SURGICAL
TECHNIQUE

INNOVERSE™
SPINAL SYSTEM

Optimized. Hybrid Quad/Double Lead Thread pattern with Triple Fluted Cutting Tip incorporating both cortical and cancellous zones, allows for rapid screw insertion.

Flexibility. Versatility in rod selection: Compatible with 5.5mm and 6.0mm rods in both CoCr (Cobalt Chromium) and Titanium, offering flexibility in construct design.

Diversity. Wide range of screw sizes: Available from ø4.5 to ø9.5mm, accommodating various anatomical requirements.

For detailed product descriptions, scan the QR code.

CG MedTech

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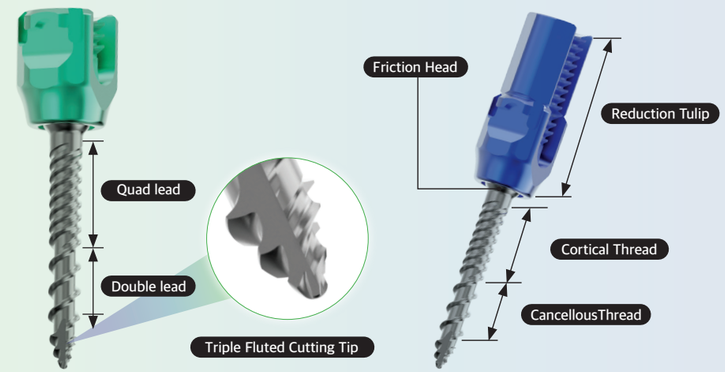
SYSTEM OVERVIEW

The INNOVERSE Spinal System is a versatile posterior spinal fixation system designed for flexibility, accommodating both 5.5mm and 6.0mm rods made from titanium alloy and CoCr. It features self-tapping pedicle screws that ensure efficient insertion and strong fixation. The system is available in various sizes, allowing for customization to meet individual patient needs while supporting spinal stability and fusion.

Key aspects of the system include dual rod diameter compatibility, which provides flexibility in rod selection for optimal spinal support and simplifies revision procedures. The Double and Quad Lead Thread design accelerates screw insertion, helping to reduce surgery time. Additionally, the dual-threaded pedicle screws combine fine proximal threads for cortical bone with coarse distal threads for cancellous bone, ensuring optimal fixation throughout the spinal construct.

IMPLANT FEATURES



▶ Optimized

Hybrid Quad/Double Lead Thread pattern with Triple Fluted Cutting Tip incorporating both cortical and cancellous fixation, allows for rapid screw insertion.

▶ Flexibility

Versatility in rod selection: Compatible with 5.5mm and 6.0mm rods in both CoCr (Cobalt Chromium) and Titanium, offering flexibility in construct design.

Diameter (mm)	Length (mm)
4.0~6.5	25~60
7.0~8.5	25~95

▶ Diversity

Wide range of screw sizes: Available from ø4.5 to ø8.5mm, accommodating various anatomical requirements.

SURGICAL TECHNIQUE GUIDE _ SITE PREPARATION

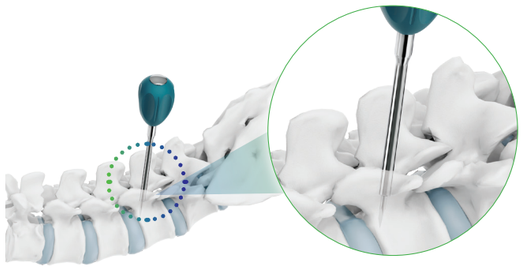


Fig. 1 ▲

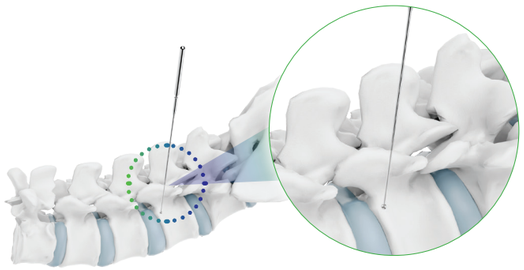


Fig. 3 ▲

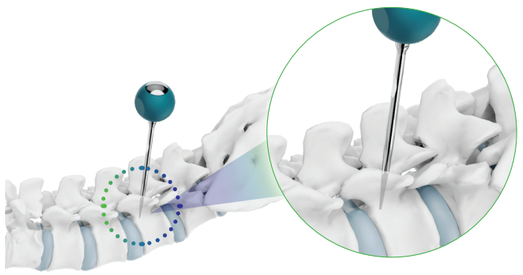


Fig. 2 ▲

Identify the correct anatomical landmarks for creating an entry point for the pedicle screw pilot hole.
Once the entry point is identified, penetrate the cortical bone using the AWL and create a pilot hole (Fig. 1).

Determine the pedicle canal entry site. Insert the PROBE into the established entry site, gently pressing through the pedicle canal to determine hole depth (Fig. 2). (Use the probe-straight or curved to the desired depth in the pedicle canal, gently press through the pedicle canal using the depth marking as a guide.)
It is important that the appropriate cephalad/caudad and converging angles are observed when engaging the PROBE. Apply slight downward pressure while rotating back and forth to advance the PROBE into the pedicle and down into the anterior column.

Insert the TESTER to palpate the hole's inner surface to verify pedicle wall integrity (Fig. 3).

Instruments

NP0010	AWL
NP0230	PROBE - STRAIGHT
NP0240	PROBE - CURVED
NP0200	TESTER - STRAIGHT
NP0210	TESTER - CURVED

TAP

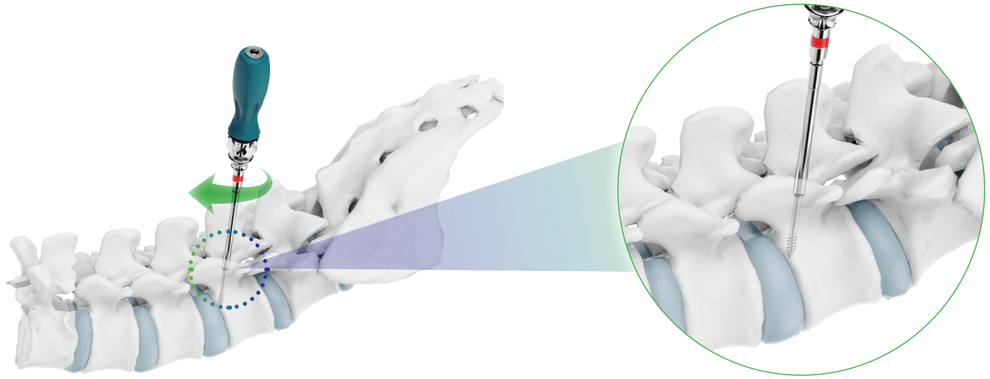


Fig. 4 ▲

Polyaxial/Monoaxial screws are fully threaded and have a self-tapping feature designed to eliminate the need to tap the pedicle canal (Fig. 4).

In many situations where patient bone quality is compromised or where there is a dense cortical layer, it may be necessary to utilize one of the size-specific taps in the INNOVERSE Spinal System.

Taps are undersized to ensure a press fit with the pedicle screw. Choose the appropriate diameter tap based on the diameter of screw to be implanted.

Attach the tap to the Ratchet Handle. And then Rotate the handle collar into the forward position and advance clockwise into the pedicle canal using marking lines on the tap as a guide (Marking lines start at 30mm with 10mm intervals).
Advance to desired depth, Rotate the ratcheting handle Collar in reverse, and remove the tap in counter-clockwise direction (Fig. 4).

Fig. 5 ▲

NOTE: ROTARY HANDLE FOR TAP can be used to prevent glove entanglement by assembling it on the tap shaft before using the tap (Fig. 5).

Instruments

NP0040 ~ NP0080	TAP Ø 4.0 ~ Ø 8.0
NP0160	ROTRAY HANDLE FOR TAP
GH1080	RATCHET I HANDLE

SCREW INSERTION

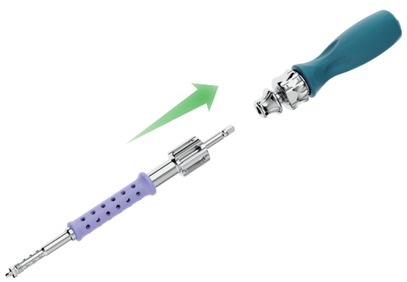


Fig. 6 ▲

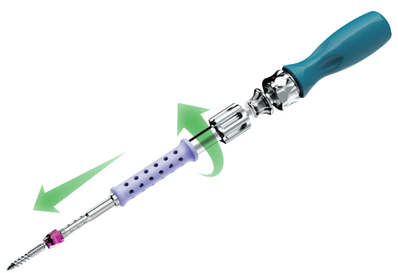


Fig. 7 ▲

Attach the RATCHET HANDLE to the appropriate SCREWDRIVER (Fig. 6).

Ensure that the distal HEX tip of the driver is fully seated into the female HEX on the pedicle screw shaft. Turn the knob clockwise to secure the pedicle screw to the screwdriver. (Fig. 7).

NOTE: Slowly insert to Polyaxial screw for screw alignment.

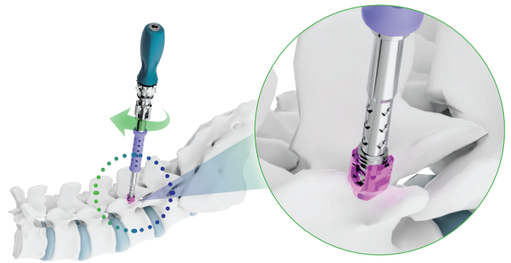


Fig. 8 ▲

Optional

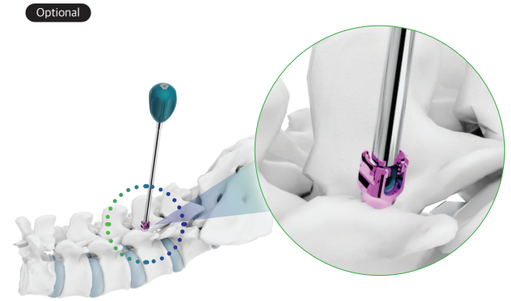


Fig. 9 ▲

Insert the screw into the prepared pedicles and advance to a depth where full angulation of the head of the screw is maintained. Disengage the screwdriver from the screw. Repeat process until all screws are placed (Fig. 8).

NOTE: Do not use a screw that is smaller diameter than the 7.0mm screw for the sacrum.

If the screw repositioning is required, the SCREW ADJUSTER can be used to adjust the screw height (Fig. 9).

NOTE: Do not Insert Polyaxial Screw via the SCREW ADJUSTER.

Instruments

NP0170	POLYAXIAL STD. SCREWDRIVER
NP0180	POLYAXIAL RED. SCREWDRIVER
GH1080	RATCHET I HANDLE

Instrument

NP0020	SCREW ADJUSTER

ROD PREPARATION

Fig. 10 ▲

The INNOVERSE Spinal System offers a wide range of pre-cut and pre-contoured rods.

Once the screws have been placed, the appropriate rod length is determined. It is recommended to oversize at least 3~5mm to allow the rod beyond the head of the screw on the superior and inferior ends of the construct.

Rod bending is sometimes necessary to ensure that the rod is fully seated within the head of the screw.

The Rod Bender is used to contour the rods. The bending radius can be adjusted by pulling and rotating the central dial on the rod bender. (Fig. 10).

Instruments

SF0500	ROD BENDER

ROD INSERTION

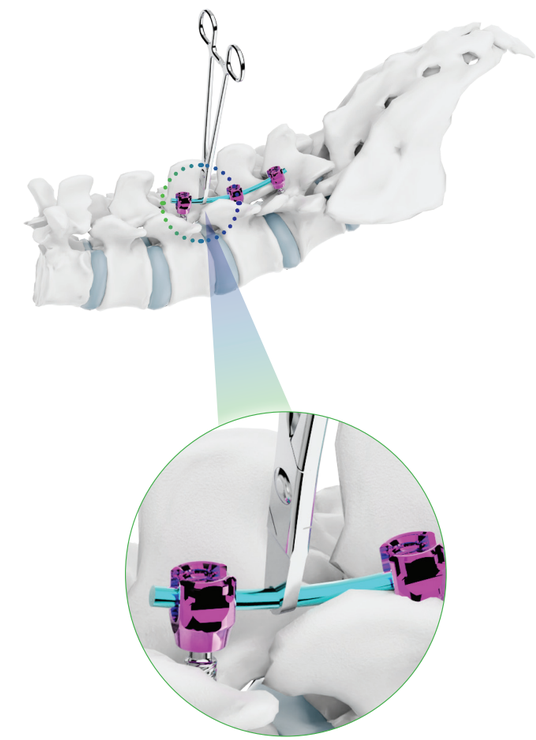


Fig. 11 ▲

Once the appropriate rod length is chosen and the contouring is complete, the rod can be placed in the screw heads using the ROD HOLDER (Fig. 11).

Instrument

NP0190	ROD HOLDER

ROD REDUCTION

Optional 1

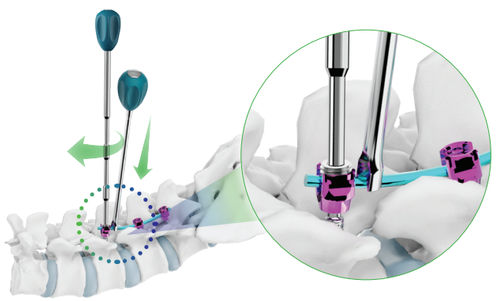


Fig. 12 ▲

Optional 2

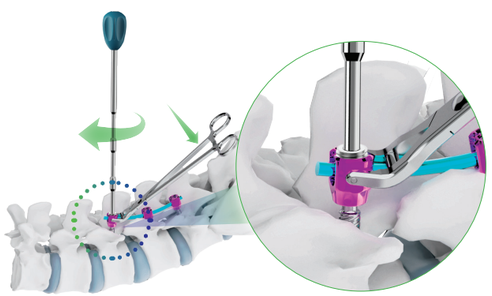


Fig. 13 ▲

Place the ROD PUSHER tip on rod and push the rod until seated within the head of the pedicle screw. Insert a set screw with provisional tightening using the LONGER SET SCREWDRIVER GUIDE (Fig. 12).

Attach the ROD ROCKER to the hole of the head of the pedicle screw and lever rod until seated within the head of the pedicle screw. Insert a set screw with provisional tightening using the LONGER SET SCREWDRIVER GUIDE (Fig. 13).

Instrument

NP0220	ROD PUSHER
SF0430	LONGER SET SCREW DRIVER GUIDE

Instrument

NP0340	ROD ROCKER
SF0430	LONGER SET SCREW DRIVER GUIDE

Optional 3

Fig. 14 ▲

Fig. 15 ▲

Place PERSUADER tip over the head of pedicle screw and seat pins into the holes for rod reducing on the head of pedicle screw. Squeeze the handle of the PERSUADER to fully seat the rod within the pedicle screw (Fig. 14). Insert a set screw with provisional tightening using the LONGER SET SCREWDRIVER GUIDE (Fig. 15).

To release the PERSUADER, Rotate the ratchet arm to disengage form handle - Once released, The PERSUADER may be removed from the pedicle screw

Instrument

NP0270	PERSUADER
SF0430	LONGER SET SCREW DRIVER GUIDE

ROD REDUCTION

Optional 4

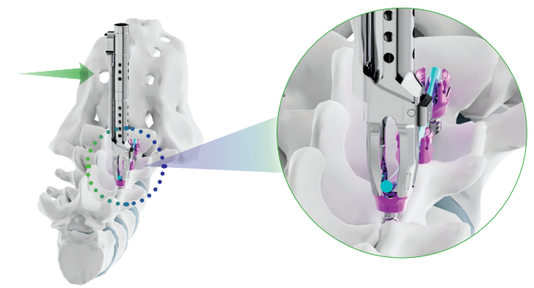


Fig. 16 ▲

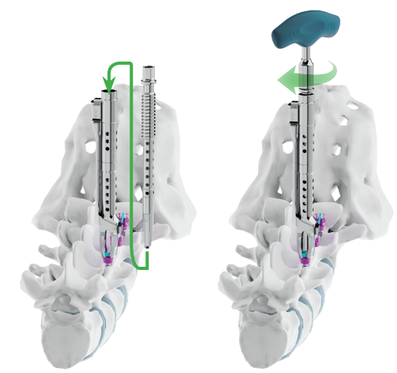


Fig. 17 ▲

Ensure that the locking lever is fully opened to allow to engage the head of pedicle screw. If not, pull up the release button to open locking lever prior to engaging the pedicle screw. Place the TOWER REDUCER tip on the head of pedicle screw until fully seated and close the locking lever to secure the pedicle screw (Fig. 16).

Insert the THREADED REDUCTION SLEEVE and turn the HEX tip of THE THREADED REDUCTION SLEEVE clockwise using HEX T-Handle until the rod is fully seated on the pedicle screw (Fig. 17).

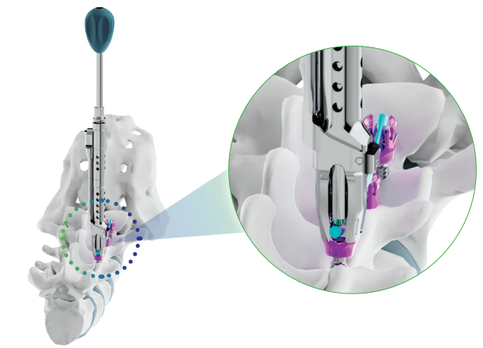


Fig. 18-1 ▲

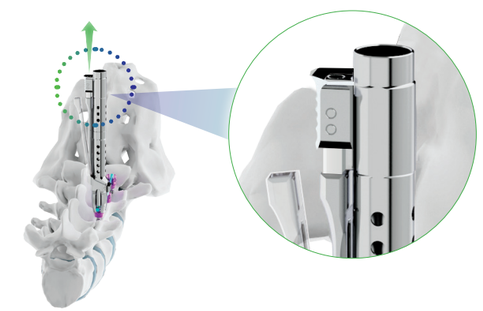


Fig. 18-2 ▲

Remove the HEX T-handle and insert a set screw with provisional tightening using the LONGER SET SCREWDRIVER GUIDE (Fig. 18-1).

To remove the TOWER REDUCER, pull up the release button again to open the locking lever to disengage the pedicle screw. Once the locking lever is fully opened, the TOWER REDUCER can be removed from the pedicle screw (Fig. 18-2).

Instrument

NP0220	TOWER REDUCER
NP0130	THREADED REDUCTION SLEEVE
NP0140	HEX T-HANDLE
SF0430	LONGER SET SCREWDRIVER GUIDE

SET SCREW INSERTION

Fig. 19 ▲

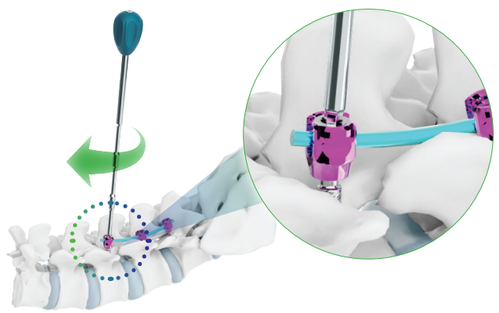


Fig. 20 ▲

Attach the Set Screw to the LONGER SET SCREWDRIVER GUIDE for inserting the set screw (Fig. 19).

Use the LONGER SET SCREWDRIVER GUIDE to provisionally tighten the Set Screws on the rod holding the corrected position (Fig. 20).

NOTE : *Do not final-tighten the Set Screw via the Set LONGER SET SCREWDRIVER GUIDE.*

NOTE : *Verify the proper engagement between the Set Screw and the Housing. Note - Do not use the LONGER SET SCREWDRIVER GUIDE with the COUNTER TORQUE.*

Instrument

SF0430	LONGER SET SCREWDRIVER GUIDE

COMPRESSION, DISTRACTION

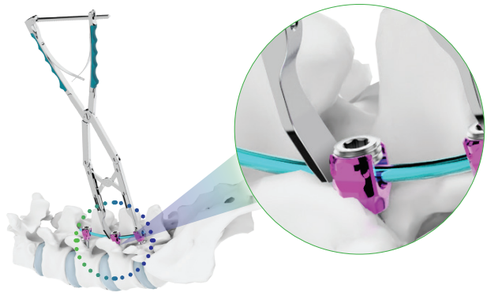


Fig. 21 ▲

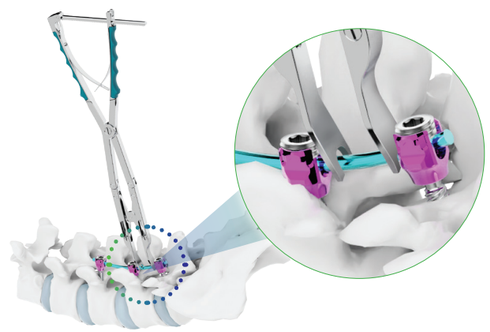


Fig. 22 ▲

Provisionally tighten the Set Screw on the side of the segment being translated, while leaving the Set Screw loose on the implant to be compressed or distracted. Perform compression or distraction against the provisionally tightened assembly with the COMPRESSOR or SPREADER, respectively (Fig. 21, 22).

Ensure that the tips of the either the COMPRESSOR or SPREADER are firmly placed to the head of Polyaxial screw and not to the tabs (Reduction polyaxial screw).

Instrument

NP0260	COMPRESSOR
NP0250	SPREADER

ROD MANIPULATIONS

Optional A

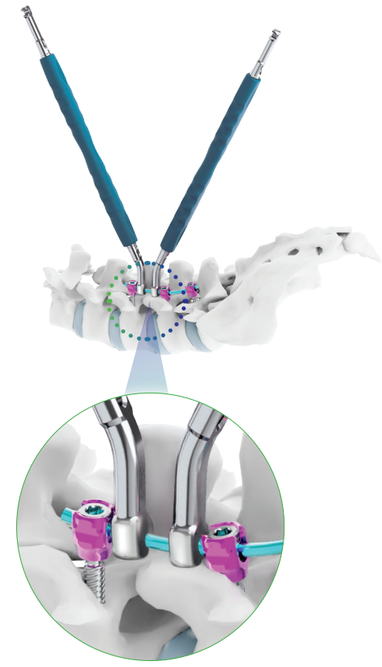


Fig. 23 ▲

Choose the appropriate IN-SITU ROD BENDER to match the rod size. Position the IN-SITU ROD BENDERS on rod. Gently push rod benders together to create a bend in the rod in the sagittal plane and increase rod lordosis (Fig 23).

NOTE : *In-situ rod bender is powerful instrument; carefully perform bending and ensure that implant fixation is not disrupted*

Instrument

NP0280	IN-SITU ROD BENDER 5.5 - LEFT
NP0290	IN-SITU ROD BENDER 5.5 - RIGHT
NP0300	IN-SITU ROD BENDER 6.0 - LEFT
NP0310	IN-SITU ROD BENDER 6.0 - RIGHT

Optional B

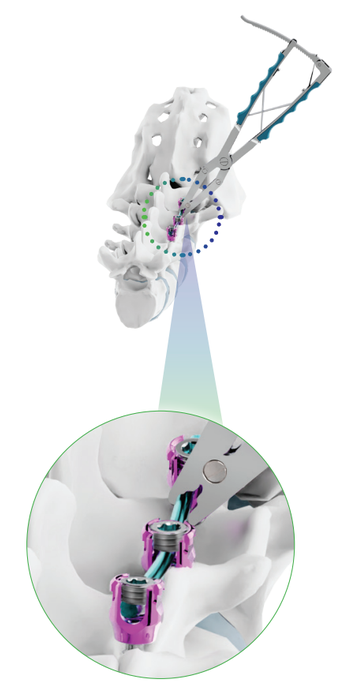


Fig. 24 ▲

Attach rod gripper to rod and apply rotational force to adjust rod orientation prior to tightening the set screw (Fig 24).

Ensure that the rod position is properly using centerline marking as a guide.

Instrument

NP0150	DUAL ACTION ROD GRIPPER

FINAL TIGHTENING

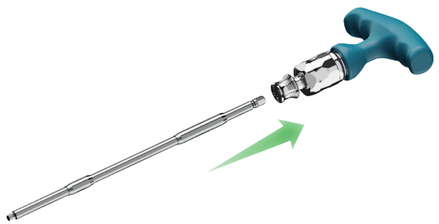


Fig. 25 ▲

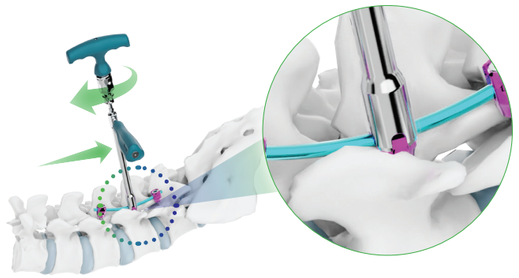


Fig. 27 ▲

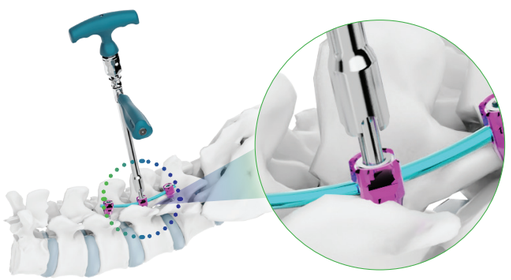


Fig. 26 ▲

Attach the TORQUE LIMITING T-HANDLE to the FINAL DRIVER (Fig. 25).

Insert the FINAL DRIVER into the COUNTER TORQUE and visually confirm the driver tip is fully engaged in the Set Screw (Fig. 26).

NOTE : *Verify the engagement between the FINAL DRIVER HEX and the Set Screw HEX.*

Slide the COUNTER TORQUE over the screw head, ensuring it is fully seated. Begin turning the TORQUE LIMITING T-HANDLE to tighten the Set Screw (Fig. 27).

While exerting opposite force with counter torque handle

The TORQUE LIMITING T-HANDLE is pre-set to approximately 88.5in-lb (10N-m) and will 'click' once the proper torque is achieved. Repeat tightening the Set Screw two or three times per each Set Screw.

NOTE : *Do not tighten FINAL DRIVER out of vertical.*

Instrument

GH2020	TORQUE LIMITING T-HANDLE
NP0100	FINAL DRIVER
NP0030	COUNTER TORQU

REDUCTION SCREW

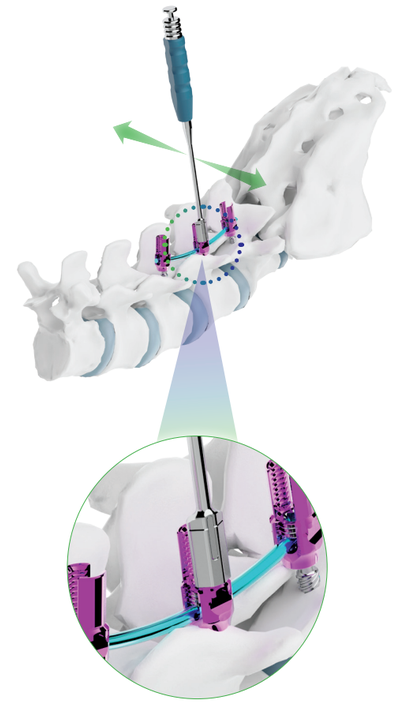


Fig. 28 ▲

When the Reduction Screws are used, all tabs are broken when reduction is complete.

Use the TAB REMOVER to break off tap and push the button of TAB REMOVER to eject the broken taps. Repeat the same step to break off all tap. (Fig. 28).

Instruments

NP0110	TAB REMOVER

CROSS LINK

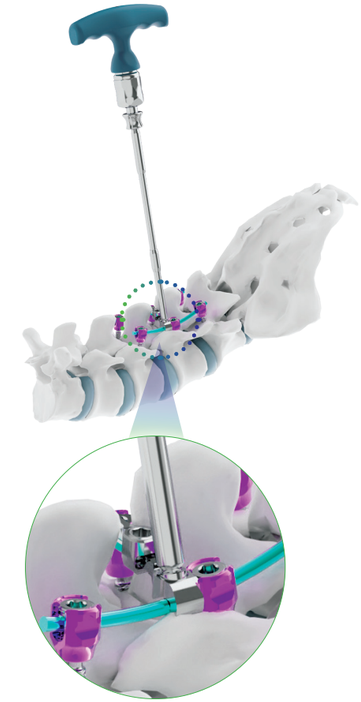


Fig. 29 ▲

Attach the TORQUE LIMITING T-HANDLE to the FINAL DRIVER. Select the appropriate size of the Cross Link for Rod. Place the selected Cross Link on the desired location.

Use the FINAL DRIVER with TORQUE LIMITING T-HANDLE to tighten the side set screw first. Turn the FINAL DRIVER with TORQUE LIMITING T-HANDLE clockwise until hearing 'click' sound. Once the side set screw are secured, tighten all set screw of the CROSS LINK using the FINAL DRIVER with TORQUE LIMITING T-Handle (Fig 29).

Instrument

GH2010	TORQUE LIMITING T-HANDLE
NP0100	FINAL DRIVER

ROD INTRODUCTION – OPTIONS

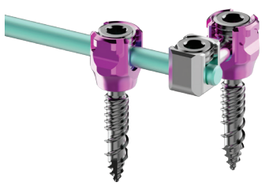


Fig. 30 ▲

Fig. 31 ▲

Fig. 32 ▲

Fig. 33 ▲

Option 1

Lateral Connector

Lateral connectors may be utilized if screw placement requires a severe bend in the rod. The lateral connectors allow for an offset, thus minimizing rod bending. The lateral connectors are secured with the same Set Screw as the pedicle screw (Fig. 30).

Place the arm of the lateral connector in the pedicle screw seat and secure the lateral connector in place by provisionally tightening the plug. Place the longitudinal rod into the seat of the lateral connector. Once the rod has been placed, insert the Set Screw into the seat of the lateral connector and tighten.

Option 2

Axial & Domino & Open Connector

A Rod Connector may be used to extend an existing construct in the event of a revision surgery or for a new multilevel construct or to connect to an offset screw

A. Axial Connector

The Axial connector is used when connecting two rods in the direction of the axis of the rod. After selecting the appropriate size of the axial connector, insert a rod in one direction of the connector through the hole of the axial connector for the rod insertion and insert another rod in the opposite direction. After inserting rods, insert the set screw into the axial connector and use the FINAL DRIVER with TORQUE LIMITING T-HANDLE to tighten the set screw. Turn the final driver assembly clockwise until hearing the 'click' sound. (Fig. 31).

B. Domino & Open Connector

The Domino and Open Connector is used when connecting two parallel rods. The Domino Connectors are closed, and the Open Connectors have open lateral and top slot for connecting a rod easily. After selecting the appropriate size and shape, place the rod on the connector. After placing the rod, insert the set screw into the connector and tighten (Fig. 32, 33).

NOTE : *The open top connectors utilize the set screw for tulip (NP 1500). (Fig.32)*

REVISION OR REMOVAL

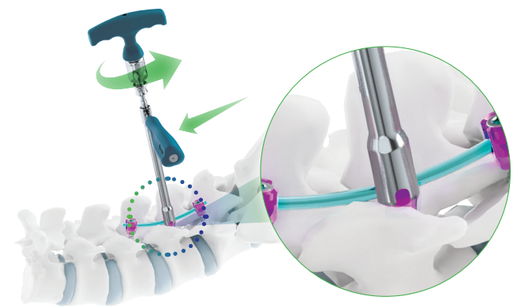


Fig. 34 ▲

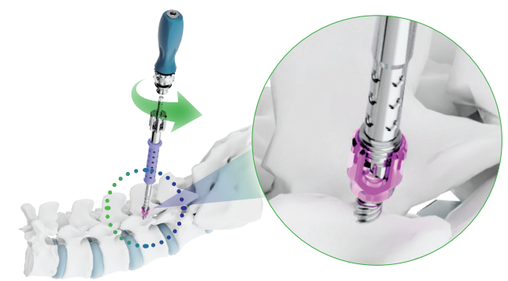


Fig. 36 ▲

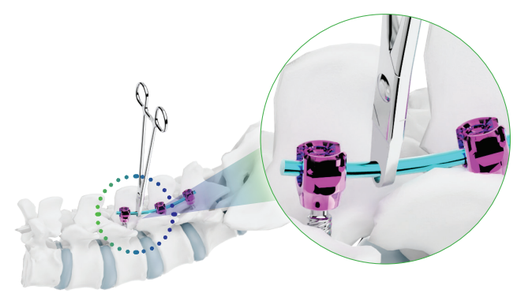


Fig. 35 ▲

If the construction has a CROSS LINK or connectors, the cross link or connectors must be removed prior to removing the pedicle screw. Use the FINAL DRIVER with the TORQUE LIMITING T-HANDLE to loosen set screws of the cross link or connectors. Then remove the CROSS LINK or connectors.

Loosen the Set Screw in the pedicle screw using the FINAL DRIVER with the TORQUE LIMITING T-HANDLE. Turn counterclockwise to loosen and remove the Set Screw from the pedicle screw (Fig. 34).

NOTE : *Use of COUNTER TORQUE is recommended to avoid damage to the pedicle.*

Remove the Rod using the ROD HOLDER (Fig. 35).
Remove the Polyaxial/Monoaxial screw using the Poly/Mono Screwdriver. Turn counterclockwise slowly. All Screws should be removed (Fig. 36).

NOTE : *In revision, use a bigger size Screw than previously used.*

Instrument

GH2010	TORQUE LIMITING T-HANDLE
NP0100	FINAL DRIVER
NP0030	COUNTER TORQUE
SF0090	ROD HOLDER
NP0170	POLYAXIAL STD. SCREWDRIVER
NP0180	POLYAXIAL RED. SCREWDRIVER
GH1080	RATCHET I HANDLE

IMPLANTS

POLYAXIAL STD. SCREW Ø4.5 mm

Part No.	Length (mm)
NPA4525PSQ	25
NPA4530PSQ	30
NPA4535PSQ	35
NPA4540PSQ	40

POLYAXIAL STD. SCREW Ø5.5 mm

Part No.	Length (mm)
NPA5530PSQ	30
NPA5535PSQ	35
NPA5540PSQ	40
NPA5545PSQ	45

POLYAXIAL STD. SCREW Ø6.5 mm

Part No.	Length (mm)
NPA6535PSQ	35
NPA6540PSQ	40
NPA6545PSQ	45
NPA6550PSQ	50
NPA6555PSQ	55

POLYAXIAL STD. SCREW Ø7.5 mm

Part No.	Length (mm)
NPA7535PSQ	35
NPA7540PSQ	40
NPA7545PSQ	45
NPA7550PSQ	50
NPA7555PSQ	55

POLYAXIAL STD. SCREW Ø8.5 mm

Part No.	Length (mm)
NPA8540PSQ	40
NPA8545PSQ	45
NPA8550PSQ	50
NPA8555PSQ	55
NPA8560PSQ	60
NPA8565PSQ	65
NPA8570PSQ	70

POLYAXIAL RED. SCREW Ø5.5 mm

Part No.	Length (mm)
NPA5535PRQ	35
NPA5540PRQ	40
NPA5545PRQ	45

POLYAXIAL RED. SCREW Ø6.5 mm

Part No.	Length (mm)
NPA6535PRQ	35
NPA6540PRQ	40
NPA6545PRQ	45
NPA6550PRQ	50

POLYAXIAL RED. SCREW Ø7.5 mm

Part No.	Length (mm)
NPA7540PRQ	40
NPA7545PRQ	45
NPA7550PRQ	50

SET SCREW for TULIP

Part No.
NP1500

SET SCREW for Connector

Part No.
NP3081

CROSS LINK(5.5/6.0) No.1~No.5

Part No.	Length (mm)
NPA2010	34-37
NPA2020	37-43
NPA2030	43-54
NPA2040	54-70
NPA2050	70-95

IMPLANTS

STRAIGHT ROD (Ti) Ø5.5 mm

Part No.	Length (mm)
NP55035TS	35
NP55040TS	40
NP55045TS	45
NP55050TS	50
NP55060TS	60
NP55070TS	70
NP55080TS	80
NP55090TS	90
NP55100TS	100
NP55120TS	120
NP55150TS	150
NP55200TS	200
NP55300TS	300
NP55480TS	480

STRAIGHT ROD (CoCr) Ø5.5 mm

Part No.	Length (mm)
NP55035CS	35
NP55040CS	40
NP55045CS	45
NP55050CS	50
NP55060CS	60
NP55070CS	70
NP55080CS	80
NP55090CS	90
NP55100CS	100
NP55120CS	120
NP55150CS	150
NP55200CS	200
NP55300CS	300
NP55480CS	480

CURVED ROD (Ti) Ø5.5 mm

Part No.	Length (mm)
NP55035TC	35
NP55040TC	40
NP55045TC	45
NP55050TC	50
NP55060TC	60
NP55070TC	70
NP55080TC	80
NP55090TC	90
NP55100TC	100
NP55110TC	110
NP55120TC	120

CURVED ROD (CoCr) Ø5.5 mm

Part No.	Length (mm)
NP55035CC	35
NP55040CC	40
NP55045CC	45
NP55050CC	50
NP55060CC	60
NP55070CC	70
NP55080CC	80
NP55090CC	90
NP55100CC	100
NP55110CC	110
NP55120CC	120

LATERAL OPEN CONNECTOR

Part No.	Length (mm)
NP3011	16.5
NP3012	35

LATERAL CLOSED CONNECTOR

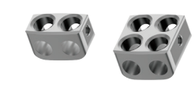
Part No.	Length (mm)
NP3021	16.5
NP3022	35

AXIAL CONNECTOR

Part No.	Description
NP3041	2HOLES
NP3042	3HOLES
NP3043	4HOLES

DOMINO CONNECTOR

Part No.	Description
NP3031	2HOLES
NP3032	4HOLES



W-CONNECTOR

Part No.	Description
NP3051	STD.
NP3052	OFS.

X-CONNECTOR

Part No.	Description
NP3061	STD.
NP3062	OFS.

UC-CONNECTOR

Part No.	Description
NP3071	STD.
NP3072	OFS.

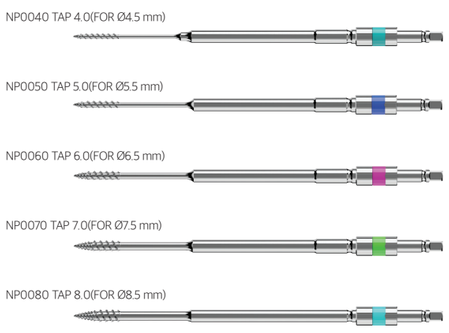
INSTRUMENTS

▶ NP0010 AWL

▶ NP0020 SCREW ADJUSTER

▶ NP0030 COUNTER TORQUE

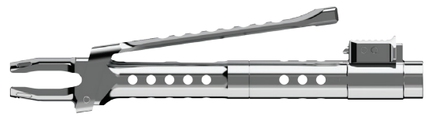
▶ NP0040 TAP 4.0 ~ NP0080 TAP 8.0



▶ NP0100 FINAL DRIVER

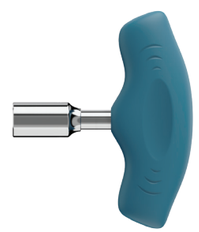
▶ NP0110 TAB REMOVER

▶ NP0120 TOWER REDUCER

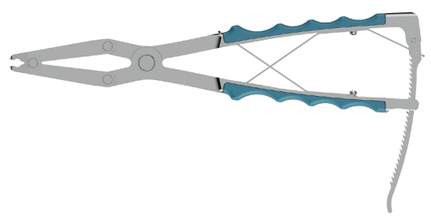


▶ NP0130 THREATED REDUCTION SLEEVE

▶ NP0140 HEX T-HANDLE



▶NP0150 DUAL ACTION ROD GRIPPER



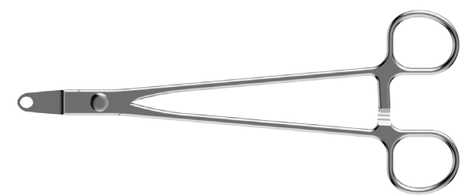
▶NP0160 ROTARY HANDLE FOR TAP

INSTRUMENTS

▶ NP0170 POLYAXIAL STD. SCREW DRIVER

▶ NP0180 POLYAXIAL RED. SCREW DRIVER

▶ NP0190 ROD HOLDER



▶ NP0200 Tester - Straight

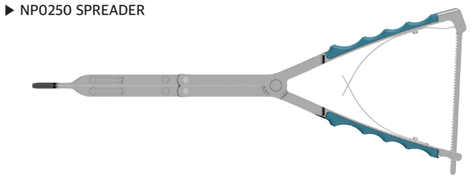
▶ NP0210 Tester - Curved

▶ NP0220 ROD PUSHER

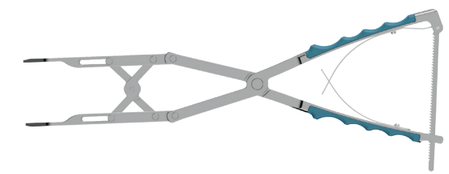
▶ NP0230 PROBE -STRAIGHT

▶ NP0240 PROBE - CURVED

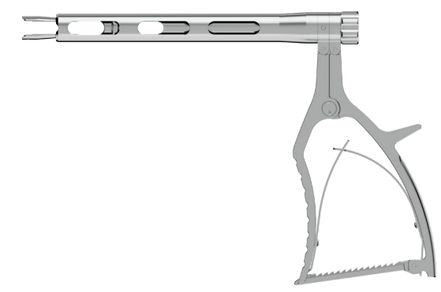
▶ NP0250 SPREADER



▶ NP0260 COMPRESSOR



▶ NP0270 PERSUADER



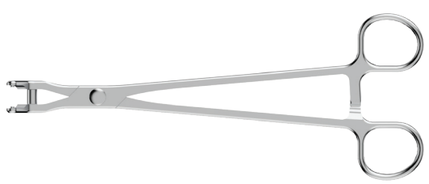
INSTRUMENTS

▶ NP0280 IN-SITU ROD BENDER LEFT - 5.5
NP0280 IN-SITU ROD BENDER LEFT - 6.0

▶ NP0290 IN-SITU ROD BENDER RIGHT - 5.5
NP0290 IN-SITU ROD BENDER RIGHT - 6.0

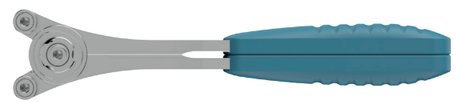
▶ NP0330 DUAL ENDED SET SCREW STARTER

▶ NP0340 ROD ROCKER



▶ SF0430 LONGER SET SCREW DRIVER GUIDE

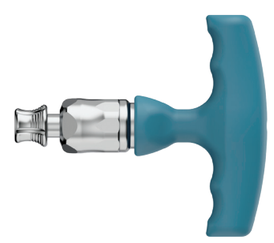
▶ SF0500 ROD BENDER



▶ GH1080 RATCHET I-HANDLE (1/4 SQUARE)

▶ GH1090 RATCHET T-HANDLE (1/4 SQUARE)

▶ GH2020 TORQUE LIMITING T-HABDLE (1/4 SQUARE, 10N-m)



IMPORTANT INFORMATION ON THE INNOVERSE SPINAL SYSTEM

DEVICE DESCRIPTION

The INNOVERSE Spinal System is manufactured by Innosys Co., Ltd. The INNOVERSE Spinal System is a top-loading multiple component, posterior spinal fixation system and minimally invasive surgery system which consist of variety pedicle screws, rods, set screws, connectors and cross link. Implant components are available in a variety sizes and can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient. Pedicle Screw is provided in Modula type (Tulip is provided in a separated state and assembled after screw insertion.) and pre-assembly type (Tulips are supplied assembled.). All pedicle screws have self-tapping function in INNOVERSE Spinal System. The tulip accommodates a 5.5 and 6.0mm diameter rod in Ti Alloy and CoCr for increased construct rigidity.
The INNOVERSE Spinal System allows surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The INNOVERSE Spinal System components are supplied non-sterile, single use and are fabricated from medical grade titanium alloy (ASTM F136) and medical grade cobalt-chromium-molybdenum alloy (ASTM F1537).

Never use stainless steel and titanium implant components in the same construct. Titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct.

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the INNOVERSE Spinal System implants.

Intended Use / Indication for Use

The INNOVERSE Spinal System is a posterior, noncervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

- Sever espondylolisthesis(grades 3 and 4)of the L5-S1 vertebra
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Trauma (i.e.,fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures(i.e.,scoliosis, kyphosis,and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

NOTE: *The INNOVERSE Spinal System Surgical Technique Manual should be followed carefully. Important information on the proper usage of implants and instruments is inc*

CONTRAINDICATIONS

- Any active or suspected latent infection in or about the spine.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and or fixation to the implant.
- Obesity, 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.
- Recent infection, fever or leukocytosis
- Bony abnormalities preventing safe screw fixation
- Open wounds
- Metal sensitivity, documented or suspected
- Bone absorption, osteopenia and/or osteoporosis
- Patients having inadequate tissue coverage over the operative site
- Pregnancy
- Excessive local inflammation
- Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery such as 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.

⚠ WARNING

- The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- Potentialrisksassociatedwiththeuseofthissystem,whichmayrequireadditionalsurgery,includedevice-component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury and vascular or visceral injury.
- Discardalldamagedormishandledimplants.
- Neverreuseanimplanteventhoughitmayappearundamaged.
- Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.
- Reuseofanimplantmaycausethecrossinfectionofthepatients.
- Contouring or bending of a screw may reduce its fatigue strength and cause failure under load. If spinal screws are bent or otherwise damaged during insertion or adjustment, they may not be implanted and must be replaced. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted.
- Mixing Metal: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants and the amount of metal compounds released into the body system may also increase. Internal fixation devices such as rods, screws, etc., which come into contact with other metal objects must be made from like or compatible metals.
- Because different manufacturers employ different materials, varying tolerances, manufacturing specifications and differing design parameters, components of the INNOVERSE Spinal System should not be used in conjunction with components from any other manufacturer's spinal systems. Any such use will negate the responsibility of Innosys Co., Ltd. for the performance of the resulting mixed component implant.
- Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically.
- Any decision by a surgeon to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Implantremovalshouldbefollowedbyadequatepostoperativemanagementtoavoidfracture.

- The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

⚠ PRECAUTIONS

- The surgeon should consider the level of implantation, the weight of the patient, the patient's activity level or general conditions and any other factor which may have an impact on the performance of the system based on published fatigue test results of the system.
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting or muscle strain), resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life to the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal fixation system. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome.
- Patients should be instructed in detail about the limitations of the implants, including but not limited to the impact of excessive loading through patient weight or activity, and should be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape and strength of the implants.)
- Care must be taken to protect the components from being marred, nicked or notched as a result of a contract with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- Sale of this product is restricted to physicians.
- The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with surgical and medical indications, the potential risks and limitations related to this type of surgery, the contraindications, side effects and precautions. The surgeon should also possess knowledge of the metallurgic and biological characteristics of the implants.
- It is recommended that the INNOVERSE Spinal System not be used in conjunction with implants from a different source, a different manufacturer or made from a different material. If this should occur, Innosys Co., Ltd. declines all responsibility.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the implant.

Unless noted otherwise on the package labeling, INNOVERSE Spinal System components are provided nonsterile.
These products need to be steam sterilized by the hospital using one of the following methods:
Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

- Recommended method to achieve a degree of sterility equal to at least 10-6.
- Sterilization procedure should conduct in accordance with the cycle specification in ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."
- Sterilize by the autoclaving procedure regularly used in the hospital.
- All products should be disassembled as Part No. unit before the sterilization.
- Only FDA-cleared wraps should be used when you perform the sterilization.
- Over-killed Method was applied to the steam sterilization.

SUGGESTED METHOD

STEAM CONDITION	TEMPERATURE	STERILIZATION TIME	DRYING TIME
Steam, Pre-vacuum Cycle	132 ℃ (270° F)	4 min	45 min

- 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 havebeen cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).
- Do not stack trays during sterilization.

NOTES

NOTES

CG MedTech

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