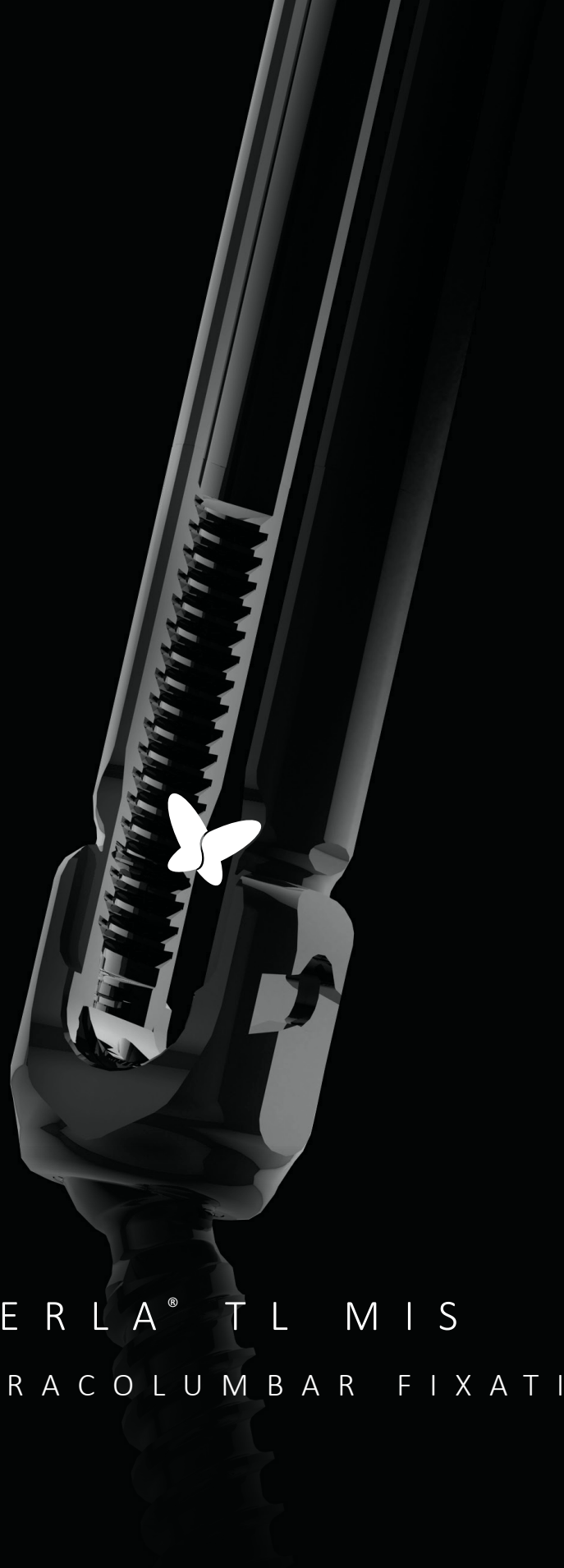


PERLA® TL MIS

MIS THORACOLUMBAR FIXATION

C O N T E N T

CONCEPT AND DESIGN

The PERLA® TL MIS Thoracolumbar Fixation system allows for 3 different options:

- pure percutaneous
- bilateral mini-open
- and hybrid approach.

PERLA®TL MIS Thoracolumbar Fixation is a versatile and safe system designed to ease minimal invasive spine surgery.

Since 2005 in each product development, Spineart is relentlessly driven by the same philosophy: Quality, Innovation, Simplicity.

AT A GLANCE

Preassembled Extended Tabs
Built-in Reduction
6 Cutting edges Screw Tip
Secured and Guided Rod Insertion

INDICATIONS

The PERLA® TL posterior osteosynthesis system is 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 disc disease;
- spondylolisthesis;
- fracture;
- dislocation;
- scoliosis;
- kyphosis;
- spinal tumor;
- and failed previous fusion (pseudarthrosis).

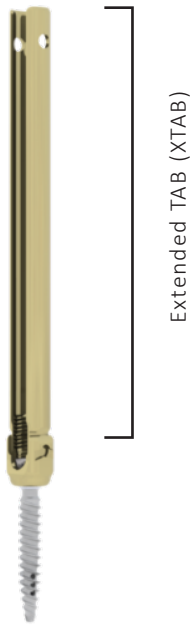
When used for posterior non-cervical pedicle screw fixation in pediatric patients, the PERLA® TL posterior osteosynthesis system is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PERLA® TL posterior osteosynthesis system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

IMPLANTS

XTAB CANNULATED FENESTRATED POLYAXIAL SCREWS

DIAMETER/ LENGTH	Ø4,5MM	Ø5,5MM	Ø6,5MM	Ø7,5MM	Ø8,5MM
L25*	MPF-PX 45 25-S	MPF-PX 55 25-S	MPF-PX 65 25-S		
L30*	MPF-PX 45 30-S	MPF-PX 55 30-S	MPF-PX 65 30-S	MPF-PX 75 30-S	MPF-PX 85 30-S
L35	MPF-PX 45 35-S	MPF-PX 55 35-S	MPF-PX 65 35-S	MPF-PX 75 35-S	MPF-PX 85 35-S
L40	MPF-PX 45 40-S	MPF-PX 55 40-S	MPF-PX 65 40-S	MPF-PX 75 40-S	MPF-PX 85 40-S
L45	MPF-PX 45 45-S	MPF-PX 55 45-S	MPF-PX 65 45-S	MPF-PX 75 45-S	MPF-PX 85 45-S
L50		MPF-PX 55 50-S	MPF-PX 65 50-S	MPF-PX 75 50-S	MPF-PX 85 50-S
L55		MPF-PX 55 55-S	MPF-PX 65 55-S	MPF-PX 75 55-S	MPF-PX 85 55-S
L60		MPF-PX 55 60-S	MPF-PX 65 60-S	MPF-PX 75 60-S	MPF-PX 85 60-S

*Not fenestrated screws



IMPLANTS

PERCUTANEOUS ROD / STRAIGHT

DIAMETER/ LENGTH	Ø5,5MM	Ø6MM
L30	MPF-ST 50 30-S	MPF-ST 60 30-S
L35	MPF-ST 50 35-S	MPF-ST 60 35-S
L40	MPF-ST 50 40-S	MPF-ST 60 40-S
L45	MPF-ST 50 45-S	MPF-ST 60 45-S
L50	MPF-ST 50 50-S	MPF-ST 60 50-S
L55	MPF-ST 50 55-S	MPF-ST 60 55-S
L60	MPF-ST 50 60-S	MPF-ST 60 60-S
L65	MPF-ST 50 65-S	MPF-ST 60 65-S
L70	MPF-ST 50 70-S	MPF-ST 60 70-S
L75	MPF-ST 50 75-S	MPF-ST 60 75-S
L80	MPF-ST 50 80-S	MPF-ST 60 80-S
L85	MPF-ST 50 85-S	MPF-ST 60 85-S
L90	MPF-ST 50 90-S	MPF-ST 60 90-S
L100	MPF-ST 51 00-S	MPF-ST 61 00-S
L110	MPF-ST 51 10-S	MPF-ST 61 10-S
L120	MPF-ST 51 20-S	MPF-ST 61 20-S
L130	MPF-ST 51 30-S	MPF-ST 61 30-S
L140	MPF-ST 51 40-S	MPF-ST 61 40-S
L150	MPF-ST 51 50-S	MPF-ST 61 50-S
L160	MPF-ST 51 60-S	MPF-ST 61 60-S
L170	MPF-ST 51 70-S	MPF-ST 61 70-S
L180	MPF-ST 51 80-S	MPF-ST 61 80-S
L190	MPF-ST 51 90-S	MPF-ST 61 90-S
L200	MPF-ST 52 00-S	MPF-ST 62 00-S
L210	MPF-ST 52 10-S	MPF-ST 62 10-S
L220	MPF-ST 52 20-S	MPF-ST 62 20-S
L230	MPF-ST 52 30-S	MPF-ST 62 30-S
L240	MPF-ST 52 40-S	MPF-ST 62 40-S
L250	MPF-ST 52 50-S	MPF-ST 62 50-S

PERCUTANEOUS ROD / PRE-BENT

DIAMETER/ LENGTH	Ø5,5MM	Ø6MM
L30	MPF-BT 50 30-S	MPF-BT 60 30-S
L35	MPF-BT 50 35-S	MPF-BT 60 35-S
L40	MPF-BT 50 40-S	MPF-BT 60 40-S
L45	MPF-BT 50 45-S	MPF-BT 60 45-S
L50	MPF-BT 50 50-S	MPF-BT 60 50-S
L55	MPF-BT 50 55-S	MPF-BT 60 55-S
L60	MPF-BT 50 60-S	MPF-BT 60 60-S
L65	MPF-BT 50 65-S	MPF-BT 60 65-S
L70	MPF-BT 50 70-S	MPF-BT 60 70-S
L75	MPF-BT 50 75-S	MPF-BT 60 75-S
L80	MPF-BT 50 80-S	MPF-BT 60 80-S
L85	MPF-BT 50 85-S	MPF-BT 60 85-S
L90	MPF-BT 50 90-S	MPF-BT 60 90-S
L100	MPF-BT 51 00-S	MPF-BT 61 00-S
L110	MPF-BT 51 10-S	MPF-BT 61 10-S
L120	MPF-BT 51 20-S	MPF-BT 61 20-S
L130	MPF-BT 51 30-S	MPF-BT 61 30-S

SETSCREW

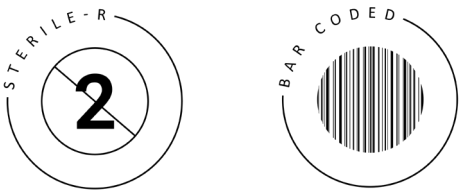
SETSCREWS PACKED BY 2	TLF-SC 02 00-S

TECHNICAL FEATURES

COMPLETE FIXATION PLATFORM

Complete range of cannulated, fenestrated, polyaxial screws to treat numerous Thoraco-Lumbar pathologies.

SAFETY



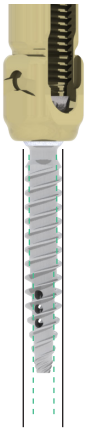
PERLA® TL MIS implants are sterile-packed and barcoded ensuring sterility and traceability.

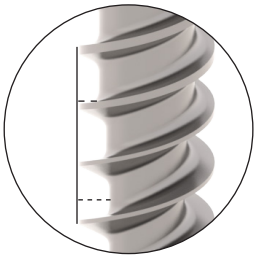
TECHNICAL FEATURES

DOUBLE THREAD

The Double Thread allows for a faster insertion compared to a single thread screw, reducing fatigue.

DUAL CORE BONE SCREW

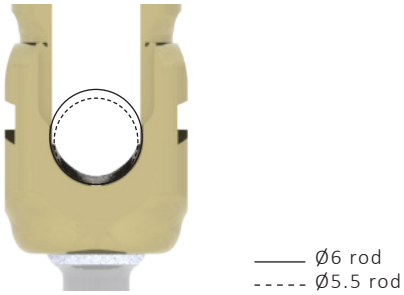




The Dual Core creates a constant external diameter with a variable thread depth. This allows a better adaptation to the vertebra anatomy and improved screw resistance and bone purchase: deeper threads for cancellous bone and shorter threads for cortical bone.

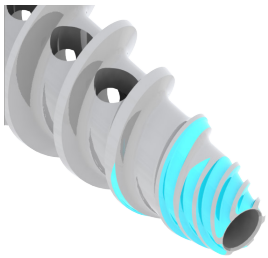
TECHNICAL FEATURES

DOUBLE ROD DIAMETER COMPATIBILITY



The PERLA® TL MIS screw head is compatible with both Ø5.5 and Ø6mm rods, for versatility in treating a wide range of pathologies.

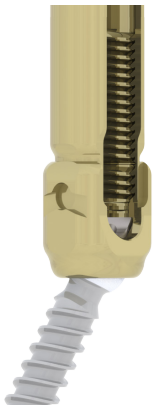
6 CUTTING EDGES SCREW TIP



The PERLA® TL MIS screw tip is designed for soft and precise insertion.

TECHNICAL FEATURES

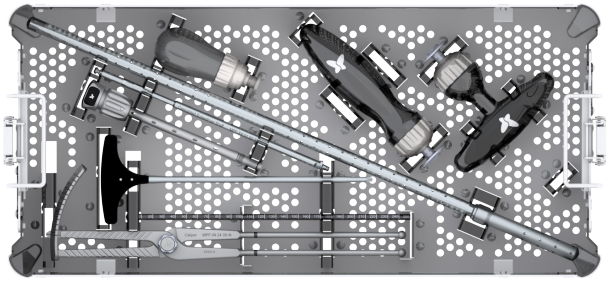
WIDE BUILT-IN REDUCTION



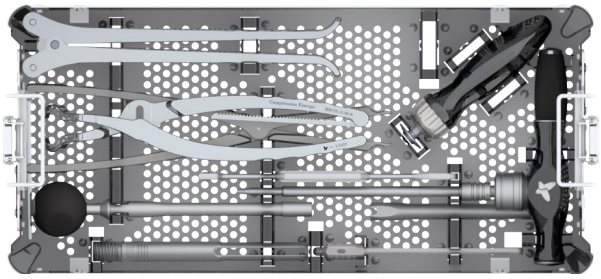
With its 20mm Built-In Reduction, the PERLA® TL MIS screw provides more versatility in treating a wide range of pathologies.

COMPACT SET

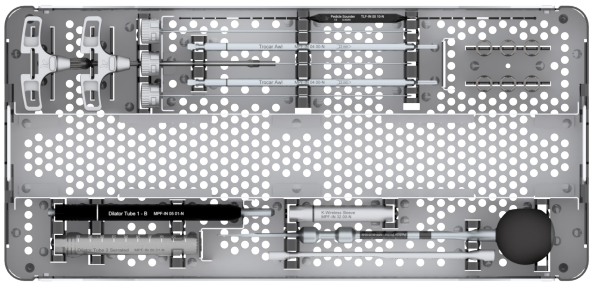
Box 1 - Base



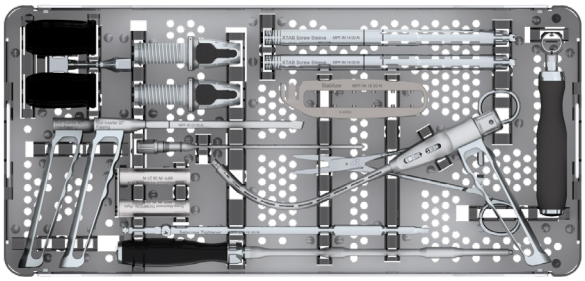
Box 2 - Base



Box 1 - Insert



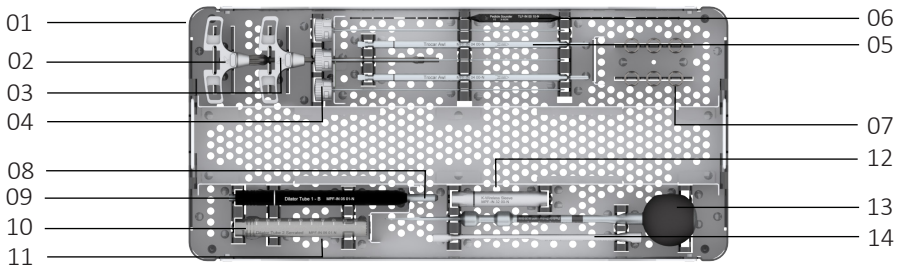
Box 2 - Insert



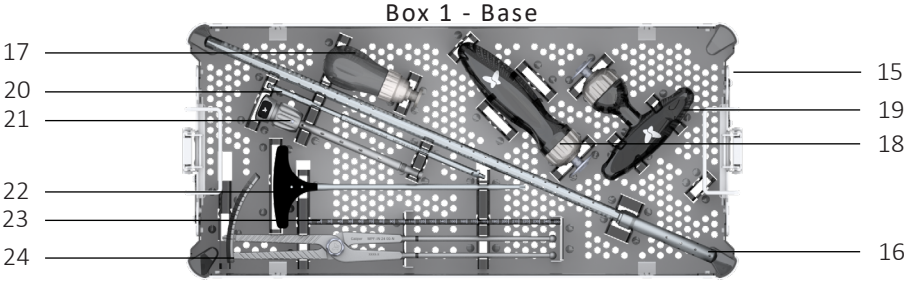
All the instrumentation needed fits in only two boxes.

INSTRUMENTS

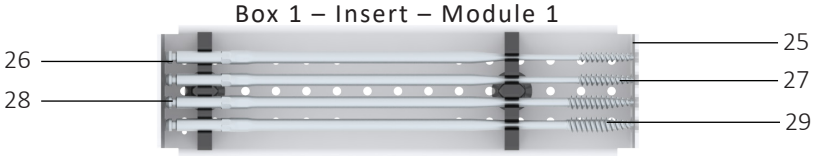
Box 1 - Insert



Box 1 - Base



Box 1 – Insert – Module 1



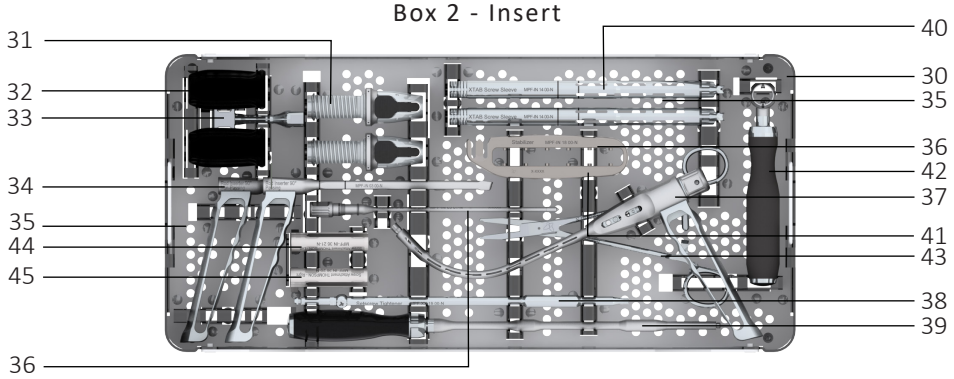
	#	DESCRIPTION	REFERENCE
	01	PERLA TL MIS - BOX 1 - INSERT UNIVERSAL LID	MPF-BX 01 10-N LID-BX 11 10-N
	02	TROCAR HANDLE	MPF-IN 04 01-N
	03	TROCAR 3 IN 1 / TI STICK	MIS-IN 03 16-N
	04	NEEDLE CAP	MPF-IN 04 02-N
	05	TROCAR AWL	MPF-IN 04 00-N
	06	PEDICLE SOUNDER	TLF-IN 00 10-N
	07	XTAB SCREW RING	MPF-IN 10 00-N
	08	DILATOR TUBE #1 - A	MPF-IN 05 00-N
	09	DILATOR TUBE #1 - B	MPF-IN 05 01-N
	10	DILATOR TUBE #2 SERRATED	MPF-IN 06 01-N
	11	DILATOR TUBE #2 - PUSHER	MPF-IN 06 10-N
•	12	K-WIRELESS SLEEVE	MPF-IN 32 00-N
•	13	PEDICLE PROBE	MPF-IN 20 00-N
	14	K-WIRE IMPACTOR	MPF-IN 13 00-N
	15	PERLA TL MIS - BOX 1 - BASE	MPF-BX 01 00-N
	16	K-WIRE TUBE	MPF-IN 35 00-N
		K-WIRE BLUNT Ø1.6 NITINOL	MPF-IN 12 00-N
		K-WIRE BLUNT Ø1.6 STAINLESS STEEL	MPF-IN 12 02-N

	17	PALM HANDLE	2RP5-C01
	18	STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
	19	T-HANDLE RATCHET	HAN-SB RF TE-N
	20	CANNULATED SCREWDRIVER SHAFT	MPF-IN 01 00-N
	21	XTAB SCREWDRIVER TUBE	MPF-IN 02 00-N
	22	SCREW ADJUSTER	MPF-IN 34 00-N
•	23	ROD TEMPLATE L250	TLF-IN 10 25-N
	24	CALIPER	MPF-IN 24 00-N
	25	PERLA TL MIS - BOX 1 - BASE - MODULE 1	MPF-BX 01 20-N
	26	CANNULATED TAP Ø5 (Ø5.5 SCREW)	MPF-IN 16 50-N
	27	CANNULATED TAP Ø6 (Ø6.5 SCREW)	MPF-IN 16 60-N
	28	CANNULATED TAP Ø7 (Ø7.5 SCREW)	MPF-IN 16 70-N
	29	CANNULATED TAP Ø8 (Ø8.5 SCREW)	MPF-IN 16 80-N

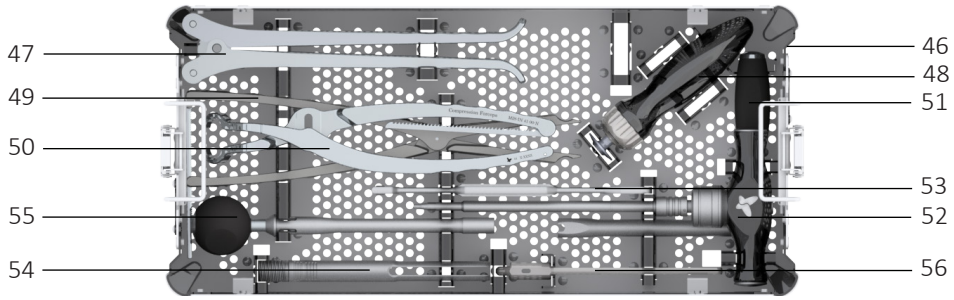
• : OPTIONAL

INSTRUMENTS

Box 2 - Insert



Box 2 - Base



	30	PERLA TL MIS - BOX 2 - INSERT UNIVERSAL LID	MPF-BX 02 10-N LID-BX 11 10-N
	31	PERSUADER	MPF-IN 15 00-N
	32	PERSUADER KNOB	MPF-IN 15 01-N
	33	QR REDUCER T-HANDLE	HAN-SS TY 14-N
	34	ROD INSERTER 90° NON PASSING	MPF-IN 03 10-N
•	35	ROD INSERTER 90° PASSING	MPF-IN 03 00-N
	36	ROD INSERTER 90° - INNER SHAFT	MPF-IN 03 01-N
•	37	ROD INSERTER PERCUTANEOUS	MPF-IN 23 00-N
	38	SETSCREW TIGHTENER	MPF-IN 19 00-N
	39	SETSCREW HOLDER	TLF-IN 05 10-N
	40	XTAB SCREW SLEEVE	MPF-IN 14 00-N
	41	STABILIZER	MPF-IN 18 00-N
	42	COUNTER TORQUE HANDLE	MPF-IN 38 00-N

	43	ROD HOLDER	ELL-IN 01 04-N
•	44	SCREW ATTACHMENT THOMPSON - RIGHT	MPF-IN 36 20-N
•	45	SCREW ATTACHMENT THOMPSON - LEFT	MPF-IN 36 21-N
	46	PERLA TL MIS - BOX 2 - BASE	MPF-BX 02 00-N
	47	ROD BENDER	ELL-IN 00 09-N
	48	STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
	49	DISTRACTION FORCEPS	MIS-IN 42 00-N
	50	COMPRESSION FORCEPS	MIS-IN 41 00-N
	51	COUNTER TORQUE	MPF-IN 26 00-N
	52	FINAL TIGHTENER	TLF-IN 05 41-N
	53	RECOVERY CENTERING GUIDE	MPF-IN 27 00-N
	54	RECOVERY TUBE	MPF-IN 28 00-N
	55	RECOVERY RELEASE TUBE	MPF-IN 29 00-N
	56	XTAB BREAKER	MPF-IN 17 00-N

• : OPTIONAL

INSTRUMENTS

TROCAR AWL	MPF-IN 04 00-N

TROCAR HANDLE	MPF-IN 04 01-N

NEEDLE CAP	MPF-IN 04 02-N

TROCAR 3 IN 1 / TI STICK	MIS-IN 03 16-N

T-HANDLE RATCHET	HAN-SB RF TE-N

STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N

K-WIRE BLUNT Ø1.6 STAINLESS STEEL	MPF-IN 12 02-N

K-WIRE TUBE	MPF-IN 35 00-N

K-WIRE IMPACTOR	MPF-IN 13 00-N

CANNULATED SCREWDRIVER SHAFT	MPF-IN 01 00-N

XTAB SCREWDRIVER TUBE	MPF-IN 02 00-N

ROD INSERTER 90° - INNER SHAFT	MPF-IN 03 01-N

INSTRUMENTS

CALIPER MPF-IN 24 00-N

ROD BENDER ELL-IN 00 09-N

FINAL TIGHTENER TLF-IN 05 41-N

SETSCREW HOLDER TLF-IN 05 10-N

PERSUADER MPF-IN 15 00-N

XTAB SCREW SLEEVE MPF-IN 14 00-N

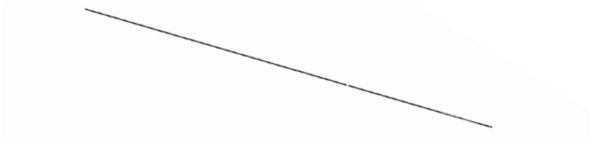
PERSUADER KNOB MPF-IN 15 01-N

QR REDUCER T-HANDLE HAN-SS TY 14-N

XTAB BREAKER MPF-IN 17 00-N

XTAB SCREW RING MPF-IN 10 00-N

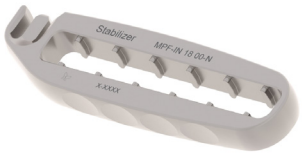
K-WIRE BLUNT Ø1.6 NITINOL MPF-IN 12 00-N



SCREW ADJUSTER MPF-IN 34 00-N

INSTRUMENTS

STABILIZER	MPF-IN 18 00-N



SETSCREW TIGHTENER	MPF-IN 19 00-N

RECOVERY TUBE	MPF-IN 28 00-N

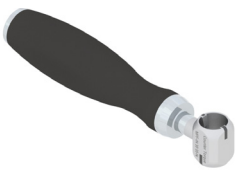
RECOVERY RELEASE TUBE	MPF-IN 29 00-N

RECOVERY CENTERING GUIDE	MPF-IN 27 00-N

COMPRESSION FORCEPS	MIS-IN 41 00-N

DISTRACTION FORCEPS	MIS-IN 42 00-N

COUNTERTORQUE HANDLE	MPF-IN 38 00-N



ROD HOLDER	ELL-IN 01 04-N

PEDICLE SOUNDER	TLF-IN 00 10-N

PALM HANDLE	2RP5-C01

ROD INSERTER 90° NON-PASSING	MPF-IN 03 10-N

INSTRUMENTS

DILATOR TUBE #1 - A	MPF-IN 05 00-N

DILATOR TUBE #1 - B	MPF-IN 05 01-N

DILATOR TUBE #2 SERRATED	MPF-IN 06 01-N

DILATOR TUBE #2 - PUSHER	MPF-IN 06 10-N

CANNULATED TAP ØX	MPF-IN 16 XX-N

COUNTER TORQUE	MPF-IN 26 00-N

INSTRUMENTS

OPTIONS

11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (NOT FENESTRATED, BEVEL STYLET)	RAN-1115N5B*

11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (FENESTRATED)	RAN-1115*

ROD TEMPLATE L250	TLF-IN 10 25-N

PEDICLE PROBE	MPF-IN 20 00-N

ROD INSERTER PERCUTANEOUS	MPF-IN 23 00-N

ROD INSERTER 90° PASSING	MPF-IN 03 00-N

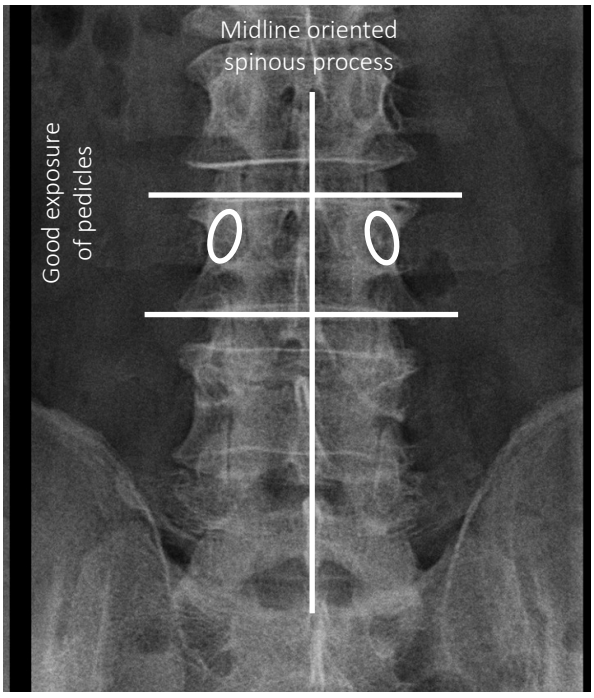
SCREW ATTACHMENT THOMPSON - LEFT	MPF-IN 36 21-N

SCREW ATTACHMENT THOMPSON - RIGHT	MPF-IN 36 20-N

K-WIRELESS SLEEVE	MPF-IN 32 00-N

* These references are sterile

_FLUOROSCOPIC ORIENTATION



Place the patient in the prone position on a radiolucent surgical table.
To obtain optimal visualization of the spine, ensure adequate clearance around the surgical table for the fluoroscopic C-arm. It should be able to rotate freely for AP, oblique and lateral views. Two C-arms can also be used in AP and lateral views.

All other tools used for patient positioning should be radiolucent too.

During the AP acquisition, verify that:

- the spinous processes are in the midline
- the endplates are linear

On the lateral view, verify that:

- the pedicles are superimposed
- the endplates are linear

Adjust the C-arm according to the lordosis of the vertebra level on the lateral image.

NOTE: It is important to start with a clear radiographic image in order to avoid any parallax distortion.

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

_STEP 1

01 02

03

04

TROCAR ASSEMBLY

The Trocar consists of:

- **Trocar Awl** 01
- **Needle Cap** 02
- **Trocar Handle** 03
- **Trocar 3 in 1 / Ti Stick** 04

Place the **Trocar Handle** onto the **Trocar Awl**.

Place the **Needle Cap** into the **Trocar Handle** and the **Trocar Awl** by clipping it clockwise.

Place the **Trocar 3 in 1 / Ti Stick** into the lateral end of the **Trocar Handle** and fix by mating the threaded parts together.

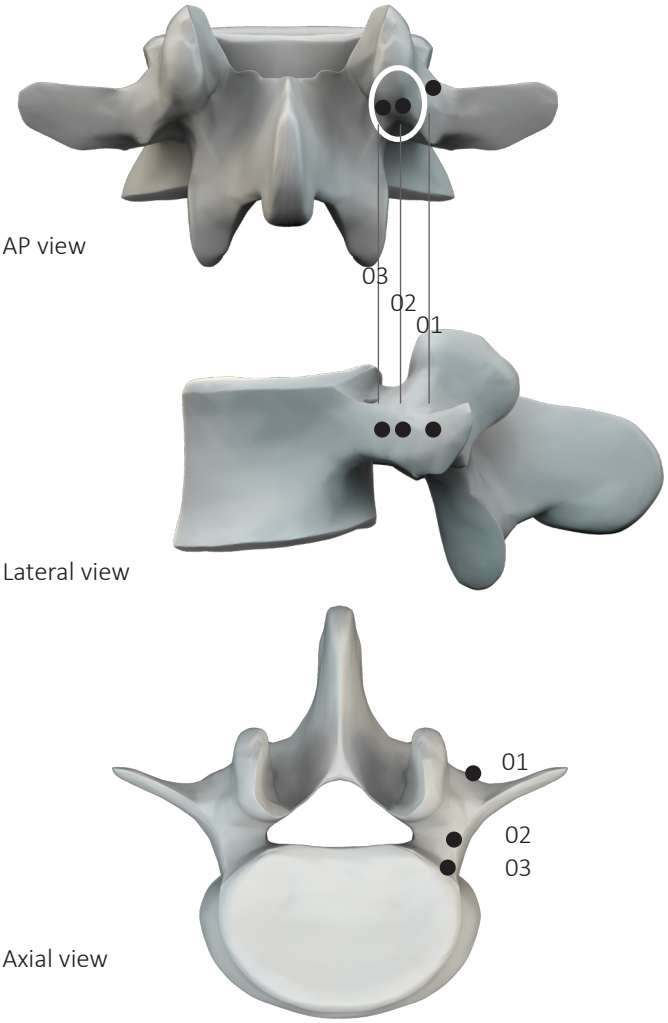
NOTE: The Trocar is used to create a path down the pedicle.

INSTRUMENT	REFERENCE
TROCAR AWL	MPF-IN 04 00-N
TROCAR HANDLE	MPF-IN 04 01-N
NEEDLE CAP	MPF-IN 04 02-N
TROCAR 3 IN 1 / TI STICK	MIS-IN 03 16-N

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

_STEP 2



AP view

Lateral view

Axial view

PEDICLE TARGETING

Place the **Trocar Awl** at the pedicle entry point.

Position 1 - on the AP view. Hold onto the **Ti Stick** during fluoroscopy in order to keep hands out of the ray field.

⚠ **WARNING :** The biplanar fluoroscopy is required for the pedicle targeting.

Using biplanar fluoroscopy, the **Trocar** is inserted into the pedicle.

Make sure that the **Trocar** tip is lateral to the medial wall of the pedicle to ensure that the **Trocar** is in the safe zone – **Position 2**.

The entry point into the vertebral body - **Position 3** – is located just at the limit of the safe zone following the lateral to medial wall trajectory of the pedicle.

Make adjustments using fluoroscopy.

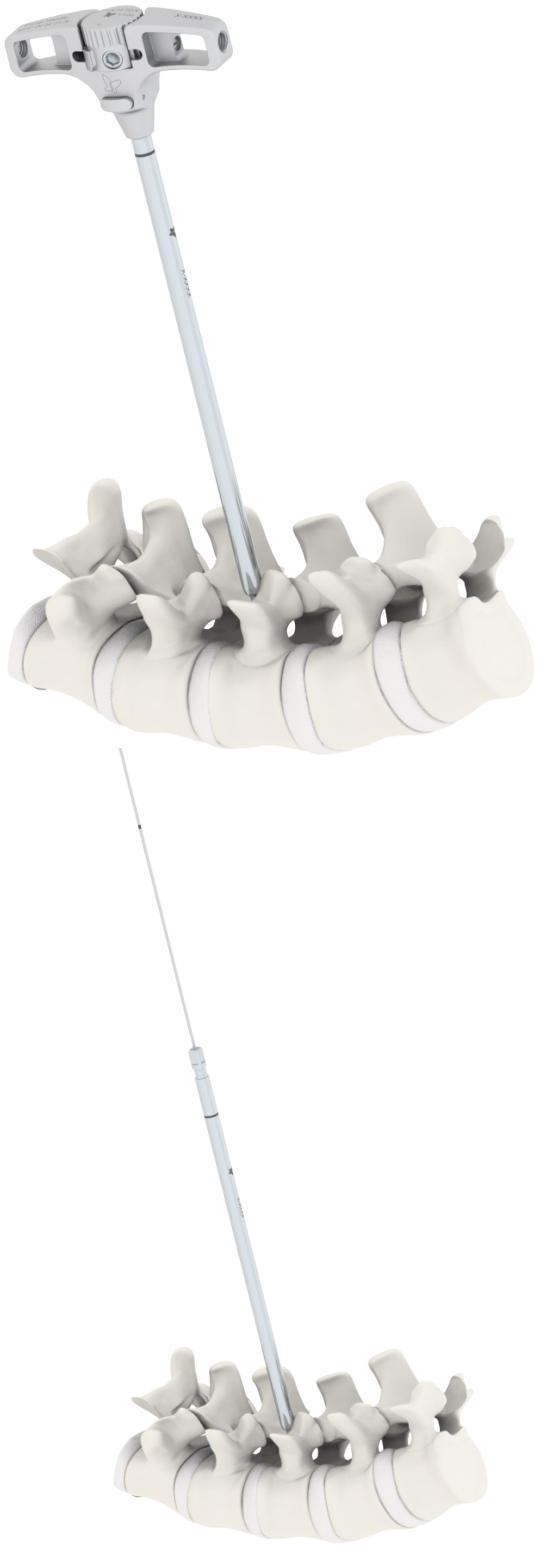
NOTE: The **Trocar Awl** has a depth-stop at 23mm with the **Needle Cap** to limit the entry point depth.

INSTRUMENT	REFERENCE
TROCAR AWL	MPF-IN 04 00-N
TROCAR HANDLE	MPF-IN 04 01-N
NEEDLE CAP	MPF-IN 04 02-N
TROCAR 3 IN 1 / TI STICK	MIS-IN 03 16-N

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

_STEP 3



PEDICLE PREPARATION

Place the **Trocar Awl** at the pedicle entry point.

As the **Trocar Awl** is inserted through the pedicle, make sure that the tip of the **Trocar Awl** is lateral to the medial wall on an AP view.

On a lateral view, the **Trocar Awl** should be at the entry of the vertebral body.

Once the **Trocar Awl** is inside the pedicle, remove the **Needle Cap** and detach the **Trocar Handle**. Then insert the **K-Wire** into the **Trocar Awl**.

NOTE: Insert the threaded side of the **K-Wire** into the **Trocar Awl** to keep benefit from laser mark ring on the **K-Wire**.

Bone Access Needle RAN-1115 / RAN-1115N5B can also be used to create a path down the pedicle.

⚠ **WARNING:** make sure to not advance the **K-Wire** beyond the anterior wall by fluoroscopic control.

INSTRUMENT	REFERENCE
TROCAR AWL	MPF-IN 04 00-N
TROCAR HANDLE	MPF-IN 04 01-N
NEEDLE CAP	MPF-IN 04 02-N
TROCAR 3 IN 1 / TI STICK	MIS-IN 03 16-N
BONE ACCESS NEEDLE (OPTIONAL) - 11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (NOT FENESTRATED), BEVEL STYLET - 11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (FENESTRATED)	RAN-1115N5B RAN-1115
K-WIRE BLUNT Ø1.6 STAINLESS STEEL	MPF-IN 12 02-N
K-WIRE BLUNT Ø1.6 NITINOL	MPF-IN 12 00-N

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

_STEP 4

SCREW SELECTION

Slide the **K-Wire Impactor** along the K-Wire onto the **Trocar Awl**.

NOTE 1: Make sure the **K-Wire Impactor** is properly seated onto the **Trocar Awl**.

NOTE 2: The insertion direction is indicated by the arrow on the **K-Wire Impactor**. (Photo zoom)

⚠ **WARNING:** The impaction is to be made under fluoroscopic control.

Screw size indication is given by the laser mark on the **K-Wire Impactor**.

Remove the **K-Wire Impactor** and **Trocar Awl**.

⚠ **WARNING:** Be sure to not advance the **K-Wire** during removal of **K-Wire Impactor** and **Trocar Awl**.

INSTRUMENT	REFERENCE
K-WIRE BLUNT Ø1.6 STAINLESS STEEL	MPF-IN 12 02-N
K-WIRE BLUNT Ø1.6 NITINOL	MPF-IN 12 00-N
K-WIRE IMPACTOR	MPF-IN 13 00-N
TROCAR AWL	MPF-IN 04 00-N

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

_STEP 5

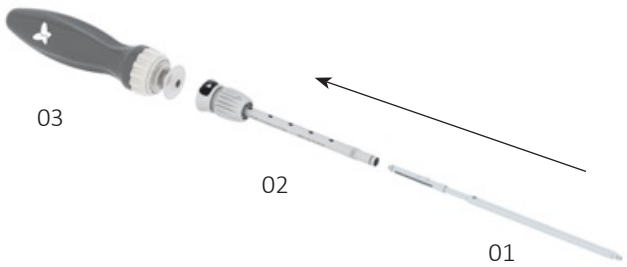


Fig. 1

Fig. 2

Unlocked position

Fig. 3

Fig. 4

Locked position

Fig. 5

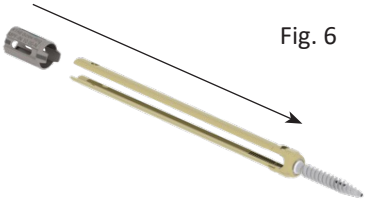


Fig. 6

SCREWDRIVER ASSEMBLY AND SCREW CONNECTION

The screwdriver is composed of:

- **Cannulated Screwdriver Shaft** 01
- **XTAB Screwdriver Tube** 02
- **Straight Handle Ratchet or T-Handle Ratchet** 03

Slide proximal end of **Cannulated Screwdriver Shaft** into distal end of **XTAB Screwdriver Tube** until it clicks.

Align laser mark on **Cannulated Screwdriver Shaft** and **XTAB Screwdriver Tube** to ease the assembly (Fig. 1)

At this step, **XTAB Screwdriver Tube** is in unlocked position with its locking button up. (Fig. 2)

Connect the assembly to the preferred handle.

Insert the **XTAB Screwdriver** through the XTAB screw and engage its distal tip into the screw head.

Rotate the knob clockwise to lock the Screwdriver with the screw.

When laser mark etched on **Cannulated Screwdriver Shaft** is flush with screw head, the Screwdriver is in right position (Fig. 3)

At this step, it's important to secure the assembly by pushing down the locking button on top of the **XTAB Screwdriver Tube** (Fig. 4).

The **Screwdriver** can be assembled with or without the **XTAB Screw Ring** (Fig. 5)

NOTE: To use **XTAB Screw Ring**, just clip it on top of tabs. (Fig. 6)

INSTRUMENT	REFERENCE
CANNULATED SCREWDRIVER SHAFT	MPF-IN 01 00-N
XTAB SCREWDRIVER TUBE	MPF-IN 02 00-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
T-HANDLE RATCHET	HAN-SB RF TE-N
XTAB SCREW RING	MPF-IN 10 00-N
PALM HANDLE	2RP5-C01

K-WIRE TECHNIQUE

_STEP 6

SCREW INSERTION

Slide down the **Screwdriver** assembly onto the **K-Wire**.

Start to anchor the screw into pedicle.

Confirm the proper trajectory and positioning of the screw by using fluoroscopy.

⚠ **WARNING:** make sure to not advance the **K-Wire** into the anterior wall by fluoroscopic control.

Once anchorage is confirmed, remove the **K-Wire** and rotate the **Screwdriver** clockwise to advance the screw.

NOTE: Make sure to not insert the screw too far into the bone which would limit the polyaxial capabilities.

Unlock **Screwdriver** assembly pressing the button on top of **XTAB Screwdriver Tube** and then remove the **Screwdriver** by rotating the knob counterclockwise.

If dilation has been performed, **Dilator Tube #2 Serrated** is removed now (See OPTIONAL / SEQUENTIAL DILATION page 43).

INSTRUMENT	REFERENCE
CANNULATED SCREWDRIVER SHAFT	MPF-IN 01 00-N
XTAB SCREWDRIVER TUBE	MPF-IN 02 00-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
T-HANDLE RATCHET	HAN-SB RF TE-N
DILATOR TUBE #2 SERRATED	MPF-IN 06 01-N
K-WIRE BLUNT Ø1.6 STAINLESS STEEL	MPF-IN 12 02-N
K-WIRE BLUNT Ø1.6 NITINOL	MPF-IN 12 00-N
PALM HANDLE	2RP5-C01

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

_STEP 7

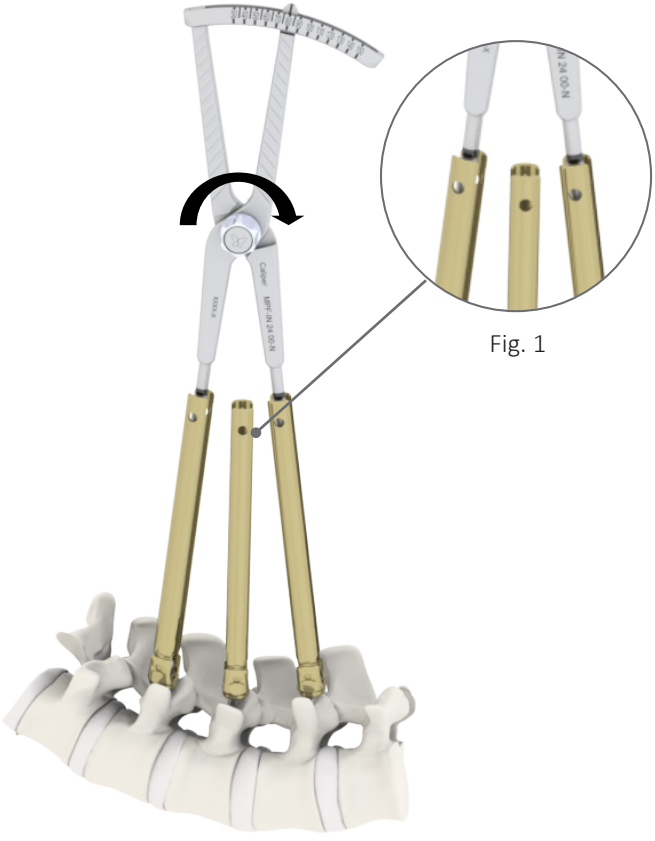


Fig. 1

Fig. 2

ROD LENGTH SELECTION

Insert the ball tips of the **Caliper** into the outer cranio-caudal screw heads.

To make sure that the ball tips are properly seated into the screw heads, check that the laser mark on the **Caliper Arms** (Fig. 1) lines up with the top of the tabs.

NOTE: The **Caliper** can be kept in a locked position with the central thumb wheel.
The **Caliper** can be used with or without the **XTAB Screw Ring** (Fig. 2).

Optional **Rod Template** can be also used for rod length selection.

If needed contour the rod with the **Rod Bender** (See OPTIONAL / ROD CONTOURING page 48).

INSTRUMENT	REFERENCE
CALIPER	MPF-IN 24 00-N
ROD TEMPLATE L250 (OPTIONAL)	TLF-IN 10 25-N
XTAB SCREW RING	MPF-IN 10 00-N

_STEP 8

ROD INSERTER CONNECTION

For **Rod Inserter 90° Passing** or **Non-Passing**, insert the **Rod Inserter Inner Shaft** into the **Rod Inserter** and turn the knob until the shaft is secured.

Connect the appropriate Rod to the **Rod Inserter 90°**assembly.

NOTE: With Pre-Bent rods and for a lordotic curvature, make sure to align the laser mark on the Rod with the laser mark on the **Rod Inserter 90°**.

Secure the connection by tightening the knob manually.

If necessary the **Setscrew Tightener** can be used to unlock the rod.

INSTRUMENT	REFERENCE
ROD INSERTER 90° PASSING (OPTIONAL)	MPF-IN 03 00-N
ROD INSERTER 90° NON-PASSING	MPF-IN 03 10-N
ROD INSERTER 90° - INNER SHAFT	MPF-IN 03 01-N

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

_STEP 9

Fig. 1

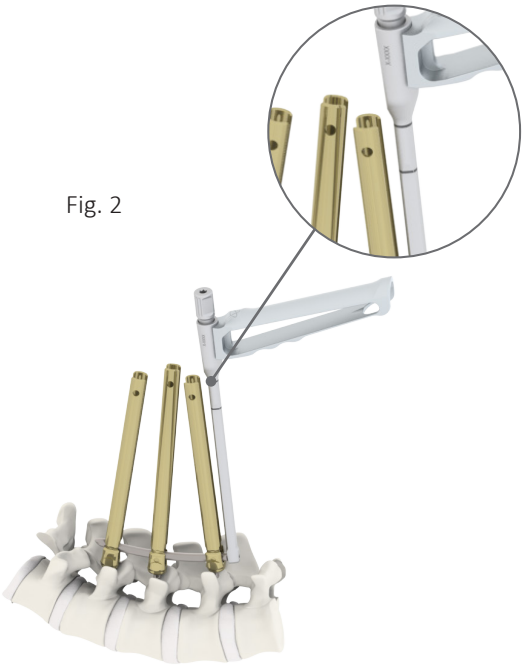


Fig. 2

ROD INSERTION

Insert the **Rod Inserter** Assembly through the outer cranial XTAB screw and insert it into the slot of subsequent caudal XTAB screws (Fig. 1).

Once the rod is correctly positionned within the screw head, upper laser mark on **Rod Inserter** is flush with the tabs proximal part (Fig. 2).

NOTE: The **Stabilizer** or the **XTAB Screw Rings** can be used to realign the XTAB Screws.

Use fluoroscopy to confirm the proper insertion of the Rod.

NOTE: When using **XTAB Screw Rings** and when the rod is properly inserted between the XTAB screws, therefore it's no more possible to rotate tabs with the **XTAB Screw Rings**.

⚠ **WARNING:** Keep the **Rod Inserter** in place so as to the rod cannot move or lose its lordotic angle.

Unlock the connection by turning the knob counterclockwise.

When using the **Rod Inserter Percutaneous**, an extra incision 80mm away from the cranial screw is required in order to insert the Rod (See OPTIONAL / PERCUTANEOUS ROD INSERTER page 45).

NOTE: For mini-open approach, the **Rod Holder** can be used.

INSTRUMENT	REFERENCE
ROD INSERTER 90° - INNER SHAFT	MPF-IN 03 01-N
ROD INSERTER 90° PASSING (OPTIONAL)	MPF-IN 03 00-N
ROD INSERTER 90° NON-PASSING	MPF-IN 03 10-N
ROD HOLDER	ELL-IN 01 04-N

_STEP 10

Fig. 1

Fig. 2

PRELIMINARY TIGHTENING

Load the setscrew to the **Setscrew Holder**.

CAUTION: Control the holding of the setscrew on the **Setscrew Holder** before insertion.

Insert the assembly into the **XTAB Screw Sleeve** (Fig. 1) or into the **Persuader** if used (See OPTIONAL / ROD REDUCTION WITH PERSUADER page 46) and slightly tighten the setscrew.

⚠ **WARNING:** Before inserting the **Setcrew Holder** assembly, the **XTAB Screw Sleeve** must be slided over the XTAB screws.

Replace the **Setscrew Holder** by the **Setscrew Tightener** and apply a preliminary tightening (Fig. 2).

The Built-In reduction allows a 20mm reduction capacity.

NOTE: The rod should be locked down with at least one setscrew before disconnecting the **Rod Inserter**.

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

Fig. 3

Fig. 4

NOTE: Once proximal tab ends are flush with the distal laser mark etched on **XTAB Screw Sleeve**, reduction with setscrew can be performed (Fig. 3).

If proximal tab ends remain below the distal laser mark etched on **XTAB Screw Sleeve**, reduction with the **Persuader** is required.

When proximal tab ends and proximal laser mark etched on **XTAB Screw Sleeve** are flush, the rod is properly seated inside the screw head (Fig. 4).

Repeat the maneuver for all **XTAB Screws** of the construct.

NOTE: If **Persuader** has been used to reduce rod, remove the **Persuader** from the **XTAB Screw Sleeve**.

INSTRUMENT	REFERENCE
SETSCREW HOLDER	TLF-IN 05 10-N
SETSCREW TIGHTENER	MPF-IN 19 00-N
PERSUADER	MPF-IN 15 00-N
PERSUADER KNOB	MPF-IN 15 01-N
XTAB SCREW SLEEVE	MPF-IN 14 00-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
T-HANDLE RATCHET	HAN-SB RF TE-N
PALM HANDLE	2RP5-C01

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

_STEP 11

Fig. 1

Fig. 2

Fig. 3

Fig. 4

FINAL TIGHTENING

Tighten every setscrew with the **Final Tightener** in combination with either the **Stabilizer** (Fig. 1) or the **Counter-Torque Handle** (Fig. 2) or the **Counter Torque**.

The **Final Tightener** is a dynamometric tightener.

When enough strength has been provided a click sound is heard.

If Compression/Distraction maneuvers have been performed, remove the **Compression Forceps** or the **Distraction Forceps**.

Remove the **XTAB Screw sleeves** after final tightening.

Use fluoroscopic control to verify the final construct.

NOTE: The **Counter Torque Handle** enables choosing medio-lateral or cranio-caudal positioning by turning it upside-down. Use the laser marks to align the **Counter Torque Handle** with the **XTAB Screw Sleeve** notches (Fig.s 3 & 4).

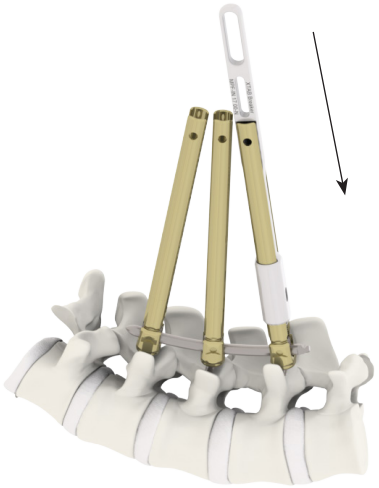
INSTRUMENT	REFERENCE
FINAL TIGHTENER	TLF-IN 05 41-N
COMPRESSION FORCEPS	MIS-IN 41 00-N
DISTRACTION FORCEPS	MIS-IN 42 00-N
XTAB SCREW SLEEVE	MPF-IN 14 00-N
COUNTER TORQUE	MPF-IN 26 00-N
STABILIZER	MPF-IN 18 00-N
COUNTER TORQUE HANDLE	MPF-IN 38 00-N

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

_STEP 12

Fig. 1



TAB BREAKING

Slide the **XTAB Breaker** down along the tabs until it stops (Fig. 1).

The laser mark on the **XTAB Breaker** is lined up with the tab ends once in place.(Fig. 2).

⚠ **CAUTION:** The tabs must not be broken before final tightening and biplanar fluoroscopic control.

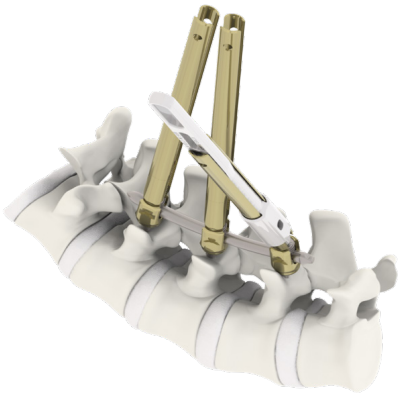
Apply a lateral swinging movement for breaking tabs (Fig. 3).

Remove the broken tabs from the **XTAB Breaker**.

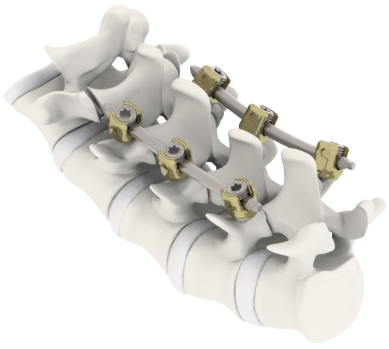
INSTRUMENT	REFERENCE
XTAB BREAKER	MPF-IN 17 00-N

Fig. 2

Fig. 3



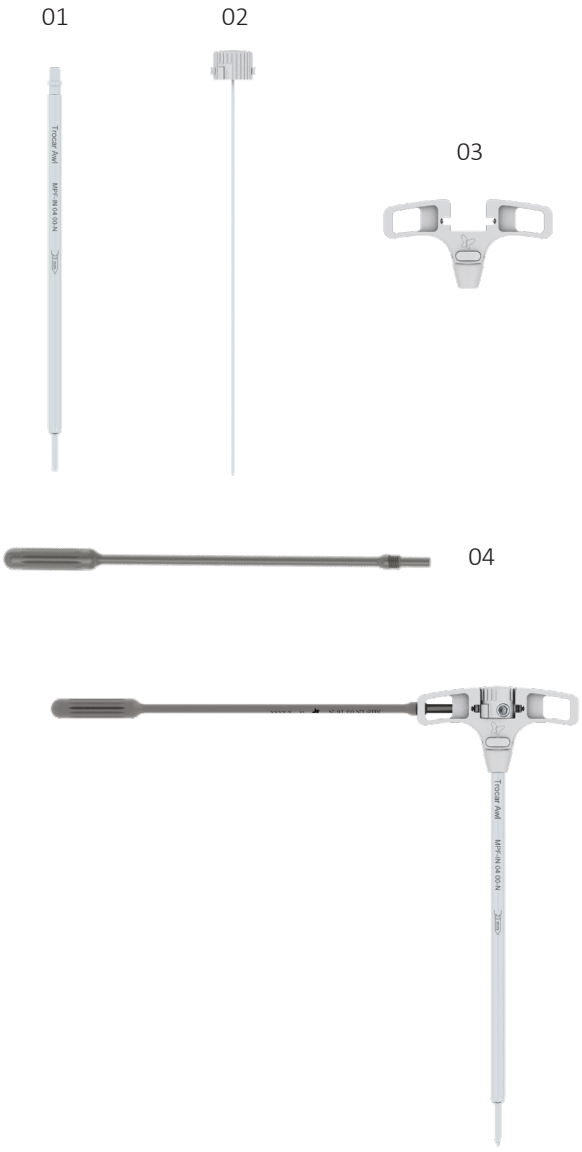
_FINAL CONSTRUCT



SURGICAL TECHNIQUE

K-WIRELESS TECHNIQUE

_STEP 1



TROCAR ASSEMBLY

The Trocar consists of:

- **Trocar Awl** 01
- **Needle Cap** 02
- **Trocar Handle** 03
- **Trocar 3 in 1 / Ti Stick** 04

Place the **Trocar Handle** onto the **Trocar Awl**.

Place the **Needle Cap** into the **Trocar Handle** and the **Trocar Awl** by clipping it clockwise.

Place the **Trocar 3 in 1 / Ti Stick** into the lateral end of the **Trocar Handle** and fix by mating the threaded parts together.

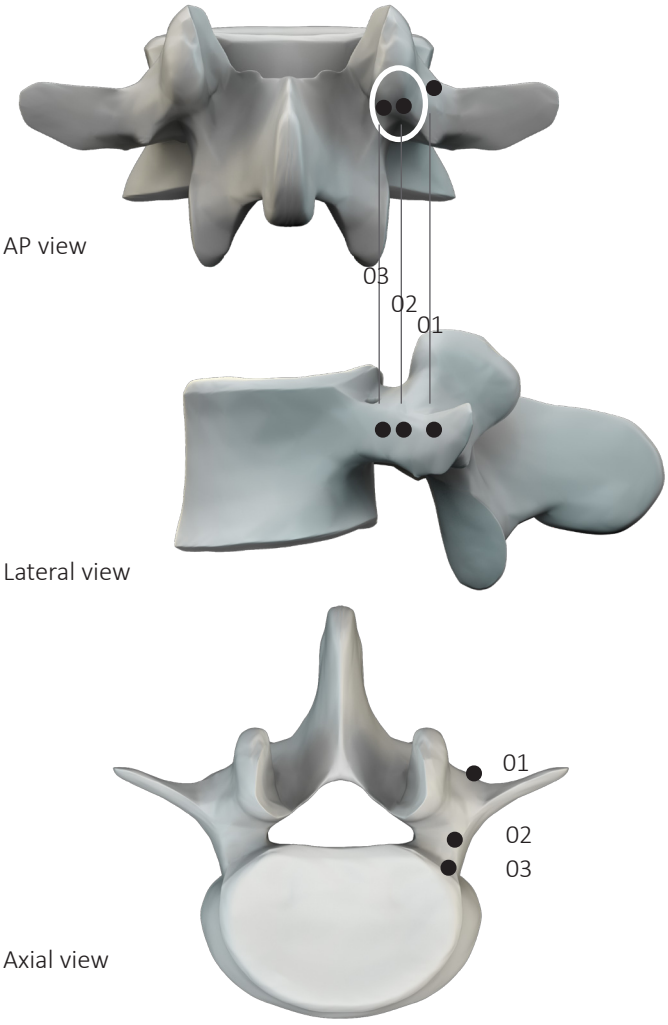
NOTE: The Trocar is used to create a path down the pedicle.

INSTRUMENT	REFERENCE
TROCAR AWL	MPF-IN 04 00-N
TROCAR HANDLE	MPF-IN 04 01-N
NEEDLE CAP	MPF-IN 04 02-N
TROCAR 3 IN 1 / TI STICK	MIS-IN 03 16-N

SURGICAL TECHNIQUE

K-WIRELESS TECHNIQUE

_STEP 2



PEDICLE TARGETING

Place the **Trocar** at the pedicle entry point.

Position 1 - on the AP view. Hold on the **Ti Stick** during fluoroscopy in order to keep hands out of the ray field.

⚠ **WARNING:** The biplanar fluoroscopy is required for the pedicle targeting.

Using biplanar fluoroscopy, the **Trocar** tip is inserted into the pedicle.

Make sure that the **Trocar** tip is lateral to the medial wall of the pedicle to ensure that the **Trocar** is in the safe zone – **Position 2**.

The entry point into the vertebral body - **Position 3** – is located just at the limit of the safe zone following the lateral to medial wall trajectory of the pedicle.

Make adjustments using fluoroscopy.

NOTE: The **Trocar Awl** has a depth-stop at 23mm with the **Needle Cap** to limit the entry point depth.

INSTRUMENT	REFERENCE
TROCAR AWL	MPF-IN 04 00-N
TROCAR HANDLE	MPF-IN 04 01-N
NEEDLE CAP	MPF-IN 04 02-N
TROCAR 3 IN 1 / TI STICK	MIS-IN 03 16-N

K-WIRELESS TECHNIQUE

_STEP 3

SEQUENTIAL DILATION

Remove the **Needle Cap** and detach the **Trocar Handle** from the **Trocar Awl**.

Slide the **Dilator Tube #1-B** onto the **Trocar Awl**, and slide the **Dilator Tube #2 Serrated** onto the **Dilator Tube #1-B**.

Place the **Dilator Tube #2 – Pusher** on top of the **Dilator Tube #2 Serrated** and lightly hammer the assembly in order to dock it to the bony structure.

⚠ **WARNING:** Do not push too hard on the **Dilator Tube #2 – Pusher**.

At this step, it's recommended to remove the **Dilator Tube #2 – Pusher**, and the **Dilator Tube #1-B**.

The **Dilator Tube #2 Serrated** should remain steady.

INSTRUMENT	REFERENCE
TROCAR AWL	MPF-IN 04 00-N
TROCAR HANDLE	MPF-IN 04 01-N
NEEDLE CAP	MPF-IN 04 02-N
DILATOR TUBE #1-B	MPF-IN 05 01-N
DILATOR TUBE #2 SERRATED	MPF-IN 06 01-N
DILATOR TUBE #2 – PUSHER	MPF-IN 06 10-N

SURGICAL TECHNIQUE

K-WIRELESS TECHNIQUE

_STEP 4

PEDICLE PREPARATION

Introduce the **Pedicle Probe** through the **Dilator Tube #2 Serrated**, the instrument is self-aligning. Prepare the pedicle path by placing the **Pedicle Probe** distal tip curvature in a medial position.

The **Pedicle Probe** is laser marked to indicate the appropriate screw size.

The **Pedicle Sounder** can be used to control vertebral body structural integrity.

⚠ **WARNING:** Carry out AP and lateral controls under fluoroscopy during pedicle preparation maneuvers.

NOTE: It's recommended to assemble the pedicle screw with the screwdriver before removing the **Pedicle Probe**.

INSTRUMENT	REFERENCE
PEDICLE PROBE (OPTIONAL)	MPF-IN 20 00-N
DILATOR TUBE #2 SERRATED	MPF-IN 06 01-N
PEDICLE SOUNDER	TLF-IN 00 10-N

SURGICAL TECHNIQUE

K-WIRELESS TECHNIQUE

_STEP 5

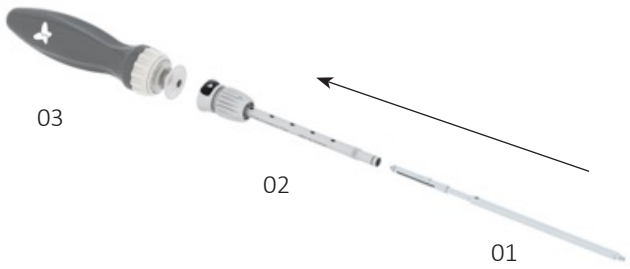


Fig. 1

Fig. 2

Unlocked position

Fig. 3

Fig. 4

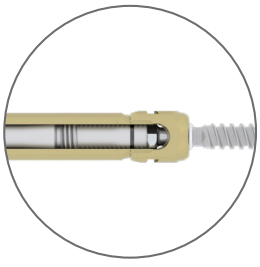


Fig. 5

Locked position

SCREWDRIVER ASSEMBLY AND SCREW CONNECTION

The screwdriver is composed of:

- **Cannulated Screwdriver Shaft** 01
- **XTAB Screwdriver Tube** 02
- **Straight Handle Ratchet or T-Handle Ratchet** 03

Slide proximal end of **Cannulated Screwdriver Shaft** into distal end of **XTAB Screwdriver Tube** until it clicks (Fig. 1). At this step, **XTAB Screwdriver Tube** is in unlocked position with its locking button up (Fig. 2).

Connect the assembly to the preferred handle.

Slide down the **K-Wireless Sleeve** over the XTAB screw (Fig. 3).

Insert the screwdriver through the assemble **K-Wireless Sleeve** and the XTAB screw and then engage the screwdriver distal tip into the screw head.

Rotate the knob clockwise to lock the Screwdriver with the screw.

When laser mark etched on **Cannulated Screwdriver Shaft** is flush with screw head, the Screwdriver is in right position (Fig. 4)

At this step, it's important to secure the assembly by pushing down the locking button on top of the **XTAB Screwdriver Tube** (Fig. 5).

INSTRUMENT	REFERENCE
CANNULATED SCREWDRIVER SHAFT	MPF-IN 01 00-N
XTAB SCREWDRIVER TUBE	MPF-IN 02 00-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
T-HANDLE RATCHET	HAN-SB RF TE-N
K-WIRELESS SLEEVE	MPF-IN 32 00-N
PALM HANDLE	2RP5-C01

SURGICAL TECHNIQUE

K-WIRELESS TECHNIQUE

_STEP 6

PEDICLE SCREW INSERTION

Keep the **Dilator Tube #2 Serrated** steady.

Remove the **Pedicle Probe** from the vertebra and place the **Screwdriver** assembly through the **Dilator Tube #2 Serrated**.

⚠ **WARNING:** Confirm the proper trajectory and positioning of the screw by using fluoroscopy.

NOTE: Make sure to not insert the screw too far into the bone which would limit the polyaxial capabilities.

Unlock **Screwdriver** assembly pushing the button on top of **XTAB Screwdriver Tube** and then remove the **Screwdriver** by rotating the knob counterclockwise.

INSTRUMENT	REFERENCE
CANNULATED SCREWDRIVER SHAFT	MPF-IN 01 00-N
XTAB SCREWDRIVER TUBE	MPF-IN 02 00-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
T-HANDLE RATCHET	HAN-SB RF TE-N
DILATOR TUBE #2 SERRATED	MPF-IN 06 01-N
PEDICLE PROBE (OPTIONAL)	MPF-IN 20 00-N
PALM HANDLE	2RP5-C01

For following steps refer to K-WIRE TECHNIQUE

SURGICAL TECHNIQUE

RECOVERY

_STEP 1

PLACING THE RECOVERY TUBE

If one or both tabs are detached from the screw head, the recovery system can be used.

Introduce the distal end of the **Recovery Centering Guide** until fully seated in the screw head.

Insert the **Recovery Tube** along the guide tracks of the **Recovery Centering Guide**.

Push on the **Recovery Tube** and connect it to the screw head until it clicks.

Remove the **Recovery Centering Guide**.

INSTRUMENT	REFERENCE
RECOVERY CENTERING GUIDE	MPF-IN 27 00-N
RECOVERY TUBE	MPF-IN 28 00-N

SURGICAL TECHNIQUE

RECOVERY

_STEP 2

ROD OR SPONDYLOLISTHESIS REDUCTION

Slide the **XTAB Screw Sleeve** through the **Recovery Tube**.
Assemble the **Persuader Knob** with the **Recovery Tube** by screwing.

Screw the **Persuader Knob** clockwise until graduation “0”. To help with the reduction maneuver, a **QR Reducer T-Handle** can be used to screw the **Persuader Knob**.

NOTE: The reduction maneuver can go up to 20mm. And can be performed bilaterally and simultaneously.

Proceed to PRELIMINARY TIGHTENING and FINAL TIGHTENING as mentioned from page 29 to 31 to fix the rod in the desired position.

INSTRUMENT	REFERENCE
RECOVERY TUBE	MPF-IN 28 00-N
QR REDUCER T-HANDLE	HAN-SS TY 14-N
PERSUADER KNOB	MPF-IN 15 01-N
XTAB SCREW SLEEVE	MPF-IN 14 00-N

RECOVERY

_STEP 3

RECOVERY TUBE RELEASE

Confirm that the final construct is completed before removing the **Recovery Tube**.

If a reduction has been previously performed, remove the **Persuader Knob** from the **Recovery Tube** by screwing counterclockwise. Then pull out the **XTAB Screw Sleeve**.

Place the **Recovery Release Tube** into the **Recovery Tube** and push down until the flanks of the **Recovery Tube** open.

Pull out the assembly to remove the **Recovery Tube**.

INSTRUMENT	REFERENCE
RECOVERY TUBE	MPF-IN 28 00-N
XTAB SCREW SLEEVE	MPF-IN 14 00-N
PERSUADER KNOB	MPF-IN 15 01-N
RECOVERY RELEASE TUBE	MPF-IN 29 00-N

_REVISION

Fig. 1

Fig. 2

Fig. 3

Fig. 4

If a surgical decision is made to remove the construct, the following steps should be followed.

Insert the **Counter Torque** over the screw head (Fig. 1). Insert the **Setscrew Tightener** assembled with **T-Handle Ratchet** through the **Counter Torque** and screw counterclockwise to release the setscrew (Fig. 2). Replace the **Setscrew Tightener** by the **Setscrew Holder** to catch and remove the setscrew (Fig. 3).

Repeat these steps with every setscrew to release and remove the rod.

Insert the distal end of the **Recovery Centering Guide** until fully seated in the screw head.

Insert the **Recovery Tube** along the guide tracks of the **Recovery Centering Guide**.

Push on the **Recovery Tube** and connect it to the screw head until it clicks.

Remove the **Recovery Centering Guide** (see RECOVERY Steps page 39 to 41 for more details).

Assemble the **XTAB Screwdriver Shaft** with the **T-Handle Ratchet** or the **Straight Handle Ratchet** and insert the assembly through the **Recovery Tube**. Screw counterclockwise and pull out the **Recovery Tube** to remove the screw (Fig. 4).

INSTRUMENT	REFERENCE
COUNTER TORQUE	MPF-IN 26 00-N
SETSCREW TIGHTENER	MPF-IN 19 00-N
T-HANDLE RATCHET	HAN-SB RF TE-N
SETSCREW HOLDER	TLF-IN 05 10-N
RECOVERY CENTERING GUIDE	MPF-IN 27 00-N
RECOVERY TUBE	MPF-IN 28 00-N
CANNULATED SCREWDRIVER SHAFT	MPF-IN 01 00-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
PALM HANDLE	2RP5-C01

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

OPTIONAL

SEQUENTIAL DILATION

Remove the **Needle Cap** and detach the **Trocar Handle** from the **Trocar Awl**.

Slide the **Dilator Tube #1 – B** over the **Trocar Awl** until pedicle entry point.

Slide the **Dilator Tube #2 Serrated** over **Dilator Tube #1 – B** until pedicle entry point.

⚠ **WARNING:** make sure to not advance the **K-Wire** into the anterior wall by fluoroscopic control.

NOTE: In case of Bone Access Needle pedicle preparation, assemble the **Dilator Tube #1 – A** with the **Dilator Tube #1 – B** and then slide the assembly over the **K-Wire** until pedicle entry point.

Then slide the **Dilator Tube #2 Serrated** over **Dilator Tube #1 – B** until pedicle entry point.

INSTRUMENT	REFERENCE
TROCAR AWL	MPF-IN 04 00-N
TROCAR HANDLE	MPF-IN 04 01-N
NEEDLE CAP	MPF-IN 04 02-N
DILATOR TUBE #1 – A	MPF-IN 05 00-N
DILATOR TUBE #1 – B	MPF-IN 05 01-N
DILATOR TUBE #2 SERRATED	MPF-IN 06 01-N
DILATOR TUBE #2 – PUSHER	MPF-IN 06 10-N
BONE ACCESS NEEDLE (OPTIONAL) - 11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (NOT FENESTRATED), BEVEL STYLET - 11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (FENESTRATED)	RAN-1115N5B RAN-1115
K-WIRE BLUNT Ø1.6 STAINLESS STEEL (OPTIONAL)	MPF-IN 12 02-N
K-WIRE BLUNT Ø1.6 NITINOL	MPF-IN 12 00-N

SURGICAL TECHNIQUE

K-WIRE TECHNIQUE

OPTIONAL

TAPPING

If tapping is desired, one may choose the appropriate **Tap** diameter (available in Ø5, Ø6, Ø7 and Ø 8mm) according to the screw diameter selected.

Connect the **Cannulated Tap** to the **T-Handle Ratchet**.

Slide down the **Cannulated Tap** onto the **K-Wire**.

Advance the **Cannulated Tap** into the bone by turning the **T-Handle Ratchet** clockwise.

⚠ **WARNING 1:** Do not use a **Cannulated Tap** in a larger diameter than the selected screw.

⚠ **WARNING 2:** make sure to not advance the **K-Wire** into the anterior wall by fluoroscopic control.

The laser marks on **Cannulated Taps** allow to control depth insertion into the pedicle

Remove the **Cannulated Tap** by turning counterclockwise.

INSTRUMENT	REFERENCE
CANNULATED TAP Ø5 (Ø5.5 SCREW)	MPF-IN 16 50-N
CANNULATED TAP Ø6 (Ø6.5 SCREW)	MPF-IN 16 60-N
CANNULATED TAP Ø7 (Ø7.5 SCREW)	MPF-IN 16 70-N
CANNULATED TAP Ø8 (Ø8.5 SCREW)	MPF-IN 16 80-N
K-WIRE BLUNT Ø1.6 STAINLESS STEEL	MPF-IN 12 02-N
K-WIRE BLUNT Ø1.6 NITINOL	MPF-IN 12 00-N
T-HANDLE RATCHET	HAN-SB RF TE-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
DILATOR TUBE #2 SERRATED	MPF-IN 06 01-N
PALM HANDLE	2RP5-C01

OPTIONAL

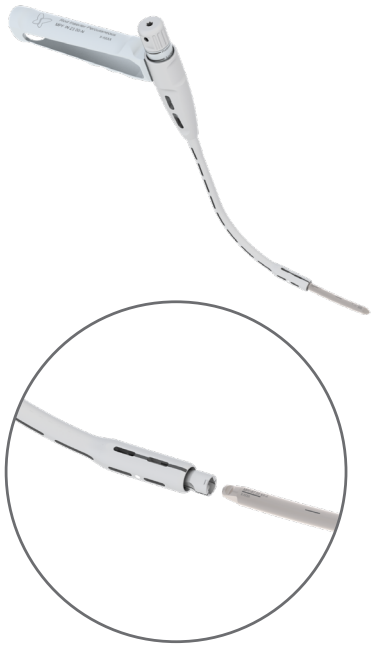


Fig. 1

Fig. 2
Unlocked position

Fig. 3
Locked position

PERCUTANEOUS ROD INSERTER

Connect the appropriate Rod to the **Rod Inserter Percutaneous** (Fig. 1).

Ensure that the knob is in the unlocked position (Fig. 2).

NOTE: With Pre-Bent rods and for a lordotic curvature, make sure to align the laser mark on the Rod with the laser mark on the **Rod Inserter Percutaneous**.

Lock the connection by turning the knob clockwise until it clicks (Fig. 3).

When using the **Rod Inserter Percutaneous**, an 80mm extra incision is required away from the outer cranial screw for rod insertion.

INSTRUMENT	REFERENCE
ROD INSERTER PERCUTANEOUS (OPTIONAL)	MPF-IN 23 00-N

OPTIONAL

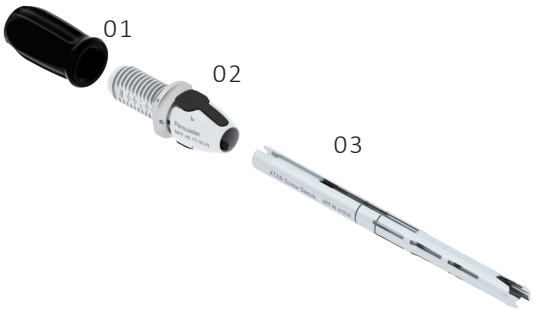


Fig. 1

Fig. 2

Unlocked position

Locked position

INSTRUMENT	REFERENCE
PERSUADER	MPF-IN 15 00-N
PERSUADER KNOB	MPF-IN 15 01-N
XTAB SCREW SLEEVE	MPF-IN 14 00-N
QR REDUCER T-HANDLE	HAN SS TY 14-N

ROD REDUCTION WITH PERSUADER

- **Persuader Knob** 01
- **Persuader** 02
- **XTAB Screw Sleeve** 03

The **Persuader** can be used to reduce the rod into the screw head, making setscrew placement easier. With the **Persuader**, the rod reduction can go up to 30 mm.

Assemble the **Persuader** and the **Persuader Knob** by screwing it until the **Persuader Knob** is aligned with position START on the **Persuader**.

Slide the **XTAB Screw Sleeve** over the XTAB screws until reaching the rod.

⚠ **WARNING:** Be sure that holes on the XTAB screw sides are visible through the **XTAB Screw Sleeve** (Fig. 1).

Clip the **Persuader** over the **XTAB Screw Sleeve** and the XTAB screws.

A clipping noise is to be heard when the connection is made.

Engage the **Persuader** locking ring in lower position to lock connection between the **Persuader** and the XTAB screw (Fig. 2).

Start the reduction by screwing the **Persuader Knob** clockwise until graduation “0”.

To help with the reduction maneuver, a **QR Reducer T-Handle** can be used to screw the **Persuader Knob**.

Spondylolisthesis reduction can be performed bilaterally and simultaneously as described above.

Use fluoroscopy to control the reduction.

OPTIONAL

COMPRESSION AND DISTRACTION

Attach the **Stabilizer** onto the **XTAB Screw Sleeves** to realign the XTAB screws..

Prior to any compression or distraction maneuver, use the **Final Tightener** to lock the setscrew at the extremity of the construct.

Use the **Compression Forceps** or the **Distraction Forceps** to get appropriated correction and maintain the correction by firmly tightening setscrews with the **Setscrew Tightener**.

INSTRUMENT	REFERENCE
STABILIZER	MPF-IN 18 00-N
SETSCREW TIGHTENER	MPF-IN 19 00-N
FINAL TIGHTENER	TLF-IN 05 41-N
COMPRESSION FORCEPS	MIS-IN 41 00-N
DISTRACTION FORCEPS	MIS-IN 42 00-N
XTAB SCREW SLEEVE	MPF-IN 14 00-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
T-HANDLE RATCHET	HAN-SB RF TE-N
PALM HANDLE	2RP5-C01

SURGICAL TECHNIQUE

OPTIONAL

ROD CONTOURING

Contour the rod if needed with the **Rod Bender** to fit in the screw head.

Pull and turn the wheel to select the appropriate bending. Align the dot from the handle with the one from the desired position.

NOTE: PERLA® TL MIS rods are 5.5mm and 6mm.

⚠ **WARNING:** Once bent, rods should not be de-contoured.

⚠ **WARNING:** Repeated bending can weaken the rod.

INSTRUMENT	REFERENCE
ROD BENDER	ELL-IN 00 09-N

GENERAL INFORMATION

REFERENCE OF THE IFU	PER-IF TL 00-W	REVISION OF THE FINAL IFU	JAN-2022

_STERILITY

The implant is provided sterile or non sterile. Under non sterile condition, implants are packaged in a single polyethylene pouch. Under sterile condition, implants are packaged in a first polyethylene pouch, included in a second PETG blister. Each of these packaging are labeled and an IFU is included. In case of non sterile condition delivery, see § "Decontamination, cleaning and sterilization".

_CAUTION

If the implant or its packaging seems to be damaged, if the expiry date is exceeded or if the sterility cannot be guaranteed for any reason, the implant mustn't be used. The re-sterilization of the gamma sterilized implant is forbidden.

Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues, even after cleaning. The implant must be discarded. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. Such re-use may also result in infection in the patient.

The PERLA® TL implant must not be used with implant other than PERLA® TL range. Never use stainless steel and titanium components in the same construct. The PERLA® TL Implant must only be used with the PERLA® TL instruments. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the Posterior osteosynthesis system. US Caution Federal law restricts these devices to be sold by or on the order of a physician.

_DESCRIPTION

PERLA® TL spine system was designed to ensure the best possible adaptation to patient's anatomic variations. This system has been designed to correct and stabilize the spine.

PERLA® TL spine system range consists of pedicle screws of various length and diameters, and hooks receiving longitudinal rods. In order to obtain additional stiffness, a transverse rod and connectors are also available.

All implants of the PERLA®TL spinal system are either made of titanium or cobalt chromium, corresponding to legal medical requirements.

_INDICATIONS

The PERLA® TL posterior osteosynthesis system is 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 disc disease;
- spondylolisthesis;
- fracture;
- dislocation;
- scoliosis;
- kyphosis;
- spinal tumor;
- and failed previous fusion (pseudarthrosis).

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the PERLA® TL posterior osteosynthesis system is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PERLA® TL posterior osteosynthesis system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

_CONTRAINDICATIONS

Include but not limited to:

- Mental illness.
- Infection.
- Severely damaged bone structures that could prevent stable implantation of the implant.
- Neuromuscular or vascular disorders or illness.
- Inadequate activity.
- Pregnancy
- Bone tumor in the region of implant.

_SIDE EFFECTS

Per operative:

Haemostatic problems, injuries to the nervous system resulting in temporary or permanent weaknesses, pain or functional handicap, fractures.

Post operative:

Venous thrombosis and pulmonary embolism, infection, cardio-vascular disorders, hematoma and late wound healing.

Specific to implant:

Implant migration, adhesion and fibrosis, limited range of movement, secondary fractures. Potential risk identified with the use of this posterior osteosynthesis system, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury

Additional potential adverse events for pediatric patients:

- Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions and/or distorted anatomy)
- Pedicle screw malpositioning, with or without neurological or vascular injury • Proximal or distal junctional kyphosis
- Pancreatitis

_WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation , scoliosis, kyphosis, spinal tumor, and failed previous fusion (i.e pseudoarthrosis). The safety and effectiveness of these devices for any others conditions are unknown.

The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients not skeletally mature that undergo spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the “crankshaft phenomenon”) due to continued differential growth of the anterior spine. Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for devicerelated injury because of their smaller stature.

Do not use titanium and stainless steel components together.

Components of PERLA® TL posterior osteosynthesis system should not be used with components of any other system or manufacturer.

The safety and effectiveness of cannulated fenestrated screws have not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

Additional Warnings for Pediatric Patients:

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of ped icle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the “crankshaft phenomenon”) due to continued differential growth of the anterior spine. Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients, and pediatric patients may be at increased risk for device-related injury because of their smaller stature.

_CAUTION - PRECAUTIONS FOR USE

An in-depth discussion of all possible complications associated with spine stabilization with implants is beyond the scope of these instructions. Every surgeon who uses these implants must take each patient’s clinical state and medical status into consideration, and be fully familiar with procedures involving the use of this type of implant and the potential complications in each case.

Implants are mechanical devices that can be worn, damaged or broken.

An implant site can become infected, painful, swollen, or inflamed. Significant weight on the implant, an implant of

inadequate size, and patient hyperactivity or a misuse will increase the risk of complications, including wear and tear or rupture.

The soft tissue and the adjacent bones may deteriorate over time, or may not be in an adequate state to support the implant, thus causing instability and/or malformation.

The benefits of this posterior osteosynthesis procedure may not meet the patient's expectations, thus requiring more surgery to replace or remove the implant, or other types of procedures.

Surgeons should therefore take several factors into consideration, in order to achieve optimal results for each patient.

It is therefore essential that each patient who must undergo this type of procedure be informed, with the supporting documentation available, of the potential complications.

Additional Precautions for Pediatric Patients:

The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients. The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

_MRI SAFETY INFORMATION

The PERLA® TL System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the PERLA® TL System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

_HANDLING

No effort has been spared to ensure that only the highest-quality materials and expertise have been deployed in producing each implant.

When handling these implants, blunt instruments should be used in order to avoid scratching, cutting, or nicking the device.

Sharp-edged, serrated or toothed instruments should not be used.

Careful preparation of the surgical site and choosing an implant of the right size will increase the chances of a successful reconstruction.

Surgeons are advised not to remove the device from its sterile packaging until after the implant site has been properly prepared and precise measurements have been taken.

_SURGERY METHODS

The implantation of an implant should be performed only by experienced 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.

The surgeon is responsible for familiarizing him/herself with the surgical technique used for implanting these devices, by studying the relevant published articles, consulting experienced colleagues, and receiving training in the methods appropriate to the particular implant being used.

Careful preparation of the surgical site and choosing an implant of the right size will increase the chances of a successful procedure.

The surgical procedure is standard for experienced surgeons. Your local representative should have communicated the handbook describing the surgical technique. In any case, the handbook is readily available by contacting either your local representative or directly Spineart®.

We strongly recommend that excessive force should not be applied when installing any of the implants. A handbook on surgical techniques, describing the standard implant procedure, is available.

_PATIENT CARE FOLLOWING TREATMENT

Detailed instructions on the use and limitations of the device should be given to the patient.

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician. The patient should be instructed regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems.

GENERAL INFORMATION

Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient.

_STORAGE CONDITION

It is mandatory that the implants are stored in their original packaging, in a clean, dry location where atmospheric pressure is moderate.

_INSTRUMENTATION

The instruments were specifically designed for use when installing these implants.

They are delivered non-sterile.

Specific markings are engraved on each instrument to facilitate identification of the corresponding implant size and type.

_DECONTAMINATION, CLEANING, AND STERILIZATION

Point-of-instruction: The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described below. Prior to starting the surgical procedure, all non sterile reusable instruments must be properly cleaned, decontaminated and sterilized. These instruments have been designed in order to avoid disassembly manipulation prior decontamination, cleaning and sterilization processes. These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments and not sterile implants.

Manual disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 1 minute, using softbristled brush to assist in the removal of gross soil debris. Devices that can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 5 minutes using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute.
- Use a syringe to flush the devices with cannulation with 2x20 ml of neutral enzymatic cleaner at room temperature (+15/+25°C).
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute. Devices with mobile parts must be manipulated through their full range of motion during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 2 minutes using soft bristled brush at room temperature (+15/+25°C). Use a syringe to flush the devices with cannulation with 2x20 ml of deionized water at room temperature (+15/+25°C).
- Rinse thoroughly the devices with deionized water for 2 minutes. Devices with mobile parts must be manipulated through their full range of motion during rinsing.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

Automatic disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 30 seconds, using softbristled brush to assist in the removal of gross soil debris. Devices that can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 1 minute using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 30 seconds. Devices with mobile parts must be manipulated through their full range of motion during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute. Devices with mobile parts must be manipulated through their full range of motion during rinsing
- Load devices into the washer-disinfector.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

WASHER-DISINFECTOR PARAMETERS

STEP	SOLUTION	TEMPERATURE	TIME
Pre-cleaning	Tap Water	<45°C	2 minutes
Cleaning	Water + Neutral enzymatic cleaner (as example NEODISHER Mediclean Forte)	55°C	10 minutes
Neutralizing	Water	<45°C	2 minutes
Rinsing	Tap water	<45°C	2 minutes
Thermal disinfection	Reversed osmosis water	90 °C	5 minutes

Sterilization trays cleaning and disinfection

All the trays must be thoroughly cleaned and disinfected after surgery completion.

Cleaning recommendations

- Remove all the instruments from the trays,
- Large and visible impurities must be removed from the trays,
- Use running water and rinse thoroughly for at least one minute,
- Use freshly prepared cleaning bath of the specified concentration for the period specified by the manufacturer,
- Use soft brush until there is no visible contamination,
- Dry trays with lint-free disposable cloths.

Disinfection recommendations

- Use a freshly disinfectant bath of the specified concentration for the period specified by the manufacturer. Rinse thoroughly three times,
- Rinse trays thoroughly with water as specified by the disinfectant manufacturer,
- Dry trays with lint-free disposable cloths.

Trays must be visually clean, if not, repeat the cleaning and disinfection protocol.

• Subsequent sterilization in containers is then recommended, using an autoclave and steam, and following a protocol that meets the minimum requirements or more, and is in compliance with current legislation (e.g., 134°C – 18 minutes) to obtain a guaranty of sterility of 10-6.The validation for sterilization have been done according to overkill/half cycle method as described in the ISO 17664, ISO 17665 standards and of AAMI TIR 12 Technical Report. Whenever applicable, implants delivered into non sterile condition must follow the same protocol of decontamination, cleaning and sterilization.

_STERILIZATION PARAMETERS

Method: Pre-vacuum cycle of Steam sterilization (moist heat - autoclave)

Cycle 1 (EU):

Exposure time: 18 minutes

Temperature: 134°C

Drying time: 30 minutes

Cycle 2 (USA):

Exposure time: 4 minutes

Temperature: 132°C

Drying time: 30 minutes

This 134°C – 18 minutes sterilization cycle is 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 (time and temperature).

"Do not stack trays during sterilization"

GENERAL INFORMATION

_PRODUCT USE LIFE

Spineart® instruments are validated for 150 steam sterilization runs.

Prior to use all components should be checked for functionality and the absence of defects such as wear, tear, corrosion, pitting and discoloration to ensure that there is no damage. Damaged components must not be used and should be returned to Spineart®.

_MAINTENANCE AND REPAIR

Spineart instruments that need to be repaired must be decontaminated and cleaned, then sent to the address mentioned in this document.

_FURTHER INFORMATION

If further directions for use of this system are needed, please check with the SPINEART Customer Service. If further information is needed or required, please see the addresses on this document.

GENERAL INFORMATION

REFERENCE OF THE IFU	SRI-00-IF-WW	REVISION OF THE FINAL IFU	OCT-2021

INSTRUCTION FOR USE - SURGICAL REUSABLE INSTRUMENTS

_DESCRIPTION

This instrument is specially designed for use when installing the corresponding product range of implant.

None of the instruments should be implanted.

_INDICATIONS

Surgical instruments from Spineart are intended for the preparation of the surgical site, installation and removal of Spineart's surgical implants during spinal surgical procedures as defined in the corresponding product range instruction for use / surgical technique manual.

_CONTRAINDICATIONS

The intended target groups including indications and contra-indications are defined in the corresponding product range instruction for use / surgical technique manual. There are no contra-indications related to the surgical instrumentation.

_INTENDED PATIENT AND USER POPULATION

Intended user

Because this is a technically demanding procedure presenting a risk of serious injury to the patient, only experienced surgeons with adequate training should perform this procedure using dedicated instrumentation.

Intended patient

Proper patient selection and operative care are critical to the success of the device and avoidance of injury during surgery.

Every surgeon who uses these implants and associated instrumentation must take each patient's clinical state and medical status into consideration, and be fully familiar with procedures involving the use of this type of implant and the potential complications in each case.

_CLINICAL BENEFIT AND PERFORMANCE

Clinical benefits are not directly linked to the instrumentation. Refer to the IFU of the dedicated implant range.

No effort has been spared to ensure that only the highest-quality materials and expertise have been deployed during conception, validation and manufacturing of this instrumentation.

_SIDE EFFECTS

Perioperative:

Hemostatic problems, neurologic and/or vascular injury, organ/tissue injuries.

Postoperative:

Pulmonary embolism, neurological disorder, cardiovascular or vascular disorder, deep infection.

Serious adverse device effects:

Pulmonary embolism, motor loss, epidural hematoma.

_COMPOSITION

Unless otherwise stated, instruments are made of a variety of materials commonly used in orthopedic procedures which meet available international standards specifications that apply to these devices.

Please refer to the individual package labeling.

_STERILITY

This instrument is a non sterile, reusable, device.

Please refer to the individual package labeling.

_PRE-REQUISITES BEFORE USE & INSTRUCTIONS FOR USE

Your local representative should have communicated the handbook describing the surgical technique. In any case, the handbook is readily available by contacting either your local representative or directly SPINEART. Read and follow all other product information supplied by SPINEART SA.

Sharp-edged, serrated or toothed instruments should not be used.

The methods of use of instruments are to be determined by the user's experience, training in surgical procedures and following the product range surgical technique.

Any surgical techniques applicable for use of this system should be carefully followed.

All instruments with an expiry date must be sent back to SPINEART before this date.

Specific markings are engraved on each instrument to facilitate identification of the corresponding implant size and type.

Markings on instruments used for measuring anatomical dimensions must be legible. These may include gauge markings, angles, inner or outer diameters, length or depth calibrations, and right/ left indications.

Notify SPINEART representative if you notice any issue with an instrument.

_CLEANING, DISINFECTION, DRYING AND STERILIZATION

Preparation before cleaning

Point-of-use: The instruments must, immediately after use, be cleaned, disinfected, dryed, inspected, and terminal sterilized as described below.

Prior to starting the surgical procedure, all non-sterile reusable instruments must be properly cleaned, disinfected, dryed and sterilized.

The instruments have been designed in order to avoid disassembly manipulation prior, cleaning and sterilization processes.

These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments.

In countries where reprocessing requirements are more stringent than those provided in this document it is the responsibility of the user/processor to comply with those prevailing laws and ordinances.

Follow the process below:

A - AUTOMATIC CLEANING PROTOCOL

B - THERMAL DISINFECTION

C – DRYING

D - INSPECTION

E - STERILIZATION TRAYS CLEANING AND DISINFECTION

F - STERILIZATION

A - AUTOMATIC CLEANING PROTOCOL

The washer-disinfector machine should be compliant with the last version of EN ISO 15883.

Pre-cleaning

- Rinse soiled devices under running cold tap water for 30 seconds, using soft-bristled brush to assist in the removal of gross soil debris. Devices that can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 1 minute using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold tap water for 30 seconds. Devices with mobile parts must be 5 times activated during rinsing through their full range of motion during rinsing.
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold tap water for 1 minute. Devices with mobile parts must be 5 times activated during rinsing through their full range of motion during rinsing.

Inspection and dry

- Visually inspect devices.
- Dry using a soft, lint free cloth.
- Load devices into the washer-disinfector.

WASHER-DISINFECTOR PARAMETERS

STEP	SOLUTION	TEMPERATURE	TIME
Pre-cleaning	Tap Water	<45°C	2 minutes
Cleaning	Tap Water + alkaline enzymatic cleaner (as example NEODISHER Mediclean Forte)	55°C	10 minutes
Neutralizing	Tap Water + Neutralizing agent (as exemple NEODISHER Z)	<45°C	2 minutes
Rinsing	Tap water	<45°C	2 minutes

B - THERMAL DISINFECTION

Following the cleaning step in the same washer-disinfector

WASHER-DISINFECTOR PARAMETERS

WASHER CYCLE	SOLUTION	TEMPERATURE	TIME
Disinfecting Rinse	Reversed osmosis water According to AAMI TIR 34	93°C	5 minutes

The thermal disinfection cycle should be performed to achieve a minimum value A0 = 3000 according to ISO 15883-1) and is compatible with Spineart instruments and not sterile implants.

C – DRYING

Following the disinfection step in the same washer-disinfector

WASHER-DISINFECTOR PARAMETERS

WASHER CYCLE	SOLUTION	TEMPERATURE	TIME
Drying	/	94.5°C	20 minutes

D - INSPECTION

Carefully inspect each device to ensure that all visible blood, soil and debris have been removed. Inspect lumens to confirm that all foreign material has been removed. Visually inspect for damage and/or wear. Check also the lack of humidity.

Note: If any damage or wear is noted that impairs the function of the instrument, contact your company representative for a replacement.

It is necessary to check the condition and functionality of the different instruments after each cleaning, disinfection and drying cycle.

In case of deterioration or wear that reduces the function of the instrument, it must be replaced.

The functionality of each instrument must be tested before using the instrument in surgery. In case of functionality issue or any doubt, do not use the instrument. Use a spare available in the ancillary instrumentation or in the OR.

Instrument should not be bent or damaged in any way.

Before sterilization, ensure that the instruments or implants are dry, otherwise use a soft, lint free cloth to dry them.

E - STERILIZATION TRAYS CLEANING, DISINFECTION

All the trays must be thoroughly cleaned and disinfected after surgery completion.

Cleaning recommendations:

- Remove all the instruments from the trays,
- Large and visible impurities must be removed from the trays,
- Use running tap water and rinse thoroughly for at least one minute,
- Use freshly prepared cleaning bath of the specified concentration for the period specified by the manufacturer,
- Use soft brush until there is no visible contamination,
- Dry trays with lint-free disposable cloths.

Disinfection recommendations:

- Use a freshly disinfectant bath of the specified concentration for the period specified by the manufacturer. Rinse thoroughly three times,
- Rinse trays thoroughly with tap water as specified by the disinfectant manufacturer,
- Dry trays with lint-free disposable cloths.

Trays must be visually clean, if not, repeat the cleaning and disinfection protocol.

GENERAL INFORMATION

F - STERILIZATION

Preparation for sterilization

Instruments must be loaded into a dedicated tray, supplied by the manufacturer, and then double wrap the tray, using wrap compliant with ISO 11607-1, following AAMI ST 79 guidelines.

• Subsequent sterilization in dedicated trays is then recommended, using an autoclave and steam, and following a protocol that meets the minimum requirements or more, and is in compliance with current legislation (e.g., 134°C – 18 minutes) to obtain a guaranty of sterility of 10^{-6}. The validation for sterilization has been done according to overkill/half cycle method as described in the ISO 17664, ISO 17665 standards and of AAMI TIR 12 Technical Report.

"Do not stack trays during sterilization"

The instruments are delivered non-sterile and must be sterilized by autoclave according to the instructions of the sterilizer manufacturer to ensure sterility.

Instruments delivered non-sterile must be sterilized in containers supplied by the manufacturer. Beforehand they must have followed a complete cycle of cleaning, disinfection and drying, as described in the previous steps. The sterilization cycle must be performed in a qualified steam sterilizer.

Sterilization must be performed according to ISO 17665-1.

Sterilization parameters:

Method: Pre-vacuum cycle of Steam sterilization (moist heat - autoclave): 3 negatives pulses and 5 positives pulses

Cycle 1 (EU):

Exposure time: 18 minutes

Temperature: 134°C

Drying time: 30 minutes

Cycle 2 (USA):

Exposure time: 4 minutes

Temperature: 132°C

Drying time: 30 minutes

_CAUTIONS AND WARNINGS

The physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the system.

Misuse of this instrument, causing corrosion, scratching, loosening, bending, and/or fracture of any or all sections of the instrument may inhibit or prevent proper function.

Breakage, slippage, misuse, or mishandling of instruments may cause injury to the patient or operative personnel.

Do not use this instrument for any action for which it was not intended.

It is important the surgeon exercise extreme caution when working in close proximity to vital organs, nerves or vessels. The forces applied while correcting the position of the instrumentation should not excessive, such that it might cause injury to the patient.

The instruments were specifically designed for use when installing these implants of the corresponding product range.

SPINEART instruments are validated for 150 steam sterilization runs.

Prior to use all components should be checked for functionality and the absence of defects such as wear, tear, corrosion, pitting and discoloration to ensure that there is no damage.

Damaged components must not be used and should be returned to SPINEART.

_USE

The methods of use of instruments are to be determined by the user's experience, training in surgical procedures and following the product range surgical technique.

If you face an issue, use a spare available in the ancillary instrumentation or in the OR.

Any surgical techniques applicable for use of this system should be carefully followed.

_STORAGE

This instrument should be treated as any precision instrument, should be carefully handled and

stored in a dry environment.

_HANDLING

Extreme care should be taken to ensure this instrument remains in good working order.

_REPAIR

SPINEART instruments that need to be repaired must be cleaned, disinfected and sterilized. Then sent to the address mentioned in this document.

GENERAL INFORMATION

_DISPOSAL

SPINEART instruments that need to be discarded can be returned to SPINEART after being cleaned, disinfected, dryed and sterilized.

_HOSPITAL RESPONSIBILITIES FOR SPINEART LOANER SETS

- Surgical instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper care should be returned to SPINEART to be discarded. Notify your SPINEART representative of any instrument problems.
- Loaner sets should undergo all steps of, cleaning, disinfection, drying, inspection, and terminal sterilization before being returned to SPINEART. Documentation of cleaning, disinfection, drying, inspection, and terminal sterilization should be provided with instruments being returned to SPINEART.
- Missing or damaged instruments from loaner sets should be brought to the attention of the operating room supervisor, to the director of the central supply department, and to your SPINEART representative to ensure that the next hospital will receive a complete set of instruments in good working condition.
- The instructions provided in this reprocessing manual have been validated by SPINEART. It is the responsibility of the Hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

_INFORMATION TO TRANSFER TO THE PATIENT

Abnormal use of the device may lead to risks of serious injury and/or health deterioration of the patient.

Any serious incident occurring in connection with the device must be notified to the manufacturer and to the competent authority of the Member State in which the user and / or patient is established.

_COMPLAINTS

Any health care professional who has a complaint or who has experienced a dissatisfaction when using a product must notify SPINEART.

The complaint form is available on SPINEART Website.

_OTHER

If further directions for use of this system are needed, please check with the SPINEART Customer Service.

If further information is needed or required, please see the addresses on this document.

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N O T E

N O T E

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