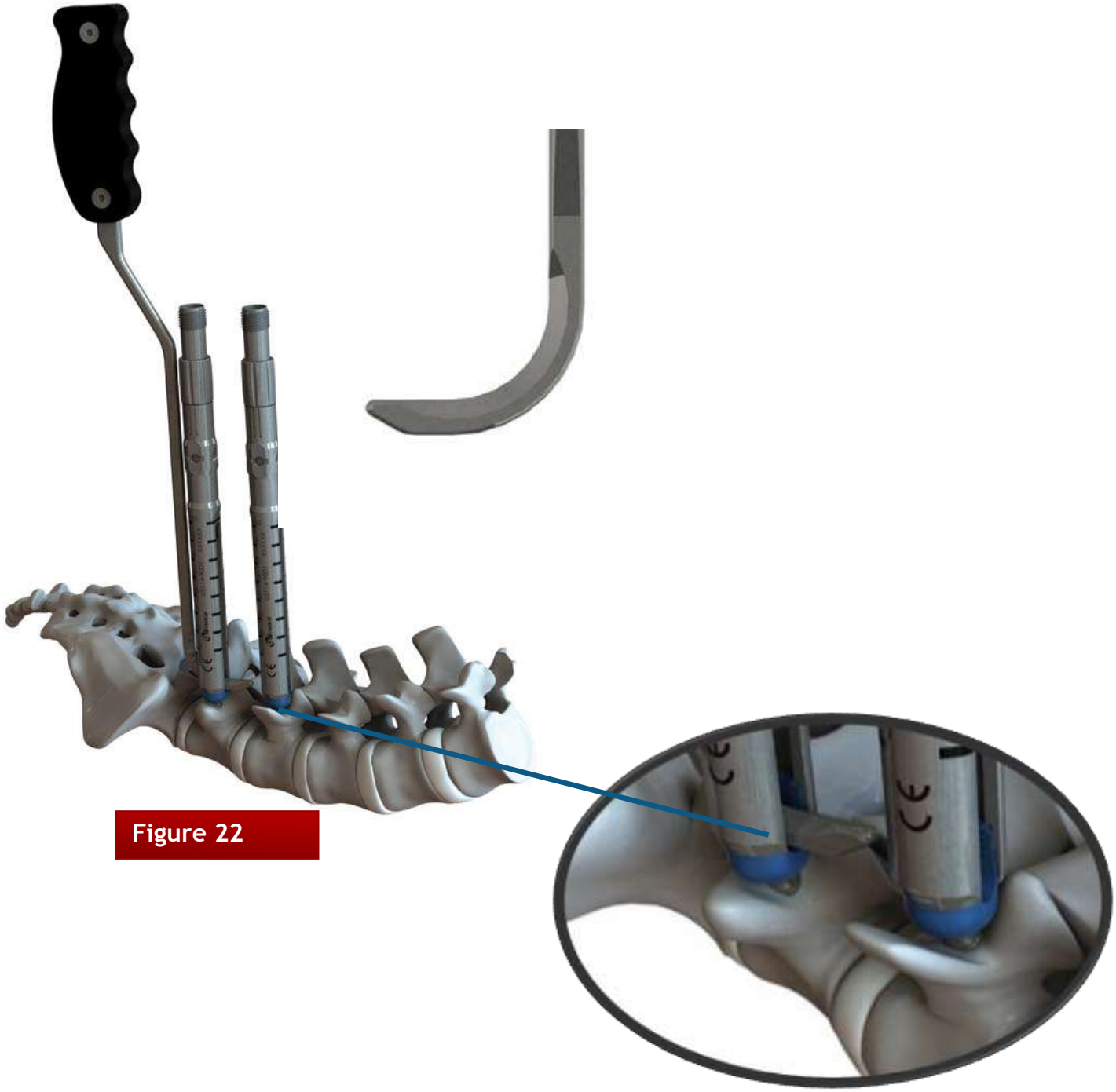


Figure 22

8. Rod Insertion

The SANTIS™ rod may be inserted using either of the following techniques:
A: Wiltsie style i.e. between the towers and
B: End of rod attachment

Unlocked

Locked

Figure 24

TECHNIQUE A

For delivery between the towers align the towers as shown and position the rod ends in the rod channels of the towers. ***Figure 23***

Advance the rod into the polyaxial screw seat and confirm rod position. ***Figure 24***

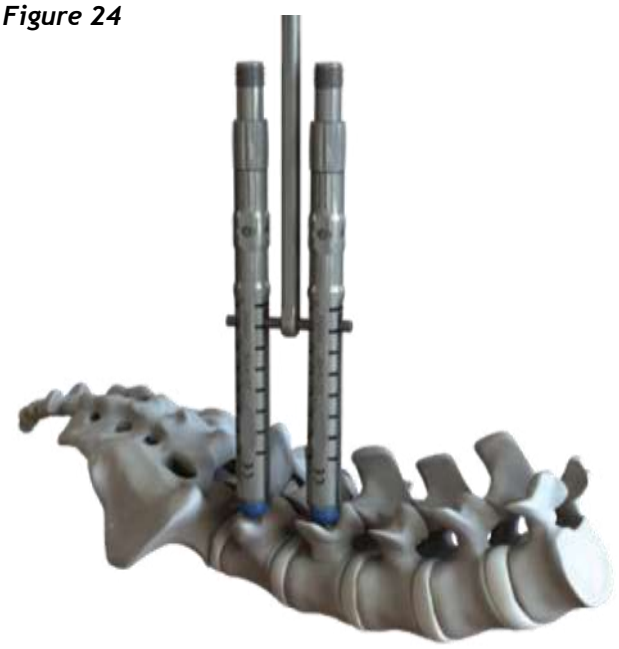


Figure 23

TECHNIQUE B

With this technique the rod is attached to the end of rod inserter and the rod is placed into the tower channel. ***Figure 25***

Advance the Rod and inserter into the channel and seat the rod into the polyaxial screw seat as shown. confirm rod position with fluoroscopy. ***Figure 26***

Locked Unlocked

Figure 25

Figure 26

9. Set Screw Insertion and Rod Reduction

Load set screw from caddy to the set screw inserter. ***Figure 27***

Thread into the seat to capture rod. ***Figure 28***

Turn silver handle of Rod Reducer clockwise to engage set screw with seat. ***Figure 28***

If Rod Reduction is needed, use the set screw inserter with the protruding tip. The tip will gently prod the rod into the seat of the screw. ***Figure 29***

Figure 27

Figure 29

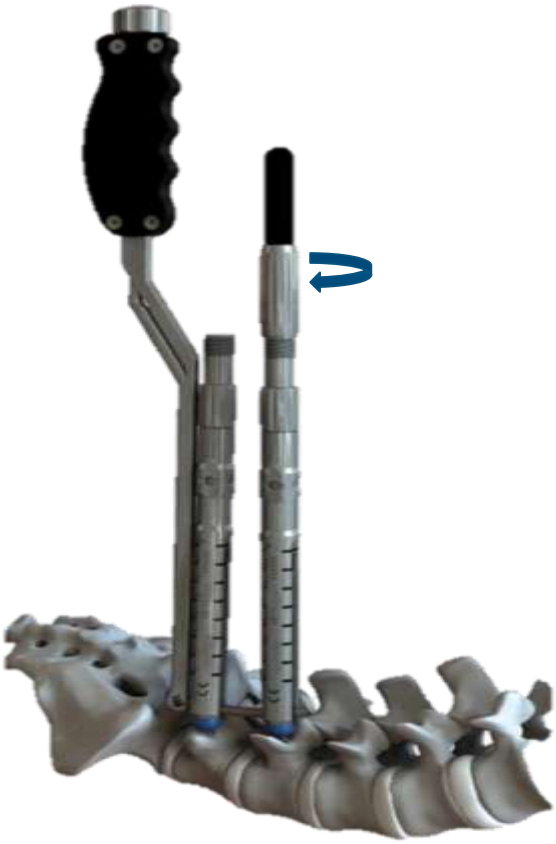


Figure 28

9. Set Screw Insertion and Rod reduction (INTERNAL)

It is important to check that the set screw is properly seated. ***Figures 31 & 32***

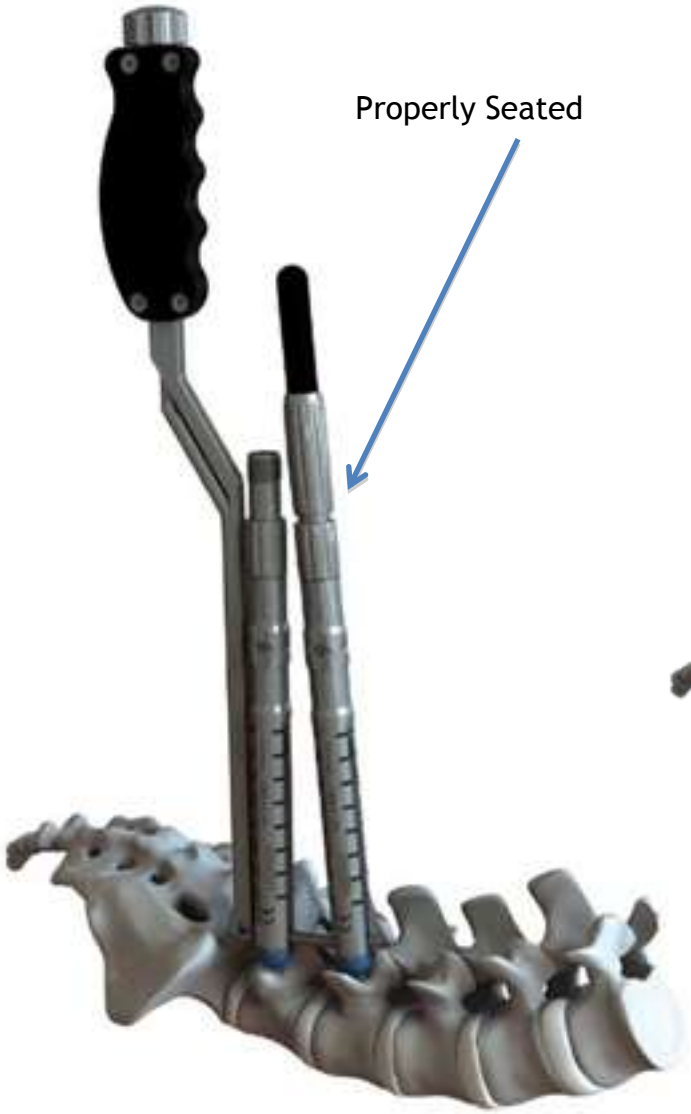


Figure 31

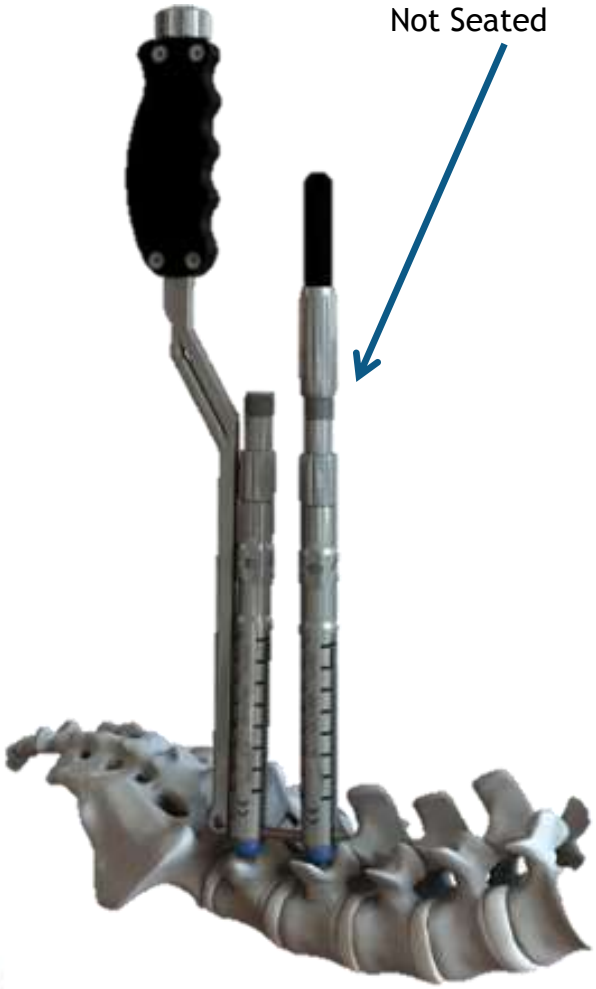


Figure 32

9. Set Screw Insertion and Rod reduction (EXTERNAL)

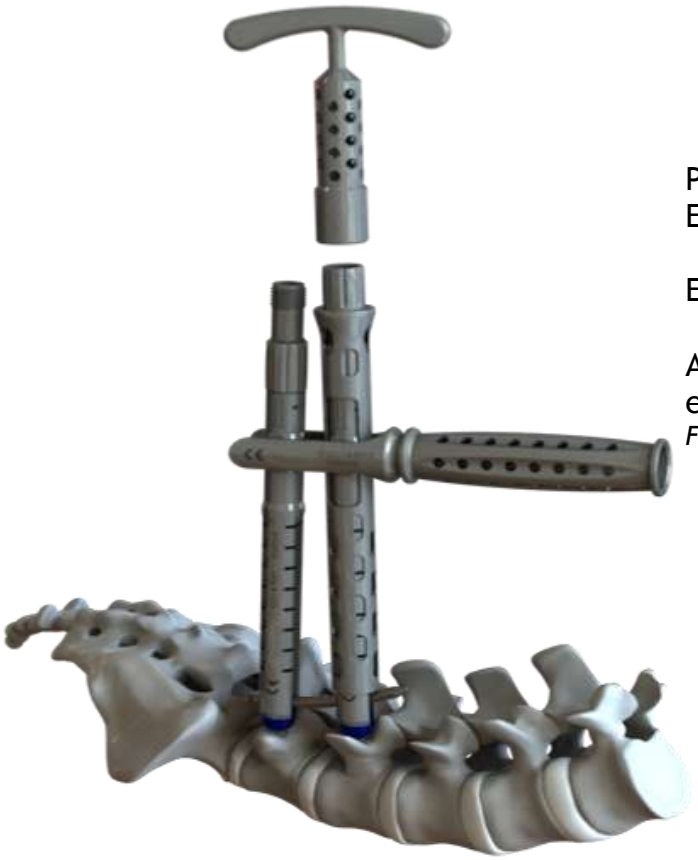


Figure 33

Place the external reducer over the screw Extender.

Engage threads on the Screw Extender.

Attach the MIS-7911 Torque control handle for extra stabilty and control during reduction *Figures 33 & 34*

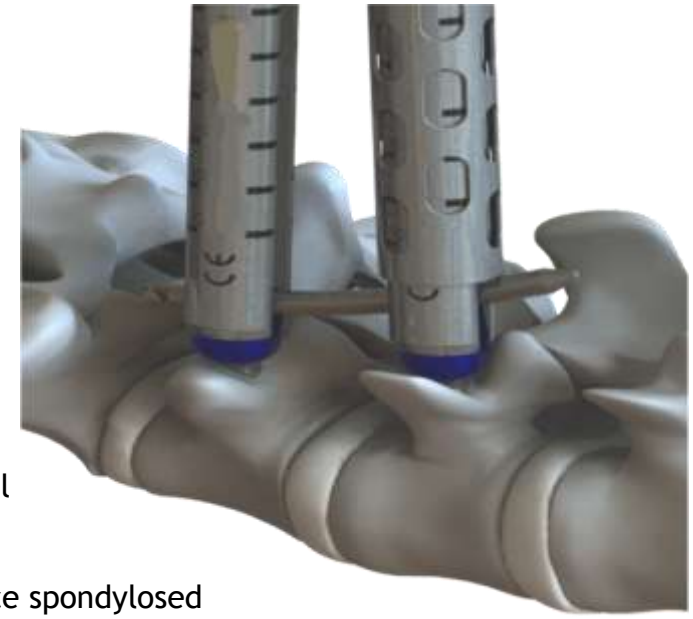


Figure 34

Turn Universal Handle to advance the External Rod Reducer.

This manouver may be employed to also reduce spondylosed vertebra. *Figures 33 & 34*

Remove the Universal Handle and place the set screw.

10. Compression and Distraction

The Compression/Distraction tool will allow you to compress or distract the operable level using the screw extenders.

Place the compression-distraction tool between the towers.

For Distraction: Attach the tool with the bar above the pivot point. ***Figures 35-37***

For Compression: Attach the tool with the bar below the pivot point. ***Figure 39***

Provisionally tighten one of the set screws and then compress or distract by rotating the T Handle. ***Figures 38 and 39***

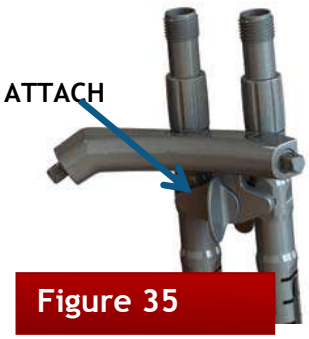


Figure 35

Figure 36

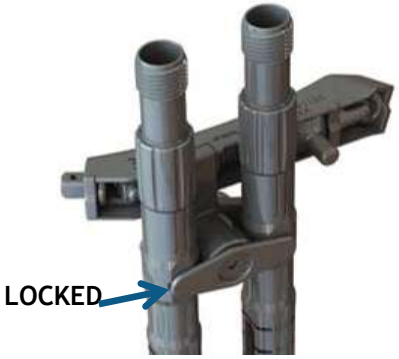


Figure 37

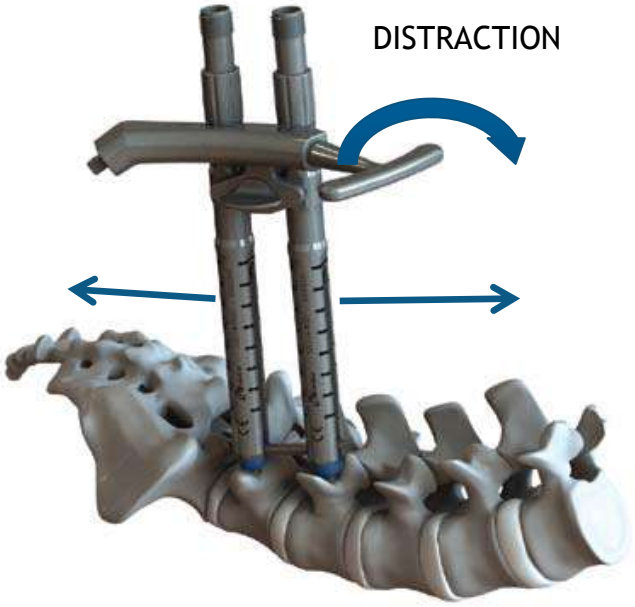


Figure 37

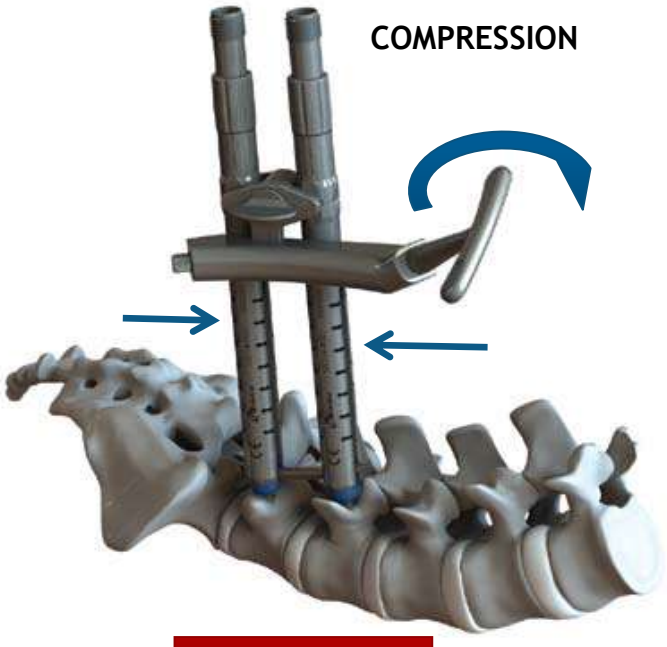


Figure 39

11. Final Tightening

Slide the anti torque wrench over the 2 towers engaging the slots as the tool advances. ***Figure 40***

Assemble the 10 Nm torque handle with the set screw driver and guide the assembled instrument through the tower into the set screw. ***Figure 41***

Turn the T-handle clockwise. Final tightening is achieved when the T-handle audibly clicks. ***Figure 41***

Remove the torque handle assembly and the anti torque wrench.

Figure 40

Figure 41

12. Tower Removal

Gently turn the knob on the tower counterclockwise and pull sleeve. ***Figure 42***

Rotate the tower 90° and remove from the surgical field. ***Figure 43***

Verify the final position of implants and close in the usual fashion. ***Figure 44***

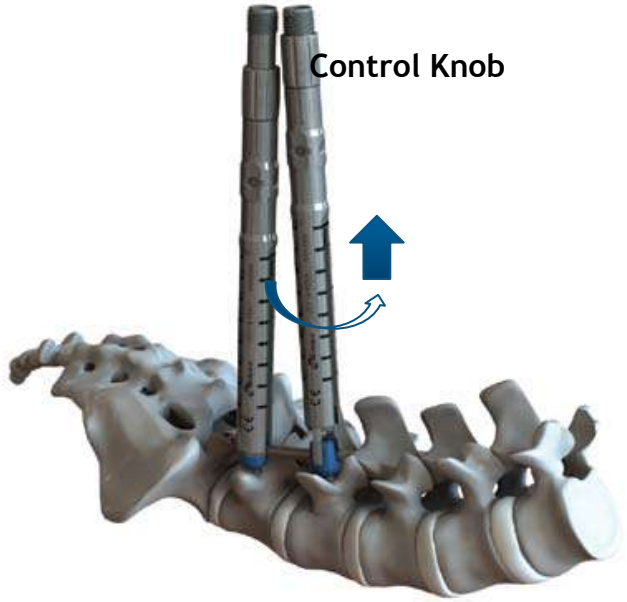


Figure 42

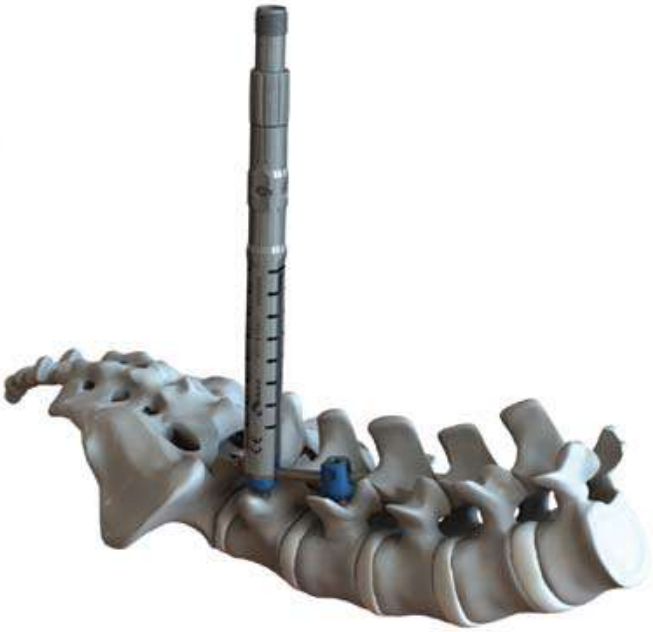


Figure 43

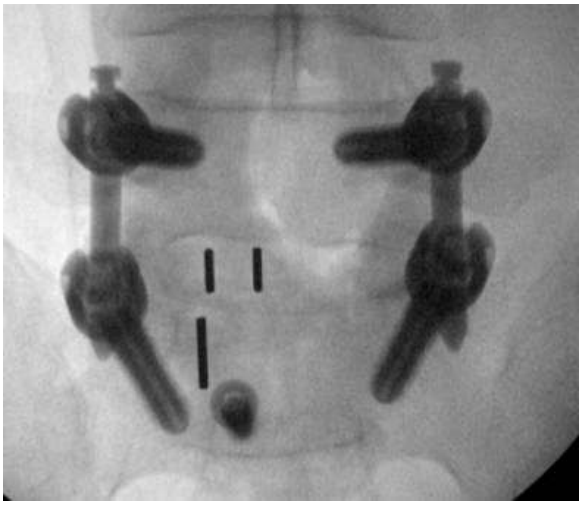


Figure 44

SANTIS™ ··HYBRID·· PEDICLE SCREW SYSTEM
MINI-OPEN OR WILTSIE METHOD

Figure 45

The mini-open approach utilizes atraumatic blunt dissection of the muscles, so that the SANTIS™ instruments and implants may be inserted through a small incision.
A Wiltsie or modified Wiltsie approach is suggested.

Using fluoroscopy, locate and mark the lateral edges of the pedicles to indicate where the fascial incision should be made. This mark should be roughly 2-4cm from the spinal midline, but will depend on the patient's anatomy and segmental level.

After determining the trajectory, an incision should be made in the skin and fascia (Approximately 2-3cm for a single level procedure). Undercutting the fascial incision with electrocautery beyond the length of the skin incision facillitates implant insertion.
Figure 45

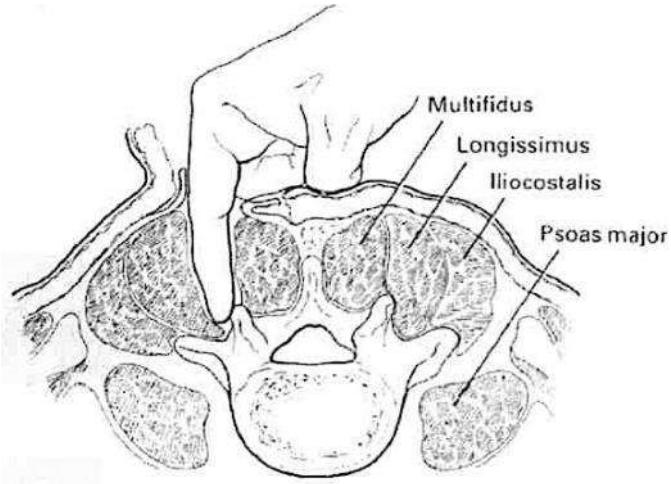


Figure 46

Locate the cleavage plane between the multifidus and longissimus muscle groups and use a Wiltsie approach to bluntly dissect the muscles between the multifidus and longissimus planes to the bony anatomy.
If separated carefully, the procedure can result in an avascular dissection.
Ensure that adequate dissection is performed in order to allow access of implants and instruments.
Figure 46

Repeat the previous steps, from Figure 1 to 44 for placement of the SANTIS™ screws and rods.

This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warning.

SANTIS™ ¨HYBRID¨ PEDICLE SCREW SYSTEM
IMPLANT REMOVAL

Figure 47

Figure 47a

Implant removal may be achieved by performing the following steps:

Step 1.
Use the SIO-6906 Set screw Driver to loosen and remove the set screws
Figure 47,47a
Step 2.
Attach the MIS-7910 Rod introducer to the rod. Remove the rod.
Figure 48a to 48c
Step 3.
Attach the SIO-6901-OP Multi purpose screwdriver to the head of the pedicle screw
Figure 49
Step 4.
Unscrew the Pedicle screw.
Figure 50

Continue with the above steps until the desired number of screws have been removed.

N.B. Implant removal should be followed by adequate postoperative management to avoid fracture.

Figure 48a

Figure 48b

Figure 48c

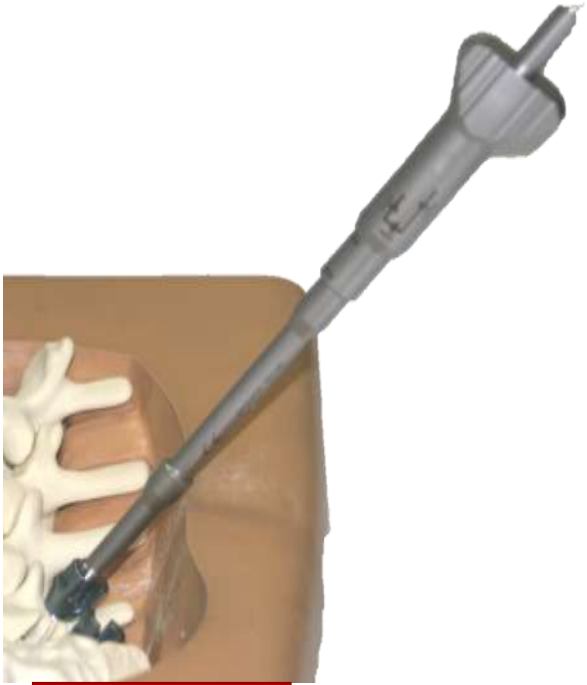


Figure 49

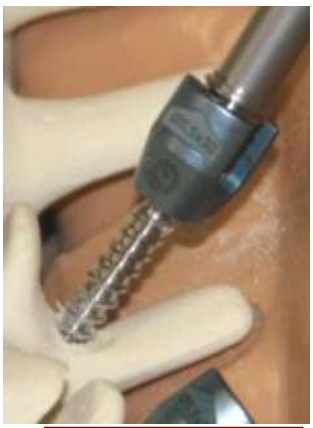


Figure 50

SANTIS™ PEDICLE SCREW SYSTEM INSTRUMENTS

SIO-6901 Cannulated Poly-axial screwdriver

SIO- 6901-OP HYBRID SCREW DRIVER CANNULATED. FOR USE IN BOTH OPEN AND CLOSED PROCEDURES

SIO-6905 Set screw starter driver

SIO-6906 Set screw driver

SIO-6907 Cannulated starting awl

Cannulated taps- SIO-6911 - 5.5mm, SIO-6912 - 6.5mm, SIO-6913 - 7.5mm

SIO-6914 Rod reducer (Internal)

MIS- 7911 Torque Control Handle

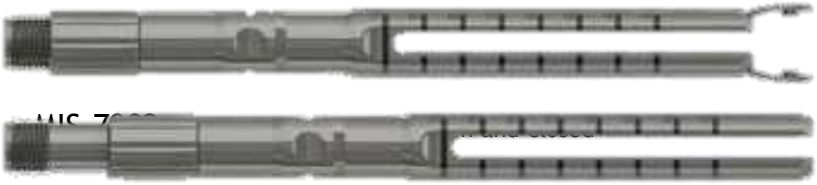
SIO-6917 Guide wire driver

SIO-6918 Ratcheting handle – straight

SIO-6919 Ratcheting T- handle

SIO-6920 PALM HANDLE

FI5560 STARTING NEEDLE



MIS-7903 Dilator # 1

MIS-7904 Dilator # 2

MIS- 7905 Dilator #3

MIS- 7906 EMG Sleeve (Radiolucent)

MIS-7907 Compressor/Distractor

MIS-7912 External Rod Reducer

MIS-7908 Wanding Blade

MIS-7910 Rod Inserter

DISASSEMBLED

SIO-6901-OP Hybrid screwdriver- Cannulated (For use with both Standard and Reduction screws)

SIO-6915 Torque Limiting T- Handle 10Nm

MIS-7909 Rod Length Guage

MIS-7913 Universal Handle

SIT- 6991 Instrument Tray

SANTIS™ Pedicle Screw System
Please read carefully
INSTRUCTIONS FOR USE

IMPORTANT NOTE
The users acknowledge that they have read and agreed on the conditions in this insert, which are considered to be contractual.

CAUTION
Federal Law restricts the device to be sold by, or on the order of a Physician.

BASIC STRUCTURE
The **Santis™ Pedicle Screw System** is comprised of: Rods, Pedicle Screw Assemblies for open and minimally invasive procedures, and Cross Connector Assemblies. Various sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology and anatomy of individual patients.

MATERIAL
Components are made of Ti6Al4V ELI, a titanium based alloy, which complies with ASTM F136. The Cobalt-Chrome rods are made from wrought Co-Cr-Mo alloy, which complies with ASTM F1537.

INDICATION FOR USE
The Santis™ Pedicle Screw System is intended for immobilization and stabilization of the spine. The Santis™ Pedicle Screw System is indicated for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

PRECAUTION:
The implantation of the Santis™ Pedicle Screw System should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw system; because this is a technically demanding procedure presenting a risk of serious injury to the patient.

LEVEL OF FIXATION
Levels of fixation are for the Thoracic, Lumbar, and Sacral spine.

GENERAL CONDITIONS OF USE
- The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with the surgical and medical indications, the potential risks, and limitations related to this type of surgery; the contraindications, side effects, and precautions defined, and in the knowledge of the nature and metallic, metallurgic and biological characteristics of the implants.
- Detailed surgical technique manuals are made available by Lanterna GmbH and supplied through sales representatives. It is recommended that an extensive review of the surgical technique manual is done before attempting surgery.
- Under no circumstances may the implants be re-used; although the device may appear intact on removal, internal modifications due to the stresses and strains placed on it, or small defect may exist which may lead to failure of the implant.

WARNING:
- The safety and effectiveness of pedicle screw spinal Systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the Thoracic, Lumbar, and Sacral Spine secondary to severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthorosis). The safety and effectiveness of these devices for any other condition are unknown.
- Benefits of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with an unstable spine;
- There are potential risks associated with the use of this system. These risks, if realized, may require additional surgery; risks include but are not limited to: device component fracture, lose of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury;
- Discard all damaged or mishandled implants;
- Never reuse an implant; even if it appears to be undamaged;
- Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stresses of full weight bearing activities, or implant failure may result;
- Contouring of or bending of a screw, hook, and/or rod may reduce its fatigue strength and cause failure under load. If a spinal screw or hook is bent or otherwise damaged during insertion or adjustment, they must not be implanted and must be replaced. Rods should only be contoured with the proper contouring instrument. Incorrectly contouring rod, or rods that have been repeatedly or excessively contoured must not be implanted;
- Mixing Metals; never mix titanium alloy or cobalt chrome with any stainless steel material.
- The Santis™ Pedicle Screw System should not be used in conjunction with components from any other manufacturer's spinal system.

Any decision, by a surgeon, to remove the internal fixation device should take into consideration such factors as the risk to the patient by undergoing an additional surgery procedure as well as the difficulty of implant removal;

- Implant removal should be followed by adequate postoperative management to avoid fracture.
- The Santis™ Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment nor tested for heating or migration in the MR environment.

CONTRA-INDICATIONS

- Any active or suspected latent infection in or about the spine;
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complication in post-operative care;
- Bone stock compromised by disease, infection, or prior implantation which cannot provide adequate support, and/or fixation to the device;
- Obesity; an overweight or obese patient can produce loads on the device that exceed maximum load design specification;
- Open wounds;
- Metal sensitivity, documented or suspected;
- Bone resorption, osteopenia and/or osteoporosis;
- Patients having inadequate tissue coverage over the operative site;
- Pregnancy;
- Excessive local inflammation;
- Other medical or surgical conditions which would preclude the potential benefit or spinal implant surgery; such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count;

PRECAUTIONS

- Based on the fatigue testing results; the physician/surgeon should consider the level of implantation, patient weight, patient activity level, or patients condition, etc. which may have an impact on the performance of the system;
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences;
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting or muscle strain) resultant forces can cause failure of the device;
- In some cases, progression of degenerative disease may be so advanced at the time of implantation; the disease may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as delaying technique or to provide temporary relief;
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the spinal fixation device. Spinal fixation systems require detailed knowledge of spinal surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement on implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome;
- The patient should be informed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal healthy bone and may bend, loosen, or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation;
- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implants service life.
- As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indication, contra-indications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risk, the size and shape of human bone presents limitations on the size shape, and strength of the implant.);
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive object. Alterations will produce defects in surfaces finish and internal stresses which may become the focal point for eventual breakage of the implant.

SIDE-EFFECTS

- Late bone grafting or no visible fusion mass and pseudarthrosis;
- Neurological complication, paralysis, soft tissue lesions, and/or migration of the implant;
- Pedicle failure while preparing and inserting the pedicle screws;
- Superficial or deep-set infection and inflammatory phenomena;
- Allergic reaction to the Ti6AL4V ELI alloy or cobalt chrome;
- Reduction in bone density due to different distribution of mechanical stresses;
- Pain and/or abnormal sensations due to hardware bulkiness;
- Neurological and spinal dura mater lesions from surgical trauma;
- Bursitis;
- Presence of micro-particles around the implants;
- Growth of the fused vertebra is altered;
- Partial loss of the degree of correction achieved during surgery;
- Modification of spinal curvature and stiffness of the vertebral column.
- Death

The above list of side-effects is not exhaustive. These side-effects can sometimes necessitate further surgical treatments.

PACKAGING, LABELING AND STORAGE

- The implants are provided in both STERILE and NON STERILE formats. NON STERILE implants must be cleaned and sterilized before use: (see below)
- The instruments are supplied NON-STERILE**.** They must be cleaned and sterilized before use; (see below)
- The packages must be intact at the time of receipt. All legal information required for this type of implant is given on the label and insert of each package;
- Use care in handling and storage of implants component. Cutting, sharply bending, or scratching the surface of the implants can significantly reduce the strength and fatigue resistance of the implant components.

CLEANING AND DISINFECTING PROCEDURES

- All reusable instruments should be cleaned and disinfected between uses. Follow the directions below to properly clean and disinfect reusable instruments prior to sterilization.
  - Disassembly – Where possible, disassemble all instruments prior to cleaning, disinfection and sterilization.
  - Clean instruments immediately after use to prevent tissue or bodily fluids from drying on the instruments.
- Decontamination – Saturate the entire surface with full strength disinfectant/cleaner and allow it to remain in contact for 5 minutes. Do not use high acidic (pH <4) or high alkaline (pH >10) products.
  - Cleaning Instructions

Pre-Cleaning	Remove gross contaminants by immersing devices in a neutral pH enzymatic cleaner.
	Rinse under warm, running, potable tap water for two(2) minutes
	Scrub with an appropriate soft-bristle brush until clean.
	Thoroughly clean the instruments.
Washing	Wash in an ultrasonic cleaning bath filled with neutral enzymatic detergent solution (e.g. Miltex EZ-Zyme) prepared according to the manufacturer's instructions
	Ultrasonicate for 10 minutes or per manufacturer's instructions
Rinsing	Disassemble the Extension Tower as described below.
	Rinse under warm, running, potable tap water for two(2) minutes.
Inspection	Visually inspect the instruments to confirm there is no visual contamination. If this end point cannot be met. Dispose of the instrument.
Drying	Dry devices using an absorbant, non-shedding cloth or industrial hot dryer, or place into a drying cabinet until all moisture is removed.

  - Preparation and Assembly – Assemble all instruments that were previously disassembled. Perform a visual and functional inspection of all instruments to verify that they are in working order. Replace any reusable instruments that are cracked or damaged or do not function.
  - Return the instruments to the instrument trays for sterilization.

STERILIZATION PROCEDURES

- Instruments are supplied NON-STERILE
- Implants are provided in both STERILE and NON STERILE formats. In the case of NON STERILE implants and all instruments, please follow these instructions.
- ANSI/AAMI ST79 guidelines for in-hospital sterilization should be followed for all implants and instruments. Implants and instruments should be sterilized in the sterilization case provided. Sterilization cases should be wrapped with two layers of FDA-Cleared wrap, with a surgical towel placed between the bottom of the tray and the wraps. Using a properly functioning and calibrated steam sterilizer, the following parameters may be used for effective sterilization:
  - Pre-Vacuum Steam Sterilization
  - 132°C (270°F) Sterilization Temperature
  - 4 Minute Sterilization Time
  - 40-50 Minute Dry Time

USEFUL LIFE OF INSTRUMENTS

Routinely inspect devices for wear and tear. If evidence of wear such as corrosion, pitting, or discoloration is observed, dispose of the instrument and obtain a new instrument from the manufacturer. If any cutting instruments become dull and do not function properly, obtain a new instrument from the manufacturer.

Disassembly, assembly and Cleaning Instructions
SANTIS™ Screw Extension Tower- Article # MIS 7902
Quick Reference Guide

LANTERNA MEDICAL TECHNOLOGIES RECOMMENDS THE FOLLOWING DISASSEMBLY, ASSEMBLY AND CLEANING SEQUENCE:

1. After use or surgery, turn the collar in a clockwise direction while applying gentle upward pressure on the internal component.

2. Remove the internal component by pulling it out of the tower. – Clean both parts thoroughly. (Refer to Cleaning and Disinfecting Procedures).

3. After cleaning, Insert the inner sleeve into the top of the TOWER and align the two prongs with the internal tracks.

4. Insert DILATOR 2 from the opposite end of the TOWER. This will properly set the prongs into the tracks of the TOWER. Advance the inner sleeve until it is fully seated in the TOWER.

5. Turn the collar counter clockwise to properly secure the inner sleeve with the TOWER.

Spine Solutions Simply Delivered

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