PERLA® TL

CORTICAL TRAJECTORY

CONTENT

CONCEPT AND DESIGN

Since 2005 Spineart has been true to the philosophy: quality, innovation, simplicity, by developing highly performing systems for the treatment of spinal pathologies.

The PERLA® TL Posterior Thoraco-Lumbar Fixation System incorporates smart technologies and simplified instrumentation.

This system offers a complete range of spinal implants delivered sterile with an intuitive and compact instrumentation.

PERLA® TL Cortical Trajectory consists of streamlined instrumentation for midline placement of PERLA® TL screws to address thoracolumbar pathologies of the spine.

AT A GLANCE

Cortical-cancellous Thread Screw

Modular Head with Double Rod Diameter Compatibility

Friction Head

Compact set

INDICATIONS

PERLA® TL system implants are designed to treat those lumbar and thoracic pathologies:

- Spondylolisthesis
- Degenerative disc disease
- Thoracic and lumbar fractures
- Thoracic and lumbar vertebra tumors
- Pseudarthrosis
- Stenosis
- Spine deformities: scoliosis, kyphosis

IMPLANTS

CORTICAL BONE SCREWS

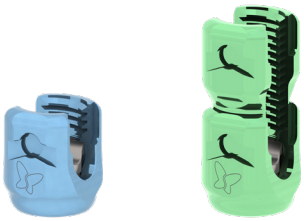
LENGTH/ DIAMETER	Ø4.5	Ø5.5	Ø6.5	Ø7.5
L25	TLF-CS 45 25-S	TLF-CS 55 25-S	TLF-CS 65 25-S	TLF-CS 75 25-S
L30	TLF-CS 45 30-S	TLF-CS 55 30-S	TLF-CS 65 30-S	TLF-CS 75 30-S
L35	TLF-CS 45 35-S	TLF-CS 55 35-S	TLF-CS 65 35-S	TLF-CS 75 35-S
L40	TLF-CS 45 40-S	TLF-CS 55 40-S	TLF-CS 65 40-S	TLF-CS 75 40-S
L45	TLF-CS 45 45-S	TLF-CS 55 45-S	TLF-CS 65 45-S	TLF-CS 75 45-S
L50		TLF-CS 55 50-S	TLF-CS 65 50-S	TLF-CS 75 50-S

SETSCREWS

SETSCREW (PACKED WITH SCREW)	TLF-SC 00 00-S
SETSCREWS (PACKED X2)	TLF-SC 02 00-S

MODULAR HEADS

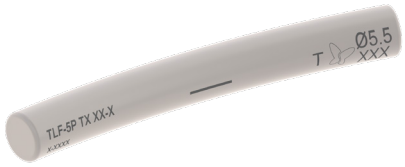
POLYAXIAL	TLF-MH PL 00-S
REDUCTION	TLF-MH RE 00-S



IMPLANTS

RODS / PREBENT TITANIUM ALLOY

LENGTH/DIAMETER	Ø5.5	Ø6*
L30	TLF-5P T0 30-S	TLF-6P T0 30-S
L35	TLF-5P T0 35-S	TLF-6P T0 35-S
L40	TLF-5P T0 40-S	TLF-6P T0 40-S
L45	TLF-5P T0 45-S	TLF-6P T0 45-S
L50	TLF-5P T0 50-S	TLF-6P T0 50-S
L55	TLF-5P T0 55-S	TLF-6P T0 55-S
L60	TLF-5P T0 60-S	TLF-6P T0 60-S
L70	TLF-5P T0 70-S	TLF-6P T0 70-S
L80	TLF-5P T0 80-S	TLF-6P T0 80-S
L90	TLF-5P T0 90-S	TLF-6P T0 90-S
L100	TLF-5P T1 00-S	TLF-6P T1 00-S
L120	TLF-5P T1 20-S	TLF-6P T1 20-S



CROSS CONNECTORS MONOBLOC*	
L18	TLF-CC ST 18-S
L21	TLF-CC ST 21-S
L24	TLF-CC ST 24-S
L27	TLF-CC ST 27-S
L30	TLF-CC ST 30-S

MULTIAXIAL CROSS CONNECTORS		
LENGTH	**STRAIGHT**	**PREBENT**
L30 TO L31	TLF-CC-MU 30-S	
L31 TO L33	TLF-CC-MU 31-S	TLF-CC MP 31-S
L33 TO L36	TLF-CC MU 33-S	TLF-CC MP 33-S
L36 TO L43	TLF-CC MU 36-S	TLF-CC MP 36-S
L43 TO L55	TLF-CC MU 43-S	TLF-CC MP 43-S
L55 TO L80	TLF-CC MU 55-S	TLF-CC MP 55-S

*Not available during Expert Phase

TECHNICAL FEATURES

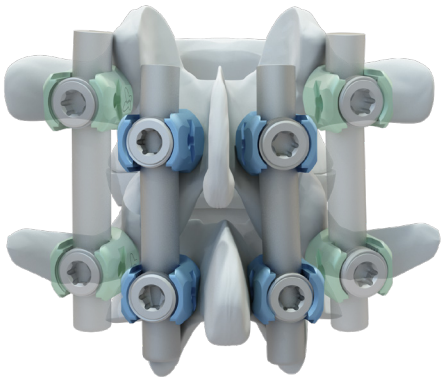
MODULAR HEAD

The modular head system allows the insertion of the bone screw only in order to avoid head interference and maximize visualization throughout procedure.

CORTICAL-CANCELLOUS THREAD

The double thread and low pitch design adapted to cortical bone maximize the screw purchase in midline approach.

MINIMALLY INVASIVE



Medial screw placement with lateralized trajectory allows for smaller incisions and less tissue disruption.

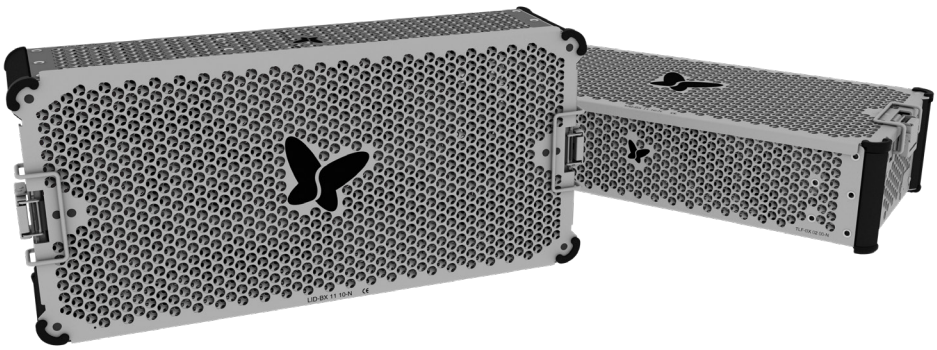
TECHNICAL FEATURES

DOUBLE ROD DIAMETER COMPATIBILITY

—— Ø6 rod
------ Ø5.5 rod

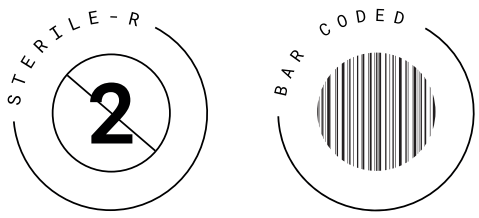
The PERLA® TL screw head is compatible with both Ø5.5 and Ø6 rods, for versatility in treating a wide range of pathology.

COMPACT SET



All the instrumentation needed fit in only 2 boxes, including standard instrumentation for pre-assembled screw.

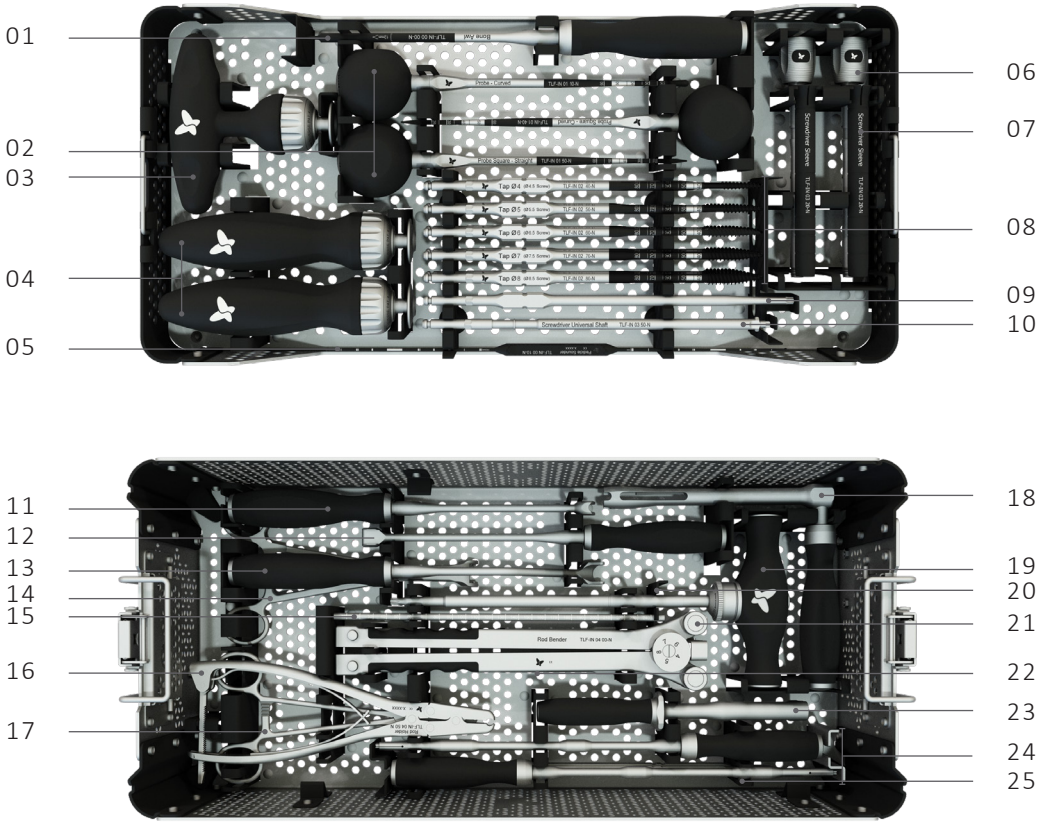
SAFETY



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

INSTRUMENT SET

BOX 1



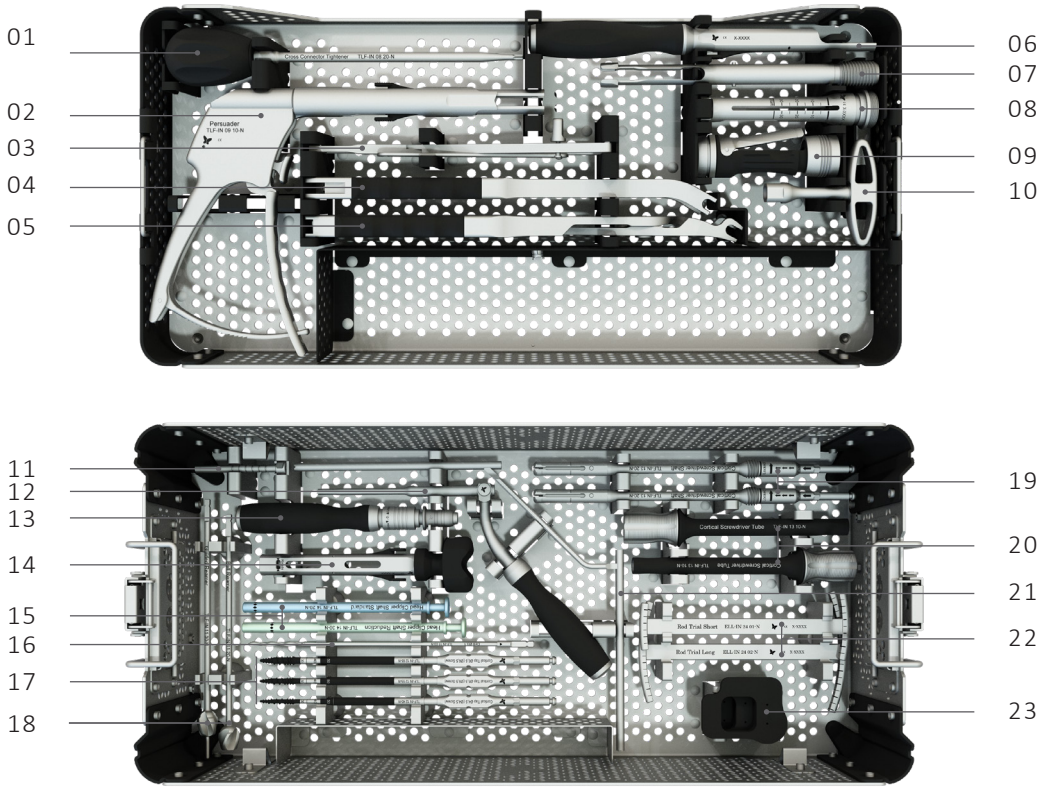
	#	DESCRIPTION	REFERENCE
	01	BONE AWL	TLF-IN 00 00-N
	02	PROBE SQUARE - CURVED	TLF-IN 01 40-N
	02	PROBE SQUARE - STRAIGHT	TLF-IN 01 50-N
•	02	PROBE - CURVED	TLF-IN 01 10-N
•	02	PROBE SMALL - CURVED	TLF-IN 01 20-N
•	02	PROBE BLUNT - STRAIGHT	TLF-IN 01 30-N
	03	T HANDLE RATCHET	HAN-SB RF TE-N
	04	STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
	05	PEDICLE SOUNDER	TLF-IN 00 10-N
	06	SCREWDRIVER TUBE	TLF-IN 03 10-N
	07	SCREWDRIVER SLEEVE	TLF-IN 03 20-N
•	07	SCREWDRIVER PROTECTION SLEEVE	TLF-IN 03 60-N
•	08	TAP Ø5 (Ø5.5 SCREW)	TLF-IN 02 50-N
•	08	TAP Ø6 (Ø6.5 SCREW)	TLF-IN 02 60-N
•	08	TAP Ø7 (Ø7.5 SCREW)	TLF-IN 02 70-N
•	08	TAP Ø4 (Ø4.5 SCREW)	TLF-IN 02 40-N
•	08	TAP Ø8 (Ø8.5 SCREW)	TLF-IN 02 80-N
•	08	TAP Ø9 (Ø9.5 SCREW)	TLF-IN 02 90-N
•	08	TAP Ø10 (Ø10.5 SCREW)	TLF-IN 02 10-N
	09	T25 SCREWDRIVER SHAFT	TLF-IN 03 00-N

	#	DESCRIPTION	REFERENCE
	10	SCREWDRIVER UNIVERSAL SHAFT	TLF-IN 03 50-N
•	10	SCREWDRIVER SHAFT MS-PS	TLF-IN 03 30-N
•	10	SCREWDRIVER SHAFT SS	TLF-IN 03 40-N
	11	ROD PUSHER	TLF-IN 04 30-N
	12	HEAD ALIGNER	TLF-IN 08 00-N
	13	ROCKER	TLF-IN 04 20-N
•	14	ROCKER (ROMEO®2)	ELL-IN 00 05-N
•	15	ROD TEMPLATE L250	TLF-IN 10 25-N
	15	ROD TEMPLATE L100	TLF-IN 10 10-N
	16	ROD HOLDER	TLF-IN 04 50-N
	17	IMPLANT HOLDER	ELL-IN 01 04-N
	18	COUNTER TORQUE	TLF-IN 05 30-N
	19	FINAL TIGHTENER	TLF-IN 05 40-N
	20	SETSCREW TIGHTENER	TLF-IN 05 20-N
	21	ROD BENDER	TLF-IN 04 00-N
•	22	ROD BENDER EXTENSION	TLF-IN 04 10-N
	23	SETSCREW TUBE	TLF-IN 05 00-N
	24	SETSCREW HOLDER	TLF-IN 05 10-N
•	25	SETSCREW HOLDER DOUBLE	TLF-IN 05 50-N

• : OPTIONAL

INSTRUMENT SET

BOX 2



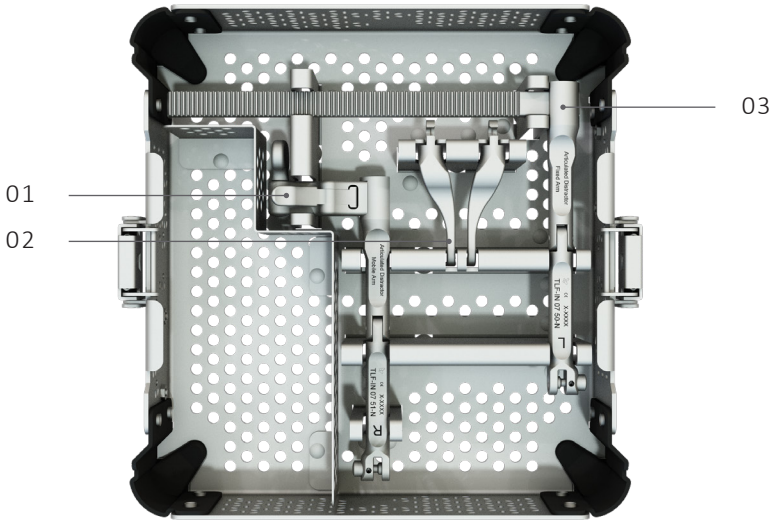
#	DESCRIPTION	REFERENCE
01	CROSS CONNECTOR TIGHTENER	TLF-IN 08 20N
02	PERSUADER	TLF-IN 09 10-N
03	CROSS CONNECTOR CALIPER	TLF-IN 08 10-N
04	DISTRACTOR	TLF-IN 07 10-N
05	COMPRESSOR	TLF-IN 07 00-N
06	HOOK HOLDER / TAB BREAKER	TLF-IN 08 30-N
• 07	QR REDUCER - INNER TUBE	ELL-IN 32 34-N
• 08	QR REDUCER - OUTER TUBE	ELL-IN 31 34-N
• 09	QR REDUCER - HANDLE	ELL-IN 33 34-N
• 10	QR REDUCER - T-HANDLE	HAN-SS TY 14-N
11	ADJUSTABLE DRILL GUIDE	ELL-IN 00 46-N
12	DRILL GUIDE	ELL-IN 00 45-N
13	STRAIGHT HANDLE RATCHET AO Ø20	HAN-RA AO 20-N
14	HEAD CLIPPER	TLF-IN 14 10-N
15	HEAD CLIPPER SHAFT STANDARD	TLF-IN 14 20-N
15	HEAD CLIPPER SHAFT REDUCTION	TLF-IN 14 30-N

#	DESCRIPTION	REFERENCE
16	RILL Ø3.1	TLF-IN 11 00-N
17	CORTICAL TAP Ø4.5 (Ø4.5 SCREW)	TLF-IN 12 45-N
17	CORTICAL TAP Ø5.5 (Ø5.5 SCREW)	TLF-IN 12 55-N
17	CORTICAL TAP Ø6.5 (Ø6.5 SCREW)	TLF-IN 12 65-N
• 17	CORTICAL TAP Ø7.5 (Ø7.5 SCREW)	TLF-IN 12 75-N
18	BALL REAMER	TLF-IN 11 20-N
18	GUIDED REAMER	TLF-IN 11 30-N
19	CORTICAL SCREWDRIVER SHAFT	TLF-IN 13 20-N
20	CORTICAL SCREWDRIVER TUBE	TLF-IN 13 10-N
• 21	FLIP DRILL GUIDE	SPE-IN 00 10-N
• 22	ROD TRIAL - SHORT	ELL-IN 24 01-N
• 22	ROD TRIAL - LONG	ELL-IN 24 02-N
23	CLIPPING BASE	TLF-IN 14 00-N

• : OPTIONAL

INSTRUMENT SET

DISTRACTOR

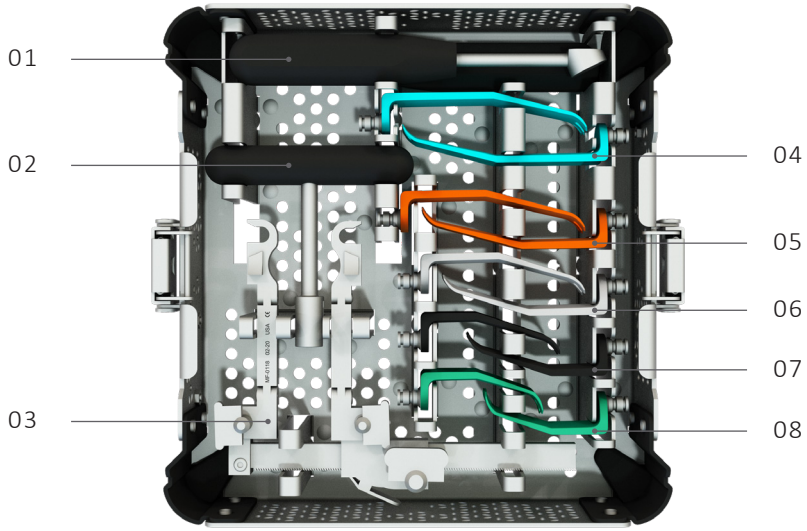


	#	DESCRIPTION	REFERENCE
•	01	ARTICULATED DISTRACTOR - MOBILE ARM	TLF-IN 07 51-N
•	02	ARTICULATED DISTRACTOR - LEFT END TIP	TLF-IN 07 60-N
•	02	ARTICULATED DISTRACTOR - RIGHT END TIP	TLF-IN 07 61-N
•	03	ARTICULATED DISTRACTOR - FIXED ARM	TLF-IN 07 50-N

• : OPTIONAL

INSTRUMENT SET

RETRACTOR



	#	DESCRIPTION	REFERENCE
•	01	SCREW-ON RETRACTOR HANDLE	MF-0098
•	02	RETRACTOR T-HANDLE	MF-0438
•	03	MIS TOEABLE RETRACTOR, 160MM RACK, 60MM ARM	MF-0118
•	04	23MM X 85MM LUMBAR TURQUOISE BLADE	MF-2385AS
•	05	23MM X 75MM LUMBAR ORANGE BLADE	MF-2347AS
•	06	23MM X 65MM LUMBAR GRAY BLADE	MF-2365AS
•	07	23MM X 55MM LUMBAR BLACK BLADE	MF-2355AS
•	08	23MM X 45MM LUMBAR GREEN BLADE	MF-2345AS

• : OPTIONAL

INSTRUMENTS

EXPOSURE - OPTIONAL

SCREW-ON RETRACTOR HANDLE	MF-0098
MIS TOEABLE RETRACTOR, 160MM RACK, 60MM ARM	MF-0118
23MM X 55MM LUMBAR BLACK BLADE	MF-2355AS
23MM X 75MM LUMBAR ORANGE BLADE	MF-2347AS

RETRACTOR T-HANDLE	MF-0438
23MM X 45MM LUMBAR GREEN BLADE	MF-2345AS
23MM X 65MM LUMBAR GRAY BLADE	MF-2365AS
23MM X 85MM LUMBAR TURQUOISE BLADE	MF-2385AS

INSTRUMENTS

PREPARATION

BONE AWL	TLF-IN 00 00-N

PEDICLE SOUNDER	TLF-IN 00 10-N

PROBE SQUARE CURVED	TLF-IN 01 40-N

PROBE SQUARE STRAIGHT	TLF-IN 01 50-N

DRILL Ø3.1	TLF-IN 11 00-N / TLF-IN 11 00-S

BALL REAMER	TLF-IN 11 20-N

GUIDED REAMER	TLF-IN 11 30-N

CORTICAL TAP Ø4.5 CORTICAL TAP Ø5.5 CORTICAL TAP Ø6.5	TLF-IN 12 45-N TLF-IN 12 55-N TLF-IN 12 65-N

DRILL GUIDE	ELL-IN 00 45-N

ADJUSTABLE DRILL GUIDE	ELL-IN 00 46-N

I N S T R U M E N T S

PREPARATION - OPTIONAL

PROBE CURVED	TLF-IN 01 10-N

PROBE SMALL – CURVED	TLF-IN 01 20-N

PROBE BLUNT – STRAIGHT	TLF-IN 01 30-N

CORTICAL TAP Ø7.5	TLF-IN 12 75-N

FLIP DRILL GUIDE	SPE-IN 00 10-N

INSTRUMENTS

SCREW INSERTION

T25 SCREWDRIVER SHAFT	TLF-IN 03 00-N

SCREWDRIVER TUBE	TLF-IN 03 10-N

SCREWDRIVER SLEEVE	TLF-IN 03 20-N

SCREWDRIVER UNIVERSAL SHAFT	TLF-IN 03 50-N

HEAD ALIGNER	TLF-IN 08 00-N

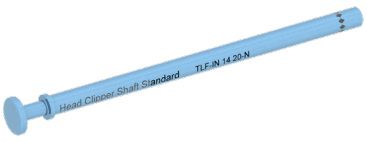
CORTICAL SCREWDRIVER TUBE	TLF-IN 13 10-N

CORTICAL SCREWDRIVER SHAFT	TLF-IN 13 20-N

CLIPPING BASE	TLF-IN 14 00-N

HEAD CLIPPER	TLF-IN 14 10-N

HEAD CLIPPER SHAFT STANDARD	TLF-IN 14 20-N



HEAD CLIPPER SHAFT REDUCTION	TLF-IN 14 30-N

INSTRUMENTS

SCREW INSERTION - OPTIONAL

SCREWDRIVER SHAFT MS-PS	TLF-IN 03 30-N

SCREWDRIVER SHAFT SS	TLF-IN 03 40-N

SCREWDRIVER PROTECTION SLEEVE	TLF-IN 03 60-N

DISTRACTION FOR POSTERIOR CAGE

ARTICULATED DISTRACTOR – FIXED ARM	TLF-IN 07 50-N

ARTICULATED DISTRACTOR – MOBILE ARM	TLF-IN 07 51-N

ARTICULATED DISTRACTOR – LEFT END TIP	TLF-IN 07 60-N

ARTICULATED DISTRACTOR – RIGHT END TIP	TLF-IN 07 61-N

INSTRUMENTS

HANDLE

STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N

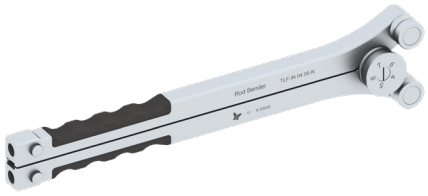
T-HANDLE RATCHET	HAN-SB RF TE-N

STRAIGHT HANDLE RATCHET AO Ø20	HAN-RA AO 20-N

INSTRUMENTS

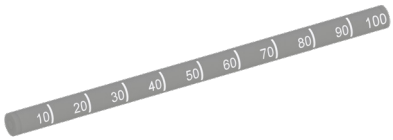
ROD SELECTION AND CONTOURING

ROD BENDER	TLF-IN 04 00-N



ROD HOLDER	TLF-IN 04 50-N

ROD TEMPLATE L100	TLF-IN 10 10-N



IMPLANT HOLDER	ELL-IN 01 04-N

ROD SELECTION AND CONTOURING - OPTIONAL

ROD BENDER – EXTENSION	TLF-IN 04 10-N

ROD TEMPLATE L250	TLF-IN 10 25-N

ROD TRIAL SHORT	ELL-IN 24 01-N

ROD TRIAL LONG	ELL-IN 24 02-N

INSTRUMENTS

ROD REDUCTION

ROCKER	TLF-IN 04 20-N

ROD PUSHER	TLF-IN 04 30-N

SETSCREW TUBE	TLF-IN 05 00-N

PERSUADER	TLF-IN 09 10-N

ROD REDUCTION – OPTIONAL

QR REDUCER	OUTER TUBE - ELL-IN 31 34-N INNER TUBE - ELL-IN 32 34-N HANDLE - ELL-IN 33 34-N

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

ROCKER (ROMEO®2)	ELL-IN 00 05-N

INSTRUMENTS

SETSCREW INSERTION

SETSCREW HOLDER	TLF-IN 05 10-N

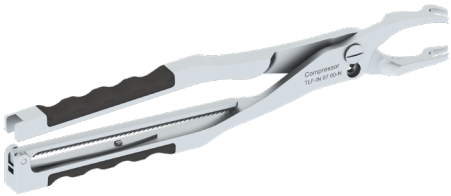
SETSCREW TIGHTENER	TLF-IN 05 20-N

SETSCREW INSERTION – OPTIONAL

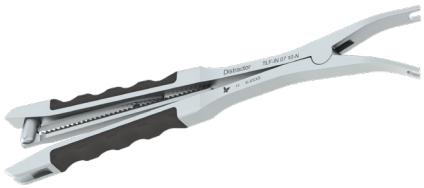
SETSCREW HOLDER DOUBLE	TLF-IN 05 50-N

MANIPULATION MANEUVERS

COMPRESSOR	TLF-IN 07 00-N



DISTRACTOR	TLF-IN 07 10-N



HOOK HOLDER / TAB BREAKER	TLF-IN 08 30-N

INSTRUMENTS

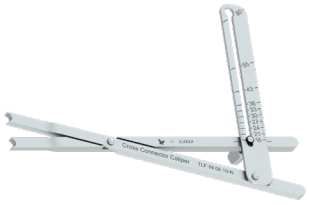
FINAL TIGHTENING

COUNTER TORQUE	TLF-IN 05 30-N

FINAL TIGHTENER	TLF-IN 05 40-N

CROSS CONNECTOR POSITIONING

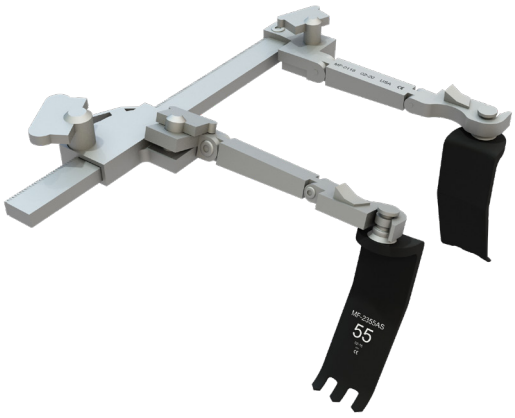
CROSS CONNECTOR CALIPER	TLF-IN 08 10-N



CROSS CONNECTOR TIGHTENER	TLF-IN 08 20-N

SURGICAL TECHNIQUE

_STEP 1



EXPOSURE

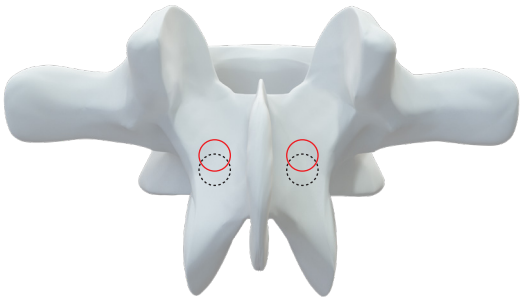
After surgical site identification and exposure adapted to a midline approach, measure the depth from skin to the pars interarticularis for appropriate blade length.

Place contour of **blades** over facet joints with deep section of blades in recess of pars. Attach blades to **retractor**.

Retract until blades sit atop facet capsules and lateral border of pars is visualized.

INSTRUMENT	REFERENCE
SCREW-ON RETRACTOR HANDLE	MF-0098
RETRACTOR T-HANDLE	MF-0438
MIS TOEABLE RETRACTOR, 160MM RACK, 60MM ARM	MF-0118
23MM X 45MM LUMBAR GREEN BLADE	MF-2345AS
23MM X 55MM LUMBAR BLACK BLADE	MF-2355AS
23MM X 65MM LUMBAR GRAY BLADE	MF-2365AS
23MM X 75MM LUMBAR ORANGE BLADE	MF-2347AS
23MM X 85MM LUMBAR TURQUOISE BLADE	MF-2385AS

_STEP 2



Entry point
Entry point of cephalad screws

PEDICLE PREPARATION – ENTRY POINT

Using the **Bone Awl**, score the cortical bone of the pars to create a starting point.

NOTE 1: If necessary, remove hypertrophic tissue of degenerative facets overriding entry points. Take care to respect facet capsule above intended fused level.

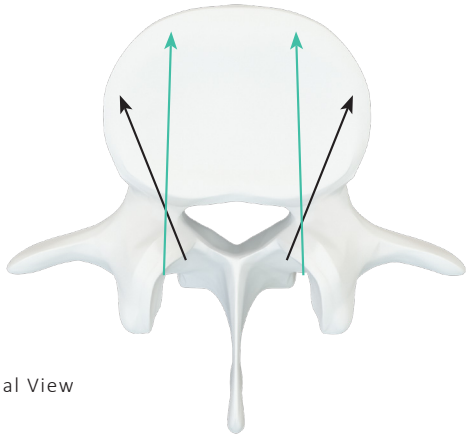
The screw entry point is located:

- 3-5mm medial to the lateral edge of the pars interarticularis
- In line with the inferior aspect of the transverse process

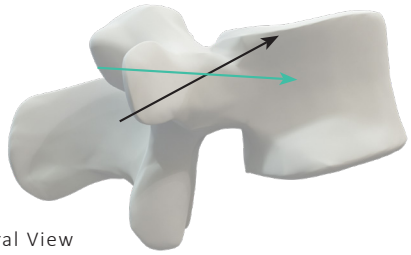
NOTE 2: To avoid facet impingement, the starting point for the cephalad-most screw is 1-2mm inferior compared to the starting point for caudal screws for a steeper trajectory and placement of a longer screw.

INSTRUMENT	REFERENCE
BONE AWL	TLF-IN 00 00-N

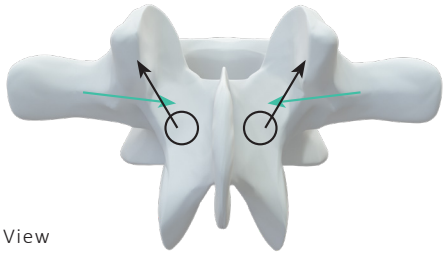
_STEP 3a



Axial View



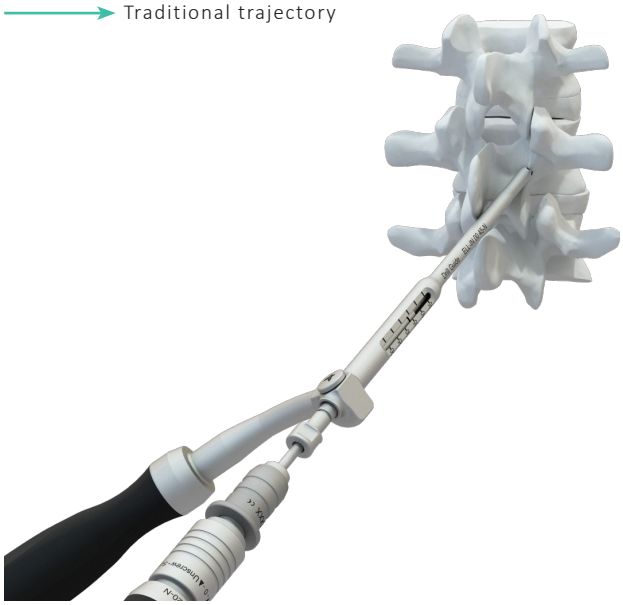
Lateral View



A/P View

Cortical trajectory

Traditional trajectory



PEDICLE PREPARATION - TRAJECTORY

Choose the appropriate length to be drilled by sliding the **Adjustable Drill Guide** into the **Drill Guide**. Press the lateral button on the **Drill Guide** and use the scale to select the desired drill depth.

Connect the **Drill Ø3.1** to the **Straight Handle Ratchet AO Ø20**.

Insert the **Drill Ø3.1** into the **Adjustable Drill Guide** and target the entry point.
With the tip placed at the entry point, use fluoroscopy to direct the **Drill Guide**:

- 30° to 45° caudal-to-cephalad on lateral view
- 20° medial-to-lateral on AP view, aiming for posterior superior lateral border of vertebral body

INSTRUMENT	REFERENCE
STRAIGHT HANDLE RATCHET AO Ø20	HAN-RA AO 20-N
DRILL Ø3.1	TLF-IN 11 00-N
DRILL GUIDE	ELL-IN 00 45-N
ADJUSTABLE DRILL GUIDE	ELL-IN 00 46-N

_STEP 3b

PEDICLE PREPARATION – TRAJECTORY

The **Flip Drill Guide** provides for drill depths of 30mm and 35mm:

- 35mm length screws are often used at cephalad-most position
- 30mm length screws are often used for remaining levels

Connect the **Drill Ø3.1** to the **Straight Handle Ratchet AO Ø20**.

Insert the **Drill Ø3.1** into the **Flip Drill Guide** and target the entry point.

After confirming starting point and trajectory, advance the **Drill Ø3.1** bit.

INSTRUMENT	REFERENCE
STRAIGHT HANDLE RATCHET AO Ø20	HAN-RA AO 20-N
DRILL Ø3.1	TLF-IN 11 00-N
FLIP DRILL GUIDE	SPE-IN 00 10-N

_STEP 4

PEDICLE SOUNDING

Insert the **Pedicle Sounder** to verify integrity of the screw path.

INSTRUMENT	REFERENCE
PEDICLE SOUNDER	TLF-IN 00 10-N

SURGICAL TECHNIQUE

_STEP 5

HOLE TAPPING

Tap must be used to prepare the screw path. Placement of screw in untapped, dense cortical bone can split the pars or pedicle.

Attach the appropriate **Tap** to a **Straight Ratchet Handle** or a **T-Handle** and tap the length of the intended screw.

NOTE 1: Taps in the set are line-to-line. Under-tapping may result in splitting cortical bone of the pars. If the screw hole is compromised, a “standard“ pedicle screw trajectory is recommended (lateral to medial) as a rescue technique.

NOTE 2: Information about insertion of degenerative pre-assembled screws and their adapted instrumentations are available in the PERLA® TL Thoracolumbar System’s Surgical Technique.

NOTE 3: Lateral fluoroscopy images should be saved for screw trajectory reference.

⚠ **CAUTION:** Select the appropriate **Cortical Taps** (TLF-IN 12 XX-N) for Cortical Bone Screws (TLF-CS XX XX-S). The standard **Taps** (TLF-IN 02 XX-N) are dedicated to all other pedicle screws. To avoid any confusion the **Cortical Tap** is colour coded and contains the mention Cortical Tap.

INSTRUMENT	REFERENCE
CORTICAL TAP Ø4.5	TLF-IN 12 45-N
CORTICAL TAP Ø5.5	TLF-IN 12 55-N
CORTICAL TAP Ø6.5	TLF-IN 12 65-N
STRAIGHT RATCHET HANDLE	HAN-SB RF ST-N
T-HANDLE RATCHET	HAN-SB RF TE-N

_STEP 6

REAMER (OPTIONAL)

The **Guided Reamer** can be used prior to the Bone Screw insertion to remove tissue and decrease potential screw head impingement.

The **Ball Reamer** can be used after the Bone Screw insertion in order to fine-tune the implant site for the screw head clipping.

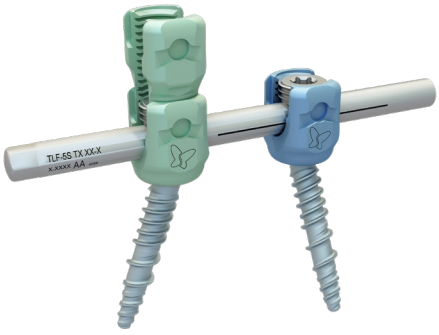
Attach the appropriate reamer to the **Straight Handle Ratchet AO Ø20**:

- **Option 1:** insert the distal end of the **Guided Reamer** into the pilot hole and rotate clockwise to remove tissue.
- **Option 2:** put the distal end of the **Ball Reamer** over the bone screw and rotate clockwise to remove tissue.

NOTE: Take care to avoid facets cephalad to fused levels to prevent damage to the non-fused segments.

INSTRUMENT	REFERENCE
GUIDED REAMER	TLF-IN 11 30-N
BALL REAMER	TLF-IN 11 20-N
STRAIGHT HANDLE RATCHET AO Ø20	HAN-RA AO 20-N

_STEP 7



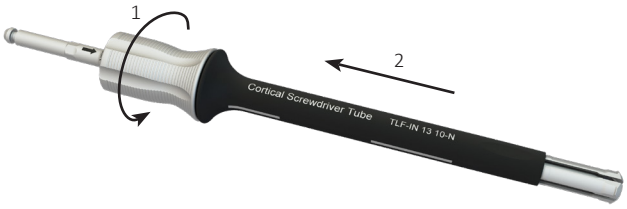
SCREW SELECTION

PERLA® TL Cortical offers a large range of diameters and length for both Polyaxial and Reduction screws. The modularity feature allows to choose the desired type of screw head after the bone screw insertion.

1. Polyaxial screw, with a 60° conical range of motion.
2. Reduction screw, also called spondylo screw. With a 60° conical range of motion, it allows for a 15mm reduction.

SURGICAL TECHNIQUE

_STEP 8



SCREWDRIVER ASSEMBLY

Slide the **Cortical Screwdriver Shaft** into the proximal end of the **Cortical Screwdriver Tube**. Make sure to align the lines on both instruments to facilitate the insertion.

Turn the grip of the **Cortical Screwdriver Tube** clockwise to secure the instrument and slide it to the top of the shaft.

Connect the instrument to the **Straight Handle Ratchet** or the **T-Handle Ratchet**.

INSTRUMENT	REFERENCE
CORTICAL SCREWDRIVER SHAFT	TLF-IN 13 20-N
CORTICAL SCREWDRIVER TUBE	TLF-IN 13 10-N
STRAIGHT RATCHET HANDLE	HAN-SB RF ST-N
T-HANDLE RATCHET	HAN-SB RF TE-N

_STEP 9

SCREW INSERTION

Insert the tip of the screwdriver assembly into the screw hexalobe recess.

Slide down the **Cortical Screwdriver Tube** to secure the bone screw, then turn its grip counterclockwise to lock the bone screw.

Place the screw tip into the entry site. Align the screwdriver assembly with the prepared hole and rotate it clockwise to advance the screw.

If Necessary, adjust the screw depth with the **T25 Screwdriver Shaft**.

NOTE 1: The **Ball Reamer** can be used to remove tissue and decrease potential screw head impingement prior to head clipping.

NOTE 2: Confirm screw positioning using lateral and A/P radiograph of fluoroscopy.

INSTRUMENT	REFERENCE
CORTICAL SCREWDRIVER SHAFT	TLF-IN 13 20-N
CORTICAL SCREWDRIVER TUBE	TLF-IN 13 10-N
STRAIGHT RATCHET HANDLE	HAN-SB RF ST-N
T-HANDLE RATCHET	HAN-SB RF TE-N
T25 SCREWDRIVER SHAFT	TLF-IN 03 00-N

SURGICAL TECHNIQUE

_POSTERIOR CAGE NOTE - DISTRACTION

Decompression and posterior cage insertion are performed prior to head screw insertion.

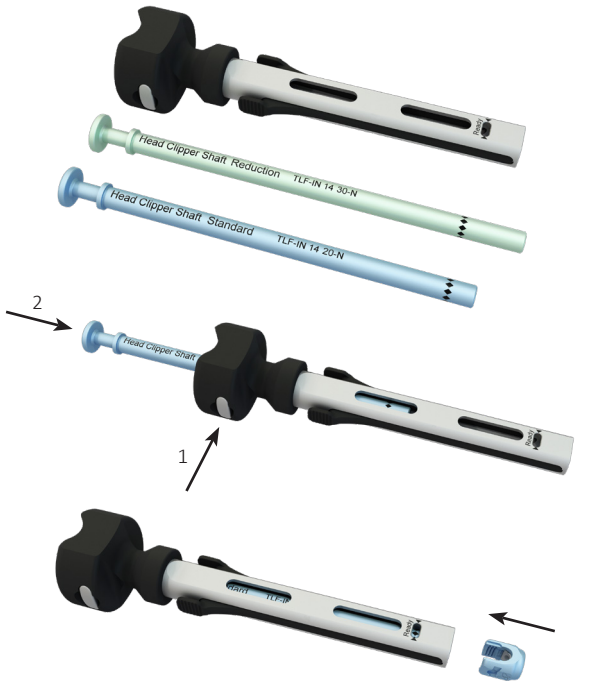
Due to the superior and lateral trajectory, head screws can interfere with a wide decompression or insertion of an oblique TLIF cage.

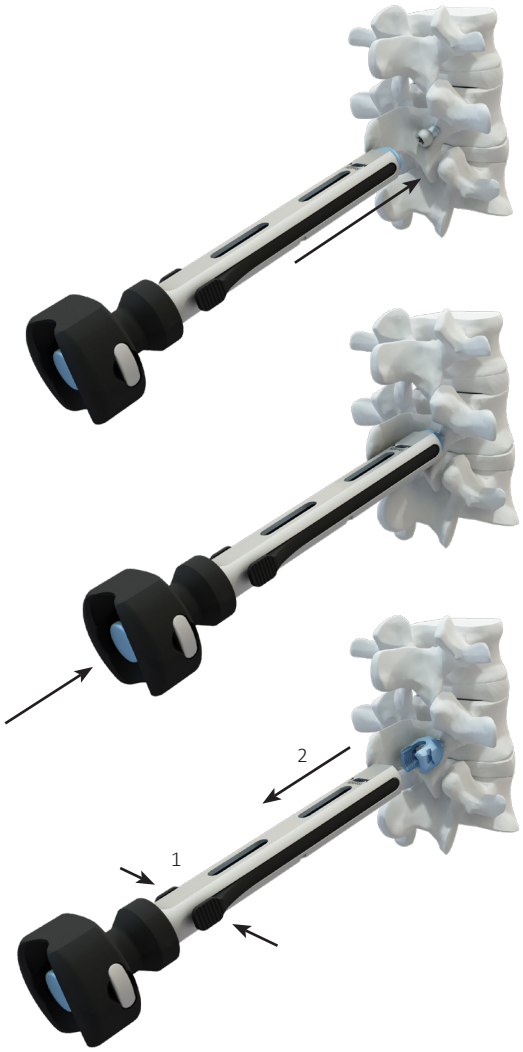
Cortical Bone Screws allow to use an **Articulated Distractor** directly on their head to help opening the disc space while maximizing visualization.

When performing a facetectomy or laminectomy preserve 3-5mm of bone around the screw entry site to prevent splitting cortical bone.

INSTRUMENT	REFERENCE
ARTICULATED DISTRACTOR – FIXED ARM	TLF-IN 07 50-N
ARTICULATED DISTRACTOR – MOBILE ARM	TLF-IN 07 51-N
ARTICULATED DISTRACTOR – LEFT END TIP	TLF-IN 07 60-N
ARTICULATED DISTRACTOR – RIGHT END TIP	TLF-IN 07 61-N

_STEP 10





HEAD CLIPPING

Select the proper Head Clipper Shaft according to the screw head selected (same colour):

- **Head Clipper Shaft Standard** (blue): Polyaxial Modular Head
- **Head Clipper Shaft Reduction** (green): Reduction Modular Head

Press on the lateral button while inserting the shaft, until reaching the stop position. Then release the lateral button.

Connect the instrument to the appropriate Modular Head.

⚠ **CAUTION:** Insert the appropriate shaft into the head clipper before connecting to the head to avoid any accidental securisation of the head.

Clip the **Modular Head** to the **Cortical Bone Screw**.

Then press on the **Head Clipper Shaft** to secure the head connection.

⚠ **WARNING 1:** To secure head connection, press on the shaft until the “click“ feedback.

⚠ **WARNING 2:** Check the proper Modular Head connection to the Cortical Bone Screw by pulling backwards on the **Head Clipper**.

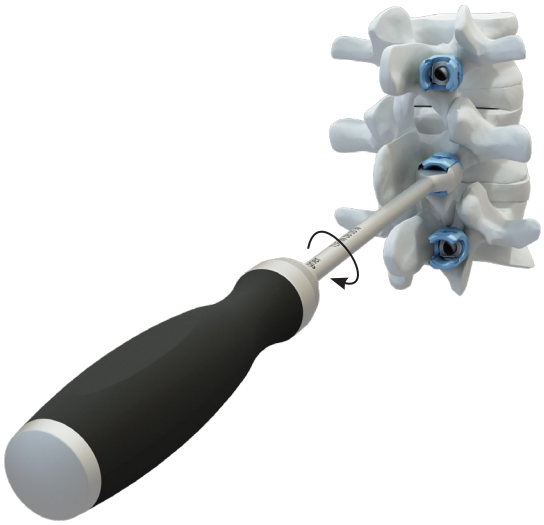
Push on the lateral wings of the **Head Clipper** to release the implant.

SURGICAL TECHNIQUE

NOTE: The Modular Head can be clipped to the Cortical Bone Screw prior to the bone screw insertion by using the same instruments with the **Clipping Base**. In this case, use the appropriate Screwdriver and technique listed in the PERLA® TL Thoracolumbar Fixation Surgical Technique.

INSTRUMENT	REFERENCE
HEAD CLIPPER	TLF-IN 14 10-N
HEAD CLIPPER SHAFT STANDARD	TLF-IN 14 20-N
HEAD CLIPPER SHAFT REDUCTION	TLF-IN 14 30-N
CLIPPING BASE	TLF-IN 14 00-N

_STEP 11



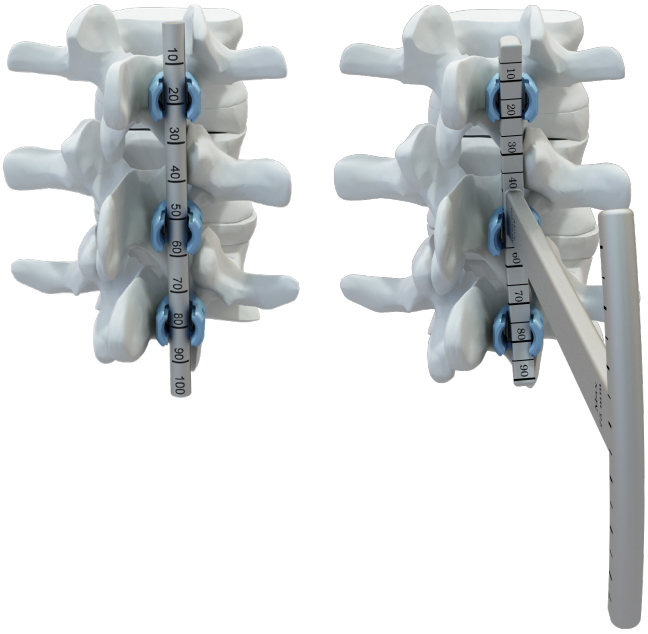
SCREW HEAD ADJUSTMENT

Set the orientation of the head with the **Head Aligner**.

INSTRUMENT	REFERENCE
HEAD ALIGNER	TLF-IN 08 00-N

SURGICAL TECHNIQUE

_STEP 12

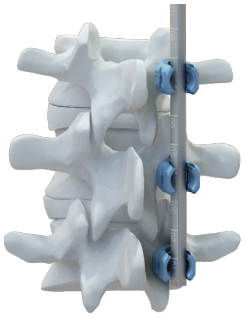


ROD SELECTION

Choose the appropriate length of rod with the **Rod Template** or **Rod Trial**.

INSTRUMENT	REFERENCE
ROD TEMPLATE L100	TLF-IN 10 10-N
ROD TRIAL SHORT	TLF-IN 24 01-N
ROD TRIAL LONG	TLF-IN 24 02-N

_STEP 13



ROD CONTOURING

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

NOTE: PERLA® TL rods are ø5.5mm and ø6mm.

NOTE 2: To contour a ø5.5mm Titanium rod, the radius selector of the **Rod Bender** can be positioned on 5, 6, 7 or 8. When a cobalt chromium rod or a ø6mm rod needs to be contoured, we recommend positioning the radius selector of the **Rod Bender** on 7 or 8.

NOTE 3: Rod Bender Extension can be connected to the rod bender for additional force.

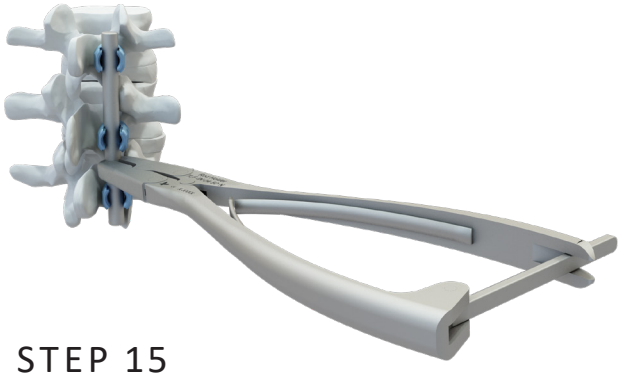
⚠ **WARNING:** Once bent, rods should not be de-contoured.

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

INSTRUMENT	REFERENCE
ROD BENDER	TLF-IN 04 00-N
ROD BENDER EXTENSION	TLF-IN 04 10-N

SURGICAL TECHNIQUE

_STEP 14



_STEP 15

ROD PLACEMENT

Insert a rod into the implant head using the **Implant Holder**. If a stronger holding is required, use the **Rod Holder**.

INSTRUMENT	REFERENCE
IMPLANT HOLDER	TLF-IN 01 04-N
ROD HOLDER	TLF-IN 04 50-N

ROD REDUCTION

Multiple instrument options are available for rod reduction (see table). The use of one of these instruments is **MANDATORY**.
They facilitate the insertion of setscrew due to the persuasion of the rod into the screw head.

Start inserting the setscrews from the caudal part of the construct. The setscrews should not be firmly locked at this stage, to allow movement of the rod in the screw heads.

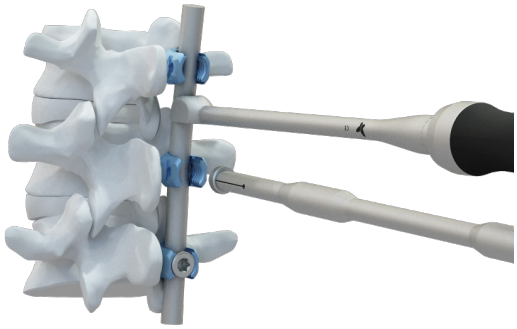
Attach a setscrew to the **Setscrew Holder** or **Setscrew Holder Double** end tip.

Introduce the setscrew into the implant head by rotating the holder clockwise. To facilitate setscrew insertion, rotate the holder counterclockwise a quarter turn or until the set screw «drops» in the head.

INSTRUMENT	REFERENCE
A. ROD PUSHER	TLF-IN 04 30-N
B. ROCKER	TLF-IN 04 20-N
C. QR REDUCER (OPTIONAL)	
OUTER TUBE	ELL-IN 31 34-N
INNER TUBE	ELL-IN 32 34-N
HANDLE	ELL-IN 33 34-N
D. PERSUADER	TLF-IN 09 10-N
E. SETSCREW TUBE	TLF-IN 05 00-N
SETSCREW HOLDER	TLF-IN 05 10-N
SETSCREW HOLDER DOUBLE (OPTION)	TLF-IN 05 50-N

SURGICAL TECHNIQUE

_STEP 15-A

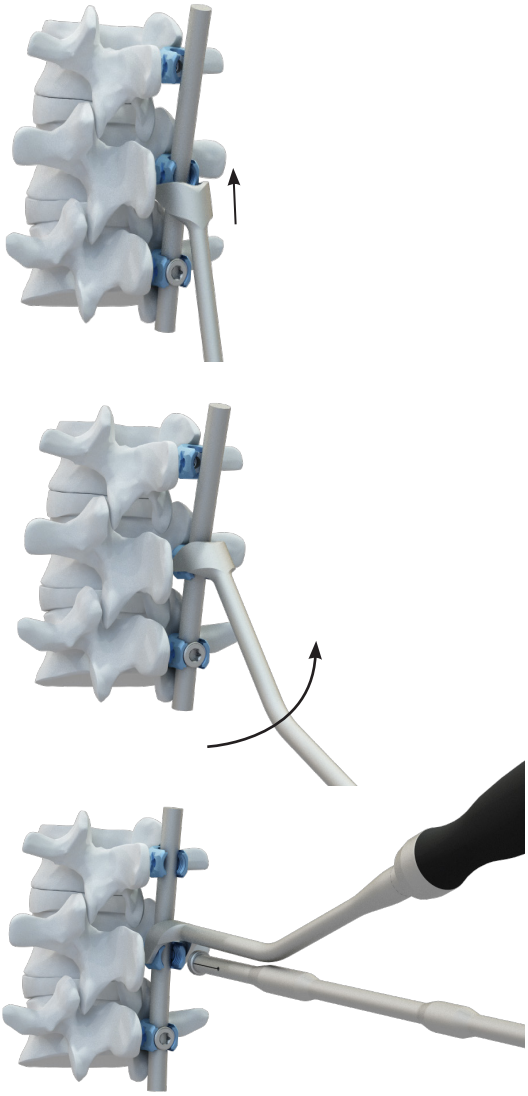


ROD REDUCTION - ROD PUSHER

Place the **Rod Pusher** on the rod to push it in the screw head. Then use the **Setscrew Holder** to insert the setscrew.

INSTRUMENT	REFERENCE
ROD PUSHER	TLF-IN 04 30-N
SETSCREW HOLDER	TLF-IN 05 10-N

_STEP 15-B



ROD REDUCTION - ROCKER

Slide the **Rocker** on the lateral groove of the screw head to connect it to the notch.

Then swing the instrument in order to reduce the rod into the screw head.

Insert the setscrew with the **Setscrew Holder**.

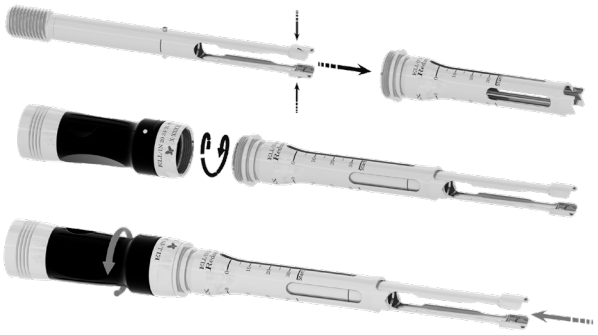
Slide the **Rocker** on the lateral groove to disconnect it from the screw head.

NOTE: The ROMEO®2 “hemostat“ version is available in option.

INSTRUMENT	REFERENCE
ROCKER	TLF-IN 04 20-N
SETSCREW HOLDER	TLF-IN 05 10-N

_STEP 15-C

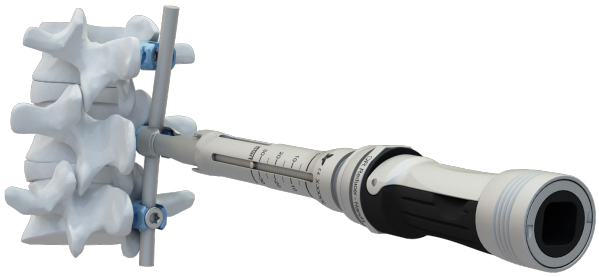
ROD REDUCTION - QR REDUCER



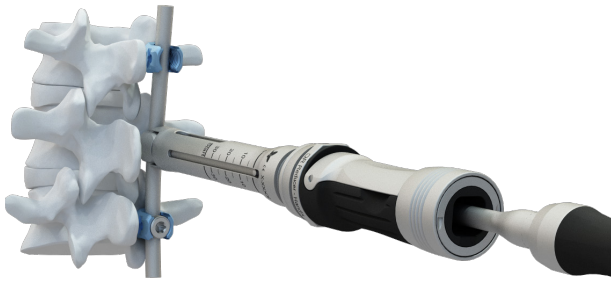
Insert the **Inner Tube** into the **Outer Tube**. The extremity of the **Inner Tube** has to be slightly squeezed to ease the insertion.

Connect the **Handle** to the tube. Firmly screw the locking ring of the handle.

Push the **Inner Tube** into the **Handle** and turn the **Handle** clockwise to engage the thread. The engagement of the tube thread into the **Handle** must be carefully performed. **DO NOT** force. The assembling procedure is finished when the position marker of the **Inner Tube** is aligned with the “START“ laser marking of the **Outer Tube**.



Connect the instrument to the screw head then persuade the rod into it by turning the **Handle**. If additional force is required to seat the rod, you can use the **QR Reducer T-Handle** by sliding it onto the top of the **QR Reducer** to finish the reduction.

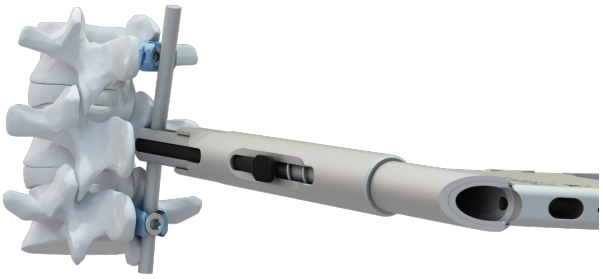


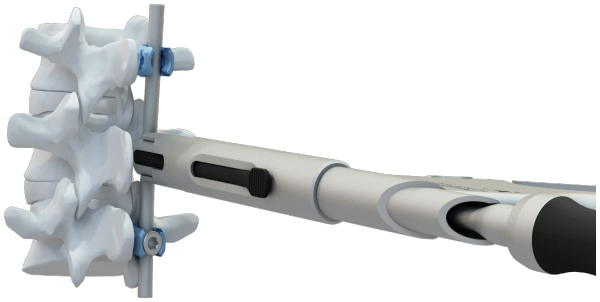
Then use the **Setscrew Holder** to insert the setscrew through the **QR Reducer** into the screw head.

INSTRUMENT	REFERENCE
QR REDUCER (OPTIONAL)	
OUTER TUBE	ELL-IN 31 34-N
INNER TUBE	ELL-IN 32 34-N
HANDLE	ELL-IN 33 34-N
QR REDUCER T-HANDLE (OPTIONAL)	HAN-TY SS 14-N
SETSCREW HOLDER	TLF-IN 05 10-N

SURGICAL TECHNIQUE

_STEP 15-D





ROD REDUCTION - PERSUADER

Press the trigger to ensure that the **Persuader** is fully released.

To connect the **Persuader**, slide its extremity on a screw head.
Press the handle in order to progressively persuade the rod into the screw head.

Once the reduction completed, insert the setscrew through the **Persuader** by using the **Setscrew Holder**.

Press the trigger to release the persuation then press the black buttons on the sides of the barrel to disconnect the **Persuader** from the screw head.

INSTRUMENT	REFERENCE
PERSUADER	TLF-IN 09 10-N
SETSCREW HOLDER	TLF-IN 05 10-N

_STEP 15-E

ROD REDUCTION - SETSCREW TUBE

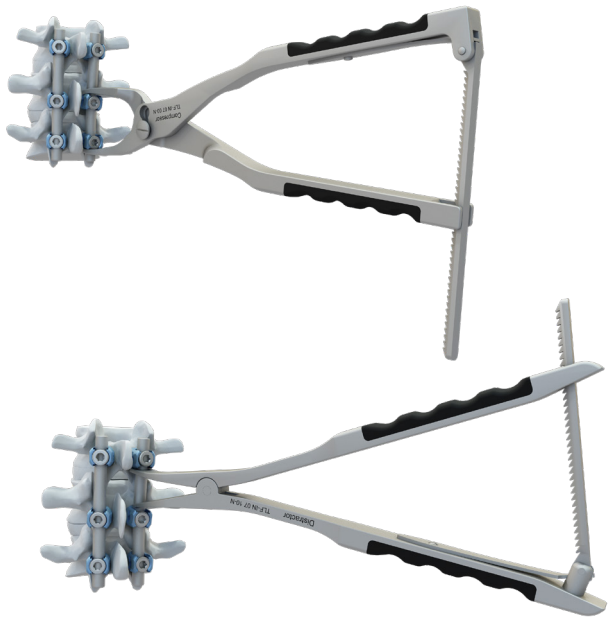
Place the **Setscrew Tube** on the top of the screw. Push down to reduce the rod into the screw head.

Insert the setscrew by sliding it through the **Setscrew Tube** with the **Setscrew Holder**.

INSTRUMENT	REFERENCE
SETSCREW TUBE	TLF-IN 05 00-N
SETSCREW HOLDER	TLF-IN 05 10-N

SURGICAL TECHNIQUE

_STEP 16

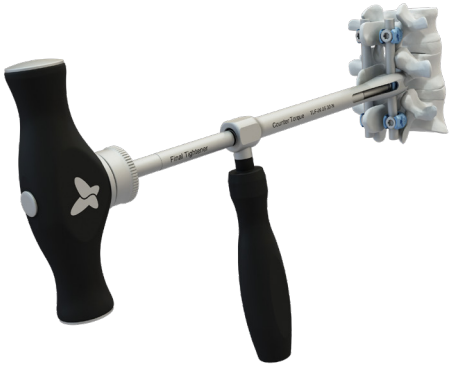


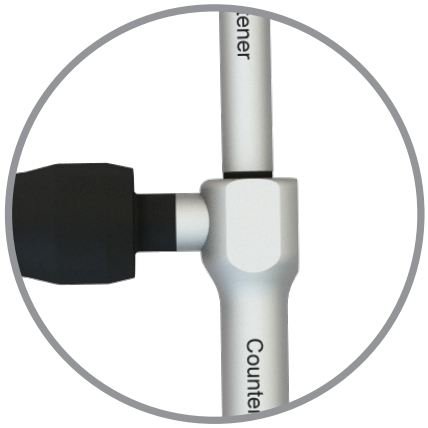
COMPRESSION AND DISTRACTION

Compression or distraction may be performed by using the **Compressor** or the **Distractor**.

INSTRUMENT	REFERENCE
COMPRESSOR	TLF-IN 07 00-N
DISTRACTOR	TLF-IN 07 10-N

_STEP 17





FINAL TIGHTENING

Pass the shaft of the **Final Tightener** through the **Counter Torque** and insert the tip into the setscrew recess. Secure the **Counter Torque** around the implant head.

NOTE: Confirm black etch line on the **Final Tightener** shaft is flush with the **Counter Torque** barrel. This indicates the instrument tip is fully seated in the set screw recess.

Rotate the handle of the **Final Tightener** clockwise until it "clicks".

Before closing, proceed final tighten each setscrew and connector of the construct.

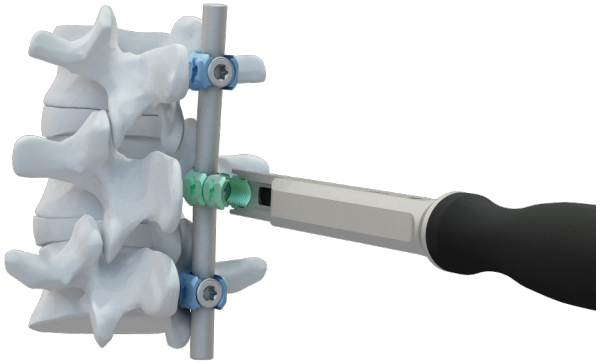
⚠ **WARNING:** The **T25 Screwdriver Shaft** must not be used with setscrews. For pedicle screws only.

⚠ **WARNING:** Always use the **Counter Torque** during final tightening to reduce torque transfer to the spine and avoid damage to the driver tip.

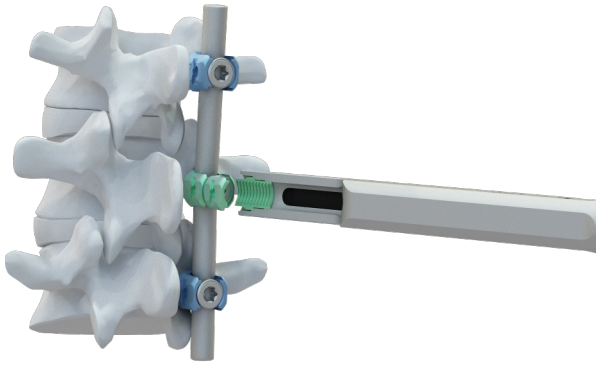
INSTRUMENT	REFERENCE
FINAL TIGHTENER	TLF-IN 05 40-N
COUNTER TORQUE	TLF-IN 05 30-N

_STEP 18

REDUCTION SCREW AND TAB BREAKING

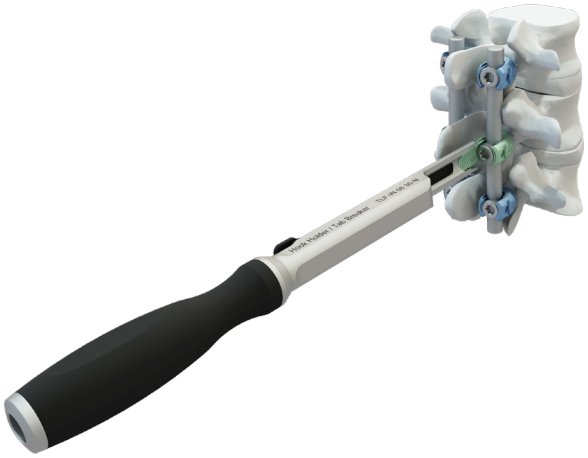


For Reduction Screws, after the Final Tightening, break the tabs with the **Hook Holder/Tab Breaker**.



Slide the instrument on a tab then rock medial / lateral to break the tab.

Press the black button on the side of the **Hook Holder/Tab Breaker** to release the broken tab.



Repeat the same steps with the second tab of the Reduction Screw.

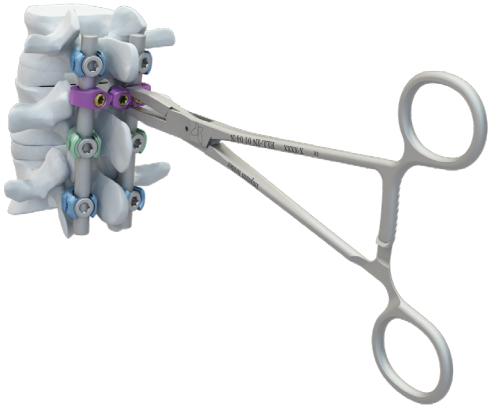
INSTRUMENT	REFERENCE
HOOK HOLDER/TAB BREAKER	TLF-IN 08 30-N

SURGICAL TECHNIQUE

_STEP 19

CROSS CONNECTOR

To select the appropriate cross connector size, measure the distance between rods using the **Caliper**. The locking nut secures the **Cross Connector Caliper**. Cross connector length is indicated on the scale.



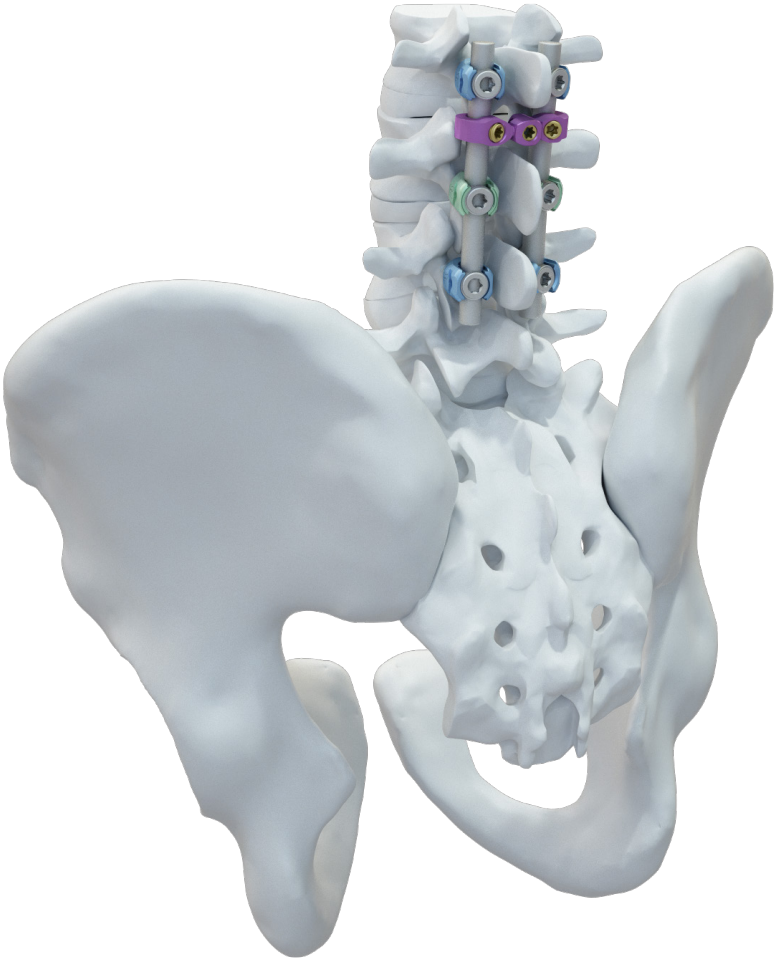
Use the **Implant Holder** to manipulate the cross connector.

Once the cross connector is positionned, use the **Cross Connector Tightener** to final tighten.

INSTRUMENT	REFERENCE
CROSS CONNECTOR CALIPER	TLF-IN 08 10-N
IMPLANT HOLDER	ELL-IN 01 04-N
CROSS CONNECTOR TIGHTENER	TLF-IN 08 20N

SURGICAL TECHNIQUE

_FINAL CONSTRUCT



_REVISION

Loosen and remove all set screws using the **Counter Torque** and the **Setscrew Tightener** connected to the **T-Handle Ratchet**. Remove rods. Fully secure the screwdriver to the screw recess and turn counterclockwise to remove screws.

INSTRUMENT	REFERENCE
T-HANDLE RATCHET	HAN-SB RF TE-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
SETSCREW TIGHTENER	TLF-IN 05 20-N
COUNTER TORQUE	TLF-IN 05 30-N
SCREWDRIVER UNIVERSAL SHAFT	TLF-IN 03 50-N
SCREWDRIVER SHAFT MS-PS	TLF-IN 03 30-N
SCREWDRIVER SLEEVE	TLF-IN 03 20-N
SCREWDRIVER TUBE	TLF-IN 03 10-N

GENERAL INFORMATION

REFERENCE OF THE IFU	PER-IF TL 00-W	REVISION OF THE FINAL IFU	JAN-2020

_STERILITY

The implant is provided sterile or non sterile.

The sterile packed instruments are for single used.

In case of non sterile condition delivery, see § "Decontamination, cleaning and sterilization".

If the implant or its packaging seems to be damaged, if the expiry date is exceeded or in the event that sterility cannot be guaranteed for any reason, the device shall not be implanted.

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 re-sterilization of the gamma sterilized implant is forbidden.

The re-sterilization of the delivered sterilized instruments is forbidden.

Please refer to the individual package labeling.

_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 a maximal stiffness, a transverse rod associated to connectors is also available.

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

_INDICATIONS

PERLA®TL system implants are designed to treat those lumbar and thoracic pathologies:

- Spondylolisthesis
- Degenerative disc disease
- Thoracic and lumbar fractures
- Thoracic and lumbar vertebra tumors
- Pseudarthrosis
- Stenosis
- Spine deformities: scoliosis, kyphosis

_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 cicatrisation.

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.

_WARNINGS

Because this is a technically demanding procedure presenting a risk of serious injury to the patient, only experienced surgeons with adequate training should perform posterior osteosynthesis. 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. Abnormal use of the device may lead to risks of serious injury and/or health deterioration of the patient.

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 requiring other types of procedures. Patients undergoing posterior osteosynthesis shall, therefore, be informed.

Significant implant overload, patient hyperactivity or abnormal behavior may increase clinical risks and require secondary surgery. Patient who underwent this type of procedure shall, therefore, be informed of the residual clinical risks.

In rare cases, the patient may have or develop hypersensitivity to medical grade titanium alloys.

The PERLA®TL implant must not be used with implant other than PERLA®TL range. The PERLA®TL Implant must only be used with the PERLA®TL instruments.

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

_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®.

_HANDLING

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

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.

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.

We strongly recommend that excessive force should not be applied when installing any of the implants.

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

_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 the PERLA®TL implants.

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

The instrument set equipment is composed of delivered sterile or non sterile instruments for single use.

_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.

The PERLA®TL 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 soft-bristled brush to assist in the removal of gross soil debris. The devices which 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 minutes. Devices with mobile parts will be activated 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 will be activated 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 soft-bristled brush to assist in the removal of gross soil debris. The devices which 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 will be activated 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 will be activated during rinsing.
- Load devices into the washer-disinfector.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

_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.

WASHER-DISINFECTOR PARAMETERS

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

GENERAL INFORMATION

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 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.

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

"Do not stack trays during sterilization"

_MAINTENANCE AND REPAIR

Spineart® instruments are guaranteed for at least 150 steam sterilization runs.

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.

N O T E

N O T E

N O T E

S P I N E A R T

SPINEART SA
CHEMIN DU PRÉ-FLEURI 3
1228 PLAN-LES-OUATES
SWITZERLAND

SEP-2020-REF-PER-CT-ST-EN CE 1984