HYDRA

Polyaxial Pedicle Screw System

Surgical Technique Guide

F320102-1_A

AURORA™

SIMPLIFYING THE COMPLEX

Contents

SIMPLIFYING THE COMPLEX

Aurora Spine, Inc.
1930 Palomar Point Way, Ste. 103
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aurora-spine.com

Implants

1125-xxxx
Mono Screw
(For 5.5 Rod)

1126-xxxx
Multi Axial Screw
(For 5.5 Rod)

1120-0550
Inside Hex Set Screw

1700-xxxx
Transverse Link

1125-xxxxL
Reduction Mono Screw
(For 5.5 Rod)

1126-xxxxL
Reduction Multi Axial Screw
(For 5.5 Rod)

1600-xxxx
Smooth Rod

Diameter from 4.5 to 7.5 mm

Length from 25 to 65 mm

Major Diameter

4.5 5 5.5 6 6.5 7 7.5

Screw specification

		Diameter (Dia)						
		4.5 mm	5.0 mm	5.5 mm	6.0 mm	6.5 mm	7.0 mm	7.5 mm
Length (L)	25 mm	●	●	●	●	●	●	●
	30 mm	●	●	●	●	●	●	●
	35 mm	●	●	●	●	●	●	●
	40 mm	●	●	●	●	●	●	●
	45 mm	●	●	●	●	●	●	●
	50 mm	●	●	●	●	●	●	●
	55 mm	●	●	●	●	●	●	●
	60 mm					●	●	●
	65 mm						●	●

Instruments

422-6600
Jamshidi Neddle

428-0302
Elastic Guide Wire

406-0201
Awl with Depth Stop

CBT-0401
Threaded Awl

406-0707
Sacral Awl

406-0301
Straight Probe

406-0302
Curved Probe

406-0401
Ball Tip Sounder

420-0511
Pedicle Marker Inserter

406-0101
Cannulated T-Handle

TR2-0545
T2 Solid Tap 4.5 mm

TR2-0555
T2 Solid Tap 5.5 mm

TR2-0565
T2 Solid Tap 6.5 mm

422-0104
T2 Cannulated Tap 4.5 mm

Instruments

422-0105
T2 Cannulated Tap 5.5 mm

422-0106
T2 Cannulated Tap 6.5 mm

406-0102
Ratcheting T-Handle

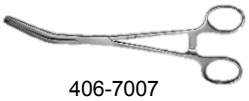
406-0103
Ratcheting Round Handle

TR2-0801
T2 Solid Screw Driver

TR2-0803C
T2 Long Cannulated Screw Driver

406-0120
Rod Template 120 mm

406-0200
Rod Template 200 mm



406-7007
Curved Rod Holder

406-1201
Rod Bender

406-0810
Rod Pusher

TR2-8003
T2 Screw Head Compress

406-1203
Rotation Wrench

406-7003
Rod Gripper

Instruments

TR2-9001
T2 Reduction Clamp

TR2-8002
T2 Nut Holder T27

406-7005B
Compressor

406-7006B
Distractor

TR2-3003
T2 Anti-rotational Wrench

406-7009
13 Nm Torque Wrench

TR2-7001
T2 Nut Driver T27

TR2-3300
T2 Long Arm Breaker

TR2-0811
Solid Screw Adjustment Driver

428-0800
Cannulated Screw Adjustment Driver

406-0008
Case for Implant 1 Level Tray

406-0004
Case for Instrument incl. 2 Level Tray

406-0303
Straight Probe with Depth Stop

Instruments

406-0702
Depth Gauge

406-7004L
In Situ Bender-Left

406-7004R
In Situ Bender-Right

407-0504
4 Nm Torque Wrench

407-0830
3 mm Hex Screwdriver

Surgical Technique Steps

A. Preparation Of The Pedicle Canal

When preparing the pedicle, avoid damage the neural and vascular structure. Precaution not to penetrate the wall of the pedicle with any instrument.

1

Determine the angle of entry and penetrate the pedicle cortex with an **Awl (406-0201)** to mark that position.

406-0201
Awl with Depth Stop

2

Using a pedicle probe, gently deepen the hole through the soft cancellous bone to the desired depth.

Note :

If a change in resistance to the probe is encountered at any time, the probe is probably misdirected. The use of image intensifier to confirm the probe's location in both AP and lateral views is recommended.

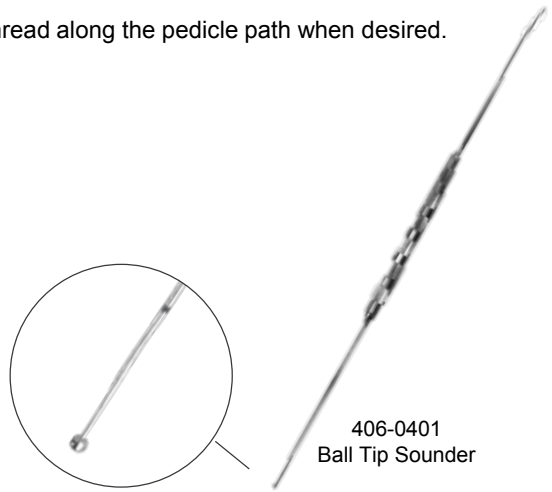
406-0301
Straight Probe

406-0302
Curved Probe

3

The **Ball Tip Sounder (406-0401)** is used to confirm whether the path is in the pedicle.

A Tap may be used to prepare the screw thread along the pedicle path when desired.



406-0401
Ball Tip Sounder

4

Use the Tap (4.5 mm、5.5 mm 、6.0 mm)

Create the thread to prevent the screw from being biased.

TR2-0545
T2 Solid Tap 4.5mm

TR2-0555
T2 Solid Tap 5.5mm

TR2-0565
T2 Solid Tap 6.5mm

B. Pedicle Screw Insertion

Step 1 : Selection of the screw

Select the appropriate screw sleeve for the multi axial screw.

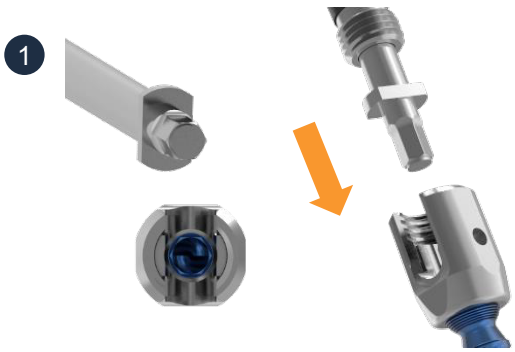
(TR2-0801)

TR2-0801
T2 Solid Screw Driver

Step 2-1 : Holding screw

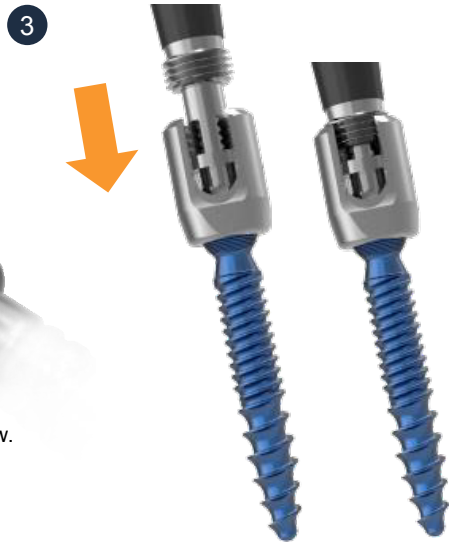
Turn the knob for locking.

Push down the knob to tighten the screw.



Holding the screw.

Turn the knob to lock the screw.



Push down the sleeve to lock the screw.

Step 2-2 : Insertion of the pedicle screw

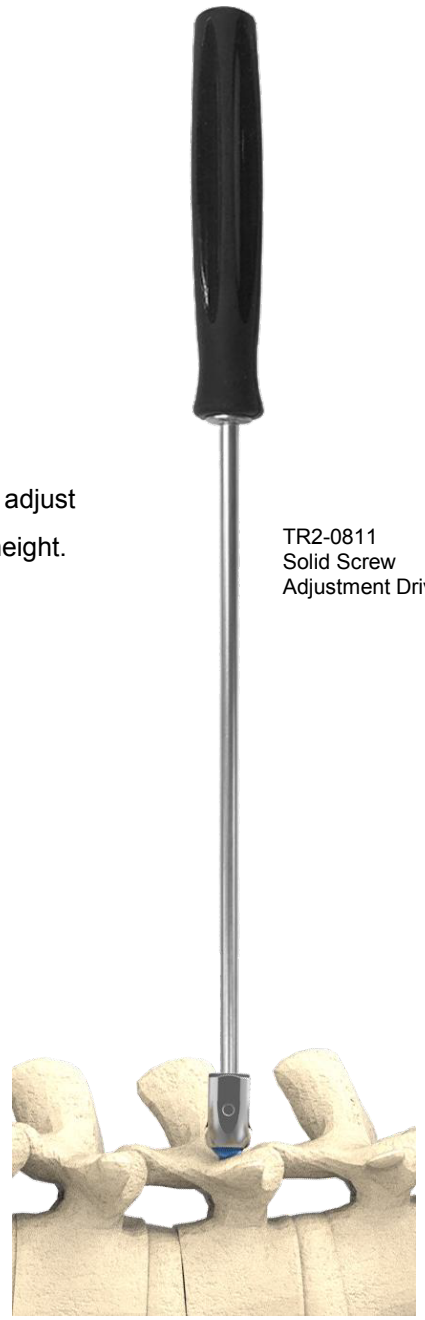
The tip of the screw is aligned with the entry point and can only be pressed by the fingertip force. If the vertebral body have spondylolisthesis or deformities, please use long arm reduction screw to achieve corrective effect.

Rotate the T-Handle to tighten the screw.

Step 2-3 : Screw adjustment

Use the **Solid Screw Adjustment Driver (TR2-0811)** to adjust the height of all screws and make them with the similar height.

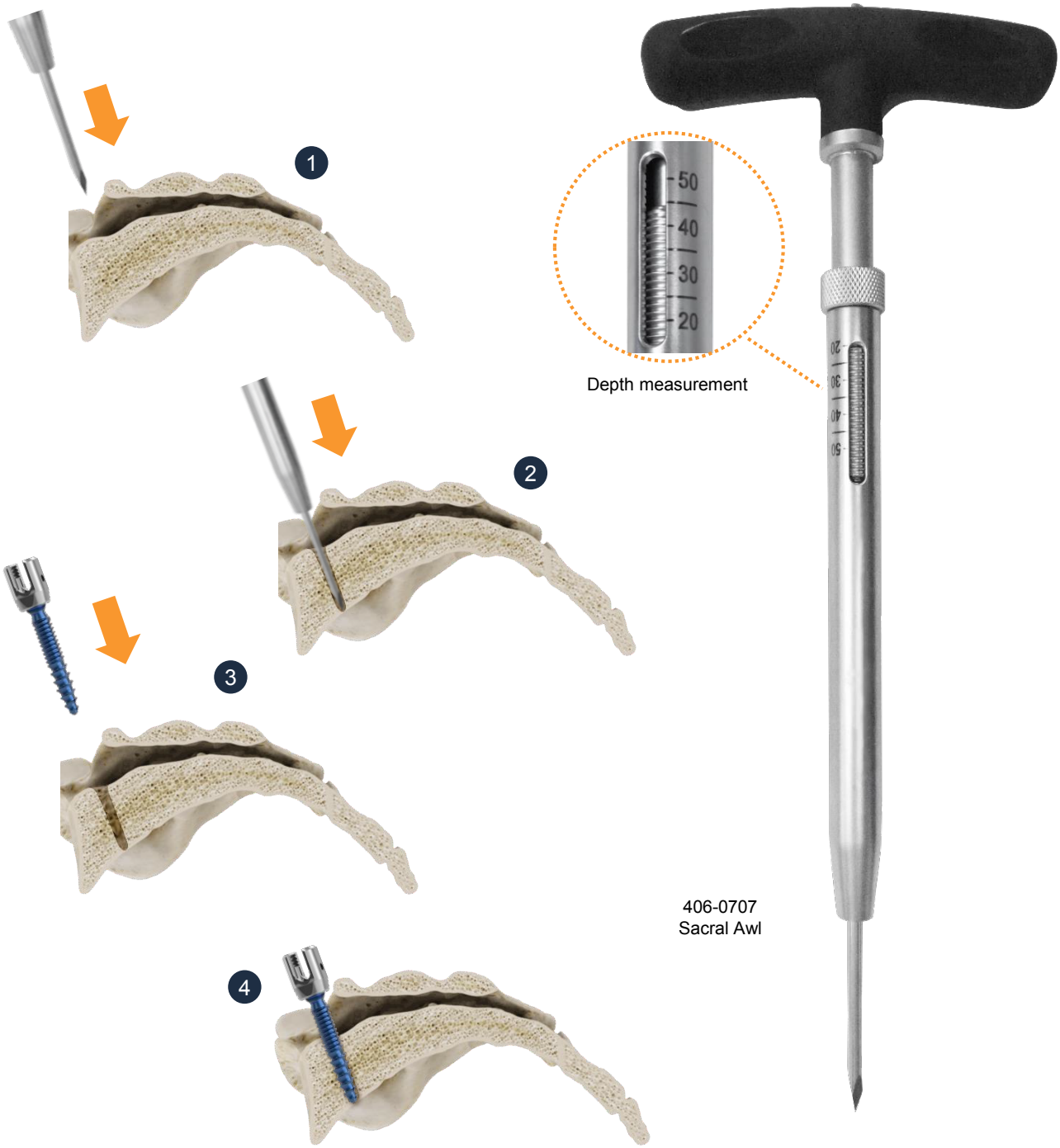
Holding the screw.



TR2-0811
Solid Screw
Adjustment Driver

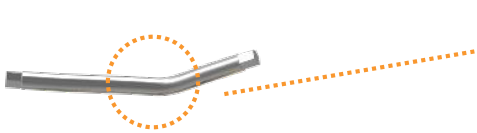
Caution:

For inserting pedicle screw into the S1 body, the optimal screw position follows the path with entry located at the inferior border of L5-S1 facet joint. The screw is advanced medially (inward direction) paralleling S1 endplate and converging with the other screw at the anterior mid-line of S1 vertebrae

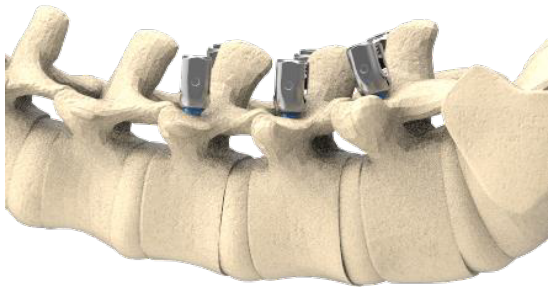


Step 3 : Measure the rod size

Rod Template (406-0120 or **406-0200)** to measure the proper length and curvature.



Length measurement



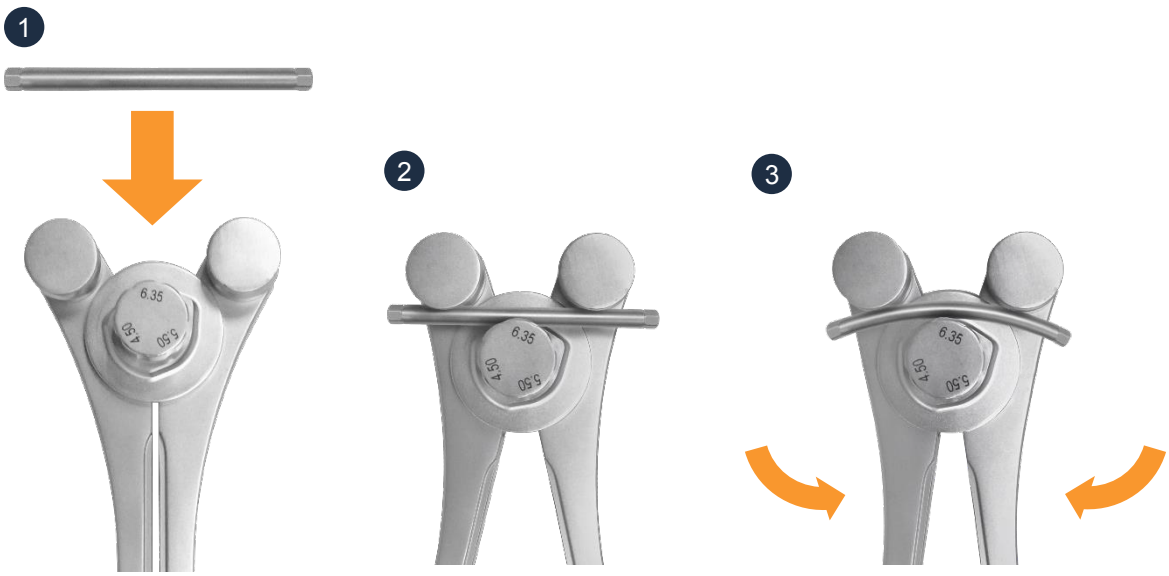
406-0120
Rod Template 120 mm

406-0200
Rod Template 200 mm

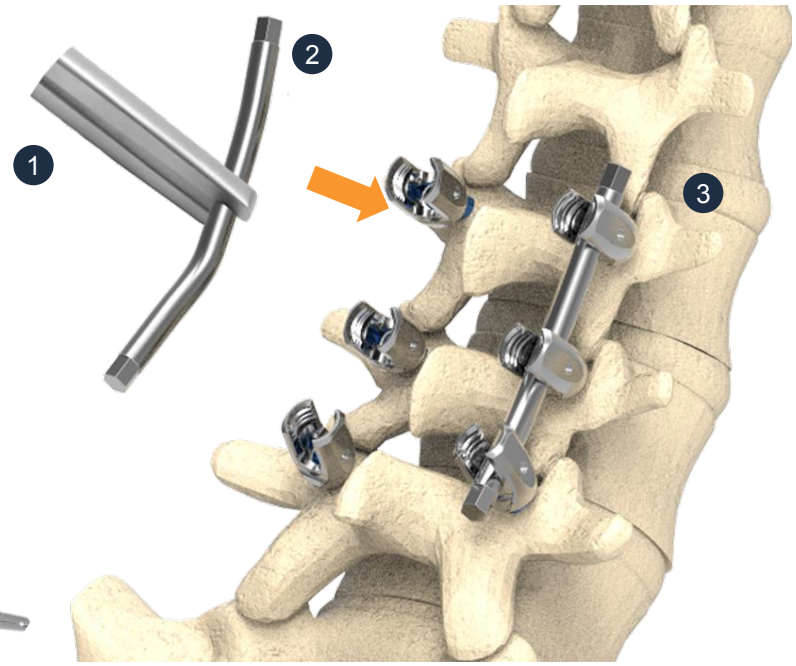
Step 4 : Use Rod Bender (406-1201) for bending rod at proper curvature

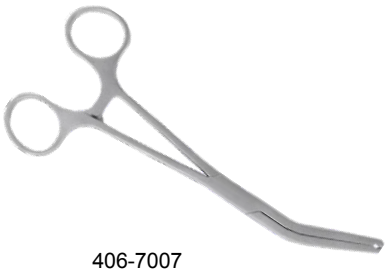
Place the rod on to Rod Bender.

Squeeze the handle to bend the rod.



Step 5 : Placing the rod on the screw





406-7007
Curved Rod Holder

Step 6 : For rotating and bending the rod if necessary (already assembling with screw)

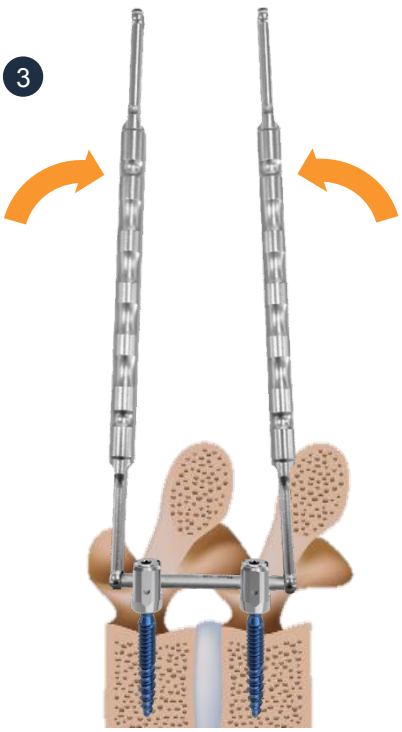
1

Use the bender to hold the rod at each hexagonal end.

2

Bend the tools inward at both end of the rod.

3



Fold the bender inward.

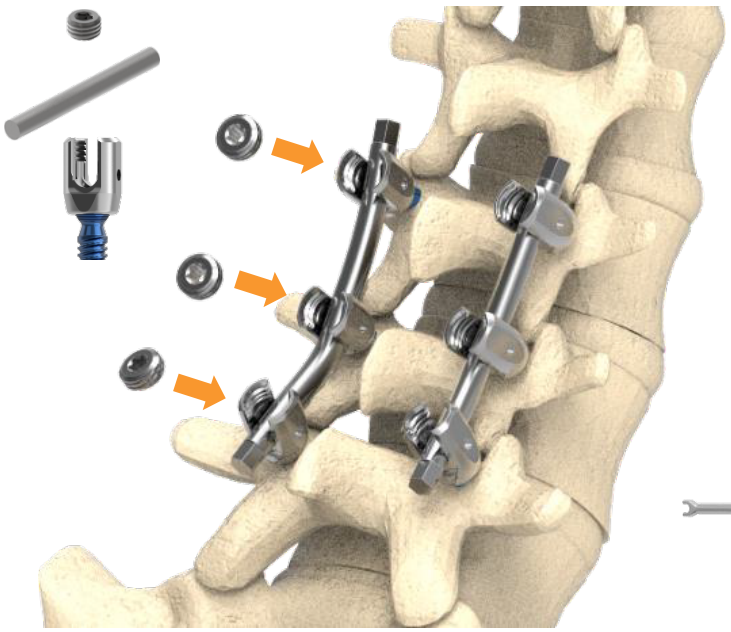
C. Tightening

Step 1 : Initial locking

Use **Nut Holder (TR2-8002)** with **T-Handle (406-0101)** to hold the nut.

Then use the **Anti-Rotational Wrench (TR2-3003)** (prevent the screw head form rotating) then insert **Nut Driver (TR2-7001)** + **T-Handle (406-0101)** for tightening the nut.

1

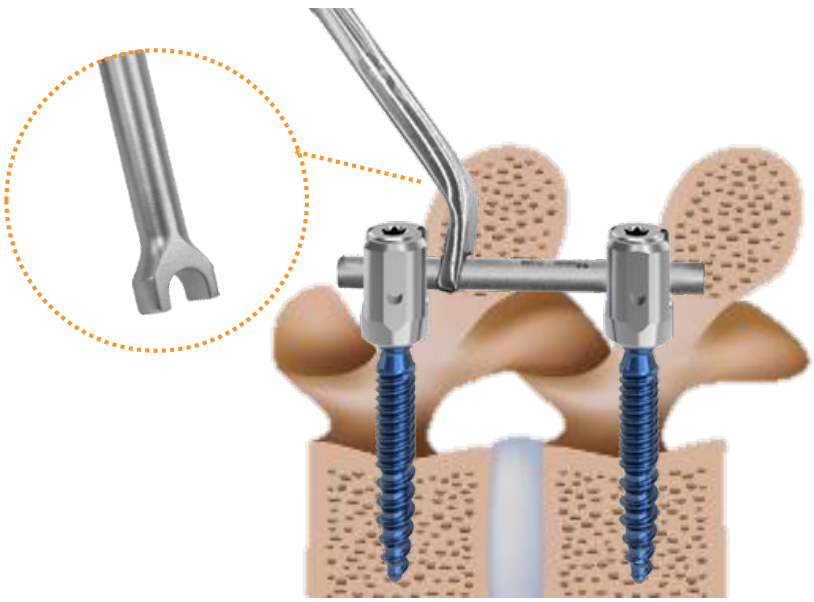


TR2-8002
T2 Nut Holder T27

TR2-3003
T2 Anti-rotational Wrench

406-0810
Rod Pusher

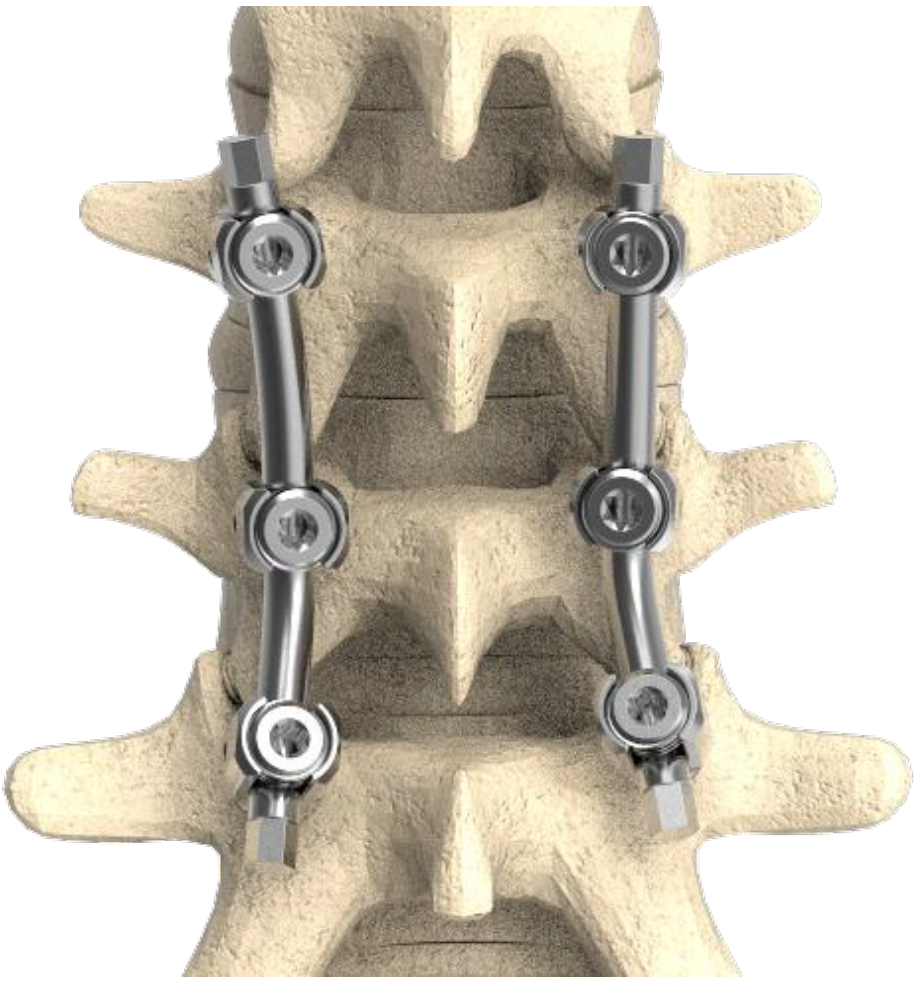
2 Use **Rod Pusher (406-0810)** to press the rod downward towards the pedicle screw, which makes the locking easier.



Important notice :

Use **13 Nm Torque Wrench (406-7009)** with Nut Driver for final lock.

Note: Don’t turn it too tight to avoid damage to the pedicle due to screw rotation.

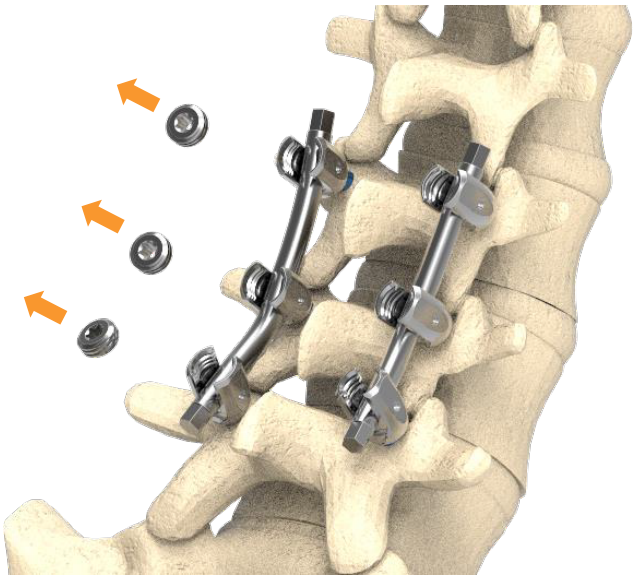


406-7009
13 Nm Torque Wrench

D. Removal procedures

Use **T2 Nut Driver T27 (TR2-7001)** with **Cannulated T-Handle (406-0101)** to engage the nut and remove it from the pedicle screw.

1



Use **Curved Rod Holder (406-7007)** to remove the rods.

2

Use **T2 Solid Screw Driver (TR2-0801)** with **Cannulated T-Handle (406-0101)** to back out and remove the pedicle screw.

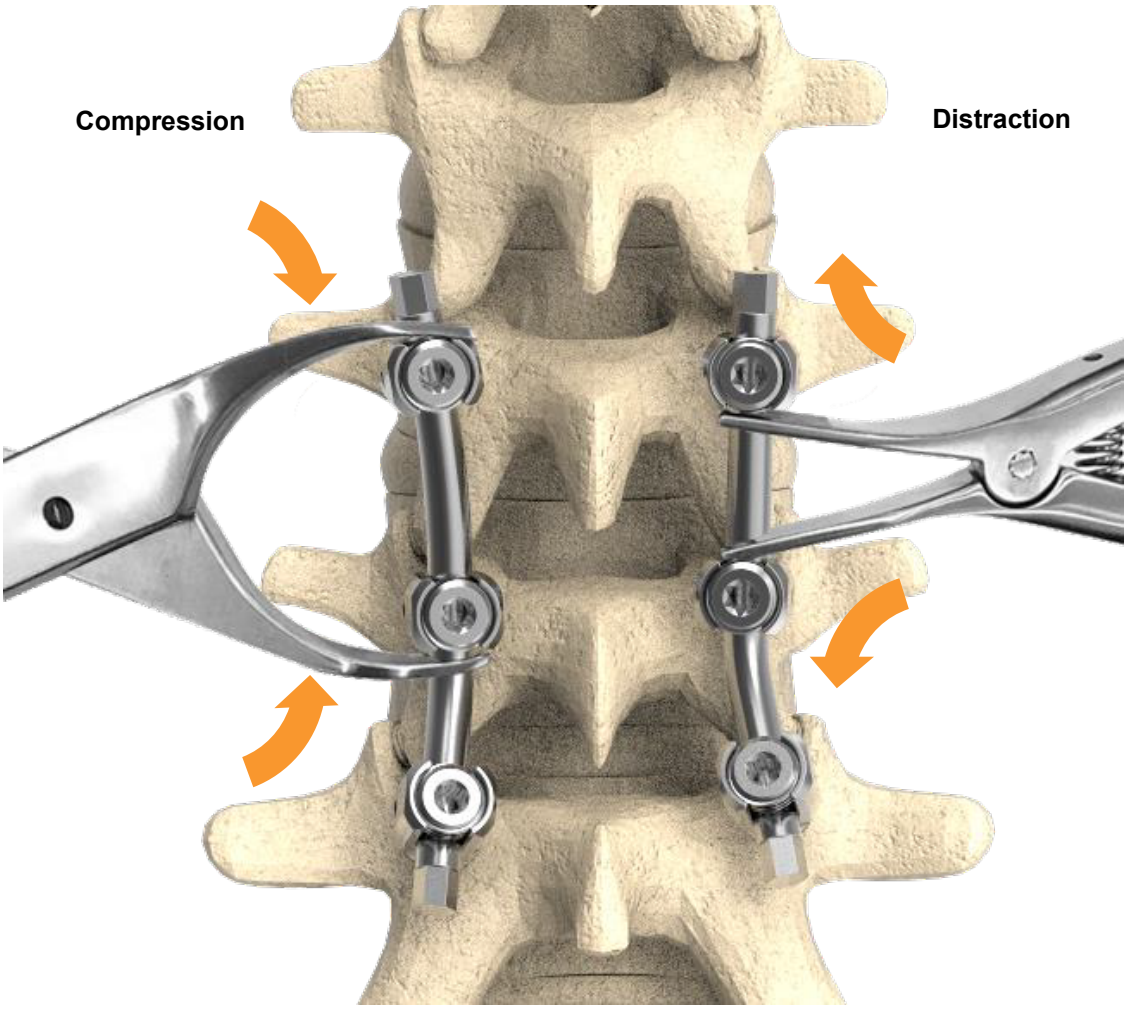
3

E. Reduction Procedures Of The Scoliosis

Compression or Distraction distance between screws before locking.

Compression - Distraction

Subject to the clinical judgement, compression and distraction are carried out at both sides at the same time by using a **Compressor (406-7005B)** or **Distractor (406-7006B)**. The lock screws are subsequently tightened.



406-7005B
Compressor

406-7006B
Distractor

Hydra® Polyaxial Pedicle Screw System - Part Numbers

Part #	Description
40265-035	6.5mm DIA x 35mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40265-040	6.5mm DIA x 40mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40265-045	6.5mm DIA x 45mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40265-050	6.5mm DIA x 50mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40275-035	7.5mm DIA x 35mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40275-040	7.5mm DIA x 40mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40275-045	7.5mm DIA x 45mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40275-050	7.5mm DIA x 50mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40280-035	8.0mm DIA x 35mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40280-040	8.0mm DIA x 40mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
40280-045	8.0mm DIA x 45mm, HYDRA CANNULATED POLYAXIAL PEDICLE SCREW ASSY
41155-035	HYDRA ROD, PRE-BENT, 35MM
41155-040	HYDRA ROD, PRE-BENT, 40MM
41155-045	HYDRA ROD, PRE-BENT, 45MM
41155-050	HYDRA ROD, PRE-BENT, 50MM
41155-051	HYDRA ROD, PRE-BENT, 75MM
41155-052	HYDRA ROD, PRE-BENT, 75MM
42155-125	HYDRA ROD, 125MM
42155-450	HYDRA ROD, 450MM
43100-000	HYDRA SET SCREW

Important Information for HYDRA® Spinal Fixation System

Please read these instructions for use, and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Description
HYDRA® Spinal Fixation System is a pedicle screw fixation system.

Material

Material	Standard
Ti6Al4V	ASTM F136, ISO 5832-3

Intended use
HYDRA® Spinal Fixation System is an internal spinal fixation system comprised of pedicle screws, rods, transverse link, connectors and hook fixation system (T1-S1) and designed to provide immobilization of the spine in skeletally mature patients.

Indications
- Degenerative disc diseases
- Spondylolisthesis
- Tumors
- Fractures
- Spinal deformities
- Failed previous fusion

Contraindications
- Osteoporosis
- Morbid obesity
- Pregnancy
- Suspected or documented metal allergy or intolerance
- Active systemic infection
- Mental illness

Side effects
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common may include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, side effects associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones, discs, or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, partial displacement of the graft, vertebral angulation.

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user. Contaminated implants must not be reprocessed. Any Aurora Spine implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Non-sterile implants

NON STERILE Non-sterile

HYDRA® Spinal Fixation System is supplied non-sterile. Implants must be cleaned and sterilized prior to use.

Recommendations for steam sterilization
Components of "HYDRA®" Spinal Fixation System are supplied clean and non-sterile. They are intended to be steam sterilized prior to surgery. Implants must be removed from packaging and placed in the sterilization tray before sterilization. Sterilization is recommended as follows: 121°C/250°F, 30 mins. The recommended sterilization cycles have been validated to assure a sterility assurance level (SAL) of 10^{-6}.

Removal of implant
All locking nuts must first be removed. Use the hexalobular driver to engage the locking nut and remove it from the pedicle screw. Using the small rod holder, disengage the rod from the pedicle screws. Then, using the inner hexalobular driver, back out and remove the polyaxial screw. If the inner driver cannot engage with the screw shaft, then use the revision driver assembly to back out and remove the screw..

Precautions
- Surgical implants must never be reused.
- Correct handling of the implant is extremely important.
- Adequately instruct the patient.
- Preoperatively: The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications of this type of implant. The surgeon must have acquainted himself before the operation with the specific technique for insertion of the product which is available from the manufacturer. As part of the preoperative examination the surgeon must check that no biological biomechanical or other factors will affect the correct conduct of the operation and the postoperative period. An appropriate range of implant sizes must be available at the time of the operation.
- Intraoperatively: The correct selection of the size of implant appropriate to the patient and the positioning of the implant are extremely important.
- Postoperatively: Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that regular postoperative follow-up is undertaken to detect early signs of failure of the implants and to consider the action to be taken.
- "HYDRA®" Spinal Fixation System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment and not been tested for heating or migration in the MR environment.

The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the corresponding surgical techniques.

Warnings
It is strongly advised that "HYDRA®" Spinal Fixation System is implanted only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical techniques.
Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

Important Information for HYDRA® Spinal Fixation System

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

Caution
This device is restricted to sale by or on the order of a physician.

Symbols and definitions

	Non-sterile		Manufacturer
	Do not re-use		Date of manufacture
	Do not use if package is damaged		Batch code
	Use-by date		Catalogue number
	Caution		Consult instructions for use

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