PERLA® TL

THORACOLUMBAR FIXATION

C O N T E N T

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.

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 is a complete posterior fixation system that offers alternative solutions to the surgeons and their patients.
Among others, the PERLA® TL 25D semi-polyaxial screw provides the benefits of monoaxial screw for controlled powerful reduction and the versatility of the polyaxial screw for ease of rod connection.

AT A GLANCE

Double Rod Diameter Compatibility
Dual Core and Double Thread Screw
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

POLYAXIAL SCREWS

DIAMETER/ LENGTH	Ø4.5	Ø5.5	Ø6.5
L25	TLF-PS 45 25-S	TLF-PS 55 25-S	TLF-PS 65 25-S
L30	TLF-PS 45 30-S	TLF-PS 55 30-S	TLF-PS 65 30-S
L35	TLF-PS 45 35-S	TLF-PS 55 35-S	TLF-PS 65 35-S
L40	TLF-PS 45 40-S	TLF-PS 55 40-S	TLF-PS 65 40-S
L45	TLF-PS 45 45-S	TLF-PS 55 45-S	TLF-PS 65 45-S
L50		TLF-PS 55 50-S	TLF-PS 65 50-S
L55			TLF-PS 65 55-S
L60			TLF-PS 65 60-S
L70			TLF-PS 65 70-S
L80			TLF-PS 65 80-S
L90			TLF-PS 65 90-S

DIAMETER/ LENGTH	Ø7.5	Ø8.5	Ø9.5	Ø10.5*
L25				
L30	TLF-PS 75 30-S	TLF-PS 85 30-S	TLF-PS 95 30-S	
L35	TLF-PS 75 35-S	TLF-PS 85 35-S	TLF-PS 95 35-S	TLF-PS 15 35-S
L40	TLF-PS 75 40-S	TLF-PS 85 40-S	TLF-PS 95 40-S	TLF-PS 15 40-S
L45	TLF-PS 75 45-S	TLF-PS 85 45-S	TLF-PS 95 45-S	TLF-PS 15 45-S
L50	TLF-PS 75 50-S	TLF-PS 85 50-S	TLF-PS 95 50-S	TLF-PS 15 50-S
L55	TLF-PS 75 55-S	TLF-PS 85 55-S	TLF-PS 95 55-S	TLF-PS 15 55-S
L60	TLF-PS 75 60-S	TLF-PS 85 60-S	TLF-PS 95 60-S	TLF-PS 15 60-S
L70	TLF-PS 75 70-S	TLF-PS 85 70-S	TLF-PS 95 70-S	TLF-PS 15 70-S
L80	TLF-PS 75 80-S	TLF-PS 85 80-S	TLF-PS 95 80-S	TLF-PS 15 80-S
L90	TLF-PS 75 90-S	TLF-PS 85 90-S	TLF-PS 95 90-S	TLF-PS 15 90-S
L100	TLF-PS 75 10-S	TLF-PS 85 10-S	TLF-PS 95 10-S	TLF-PS 15 10-S
L110	TLF-PS 75 11-S	TLF-PS 85 11-S	TLF-PS 95 11-S	TLF-PS 15 11-S
L120	TLF-PS 75 12-S	TLF-PS 85 12-S	TLF-PS 95 12-S	TLF-PS 15 12-S

*Not available during Expert Phase

IMPLANTS

REDUCTION SCREWS

DIAMETER/ LENGTH	Ø4.5	Ø5.5	Ø6.5
L25	TLF-SS 45 25-S	TLF-SS 55 25-S	TLF-SS 65 25-S
L30	TLF-SS 45 30-S	TLF-SS 55 30-S	TLF-SS 65 30-S
L35	TLF-SS 45 35-S	TLF-SS 55 35-S	TLF-SS 65 35-S
L40	TLF-SS 45 40-S	TLF-SS 55 40-S	TLF-SS 65 40-S
L45	TLF-SS 45 45-S	TLF-SS 55 45-S	TLF-SS 65 45-S
L50		TLF-SS 55 50-S	TLF-SS 65 50-S
L55			TLF-SS 65 55-S
L60			TLF-SS 65 60-S
L70			TLF-SS 65 70-S
L80			TLF-SS 65 80-S
L90			TLF-SS 65 90-S

DIAMETER/ LENGTH	Ø7.5	Ø8.5	Ø9.5	Ø10.5*
L25				
L30	TLF-SS 75 30-S	TLF-SS 85 30-S	TLF-SS 95 30-S	
L35	TLF-SS 75 35-S	TLF-SS 85 35-S	TLF-SS 95 35-S	TLF-SS 15 35-S
L40	TLF-SS 75 40-S	TLF-SS 85 40-S	TLF-SS 95 40-S	TLF-SS 15 40-S
L45	TLF-SS 75 45-S	TLF-SS 85 45-S	TLF-SS 95 45-S	TLF-SS 15 45-S
L50	TLF-SS 75 50-S	TLF-SS 85 50-S	TLF-SS 95 50-S	TLF-SS 15 50-S
L55	TLF-SS 75 55-S	TLF-SS 85 55-S	TLF-SS 95 55-S	TLF-SS 15 55-S
L60	TLF-SS 75 60-S	TLF-SS 85 60-S	TLF-SS 95 60-S	TLF-SS 15 60-S
L70	TLF-SS 75 70-S	TLF-SS 85 70-S	TLF-SS 95 70-S	TLF-SS 15 70-S
L80	TLF-SS 75 80-S	TLF-SS 85 80-S	TLF-SS 95 80-S	TLF-SS 15 80-S
L90	TLF-SS 75 90-S	TLF-SS 85 90-S	TLF-SS 95 90-S	TLF-SS 15 90-S
L100	TLF-SS 75 10-S	TLF-SS 85 10-S	TLF-SS 95 10-S	TLF-SS 15 10-S
L110	TLF-SS 75 11-S	TLF-SS 85 11-S	TLF-SS 95 11-S	TLF-SS 15 11-S
L120	TLF-SS 75 12-S	TLF-SS 85 12-S	TLF-SS 95 12-S	TLF-SS 15 12-S

*Not available during Expert Phase

IMPLANTS

25D SCREWS

DIAMETER/ LENGTH	Ø4.5	Ø5.5	Ø6.5
L25	TLF-DS 45 25-S	TLF-DS 55 25-S	TLF-DS 65 25-S
L30	TLF-DS 45 30-S	TLF-DS 55 30-S	TLF-DS 65 30-S
L35	TLF-DS 45 35-S	TLF-DS 55 35-S	TLF-DS 65 35-S
L40	TLF-DS 45 40-S	TLF-DS 55 40-S	TLF-DS 65 40-S
L45	TLF-DS 45 45-S	TLF-DS 55 45-S	TLF-DS 65 45-S
L50		TLF-DS 55 50-S	TLF-DS 65 50-S
L55			TLF-DS 65 55-S
L60			TLF-DS 65 60-S
L70			TLF-DS 65 70-S
L80			TLF-DS 65 80-S
L90			TLF-DS 65 90-S

MONOAXIAL SCREWS*

DIAMETER/ LENGTH	Ø4.5	Ø5.5	Ø6.5	Ø7.5	Ø8.5	Ø9.5
L25	TLF-MS 45 25-S	TLF-MS 55 25-S	TLF-MS 65 25-S			
L30	TLF-MS 45 30-S	TLF-MS 55 30-S	TLF-MS 65 30-S	TLF-MS 75 30-S	TLF-MS 85 30-S	TLF-MS 95 30-S
L35	TLF-MS 45 35-S	TLF-MS 55 35-S	TLF-MS 65 35-S	TLF-MS 75 35-S	TLF-MS 85 35-S	TLF-MS 95 35-S
L40	TLF-MS 45 40-S	TLF-MS 55 40-S	TLF-MS 65 40-S	TLF-MS 75 40-S	TLF-MS 85 40-S	TLF-MS 95 40-S
L45	TLF-MS 45 45-S	TLF-MS 55 45-S	TLF-MS 65 45-S	TLF-MS 75 45-S	TLF-MS 85 45-S	TLF-MS 95 45-S
L50		TLF-MS 55 50-S	TLF-MS 65 50-S	TLF-MS 75 50-S	TLF-MS 85 50-S	TLF-MS 95 50-S
L55			TLF-MS 65 55-S	TLF-MS 75 55-S	TLF-MS 85 55-S	TLF-MS 95 55-S
L60			TLF-MS 65 60-S	TLF-MS 75 60-S	TLF-MS 85 60-S	TLF-MS 95 60-S
L70			TLF-MS 65 70-S	TLF-MS 75 70-S	TLF-MS 85 70-S	TLF-MS 95 70-S
L80			TLF-MS 65 80-S	TLF-MS 75 80-S	TLF-MS 85 80-S	TLF-MS 95 80-S
L90			TLF-MS 65 90-S	TLF-MS 75 90-S	TLF-MS 85 90-S	TLF-MS 95 90-S
L100				TLF-MS 75 10-S	TLF-MS 85 10-S	TLF-MS 95 10-S
L110				TLF-MS 75 11-S	TLF-MS 85 11-S	TLF-MS 95 11-S
L120				TLF-MS 75 12-S	TLF-MS 85 12-S	TLF-MS 95 12-S

*Not available during Expert Phase

IMPLANTS

ROD CONNECTOR PARALLEL OPEN/CLOSE	TLF-PC OP CL-S

ROD CONNECTOR PARALLEL OPEN/OPEN	TLF-PC-OP OP-S

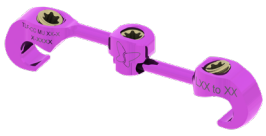
SETSCREWS

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

ROD CONNECTOR AXIAL OPEN/CLOSE	TLF-AC OP CL-S

LATERAL CONNECTORS		
LENGTH	**CLOSE***	**OPEN**
L15	TLF-LC CL 15-S	TLF-LC OP 15-S
L20	TLF-LC CL 20-S	TLF-LC OP 20-S
L30	TLF-LC CL 30-S	TLF-LC OP 30-S
L40	TLF-LC CL 40-S	TLF-LC OP 40-S
L50	TLF-LC CL 50-S	TLF-LC OP 50-S
L60	TLF-LC CL 60-S	TLF-LC OP 60-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



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

*Not available during Expert Phase

IMPLANTS

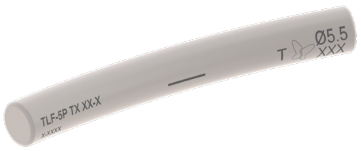
STRAIGHT RODS*

	Ø5.5mm		Ø6mm**	
LENGTH	**TITANIUM ALLOY**	**COBALT CHROMIUM**	**TITANIUM ALLOY**	**COBALT CHROMIUM**
L30	TLF-5S T0 30-S		TLF-6S T0 30-S	
L35	TLF-5S T0 35-S		TLF-6S T0 35-S	
L40	TLF-5S T0 40-S		TLF-6S T0 40-S	
L45	TLF-5S T0 45-S		TLF-6S T0 45-S	
L50	TLF-5S T0 50-S		TLF-6S T0 50-S	
L55	TLF-5S T0 55-S		TLF-6S T0 55-S	
L60	TLF-5S T0 60-S		TLF-6S T0 60-S	
L70	TLF-5S T0 70-S		TLF-6S T0 70-S	
L80	TLF-5S T0 80-S		TLF-6S T0 80-S	
L90	TLF-5S T0 90-S		TLF-6S T0 90-S	
L110	TLF-5S T1 10-S	TLF-5S C1 10-S	TLF-6S T1 10-S	TLF-6S C1 10-S
L120	TLF-5S T1 20-S	TLF-5S C1 20-S	TLF-6S T1 20-S	TLF-6S C1 20-S
L140	TLF-5S T1 40-S	TLF-5S C1 40-S	TLF-6S T1 40-S	TLF-6S C1 40-S
L160	TLF-5S T1 60-S	TLF-5S C1 60-S	TLF-6S T1 60-S	TLF-6S C1 60-S
L180	TLF-5S T1 80-S	TLF-5S C1 80-S	TLF-6S T1 80-S	TLF-6S C1 80-S
L200	TLF-5S T2 00-S	TLF-5S C2 00-S	TLF-6S T2 00-S	TLF-6S C2 00-S
L240	TLF-5S T2 40-S	TLF-5S C2 40-S	TLF-6S T2 40-S	TLF-6S C2 40-S
L280	TLF-5S T2 80-S	TLF-5S C2 80-S	TLF-6S T2 80-S	TLF-6S C2 80-S
L350	TLF-5S T3 50-S	TLF-5S C3 50-S	TLF-6S T3 50-S	TLF-6S C3 50-S
L500	TLF-5S T5 00-S	TLF-5S C5 00-S	TLF-6S T5 00-S	TLF-6S C5 00-S
L550	TLF-5S T5 50-S	TLF-5S C5 50-S	TLF-6S T5 50-S	TLF-6S C5 50-S

*Hexagonal tip starting from L100

**Not available during Expert Phase

IMPLANTS



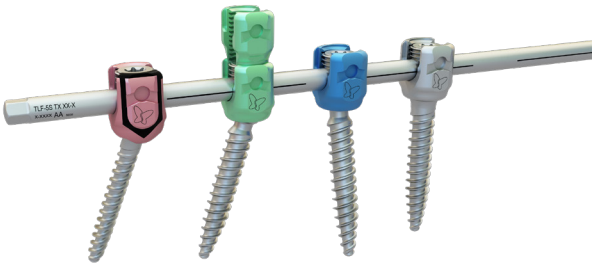
RODS PRE-BENT - TITANIUM ALLOY		
LENGTH	**Ø5.5mm**	**Ø6mm***
L30	TLF-5P T0 30-S	TLF-6P T0 30-S
L35	TLF-5P T0 35-S	TLF-6P T0 35-S
L40	TLF-5P T0 40-S	TLF-6P T0 40-S
L45	TLF-5P T0 45-S	TLF-6P T0 45-S
L50	TLF-5P T0 50-S	TLF-6P T0 50-S
L55	TLF-5P T0 55-S	TLF-6P T0 55-S
L60	TLF-5P T0 60-S	TLF-6P T0 60-S
L70	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

PREBENT RODS - COBALT CHROMIUM*			
LENGTH	**ANGULATION**	**Ø5.5mm**	**Ø6mm**
L550	40°	TLF-R4 55 50-S	TLF-R4 65 50-S
	60°	TLF-R6 55 50-S	TLF-R6 65 50-S
	80°	TLF-R8 55 50-S	TLF-R8 65 50-S

*Not available during Expert Phase

TECHNICAL FEATURES

COMPLETE TL FIXATION PLATFORM



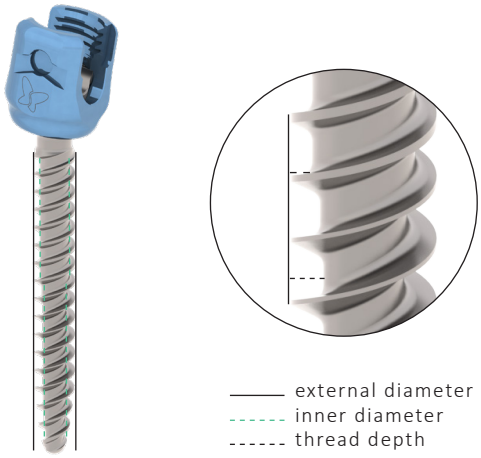
Complete range of polyaxial, semi-polyaxial, monoaxial, reduction screws, cross connectors and rod connectors provide versatile options to treat numerous pathologies from T1 to the ilium.

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.

DUAL CORE BONE SCREW

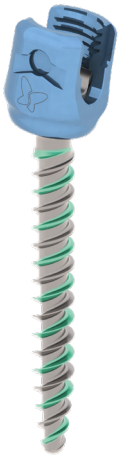


—— external diameter
------ inner diameter
------ thread depth

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 thread for cortical bone.

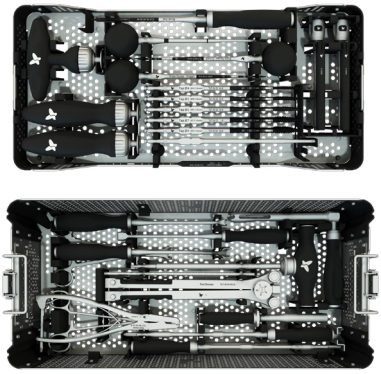
TECHNICAL FEATURES

DOUBLE THREAD



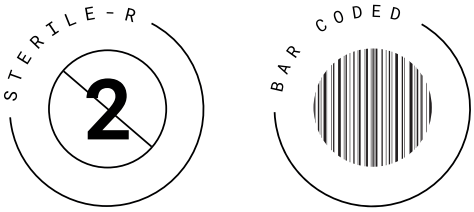
The Double Thread allows for a faster insertion compared to a single thread screw, reducing fatigue.

COMPACT SET



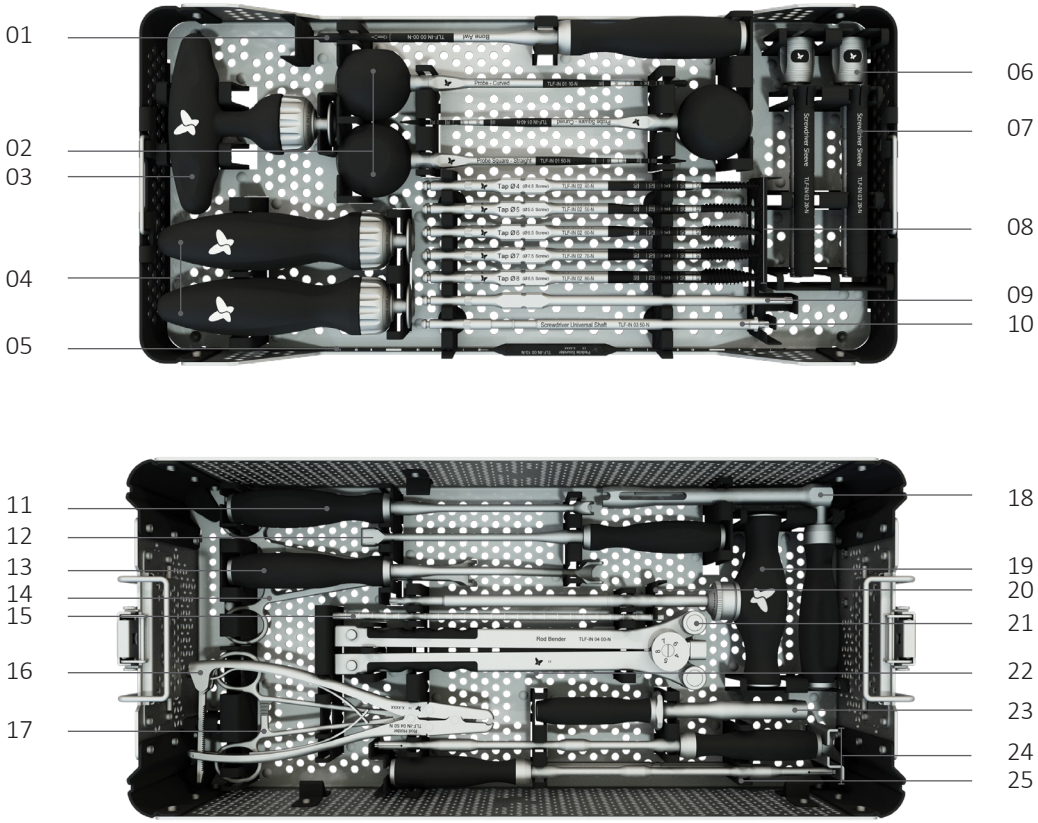
All the instrumentation needed fits in only two boxes.

SAFETY



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

INSTRUMENTS

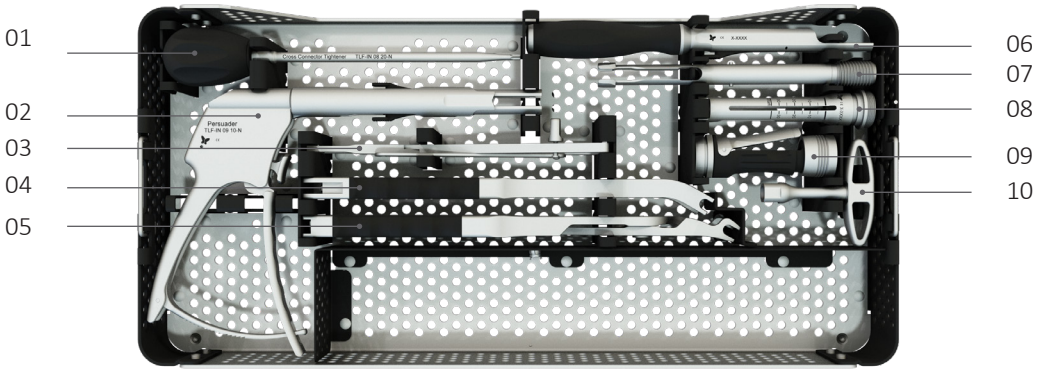


	#	DESCRIPTION	REFERENCE
	01	BONE AWL	TLF-IN 00 00-N
	02	PROBE SQUARE - CURVED	TLF-IN 01 40-N
	02	PROBE SQUARE - STRAIGHT	TLF-IN 01 50-N
•	02	PROBE - CURVED	TLF-IN 01 10-N
•	02	PROBE SMALL - CURVED	TLF-IN 01 20-N
•	02	PROBE BLUNT - STRAIGHT	TLF-IN 01 30-N
	03	T HANDLE RATCHET	HAN-SB RF TE-N
	04	STRAIGHT 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

INSTRUMENTS



	#	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

• : OPTIONAL

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

TAP Ø5 (Ø5.5 SCREW)	TLF-IN 02 50-N
TAP Ø6 (Ø6.5 SCREW)	TLF-IN 02 60-N
TAP Ø7 (Ø7.5 SCREW)	TLF-IN 02 70-N

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

TAP Ø4 (Ø4.5 SCREW)	TLF-IN 02 40-N
TAP Ø8 (Ø8.5 SCREW)	TLF-IN 02 80-N
TAP Ø9 (Ø9.5 SCREW)	TLF-IN 02 90-N
TAP Ø10 (Ø10.5 SCREW)	TLF-IN 02 10-N

INSTRUMENTS

SCREW INSERTION

T25 SCREWDRIVER SHAFT	TLF-IN 03 00-N

SCREWDRIVER SLEEVE	TLF-IN 03 20-N

SCREWDRIVER TUBE	TLF-IN 03 10-N

SCREWDRIVER UNIVERSAL SHAFT	TLF-IN 03 50-N

HEAD ALIGNER	TLF-IN 08 00-N

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

INSTRUMENTS

HANDLE

STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N

T-HANDLE RATCHET	HAN-SB RF TE-N

ROD SELECTION AND CONTOURING

ROD BENDER	TLF-IN 04 00-N

ROD HOLDER	TLF-IN 04 50-N

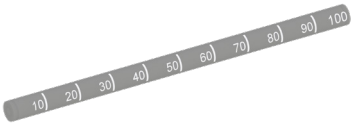
ROD TEMPLATE L250	TLF-IN 10 25-N

IMPLANT HOLDER	ELL-IN 01 04-N

ROD SELECTION AND CONTOURING - OPTIONAL

ROD BENDER - EXTENSION	TLF-IN 04 10-N

ROD TEMPLATE L100	TLF-IN 10 10-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

ROCKER (ROMEO2®)	ELL-IN 00 05-N

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-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 POSITIONNING

CROSS CONNECTOR CALIPER	TLF-IN 08 10-N

CROSS CONNECTOR TIGHTENER	TLF-IN 08 20N

SURGICAL TECHNIQUE

_STEP 1

PEDICLE PREPARATION

After having determined the entry point of the pedicle, perforate the outer cortex with the **Bone Awl** and open the pedicle canal with the **Probe**.

The probes are LASER marked to determine the appropriate length of the screws.

⚠ **WARNING:** When implanting a Ø4.5mm Screw, it is mandatory to use the **Probe Small - Curved**.

INSTRUMENT	REFERENCE
BONE AWL	TLF-IN 00 00-N
PROBE BLUNT - STRAIGHT	TLF-IN 01 30-N
PROBE SQUARE - CURVED	TLF-IN 01 40-N
PROBE SQUARE - STRAIGHT	TLF-IN 01 50-N
PROBE - CURVED	TLF-IN 01 10-N
PROBE SMALL - CURVED	TLF-IN 01 20-N

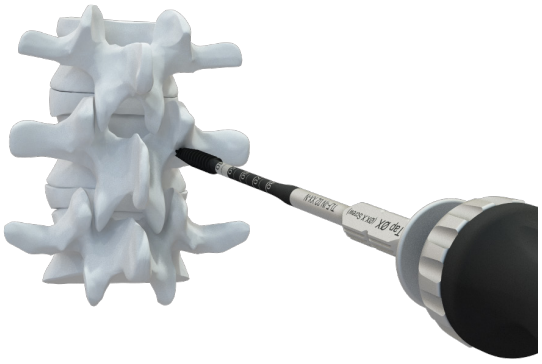
_STEP 2

PEDICLE SOUNDING

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

INSTRUMENT	REFERENCE
PEDICLE SOUNDER	TLF-IN 00 10-N

_STEP 3



HOLE TAPPING

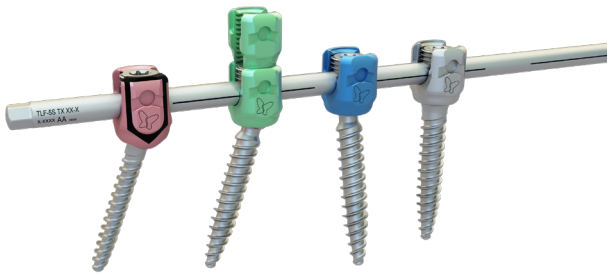
Taps are available and may be utilized to prepare the pedicle hole.

Select the **Tap** undersized by 0.5mm to the chosen screw diameter, connect it to the selected handle and advance the **Tap** into the pedicle hole.

⚠ **CAUTION:** Always undersize the **Tap** compared to the screw that will be inserted.

INSTRUMENT	REFERENCE
TAP Ø4 (Ø4.5 SCREW)	TLF-IN 02 40-N
TAP Ø5 (Ø5.5 SCREW)	TLF-IN 02 50-N
TAP Ø6 (Ø6.5 SCREW)	TLF-IN 02 60-N
TAP Ø7 (Ø7.5 SCREW)	TLF-IN 02 70-N
TAP Ø8 (Ø8.5 SCREW)	TLF-IN 02 80-N
TAP Ø9 (Ø9.5 SCREW)	TLF-IN 02 90-N

_STEP 4



SCREW SELECTION

PERLA® TL offers a full range of screws to better adapt to the surgical needs:

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 capacity.
3. **Monoaxial screw** is monobloc.
4. **25D screw** with a semi-polyaxiality has a controlled side and a polyaxial side. This screw is designed to facilitate apical vertebrae derotation while keeping easy rod introduction.

NOTE: All screws work with the **Screwdriver Universal Shaft**. Polyaxial, Monoaxial and 25D screws work with the **Screwdriver Shaft MS-PS**. Reduction screw works with **Screwdriver Shaft SS**.

INSTRUMENT	REFERENCE
SCREWDRIVER UNIVERSAL SHAFT	TLF-IN 03 50-N
SCREWDRIVER SHAFT MS-PS	TLF-IN 03 30-N
SCREWDRIVER SHAFT SS	TLF-IN 03 40-N

_STEP 5

01

02

03

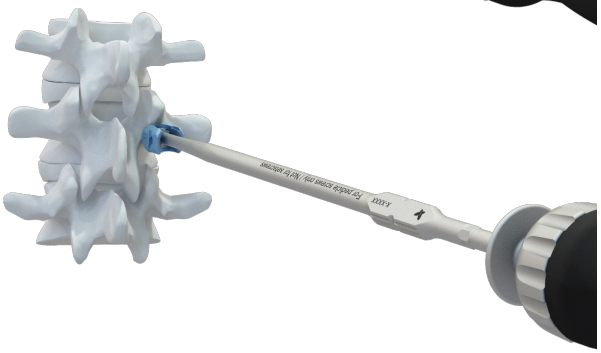
SCREWDRIVER ASSEMBLY

1. Insert the **Screwdriver Universal Shaft**, **Screwdriver shaft MS-PS** (blue ring) or **Screwdriver Shaft SS** (green ring) into the **Screwdriver Tube**
2. Insert the **Screwdriver Sleeve** or the **Screwdriver Protection Sleeve** onto the previous assembly
3. Connect the instrument to the **Straight Handle Ratchet** or the **T-Handle Ratchet**

INSTRUMENT	REFERENCE
SCREWDRIVER SLEEVE	TLF-IN 03 20-N
SCREWDRIVER TUBE	TLF-IN 03 10-N
SCREWDRIVER UNIVERSAL SHAFT	TLF-IN 03 50-N
STRAIGHT HANDLE RATCHET	HAN-SB RF ST-N
SCREWDRIVER PROTECTION SLEEVE	TLF-IN 03 60-N
SCREWDRIVER SHAFT MS-PS	TLF-IN 03 30-N
SCREWDRIVER SHAFT SS	TLF-IN 03 40-N

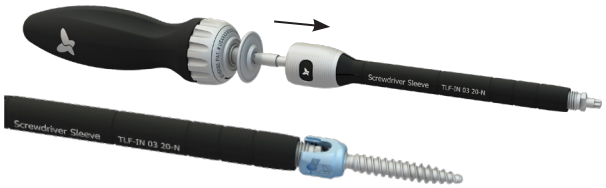
_STEP 6

SCREW INSERTION

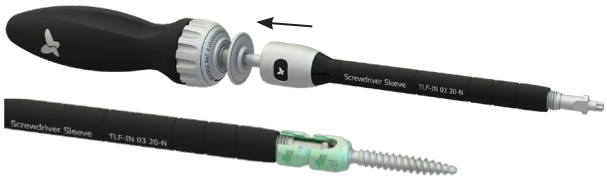


Insert the tip of the screwdriver assembly into the screw hexalobe recess. Turn the **Screwdriver Tube** clockwise to secure the screw.
Place the tip of the screw into the entry site. Align the screwdriver assembly with the prepared hole and rotate it clockwise to advance the screw.

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



NOTE 1: for **Screwdriver Universal Shaft** user, press the black button on the **Screwdriver Tube** to slide it up for reduction screw or slide it down for polyaxial, monoaxial and 25D screws

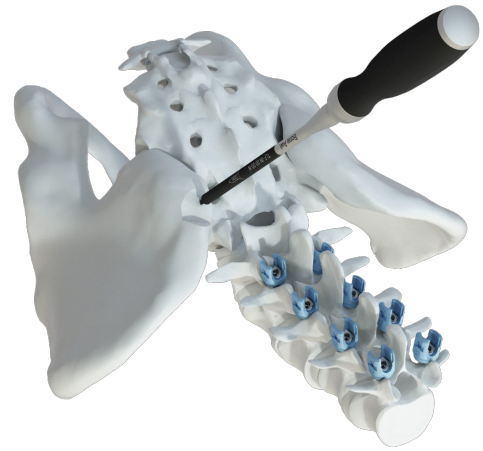


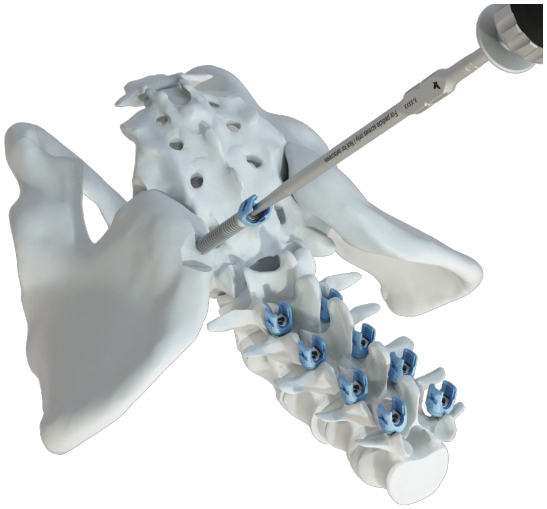
NOTE 2: for screwdriver assembly with a **Protection Sleeve**, once the screw attached to the instrument, slide the sleeve up to cover the nut by pressing its grey button

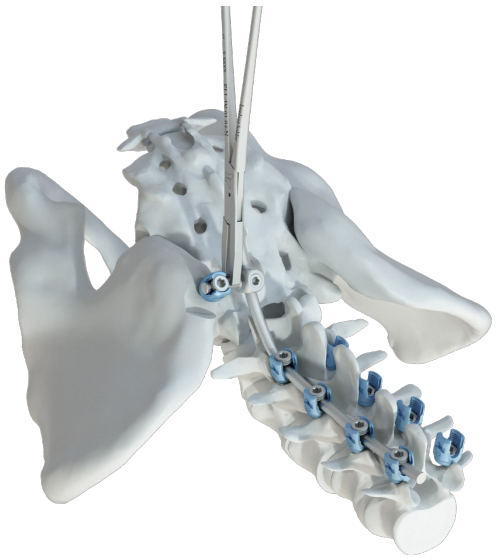
NOTE 3: confirm screw positioning using lateral and A/P radiograph of fluoroscopy.

INSTRUMENT	REFERENCE
SCREWDRIVER TUBE	TLF-IN 03 10-N
SCREWDRIVER PROTECTION SLEEVE	TLF-IN 03 60-N
SCREWDRIVER SHAFT SS	TLF-IN 03 40-N
SCREWDRIVER UNIVERSAL SHAFT	TLF-IN 03 50-N
T25 SCREWDRIVER SHAFT	TLF-IN 03 00-N
SCREWDRIVER SHAFT MS-PS	TLF-IN 03 30-N

_STEP 6 (OPTION)







SCREW INSERTION – ILIAC FIXATION

After performing desired osteotomy of the iliac crest, determine the entry point of the iliac screw, initiate the pilot hole with the **Bone Awl**.

Penetrate into the cancellous bone with the **Probe**.

INSTRUMENT	REFERENCE
BONE AWL	TLF-IN 00 00-N
PROBE BLUNT - STRAIGHT	TLF-IN 01 30-N
PROBE SQUARE - CURVED	TLF-IN 01 40-N
PROBE SQUARE - STRAIGHT	TLF-IN 01 50-N
PROBE - CURVED	TLF-IN 01 10-N

Connect the screw to the **Screwdriver** and proceed to implantation.

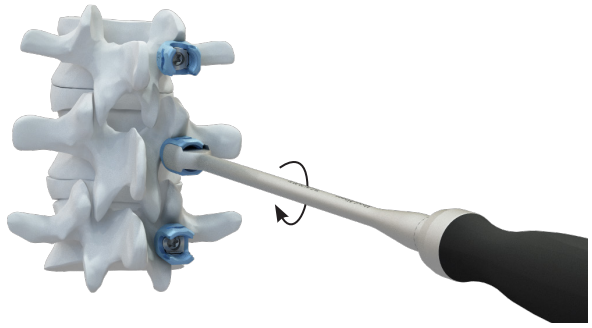
Once the screw is implanted, a lateral connector will help to align with the rod. Take the lateral connector with the **Implant Holder**, place it inside the screw head. Secure it with a setscrew introduced with the **Setscrew Holder** or **Setscrew Holder Double**.

If a lateral connection is not needed, link the rod directly to the screw seated in the iliac bone.

INSTRUMENT	REFERENCE
IMPLANT HOLDER	ELL-IN 01 04-N
SETSCREW HOLDER	TLF-IN 05 10-N
SETSCREW HOLDER DOUBLE	TLF-IN 05 50-N

SURGICAL TECHNIQUE

_STEP 7

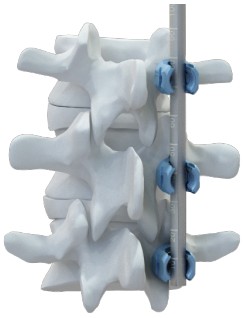


SCREW HEAD ADJUSTMENT

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

INSTRUMENT	REFERENCE
HEAD ALIGNER	TLF-IN 08 00-N

_STEP 8



ROD SELECTION

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

INSTRUMENT	REFERENCE
ROD TEMPLATE L250	TLF-IN 10 25-N

_STEP 9

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 Titatinum 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.

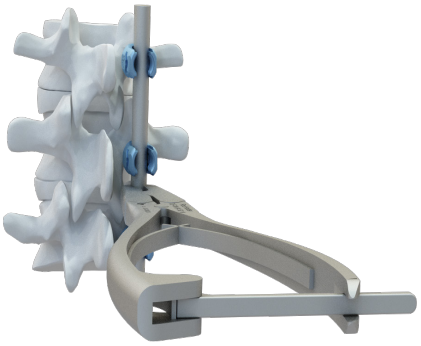
⚠ **WARNING:** Once bent, rods should not be de-contoured.

⚠ **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 10



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	ELL-IN 01 04-N
ROD HOLDER	TLF-IN 04 50-N

_STEP 11

ROD REDUCTION / SETSCREW INSERTION

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.

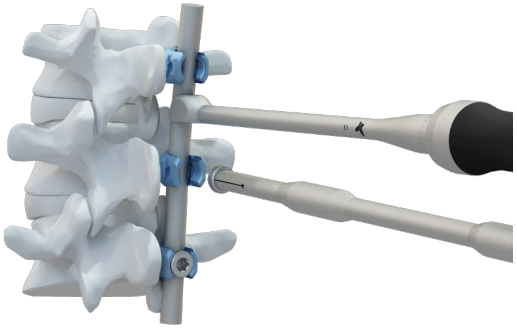
Start inserting the setscrews from the caudal part of the construct. The setscrews should not be firmly locked at this stage, to allow movement of the rod in the screw heads.

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

_STEP 11-A

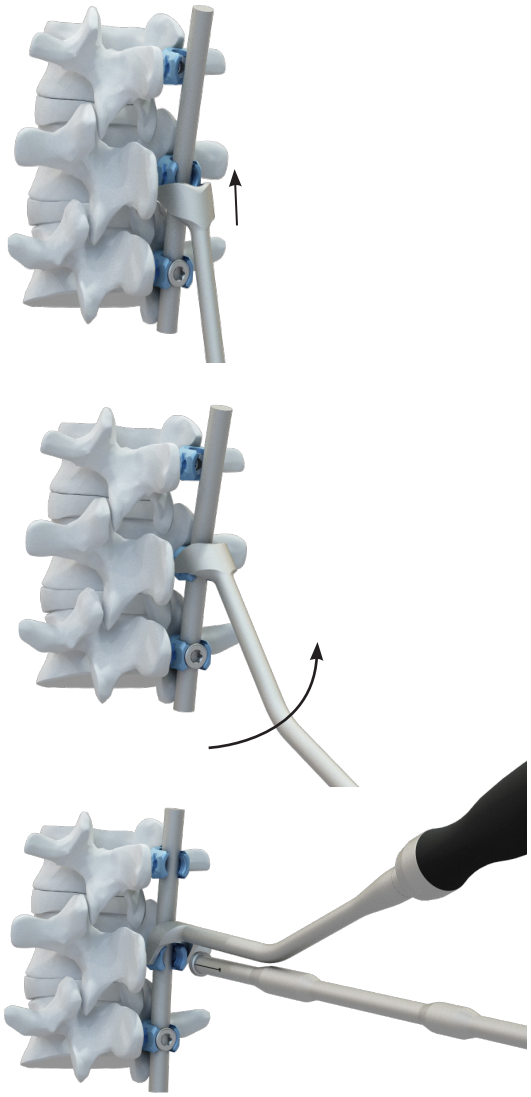


ROD REDUCTION - ROD PUSHER

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 11-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.

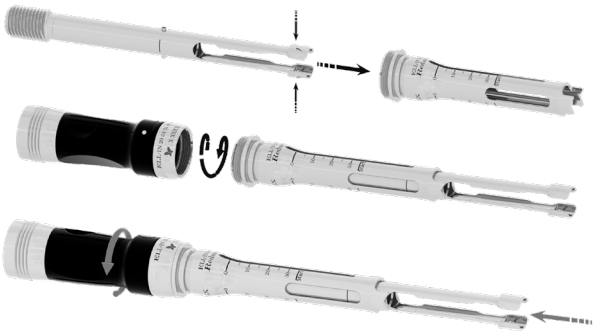
Insert the setscrew with the **Setscrew Holder**.

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 11-C

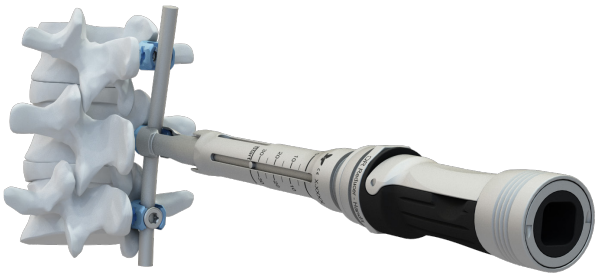


ROD REDUCTION - QR REDUCER

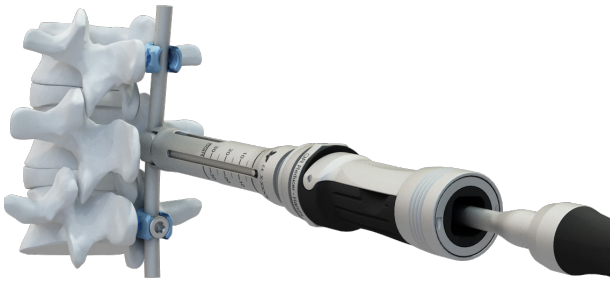
Insert the **Inner Tube** into the **Outer Tube**. The extremity of the **Inner Tube** has to be slightly squeezed to ease the insertion.

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**.



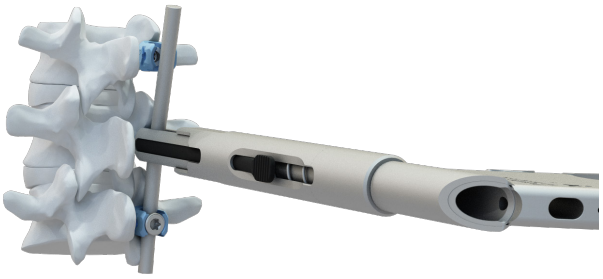
Connect the instrument to the screw head then persuade the rod into it by turning the **Handle**. If additional force is required to seat the rod, you can use the **QR Reducer T-Handle** by sliding it onto the top of the **QR Reducer** to finish the reduction.

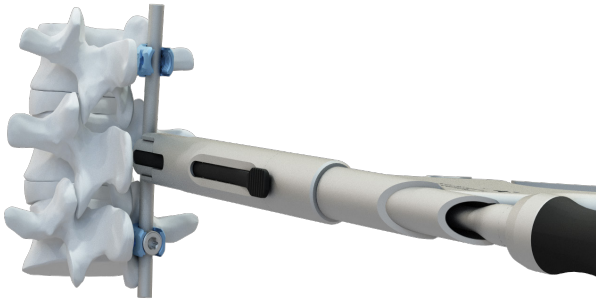


Then use the **Setscrew Holder** to insert the setscrew through the **QR Reducer** into the screw head.

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

_STEP 11-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 11-E

ROD REDUCTION - SETSCREW TUBE

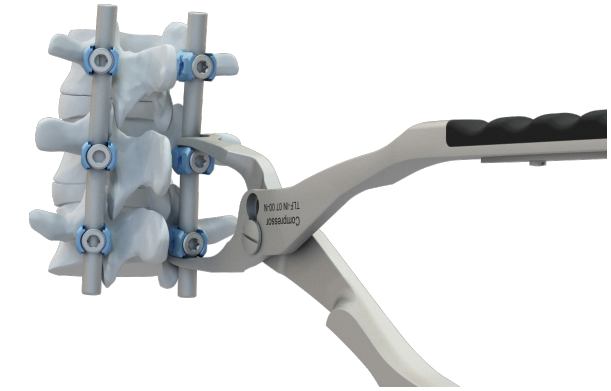
Place the **Setscrew Tube** on the top of the screw. Push down to reduce the rod into the screw head.

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 12

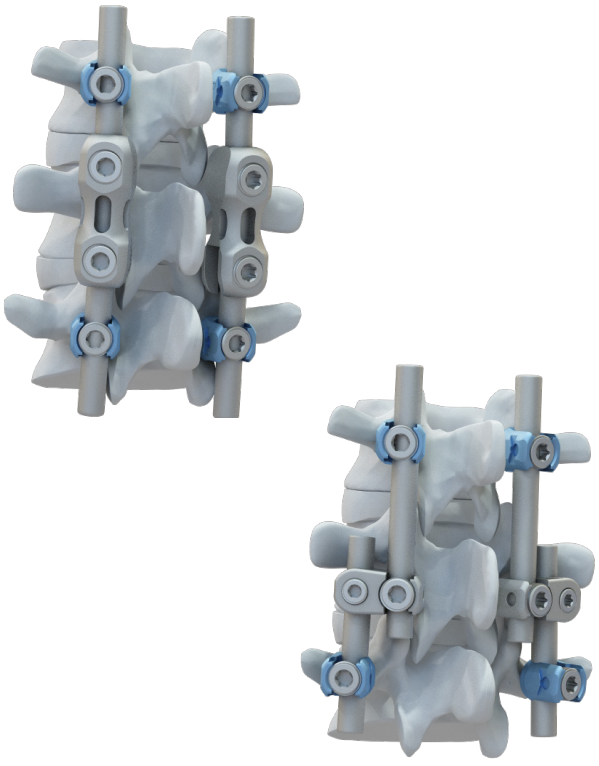


COMPRESSION AND DISTRACTION

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

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

_STEP 13 (OPTIONAL)



ROD CONNECTOR

Use the **Implant Holder** to place the appropriate parallel or axial Rod Connector.

INSTRUMENT	REFERENCE
IMPLANT HOLDER	ELL-IN 01 04-N

_STEP 14

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.

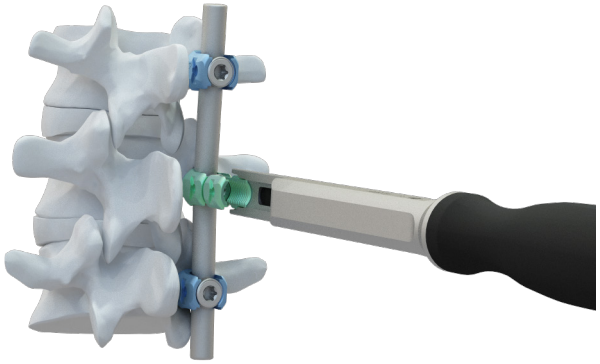
⚠ **WARNING:** The T25 screwdriver shaft must not be used with setscrews. For pedicle screws only.

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

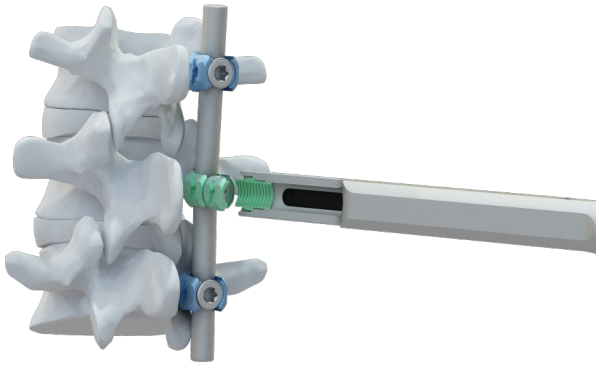
INSTRUMENT	REFERENCE
FINAL TIGHTENER	TLF-IN 05 40-N
COUNTER TORQUE	TLF-IN 05 30-N

_STEP 15

REDUCTION SCREW AND TAB BREAKING

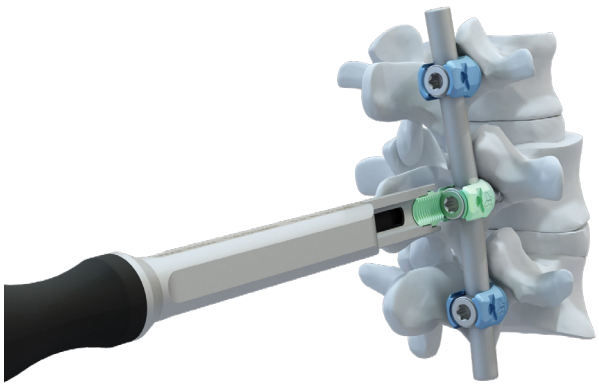


For Reduction Screws, after the Final Tightening, break the tabs with the **Hook Holder/Tab Breaker**.



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.



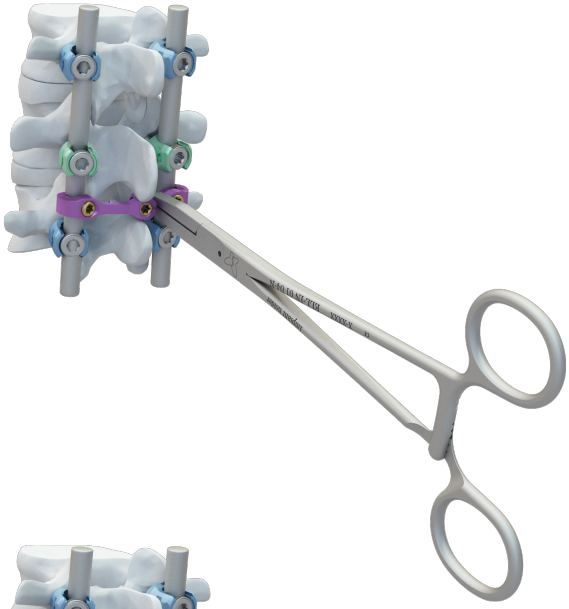
Repeat the same steps with the second tab of the Reduction Screw.

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

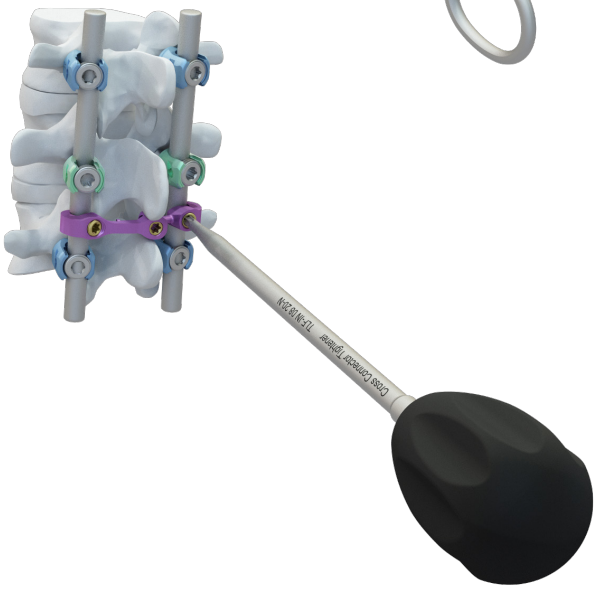
_STEP 16

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.

GENERAL INFORMATION

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.

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

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 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.

SPINEART

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