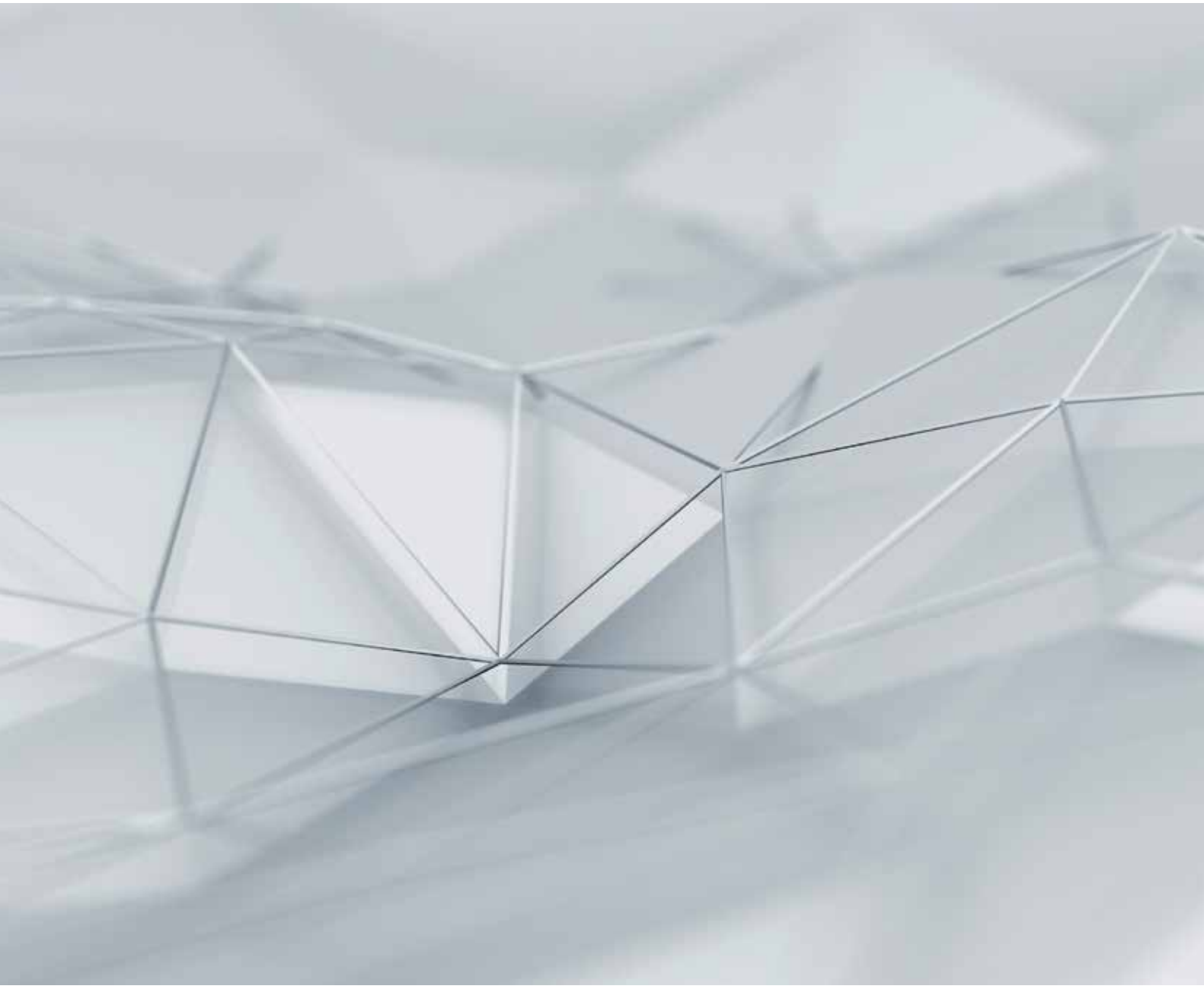
ARTFX
MEDICAL

SPINAL FIXATION SYSTEM

SURGICAL TECHNIQUE



INTRODUCTION

ARTFX Spinal Fixation System is designed to provide immobilization and stabilization as spinal segments as an adjunct to fusion of the thoracic, lumbar and/ or sacral spine. It is used for the treatment, the stabilization and defects on the spine.

ARTFX Spinal Fixation System is the next generation in top-loading, top-tightening systems that support a spine for optimal deformity correction. Deformity correction requires a comprehensive selection of implants and well designed instruments.

Thus **ARTFX** Spinal Fixation System has a wide and high quality series of implants that support posterior corrective techniques.

It consists of surgically invasive long-term use and implantable devices, different sizes of polyaxial self-tapping pedicle screws, rods in symmetric, bilateral arrangement and setscrews for rod connection. **ARTFX** Spinal Fixation System is created in sufficient range and specification

The pedicle screws are placed axially in the pedicles with two screws in the cephalad position and two screws in the cauded position. The rods are secured in the heads of the pedicle screw so that fixed stabilization is provided between cephalad and cauded vertebrae.

Overall, in spinal deformity, pedicle screw fixation has shown greater threedimensional correction, decreased rates of postoperative curve progression, and potentially higher fusion rates. It is a complete and comprehensive universal system that offers significant performance and ease of use benefits and brings innovation, versatility, and reliability to every surgical case and provides three dimensional adjustability for simple, stable construct assembly.

INDEX

I. PATIENT POSITIONING

Analysis of the deformation is dependent upon patient's historical lifecycle, physical find ngs and radiographic assessment.

The patient is laid prone on an appropriate spinal surgery table. The abdomen should not be compressed to facilitate venous drainage. Being careful to pad all bony prominences is important. (Figure: 1)

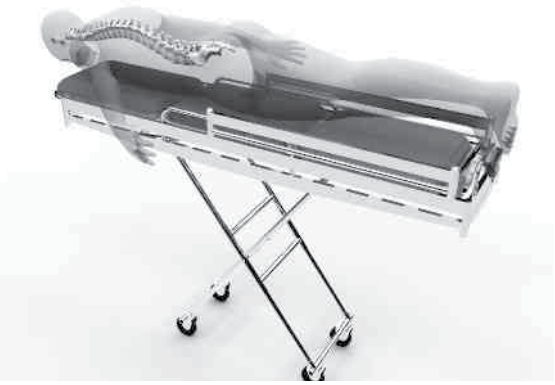


Figure: 1

Clinical or radiographical verification can be used for surgical levels.

The incision is made to spread just beyond the length of the intended fusion to guarantee certain contact. (Figure: 2)

A sufficient planning before the surgery ensures the most appropriate implants and optimal location of them.

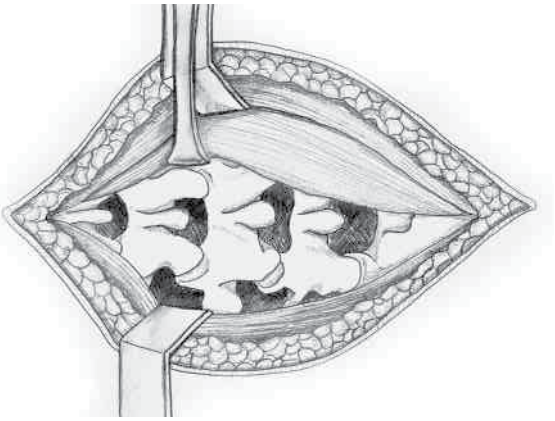


Figure: 2

2. PREPARATION OF THE PEDICLE

Pedicle Entry Point Location (Figure: 3 - 4) Entry site for individual patients may slightly be different according to the anatomical variations between patients. Such kind of differences must be noted on the pre operative MRI, CT images as well as on the intra-operative x-rays.

The pedicle entry point is intersected by the vertical line connecting the lateral edges of bony crest extension of the pars inter-articularis, and the horizontal line that bisects the middle of the transverse process.

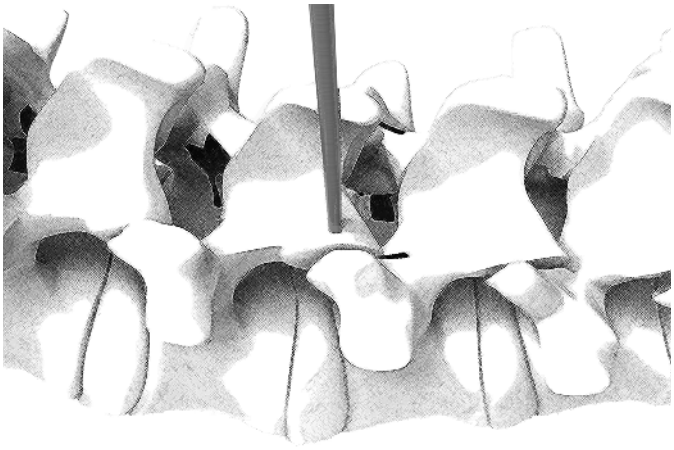


Figure: 3

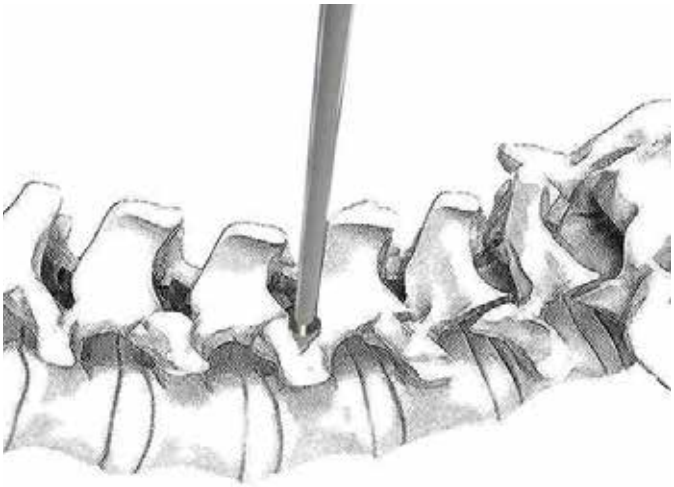


Figure: 4

The instrument to be used:
ARTFX103 Bone Awl (Picture: 1)
ARTFX103 Bone Awl Large

Picture: 1

Perforation of the pedicle is performed with the straight or curved blunt tip pedicle probes ARTFX106 and ARTFX109.

The probes have ruled markings to determine the depth measurement in the pedicle canal.

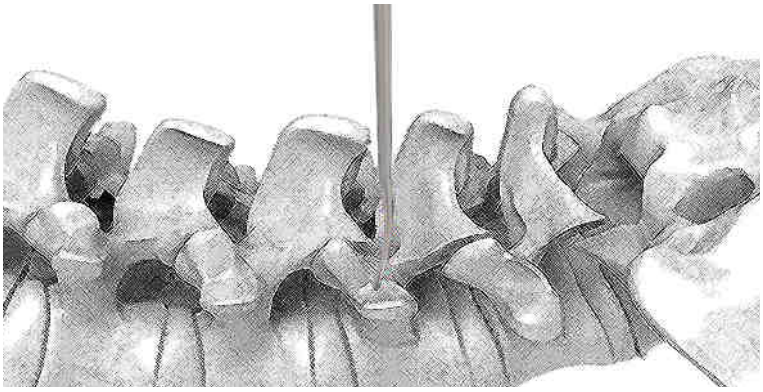


Figure: 5

GUIDE PINS INSERTION

The guide pins are inserted into the pedicle canal by using the Bone Probe Straight (Figure: 6). All grooved guide pins must be inserted on the same side of the spinal column. This is necessary for identification on t e x-ray.

After the insertion of all the guide pins, intra-operative x-rays should be taken and checked if the position of the guide pins relative to the pedicle canal is suitable.

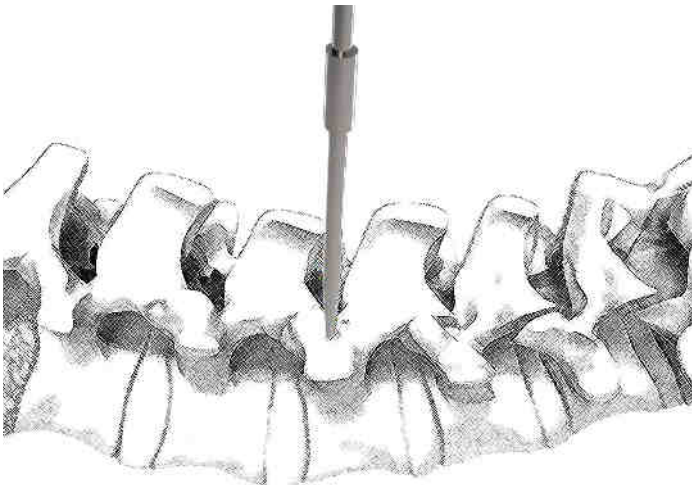


Figure: 6

The instrument to be used: ARTFX112/113 Pedicle Marker with/without stoper (Picture: 2)

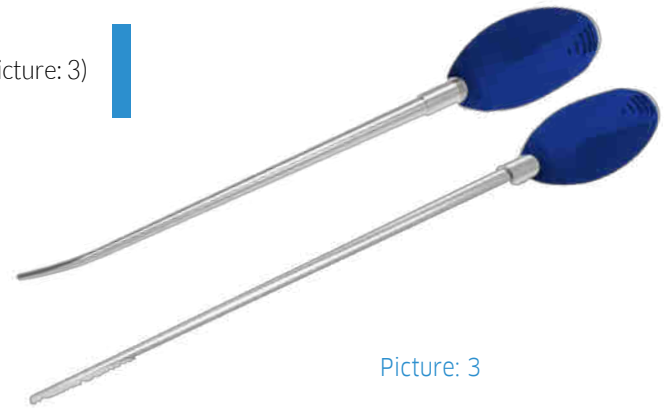
Picture: 2

PROBING

If the position of the guide pins relative to the pedicle canal is suitable, the probe is inserted through the entry hole (Figure: 7). After insertion it is gently pressed into the pedicle canal until the anterior cortex of the vertebral body is reached. Attention must be paid not to violate the anterior wall of the vertebral body or the cortical walls.

Then, with using Bone Probe, a pathway is opened up. The probe should contact bone at all times. The correct rotational insertion of the instrument will allow the probe to follow a path of least resistance without violating the pedicle walls. The entry point and trajectory should be re-evaluated in the event that resistance is felt. To help indicate the depth in which the probe has been inserted as well as to help determine proper screw length, The Pedicle (Bone) Probe is calibrated and laser etched with 5mm intervals.

The instrument to be used:
ARTFX106 Bone Probe Straight (Picture: 3)
ARTFX109 Bone Probe Curved



Picture: 3

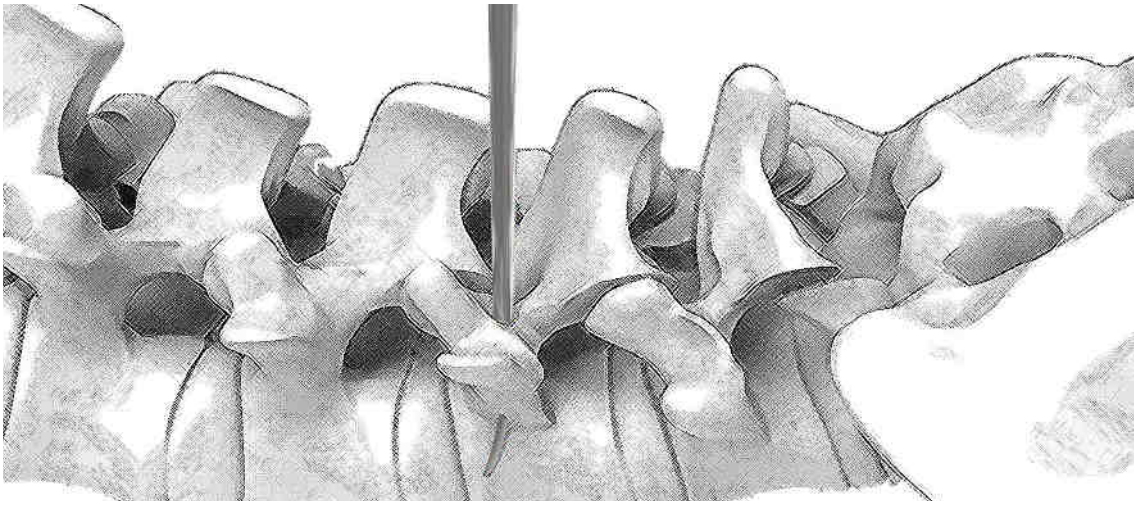


Figure: 7

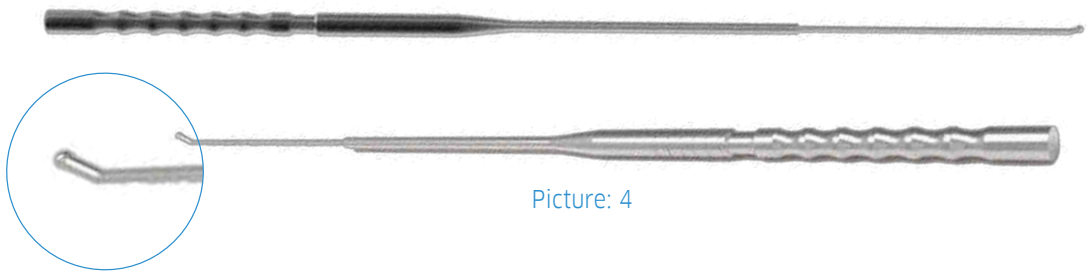
TESTING PROBE

Continuity of the cortical walls of the pedicle is tested and confirmed by us ng the curved tester.

To palpate the inner surface of the pedicle canal for checking for defects or perforations of the cortical wallsthe straight tester can also be used.

The Probe Feeler (Tester) is calibrated in the same manner as the Pedicle (Bone) Probe. In order to verify that all walls of the pedicle have not been violated and that cancellous bone is felt at the distal end of the path, the prepared pathway is checked with the Probe Feeler (Tester).

The instrument to be used:
ARTFX094 Tester (Straight) (Picture: 4)
ARTFX096 Tester (Curved)



Picture: 4

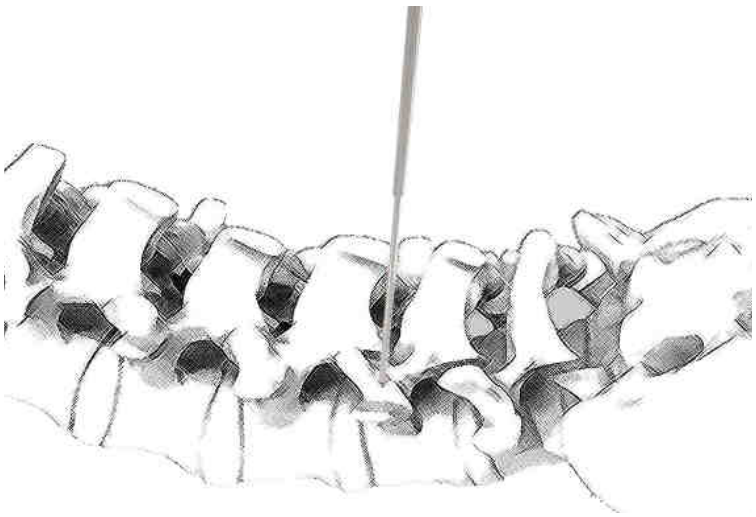


Figure: 8

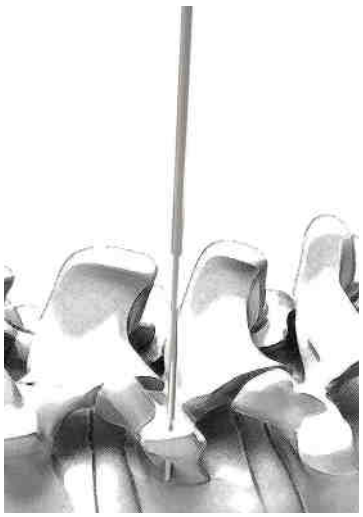


Figure: 9

DEPTH GAUGING

To determine the most appropriate length of the screw to be used, the depth is measured with the depth signs on instruments (Figure: 10). The gauge is placed into the pedicle canal and advanced through until the tip of it reaches to the anterior wall of the vertebral body. The depth of the vertebral body is indicated by the ruler on the gauge.

The instrument to be used:
Screw Depth Gauging (Picture: 5)

Picture: 5

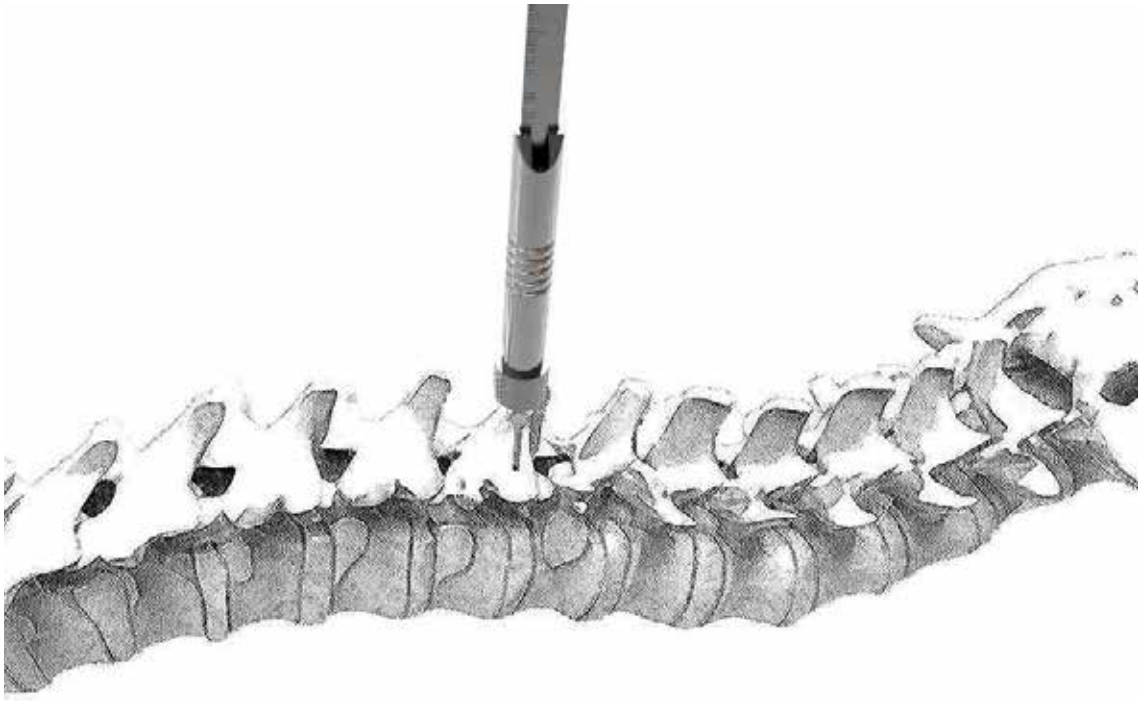


Figure: 10

Thoracic Pedicle Entry:

In order to verify any anatomic variations, CT scans may be used. Landmarks usually lie at the intersection of a vertical line through the middle of the convex part of each articular process and a horizontal line drawn across the middle to upper third of the base of the transverse process. This intersection is just level with the small horizontal crest of bone and usually 2mm below the edge of the articular cartilage. (Figure: 11)

Note: The posterior plane of the vertebra, which is the plane of the transverse process, is usually globally perpendicular to a pedicle, and the drilling direction. Especially when instrumenting the apical vertebrae, which are usually the most rotated ones, this is an important point to consider.

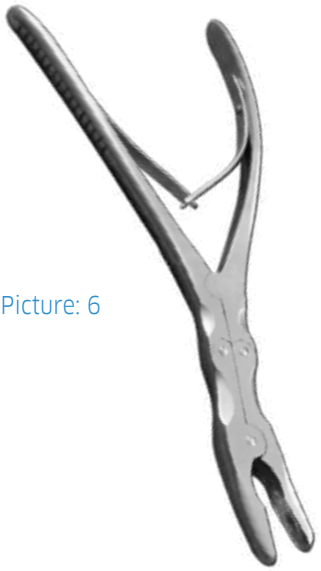
Lumbar Pedicle Entry:

At the intersection of a vertical line through the facet joint space and a horizontal line through the middle of the base of the transverse process, Landmarks are located.

These two lines intersect at a small sharp crest of cortical bone, which can be a reliable landmark since it is extra articular and not affected by osteoarthritic deformities.

A small sharp crest of cortical bone is at intersection of these two lines. It is extra articular and not affected by osteoarthritic deformities. So it can be reliable landmark.

The instrument to be used:
Bone Ronger (Picture: 6)



Picture: 6

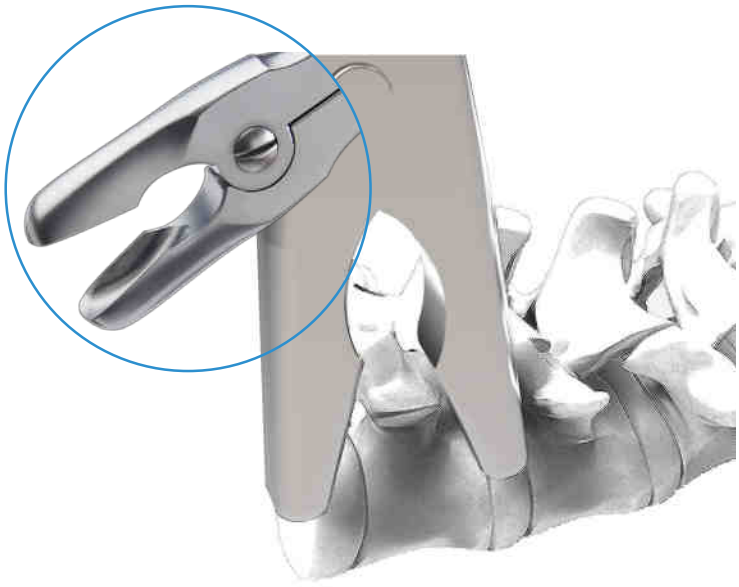


Figure: 11

The small cortical crest is removed with a rongeur or power burr to expose the underlying cancellous bone.

Screw Preparation and Insertion:

If the bone is too hard, the appropriate tap may be used to prepare the pedicle screw canal (Figure: 12). The tap sizes are 4.0mm/5.0mm and 6.0mm. The taps are calibrated in the same manner as the probe and feeler.

The instrument to be used: ARTFX099/100/101 Modular Tap 4.0 - 5.0 - 6.0 mm (Picture: 7)

Picture: 7

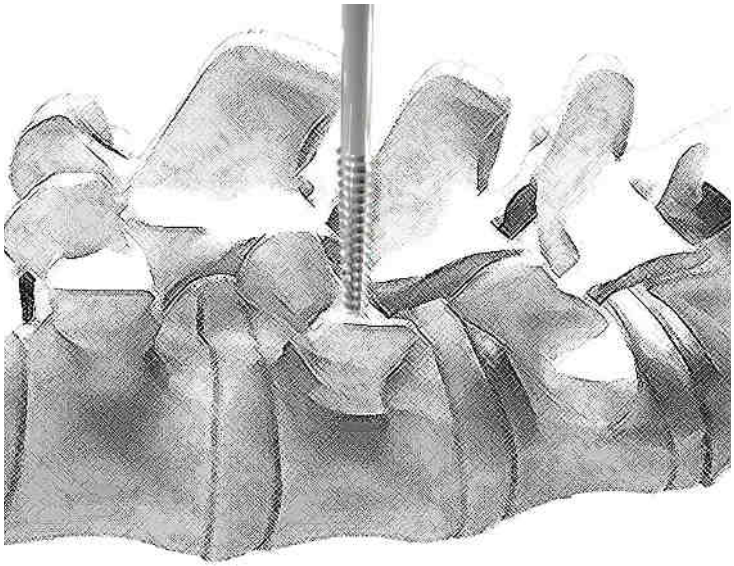


Figure: 12

3. SCREW INSERTION

Screw Driving

The screw is inserted by using a set of T-Handle or I-handle, Screw Guide and Poly Screw Driver (Figure: 13). The poly screw driver head is inserted into the screw housing and then driven by the screw guide into the vertebral body to the depth desired (Picture: 8). The poly screw driver is disangaged from the housing by utrning it counterclockwise.

Note: The ARTFX Spinal Fixation System screws are self tapping and doesn't requre tapping. But due to the abnormal bone density, tapping may be needed. The need to tap is at the discretion of each surgeon.

Both Polyaxial and Reduction Polyaxial Screwdrivers are same and provide a very rigid connection between the polyaxial and reduction polyaxial screws and the screwdriver.

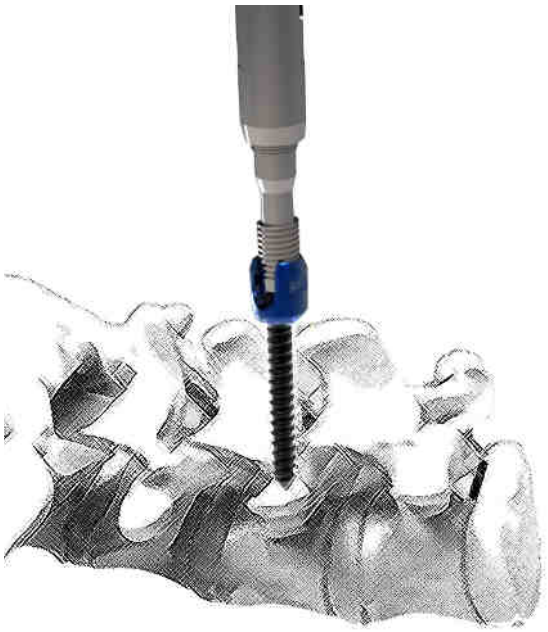


Figure: 13

The instrument to be used:
ARTFX102 T-Handle
ARTFX098 Polyaxial Screw Driver (Picture: 8)
ARTFX091 Screw Guide

Picture: 8

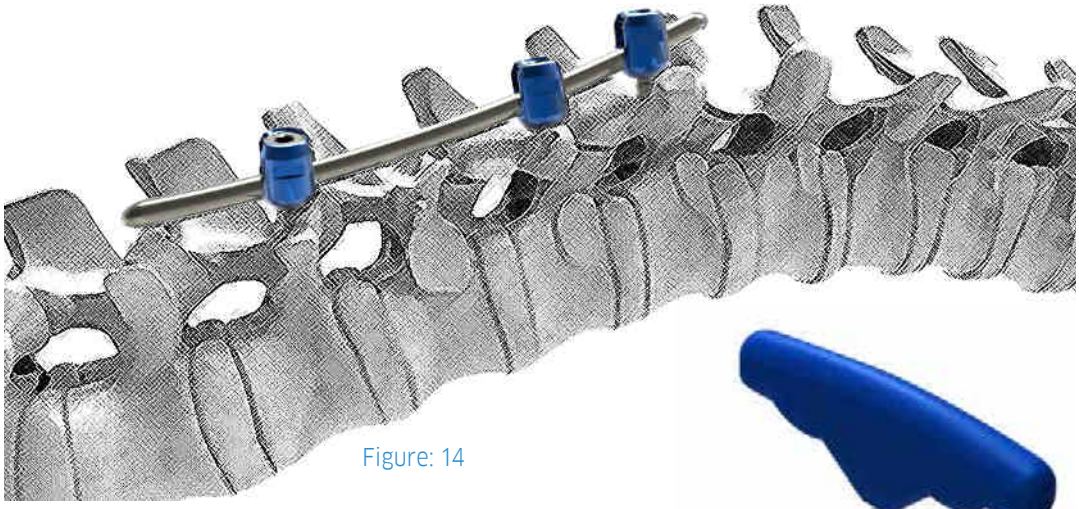


Figure: 14

Figure: 15

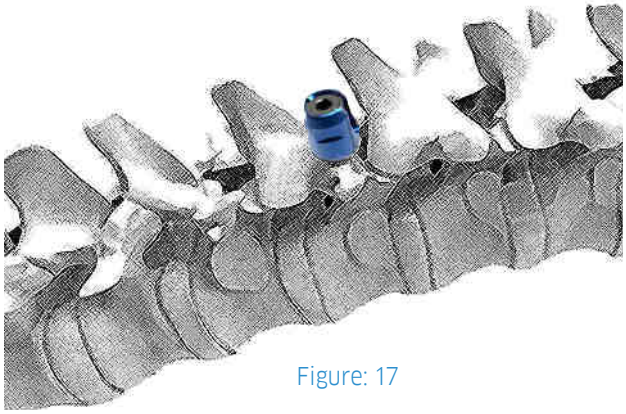


Figure: 17

Figure: 16

With the pedicle pathways prepared and proper screw length and diameter determined, the screw is prepared for insertion.

4. ROD CONTOURING

Once all screws are inserted, the appropriate length rod is cut according to the required construction. The ARTFX Spinal Fixation System Template is utilized to accurately determine the appropriate rod length.

Figure: 18

After inserting all screws, the appropriate length rod is cut according to the required construction. In order to determine the appropriate rod length accurately, The ARTFX Spinal Fixation System is utilized.

A Tabletop rod cutter is available. Appropriate pre-cut rods can be used or it can be cut a longer rod with the Rod Cutter. Pre-bent rods are also offered with the ARTFX Spinal Fixation System.

Use the appropriate pre-cut rods or cut a longer rod with the Rod Cutter.

SELECTING AND BENDING THE ROD

After the rod with the appropriate length is choosen, the lordosis is bent into the rod by using the rod bender. (Figure: 19). Because of the polyaxial system, the rod doesn't need a precision bending. According to the anatomy of the patient, amount of lordosis is decided. The central button on the rod bender is used to adjust the angle of bend. The button is pulled out and the desired radius as small, medium and large is selected. To fit the desired spinal contours, the rod bending is used.

The ARTFX Spinal Fixation System Turkish Benders can be used to perform Bending. A series of small incremental adjustments will bend the rod gradually and ensure even stress distribution on the rod to contour the rod. The rod bending is performed to fit the desired spinal contours. The orientation clip is useful in maintaining spacial orientation during bending Bending can be performed with the Bending Pliers. To contour the rod, a series of small incremental adjustments will bend the rod gradually and ensure even stress distribution on the rod.

The instrument to be used:
ARTFX118 Rod Bender (Picture: 11)

Figure: 19

ROD INSERTION

The Rod Insertion Forceps can be used to facilitate the rod into the grooves of the implant, after the rod is bent to the desired contour. At the discretion of the surgeon, this can be done in any sequence. Beginning the closure at the easiest place may help facilitate the seating of the rod in adjacent screw.

Once the rod is bent to the desired contour, the Rod Insertion Forceps can be used to facilitate the rod into the grooves of the implant (Figure: 20). This can be done in any sequence at the discretion of the surgeon. It can be helpful to begin the closure at the easiest place. This may help facilitate the seating of the rod in adjacent implants.

Note: The polyaxial screws may lock upon insertion. Use the Inserter to unlock the heads before introducing the rod.

The instrument to be used:
ARTFX119 Rod Holder (Picture: 12)

Picture: 12

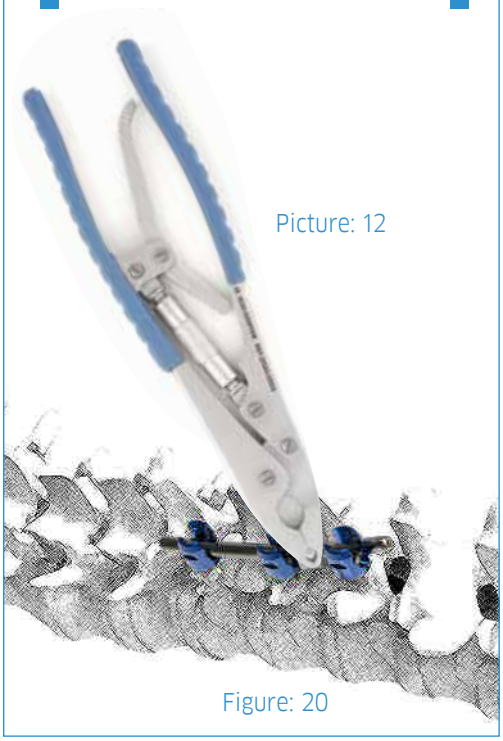


Figure: 20

Figure: 21

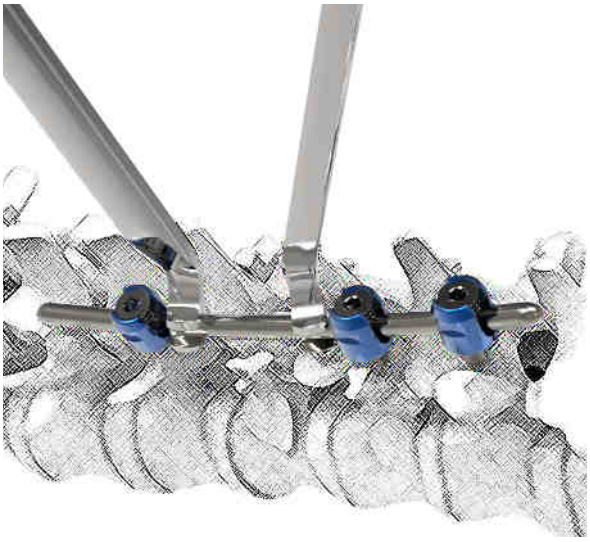


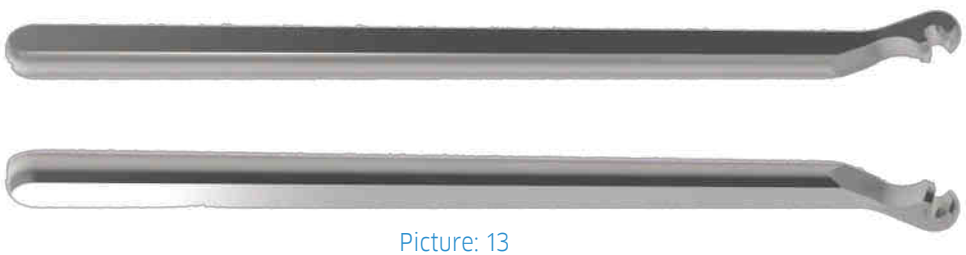
Figure: 22

After inserting the rods in place, the setscrews are placed to keep the rods stable, prior to final tightening (Figure: 21).

The Bending Irons can be used for insitu bending to achieve final ncremental correction maneuvers (Figure: 22). Care should be taken to not make extreme bends, so as to avoid stress concentration and notching of the rod.

For insitu bending to achieve final incremental correction maneuvers, The Bending Irons can be used. In order not to make extreme bends, it should be bended carefully. So stress concentration and notching of the rod are avoided.

The instrument to be used:
ARTFX123/124 In-Situ Bender (Left) (Picture: 13)



Picture: 13

5. ROD LINKAGE

Inserter and Universal Tightener

ARTFX Spinal Fixation System offers three options for linking the rod to the spine:

Option 1:

The Inserter can help align the Universal Tightener and the Closure Screw with the implant (Figure: 23). The two engraved lines on the Universal Tightener denote the following:

- When the lower line is aligned with the top of the Inserter, the Closure Screw is at the top of the implant.

- When the upper line is aligned with the top of the Inserter, the Closure Screw is fully introduced into the implant.

Note: Performing final tightening of the Closure Screw with the Inserter in place makes removal of the Inserter impossible. (Figure: 24)

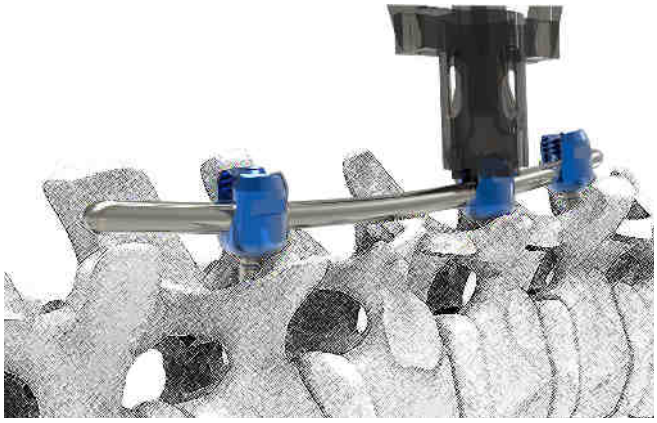
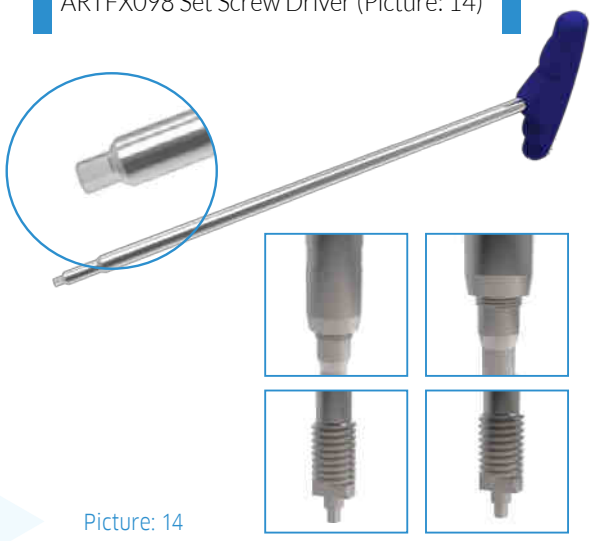


Figure: 23

Figure: 24

The instrument to be used:
ARTFX098 Set Screw Driver (Picture: 14)



Picture: 14

Proper Positioning of the Rod

After all the set screws are loosely inserted (Figure: 25) as defined before, the rod is rotated slightly into the lordosis contour by using the rod gripper (Figure: 26). For the proper position of the rod, the centerline laser mark on the rod must be visible from the top and it must be parallel to the floor. While keeping the rod in its proper position by using the rod gripper, one of the set screws is tightened with the Hexwrench 4.0 mm. Driver. Be sure that only one set screw is tightened yet and the others are still loose.

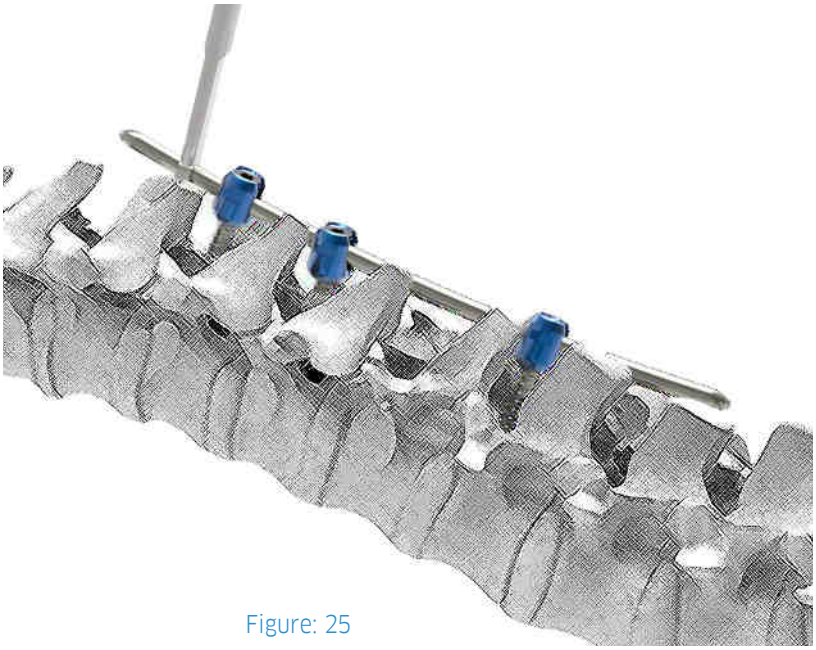


Figure: 25

The instrument to be used:
ARTFX119 Large Locking Power Rod Gripper

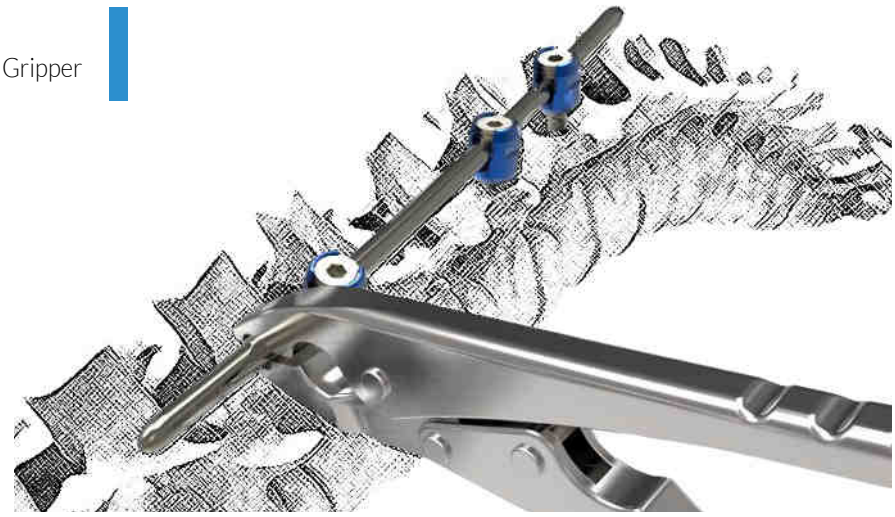


Figure: 26

Option 2: Rod Fork and Universal Tightener

The Rod Fork is used when the rod is slightly proud with respect to the seat of the implant. (Figure: 27) The Rod fork easily slides into the lateral grooves on the implant head and is rotated backwards. This levers the rod into the head of the implant. The Closure Screw is inserted with the Universal Tightener when the rod is fully seated into the head of the implant. (Figure: 28)

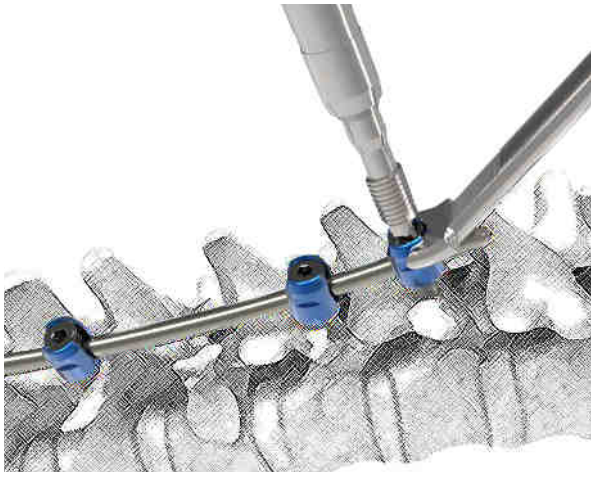


Figure: 27

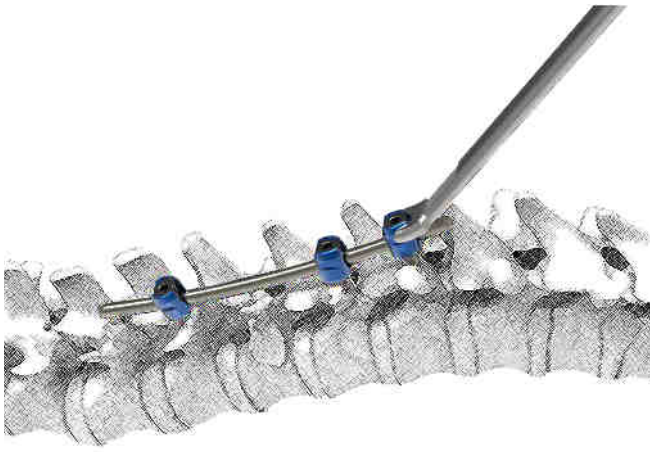


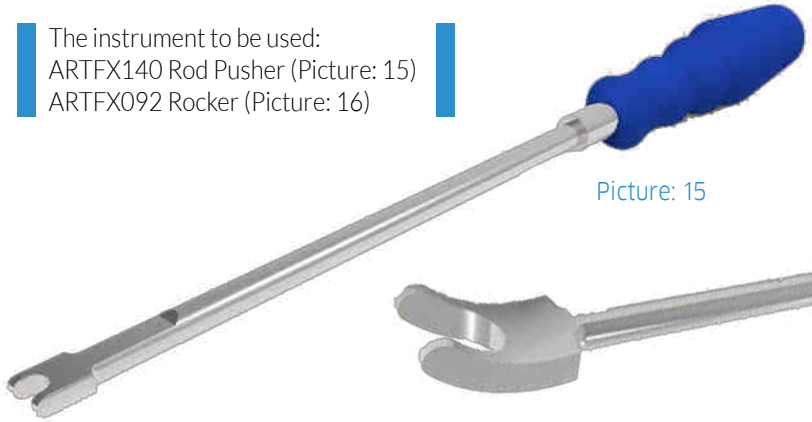
Figure: 28

Adjusting the Position of the Rod

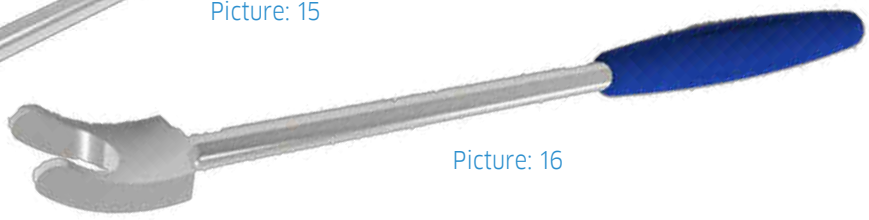
The position of the rod is made by making the advantage of swivel head of the polyaxial screw.

Once the position of the rod is adjusted, the housing of the screw is stabilized by using the suitable accessories.

The instrument to be used:
ARTFX140 Rod Pusher (Picture: 15)
ARTFX092 Rocker (Picture: 16)



Picture: 15



Picture: 16

Option 3: Using the Persuader

The Persuader is used when additional force is needed to bring the rod to the implant. (Figure: 29)

If additional force is needed to bring the rod to the implant, The Persuader is used. Connect the Persuader to the head of the implant in the position “0”.

If the head of the Persuader is turned until the indication line moves to the position “1”, The Persuader is now locked to the implant. The rod can be pushed into the screw from this position.

If the head of the Persuader is turned until the indication line moves into position “2“, allowing insertion of the Closure Screw, the rod is now fully seated.

In the position “0”, connect the Persuader to the head of the implant.

Turn the head of the Persuader until the indication line moves to the position “1”. The Persuader is now locked to the implant. From this position the rod can be pushed into the screw. (Figure: 30)

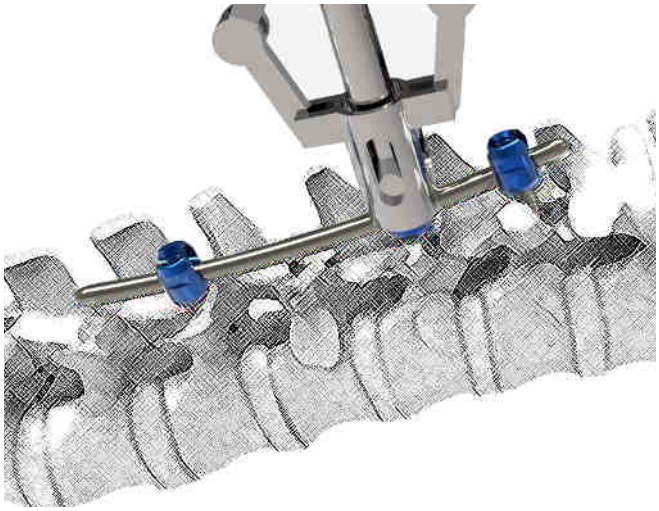


Figure: 29

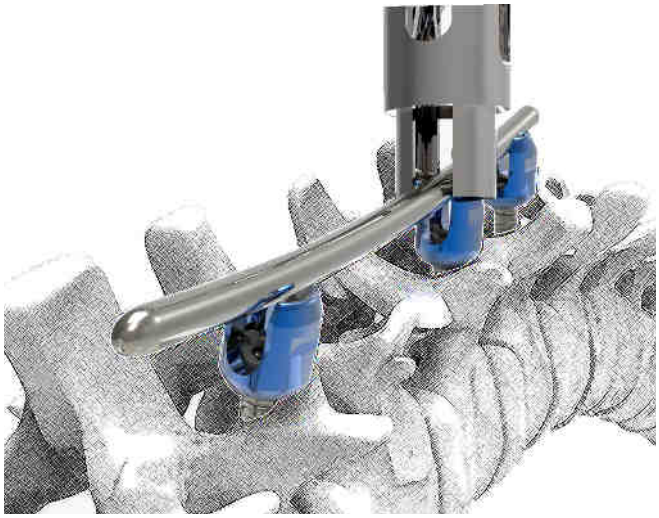


Figure: 30

In the position “0”, connect the Persuader to the head of the implant.

Turn the head of the Persuader until the indication line moves to the position “1”. The Persuader is now locked to the implant. From this position the rod can be pushed into the screw. (Figure: 31)

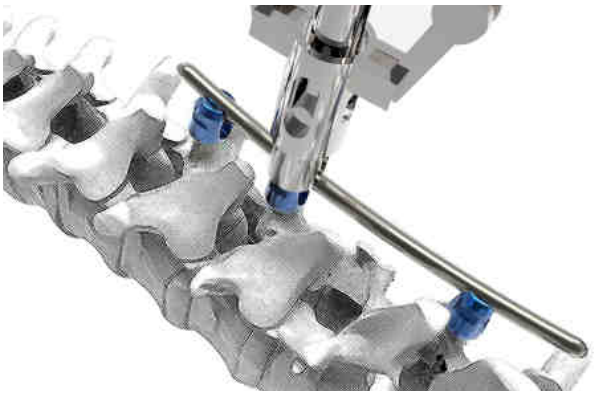


Figure: 31

The instrument to be used:
ARTFX056 Persuader (Picture: 17)

Picture: 17

To remove the Persuader, turn the head of the instrument back to the position “0“ and rotate the complete instrument. (Figure: 32)

Tip 1: The rod cannot be linked to the screws or the hooksif the rod has a sharp, acute bend at the point of linkage.

Tip 2: If the position “2” cannot be achieved by turning the Persuader, it may not be positioned properly on the implant. Remove the instrument and start the application process from the beginning.

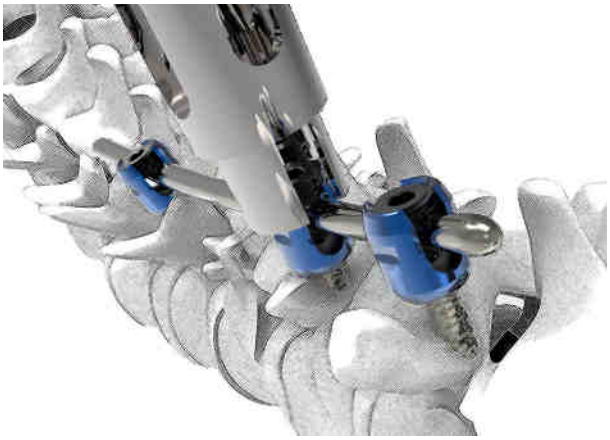


Figure: 32

Persuader and Universal Tightener With the Universal Tightener through the Persuader, using the Closure Screw.

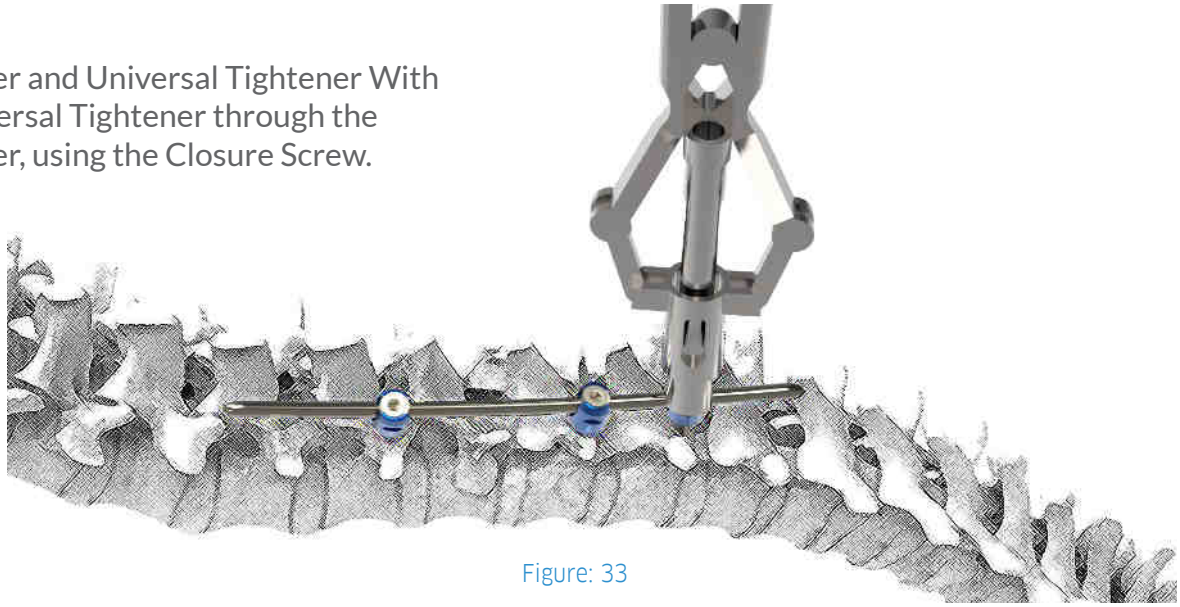


Figure: 33

Figure: 34

Turn the head of the instrument back to the position “O” and rotate the complete instrument in order to remove the Persuader.

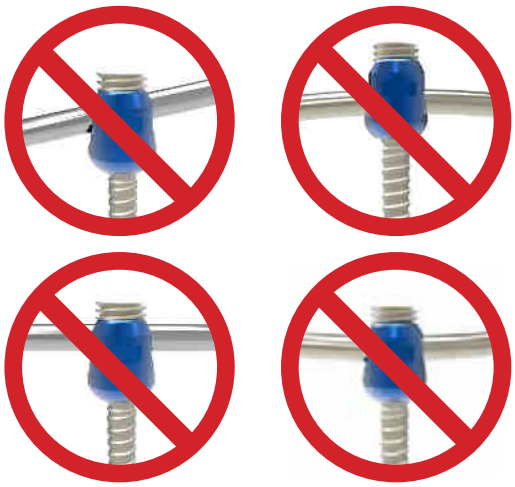
Point 1: If the rod has a sharp, acute bend at the point of linkage, the rod cannot be linked to the screws

Point 2: It may not be positioned properly on the implant, if the position “2” cannot be achieved by turning the Persuader. Then start the application process from the beginning by re moving t he i nstrument.

Point 3: The Persuader is not designed to bend the rod. Be sure that the Closure Screw is fully engaged into the screw head in the event the rod is forced down while tightening the Closure Screw. The high reactive forces generated by the final-ti htening maneuvers will be avoided by this way.

Be extra careful in case:

- The rod is not horizontally placed into the screw head.
- The rod is high in the screw head.
- An acute convex or concave bend is contoured into the rod.



In the event the rod is forced down while tight- ening the Closure Screw, be sure that the Closure Screw is fully engaged into the screw head. This will help resist the high reactive forces generated by the final tightening maneuvers.

Extra caution is advised when :

1) The rod is not horizontally placed into the screw head

2) The rod is high in the screw head

3) An acute convex or concave bend is contoured into the rod.

Segmental Compression

The compressor is fitted onto the rod on the outside of tightened screw and the other screw to be compressed. (Figure: 35) When the handle of the compressor is closed, the untightened (loose) screw moves toward the tightened one. This process accomplishes the compression of one segment. If the amount of compression is achieved, the loose screw is tightened by using 4.0 mm. Screw driver while it is being hold with the compressor.

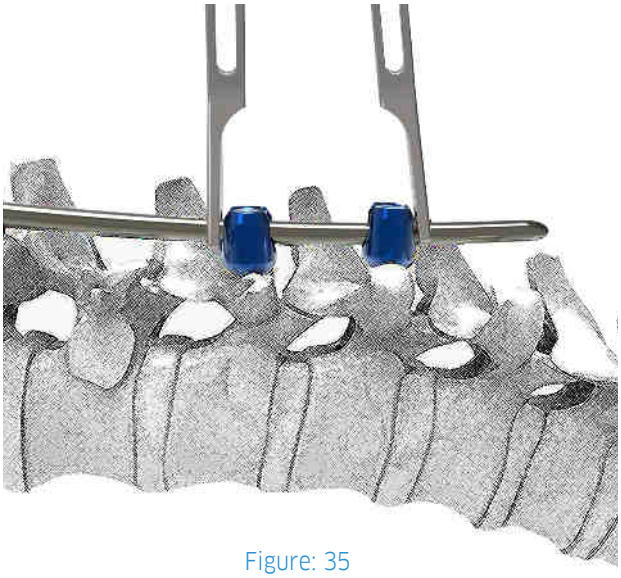


Figure: 35

The instrument to be used:
ARTFX126 SPS Compressor (Picture: 18)

Picture: 18

Segmental Distraction

Distraction is performed by using the spreader. (Figure: 36) The spreader is fitted onto the rod on the inside of tightened screw and the other screw to be distracted. When the handle of the distractor is closed, the untightened (loose) screw moves away the tightened one.

This process accomplishes the distraction of one segment. If the amount of distraction is achieved, the loose screw is tightened by using 4.0 mm. Screw driver while it is being hold with the spreader.

Figure: 36

The instrument to be used:
ARTFX127 Distractor (Picture: 19)

Picture: 19

6. FINAL TIGHTENING

Torque and Anti Torque

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the fina tightening of the Closure Screw is done by utilizing the Anti-Torque Key and the Torque Wrench.

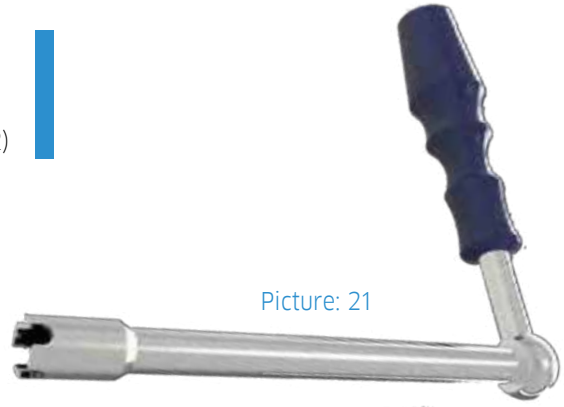
The Torque Wrench indicates the opti mum force which has to be applied to the implant for final tightening. Line up the two arrows to achieve this optimum torque of 12Nm.

Note: It is not recommended to exceed 12Nm during final ti htening.

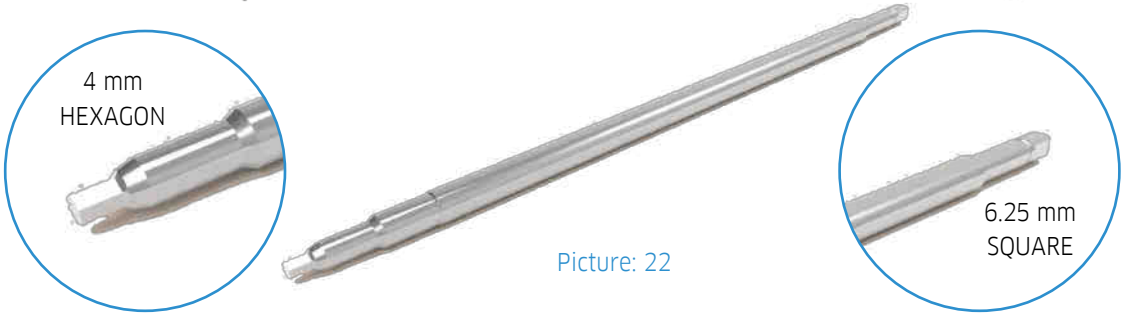
After compression and distraction are accomplished the final tightening of the screws is performed by anti torque device. The 4.0 mm. Screw driver attached to the toeque limiting T-handle is inserted through the anti torque device and engaged onto the rod. Be sure that the anti torque device is fully inserted over the screw housing. The screws are tightened sequentally while being stabilized by using the anti torque device. The torque limiting T-handle device is slowly turned counterclockwise until the mechanism indicates that the torque applied is 12 N-m which is the torque limit.

The instrument to be used:
ARTFX120 L - Anti Torque (Picture: 21)
ARTFX122 T-Torque Handle (Picture: 20)
ARTFX098 Set Screw Driver Open (Picture: 22)

Picture: 20



Picture: 21



Picture: 22

Note: For final tightening, The Anti-Torque Key must be used. The Anti-Torque performs two important functions: (Figure: 37)

• It allows the Torque Wrench to align with the axis of the tightening axis.

• It indicates one to maximize the torque needed to lock the implant assembly.

Note: The rod may not be fully seated, if the Anti-Torque Key cannot be easily removed from the implant head.

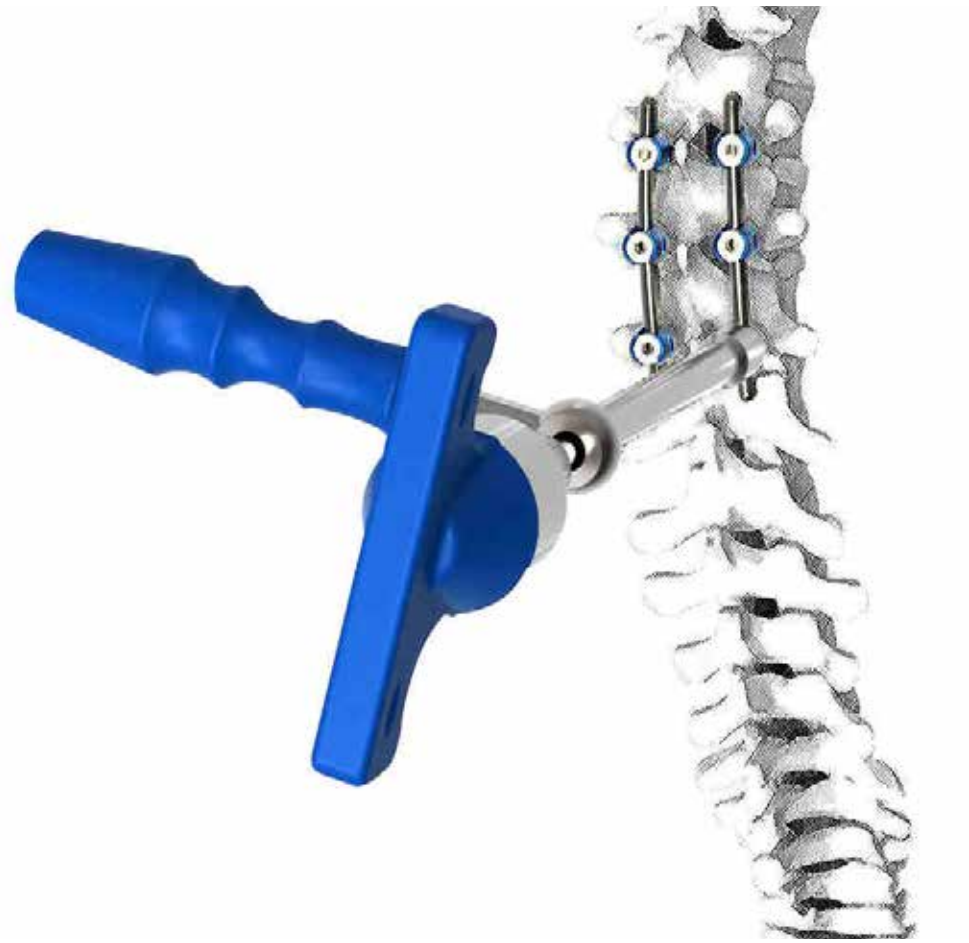


Figure: 37

7. REDUCTION PROCEDURES- DEFORMITY CORRECTION

The ARTFX Spinal Fixation System was designed to offer solutions that adapt various surgical attitudes. Using one of three different reduction procedures, deformity correction may be obtained:

1. Rod Derotation
2. In - Situ Bending
3. Distraction/Compression

Straight or pre-bent rods may be selected as a startingpoint, as per the associated deformity to be corrected.To facilitate optimal spinal deformity correction, abovemaneuvers may be utilized independently or in anycombination.

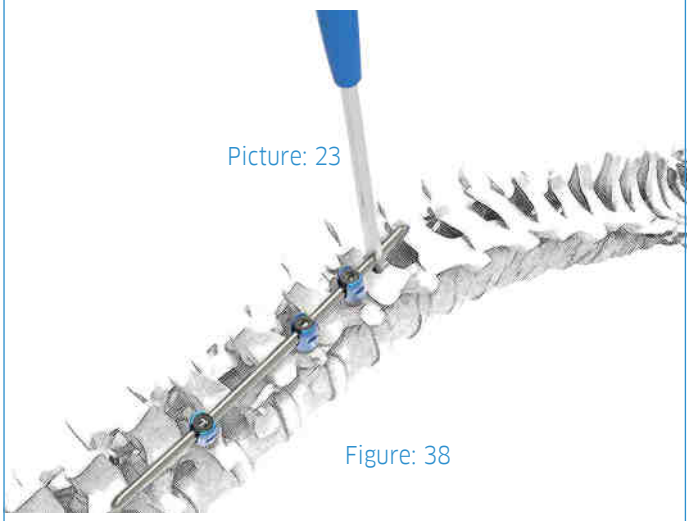
Rod Derotation

The rotational correction maneuver can be applied with the rod inserted into all of the implants and the Set Screws inserted but not tightened.

The rod may be rotated using the two Rod Rotation Forceps. In order to allow free movement of the rod, be sure that the Set Screws are only provisionally tightened.

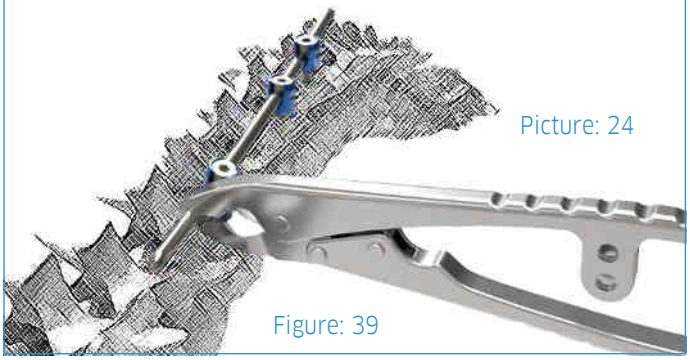
While the rod rotation maneuver is performed, The C-Ring instrumentation can be utilized to maintain hook position. Typically, the rod is then rotated to an arch of 90 degrees converting a scoliotic deformity in the thoracic spine into a sagittal kyphosis and translating a lumbar scoliotic deformity into lumbar lordosis. Once the rod has been fully rotated, the Set Screws are provisionally tightened. By further distraction/ compression maneuvers, additional deformity correction may be obtained (Figure 39 and 40).

The instrument to be used:
MSS.0026 Hexwrench-Rod Rotater (Picture: 23)
MSS.0014 Locking Power Rod Gripper (Picture: 24)



Picture: 23

Figure: 38



Picture: 24

Figure: 39

Option 1: Rod Rotation for implant approximation:

Contouring the rod in the sagittal plane to the desired shape is the rotation technique for approximation. The rod can then be inserted in the implants up to 90 degrees out of phase to minimize the implant approximation necessary. The rod is then rotated, not to derotate the spine, but to place the implants in the proper alignment.

Using distraction and compression techniques, final correction is erformed (Figure 39).

In - Situ Bending

In order not to overload the bone implant interface, being very careful is important during in situ bending. Acutely notching the rod may weaken the implant, so care must be taken also.

During rotation maneuvers or the compression / distraction process, the Set Screws should not be completely tightened.

Distraction / Compression

By creating a distraction in the concavity of the deformity and compression on the convexity of the deformity, spinal deformities can be further effected.

Note: Posterior distraction creates a kyphosis in the sagittal plane, compression creates a lordosis in the sagittal plane. Distraction can be achieved with the Spreader and Compression is achieved with the Compressor.

Lock the Set Screws with the Universal Tightener, when the construct is in the desired position.

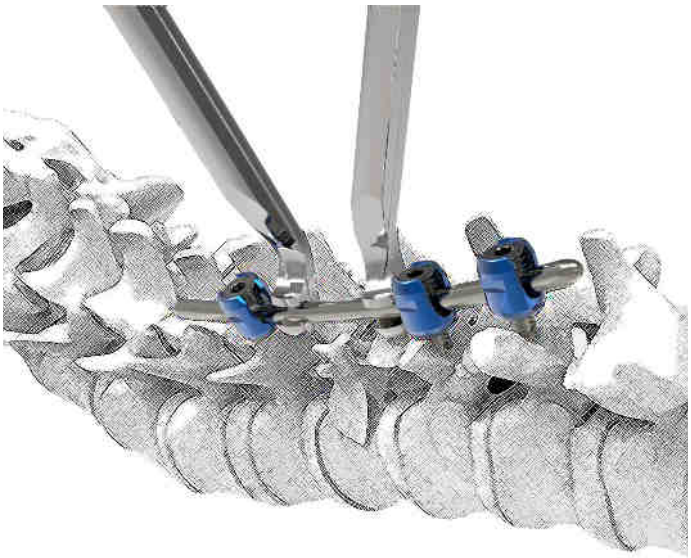


Figure: 40

The instrument to be used:
ARTFX123/124 In-Situ Bender (Left)
(Picture: 13)

Picture: 13

SET COMPONENTS FOR SCOLIOSIS REDUCTION INSTRUMENTS

FIGURE 1

After the screw insertion to the bone and the rod placement, the Reducer Clip is connected to the head of the screw.

Designed with a space between its two clips, the reducer clip grips the screw and rod with precision to allow the reducer tower to be connected to the screw and Rod.

FIGURE 2

The Reducer Tower is inserted throughout the Reducer Clip, when the rod is positioned above the screw head.

The Modular Handle is used to lower it and seat it to the head of the screw and the rod afterwards.

LOWERING THE REDUCER TOWER AND INSERT SET SCREWS

FIGURE 3

The Modular Handle is placed on the top of the Reducer Tower, it is turned clockwise to lower the Reducer.

It is turned until the Reducer is connected to the head of the screw and the rod.

The Modular Handle is removed and The Tower Connector is placed.

FIGURE 4

Set Screw Application Through Reducer Tower

• A Set Screw is inserted using the Set Screw Holder through the cannulation in the Reducer Tower.

• All set screws are inserted and provisionally tightened in the construction.

• These steps are repeated for the subsequent screws.

• The set screw holder is removed from the reducer tower and it is replaced with the torque wrench.

Please do not make the final tightening, the rod should be semi-locked.

LOWERING THE REDUCER TOWER AND INSERT SET SCREWS

FIGURE5

Once the rod is fully seated in each screw head, the set screw driver is used to introduce the set screw into the tulip.

The Torque Wrench is guided down the length of the reducer tower and the handle is turned clockwise until the handle has been fully seated.

The final tightening of the set screws is made from the distal end of the construct to the proximal end.

Please note that the final tightening can be done before or after the segmental and/or the En bloc connectors are attached to the Tower connectors.

ATTACHING THE TOWER CONNECTOR

FIGURE6

The Tower connector is attached to the Reducer tower, and turned until it is locked.

Depending on the anatomy of the patient, you can choose to use the Segmental connector or the En Bloc connector or both of them.

The Segmental or En Bloc connector is attached to the Tower connector for segmental or En Bloc Derotation

ATTACHING/RELEASING THE TOWER CONNECTORS

FIGURE 7

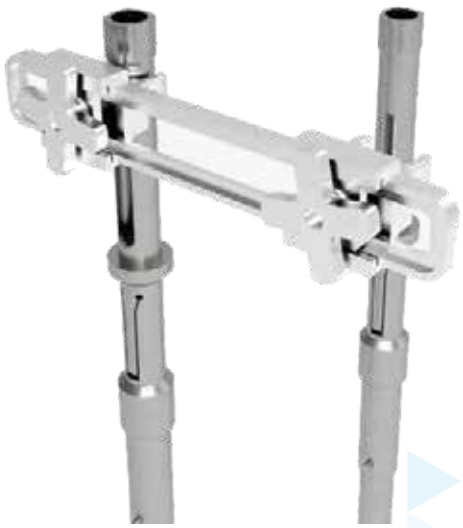
Using the segmental Connectors to bilaterally attach tower connectors, Direct Vertebral Rotation can be performed to the desired level.

The segmental Connector is attached to the proximal ends of the tower connectors by sliding a spherical interface over each reducer.

To adjust the medial/lateral size of the Segmental Connector, the rack is slid to the desired length, the position is locked by pushing the end button of the segmental connector, and its two sides are closed.

To adjust the trajectory of the tower connectors based on pedicle anatomy, the desired orientation is found and the lever is turned at each end of the segmental Connector, and it is turned until the spherical interfaces are tightened.

To remove Segmental Connectors from Tower connectors, the end button of the segmental connector is pushed and its two sides are opened.



CONNECTING THE REDUCER TOWER WITH THE DEROTATION FRAME

FIGURE 8

Using the End Bloc Connectors to vertically attach tower connectors, Direct Vertebral Rotation can be performed to the desired level.

The En Bloc Connector is attached to the proximal ends of the tower connectors by sliding its clips over each reducer.

To adjust the size of the En Bloc Connector, the rack is slid to the desired length, a clip is inserted and the knob is turned to lock the position.

To adjust the trajectory of the En Bloc connectors based on pedicle anatomy, the desired orientation is found and the clip knob is turned at each end of the En Bloc Connector turn until the spherical interfaces are tightened.

To remove En Bloc Connectors from Tower connectors, the knobs are turned until spherical interfaces are loosened around Tower connectors and the clips are removed.

ADDING MODULAR CLAMPS

FIGURE 9

Derotation Tube is used to adjust and orientate vertebras to the desired position.

The Derotation Tubes are connected to the head of the screws and the instrument is firmly compressed to reach the desired position of the bones.

Please note that the Derotation tube can be used without the Reducer Clip.

8. GENERAL INFORMATION

General

The ARTFX Spinal Fixation System is a top-loading, multiple component, posterior spinal fixation system consisting of polyaxial pedicle screws, rods and setscrews. The system allows surgeons and functions to build a spinal implant construction to stabilize and promote spinal fusion. Various forms and sizes of these implants are available, to ensure the construct to fit n particular patient anatomies.

The ARTFX Spinal Fixation System components are supplied clean, yet NON-sterile and for single use, and must be sterilized prior to use. Instruments should be cleaned and sterilized prior to use.

The implantable components of the Device, namely Polyaxial Pedicle Screws, Setscrews and Straight/Pre-bent Rods, are listed in 1 below.

Component Name	Part Number	Dimensions (mm)		Levels of Attachment
		Diameter	Length	
Polyaxial Pedicle Screw	ARTFX-xx**	4.5 - 8.0	20 - 100	Thoracic, Lumbar and Sacral
Setscrew	ARTFX-xx*	9	4.5	Thoracic, Lumbar and Sacral
Straight Rod	ARTFX-xx*	5.5	35 - 600	Thoracic, Lumbar and Sacral
Pre-bent Rod	ARTFX-xx*	5.5	35 - 200	Thoracic, Lumbar and Sacral

Table 1 - Components of the Device

Material

All components of the ARTFX Spinal Fixation System are manufactured from titanium alloy (Ti6Al4V-ELI) as perASTM F-136.

MRI Safety Information

The ARTFX Spinal Fixation System has not been evaluated for safety and compatibility in the MR environment. The ARTFX Spinal Fixation System has not been tested for heating or migration in the MR environment.

Intended Use

ARTFX Spinal Fixation System is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogeneous bone graft having implants attached to the noncervical spine.

ARTFX Spinal Fixation System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following indications of the thoracic and lumbar spine: Fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

Indications for Use

ARTFX Spinal Fixation System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogeneous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attachment of a solid fusion. ARTFX Spinal Fixation System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: Degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Contraindications

The type and size of the device is selected as per the overall assessment of the patient. The below-listed contraindications may be relative or absolute and when making this decision. The contraindications include, but are not limited to:

• The normal process of bone remodeling, i.e. severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis, is affected by any abnormality present.

• According to the W.H.O. standards, an overweight or obese patient can produce loads on the spinal system, which can lead to failure of the fixation of the device or to failure of the device itself.

• Rigid device fixation is reduced, if there is insufficien quantity and bone has inappropriate quality.

• Placing an unsafe load level on the device during the healing period, any neuromuscular deficit

• Inadequate tissue coverage of the local area of the Patients.

• Too much inflammation n local area.

• Infection occurred previously.

• Pregnancy.

• Open wounds.

• Substance abuse, senility, mental illness, etc. may cause failure and other complications. As because the patient may ignore certain necessary limitations and precautions in the use of the implant.

• Body sensitivity of the patient. Certain tests should be applied, if any sensitivity of the material is doubted.

• The presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count etc. medical or surgical conditions may also prevent the potential benefit of spinal implant surgery.

The opportunity of a successful outcome may be reduced by these circumstances.

Adverse Effects

The patients should be made aware of the following probable adverse effects, and the possibility that a new surgery might be necessary to correct them, prior to surgery. These effects include, but are not limited to:

• Ineligibility or restriction of activity level and loads, as same as normal healthy bone.

• Disassembly, bending or breakage of any or all implant components.

• Fatigue fracture of spinal fixation devices,including screws and rods.

• Pain, discomfort or abnormal sensations.

• Pressure on skin from components with the potential extrusion through the skin.

• Dural leak.

• Loss of proper spinal curvature, correction, height and/or reduction.

• Delayed union or non-union.

• Early mechanical or late loosening of spinal fixation implants.

• Trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.

• Nerve damage, peripheral neuropathies, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop.

• Serious complications as genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.

• Neurological, vascular, or soft tissue damage due to movable nature of fracture, or surgical trauma.

• Distraction or stress shielding of the graft or fusion massdue to inappropriate or improper surgical placement of the device.

• Failure of an adequate fusion mass with the contribution of improper placement.

• Decrease in bone density due to stress shielding.

• Intraoperative fissure, fracture, or perforation of the spine due to implantation of the components.

• Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery due to trauma, the presence of defects, or poor bone stock.

• Reoperation or revision may be necessary for the adverse effects.

Warnings

• ARTFX Spinal Fixation System components have not been tested for heating or migration in MR environment.

• The safety and effectiveness of these devices for any other conditions are unknown.

• But the safety and effectiveness of pedicle screw spinal fixation 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 spondylolisthesis (grades 3 and 4) of the L5- S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

• The ARTFX Spinal Fixation System is not intended to be used without bone graft, which is required to provide additional spinal support.

• Use of this product without bone graft or in cases that develop into a non- union will eventually be unsuccessful.

• No posterior spinal fixation system can withstand body loads without the support of bone.

• In the event that bone is not provided to facilitate fusion, bending, loosening, disassembling, and/or breakage of the implant will eventually occur.

• The patients should be made aware that a successful result, as defined by reduced pain, increased function, and the establishment of solid fusion, is not always achieved in every surgical case.

• Proper patient selection will greatly affect the results. Patents who smoke have shown to have an increased incidence of non-union.

• These patients should be informed of this increased risk and counseled to discontinue tobacco use prior to and immediately after surgery.

• Obese, malnourished, and/or nerve paralysis are also poor candidates for spinal fusion.

• In addition to the above specified warnings and precautions, general surgical risks should be explained to the patient prior to surgery.

Note: The ARTFX Spinal Fixation System Surgical Technique Manual should be followed carefully, which includes important information about the proper usage of implants and instruments.

Selection of the Implant

Implant Selection and Use

• Appropriate size, shape and design of the implant for each patient is criitical for the success of the procedure.

• The overall assessment of each patient and selection of the proper implant accordingly are under the surgeon's responsibility.

• Overweight patients might cause extra stress/ strain on the implants, and result in metal fatigue and help to deformation or failure of the implants.

• So overweight patients may be responsible for additional

stress and strain on the device.

• The type of the implants is determined by the size and shape of the bone structures.

• The surgeon should take into consideration at the time of selection of the implants that there could be repeated stresses and strains during the implantation, and also in post-operative follow-up period and implants should be chosen according to.

• Before the bone graft has become completely combined, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants.

• At this stage some worse side effects may occur or the early removal of the osteosynthesis device may become indispensible.

• By shortening service life of the implant, unusual stress conditions may occur as a result of inappropriate selection, placement, positioning and fixation of t ese devices.

• If the surgical technique of each system necessitates, contouring or bending of rods or plates is rceommended.

• Adequate contouring instruments should be used for contouring of rods or plates. Incorrectly contoured rods/ plates, or repeatedly or excessively contoured rods/plates must not be implanted.

• Before starting the procedure, the surgeon is to be completely familiar with the surgical procedure, instruments and implant characteristics.

• The position and state of the implants and also the condition of the adjoining bone may be monitored and followed-up periodically.

Precautions

• Only experienced spinal surgeons with specific training in the use of this pedicle screw spinal system should perform the implantation of pedicle screw spinal systems.

• This is a technically serious procedure, as it comprises risk of serious injury to the patient.

• The physician/surgeon should consider the factors that could affect the system's performance as per the fatigue test results -such as implantation level, patient weight, patient activity level, patient's general condition, etc.

• Anyone using ARTFX Spine products can have a Surgical Technique brochure. It is advised that users ask an updated version, if brochures are published more than two years before the surgical intervention.

• Surgeons must follow the operational procedure defined in the Surgical Technique Manual provided by ARTFX, and he/ she shouldn't use the instruments to apply inappropriate stress on the spine or the implants.

• Surgeon must be careful not to deform the implants or incision, hit or score them with the instruments unless otherwise specified by the appropriate ARTFX Spine Surgical Technique for reducing the risks of breakage.

• When the instruments are used near vital organs, nerves or vessels, must be treated with extreme care.

• The instruments can be reused after decontamination, cleaning and sterilization, unless otherwise specified on the label.

• Components of competitive spinal fixation systems should not be used with components of the ARTFX Spinal Fixation System.

• Components of dissimilar material should not be used together due to the potential for accelerating the corrosion process by mixing of dissimilar materials.

• No component of the ARTFX Spinal Fixation System should be reused after being removed from the body. An implant should never be re-sterilized after contact with body tissues or body fluids

• Damage to the implant can occur if the clamping screw is overtightened.

• Do not tighten the clamping screw without using the countering instrument or screw head expansion can occur.

• Damage to the implant can occur when implant set screw is over torqued.

• Damage to the implant can occur if the repositioning instruments are positioned too high in relation to the implant.

• Always apply repositioning instruments (e.g. distraction and compression forceps) below the rod at the implant.

• Over insertion of Polyaxial screws of ARTFX Spinal Fixation System may result in contact between the polyaxial screw body and the bone surface. This contact may result in damage to the implant or instrumentation.

• During derotation, screw head expansion may occur if derotation Sleeves are not used.

• The implant can be damaged by spondylolisthesis repositioning through the clamping screw. Always use the rod persuader for spondylolisthesis repositioning.

Removal Of Implant & Disposal

• Designed to stabilize the operative site during the normal healing process, internal fixation devices are impermanent implants.

• Once healing occurs, there is no functional purpose for these devices and they can be removed.

• In such other cases, removal may also be recommended:

• reduction in bone density due to the different distribution of mechanical and physiological stresses and strains,

• migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions,

• pain or abnormal sensations due to the presence of the implants,

• failure or mobilization of the implant,

• infection or inflammatory reactions

• corrosion with a painful reaction.

• In order to remove the implants, ARTFX Spinal Fixation System Spine standard instruments can be used.

• If a physician decides to remove the internal fixatio device, it must take into consideration.

• There is the risk of another surgical procedure and the difficulty of removal

• The use of special instruments to disrupt the interface at the implant surface can be needed for removal of an unloosened spinal screw.

• Before attempting such kind of clinical operation, the technique may necessitate practice in the laboratory. In order to prevent fracture or refracture, correct postoperative management should be performed for the implant removal.

• Please apply disposal procedure for implants accordance with hospital rules.

Manual Cleaning/Disinfection

A manual cleaning and disinfection procedure, even when using an ultrasound bath, should generally be avoided and should only be used if an automatic process is not available, due to very low levels of efficiency. In addition, the manual procedure can be used to support automatic reconditioning, particularly in the case of heavily soiled instruments.

Recommended equipment: Commercially available cleaning agent authorised for medical products (pH value 9-11) or combined cleaning agent and; nylon brushes with soft bristles; running water.

Sterilization

The implants are supplied NON-STERILE to market. The implants must be sterilized with steam sterilization process.

Sterilization parameters:

Minimum 4 minutes @ 134 ° C, drying time: 15 minutes

The mentioned sterilization cycles are not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (t ime and t emperature)

Non-sterile symbol » 

must be on the packing

Packaging

The implants & instruments are supplied NON-STERILE. Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all components including instruments should be carefully checked to ensure that there is no damage prior to use.

Non-sterile products are packed by ARTFX Medical after ultrasonic washing process (for packing tyvek paper or plastic bags can be used)

Storage / Shelf Life

*Keep the implants dry and clean at room temprature under normal atmospheric pressure.

*Keep away from direct sun light.

** A shelf life is not determined for the ARTFX Spinal Fixation System products.

Glossary of Symbols:

A glossary of symbols showing the description for the symbols used in the package labels, given in Table A below, is included in the packages together with the package insert.

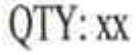
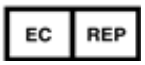
Symbol	Description
	Manufacturer
	Date of Manufacture
	Batch No
	Use by Date
	Catalogue Number
	Non-Sterile
	Single use only
	Do not use if packing is damaged
	Quantity
	EU Represantative
	Keep away from direct sunlight
	Consult instruction for use
	Professional Use Only

Table A - Glossary of symbols used in the package labels

ARTFX Medical Co. Ltd. has right to use the TS EN ISO EC certificate by the audit of Notified Body -UDEM- and 13485:2016 certificate by the audit of KGS Certification and also continue manufacturing according to the related standards.

ISO 13485:2016 Certificate No : SISTURMD032020102

Medical Devices Directive ANNEX II of 93/42/

CE 2292

MANUFACTURER:

EEC

ARTFX Medical

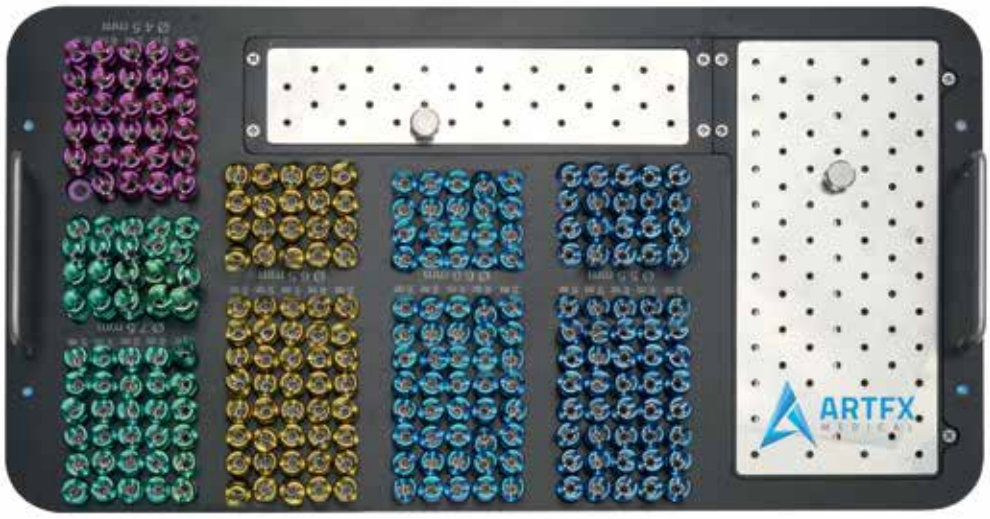
Address: 50 Laura St N 25th Floor

Jacksonville, FL 32202 U.S.A.

Web: www.artfxmed.com

THORACOLUMBAR POSTERIOR POLYAXIAL SET

THORACOLUMBAR POSTERIOR POLYAXIAL SET - TRAY I



CATALOG NO	Description	Qty
ARTFXSTRAY	Screw Tray	1

THORACOLUMBAR POSTERIOR POLYAXIAL SET - TRAY 2

CATALOG NO	Description	Qty
ARTFX088	Lysthesis Polyaxial Screw Driver	1
ARTFX089	Lysthesis Cutter	1
ARTFX090	Monoaxial Screw Driver	1
ARTFX091	Polyaxial Screw Driver	2
ARTFX092	Rocker	1
ARTFX093	Rod Rotator	1
ARTFX094	Straight Tester Probe	1
ARTFX095	Straight Tester ProbeWith Titanium Holder	1
ARTFX096	Curved Tester Probe	1
ARTFX097	Curved Tester Probe With Titanium Holder	1
ARTFX098	Open Set Screw Driver	2
ARTFX099	Tab 4mm	1
ARTFX100	Tab 5mm	1
ARTFX101	Tab 6mm	1
ARTFX102	T Handle Quick Coupling	1

ARTFX088
Lysthesis Polyaxial Screw Driver

ARTFX089
Lysthesis Cutter

ARTFX090
Monoaxial Screw Driver

ARTFX091
Polyaxial Screw Driver

ARTFX092
Rocker

ARTFX093
Rod Rotator

ARTFX094
Straight Tester Probe

ARTFX095
Straight Tester Probe With Titanium Holder

ARTFX096
Curved Tester Probe

ARTFX097
Curved Tester Probe With Titanium Holder

ARTFX098
Open Set Screw Driver

ARTFX099
Tab 4 mm

ARTFX100
Tab 5 mm

ARTFX101
Tab 6 mm

ARTFX102
T Handle Quick Coupling

THORACOLUMBAR POSTERIOR POLYAXIAL SET - TRAY 3

CATALOG NO	Description	Qty
ARTFX103	Bone Awl	1
ARTFX104	Connector Set Screw Driver	2
ARTFX105	Screw Holder	2
ARTFX106	Straight Probe	1
ARTFX107	Thin Straight Probe	1
ARTFX108	Thick Straight Probe	1
ARTFX109	Curved Probe	1
ARTFX110	Thin Curved Probe	1
ARTFX111	Thick Curved Probe	1
ARTFX112	Pin	3
ARTFX113	Pin With Stopper	3

ARTFX103
Bone Awl

ARTFX104
Connector Set
Screw Driver

ARTFX105
Screw Holder

ARTFX106
Straight Probe

ARTFX107
Thin Straight Probe

ARTFX108
Thick Straight Probe

ARTFX109
Curved Probe

ARTFX110
Thin Curved Probe

ARTFX111
Thick Curved Probe

ARTFX112
Pin

ARTFX113
Pin With Stopper

THORACOLUMBAR POSTERIOR POLYAXIAL SET - TRAY 4

CATALOG NO	Description	Qty
ARTFX114	Mallet	1
ARTFX115	I Persuader	1
ARTFX116	Compressor	1
ARTFX117	Distractor	1
ARTFX118	Rod Bender	1
ARTFX119	Rod Gripper	1
ARTFX120	L Anti Torque	1
ARTFX121	4NM Torque	1
ARTFX122	12NM Torque	1
ARTFX123	Instute Bender Left	1
ARTFX124	Instute Bender Right	1
ARTFX125	Open Connector Screw Driver	1

ARTFX114
Mallet

ARTFX115
I Persuader

ARTFX116
Compressor

ARTFX117
Distractor

ARTFX118
Rod Bender

ARTFX119
Rod Gripper

ARTFX120
L Anti Torque

ARTFX121
4NM Torque

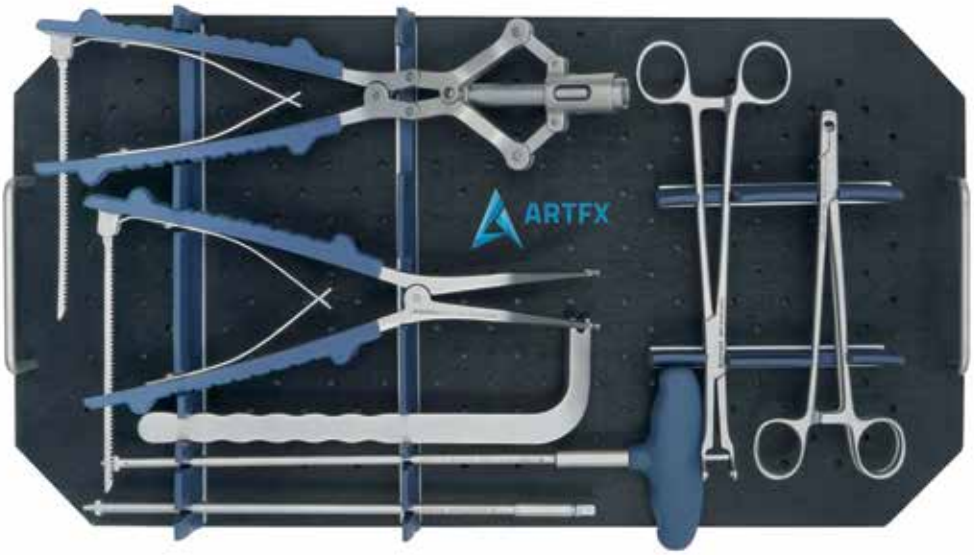
ARTFX122
12NM Torque

ARTFX123
Instute Bender Left

ARTFX124
Instute Bender Right

ARTFX125
Open Connector
Screw Driver

THORACOLUMBAR POSTERIOR POLYAXIAL SET - TRAY 5



CATALOG NO	Description	Qty
ARTFX126	Compressor	1
ARTFX127	Distractor	1
ARTFX128	Persuader	1
ARTFX129	Tulip Screw Driver	1
ARTFX130	Open Tulip Screw Driver	1
ARTFX131	Rocker	1
ARTFX132	Rod Holder	1
ARTFX133	L In Situ Bender Left	1
ARTFX134	L In Situ Bender Right	1

ARTFX126
Compressor

ARTFX127
Distractor

ARTFX128
Persuader

ARTFX129
Tulip Screw Driver

ARTFX130
Open Tulip Screw Driver

ARTFX131
Rocker

ARTFX132
Rod Holder

ARTFX133
L In Situ Bender Left

ARTFX134
L In Situ Bender Right

10. SURGICAL TOOLKITS-INSTRUCTIONS FOR USE

General

These instructions of use are valid for all ARTFX SPINAL FIXATION SURGICAL TOOLKITS (Aluminum Sterilizing Containers and accessories). ARTFX SPINAL FIXATION SURGICAL TOOLKITS are incompliance with ARTFX Spinal Fixation System Implants

1. Description

ARTFX SPINAL FIXATION SURGICAL TOOLKITS (Aluminum Sterilizing Containers and accessories) are reusable, metal, sterilization containers. They are designed for holding operating room instruments and/ or textiles during vacuumsteam sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions. (EN 285 ,EN 868-1, EN 868-8). Sterilization containers are consist of three main parts such lid,bottom and filter retainers. The sterilization containers should be handled by qualified personnel that are trained and instructed about sterilization containers,hospital hygiene and sterilization technology, in order to prevent damage to the containers,fasteners,seals and sterilization filters, during usage. This user manual describes important instructions on the proper usage and maintenance of ARTFX SPINAL FIXATION SURGICAL TOOLKITS, and possible hazards that could result from failure to observe the instructions.. Container lids are dark blue.

2. Filter System

ARTFX SPINAL FIXATION SURGICAL TOOLKITS (Aluminum Sterilizing Containers and accessories) are available with a unperforated base and perforated filter lid or with perforated bottom and lid (can be covered by a unperforated lid).

They are designed to be used with single use (disposable) filters or reusable textile filters.

It's necessary to use same type of filters dur ng usage of the containers.

In case of use of filters, which are not supplied from ARTFX Medical, the user must validate the permeability and barrier properties of the filters imself.

Filters;
Disposable single use paper sterilization filters have to be changed before each new sterilization. Long-term textile filters can be used for about 45-50 sterilization cycles.Visually deformed and dirty textile filter should not be used.

Permanent filters (PTFE) can be used for over 1000 sterilization cycle.

During storage after sterilization, in order to prevent damage (puncture,tear) to sterilization filters, sharp and pointed objects should not be placed on the containers. ARTFX Medical recommendes usage of safety lids on the containers during transportaion and the storage of the containers in order to prevent contamination risks that may be caused by such negative situations.

3. Control Before Usage

During storage, usage of metal sterilization containers is safer than other storage method of sterile materials regard to protection against contamination. Like all reusable equipment, however, the ARTFX SPINAL FIXATION SURGICAL TOOLKITS tough robust also needs to be treated with care in order to ensure that its protective qualities are preserved. The relevant personnel (including delivery and collection services) must therefore be familiar with the correct handling practices.

Caution: Careless handling or the use of inappropriate chemicals can cause damage on the containers, thereby putting at risk the

ability to attain and preserve sterility. ARTFX SPINAL FIXATION SURGICAL TOOLKITS therefore require regular visual and, if necessary, functional checks.If cautions and the instructions in the user manual is followed, containers may serve for 1000 sterilization cycle and seals may serve for 500 sterilization cycles.

Undamaged shape:

• Containers must be checked visually before each usage.

• Container bottoms, container lids and the surfaces where the seals sit must be free of dents and visible deformations.

• Do not use any spray,oil or solvents on the lid seals.

• The seal in the inner lid must be completely inserted and undamaged.If any kind of damage detected lids should not be used.

• When the container is closed, tray, lid and locking parts have to be stable. (No "wobble").

• Maintenance and repairs of the sterilizations containers must be carried out by qualified personnel. Do not atempt to carry out repairs on containers,lids, fasteners and seals yourself, in order not to jeopardize the safety in use of the containers.

Filters and Filter Retainers

These parts must show no visual deformations. These parts must also be checked visually and for their functionality before usage.Filters should cover all the perforation holes, properly. Filters retainers should function properly when mechanically checked and filter retainers should be easily attachable and detachable.

After any accident (such as a container being dropped on the ground), it is essential that the sterile container undergo a thorough check.

Make sure that filters and filter retainers are placed in to their places properly. "Click" sound that is heard while placing filter retainers by pressing on them indicates that locking is realized.

4. Safety Seal

It is recommended and required by DIN 58953/9 that containers are sealed in such a way as to prevent inadvertent opening of containers and to ensure that it is evident whether or not a container has been opened ARTFX SPINAL FIXATION SURGICAL TOOLKITS can be protected by disposable plastic seals (security seals), which, once attached, can be opened by breaking only.

5. Internal Packing

We recommend using ARTFX SPINAL FIXATION SURGICAL TOOLKITS with simple internal packaging (e.g. cloth wraps or drip sheets). These assist the final drying stage, allow a longer storage period according to DIN 58953/9, and makes aseptic presentation of the sterile goods possible.

The size of the cloth wraps should be calculated so that when they are unfolded all the external walls of the container can be covered.

As an alternative to reusable cloths, easily wrap able (nonwoven) disposable materials can also be used. In internal packing case we recommend, corner of the package materials should be fix with the adhesive tape. In this way the package cannot then open during sterilization and block the inlet and outlet filter holes of the container and raised flow pressure won't damage the container. Because of the problem associated with folding, the use of sterilization paper is not recommended. In order to prevent colors leaching and thereby staining the containers, non-colored materials (or in the case of green or blue cloths, previously washed sheets) should be used.

Caution: Never sterilize the container wrapped in additional packaging. Apart from the risk of lack of sterility, the increased flow resistance could impair the sterilization effect (non-sterility) or even destroy the container.

6. Sterilization Operational Limits

In order to ensure that the lid can close properly, sterilization containers must not be filled above the level of the lower ridge of the edge indentation on the container bottoms.

The lid must lie flat on the lower section without being forced and so that it does not wobble even when the claps are open. It must also be possible to close the claps without additional pressure on the lid.

In the case of instrument sterilization,the load weight (including perforated tray) should not exceed 10 kg for 1/1 size containers. Load weight should be 5kg for 1/2 size containers and smaller loads should be arranged for smaller containers (DIN 58953/9).

• With cloth loads (or similar), the load weight should not exceed 7-8 kg. Make sure that folded textile or cloth loads are placed horizontally in containers (DIN 58953/9). When using internal packaging (nonwoven or cloth), care should be taken that the correct closing of the lid is not impeded, for example, by a protruding corner of the packaging.

• ARTFX SPINAL FIXATION SURGICAL TOOLKITS (Aluminum Sterilizing Containers and accessories) to be used together with ARTFX Spinal Fixation System implants must be sterilized prior to use as per the instructions and parameters below:

After being washed and dried properly, the hand tools should be checked for their proper shape and functions before each use and the sterilization process. The tools should be taken out of any package and placed in the ARTFX Spinal Fixation System toolkit boxes. All tools must be left assembled in the boxes, unless marked to state otherwise on them.

Once all components are prepared, the boxes must be placed in the autoclave and sterilized as per the parameters below:

Method	Autoclave Cycle Type	Temperature	Minimum Exposure Time
Steam (Moist Heat)	Pre-vacuum	134°C	4 minutes

Caution: For example, there is a risk of non-sterility if protruding cloth corners prevent the container from closing correctly.

Caution: If the sterilization procedure causes sterilization containers to become deformed in any way, then there is no guarantee of sterility. In such cases, the entire batch must not be used, they should be sterilized again and an investigation should be started to determine the cause.

• In order to prevent damage to the parts of the container and/or its load, we recommend that the container should be transported with its lid closed whenever possible.

7. Placing Into Sterilizers

Serilization containers are made for use in general steam sterilizers (EN 285). Make sure that heavier containers are placed at the bottom of the sterilization chamber, first. The containers are designed that they can be stacked during sterilization. In order to prevent accidents and mechanical damages on the containers it is important to work very carefully with the stacked containers.To prevent condensation collecting on one side (and thus causing drying problems), the containers should be placed horizontally in the sterilizer.

The loading instructions of the sterilizer manufacturer should aslo be observed.

8. Data Cards / Indicators

We recommend use of information cards with chemical sterilization indicators in the outer holding frame of the containers (DIN58953/9).

9. Caution

If chemical sterilization indicators are not used, then other organizational measures should be taken to ensure validation of the sterilization and non-sterile-containers being used(released) by ismtake.

10. After Sterilization

To safeguard against accidents (burns, dropping, etc.), containers that are still hot should never be handled with bare hands. The containers should not be cooled to room temperature too rapidly (e.g. do not place on cold surfaces or

expose to a cold draught), as excessively rapid external cooling can lead to recondensation of the water vapour inside the container with an unwanted accumulation of condensation.

11. Storage / Transportation

In practice sterility can be maintained for unlimited period with proper packaging, during storage in controled hospital storage room conditions (temperature, humidity, air filtration etc. controled). Acceptable storage period should be determined by responsible hygiene personnel. Requirments and suggestions of DIN 58953-9 should be taken under consideration while determining storage time and storage conditions. Depending upon storage duration and conditions, however, external contamination occurs, and this represents a potential risk during subsequent use, transport and aseptic presentation. According to DIN 58953/9 this risk factor can be reduced by the following measures:

• The use of internal packaging.

• Storage under dust protected conditions. The recommendations of DIN 58953-9 on limitation of storage period.

• Containers with internal packaging, protected storage up to:6 months.

• Containers with internal packaging, unprotected storage up to: 6 weeks.

• Containers without internal packaging, protected storage up to: 6 weeks.

• Containers without internal packaging, unprotected storage use “as soon as possible”

* Storage Media Conditions,

• Temperature: -20°C to +50°C.

Atmospheric Pressure : 50-106 kPa

Relative Humidity : 0- 75 % , non-condensing

12. Special Cases

When storing or transporting sterile containers under nonstandard conditions (e.g. in case of getting sterilization service for containers from places such as central sterilization departments), then internal packaging and transport packaging should be used to reduce the contamination risks that are associated with outer environment conditions.

13. Aseptic Presentation

If containers are to be opened after a long period of storage or after storage under non-ideal conditions, then we recommend wiping the unperforated cover with a disinfectant before handling in order to minimize the risk of contamination by air-borne particles.

14. Cleaning And Disinfection

Requirments according to DIN 58953/9 ;

• Users have to specify by means of a disinfection and cleaning plan, when and how the sterilization containers have to be cleaned and/or disinfected.

• Containers used for waste disposal have to be cleaned and disinfected each time after use.

• Cleaning materials shoul be suitable to available water quality in hand.

Manual Cleaning

• Only use neutral cleners or neutral cleaners and disinfectants for cleaning.

• Do not use metal brushes or cleaning materials that may cause chemical or physical corrosions.

• All part must be rinsed with demineralised water without leaving any stain or residue on them and dried by hand and stored.

Mechanical Cleaning

• Mechanical cleaning of the containers is to be prefered to manual cleaning.

• Cleaning of the containers with machines is only recommended if the washing machine has a special washing program for aluminum containers.

• Only use neutral cleners or neutral cleaners and disinfectants for cleaning. Do not use any cleaning solutions that contains soda or caustic soda.

• Do not use additional acidic neutralizers.

• Observe the instructions of the manufacturer of neutral cleaners and disinfectants for cleaning aluminum containers.

• Use demineralised water for final rinsing since salt in the water may cause spotting during subsequent sterilizations.

• Cleaning(washing) machine has to be designed for cleaning sterilization containers. This applies in particular to ensure secure replacement in the washing baskets and the arrangement of the spray jets or arms.

• Remove the lids and filter retainers before cleaning the containers and clean them individually.

e-catalog

ARTFX MEDICAL

www.artfxmed.com

50 Laura St N 25th Floor
Jacksonville, FL 32202 U.S.A.