



ROMEO[®] 2
THORACOLUMBAR FIXATION

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GENERAL INFORMATION

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.

ROMEО®2 posterior fixation system incorporates smart technologies and simplified instrumentation.

The first system offering a complete range of spinal implants delivered sterile with an intuitive and compact instrumentation.

Spineart is innovating with an expanded platform to address complex spinal cases.

ROMEО®2 is a complete posterior fixation system that offers alternative solutions to the surgeons and their patients.

Among others, the ROMEО®2 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.

The combination of the ROMEО®2 25D screw with the powerful QR Reducer allows multi-segmental vertebral derotation and 'en bloc' apical derotation maneuvers.



AT A GLANCE

Streamlined Tip
Polyaxial Head
Low Profile Implants
Compact Set

INDICATIONS

ROME0[®]2 system implants are designed to treat those dorsal 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

LENGTH / DIAMETER	Ø4	Ø5	Ø6	Ø7	Ø8
L25	ELL-PS 04 25-S	ELL-PS 05 25-S	ELL-PS 06 25-S		
L30	ELL-PS 04 30-S	ELL-PS 05 30-S	ELL-PS 06 30-S	ELL-PS 07 30-S	ELL-PS 08 30-S
L35	ELL-PS 04 35-S	ELL-PS 05 35-S	ELL-PS 06 35-S	ELL-PS 07 35-S	ELL-PS 08 35-S
L40	ELL-PS 04 40-S	ELL-PS 05 40-S	ELL-PS 06 40-S	ELL-PS 07 40-S	ELL-PS 08 40-S
L45	ELL-PS 04 45-S	ELL-PS 05 45-S	ELL-PS 06 45-S	ELL-PS 07 45-S	ELL-PS 08 45-S
L50		ELL-PS 05 50-S	ELL-PS 06 50-S	ELL-PS 07 50-S	ELL-PS 08 50-S
L55		ELL-PS 05 55-S	ELL-PS 06 55-S	ELL-PS 07 55-S	ELL-PS 08 55-S
L60			ELL-PS 06 60-S	ELL-PS 07 60-S	ELL-PS 08 60-S
L70			ELL-PS 06 70-S	ELL-PS 07 70-S	ELL-PS 08 70-S
L80			ELL-PS 06 80-S	ELL-PS 07 80-S	ELL-PS 08 80-S
L90			ELL-PS 06 90-S	ELL-PS 07 90-S	ELL-PS 08 90-S
L100				ELL-PS 07 10-S	ELL-PS 08 10-S
L110				ELL-PS 07 11-S	ELL-PS 08 11-S
L120				ELL-PS 07 12-S	ELL-PS 08 12-S



REDUCTION SCREWS

LENGTH / DIAMETER	Ø4	Ø5	Ø6	Ø7	Ø8
L25	ELL-SS 04 25-S	ELL-SS 05 25-S	ELL-SS 06 25-S		
L30	ELL-SS 04 30-S	ELL-SS 05 30-S	ELL-SS 06 30-S	ELL-SS 07 30-S	ELL-SS 08 30-S
L35	ELL-SS 04 35-S	ELL-SS 05 35-S	ELL-SS 06 35-S	ELL-SS 07 35-S	ELL-SS 08 35-S
L40	ELL-SS 04 40-S	ELL-SS 05 40-S	ELL-SS 06 40-S	ELL-SS 07 40-S	ELL-SS 08 40-S
L45	ELL-SS 04 45-S	ELL-SS 05 45-S	ELL-SS 06 45-S	ELL-SS 07 45-S	ELL-SS 08 45-S
L50		ELL-SS 05 50-S	ELL-SS 06 50-S	ELL-SS 07 50-S	ELL-SS 08 50-S
L55		ELL-SS 05 55-S	ELL-SS 06 55-S	ELL-SS 07 55-S	ELL-SS 08 55-S
L60			ELL-SS 06 60-S	ELL-SS 07 60-S	ELL-SS 08 60-S
L70				ELL-SS 07 70-S	ELL-SS 08 70-S
L80				ELL-SS 07 80-S	ELL-SS 08 80-S
L90				ELL-SS 07 90-S	ELL-SS 08 90-S



IMPLANTS

25D SCREWS

LENGTH / DIAMETER	Ø4	Ø5	Ø6	Ø7
L25	ELL-DS 04 25-S			
L30	ELL-DS 04 30-S	ELL-DS 05 30-S	ELL-DS 06 30-S	ELL-DS 07 30-S
L35	ELL-DS 04 35-S	ELL-DS 05 35-S	ELL-DS 06 35-S	ELL-DS 07 35-S
L40	ELL-DS 04 40-S	ELL-DS 05 40-S	ELL-DS 06 40-S	ELL-DS 07 40-S
L45	ELL-DS 04 45-S	ELL-DS 05 45-S	ELL-DS 06 45-S	ELL-DS 07 45-S
L50		ELL-DS 05 50-S	ELL-DS 06 50-S	ELL-DS 07 50-S
L55			ELL-DS 06 55-S	ELL-DS 07 55-S
L60			ELL-DS 06 60-S	ELL-DS 07 60-S



MONOAXIAL SCREWS

LENGTH / DIAMETER	Ø4	Ø5	Ø6	Ø7	Ø8
L25	ELL-MS 04 25-S				
L30	ELL-MS 04 30-S	ELL-MS 05 30-S	ELL-MS 06 30-S	ELL-MS 07 30-S	ELL-MS 08 30-S
L35	ELL-MS 04 35-S	ELL-MS 05 35-S	ELL-MS 06 35-S	ELL-MS 07 35-S	ELL-MS 08 35-S
L40	ELL-MS 04 40-S	ELL-MS 05 40-S	ELL-MS 06 40-S	ELL-MS 07 40-S	ELL-MS 08 40-S
L45	ELL-MS 04 45-S	ELL-MS 05 45-S	ELL-MS 06 45-S	ELL-MS 07 45-S	ELL-MS 08 45-S
L50		ELL-MS 05 50-S	ELL-MS 06 50-S	ELL-MS 07 50-S	ELL-MS 08 50-S
L55			ELL-MS 06 55-S	ELL-MS 07 55-S	ELL-MS 08 55-S
L60			ELL-MS 06 60-S	ELL-MS 07 60-S	ELL-MS 08 60-S
L70			ELL-MS 06 70-S	ELL-MS 07 70-S	ELL-MS 08 70-S
L80			ELL-MS 06 80-S	ELL-MS 07 80-S	ELL-MS 08 80-S



IMPLANTS

ROD CONNECTOR
PARALLEL

ELL-RC PA 00-S



ROD CONNECTOR
AXIAL

ELL-RC AX 00-S



ILIAC CONNECTORS

L15	ELL-IC 00 15-S
L20	ELL-IC 00 20-S
L30	ELL-IC 00 30-S
L40	ELL-IC 00 40-S
L50	ELL-IC 00 50-S
L60	ELL-IC 00 60-S



ROD CONNECTOR
PARALLEL OPEN

ELL-RC PA 01-S



ILIAC T CONNECTOR

ELL-RC TE 00-S



OPEN ILIAC CONNECTORS

L15	ELL-IC 01 15-S
L20	ELL-IC 01 20-S
L30	ELL-IC 01 30-S
L40	ELL-IC 01 40-S
L50	ELL-IC 01 50-S
L60	ELL-IC 01 60-S



SET SCREW

ELL-SC 00 00-S



SET SCREW HEXALOBE *

ELL-SC 01 00-S



* The hexalobe set screw **must be used** with the following instruments:
 ELL-IN 07 06-N / SET SCREW TIGHTENER
 ELL-IN 08 06-N / FINAL TIGHTENER (11Nm HEXALOBE)

IMPLANTS

CROSS CONNECTORS /MULTIAXIAL	
L30 TO L31	ELL-CC-MU 30-S
L31 TO L33	ELL-CC-MU 31-S
L33 TO L36	ELL-CC MU 33-S
L36 TO L43	ELL-CC MU 36-S
L43 TO L55	ELL-CC MU 43-S
L55 TO L80	ELL-CC MU 55-S



TRANSVERSE ROD CONNECTORS	
L20	ELL-TR 00 20-S
L30	ELL-TR 00 30-S
L40	ELL-TR 00 40-S
L50	ELL-TR 00 50-S
L60	ELL-TR 00 60-S
L70	ELL-TR 00 70-S
L80	ELL-TR 00 80-S



CROSS CONNECTORS / MULTIAXIAL PREBENT	
L33 to L36	ELL-CC MP 33-S
L36 to L43	ELL-CC MP 36-S
L43 to L55	ELL-CC MP 43-S
L55 to L80	ELL-CC MP 55-S



CROSS CONNECTORS TRANSVERSE HOOKS	
	ELL-TC 00 00-S



CROSS CONNECTORS / STRAIGHT	
L18	ELL-CC ST 18-S
L21	ELL-CC ST 21-S
L24	ELL-CC ST 24-S
L27	ELL-CC ST 27-S
L30	ELL-CC ST 30-S



I M P L A N T S

RODS STRAIGHT HEX TIP Ø5.4MM		
LENGTH	TITANIUM ALLOY	COBALT CHROMIUM
L100	ELL-RD 21 00-S	ELL-RD 11 00-S
L120	ELL-RD 21 20-S	ELL-RD 11 20-S
L140	ELL-RD 21 40-S	ELL-RD 11 40-S
L160	ELL-RD 21 60-S	ELL-RD 11 60-S
L180	ELL-RD 21 80-S	ELL-RD 11 80-S
L200	ELL-RD 22 00-S	ELL-RD 12 00-S
L220	ELL-RD 22 20-S	ELL-RD 12 20-S
L240	ELL-RD 22 40-S	ELL-RD 12 40-S
L350	ELL-RD 23 50-S	ELL-RD 13 50-S
L500	ELL-RD 25 00-S	ELL-RD 15 00-S
L550	ELL-RD 25 50-S	ELL-RD 15 50-S











RODS PRE-BENT Ø5.4MM TITANIUM ALLOY	
L30	ELL-RD 00 30-S
L35	ELL-RD 00 35-S
L40	ELL-RD 00 40-S
L45	ELL-RD 00 45-S
L50	ELL-RD 00 50-S
L55	ELL-RD 00 55-S
L60	ELL-RD 00 60-S
L70	ELL-RD 00 70-S
L80	ELL-RD 00 80-S
L90	ELL-RD 00 90-S
L100	ELL-RD 01 00-S
L110	ELL-RD 01 10-S
L120	ELL-RD 01 20-S
L130	ELL-RD 01 30-S



J-RODS Ø5.4MM COBALT CHROME		
L500	40°	ELL-R4 15 00-S
	60°	ELL-R6 15 00-S
L550	40°	ELL-R4 15 50-S
	60°	ELL-R6 15 50-S
	80°	ELL-R8 15 50-S



IMPLANTS

LAMINAR LUMBAR SMALL	ELL-HO LL 0S-S	LAMINAR LUMBAR LARGE	ELL-HO LL 0L-S
			
LAMINAR LUMBAR EXTENDED	ELL-HO LL-EX-S	PEDICULAR	ELL-HO P0 00-S
			
LAMINAR THORACIC SUPRA	ELL-HO LT SU-S	LAMINAR INFRA	ELL-HO LT IN-S
			
ANGLED LEFT	ELL-HO AN 0L-S	OFFSET LEFT	ELL-HO OF 0L-S
ANGLED RIGHT	ELL-HO AN 0R-S	OFFSET RIGHT	ELL-HO OF 0R-S
			

Implants can be delivered Non Sterile (ELL-xx xx xx-**N**) on demand.

TECHNICAL FEATURES

COMPLETE TL FIXATION PLATFORM



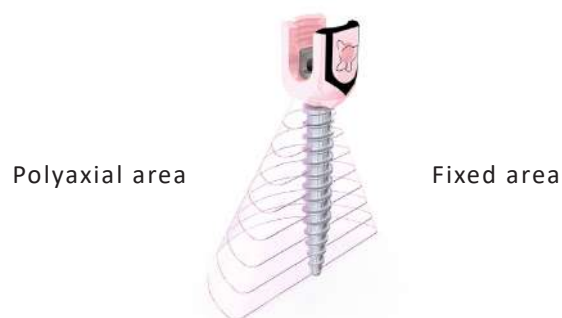
Complete range of polyaxial, semi-polyaxial, monoaxial, reduction screws, transverse connectors and rod connectors provide versatile options to treat numerous pathologies from T1 to the ilium.

STREAMLINED SCREW TIP & LOW PROFILE IMPLANTS



The screw tip is designed to allow an effortless and self-centering insertion of the screw. The low profile ROMEO®2 implants are designed to enable an atraumatic implantation and minimize anatomical interference.

DEFORMITY SCREW



The ROMEO®2 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.

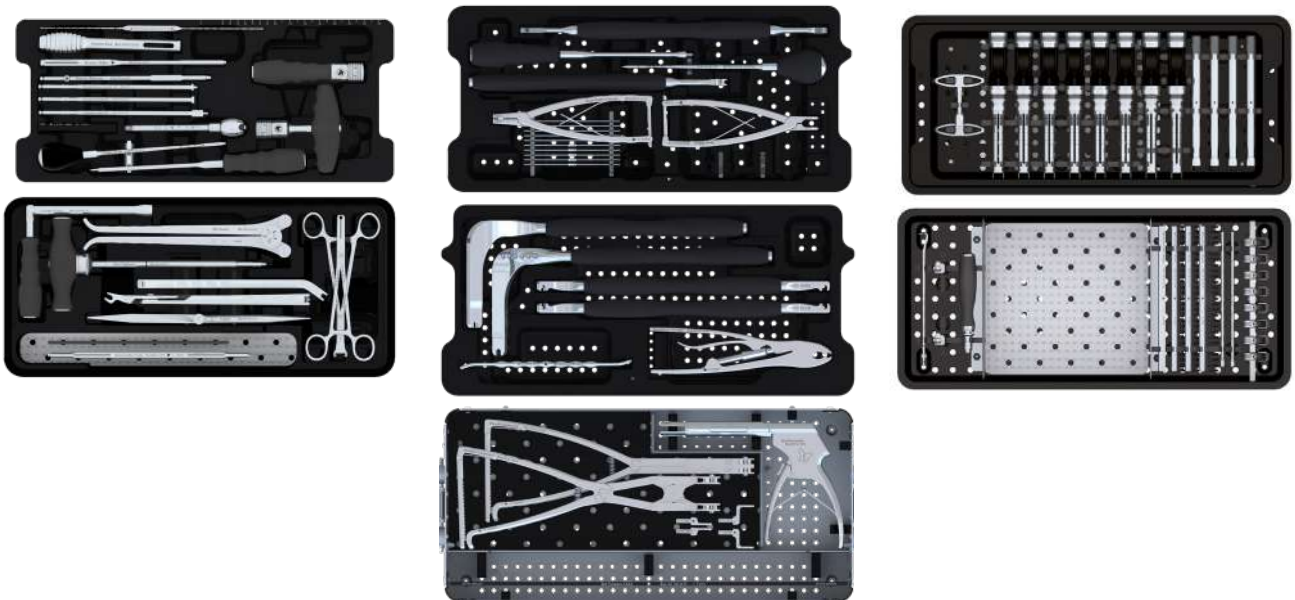
TECHNICAL FEATURES

HOOKS



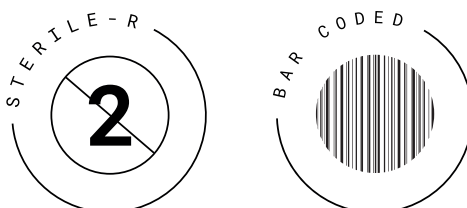
A full range of hooks with various sizes is available with ROMEO®2. Their autostatic teeth enhance their stability once impacted

COMPLETE SETS



One box of specific and intuitive instruments is needed for degenerative cases. A second box of instruments is available for more complex surgeries requesting longer construct. A third one is dedicated to derotation manoeuvre for deformity cases.

SAFETY



ROMEO®2 implants are sterile packaged and barcoded ensuring sterility and traceability.

INSTRUMENT SET

DEGENERATIVE KIT

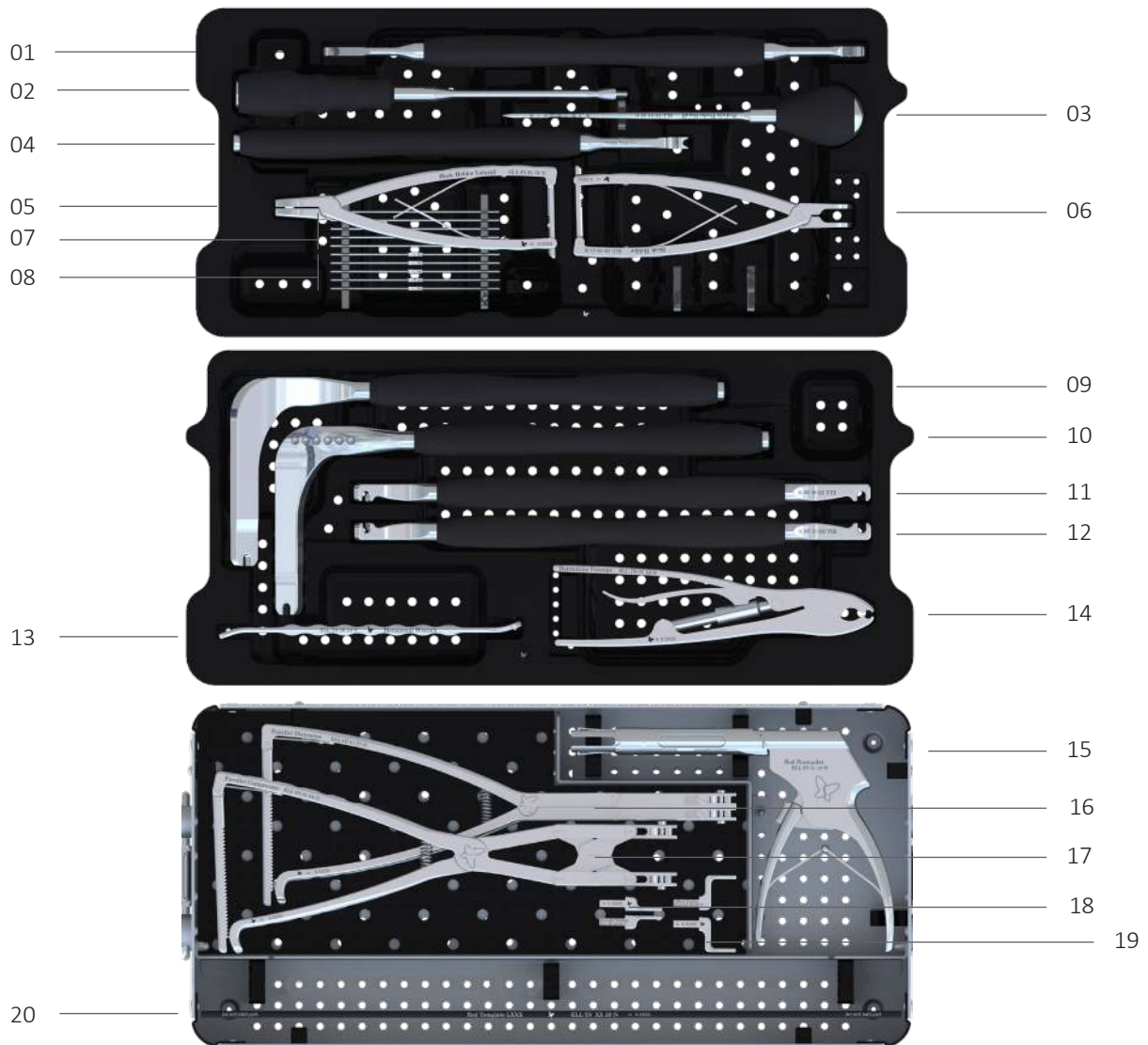


#	DESCRIPTION	REFERENCE
01	PEDICLE SOUNDER	ELL-IN 01 02-N
02	SET SCREW TUBE	ELL-IN 01 15-N
03	SET SCREW HOLDER W	ELL-IN 03 10-N
04	SET SCREW TIGHTENER	ELL-IN 04 06-N
05	SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
06	SCREWDRIVER SHAFT MS	ELL-IN 01 20-N
07	SCREWDRIVER SHAFT SS	ELL-IN 01 16-N
08	SCREWDRIVER SLEEVE	ELL-IN 20 03-N
09	SCREWDRIVER TUBE	ELL-IN 21 03-N
10	PEDICLE PROBE	ELL-IN 02 22-N
11	BONE AWL	ELL-IN 02 01-N
12	STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N
13	T-HANDLE RATCHET	HAN-SI RA TE-N

#	DESCRIPTION	REFERENCE
14	COUNTER TORQUE	ELL-IN 03 11-N
15	ROD BENDER	ELL-IN 00 09-N
16	FINAL TIGHTENER (11Nm - HEXAGONAL)	ELL-IN 05 06-N
17	DISTRACTION FORCEPS	ELL-IN 00 07-N
18	COMPRESSION FORCEPS	ELL-IN 00 08-N
19	CALIPER	ELL-IN 00 12-N
20	IMPLANT HOLDER	ELL-IN 01 04-N
21	ROCKER	ELL-IN 00 05-N
22	ROD TEMPLATE L250	ELL-IN 00 28-N
• 23	SET SCREW HOLDER DOUBLE	ELL-IN 02 10-N
	INSTRUMENTS CONTAINER	ROM-BX 10 01-N

INSTRUMENT SET

LONG CONSTRUCT KIT



ROMEO®2 - THORACOLUMBAR FIXATION

#	DESCRIPTION	REFERENCE
01	LAMINA PREPARER	ELL-IN 00 30-N
02	HOOK PUSHER	ELL-IN 00 32-N
03	PEDICLE PROBE SMALL	ELL-IN 02 23-N
04	PEDICLE PREPARER	ELL-IN 00 29-N
05	HOOK HOLDER LATERAL	ELL-IN 01 31-N
06	HOOK HOLDER	ELL-IN 00 31-N
07	MARKER LEFT	ELL-IN 00 25-N
08	MARKER RIGHT	ELL-IN 00 24-N
09	CORONAL BENDER LEFT	ELL-IN 00 27-N
10	CORONAL BENDER RIGHT	ELL-IN 01 27-N

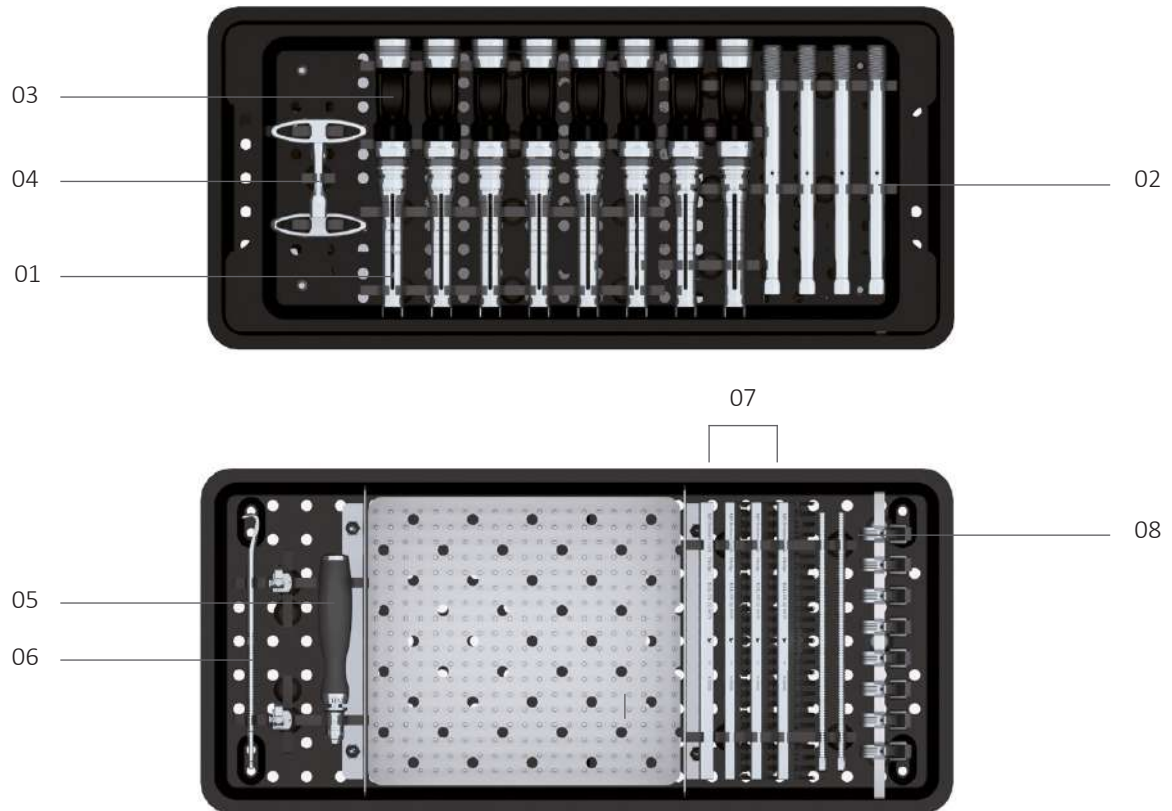
#	DESCRIPTION	REFERENCE
11	SAGITTAL BENDER LEFT	ELL-IN 00 26-N
12	SAGITTAL BENDER RIGHT	ELL-IN 01 26-N
13	HEXAGONAL WRENCH	ELL-IN 00 33-N
14	DEROTATION FORCEPS	ELL-IN 01 18-N
15	ROD PERSUADER	ELL-IN 01 19-N
• 16	PARALLEL DISTRACTOR	ELL-IN 01 07-N
• 17	PARALLEL COMPRESSOR	ELL-IN 01 08-N
• 18	STRAIGHT ENDTIP	ELL-IN 02 08-N
• 19	OFFSET ENDTIP	ELL-IN 03 08-N
20	ROD TEMPLATE L500	ELL-IN 01 28-N

	INSTRUMENTS CONTAINER LC	ROM-BX 40 01-N
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• : OPTIONAL

INSTRUMENT SET

QR LINK KIT



#	DESCRIPTION	REFERENCE
01	QR REDUCER - OUTER TUBE	ELL-IN 31 34-N
02	QR REDUCER - INNER TUBE	ELL-IN 32 34-N
03	QR REDUCER - HANDLE	ELL-IN 33 34-N
04	QR REDUCER T-HANDLE	HAN-SS TY 14-N
05	AO HANDLE	HAN-SI AO 08-N
06	RIBAC	ELL-IN 23 34-N
07	QR REDUCER LINK BRIDGE	ELL-IN 22 34-N
08	QR REDUCER LINK	ELL-IN 21 34-N
	QR LINK INSTRUMENT BOX	ROM-BX 41 01-N

INSTRUMENTS

PREPARATION

BONE AWL ELL-IN 02 01-N



PEDICLE PROBE ELL-IN 02 22-N



PEDICLE SOUNDER ELL-IN 01 02-N



PEDICLE PROBE SMALL ELL-IN 02 23-N



MARKER LEFT ELL-IN 00 25-N



MARKER RIGHT ELL-IN 00 24-N



PREPARATION - OPTION

CURETTE ELL-IN 00 13-N



TAP ϕ (4 - 4.5 - 5.5 - 6.5 - 7.5) ELL-IN XX 30-N



PEDICLE PROBE STRAIGHT ELL-IN 02 24-N



PEDICLE PROBE LENKE CURVED ELL-IN 02 25-N



PEDICLE PROBE LENKE STRAIGHT ELL-IN 02 26-N



INSTRUMENTS

SCREW INSERTION

SCREWDRIVER SHAFT PS

ELL-IN 05 03-N



SCREWDRIVER SLEEVE

ELL-IN 20 03-N



SCREWDRIVER SHAFT SS

ELL-IN 01 16-N



SCREWDRIVER TUBE

ELL-IN 21 03-N



SCREWDRIVER SHAFT MS

ELL-IN 01 20-N



HANDLE

T HANDLE RATCHET

HAN-SI RA TE-N



STRAIGHT HANDLE RATCHET

HAN-SI RA ST-N



HANDLE - OPTION

T HANDLE

HAN-SI MD TE-N



MODULAR STRAIGHT HANDLE

HAN-SI MD ST-N



INSTRUMENTS

HOOK PREPARATION AND INSERTION

LAMINA PREPARER

ELL-IN 00 30-N



PEDICLE PREPARER

ELL-IN 00 29-N



HOOK PUSHER

ELL-IN 00 32-N



HOOK HOLDER

ELL-IN 00 31-N



HOOK HOLDER LATERAL

ELL-IN 01 31-N



HOOK PREPARATION AND INSERTION - OPTION

J-HOOK

ELL-IN 00 40-N



INSTRUMENTS

ROD SELECTION AND PREPARATION

ROD TEMPLATE L250

ELL-IN 00 28-N



ROD TEMPLATE L500

ELL-IN 01 28-N



ROD BENDER

ELL-IN 00 09-N



CALIPER

ELL-IN 00 12-N



HEXAGONAL WRENCH

ELL-IN 00 33-N



DEROTATION FORCEPS

ELL-IN 01 18-N



IMPLANT HOLDER

ELL-IN 01 04-N



INSTRUMENTS

SET SCREW INSERTION

SET SCREW HOLDER W

ELL-IN 03 10-N



SET SCREW TUBE

ELL-IN 01 15-N



SET SCREW TIGHTENER

ELL-IN 04 06-N



SET SCREW INSERTION - OPTION

SET SCREW HOLDER DOUBLE

ELL-IN 02 10-N



SET SCREW HOLDER

ELL-IN 01 10-N



INSTRUMENTS

ROD PERSUASION

ROD PERSUADER

ELL-IN 01 19-N



ROCKER

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



ROD PERSUASION - OPTION

ROD PUSHER

ELL-IN 00 39-N



INSTRUMENTS

REDUCTION MANEUVERS

COMPRESSION FORCEPS ELL-IN 00 08-N



DISTRACTION FORCEPS ELL-IN 00 07-N



CORONAL BENDER LEFT ELL-IN 00 27-N



CORONAL BENDER RIGHT ELL-IN 01 27-N



SAGITTAL BENDER LEFT ELL-IN 00 26-N



SAGITTAL BENDER RIGHT ELL-IN 01 26-N



REDUCTION MANEUVERS - OPTION

PARALLEL COMPRESSOR ELL-IN 01 08-N

STRAIGHT ENDTIP ELL-IN 02 08-N

OFFSET ENDTIP ELL-IN 03 08-N



PARALLEL DISTRACTOR ELL-IN 01 07-N

STRAIGHT ENDTIP ELL-IN 02 08-N

OFFSET ENDTIP ELL-IN 03 08-N



INSTRUMENTS

QR LINK INSTRUMENTS

QR REDUCER LINK

ELL-IN 21 34-N



QR REDUCER LINK BRIDGE

ELL-IN 22 34-N



RIBAC*

ELL-IN 23 34-N



AO HANDLE

HAN-SI AO 08-N



TRANSVERSE CONNECTION

3.5 TIGHTENER

ELL-IN 00 36-N



CALIPER

ELL-IN 00 35-N



FINAL TIGHTENING

FINAL TIGHTENER - TORQUE LIMITER

ELL-IN 05 06-N



COUNTER TORQUE - TIGHT FIT

ELL-IN 03 11-N **



FINAL TIGHTENING - OPTION

COUNTER TORQUE

ELL-IN 02 11-N ***



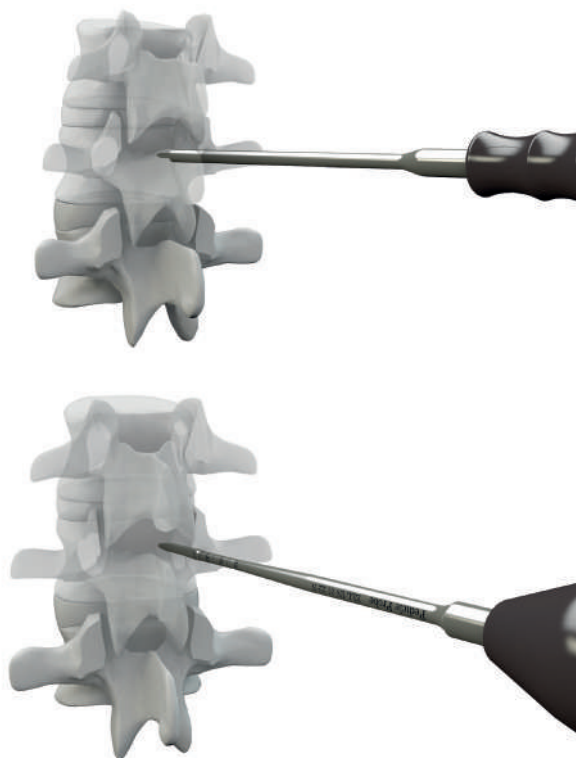
* RiB Attachment

** Not compatible with extended tabs of reduction screws.
Break the tabs or use the optional counter torque version (see p.24)

*** Compatible with extended tabs of reduction screw.

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.

NOTE: When implanting a $\varnothing 4\text{mm}$ Screw, it is mandatory to use the **Pedicle Probe Small**. For $\varnothing 5$, $\varnothing 6$, $\varnothing 7$ and $\varnothing 8\text{mm}$ use the **Pedicle Probe**.

INSTRUMENT	REFERENCE
BONE AWL	ELL-IN 02 01-N
PEDICLE PROBE	ELL-IN 02 22-N
PEDICLE PROBE SMALL	ELL-IN 02 23-N

_STEP 2



PEDICLE SOUNDING

Insert the **Pedicle Sounder** to verify integrity of the screw path. **Markers** can be used to check proper path orientation under x-ray.

INSTRUMENT	REFERENCE
PEDICLE SOUNDER	ELL-IN 01 02-N
MARKER LEFT	ELL-IN 00 25-N
MARKER RIGHT	ELL-IN 00 24-N

SURGICAL TECHNIQUE

_STEP 3 (OPTION)



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.

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

INSTRUMENT	REFERENCE
TAP Ø4 (FOR SCREW Ø4 ONLY)	ELL-IN 40 30-N
TAP Ø4.5MM	ELL-IN 45 30-N
TAP Ø5.5MM	ELL-IN 55 30-N
TAP Ø6.5MM	ELL-IN 65 30-N
TAP Ø7.5MM	ELL-IN 75 30-N

_STEP 4



SCREW SELECTION

ROMEО®2 offers a full range of screws to better adapt to the surgical needs:

1. **Polyaxial screw**, with a 50° conical range of motion. The polyaxial screw works with the **Screwdriver shaft PS**.
2. **Reduction screw**, also called spondylo screw. With a 50° conical range of motion, it allows for a 15mm reduction capacity. The spondylo screw works with the **Screwdriver shaft SS**.
3. **Monoaxial screw** is monobloc. The **Monoaxial screw** works with the **Screwdriver shaft MS**.
4. **25D deformity screw** with a semi-polyaxiality has a controlled side and a polyaxial side. This screw is designed to give control of the apical vertebrae derotation while keeping easy rod introduction. The **25D screw** works with the **Screwdriver shaft PS**.

INSTRUMENT	REFERENCE
SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
SCREWDRIVER SHAFT MS	ELL-IN 01 20-N
SCREWDRIVER SHAFT SS	ELL-IN 01 16-N

SURGICAL TECHNIQUE

_STEP 5



SCREWDRIVER ASSEMBLY

01. Locate the end of the **Screwdriver Sleeve** marked «UP». Pass the **Screwdriver Tube** through this end and secure with a «click».
02. Slide the **Screwdriver Shaft PS** (polyaxial screws), **MS** (monoaxial screws) or **SS** (reduction screws) into the distal end of the **Screwdriver Tube** and secure with a «click».
03. Connect the assembly to a Straight Handle or a T-Handle.

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

INSTRUMENT	REFERENCE
SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
SCREWDRIVER SHAFT MS	ELL-IN 01 20-N
SCREWDRIVER SHAFT SS	ELL-IN 01 16-N
SCREWDRIVER TUBE	ELL-IN 21 03-N
SCREWDRIVER SLEEVE	ELL-IN 20 03-N
STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N
T-HANDLE RATCHET	HAN-SI RA TE-N

_STEP 6



SCREW INSERTION

Insert the tip of the screwdriver assembly into the screw hex 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.

Note: The **25D screws** can selectively be implanted in the vertebrae that need to be directly derotated. As shown, thoracic vertebrae 7 to 9 are instrumented with **25D screws**, i.e. targeted apical vertebrae that will need coronal and axial corrections.

SURGICAL TECHNIQUE

_STEP 6 (OPTION)



SCREW INSERTION – ILIAC FIXATION

After performing small 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 **Pedicle Probe**.

INSTRUMENT	REFERENCE
BONE AWL	ELL-IN 02 01-N
PEDICLE PROBE	ELL-IN 02 22-N



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

Once the screw is implanted, an iliac connector will help to align with the rod. Take the iliac connector with the **Implant Holder**, place it inside the screw head. Secure it with a **Set screw** introduced with the **Set Screw Holder W**.

If an iliac 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
SET SCREW HOLDER W	ELL-IN 03 10-N
FINAL TIGHTENER (11Nm - HEXAGONAL)	ELL-IN 05 06-N
COUNTER TORQUE	ELL-IN 03 11-N

SURGICAL TECHNIQUE

_STEP 7



HOOK INSERTION – PEDICULAR HOOK

Locate the vertebra where the pedicular hook will be implanted. Partially remove the lower part of the upper vertebra facet joint. Use the **Pedicle Preparer** to adapt the pedicular hook site, until a correct stability is achieved.

Attach the selected pedicular hook to the **Hook Holder**.

Using both **Hook Holder** and **Hook Pusher**, impact the pedicular hook in place. A slight hammering on the **Hook Pusher** will gently impact the hook into the pedicle.

INSTRUMENT	REFERENCE
HOOK PUSHER	ELL-IN 00 32-N
PEDICLE PREPARER	ELL-IN 00 29-N
HOOK HOLDER	ELL-IN 00 31-N

_STEP 7 - BIS



HOOK INSERTION – LAMINAR HOOK

Locate the vertebra where the laminar hook will be implanted.

Use the **Lamina Preparer** to adapt the lamina hook site, until a correct stability is achieved.

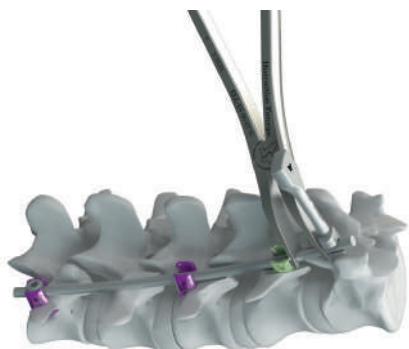
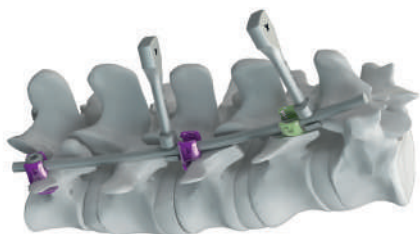
Attach the selected laminar hook to the **Hook Holder**.

Using both **Hook Holder** and **Hook Pusher**, impact the hook in place.

INSTRUMENT	REFERENCE
HOOK PUSHER	ELL-IN 00 32-N
LAMINA PREPARER	ELL-IN 00 30-N
HOOK HOLDER	ELL-IN 00 31-N

SURGICAL TECHNIQUE

HOOK OPTIONAL INSTRUMENTS 1

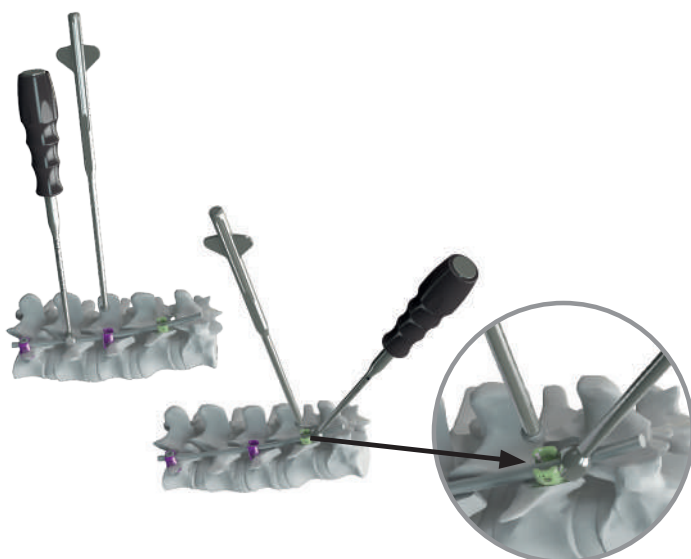


The **J-Hooks** can be placed and tightened with only one hand on the $\varnothing 5.4\text{mm}$ rod in order to keep the hook in position and prevent back-out of the hook during in-situ maneuvers as rotation or bending maneuvers.

The **J-Hook** can also be positioned and tightened on the rod and act as a fixed point for compression or distraction maneuvers.

INSTRUMENT	REFERENCE
J-HOOK	ELL-IN 00 40-N

HOOK OPTIONAL INSTRUMENTS 2



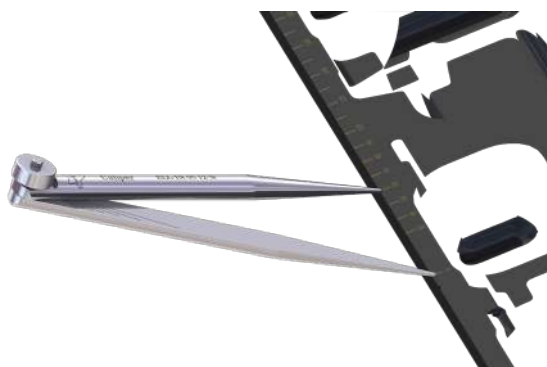
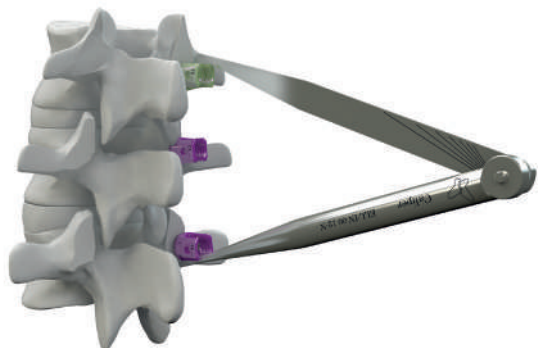
The **Rod Pusher** is a bi-functional instrument due to its specific design and provides intuitive and simple solution during hook surgeries. It can be simply use to push down the rod towards the implant head and ease the insertion of the set screw.

This instrument can also play the role of a hook pusher when the rod has already been added to the construct.

INSTRUMENT	REFERENCE
ROD PUSHER	ELL-IN 00 39-N

SURGICAL TECHNIQUE

_STEP 8



ROD SELECTION & CONTOURING

Alternatively choose the appropriate length of the rod using the **Caliper** (confirm the exact length with the measuring scale on the instrument tray) or the **Rod Template**.

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

NOTE: ROMEO®2 rods are $\varnothing 5.4\text{mm}$. To contour a Titanium rod, the radius selector of the **Bender** can be positioned on 5, 6, 7 or 8. When a cobalt chromium rod needs to be contoured, we recommend positioning the radius selector of the **Bender** on 7 or 8.

NOTE 2: Once bent, rods should not be de-contoured. Repeated bending can weaken the rod.

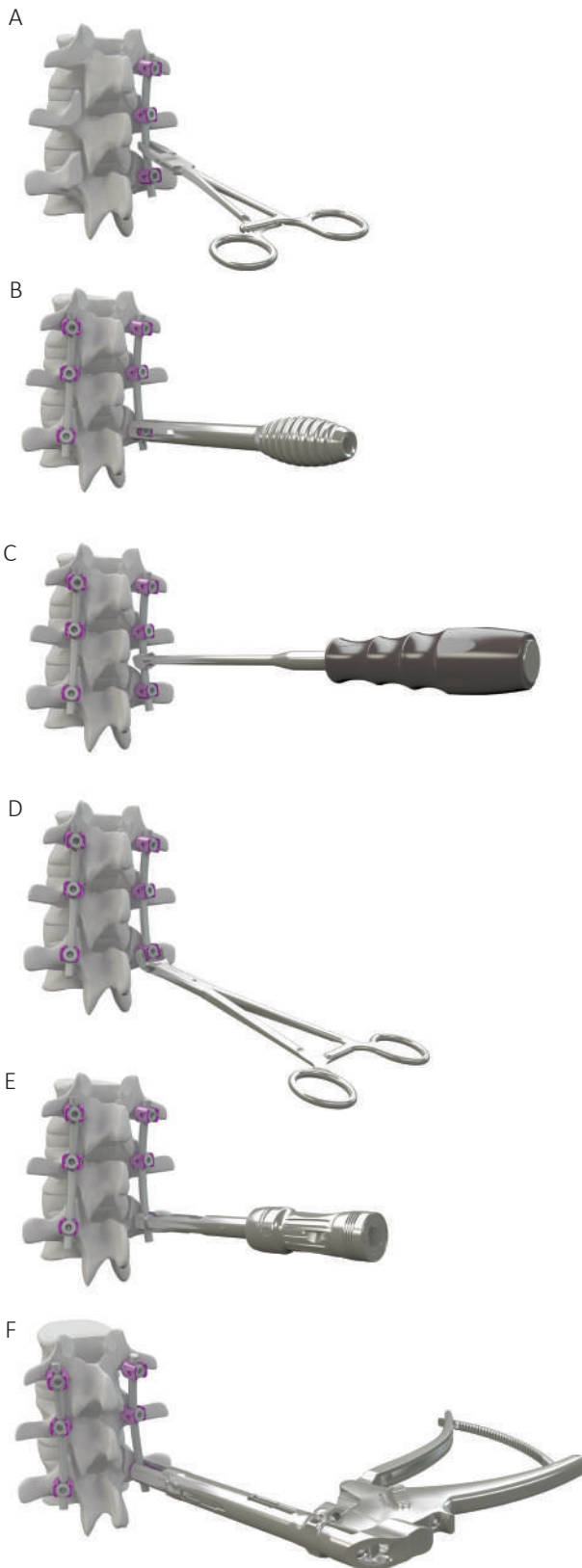
INSTRUMENT	REFERENCE
CALIPER	ELL-IN 00 12-N
ROD TEMPLATE L250	ELL-IN 00 28-N
ROD TEMPLATE L500	ELL-IN 01 28-N
ROD BENDER	ELL-IN 00 09-N

SURGICAL TECHNIQUE

_STEP 9

ROD PLACEMENT- DEGENERATIVE CASE

Attach the selected rod to the **Implant Holder** and place into screw heads. Multiple instrument options are available for rod reduction (see table). The use of one of these instruments is **MANDATORY**.



INSTRUMENT	REFERENCE
A. IMPLANT HOLDER	ELL-IN 01 04-N
B. SET SCREW TUBE	ELL-IN 01 15-N
C. ROD PUSHER	ELL-IN 00 39-N
D. ROCKER	ELL-IN 00 05-N
E. QR REDUCER (OPTIONAL)	
OUTER TUBE	ELL-IN 31 34-N
INNER TUBE	ELL-IN 32 34-N
HANDLE	ELL-IN 33 34-N
F. PERSUADER	ELL-IN 01 19-N

SURGICAL TECHNIQUE

_STEP 9 (BIS)



ROD PLACEMENT - DEFORMITY CASE

According to the surgeon's philosophy, different approaches can be considered for rod placement prior to derotation:

- One rod only in the concavity of the curve.
- One rod only in the convexity of the curve.
- Two rods at the same time.

This surgical technique describes the approach based on one rod placed in the concavity. Start at the lower levels of the construct.

Implant holder and/or **Derotation Forceps** can be used for rod insertion.

NOTE: Spineart provides rods with different mechanical properties: Titanium and Cobalt Chromium rods, both in Ø5.4mm. Cobalt Chromium rods present a stiffness value that is twice that of the Titanium rods.

When used, Cobalt Chromium rods reduce the loss of correction after derotation of the scoliotic spine.

INSTRUMENT	REFERENCE
IMPLANT HOLDER	ELL-IN 01 04-N
DEROTATION FORCEPS	ELL-IN 01 18-N

_STEP 10



25D SCREWHEAD POSITIONNING

Before proceeding with rod placement in the upper levels, the 25D screw head orientation must be checked.

The **LASER mark** must be positioned medially for screws located on the concave side and laterally for screws located on the convex side.

SURGICAL TECHNIQUE

_STEP 11



HOOK SECURING

If hooks have been used, **J-Hooks** could be placed on the rod to keep the hooks in place during the reduction maneuvers.

For hook placement when the rod is already in place, follow the same procedure as described in chapter 7 while using the **Hook Holder Lateral** instead of the **Hook Holder**.

INSTRUMENT	REFERENCE
J-HOOK	ELL-IN 00 40-N
HOOK HOLDER LATERAL	ELL-IN 01 31-N

_STEP 12



SET SCREW INSERTION

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

Align the tip of the **Set screw Holder** with the recess of the set screw and firmly attach.

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

INSTRUMENT	REFERENCE
SET SCREW HOLDER W	ELL-IN 03 10-N
SET SCREW HOLDER (OPTION)	ELL-IN 01 10-N
SET SCREW HOLDER DOUBLE (OPTION)	ELL-IN 02 10-N
SET SCREW TUBE	ELL-IN 01 15-N

SURGICAL TECHNIQUE

_STEP 13

CHOICE OF THE REDUCTION TECHNIQUE

ROMEIO®2 thoracolumbar fixation system offers multiple options for the reduction technique.

- Distraction / Compression
- Rod derotation
- In situ contouring
- Direct vertebral derotation (DVR)
- Bilateral apical vertebral derotation (BAVD)
- 'En bloc' derotation

The surgical technique describes the Distraction/Compression and the 'En bloc' derotation technique.

_STEP 14

COMPRESSION AND DISTRACTION

If necessary at this surgical step, **Derotation Forceps** and **Sagittal and Coronal Benders** (available in the LC kit) can also be used for the rod contouring.

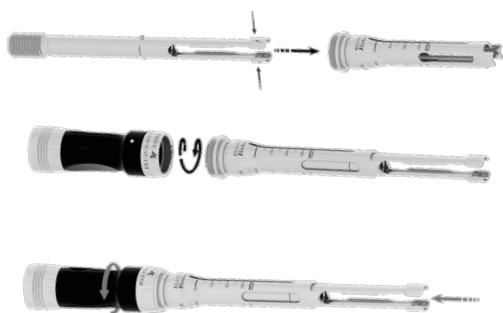
Compression or distraction may be performed by using the **Compression** or the **Distraction Forceps**.



INSTRUMENT	REFERENCE
SAGITTAL BENDER RIGHT	ELL-IN 01 26-N
SAGITTAL BENDER LEFT	ELL-IN 00 26-N
CORONAL BENDER RIGHT	ELL-IN 01 27-N
CORONAL BENDER LEFT	ELL-IN 00 27-N
DEROTATION FORCEPS	ELL-IN 01 18-N
COMPRESSION FORCEPS	ELL-IN 00 08-N
DISTRACTION FORCEPS	ELL-IN 00 07-N

S U R G I C A L T E C H N I Q U E

_STEP 15



QR REDUCER ASSEMBLY

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**.

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



Slide the ring onto the **QR Reducer** until it clicks when reaching its position.

The picture shows the correct position of the ring. When connected to the **QR Reducer**, the **QR Link** ring is free to rotate.

If at any time you need to disassemble the ring, unlock it by pushing on the button. Keeping the pressure on the button will allow to slide and disengage it from the **QR Reducer**.

INSTRUMENT	REFERENCE
QR REDUCER LINK	ELL-IN 21 34-N

SURGICAL TECHNIQUE

_STEP 16



ROD PERSUASION

Persuade the rod into the implant head by turning the handle part of the **QR Reducer** or the **QR Reducer T-Handle**. Sequential manipulation of the **QR Reducer** can be performed for multilevel rod persuasion.

In case of particular anatomy configuration, the **QR Reducer T-Handle** can be used. The rod must be loose enough to allow its rotation in the next steps.

If the rod is not fully seated, you can use the **QR Reducer T-Handle** to push the rod in the screw head.

When the rod is in the screw head, one of the **Set screw Holder** could be used to insert it through the **QR Reducer** into the screw head.

Repeat this step for all the screws that will be part of the apical cluster.

INSTRUMENT	REFERENCE
QR REDUCER T-HANDLE	HAN-SS TY 14-N
SET SCREW HOLDER W	ELL-IN 03 10-N
SET SCREW HOLDER (OPTION)	ELL-IN 01 10-N
SET SCREW HOLDER DOUBLE (OPTION)	ELL-IN 02 10-N

SURGICAL TECHNIQUE

_STEP 17

CREATE APICAL CLUSTER

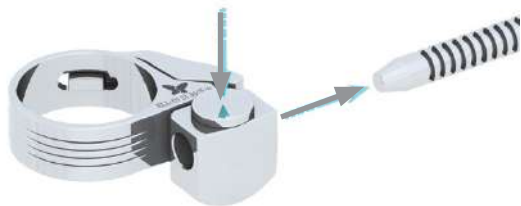
Position the **QR Reducer** on the screws. At least one rod should be introduced, but still free to move within the screw head. Start creating the apical cluster.

The first step will link the **QR Reducers** in the axial plane.

From the concave side and for the two **QR Reducer** of the same vertebra, introduce the **QR Link Stick** through the **QR Link Ring** of the concave **QR Reducer** then convex **QR Reducer**.

To ease **QR Link Stick** introduction, press on the button. When the button is released, the **QR Link Stick** will be locked along its axis.

Repeat this step for all vertebrae part of the apical cluster.



INSTRUMENT	REFERENCE
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QR REDUCER LINK	ELL-IN 21 34-N
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SURGICAL TECHNIQUE

_STEP 18



CONNECT THE QR REDUCERS

The second step will link the **QR Reducer** on the sagittal plane. Take a **QR Link Bridge** and attach it to the **QR Link Stick**.

As the deformity convex side has a larger distance between the pedicle, it is preferable to place the **QR Link Bridge** on that side. Due to the vertebrae kinematics, the distraction of the posterior elements of the spine will induce restoration of the thoracic kyphosis.

Two **QR Link Bridges** are available in the box, it could be used to add some stability of the cluster.

INSTRUMENT	REFERENCE
QR REDUCER LINK BRIDGE	ELL-IN 22 34-N

SURGICAL TECHNIQUE

_STEP 19

ROD DEROTATION

The rod is axially rotated at 90° to restore the sagittal plane balance.

Attach two **Derotation Forceps** to the rod and/or one **Hexagonal Wrench** on the hexagonal endtip of the rod.

Derotate the rod to have its curvature moving from the frontal plane to the sagittal plane.

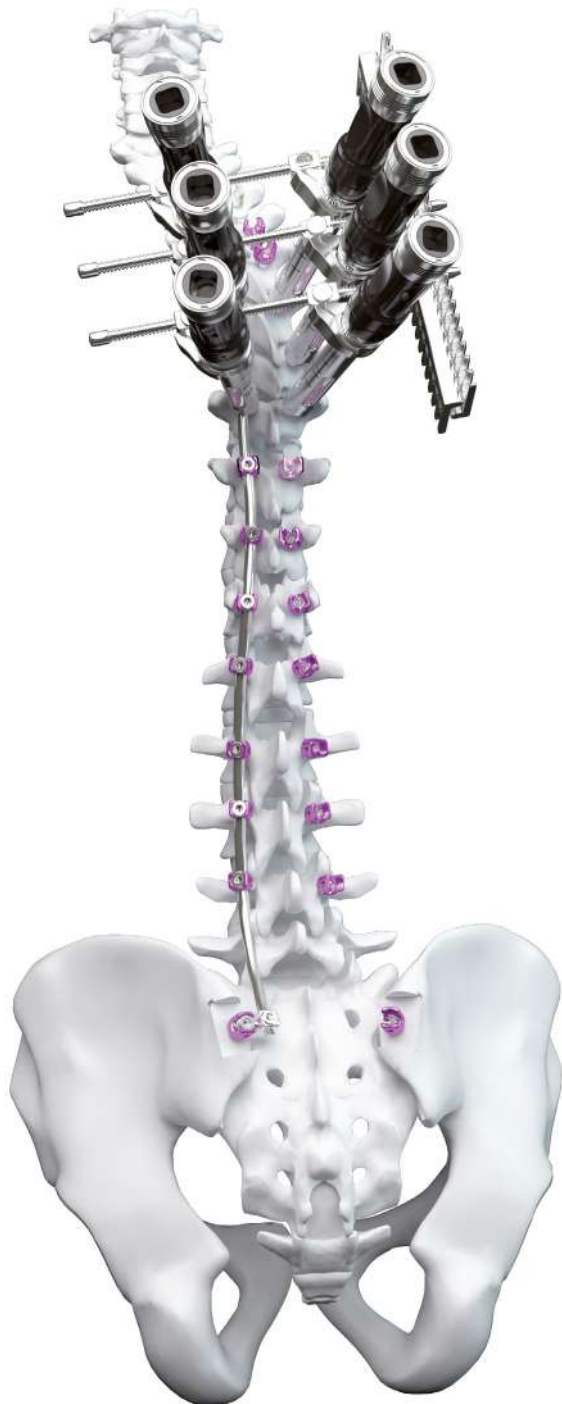
NOTE: Make sure to have all the set screws slightly loose before performing any rod derotation maneuvers.



INSTRUMENT	REFERENCE
DEROTATION FORCEPS	ELL-IN 01 18-N
HEXAGONAL WRENCH	ELL-IN 00 33-N

SURGICAL TECHNIQUE

_STEP 20



ROD DEROTATION

Once the derotation of the rod is complete, firmly tighten the set screws of the most proximal screw.

Tightening is achieved with the **Set screw tightener** attached to the **T-handle Ratchet Handle**.

Remove the **Derotation Forceps / Hexagonal Wrench**.

<u>INSTRUMENT</u>	<u>REFERENCE</u>
SET SCREW TIGHTENER	ELL-IN 04 06-N
T-HANDLE RATCHET	HAN-SI RA TE-N

SURGICAL TECHNIQUE

_STEP 21



VERTEBRAL DEROTATION

Further correction can be achieved via 'En bloc' derotation.

The vertebral derotation maneuver is performed by applying a cantilever force on the cluster created by linking the **QR Reducers**.

The maneuver's force will be shared among the **QR Reducer** of the cluster. Then transmitted from the **QR Reducer** to the **25D screws** to make the vertebrae rotate. A **Derotation Forceps** or **Hexagonal Wrench** should be used to make a counter-force against the cluster rotation.

Under intraoperative neurophysiological monitoring, continue derotation until desired position is reached.

Tighten the set screws of the construct. Insert the second rod following the steps 8 to 11.

INSTRUMENT	REFERENCE
SET SCREW TIGHTENER	ELL-IN 04 06-N
T-HANDLE RATCHET	HAN-SI RA TE-N

SURGICAL TECHNIQUE

_STEP 22



CROSS CONNECTOR SYSTEM 1

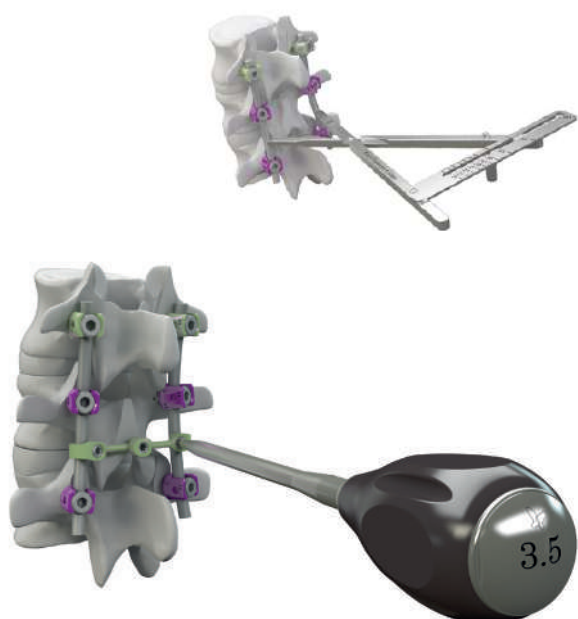
For long construct, it is recommended to add transverse connectors to increase the rotational stability of the construct. Hold the transverse hooks with the **Implant Holder** and place them onto the rod. The length of the transverse rod is measured by using the **Caliper**.

NOTE: For the transverse rod selection, 10mm should be added to the length measured by the caliper.

Hold the transverse rod with the **Implant Holder** to place it into the transverse hooks. Tighten the set screw of the transverse hooks with the **Screwdriver shaft PS**.

INSTRUMENT	REFERENCE
IMPLANT HOLDER	ELL-IN 01 04-N
CALIPER	ELL-IN 00 12-N
SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N

_STEP 23



CROSS CONNECTOR SYSTEM 2

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

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

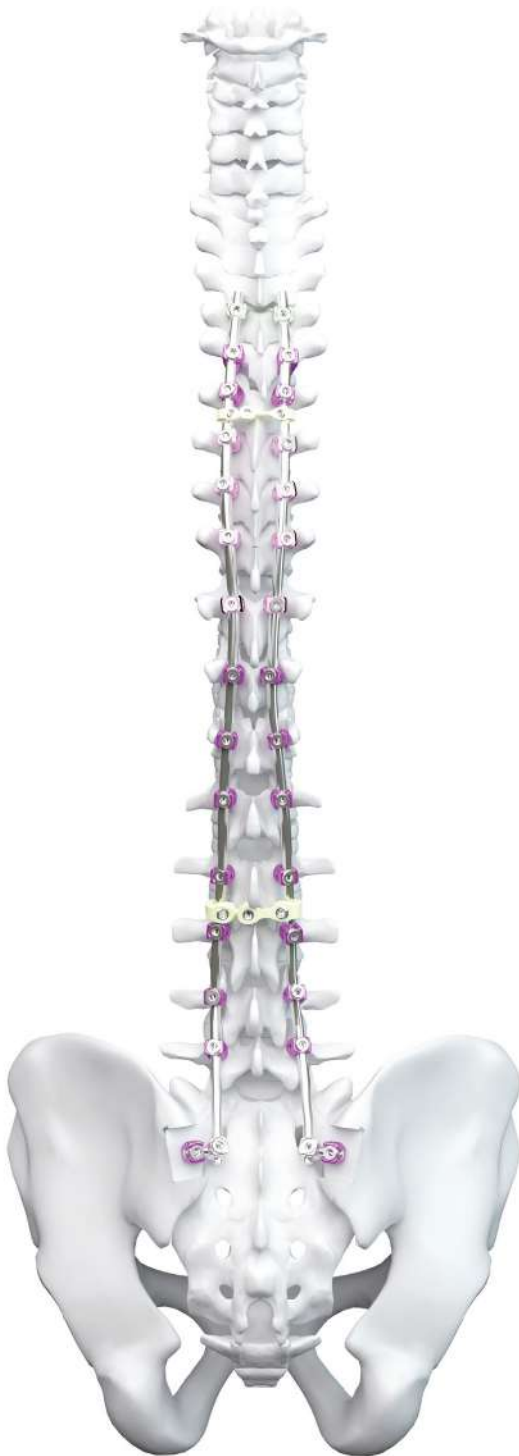
Once the cross connector is positioned, use the **3.5 Tightener** to final tighten.

NOTE: For the cross connector option, the 2 instruments listed in the table below need to be additionally ordered.

INSTRUMENT	REFERENCE
IMPLANT HOLDER	ELL-IN 01 04-N
CALIPER	ELL-IN 00 35-N
3.5 TIGHTENER	ELL-IN 00 36-N

SURGICAL TECHNIQUE

_STEP 24



FINE-TUNING

Remove the **QR Link Bridge**, the **QR Link** and the **QR Reducers**. At this step a long cassette X-ray will help to understand the frontal correction and shoulder balance. If needed, fine-tune the correction by performing compression, distraction and/or in situ bending.

INSTRUMENT	REFERENCE
CORONAL BENDER LEFT	ELL-IN 00 27-N
CORONAL BENDER RIGHT	ELL-IN 01 27-N
SAGITTAL BENDER LEFT	ELL-IN 00 26-N
SAGITTAL BENDER RIGHT	ELL-IN 01 26-N
COMPRESSION FORCEPS	ELL-IN 00 08-N
DISTRACTION FORCEPS	ELL-IN 00 07-N
PARALLEL COMPRESSOR (OPTIONAL)	ELL-IN 01 08-N
PARALLEL DISTRACTOR (OPTIONAL)	ELL-IN 01 07-N
STRAIGHT ENDTIP (OPTIONAL)	ELL-IN 02 08-N
OFFSET ENDTIP (OPTIONAL)	ELL-IN 03 08-N

SURGICAL TECHNIQUE

_STEP 25



FINAL TIGHTENING

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

NOTE : Confirm 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».

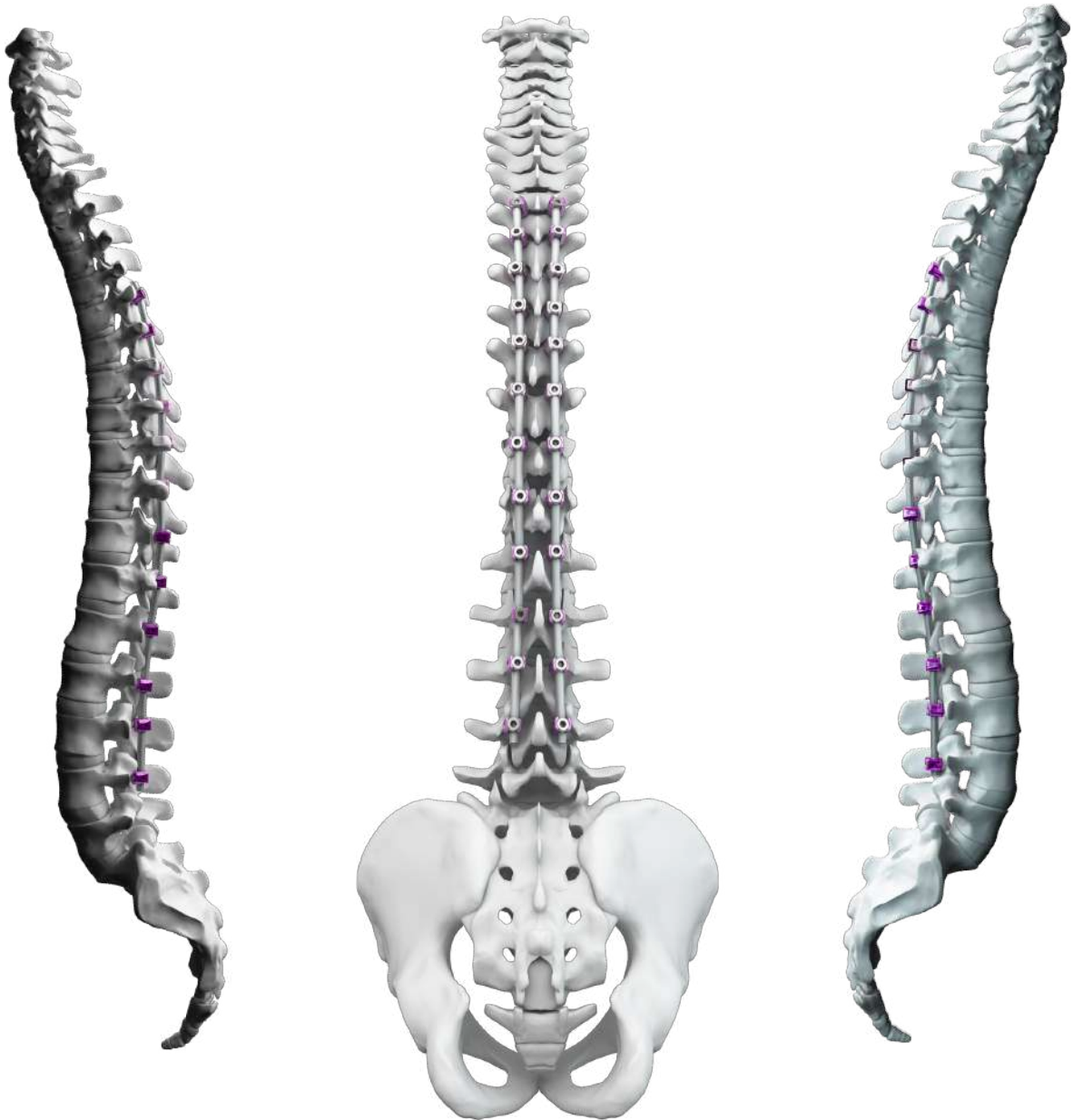
Before closing, proceed to the final tightening of each screw, hook and connector of the construct.

NOTE: For final tightening of reduction screw with extended tabs, use the optional **Counter Torque** with enlarged extremity or break the tabs and use the standard **Counter Torque**.

INSTRUMENT	REFERENCE
FINAL TIGHTENER (11Nm - HEXAGONAL)	ELL-IN 05 06-N
COUNTER TORQUE	ELL-IN 03 11-N
COUNTER TORQUE (ENLARGED EXTREMITY)	ELL-IN 02 11-N

SURGICAL TECHNIQUE

_FINAL CONSTRUCT





ROMEО®2 deformity screws 25D

Innovative implants.



Dear collaboration partner,

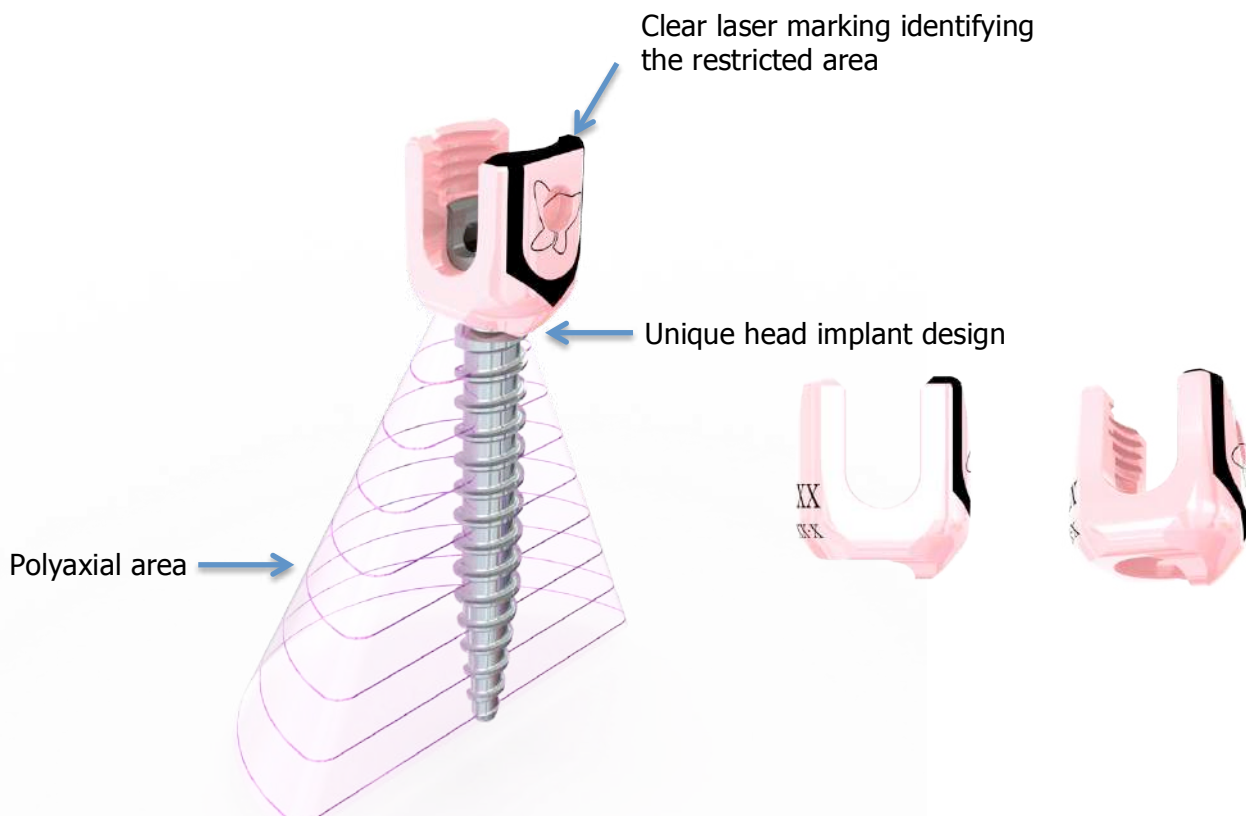
Spineart® is pleased to inform you of the development of the 25D screws, extending the range of ROMEО®2 screws and opening on surgical solutions for the treatment of spinal deformities.

The 25D screws are deformity-oriented screws sharing the same “streamlined tip” and “low profile” features as the currently available ROMEО®2 screws.

New feature: SEMI POLYAXIALITY.

The 25D Deformity screws have a specific design offering a semi polyaxial movement. While the polyaxial area eases rod insertion, the locked direction helps manage derotation maneuvers.

A unique design that combines the comfort of polyaxiality and the precision of monoaxiality.





PRODUCT MANAGEMENT INFORMATION

ROMEО[®] 2 | No. 01/2013-E

The insertion of the screw is achieved using the ROMEО[®] 2 screwdriver assembled with the screwdriver shaft PS (ELL-IN 01 03-N).

With the use of reducers (ELL-IN 00 34-N) or reducers QR (ELL-IN 10 34-N) surgeons can proceed to derotation maneuvers of the spine.






PRODUCT MANAGEMENT INFORMATION

ROMEO[®] 2 | No. 01/2013-E

Implants available

	Reference	Ø in mm	Length in mm
	ELL-DS 04 25-S	4	25
	ELL-DS 04 30-S	4	30
	ELL-DS 04 35-S	4	35
	ELL-DS 04 40-S	4	40
	ELL-DS 04 45-S	4	45
	ELL-DS 05 30-S	5	30
	ELL-DS 05 35-S	5	35
	ELL-DS 05 40-S	5	40
	ELL-DS 05 45-S	5	45
	ELL-DS 05 50-S	5	50
	ELL-DS 06 30-S	6	30
	ELL-DS 06 35-S	6	35
	ELL-DS 06 40-S	6	40
	ELL-DS 06 45-S	6	45
	ELL-DS 06 50-S	6	50
	ELL-DS 06 55-S	6	55
	ELL-DS 06 60-S	6	60
	ELL-DS 06 70-S	6	70
	ELL-DS 06 80-S	6	80
	ELL-DS 06 90-S	6	90
	ELL-DS 07 30-S	7	30
	ELL-DS 07 35-S	7	35
	ELL-DS 07 40-S	7	40
	ELL-DS 07 45-S	7	45
ELL-DS 07 50-S	7	50	
ELL-DS 07 55-S	7	55	
ELL-DS 07 60-S	7	60	
ELL-DS 07 70-S	7	70	
ELL-DS 07 80-S	7	80	
ELL-DS 07 90-S	7	90	

The 25D screws are delivered **sterile** and **single packed** (including setscrew).

For any further request please do not hesitate to contact me,

Best regards,

OLIVIER PAPUGA
Product Manager
SPINEART[®]





ROME[®] 2_{MIS} trauma screws 25T

Innovative implants.



Dear collaboration partner,

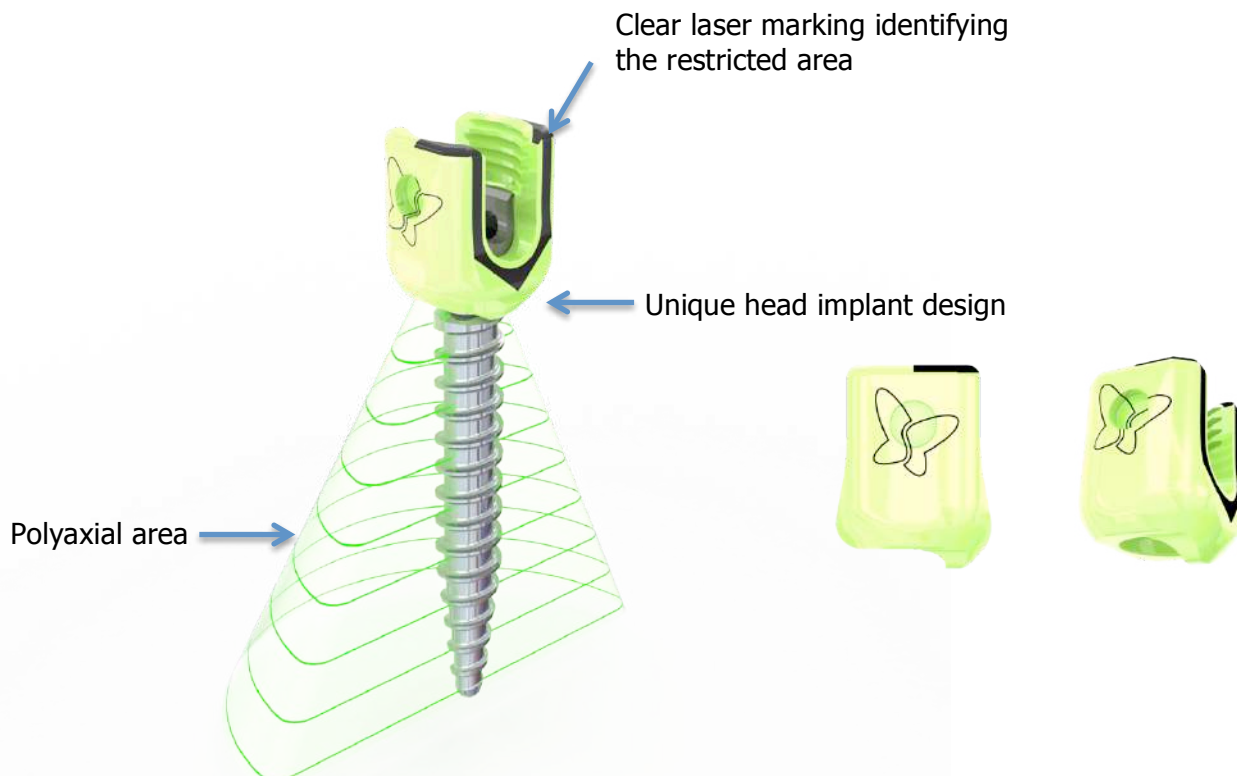
Spineart[®] is pleased to inform you of the development of the 25T screws, extending the range of ROME[®] 2_{MIS} screws and providing an innovative alternative for the treatment of spinal trauma cases during minimally invasive surgeries.

The 25T screws are trauma-oriented cannulated screws and present "streamlined tip" and "low profile" features as the currently available ROME[®] 2_{MIS} screws.

New feature: SEMI POLYAXIALITY.

The 25T Trauma screws have a specific design offering a semi polyaxial movement. While the polyaxial area eases rod insertion, the locked direction helps manage fracture reduction.

A unique design that combines the comfort of polyaxiality and the precision of monoaxiality.





PRODUCT MANAGEMENT INFORMATION


ROMEO[®] 2_{MIS} | No. 01/2013-E

The insertion of the screw is achieved using the ROMEO[®] 2_{MIS} screwdriver assembled with the screwdriver shaft PS cannulated (MIS-IN 33 01-N). It is **mandatory** to associate the clipping tube (MIS-IN 17 01-N) when using the 25T trauma screws, by matching the "2 windows" side of the clipping tube with the LASER marking on the head of the 25T screw.





Implants available

	Reference	Ø in mm	Length in mm
	MIS-TS 05 30-S	5	30
MIS-TS 05 35-S	5	35	
MIS-TS 05 40-S	5	40	
MIS-TS 05 45-S	5	45	
MIS-TS 05 50-S	5	50	
MIS-TS 06 30-S	6	30	
MIS-TS 06 35-S	6	35	
MIS-TS 06 40-S	6	40	
MIS-TS 06 45-S	6	45	
MIS-TS 06 50-S	6	50	
MIS-TS 06 55-S	6	55	
MIS-TS 06 60-S	6	60	
MIS-TS 07 30-S	7	30	
MIS-TS 07 35-S	7	35	
MIS-TS 07 40-S	7	40	
MIS-TS 07 45-S	7	45	
MIS-TS 07 50-S	7	50	
MIS-TS 07 55-S	7	55	
MIS-TS 07 60-S	7	60	

The 25T screws are delivered **sterile** and **packed by two** (including setscrews).

For any further request please do not hesitate to contact me,

Best regards,

OLIVIER PAPUGA
Product Manager
SPINEART[®]



SCARLET® AL-T
SECURED LUMBAR ANTERIOR CAGE

C O N T E N T

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GENERAL INFORMATION

C O N C E P T A N D D E S I G N

Building on the success and experience acquired with our Posterior Lumbar Titanium range, Spineart developed a new Titanium secured lumbar anterior cage, featuring the Ti-LIFE Technology, a state-of-the-art porous, interconnected structure replicating the trabecular bone geometry.

With each product development, Spineart is relentlessly driven by the same philosophy: Quality, Innovation and Simplicity.



AT A GLANCE

Ti-LIFE Technology
Integrated Screw Channel
High Performance Screw
One Step Cam Lock

INDICATIONS

The SCARLET® AL-T system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one isolated level from L5-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level. These spinal implants are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Used with the integrated fixation by the mean of the bone screws provided, the SCARLET® AL-T is a stand-alone system and requires no additional supplemental fixation system.

I M P L A N T S



SMALL FOOTPRINT D24 MM X W32 MM
LORDOSIS: 10°

HEIGHT	REFERENCE
H10	SCA-LS 10 10-S
H12	SCA-LS 10 12-S
H14	SCA-LS 10 14-S
H16	SCA-LS 10 16-S



SMALL FOOTPRINT D24 MM X W32 MM
LORDOSIS: 15°

HEIGHT	REFERENCE
H10	SCA-LS 15 10-S
H12	SCA-LS 15 12-S
H14	SCA-LS 15 14-S
H16	SCA-LS 15 16-S

MEDIUM FOOTPRINT D27 MM X W36 MM
LORDOSIS: 10°

HEIGHT	REFERENCE
H10	SCA-LM 10 10-S
H12	SCA-LM 10 12-S
H14	SCA-LM 10 14-S
H16	SCA-LM 10 16-S

MEDIUM FOOTPRINT D27 MM X W36 MM
LORDOSIS: 15°

HEIGHT	REFERENCE
H12	SCA-LM 15 12-S
H14	SCA-LM 15 14-S
H16	SCA-LM 15 16-S

LARGE FOOTPRINT D30 MM X W40 MM
LORDOSIS: 10°

HEIGHT	REFERENCE
H10	SCA-LL 10 10-S
H12	SCA-LL 10 12-S
H14	SCA-LL 10 14-S
H16	SCA-LL 10 16-S

LARGE FOOTPRINT D30 MM X W40 MM
LORDOSIS: 15°

HEIGHT	REFERENCE
H12	SCA-LL 15 12-S
H14	SCA-LL 15 14-S
H16	SCA-LL 15 16-S

I M P L A N T S



DIA 5.0 MM

LENGTH	REFERENCE
L25	SJT-LS 50 25-S
L30	SJT-LS 50 30-S
L35	SJT-LS 50 35-S
L40	SJT-LS 50 40-S

DIA 5.5 MM

LENGTH	REFERENCE
L25	SJT-LS 55 25-S
L30	SJT-LS 55 30-S
L35	SJT-LS 55 35-S
L40	SJT-LS 55 40-S

TECHNICAL FEATURES

Ti-LIFE TECHNOLOGY



The structure mimics the bone trabecular geometry and is designed to allow bone in-growth. This technology is based on a propriety algorithm associated with a unique additive manufacturing process, commonly referred to as 3D printing.

ZERO PROFILE



The screw heads are completely integrated within the cage. Zero-profile implants may limit the risk of damage to vessels and adjacent soft tissues.

SCREW ANTI-BACKOUT SYTEM



The cages feature a channel to ease screw insertion. The zero-profile one-step locking mechanism with pre-assembled cam locks prevent screw migration.

COMPREHENSIVE RANGE



10° and 15° lordosis
3 footprints

INSTRUMENT SETS

DISC PREPARATION 1

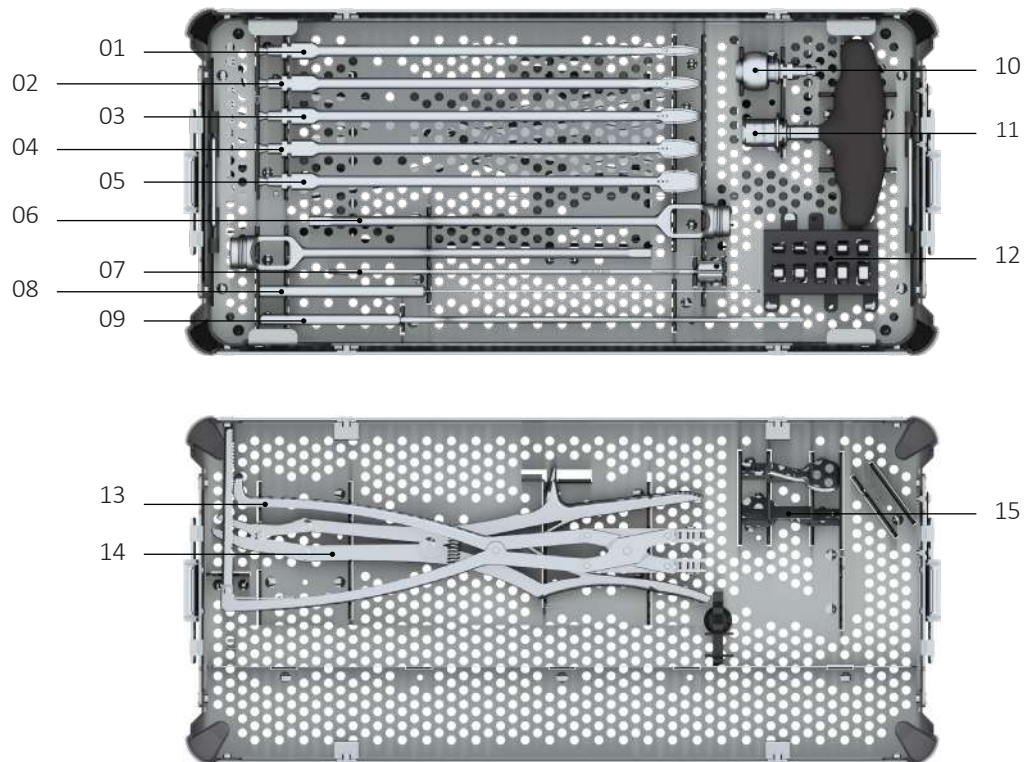


#	DESCRIPTION	REFERENCE
01	PITUITARY RONGEUR, STRAIGHT, 5MM	SCA-IN 21 00-N
02	PITUITARY RONGEUR, STRAIGHT, 3MM	SCA-IN 22 00-N
03	PITUITARY RONGEUR, 3MM, UP	SCA-IN 21 01-N
04	PITUITARY RONGEUR, 5MM, UP	SCA-IN 22 01-N
05	KERRISON RONGEUR, 5MM, 40DEG UP	JLL-IN 14 05-N
06	KERRISON RONGEUR, 3MM, 40DEG UP	SCA-IN 23 00-N

#	DESCRIPTION	REFERENCE
07	STRAIGHT RING CURETTE, 15MM	SCA-IN 09 02-N
08	ANGLED RING CURETTE, 15MM	SCA-IN 09 03-N
09	CUP CURETTE, STRAIGHT, SIZE «2»	SCA-IN 12 00-N
10	CUP CURETTE, ANGLED, DOWN, SIZE «2»	SCA-IN 12 01-N
11	CUP CURETTE, STRAIGHT, SIZE «4»	SCA-IN 24 00-N
12	CUP CURETTE, ANGLED, DOWN, SIZE «4»	SCA-IN 24 01-N
13	FLAT COBB, 30 MM	SCA-IN 10 02-N
14	COBB, 25MM, 10° UP	SCA-IN 10 01-N
15	RASP, STRAIGHT, 14MM	SCA-IN 08 00-N

INSTRUMENT SETS

DISC PREPARATION 2

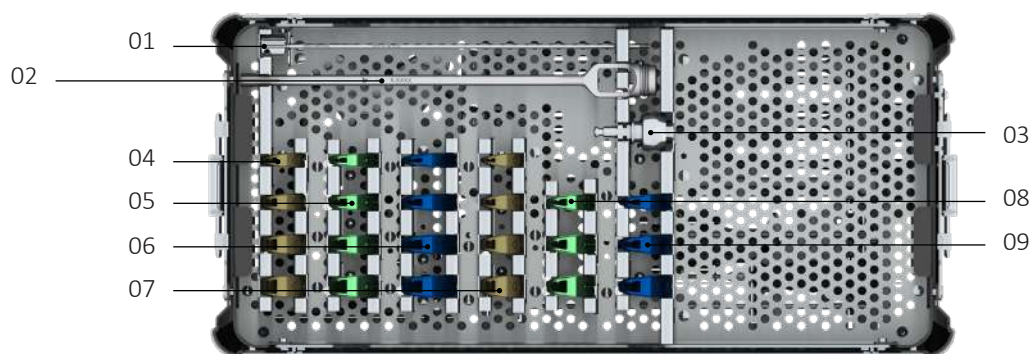


#	DESCRIPTION	REFERENCE
01	DISC SHAVER H08	SCA-IN 14 08-N
02	DISC SHAVER H10	SCA-IN 14 10-N
03	DISC SHAVER H12	SCA-IN 14 12-N
04	DISC SHAVER H14	SCA-IN 14 14-N
05	DISC SHAVER H16	SCA-IN 14 16-N
06	PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N
07	THREADED SHAFT	SCA-IN 18 00-N
08	BALL TIP PROBE	SCA-IN 20 00-N
09	BLUNT DISSECTOR	JLL-IN 00 01-N
10	HUDSON CONNECTOR	SCA-IN 17 00-N
11	T-HANDLE (HUDSON CONNECTION)	HAN-SI MH TE-N

#	DESCRIPTION	REFERENCE
12	PADDLE DISTRACTOR H07	SCA-IN 15 07-N
	PADDLE DISTRACTOR H08	SCA-IN 15 08-N
	PADDLE DISTRACTOR H09	SCA-IN 15 09-N
	PADDLE DISTRACTOR H10	SCA-IN 15 10-N
	PADDLE DISTRACTOR H11	SCA-IN 15 11-N
	PADDLE DISTRACTOR H12	SCA-IN 15 12-N
	PADDLE DISTRACTOR H13	SCA-IN 15 13-N
	PADDLE DISTRACTOR H14	SCA-IN 15 14-N
	PADDLE DISTRACTOR H15	SCA-IN 15 15-N
PADDLE DISTRACTOR H16	SCA-IN 15 16-N	
13	PARALLEL DISTRACTOR	ELL-IN 01 07-N
14	LEKSELL DOUBLE-ACTION RONGEUR, 8MM	SCA-IN 13 00-N
15	PARALLEL DISTRACTOR / ENDTIP	SCA-IN 01 00-N

INSTRUMENT SETS

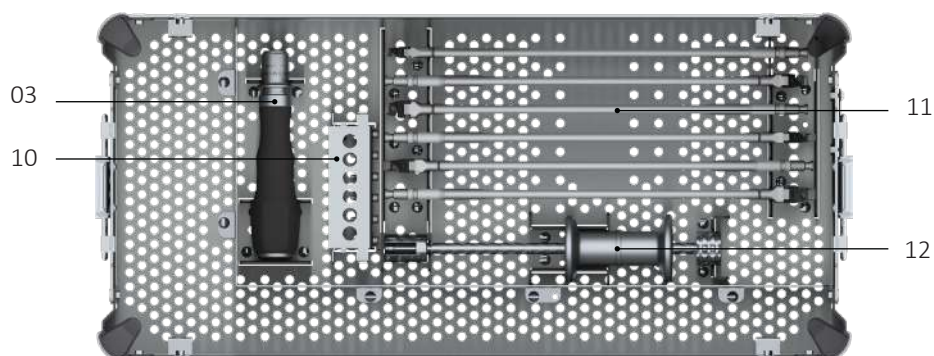
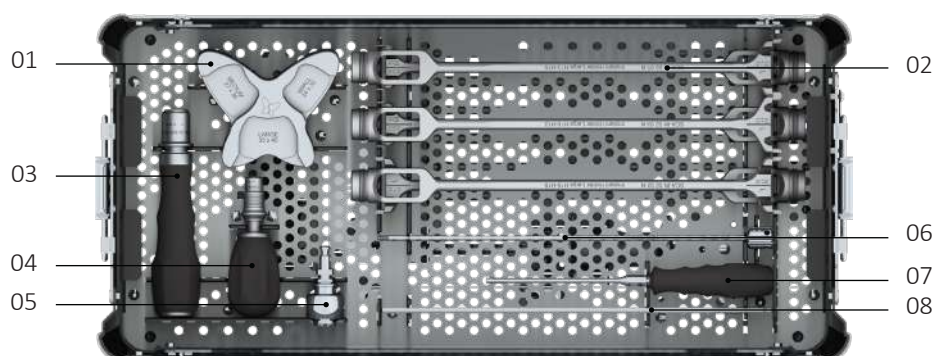
IMPLANT TRIALS AND CAGES INSERTION



#	DESCRIPTION	REFERENCE
01	THREADED SHAFT	SCA-IN 18 00-N
02	TRIAL INSERTER	SCA-IN 05 00-N
03	HUDSON CONNECTOR	SCA-IN 17 00-N
04	TRIAL SMALL H10 LORDOSIS 10°	SCA-TS 10 10-N
	TRIAL SMALL H12 LORDOSIS 10°	SCA-TS 10 12-N
	TRIAL SMALL H14 LORDOSIS 10°	SCA-TS 10 14-N
	TRIAL SMALL H16 LORDOSIS 10°	SCA-TS 10 16-N
05	TRIAL MEDIUM H10 LORDOSIS 10°	SCA-TM 10 10-N
	TRIAL MEDIUM H12 LORDOSIS 10°	SCA-TM 10 12-N
	TRIAL MEDIUM H14 LORDOSIS 10°	SCA-TM 10 14-N
	TRIAL MEDIUM H16 LORDOSIS 10°	SCA-TM 10 16-N
06	TRIAL LARGE H10 LORDOSIS 10°	SCA-TL 10 10-N
	TRIAL LARGE H12 LORDOSIS 10°	SCA-TL 10 12-N
	TRIAL LARGE H14 LORDOSIS 10°	SCA-TL 10 14-N
	TRIAL LARGE H16 LORDOSIS 10°	SCA-TL 10 16-N
07	TRIAL SMALL H10 LORDOSIS 15°	SCA-TS 15 10-N
	TRIAL SMALL H12 LORDOSIS 15°	SCA-TS 15 12-N
	TRIAL SMALL H14 LORDOSIS 15°	SCA-TS 15 14-N
	TRIAL SMALL H16 LORDOSIS 15°	SCA-TS 15 16-N
08	TRIAL MEDIUM H12 LORDOSIS 15°	SCA-TM 15 12-N
	TRIAL MEDIUM H14 LORDOSIS 15°	SCA-TM 15 14-N
	TRIAL MEDIUM H16 LORDOSIS 15°	SCA-TM 15 16-N
09	TRIAL LARGE H12 LORDOSIS 15°	SCA-TL 15 12-N
	TRIAL LARGE H14 LORDOSIS 15°	SCA-TL 15 14-N
	TRIAL LARGE H16 LORDOSIS 15°	SCA-TL 15 16-N

INSTRUMENT SETS

IMPLANT TRIALS AND CAGES INSERTION

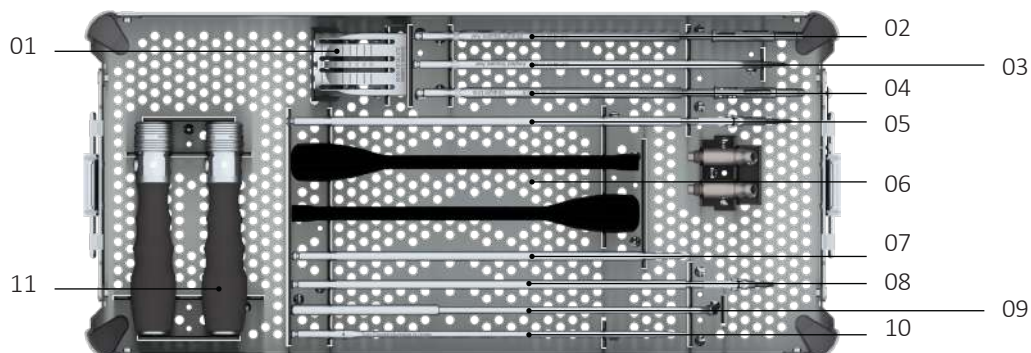


#	DESCRIPTION	REFERENCE
01	COMPACTION BASE	SCA-IN 07 00-N
02	IMPLANT HOLDERS:	
	SMALL/MEDIUM H10-H12	SCA-IN 01 01-N
	SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
	SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
	LARGE H10-H12	SCA-IN 02 00-N
	LARGE H13-H15	SCA-IN 02 01-N
	LARGE H16-H18	SCA-IN 02 02-N
03	STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
04	TORQUE LIMITING HANDLE (1NM) (PALM HANDLE)	HAN-SI AO PA-N
05	HUDSON CONNECTOR	SCA-IN 17 00-N
06	THREADED SHAFT	SCA-IN 18 00-N
07	COMPACTOR	SCA-IN 19 00-N
08	CAMLOCKER DRIVER	SCA-IN 06 00-N

#	DESCRIPTION	REFERENCE
10	LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N
11	LATERAL IMPLANT HOLDERS:	
	SMALL/MEDIUM H10-H12	SCA-IN 03 00-N
	SMALL/MEDIUM H13-H15	SCA-IN 03 01-N
	SMALL/MEDIUM H16-H18	SCA-IN 03 02-N
	LARGE H10-H12	SCA-IN 04 00-N
	LARGE H13-H15	SCA-IN 04 01-N
	LARGE H16-H18	SCA-IN 04 02-N
12	SLAP HAMMER	JLL-IN 12 00-N

INSTRUMENT SETS

SCREW INSERTION



#	DESCRIPTION	REFERENCE
01	SCREW LOADER	SJT-IN 04 00-N
02	STRAIGHT SQUARE AWL	SJT-IN 01 00-N
03	ANGLED SQUARE AWL	SJT-IN 01 01-N
04	STRAIGHT DRILL	SJT-IN 02 00-N
05	U-JOINT DRILL	SJT-IN 02 01-N
06	UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N
07	STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
08	U-JOINT SCREWDRIVER	SJT-IN 03 01-N
09	U-JOINT GUIDE	SJT-IN 05 00-N
10	REVISION SCREWDRIVER	SJT-IN 03 02-N
11	STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N

INSTRUMENTS

DISC PREPARATION

STRAIGHT RING CURETTE, 15MM SCA-IN 09 02-N



CUP CURETTE, ANGLED, DOWN, SIZE «4» SCA-IN 24 01-N



ANGLED RING CURETTE, 15MM SCA-IN 09 03-N



FLAT COBB, 30 MM SCA-IN 10 02-N



CUP CURETTE, STRAIGHT, SIZE «2» SCA-IN 12 00-N



COBB, 25MM, 10° UP SCA-IN 10 01-N



CUP CURETTE, STRAIGHT, SIZE «4» SCA-IN 24 00-N



RASP, STRAIGHT, 14MM SCA-IN 08 00-N



CUP CURETTE, ANGLED, DOWN, SIZE «2» SCA-IN 12 01-N



PADDLE DISTRACTOR HOLDER SCA-IN 15 00-N



PADDLE DISTRACTORS H07 TO H16 SCA-IN 15 07-N TO SCA-IN 15 16-N



THREADED SHAFT SCA-IN 18 00-N



INSTRUMENTS

DISC PREPARATION

T-HANDLE (HUDSON CONNECTION) HAN-SI MH TE-N



PITUITARY RONGEUR, STRAIGHT, 5MM SCA-IN 21 00-N

PITUITARY RONGEUR, STRAIGHT, 3MM SCA-IN 22 00-N

PITUITARY RONGEUR, 3MM, UP SCA-IN 21 01-N

PITUITARY RONGEUR, 5MM, UP SCA-IN 22 01-N



BALL TIP PROBE SCA-IN 20 00-N



CUP CURETTE, STRAIGHT, SIZE «0» SCA-IN 11 00-N
(OPTIONAL)

CUP CURETTE, ANGLED, SIZE «0» SCA-IN 11 01-N
(OPTIONAL)



KERRISON RONGEUR, 3MM, 40DEG UP SCA-IN 23 00-N

KERRISON RONGEUR, 5MM, 40DEG UP JLL-IN 14 05-N



STRAIGHT AND ANGLED RING SCA-IN 09 00-N
CURETTE, 11MM (OPTIONAL) SCA-IN 09 01-N



LEKSELL DOUBLE-ACTION RONGEUR, 8MM SCA-IN 13 00-N



INSTRUMENTS

DISC PREPARATION

PARALLEL DISTRACTOR

ELL-IN 01 07-N



BLUNT DISSECTOR

JLL-IN 00 01-N



PARALLEL DISTRACTOR / ENDTIP

SCA-IN 01 00-N



HUDSON CONNECTOR

SCA-IN 17 00-N



DISC SHAVERS

SCA-IN 14 08-N TO
SCA-IN 14 16-N



INSTRUMENTS

IMPLANT TRIALS

TRIAL INSERTER SCA-IN 05 00-N



THREADED SHAFT SCA-IN 18 00-N



SLAP HAMMER JLL-IN 12 00-N



HUDSON CONNECTOR SCA-IN 17 00-N



TRIAL SMALL H10 TO H16 LORDOSIS 10° SCA-TS 10 XX-N

TRIAL SMALL H10 TO H16 LORDOSIS 15° SCA-TS 15 XX-N



TRIAL MEDIUM H10 TO H16 LORDOSIS 10° SCA-TM 10 XX-N

TRIAL MEDIUM H12 TO H16 LORDOSIS 15° SCA-TM 15 XX-N



TRIAL LARGE H10 TO H16 LORDOSIS 10° SCA-TL 10 XX-N

TRIAL LARGE H12 TO H16 LORDOSIS 15° SCA-TL 15 XX-N



INSTRUMENTS

CAGES INSTRUMENTS

IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 01 01-N
IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
IMPLANT HOLDER LARGE H10-H12	SCA-IN 02 00-N
IMPLANT HOLDER LARGE H13-H15	SCA-IN 02 01-N
IMPLANT HOLDER LARGE H16-H18	SCA-IN 02 02-N



LATERAL IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 03 00-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 03 01-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 03 02-N
LATERAL IMPLANT HOLDER LARGE H10-H12	SCA-IN 04 00-N
LATERAL IMPLANT HOLDER LARGE H13-H15	SCA-IN 04 01-N
LATERAL IMPLANT HOLDER LARGE H16-H18	SCA-IN 04 02-N



LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N
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COMPACTOR	SCA-IN 19 00-N
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COMPACTION BASE	SCA-IN 07 00-N
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CAMLOCKER DRIVER	SCA-IN 06 00-N
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STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
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TORQUE LIMITING HANDLE (1NM) (PALM HANDLE)	HAN-SI AO PA-N
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INSTRUMENTS

SCREW INSERTION

STRAIGHT SQUARE AWL SJT-IN 01 00-N



ANGLED SQUARE AWL SJT-IN 01 01-N



STRAIGHT DRILL SJT-IN 02 00-N



U-JOINT DRILL SJT-IN 02 01-N



STRAIGHT SCREWDRIVER SJT-IN 03 00-N



U-JOINT SCREWDRIVER SJT-IN 03 01-N



REVISION SCREWDRIVER SJT-IN 03 02-N



U-JOINT GUIDE SJT-IN 05 00-N



SCREW LOADER SJT-IN 04 00-N



UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART SJT-IN 06 00-N



STRAIGHT HANDLE RATCHET HAN-SI RA ST-N



INSTRUMENT ASSEMBLY



TRIALS AND CAGES INSERTION
HUDSON CONNECTION HANDLES



SCREWS INSERTION
RATCHET HANDLE



TORQUE LIMITING
HANDLE



HUDSON CONNECTION HANDLE ATTACHMENT

Align parallel flat surfaces of the instrument shaft with corresponding handle recess. Pull the adaptor barrel while inserting the shaft. Release the adaptor barrel.

INSTRUMENT	REFERENCE
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
T-HANDLE (HUDSON CONNECTION)	HAN-SI MH TE-N



TRIAL INSERTER & IMPLANT HOLDER ASSEMBLY

Insert the threaded shaft into the implant holder or trial inserter. Align the Hudson connector onto the implant holder or trial inserter and turn clockwise to secure the assembly.

INSTRUMENT	REFERENCE
THREADED SHAFT	SCA-IN 18 00-N
HUDSON CONNECTOR	SCA-IN 17 00-N
TRIAL INSERTER	SCA-IN 05 00-N
IMPLANT HOLDER SMALL/MEDIUM	SCA-IN 01 XX-N
IMPLANT HOLDER LARGE	SCA-IN 02 XX-N
PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N

INSTRUMENT ASSEMBLY



SLAP HAMMER ATTACHMENT

The Slap Hammer can be used if additional force is needed for instrument removal. Attach instruments per respective connection end:

Hudson Connection

Align and insert the proximal end of the instrument shaft into the Slap Hammer slot. Rotate the slap hammer shaft clockwise 90°.

INSTRUMENT	REFERENCE
SLAP HAMMER	JLL-IN 12 00-N



ASSEMBLY OF THE U-JOINT INSTRUMENTS

1. Connect the U-Joint instrument with the universal U joint angled part
2. Thread the U-Joint Tube onto the universal U joint angled part using a counter clockwise rotation

S U R G I C A L T E C H N I Q U E

_STEP 1



PATIENT POSITIONING AND EXPOSURE

For an anterior approach of the lower lumbar levels, place the patient supine in a slight Trendelenburg position, per surgeon preference.

Locate the operative disc level and incision location via lateral fluoroscopy.

Determine surgical approach (anterior or anterolateral) based on the surgeon preference.

Through a standard retroperitoneal approach, dissect and retract the soft tissue to reach the operative disc level.

Cut an appropriately sized window through the anterior longitudinal ligament and the annulus fibrosus, to access the target disc space.

S U R G I C A L T E C H N I Q U E

_STEP 2



DISCECTOMY AND DISTRACTION

Begin discectomy and endplate preparation with a curette.

Use a Cobb elevator to clearly define the endplates.

Distract the discectomy site, using the parallel distractor and/or paddle distractors.

Complete endplate preparation with the rasp and disc shavers. Care must be taken to ensure excessive bone is not removed, which may weaken the endplate.

INSTRUMENT	REFERENCE
STRAIGHT RING CURETTE, 15MM	SCA-IN 09 02-N
ANGLED RING CURETTE, 15MM	SCA-IN 09 03-N
CUP CURETTE, STRAIGHT, SIZE «2»	SCA-IN 12 00-N
CUP CURETTE, STRAIGHT, SIZE «4»	SCA-IN 24 00-N
CUP CURETTE, ANGLED, DOWN, SIZE «2»	SCA-IN 12 01-N
CUP CURETTE, ANGLED, DOWN, SIZE «4»	SCA-IN 24 01-N
FLAT COBB, 30MM	SCA-IN 10 02-N
COBB, 25MM, 10° UP	SCA-IN 10 01-N
PARALLEL DISTRACTOR	ELL-IN 01 07-N
PARALLEL DISTRACTOR / ENDTIP	SCA-IN 01 00-N
PADDLE DISTRACTOR HOLDER	SCA-IN 15 00-N
PADDLE DISTRACTORS H07 TO H16	SCA-IN 15 07-N TO SCA-IN 15 16-N
RASP, STRAIGHT, 14MM	SCA-IN 08 00-N
DISC SHAVERS	SCA-IN 14 08-N TO SCA-IN 14 16-N
BLUNT DISSECTOR	JLL-IN 00 01-N
T-HANDLE (HUDSON CONNECTION)	HAN-SI MH TE-N
BALL TIP PROBE	SCA-IN 20 00-N
PITUITARY RONGEUR, STRAIGHT, 5MM	SCA-IN 21 00-N
PITUITARY RONGEUR, STRAIGHT, 3MM	SCA-IN 22 00-N
PITUITARY RONGEUR, 3MM, UP	SCA-IN 21 01-N
PITUITARY RONGEUR, 5MM, UP	SCA-IN 22 01-N
KERRISON RONGEUR, 3MM, 40DEG UP	SCA-IN 23 00-N
KERRISON RONGEUR, 5MM, 40DEG UP	JLL-IN 14 05-N
LEKSELL DOUBLE-ACTION RONGEUR, 8MM	SCA-IN 13 00-N
HUDSON CONNECTOR	SCA-IN 17 00-N
THREADED SHAFT	SCA-IN 18 00-N

S U R G I C A L T E C H N I Q U E

_STEP 3



ANTERIOR APPROACH



ANTEROLATERAL APPROACH

SELECTION OF THE IMPLANT SIZE

Straight Anterior Approach:

Thread the trial implant onto the trial inserter using the midline hole of the trial implant.

Anterolateral Approach:

Thread the trial implant onto the trial inserter using the appropriate lateral hole of the trial implant.

Insert the trial implant into the intervertebral space to determine the cage height, footprint and angulation.

If the chosen trial implant is too small, use incrementally larger trials until a tight fit is achieved.

A mallet may be used to gently insert the trial. Verify correct size with AP and Lateral imaging.

Implant size selection is dependent on the intervertebral space, patient anatomy and technical preparation.

With appropriate size verified, open the corresponding cage footprint and height and thread it onto the implant holder.

INSTRUMENT	REFERENCE
TRIAL INSERTER	SCA-IN 05 00-N
THREADED SHAFT	SCA-IN 18 00-N
HUDSON CONNECTOR	SCA-IN 17 00-N
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
TRIAL SMALL H10 TO H16 LORDOSIS 10°	SCA-TS 10 10-N TO SCA-TS 10 18-N
TRIAL SMALL H10 TO H16 LORDOSIS 15°	SCA-TS 15 10-N TO SCA-TS 15 18-N
TRIAL MEDIUM H10 TO H16 LORDOSIS 10°	SCA-TM 10 10-N TO SCA-TM 10 18-N
TRIAL MEDIUM H12 TO H16 LORDOSIS 15°	SCA-TM 15 12-N TO SCA-TM 15 18-N
TRIAL LARGE H10 TO H16 LORDOSIS 10°	SCA-TL 10 10-N TO SCA-TL 10 18-N
TRIAL LARGE H12 TO H16 LORDOSIS 15°	SCA-TL 15 12-N TO SCA-TL 15 18-N
SLAP HAMMER	JLL-IN 12 00-N

SURGICAL TECHNIQUE

_STEP 4



CAGE PREPARATION

Please refer to the instrument assembly section of this guide to determine proper instrument selection and assembly instructions based on preferred approach technique of the surgeon.

Place the cage onto the compaction base and fill it with bone graft.

INSTRUMENT	REFERENCE
IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 01 01-N
IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
IMPLANT HOLDER LARGE H10-H12	SCA-IN 02 00-N
IMPLANT HOLDER LARGE H13-H15	SCA-IN 02 01-N
IMPLANT HOLDER LARGE H16-H18	SCA-IN 02 02-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 03 00-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 03 01-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 03 02-N
LATERAL IMPLANT HOLDER LARGE H10-H12	SCA-IN 04 00-N
LATERAL IMPLANT HOLDER LARGE H13-H15	SCA-IN 04 01-N
LATERAL IMPLANT HOLDER LARGE H16-H18	SCA-IN 04 02-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
THREADED SHAFT	SCA-IN 18 00-N
LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N
COMPACTION BASE	SCA-IN 07 00-N
COMPACTOR	SCA-IN 19 00-N
HUDSON CONNECTOR	SCA-IN 17 00-N
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N

SURGICAL TECHNIQUE

_STEP 5



INSERTION OF THE FINAL IMPLANT

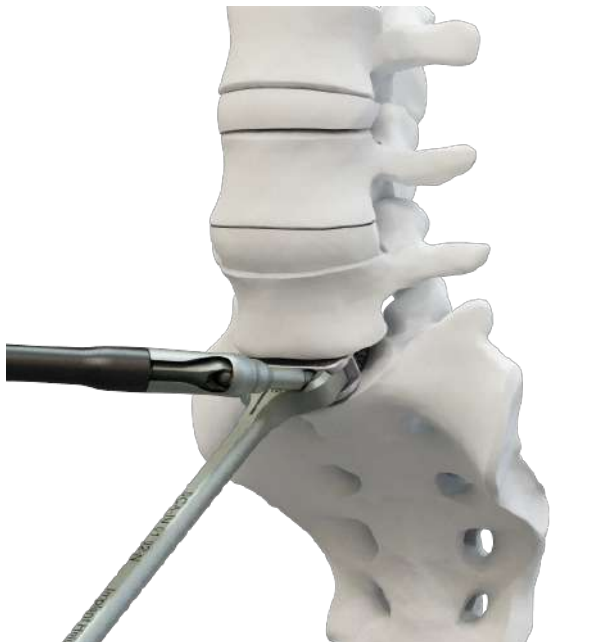
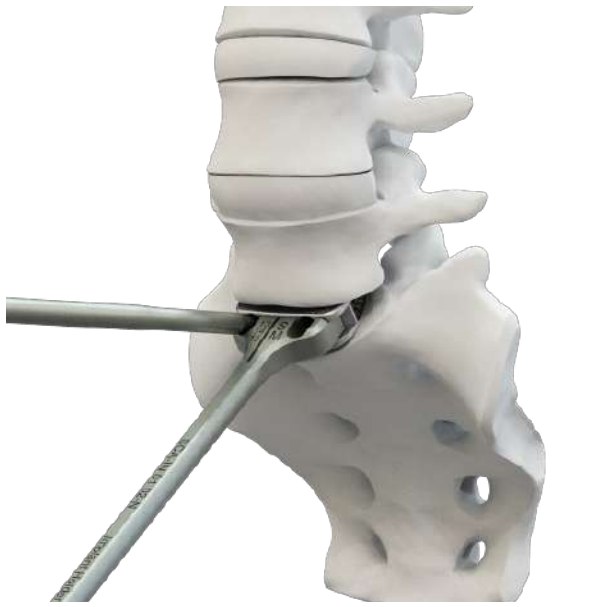
Insert the cage into the intervertebral space, according to preferred approach technique of the surgeon.

A mallet may be used to gently insert the final implant.

INSTRUMENT	REFERENCE
IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 01 01-N
IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 01 02-N
IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 01 03-N
IMPLANT HOLDER LARGE H10-H12	SCA-IN 02 00-N
IMPLANT HOLDER LARGE H13-H15	SCA-IN 02 01-N
IMPLANT HOLDER LARGE H16-H18	SCA-IN 02 02-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H10-H12	SCA-IN 03 00-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H13-H15	SCA-IN 03 01-N
LATERAL IMPLANT HOLDER SMALL/MEDIUM H16-H18	SCA-IN 03 02-N
LATERAL IMPLANT HOLDER LARGE H10-H12	SCA-IN 04 00-N
LATERAL IMPLANT HOLDER LARGE H13-H15	SCA-IN 04 01-N
LATERAL IMPLANT HOLDER LARGE H16-H18	SCA-IN 04 02-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
THREADED SHAFT	SCA-IN 18 00-N
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
HUDSON CONNECTOR	SCA-IN 17 00-N
LATERAL IMPLANT HOLDER SCREW M4X0.7	SCA-IN 16 00-N

SURGICAL TECHNIQUE

_STEP 6



PREPARATION OF LATERAL SCREW HOLES

The SCARLET® AL-T system offers four instruments for screw hole preparation:

- Straight square awl
- Angled square awl
- Straight drill
- U-Joint drill

NOTE: Straight and angled hole preparation instruments can be used interchangeably according to surgeon preference.

Begin hole preparation with the two lateral screw holes.

Insert preferred instrument into the guide hole of the implant holder to prepare each lateral screw hole.

The U-joint guide may also be used during screw hole preparation to provide correct trajectory.

NOTE: The screw hole preparation instruments have a tip length of 25mm, which represents the shortest length screw available. Lateral imaging during hole creation may assist with determining the appropriate screw length.

INSTRUMENT	REFERENCE
STRAIGHT SQUARE AWL	SJT-IN 01 00-N
ANGLED SQUARE AWL	SJT-IN 01 01-N
STRAIGHT DRILL	SJT-IN 02 00-N
U-JOINT DRILL	SJT-IN 02 01-N
UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N
U-JOINT GUIDE	SJT-IN 05 00-N

S U R G I C A L T E C H N I Q U E

_STEP 7



Laser mark should be visible

IMPLANTATION OF THE LATERAL SCREWS

Load the screw into the screw loader. It will facilitate a secure connection between the screw and the screwdriver. It also provides a verification of screw length.

While keeping the implant holder in place, insert the first lateral screw using the straight or U-joint screwdriver.

AP and Lateral images may be used to verify screw position.

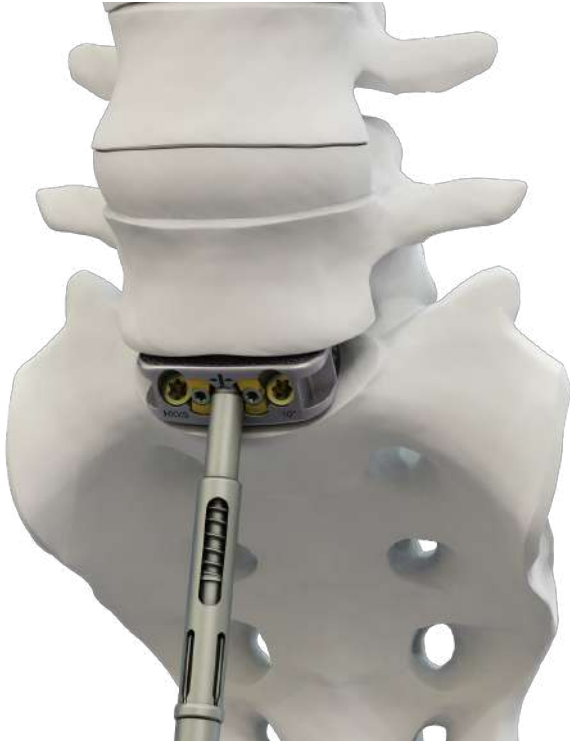
Repeat this step to insert the second lateral screw.

For visual confirmation of correct screw depth, a laser mark is positioned within the screw holes. The head of the screw should be inserted beyond this landmark.

INSTRUMENT	REFERENCE
SCREW LOADER	SJT-IN 04 00-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
U-JOINT GUIDE	SJT-IN 05 00-N
UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N

S U R G I C A L T E C H N I Q U E

_STEP 8



PREPARATION OF THE CENTRAL SCREW HOLE

Remove the implant holder.

Prepare the central screw hole of the vertebra using the preferred instruments of the surgeon. The U-Joint guide may also be used during central screw hole creation to provide correct trajectory of central screw hole.

INSTRUMENT	REFERENCE
STRAIGHT SQUARE AWL	SJT-IN 01 00-N
ANGLED SQUARE AWL	SJT-IN 01 01-N
STRAIGHT DRILL	SJT-IN 02 00-N
U-JOINT DRILL	SJT-IN 02 01-N
UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N
U-JOINT GUIDE	SJT-IN 05 00-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N

SURGICAL TECHNIQUE

_STEP 9



IMPLANTATION OF THE CENTRAL SCREW

Insert the central screw using the straight or U-joint screwdriver.

AP and Lateral images may be used to verify screw position.

INSTRUMENT	REFERENCE
SCREW LOADER	SJT-IN 04 00-N
STRAIGHT SCREWDRIVER	SJT-IN 03 00-N
U-JOINT SCREWDRIVER	SJT-IN 03 01-N
U-JOINT GUIDE	SJT-IN 05 00-N
UNIVERSAL-JOINT TUBE AND UNIVERSAL JOINT ANGLED PART	SJT-IN 06 00-N

_STEP 10



SECURING OF THE SCREWS

The screws are secured with cam locks.

The cage is delivered with the cams unlocked in the open position (Figure 10a).

Using the cam lock driver with the torque limiting handle the cam locking mechanism is activated by rotating the cams in the direction indicated by the arrows laser marked on the front of the cage. The cams are now locked in the closed position (Figure 10b).

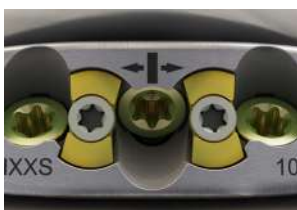


Figure 10a

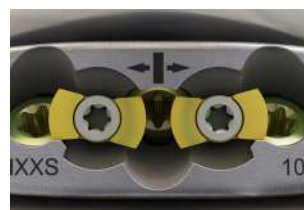


Figure 10b

INSTRUMENT	REFERENCE
CAMLOCKER DRIVER	SCA-IN 06 00-N
TORQUE LIMITING HANDLE (1Nm) (PALM HANDLE)	HAN-SI AO PA-N

S U R G I C A L T E C H N I Q U E

_FINAL CONSTRUCT



_REVISION



In the case of a revision, unlock the cam locks using the camlocker driver and torque limiting handle.

Remove the screws using the revision screwdriver.

Screw the revision screwdriver counter clockwise into the screw while taking it out.

Connect the corresponding implant holder to remove the implant

Gently pull the implant out of the vertebral space.

INSTRUMENT	REFERENCE
REVISION SCREWDRIVER	SJT-IN 03 02-N
CAMLOCKER DRIVER	SCA-IN 06 00-N
TORQUE LIMITING HANDLE (1Nm) (PALM HANDLE)	HAN-SI AO PA-N
STRAIGHT HANDLE (HUDSON CONNECTION)	HAN-SI MH SM-N
IMPLANT HOLDERS (see page 18)	

X-PS[®]

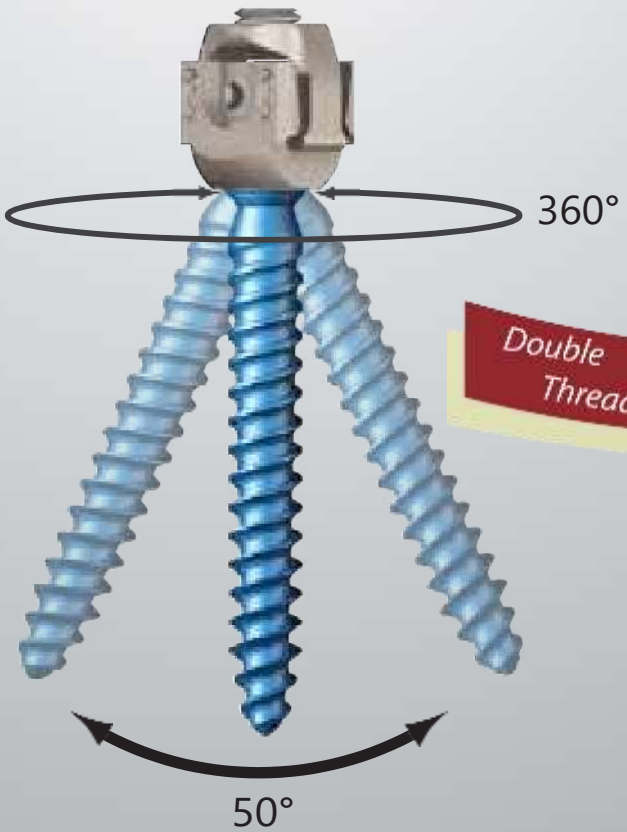
PS[®]

LorX[®] ACIF

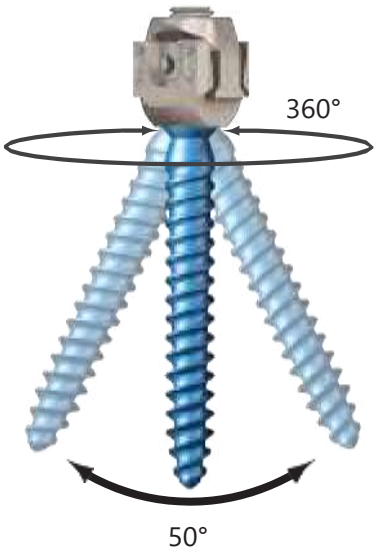
LorX[®] PLIF

LorX[®] TLIF

X-PS[®] thoraco-lumbar system



design features



6mm rod system
6mm rod system for stronger constructs and universal use



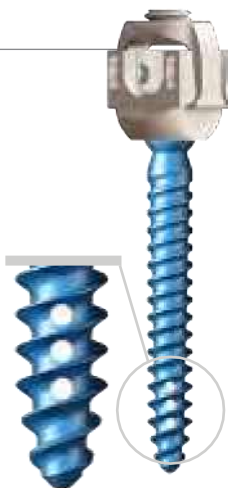
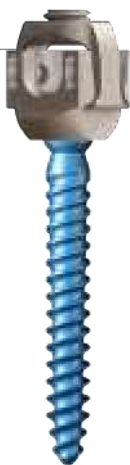
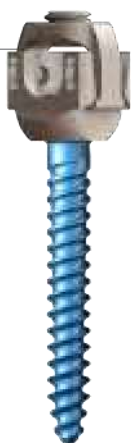
Variation of 70°
Provides a variation of 70° in angle in total for best anatomic position



Screw tip
Improved screw tip for easy insertion



Adjustable cross links
Adjustable cross links for every construct in 4 sizes between 30mm and 70mm



- Mono-Axial Screw

- Diameter :4.0mm to 8.0mm
- Length :25mm to 60mm

- Multi-Axial Screw

- Diameter :4.0mm to 8.0mm
- Length :25mm to 60mm

- Multi-Axial Cement Type Screw

- Diameter :5.5mm and 6.5mm
- Length :35mm to 55mm

- Rod & Pre-BendRod

- 13 different sizes from 50mm to 500mm

- Clip & Hook

- Multi-Axial Adjustable CrossLink

- 4 different sizes from 30mm to 70mm
- S, M, L, XL



Multi-Axial System

- Provides 70° in angle
- Well known technique
- Easy to use

Wide Application Area

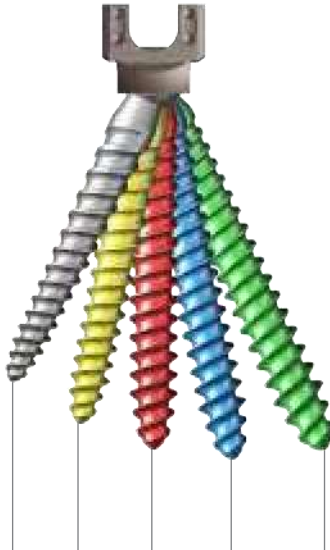
- Suitable for thoraco-lumbar and sacral spine
- Perfect implantation in stenosis, spondylolisthesis, scoliosis, kyphosis, trauma, fractures, tumor and lordosis cases
- Compatible implants and instruments for human anatomy
- Spondylolisthesis (up to Grade 2) without any extra implant or instrument

Better Design

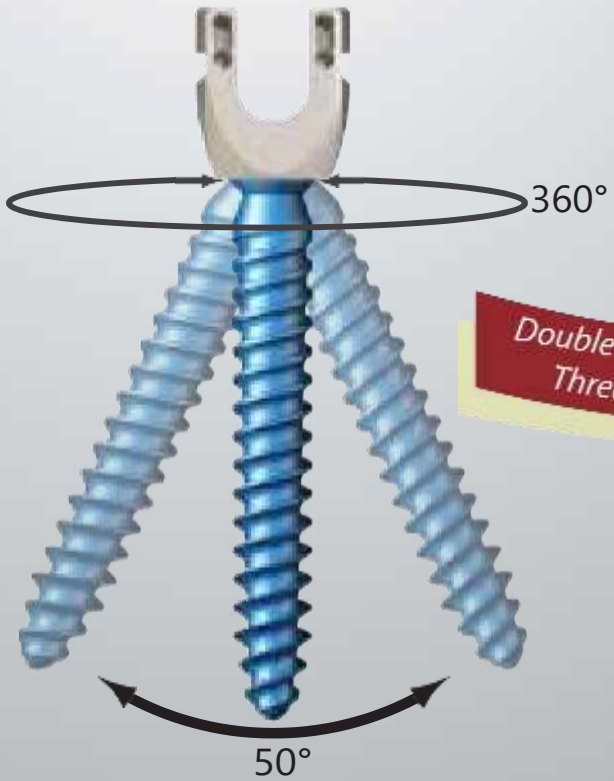
- Double-threaded structure, cortical screw body
- Improved screw tip
- Threaded screw head
- Titanium (6) - Aluminium (4) - Vanadium alloy (ISO 5832-3)
- Biomechanically tested implants according to ASTM F1717 and ASTM F1798

Implant Features

- Color coded screw bodies
- Clip locking mechanism
- Improved adjustable crosslink
- 6mm rod system
- Various sizes and types of screw



PS[®] spine system





6mm rod system*

6mm rod system for stronger constructs and universal use

*5.5mm rods available upon request

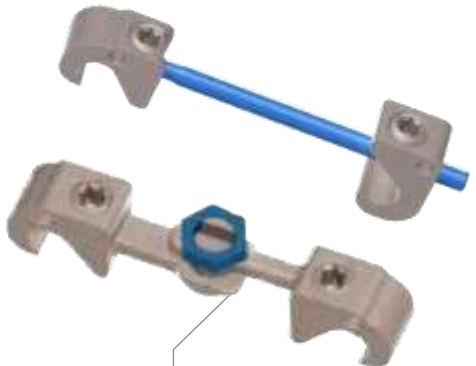
Screw tip

Improved screw tip for easy insertion



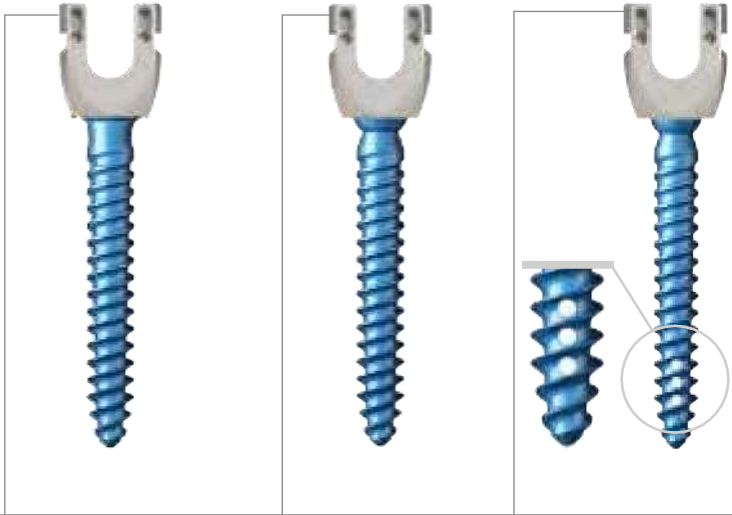
Variation of 50°

Provides a variation of 50° in angle to achieve best anatomic position



Adjustable transverse connectors

Adjustable transverse connectors for every construct in 4 sizes between 30mm and 80mm



- Mono-Axial Screw

- Diameter :4.0mm to 8.0mm
- Length :25mm to 60mm

- Multi-Axial Screw

- Diameter :4.0mm to 8.0mm
- Length :25mm to 60mm

- Multi-Axial Cement Type Screw

- Diameter :5.5mm, 6.5mm, 7.5mm
- Length :25mm to 60mm

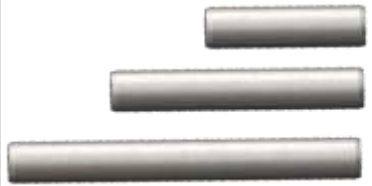
- Multi-Axial Adjustable Transverse Connector

- 4 different sizes from 30mm to 80mm
- S, M, L, XL

- Set Screw & Hook

- Rod

- 13 different sizes from 50mm to 500mm



Multi-Axial System

- Provides 50° in angle
- Well known technique
- Easy to use

Wide Application Area

- Suitable for thoraco-lumbar and sacral spine
- Perfect implantation in stenosis, spondylolisthesis, scoliosis, kyphosis, trauma, fractures, tumor and lordosis cases
- Compatible implants and instruments for human anatomy

Better Design

- Double-threaded structure, cortical screw body
- Improved rounded screw tip
- Threaded screw head
- Titanium (6) - Aluminium (4) - Vanadium alloy (ISO 5832-3)
- Biomechanically tested implants according to ASTM F1717 and ASTM F1798

Implant Features

- Color coded screw bodies
- Enhanced locking mechanism
- Adjustable transverse connector
- 6mm rod system
- Various sizes and types of screw



LorX[®]

cervical peek cage with blade



 Tria Spine[®]
...evolution of spine

design features

Better stability

Two instrument holes for extra stability during insertion
1.5mm fixation of blade into the each endplate



Anatomical shape

Original and anatomical design for a secure and better placement



Biocompatibility

Radiolucent and biocompatible PEEK material (VESTAKEEP by Evonik , ASTM F2026) which provides modulus of elasticity similar to the bone



Tantalum pins

3 tantalum markers (ASTM F560) for the verification of anterior and posterior implant placement

Special blade design

Specially designed (patent pending) titanium (ASTM F136) blade, positioned in the middle of the cage for perfect fixation
No need of extra fixation implants (plates etc.)

Enhanced bone fusion

Two adequate graft spaces for bone fusion

Cervical PEEK Cage

Ref LX-01-525 :	12X15 mm	5 mm
Ref LX-01-526 :	12X15 mm	6 mm
Ref LX-01-527 :	12X15 mm	7 mm
Ref LX-01-528 :	12X15 mm	8 mm

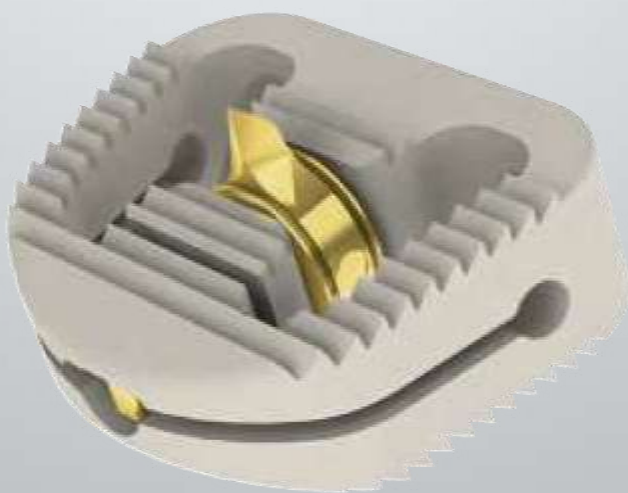
Cervical PEEK Cage with Blade


Ref LX-02-525 :	12X15 mm	5 mm
Ref LX-02-526 :	12X15 mm	6 mm
Ref LX-02-527 :	12X15 mm	7 mm
Ref LX-02-528 :	12X15 mm	8 mm

LorX[®]

NEW

expandable cervical peek cage with blade



 Tria Spine[®]
...evolution of spine

design features

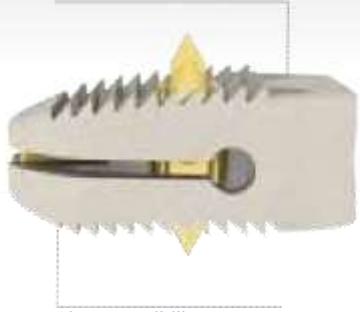
Better stability

Enhanced instrumentation for secure insertion



Anatomical shape

Original and anatomical design for a secure and better placement

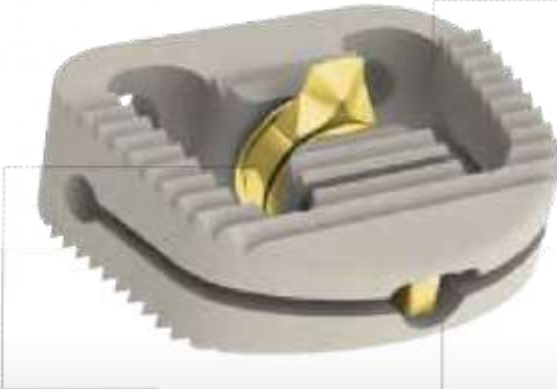


Biocompatibility

Radiolucent and biocompatible PEEK material (VESTAKEEP by Evonik , ASTM F2026) which provides modulus of elasticity similar to the bone

Enhanced bone fusion

Two adequate graft spaces for bone fusion



Special blade design

Specially designed (patent pending) titanium (ASTM F136) blade, positioned in the middle of the cage for perfect fixation
No need of extra fixation implants (plates etc.)

Improved mechanism

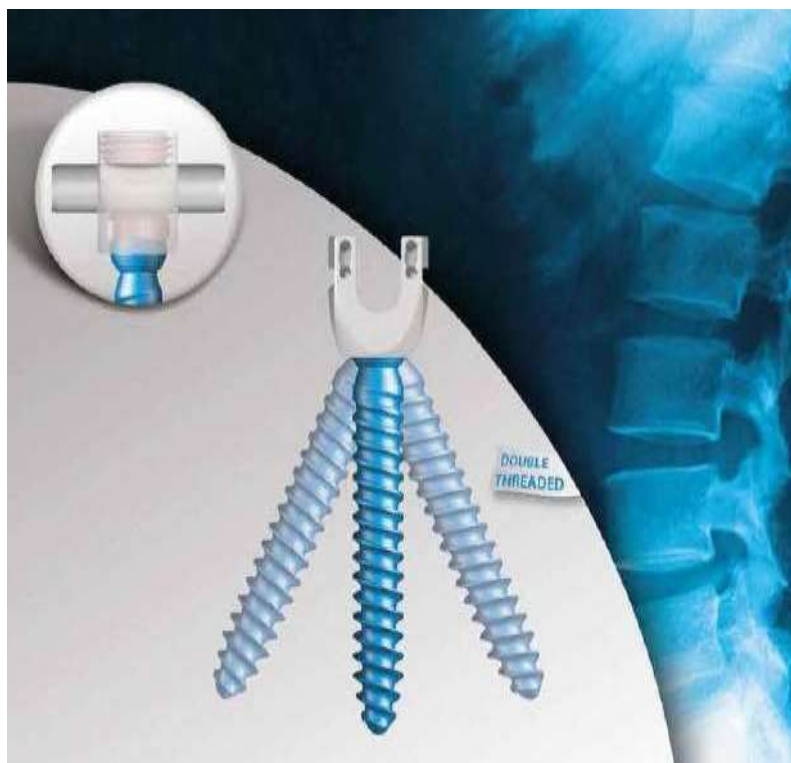
Improved mechanism for secure expanding and placement

Expandable Cervical PEEK Cage with Blade

Ref LX-03-525	:	12X15 mm	5 mm
Ref LX-03-526	:	12X15 mm	6 mm
Ref LX-03-527	:	12X15 mm	7 mm
Ref LX-03-528	:	12X15 mm	8 mm

PS[®] SPINE SYSTEM

TECHNICAL GUIDE



 **Tria Spine[®]**
SPINE | ORTHOPEDICS

www.triaspine.com

Description:

PS® Spine System is composed of various types and sizes of pedicle screws, rods, transverse connectors, nuts, clips, hooks, dominos and lateral connectors for thoracolumbar and sacral spine.

PS® Spine System is suitable for adults who have enough spinal stability and meet the main indications.

Material:

System elements are made of titanium alloy (Ti6Al4V) as per ISO 5832-3 (ASTM F136 and BS 7252-3) and CoCr Vitallium (ASTM F75). All system elements are MRI compatible.

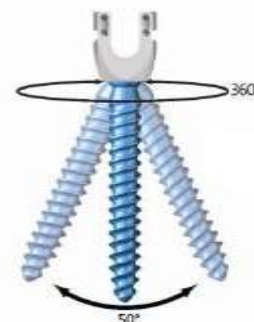
Indications:

PS® Spine System is indicated for degenerated disc disease, spinal stenosis, scoliosis, kyphosis, trauma, fracture, tumor, lordosis, failed previous fusion (pseudoarthrosis) and spondylo listhesis (grade 1 and 2).

Contraindications:

Contraindications include but are not limited to:

- Pathological obesity, pregnancy, significant osteoporosis, open wounds, severe local inflammation, dependency on pharmaceutical drugs, drug abuse or alcoholism, mental illnesses, significant osteopenia, known or suspected allergy or intolerance to implant material (foreign body sensitivity to the implant material), acute or chronic infections, lack of patient cooperation.



Product Features:

Multi-Axial System

- Provides 50° in angle
- Well known technique
- Easy to use

Wide Application Area

- Suitable for thoraco-lumbar and sacral spine
- Perfect implantation in stenosis, spondylolisthesis, scoliosis, kyphosis, trauma, fractures, tumor and lordosis cases
- Compatible implants and instruments for human anatomy

Better Design

- Double-threaded structure, cortical screw body
- Improved blunt rounded screw tip
- Threaded screw head
- Titanium (6) - Aluminium (4) - Vanadium alloy (ISO 5832-3)
- CoCr Vitallium alloy (ASTM F75)
- Biomechanically tested implants according to ASTM F1717 and ASTM F1798

Implant Features

- Color coded screw bodies
- Enhanced locking mechanism
- Adjustable transverse connector
- 6mm rod system*
- Various sizes and types of screw



Implants:

Pedicle Screws

Diameter : 4.5mm, 5.5mm, 6.5mm, 7.5mm

Length : 25mm to 60mm



Multi-Axial Screws

Diameter : 4.0mm, 4.5mm, 5.5mm, 6.5mm, 7.5mm

Length : 25mm to 60mm

Multi-Axial Revision Screws

Diameter : 8.0mm

Length : 25mm to 60mm

Mono-Axial Reduction Screws

Diameter : 5.5mm, 6.5mm and 7.5mm

Length : 25mm to 60mm



NON-CONFIDENTIAL

Implants:

Multi-Axial Reduction Screws

Diameter : 4.5mm, 5.5mm, 6.5mm, 7.5mm

Length : 25mm to 60mm

Multi-Axial Cement Type Screws

Diameter : 5.5mm, 6.5mm, 7.5mm

Length : 25mm to 60mm

Multi-Axial Iliac Screws

Diameter : 7.5mm, 8.0mm, 9.0mm

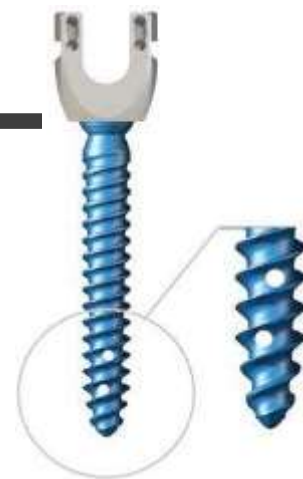
Length : 60mm to 110mm

Rods

Diameter : 6.0mm, hexagonal ends

5.5mm, hexagonal ends

Length : 50mm to 500mm



NON-CONFIDENTIAL

Implants:

Multi-Axial Transverse Links

Size : Small , Medium, Large and X-Large

Length : 30 - 80mm



Nut

PS Set Screw



Domino Connectors

Size : Single and Double

Fixation : 2 or 4 screws



Lateral Connector

PS Lateral Connector



Packaging & Sterilization:

System elements are supplied clean but not sterile. Re-usable instruments should be cleaned before use and all system elements should be sterilized following the below mentioned methods.

As per ISO 17665-1:2006, AAMI TIR 12:2004 and other respective standards

* 5.5mm rods and even sizes pedicular screws available upon request

Additional Information:

Code	Product Name
Pedicle Screw	
TP-5525	PS® Pedicle Screw Set 5.5x25mm
TP-5530	PS® Pedicle Screw Set 5.5x30mm
TP-5535	PS® Pedicle Screw Set 5.5x35mm
TP-5540	PS® Pedicle Screw Set 5.5x40mm
TP-5545	PS® Pedicle Screw Set 5.5x45mm
TP-5550	PS® Pedicle Screw Set 5.5x50mm
TP-5555	PS® Pedicle Screw Set 5.5x55mm
TP-5560	PS® Pedicle Screw Set 5.5x60mm
TP-6525	PS® Pedicle Screw Set 6.5x25mm
TP-6530	PS® Pedicle Screw Set 6.5x30mm
TP-6535	PS® Pedicle Screw Set 6.5x35mm
TP-6540	PS® Pedicle Screw Set 6.5x40mm
TP-6545	PS® Pedicle Screw Set 6.5x45mm
TP-6550	PS® Pedicle Screw Set 6.5x50mm
TP-6555	PS® Pedicle Screw Set 6.5x55mm
TP-6560	PS® Pedicle Screw Set 6.5x60mm
TP-7525	PS® Pedicle Screw Set 7.5x25mm
TP-7530	PS® Pedicle Screw Set 7.5x30mm
TP-7535	PS® Pedicle Screw Set 7.5x35mm
TP-7540	PS® Pedicle Screw Set 7.5x40mm
TP-7545	PS® Pedicle Screw Set 7.5x45mm
TP-7550	PS® Pedicle Screw Set 7.5x50mm
TP-7555	PS® Pedicle Screw Set 7.5x55mm
TP-7560	PS® Pedicle Screw Set 7.5x60mm
Multi-Axial Screw	
TM-4025	PS® Multi-Axial Screw Set 4.0x25mm
TM-4030	PS® Multi-Axial Screw Set 4.0x30mm
TM-4035	PS® Multi-Axial Screw Set 4.0x35mm
TM-4040	PS® Multi-Axial Screw Set 4.0x40mm
TM-4045	PS® Multi-Axial Screw Set 4.0x45mm
TM-4050	PS® Multi-Axial Screw Set 4.0x50mm
TM-4525	PS® Multi-Axial Screw Set 4.5x25mm
TM-4530	PS® Multi-Axial Screw Set 4.5x30mm
TM-4535	PS® Multi-Axial Screw Set 4.5x35mm
TM-4540	PS® Multi-Axial Screw Set 4.5x40mm
TM-4545	PS® Multi-Axial Screw Set 4.5x45mm
TM-4550	PS® Multi-Axial Screw Set 4.5x50mm
TM-4555	PS® Multi-Axial Screw Set 4.5x55mm
TM-4560	PS® Multi-Axial Screw Set 4.5x60mm
TM-5525	PS® Multi-Axial Screw Set 5.5x25mm
TM-5530	PS® Multi-Axial Screw Set 5.5x30mm
TM-5535	PS® Multi-Axial Screw Set 5.5x35mm
TM-5540	PS® Multi-Axial Screw Set 5.5x40mm
TM-5545	PS® Multi-Axial Screw Set 5.5x45mm
TM-5550	PS® Multi-Axial Screw Set 5.5x50mm
TM-5555	PS® Multi-Axial Screw Set 5.5x55mm
TM-5560	PS® Multi-Axial Screw Set 5.5x60mm
TM-6525	PS® Multi-Axial Screw Set 6.5x25mm
TM-6530	PS® Multi-Axial Screw Set 6.5x30mm
TM-6535	PS® Multi-Axial Screw Set 6.5x35mm
TM-6540	PS® Multi-Axial Screw Set 6.5x40mm
TM-6545	PS® Multi-Axial Screw Set 6.5x45mm
TM-6550	PS® Multi-Axial Screw Set 6.5x50mm
TM-6555	PS® Multi-Axial Screw Set 6.5x55mm
TM-6560	PS® Multi-Axial Screw Set 6.5x60mm
TM-7525	PS® Multi-Axial Screw Set 7.5x25mm
TM-7530	PS® Multi-Axial Screw Set 7.5x30mm
TM-7535	PS® Multi-Axial Screw Set 7.5x35mm
TM-7540	PS® Multi-Axial Screw Set 7.5x40mm
TM-7545	PS® Multi-Axial Screw Set 7.5x45mm
TM-7550	PS® Multi-Axial Screw Set 7.5x50mm
TM-7555	PS® Multi-Axial Screw Set 7.5x55mm
TM-7560	PS® Multi-Axial Screw Set 7.5x60mm

Code	Product Name
Multi-Axial Revision Screw	
TM-8030	PS® Multi-Axial Screw Set 8.0x30mm
TM-8035	PS® Multi-Axial Screw Set 8.0x35mm
TM-8040	PS® Multi-Axial Screw Set 8.0x40mm
TM-8045	PS® Multi-Axial Screw Set 8.0x45mm
TM-8050	PS® Multi-Axial Screw Set 8.0x50mm
TM-8055	PS® Multi-Axial Screw Set 8.0x55mm
TM-8060	PS® Multi-Axial Screw Set 8.0x60mm
Multi-Axial Cement Type Screw	
TC-5525	PS® Multi-Axial Screw Cement Type Set 5.5X25mm
TC-5530	PS® Multi-Axial Screw Cement Type Set 5.5X30mm
TC-5535	PS® Multi-Axial Screw Cement Type Set 5.5X35mm
TC-5540	PS® Multi-Axial Screw Cement Type Set 5.5X40mm
TC-5545	PS® Multi-Axial Screw Cement Type Set 5.5X45mm
TC-5550	PS® Multi-Axial Screw Cement Type Set 5.5X50mm
TC-5555	PS® Multi-Axial Screw Cement Type Set 5.5X55mm
TC-5560	PS® Multi-Axial Screw Cement Type Set 5.5X60mm
TC-6535	PS® Multi-Axial Screw Cement Type Set 6.5X35mm
TC-6540	PS® Multi-Axial Screw Cement Type Set 6.5X40mm
TC-6545	PS® Multi-Axial Screw Cement Type Set 6.5X45mm
TC-6550	PS® Multi-Axial Screw Cement Type Set 6.5X50mm
TC-6555	PS® Multi-Axial Screw Cement Type Set 6.5X55mm
TC-6560	PS® Multi-Axial Screw Cement Type Set 6.5X60mm
TC-7525	PS® Multi-Axial Screw Cement Type Set 7.5X25mm
TC-7530	PS® Multi-Axial Screw Cement Type Set 7.5X30mm
TC-7535	PS® Multi-Axial Screw Cement Type Set 7.5X35mm
TC-7540	PS® Multi-Axial Screw Cement Type Set 7.5X40mm
TC-7545	PS® Multi-Axial Screw Cement Type Set 7.5X45mm
TC-7555	PS® Multi-Axial Screw Cement Type Set 7.5X55mm
TC-7560	PS® Multi-Axial Screw Cement Type Set 7.5X60mm
Mono-Axial Reduction Screw	
TLM-5525	PS® Reduction Screw Mono Set 5.5x25mm
TLM-5530	PS® Reduction Screw Mono Set 5.5x30mm
TLM-5535	PS® Reduction Screw Mono Set 5.5x35mm
TLM-5540	PS® Reduction Screw Mono Set 5.5x40mm
TLM-5545	PS® Reduction Screw Mono Set 5.5x45mm
TLM-5550	PS® Reduction Screw Mono Set 5.5x50mm
TLM-5555	PS® Reduction Screw Mono Set 5.5x55mm
TLM-5560	PS® Reduction Screw Mono Set 5.5x60mm
TLM-6530	PS® Reduction Screw Mono Set 6.5x30mm
TLM-6535	PS® Reduction Screw Mono Set 6.5x35mm
TLM-6540	PS® Reduction Screw Mono Set 6.5x40mm
TLM-6545	PS® Reduction Screw Mono Set 6.5x45mm
TLM-6550	PS® Reduction Screw Mono Set 6.5x50mm
TLM-6555	PS® Reduction Screw Mono Set 6.5x55mm
TLM-6560	PS® Reduction Screw Mono Set 6.5x60mm
TLM-7530	PS® Reduction Screw Mono Set 7.5x30mm
TLM-7535	PS® Reduction Screw Mono Set 7.5x35mm
TLM-7540	PS® Reduction Screw Mono Set 7.5x40mm
TLM-7545	PS® Reduction Screw Mono Set 7.5x45mm
TLM-7550	PS® Reduction Screw Mono Set 7.5x50mm
TLM-7555	PS® Reduction Screw Mono Set 7.5x55mm
TLM-7560	PS® Reduction Screw Mono Set 7.5x60mm
Multi-Axial Reduction Screw	
TL-4525	PS® Reduction Screw Multi Set 4.5x25mm
TL-4530	PS® Reduction Screw Multi Set 4.5x30mm
TL-4535	PS® Reduction Screw Multi Set 4.5x35mm
TL-4540	PS® Reduction Screw Multi Set 4.5x40mm
TL-4545	PS® Reduction Screw Multi Set 4.5x45mm
TL-4550	PS® Reduction Screw Multi Set 4.5x50mm
TL-4555	PS® Reduction Screw Multi Set 4.5x55mm
TL-4560	PS® Reduction Screw Multi Set 4.5x60mm
TL-5525	PS® Reduction Screw Multi Set 5.5x25mm
TL-5530	PS® Reduction Screw Multi Set 5.5x30mm
TL-5535	PS® Reduction Screw Multi Set 5.5x35mm
TL-5540	PS® Reduction Screw Multi Set 5.5x40mm
TL-5545	PS® Reduction Screw Multi Set 5.5x45mm
TL-5550	PS® Reduction Screw Multi Set 5.5x50mm

TL-5555	PS® Reduction Screw Multi Set 5.5x55mm
TL-5560	PS® Reduction Screw Multi Set 5.5x60mm
TL-6530	PS® Reduction Screw Multi Set 6.5x30mm
TL-6535	PS® Reduction Screw Multi Set 6.5x35mm
TL-6540	PS® Reduction Screw Multi Set 6.5x40mm
TL-6545	PS® Reduction Screw Multi Set 6.5x45mm
TL-6550	PS® Reduction Screw Multi Set 6.5x50mm
TL-6555	PS® Reduction Screw Multi Set 6.5x55mm
TL-6560	PS® Reduction Screw Multi Set 6.5x60mm
TL-7530	PS® Reduction Screw Multi Set 7.5x30mm
TL-7535	PS® Reduction Screw Multi Set 7.5x35mm
TL-7540	PS® Reduction Screw Multi Set 7.5x40mm
TL-7545	PS® Reduction Screw Multi Set 7.5x45mm
TL-7550	PS® Reduction Screw Multi Set 7.5x50mm
TL-7555	PS® Reduction Screw Multi Set 7.5x55mm
TL-7560	PS® Reduction Screw Multi Set 7.5x60mm

Code	Product Name
Multi-Axial Iliac Screw	
TI-7560	PS® Multi-Axial Iliac Screw Set 7.5x60mm
TI-7570	PS® Multi-Axial Iliac Screw Set 7.5x70mm
TI-7580	PS® Multi-Axial Iliac Screw Set 7.5x80mm
TI-7590	PS® Multi-Axial Iliac Screw Set 7.5x90mm
TI-7500	PS® Multi-Axial Iliac Screw Set 7.5x100mm
TI-7510	PS® Multi-Axial Iliac Screw Set 7.5x110mm
TI-8060	PS® Multi-Axial Iliac Screw Set 8.0x60mm
TI-8070	PS® Multi-Axial Iliac Screw Set 8.0x70mm
TI-8080	PS® Multi-Axial Iliac Screw Set 8.0x80mm
TI-8090	PS® Multi-Axial Iliac Screw Set 8.0x90mm
TI-8000	PS® Multi-Axial Iliac Screw Set 8.0x100mm
TI-8010	PS® Multi-Axial Iliac Screw Set 8.0x110mm
TI-9060	PS® Multi-Axial Iliac Screw Set 9.0x60mm
TI-9070	PS® Multi-Axial Iliac Screw Set 9.0x70mm
TI-9080	PS® Multi-Axial Iliac Screw Set 9.0x80mm
TI-9090	PS® Multi-Axial Iliac Screw Set 9.0x90mm
TI-9000	PS® Multi-Axial Iliac Screw Set 9.0x100mm
TI-9010	PS® Multi-Axial Iliac Screw Set 9.0x110mm
Rod	
TR-0050	PS® Rod 6.0 x 50mm
TR-0060	PS® Rod 6.0 x 60mm
TR-0070	PS® Rod 6.0 x 70mm
TR-0080	PS® Rod 6.0 x 80mm
TR-0090	PS® Rod 6.0 x 90mm
TR-0100	PS® Rod 6.0 x 100mm
TR-0120	PS® Rod 6.0 x 120mm
TR-0140	PS® Rod 6.0 x 140mm
TR-0160	PS® Rod 6.0 x 160mm
TR-0200	PS® Rod 6.0 x 200mm
TR-0400	PS® Rod 6.0 x 400mm
TR-0500	PS® Rod 6.0 x 500mm
* 5.5mm rods available upon request	
CoCr Vitallium Rod	
TVR-0140	PS® Rod 6.0 x 140mm
TVR-0160	PS® Rod 6.0 x 160mm
TVR-0200	PS® Rod 6.0 x 200mm
TVR-0400	PS® Rod 6.0 x 400mm
TVR-0500	PS® Rod 6.0 x 500mm
* 5.5mm rods available upon request	
Multi-Axial Transverse Link	
TT-0030	PS® Multi-Axial Transverse Link S
TT-0034	PS® Multi-Axial Transverse Link M
TT-0040	PS® Multi-Axial Transverse Link L
TT-0050	PS® Multi-Axial Transverse Link XL
Set Screw	
TS-0010	PS® Set Screw
Domino	
TDS-2205	PS® Domino Single
TDD-2210	PS® Domino Double
Lateral Connector	
TLC-1100	PS® Multi-Axial Offset Lateral Connector
TLC-1110	PS® Lateral Connector

Additional Information:



WARNING:

BY LAW, THIS DEVICE CAN BE SOLD BY OR ON THE ORDER OF A PHYSICIAN.

System elements can only be implanted by a surgeon with a good working knowledge of the device, its applications, the instruments and the required surgical technique.



WARNING:

Please contact Tria Spine or authorized representative for further information about this product.

Tria Spine Medikal Ltd. Sti

Ivedik Mah. 1551. Cad. No: 35/33
06378 Yenimahalle – Ankara /TURKEY
Tel: +90 312 2194104
Fax: +90 312 2194103
E-mail: mail@triaspine.com

www.triaspine.com



Description:

PS® Mini Occipito-Cervico-Thoracic System is a posterior spinal fixation system for stabilization of the upper spine (occiput-T3) in the aim of the treatment of occipito- cervico-thoracic spine diseases.



ADONIS®

Transforaminal lumbale interkorporelle Fusion

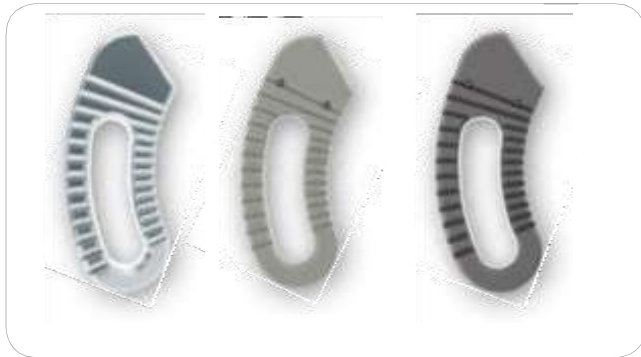
TLIF



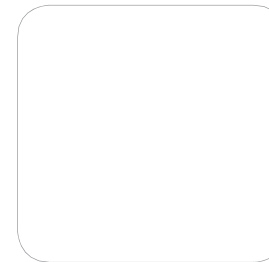
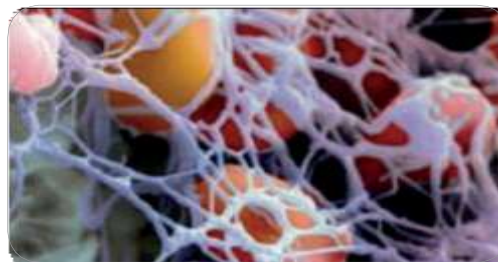
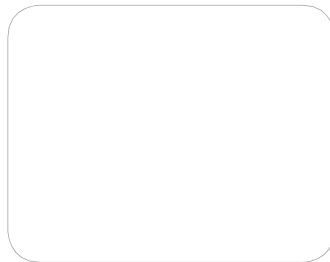
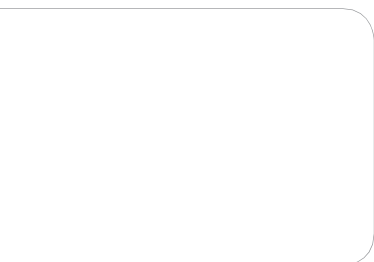
ADONIS® -TLIF

Interbody Device System

Produktspezifische Vorteile



- modular
- integer
- stabil
- anatomisch
- osseointegrativ



ADONIS®-TLIF Classic

ADONIS® Classic ist ein solides Titan-Interbody-Device-System und stellt somit eine allseits anerkannte Produktlinie für thorakolumbale Indikationen dar. Kombiniert mit einem zuverlässigen und einfachen Instrumentarium wird ADONIS® Classic zu der Lösung für thorakolumbale, interkorporelle Fusionen. Die neuesten Erkenntnisse werden zur Herstellung von Titan-Implantatwerkstoffen mit maßgeschneiderten Oberflächeneigenschaften genutzt. Wir verwenden ausschließlich Titan Ti 6Al-4V ELI (nach DIN ISO 5832-3).



ADONIS®-TLIF Avantgarde

ADONIS® Avantgarde ist ein Implantat aus bioverträglichem PEEK-Optima® zur thorakolumbalen, interkorporellen Fusion und wird bei degenerativen Bandscheibenerkrankungen und Instabilitäten eingesetzt. Das röntgentransparente Material ermöglicht eine schnelle und einfache Beurteilung der Knochenstruktur und des Fusionsprozesses. Röntgenmarker dienen der Positionsverifizierung. Die mechanische Festigkeit von 3,6 GPa ermöglicht eine optimale Kraftübertragung zwischen dem Implantatmaterial und dem natürlichen Knochen. Dadurch werden die Prozesse der Knochenheilung stimuliert. Unser PEEK-Material ist nach ISO 10993 getestet und nach USP-VI klassifiziert, die entsprechenden FDA Device und Drug Master Files sind erhältlich. PEEK ist hinsichtlich der Eigenschaften und den Zulassungen für die Verwendung als Implantatwerkstoff prädestiniert.



Classic Titanium

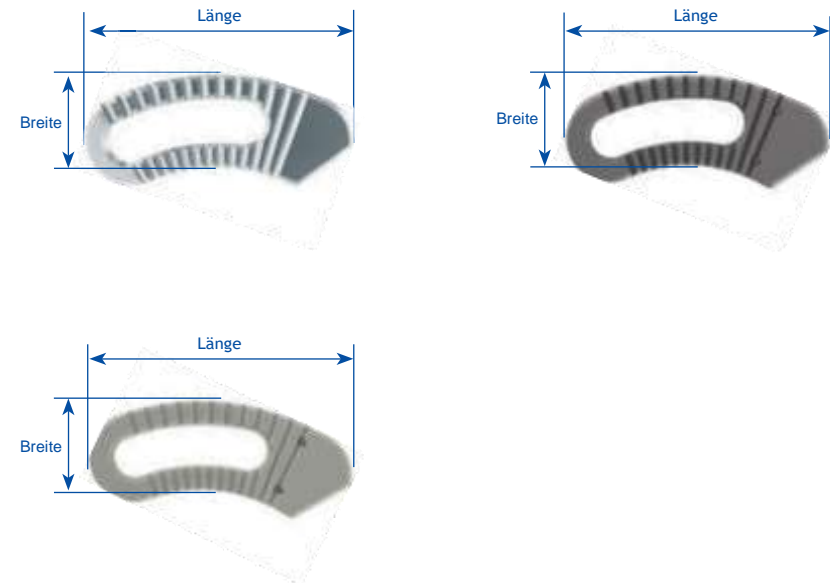
Art.Nr.	Bezeichnung	Länge	Breite	Höhe	Winkel
1801051207	Adonis TLIF Ti 35x12x07	35	12	07	
1801051209	Adonis TLIF Ti 35x12x09	35	12	09	
1801051211	Adonis TLIF Ti 35x12x11	35	12	11	
1801051213	Adonis TLIF Ti 35x12x13	35	12	13	
1801051215	Adonis TLIF Ti 35x12x15	35	12	15	
1801091207	Adonis TLIF Ti 35x12x07 5°	35	12	07	5°
1801091209	Adonis TLIF Ti 35x12x09 5°	35	12	09	5°
1801091211	Adonis TLIF Ti 35x12x11 5°	35	12	11	5°
1801091213	Adonis TLIF Ti 35x12x13 5°	35	12	13	5°
1801091215	Adonis TLIF Ti 35x12x15 5°	35	12	15	5°

Exclusive R-PEEK-Ti-coated

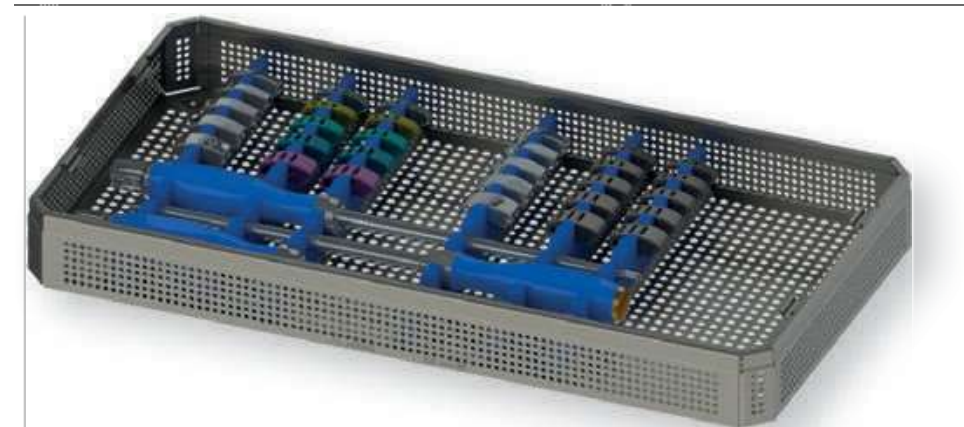
Art.Nr.	Bezeichnung	Länge	Breite	Höhe	Winkel
1803061207	Adonis-TLIF R-PEEK-Ti 35x12x07	35	12	07	
1803061209	Adonis-TLIF R-PEEK-Ti 35x12x09	35	12	09	
1803061211	Adonis-TLIF R-PEEK-Ti 35x12x11	35	12	11	
1803061213	Adonis-TLIF R-PEEK-Ti 35x12x13	35	12	13	
1803061215	Adonis-TLIF R-PEEK-Ti 35x12x15	35	12	15	

Avantgarde PEEK

Art.Nr.	Bezeichnung	Länge	Breite	Höhe	Winkel
1801041207	Adonis TLIF PEEK 35x12x07	35	12	07	
1801041209	Adonis TLIF PEEK 35x12x09	35	12	09	
1801041211	Adonis TLIF PEEK 35x12x11	35	12	11	
1801041213	Adonis TLIF PEEK 35x12x13	35	12	13	
1801041215	Adonis TLIF PEEK 35x12x15	35	12	15	
1801041307	Adonis TLIF PEEK 35x12x07 5°	35	12	07	5°
1801041309	Adonis TLIF PEEK 35x12x09 5°	35	12	09	5°
1801041311	Adonis TLIF PEEK 35x12x11 5°	35	12	11	5°
1801041313	Adonis TLIF PEEK 35x12x13 5°	35	12	13	5°
1801041315	Adonis TLIF PEEK 35x12x15 5°	35	12	15	5°



Art.Nr.	Bezeichnung	
1801011207 1801011209 1801011211 1801011213 1801011215 1801011307 1801011309 1801011311 1801011313 1801011315	TLIF Trial 35x12x07mm TLIF Trial 35x12x09mm TLIF Trial 35x12x11mm TLIF Trial 35x12x13mm TLIF Trial 35x12x15mm TLIF Trial 35x12x07mm 5° TLIF Trial 35x12x09mm 5° TLIF Trial 35x12x11mm 5° TLIF Trial 35x12x13mm 5° TLIF Trial 35x12x15mm 5°	
1801010403	TLIF Trial-Insenter	
1701010600	Extractor Handle	
1801010401	TLIF Insenter	
1801010000	Multiaxial TLIF Insenter	
1801010002	Slap Hammer	



BonOs® Inject

PMMA is been used in orthopedics for almost 50 years. Within that time the indication fields have been extended step by step until in the 80's PMMA cements were applied in spinal surgery, too. There, they serve to stabilize and fill cavities of erected vertebral bodies. For these specific indications BonOs® Inject was developed.

BonOs® Inject fulfills all requirements for bone cements in spinal surgery:

- a Suitable viscosity for Vertebroplasty and Kyphoplasty
- a Short mixing time, long application time
- a Rapid application viscosity due to improved cohesion
- a High radiopacity with 45% ZrO_2
- a Excellent mechanical properties
- a Low hardening temperature of about 70°C

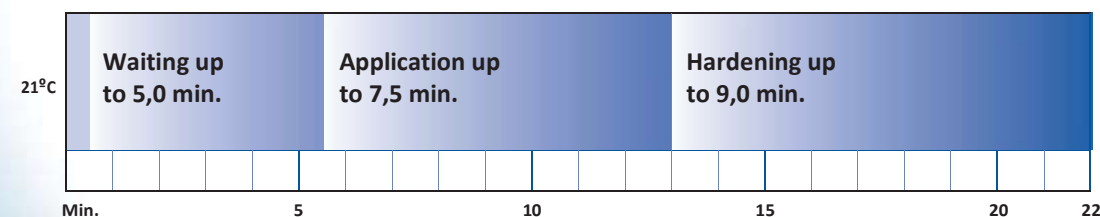
Long application time

Both components dash quickly to a homogenous paste with the right viscosity for percutaneous injection. After a short mixing time the surgeon has a long application time to apply BonOs® Inject without time pressure.

Max. Zeit [Min.] at 21°C

Mixing	0,5
Waiting	5,0
Application	7,5
Hardening	9,0

Temperature-Time Chart (e.g. 21°C)*



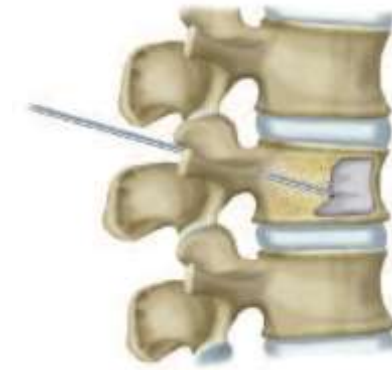
* For further information see the Instructions for Use

Test conditions

Application needle: \varnothing 3 mm, length 120 mm
Syringe capacity: 1 ml

Initially high viscosity for rapid application due to improved cohesion

The chemical composition of the polymers ensures a high initial cohesion and therefore reduces the risk of cement leakage. After a short waiting time the cement attains an ideal viscosity for application. That can be used for Vertebroplasty and Kyphoplasty.



Example of a cemented vertebra

Chemical composition

Powder (24 g)

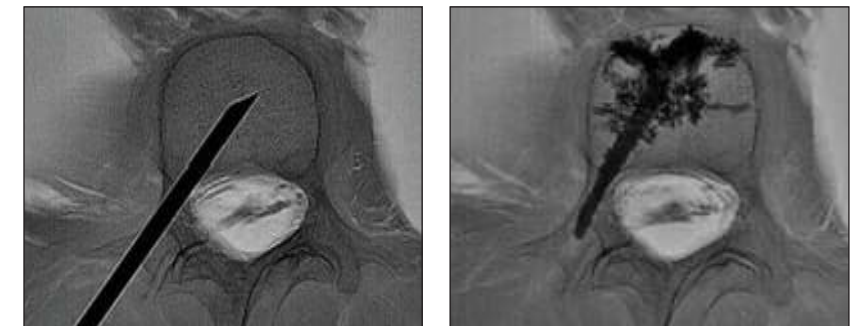
Poly (MMA)	10,95g
Poly (MA, MMA)	1,75g
Zirconium dioxid	10,80g
Benzoyl peroxid	0,50g

Liquid (10 ml)

MMA	9,93 ml
Dimethyl-p-toluidine	0,07 ml
Hydroquinone	60 ppm

High radiopacity

The addition of a high amount of zirconium dioxide (ZrO_2) allows an optimal X-ray visualization of BonOs® Inject for a safe use. Zirconium dioxide has a positive influence on the mechanical stability.



X-ray Images Cadaver Tests
© PD Dr. K. Wilhelm, Bonn

Good mechanical properties

The chemical composition of BonOs® Inject guarantees optimized mechanical properties which exceed the respective requirements of the ISO 5833 standard.

	ISO 5833	BonOs® Inject
Compression strength [MPa]	≥ 70	$122 \pm 1,5$
E-modulus [MPa]	≥ 1800	4240 ± 177
Bending strength [MPa]	≥ 50	$70 \pm 5,4$

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Mfg. : Orthopedic Implant & Instruments



SAMAY
Surgical

An **ISO 13485:2003**
Certified Company

CE
0801-1

**Product
Catalogue**





4.0 mm Pediatric Mono Screw (Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 401 & Titanium TT 401



Code No.	Length
SS 401-120	20 mm
SS 401-125	25 mm
SS 401-130	30 mm
SS 401-135	35 mm
SS 401-140	40 mm

5.0 mm Mono Screw (Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 402 & Titanium TT 402



Code No.	Length
SS 402-130	30 mm
SS 402-135	35 mm
SS 402-140	40 mm
SS 402-145	45 mm
SS 402-150	50 mm

6.0 mm Mono Screw (Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 403 & Titanium TT 403



Code No.	Length
SS 403-130	30 mm
SS 403-135	35 mm
SS 403-140	40 mm
SS 403-145	45 mm
SS 403-150	50 mm

4.0 mm Pediatric Poly Screw (Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 404 & Titanium TT 404



Code No.	Length
SS 404-120	20 mm
SS 404-125	25 mm
SS 404-130	30 mm
SS 404-135	35 mm
SS 404-140	40 mm

5.0 mm Poly Screw (Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 405 & Titanium TT 405



Code No.	Length
SS 405-130	30 mm
SS 405-135	35 mm
SS 405-140	40 mm
SS 405-145	45 mm
SS 405-150	50 mm

6.0 mm Poly Screw (Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 406 & Titanium TT 406

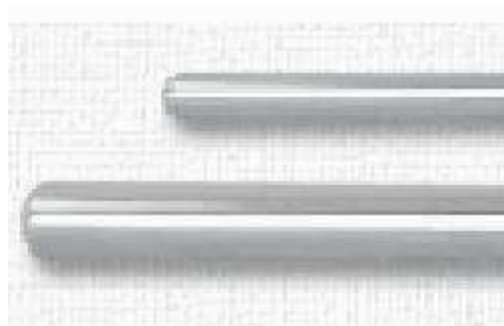


Code No.	Length
SS 406-130	30 mm
SS 406-135	35 mm
SS 406-140	40 mm
SS 406-145	45 mm
SS 406-150	50 mm



Connecting Road (Stainless Steel & Titanium)

Note: Define Code for
S.S. SS 427 & Titanium TT 427



Length	20 mm Dia. Code No.	30 mm Dia. Code No.	40 mm Dia. Code No.	50 mm Dia. Code No.
50 mm	SS 427-201	SS 427-301	SS 427-401	SS 427-501
75 mm	SS 427-202	SS 427-302	SS 427-402	SS 427-502
80 mm	SS 427-203	SS 427-303	SS 427-403	SS 427-503
100 mm	SS 427-204	SS 427-304	SS 427-404	SS 427-504
120 mm	SS 427-205	SS 427-305	SS 427-405	SS 427-505
125 mm	SS 427-206	SS 427-306	SS 427-406	SS 427-527
150 mm	SS 427-207	SS 427-307	SS 427-407	SS 427-507
200 mm	SS 427-208	SS 427-308	SS 427-408	SS 427-508
250 mm	SS 427-209	SS 427-309	SS 427-409	SS 427-509
300 mm	SS 427-210	SS 427-310	SS 427-410	SS 427-510
480 mm	SS 427-211	SS 427-311	SS 427-411	SS 427-511

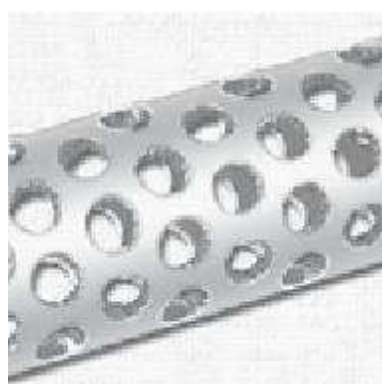
Anterior Cervical Plate (Titanium)



Code No.	Length
SS 429-020	20 mm
SS 429-025	25 mm
SS 429-030	30 mm
SS 429-035	35 mm
SS 429-040	40 mm
SS 429-045	45 mm
SS 429-050	50 mm
SS 429-055	55 mm
SS 429-060	60 mm
SS 429-065	65 mm
SS 429-070	70 mm
SS 429-075	75 mm
SS 429-080	80 mm
SS 429-085	85 mm
SS 429-090	90 mm
SS 429-095	95 mm
SS 429-100	100 mm
SS 429-105	105 mm
SS 429-110	110 mm

Cage (Stainless Steel & Titanium)

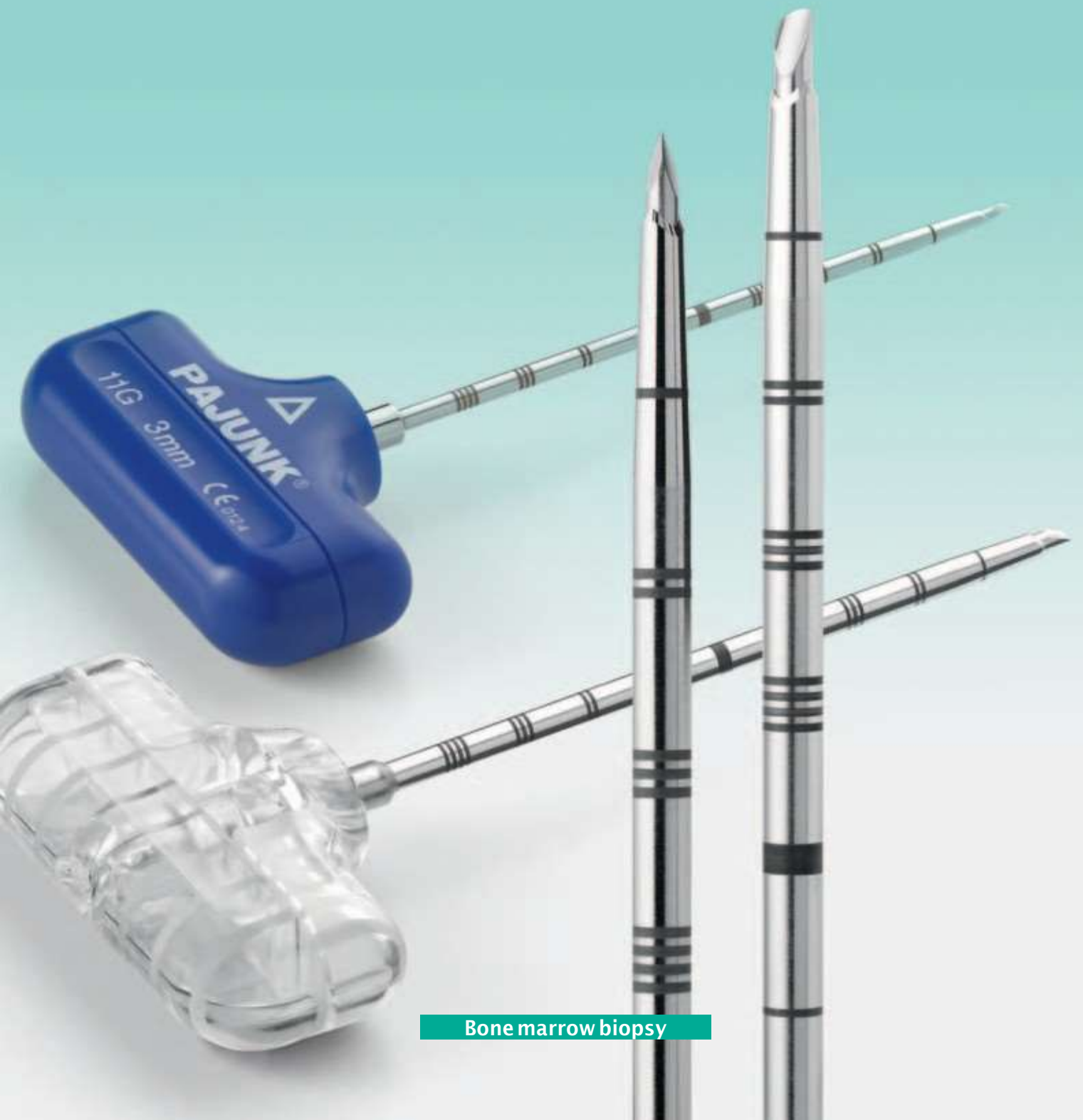
Note: Define Code for
S.S. SS 428 & Titanium TT 428



Length	10 mm Dia. Code No.	12 mm Dia. Code No.	14 mm Dia. Code No.	16 mm Dia. Code No.	18 mm Dia. Code No.	20 mm Dia. Code No.	22 mm Dia. Code No.	24 mm Dia. Code No.
20 mm	SS 428-120	SS 428-220	SS 428-320	SS 428-420	SS 428-520	SS 428-620	SS 428-720	SS 428-820
25 mm	SS 428-125	SS 428-225	SS 428-325	SS 428-425	SS 428-525	SS 428-625	SS 428-725	SS 428-825
30 mm	SS 428-130	SS 428-230	SS 428-330	SS 428-430	SS 428-530	SS 428-630	SS 428-730	SS 428-830
35 mm	SS 428-135	SS 428-235	SS 428-335	SS 428-435	SS 428-535	SS 428-635	SS 428-735	SS 428-835
40 mm	SS 428-140	SS 428-240	SS 428-340	SS 428-440	SS 428-540	SS 428-640	SS 428-740	SS 428-840
45 mm	SS 428-145	SS 428-245	SS 428-345	SS 428-445	SS 428-545	SS 428-645	SS 428-745	SS 428-845
50 mm	SS 428-150	SS 428-250	SS 428-350	SS 428-450	SS 428-550	SS 428-650	SS 428-750	SS 428-850

PAJUNK®

TrokaBone / TrokaCut
Aspiration and puncture cannulas
for bone marrow biopsy

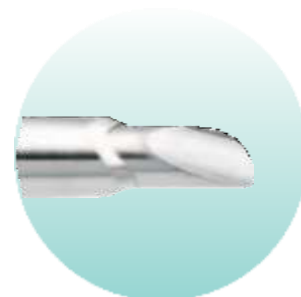


Bone marrow biopsy

TrokaCut and TrokaBone

Cannula systems for bone marrow biopsy

The manufacture of cannula systems for biopsy has been the core competence of PAJUNK® for more than 45 years. Together with doctors from different fields, PAJUNK® develops sophisticated solutions for bone marrow biopsy, fine-needle biopsy, cutting and punch biopsy, brachytherapy and tumour markers. PAJUNK® offers three systems in the field of bone marrow biopsy: TrokaCut, TrokaBone and TrokaBone Sternal. They differ with respect to material usage, design and the field of application.



Tip with bevelled hollow grind

TrokaCut

*the combined aspiration and punch
cannula for pelvic crust puncture*



The semi-transparent plastic bayonet lock of TrokaCut allows the outer cannula and full stylet to be permanently connected to each other.

TrokaBone

*the combined aspiration and punch
cannula for pelvic crest puncture*



A stable metal anchoring system is used to fasten the outer cannula in the handle for TrokaBone. This complete system is manufactured from robust materials and is characterised by its excellent stability and the ergonomic handle.



Tip with bevelled hollow grind



Tip with trocar grind

TrokaBone Sternal

*the puncture set for safe aspiration
of bone marrow from the pelvic and
sternum region*



Tip with bevelled grind

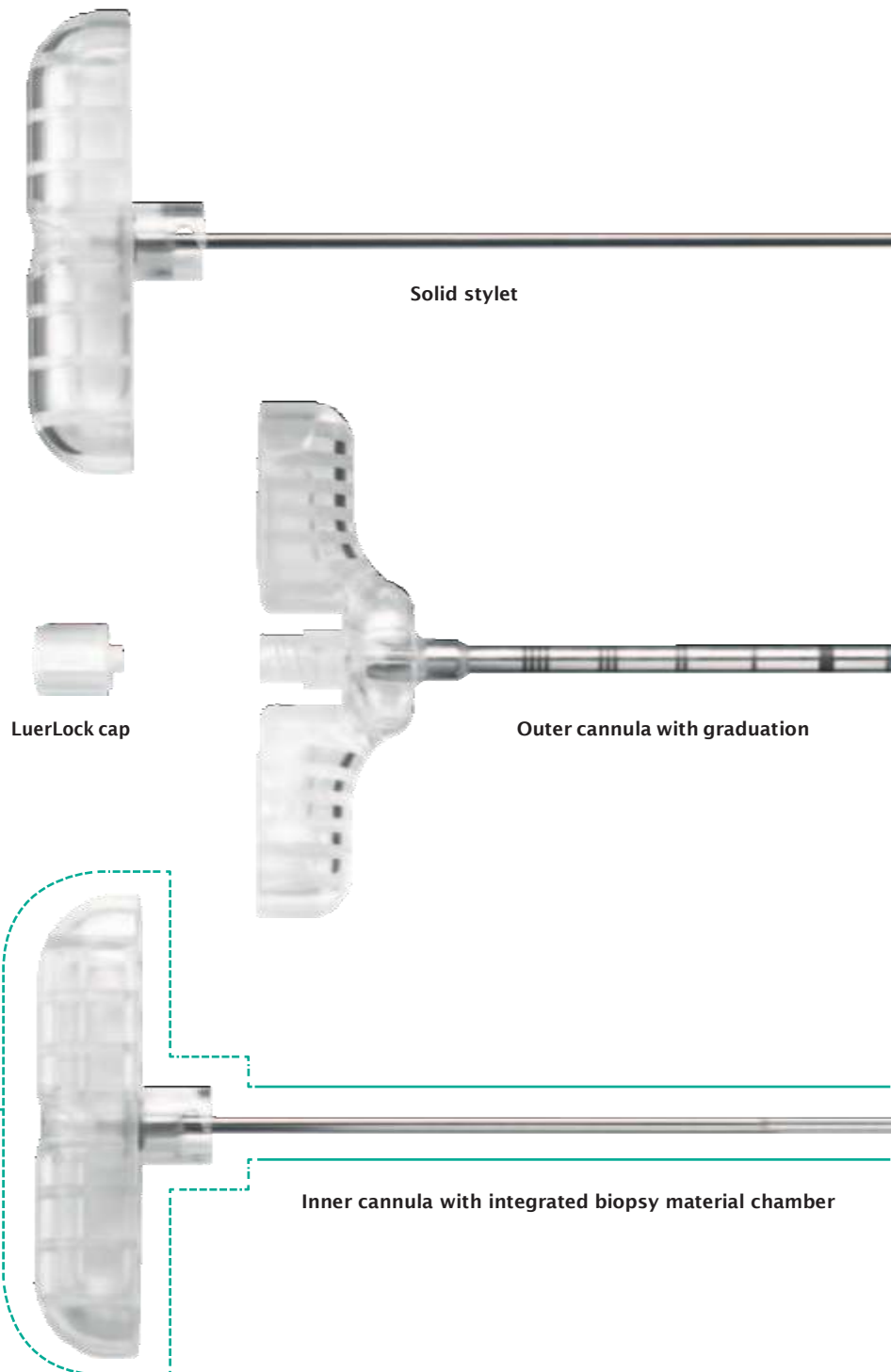
TrokaCut

The complete system for bone marrow puncture

The TrokaCut puncture set of equipment from PAJUNK® is a cost effective complete system for the extraction of bone marrow samples. It is very easy to use during puncture and aspiration.

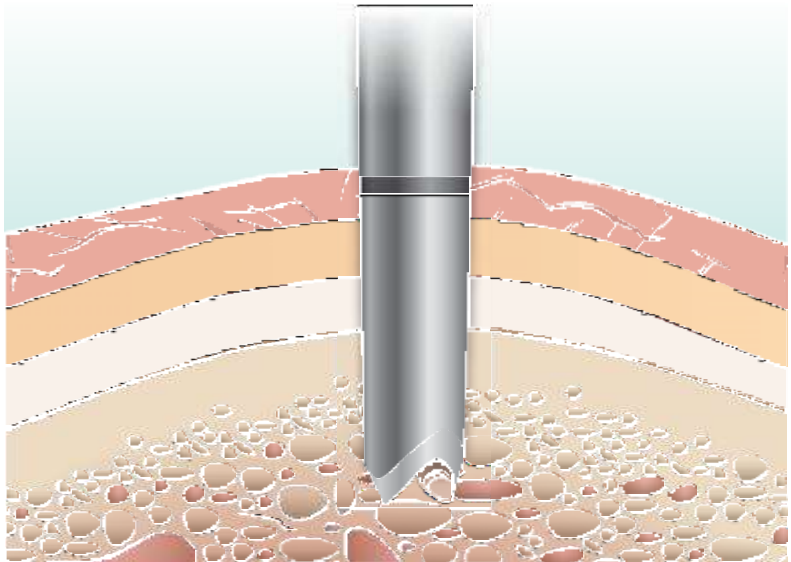
Single biopsy

The TrokaCut set includes a stable full stylet with a sharp tip and bevelled hollow grind as well as an outer cannula with ejection stylet that are both provided with a graduation. The introductory aid covers the sharp tip of the outer cannula when extracting biopsy material and so prevents injuries.



Biopsy safety

It is recommended to use an inner cannula with a biopsy material chamber for a safe biopsy. This inner cannula collects the sample when penetrating and can be pulled out for extraction without having to change the position of the outer cannula.



The outer cannula with its very sharp, wavelike tip penetrates the inside of the bone under rotary movements without problem.



Introductory aid

Ejection stylet with graduation

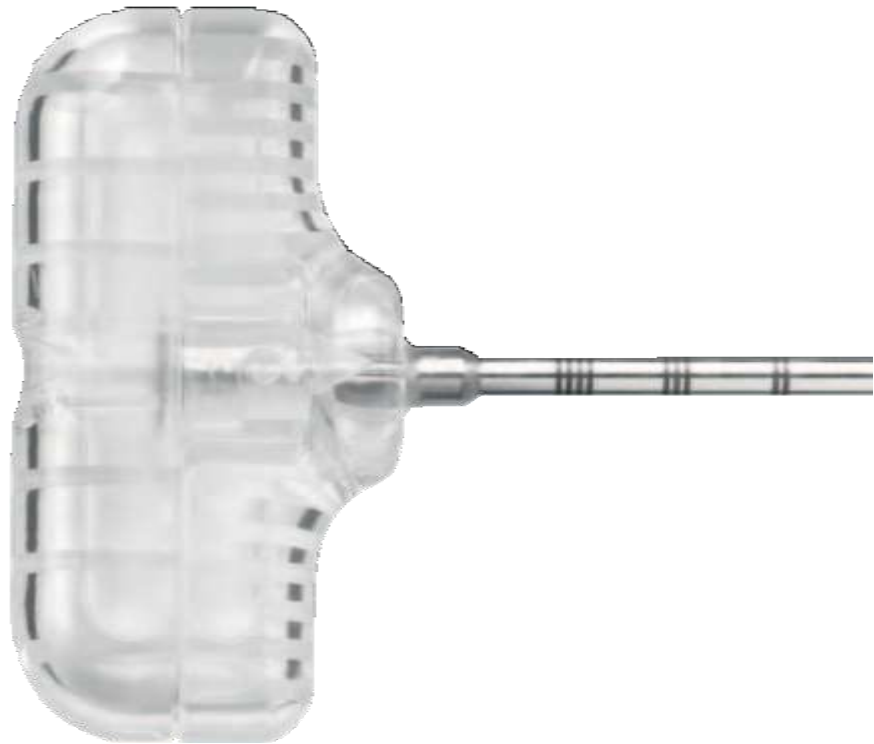


Integrated biopsy material chamber

The safe lock

TrokaCut with bayonet lock

The outer cannula is advanced together with the full stylet into the bone wall by turning clockwise and anticlockwise while applying firm and constant pressure. When it has penetrated and the resistance is reduced, the stylet is released from the bayonet lock, i.e. turned by 90° and pulled out. The outer cannula with its very sharp, wavelike tip continues to penetrate the inside of the bone under rotary movements without problem. The cannula tip is cylindrical and tapers towards the front. This eases collection and subsequent extraction of the sample. At the same time, its conical shape contributes to the tissue cylinder maintaining its structure during tissue extraction.



The essential features at a glance:

- ➔ anatomically shaped handle
- ➔ extremely sharp serrated tip of the outer cannula
- ➔ full stylet made of stainless steel with high stability
- ➔ tapered outer cannula for simplified sample extraction
- ➔ safe sample extraction by specially shaped cannula shaft
- ➔ aspiration connection with LuerLock connector
- ➔ specially shaped internal lumen
- ➔ bayonet lock



Bayonet lock
Full stylet and inner cannula are securely connected to the outer cannula using a bayonet lock.



Cannula tip with sharp bevelled hollow grind

⇒ simplifies puncture of the pelvic crest in interaction with the rotary movements and pressure



Sharp serrated tip of the outer cannula

⇒ enables continued penetration of the outer cannula in the inside of the bone after removal of the full stylet and collection of the bone marrow sample



Inner cannula with integrated biopsy material chamber

⇒ additional biopsy safety and simple extraction

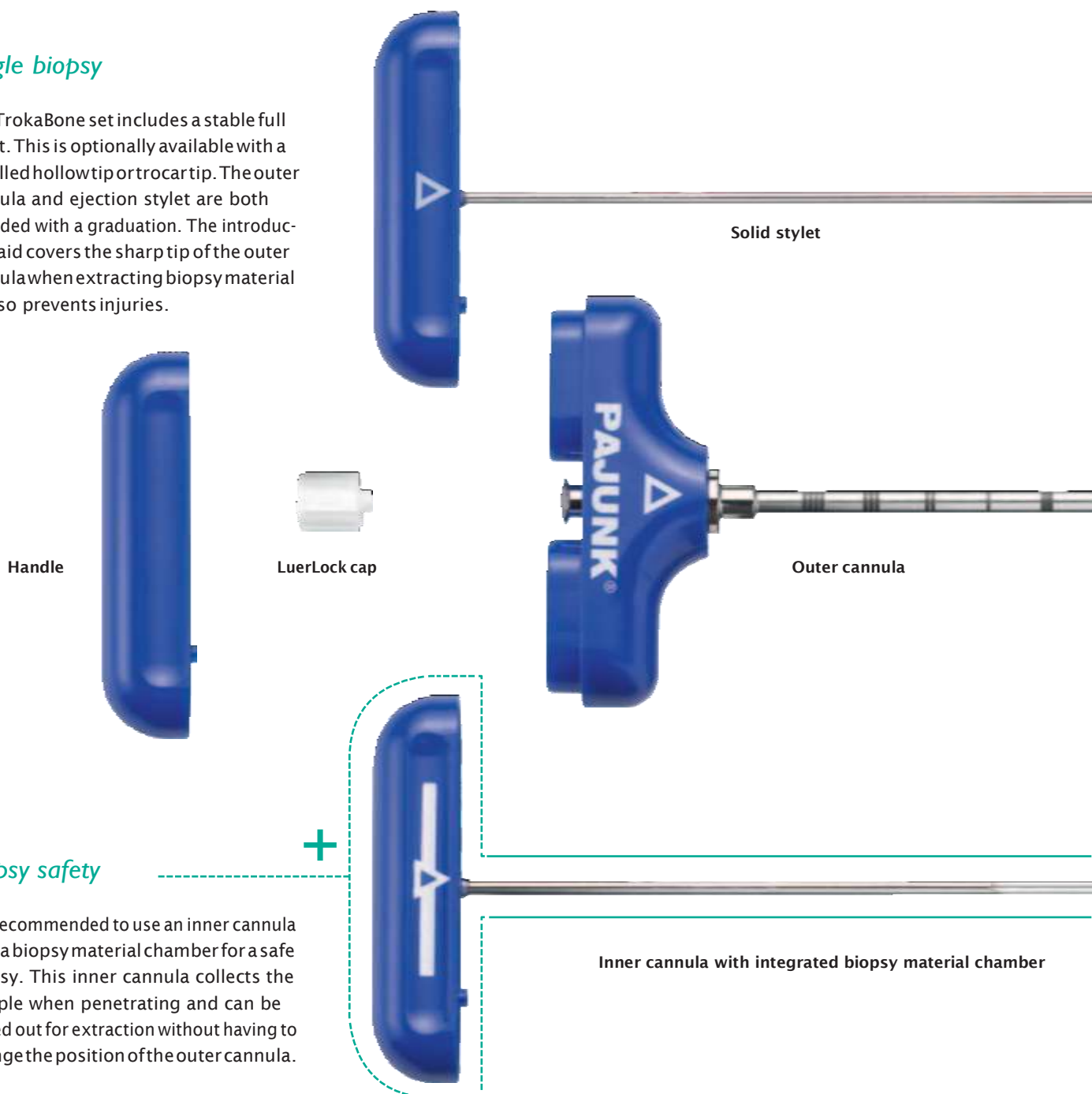
TrokaBone

The robust complete system with stainless steel connection

The TrokaBone puncture set of equipment from PAJUNK® consists of a modular system for the extraction of bone marrow samples. This set is very easy to use for puncture and aspiration. Fitted with an ergonomic handle and manufactured in robust stainless steel, TrokaBone is characterised by its high level of stability.

Single biopsy

The TrokaBone set includes a stable full stylet. This is optionally available with a bevelled hollow tip or trocar tip. The outer cannula and ejection stylet are both provided with a graduation. The introductory aid covers the sharp tip of the outer cannula when extracting biopsy material and so prevents injuries.



Biopsy safety

It is recommended to use an inner cannula with a biopsy material chamber for a safe biopsy. This inner cannula collects the sample when penetrating and can be pulled out for extraction without having to change the position of the outer cannula.



Robust anchoring system made of metal with LuerLock connection.



Introductory aid

Ejection stylet with graduation



Integrated biopsy material chamber

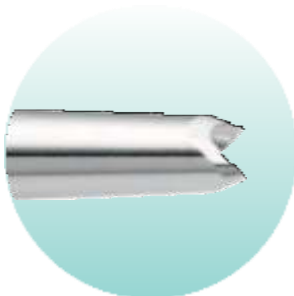
TrokaBone

Biopsy cannula with alternative tip geometries

A bevelled tip or trocar tip is used to puncture at the pelvic crest. The puncture cannula is advanced forward into the bone wall under clockwise / counter clockwise rotation while applying firm and constant pressure. When it has penetrated and the resistance is reduced, the stylet is pulled out. The outer cannula has a very sharp, serrated tip. The cannula continues to penetrate into the inside of the bone under rotary movements without problem. The cannula tip is cylindrical and tapers towards the front. This eases collection and subsequent extraction of the sample. At the same time, its conical shape contributes to the tissue cylinder maintaining its structure during tissue extraction.

The essential features at a glance:

- ➔ anatomically shaped handle
- ➔ extremely sharp serrated tip of the outer cannula
- ➔ full stylet made of stainless steel with high stability
- ➔ cannula versions with bevelled tip, trocar tip and inner cannula
- ➔ tapered outer cannula for simplified sample extraction
- ➔ specially shaped internal lumen
- ➔ aspiration connection with LuerLock connector



Tapered cannula tip, serrated tip



Cutting tip with bevelled hollow grind



Sharp tip with trocar grind

TrokaBone Sternal

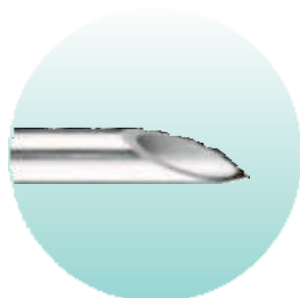
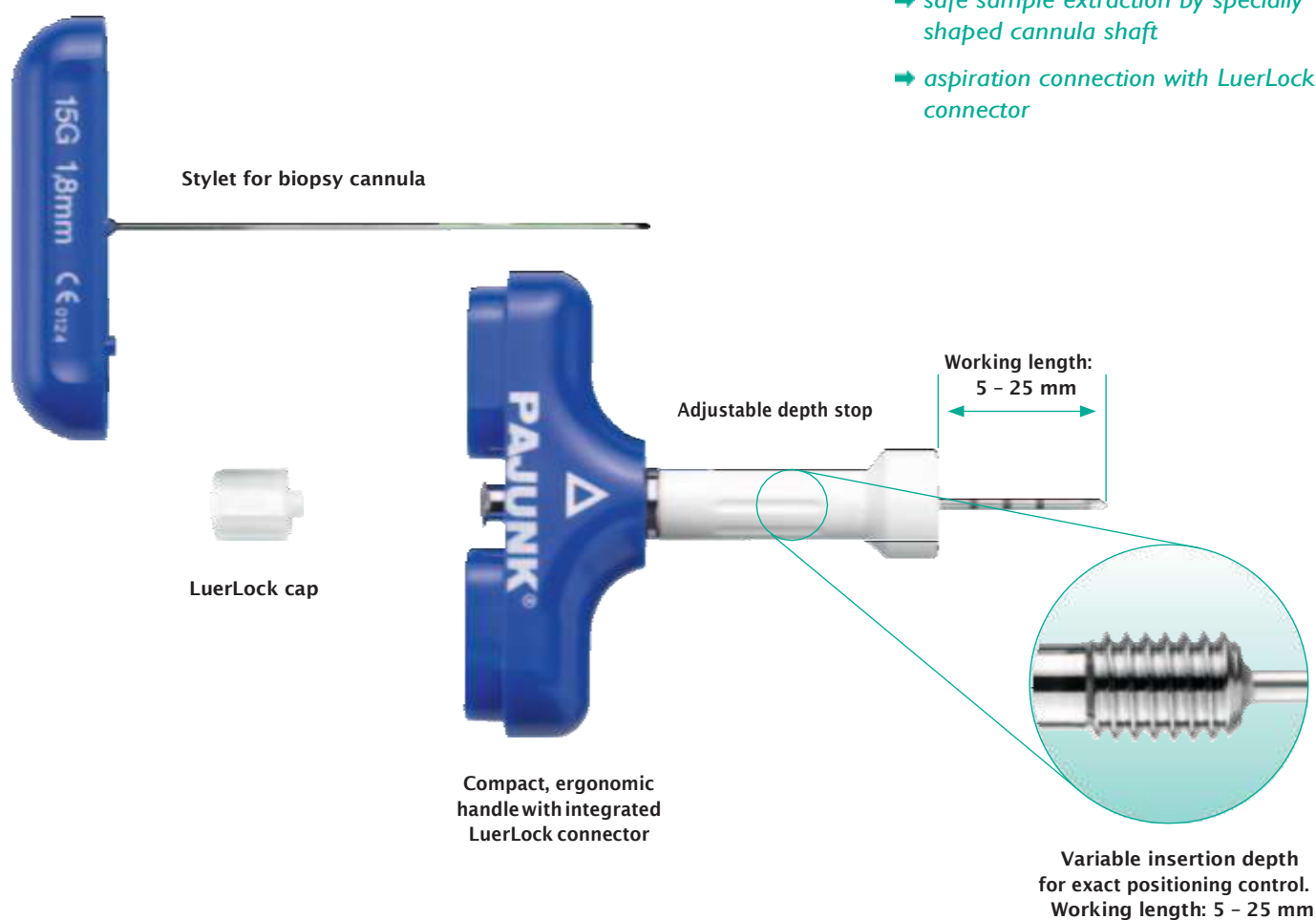
Puncture set of equipment for single biopsy

TrokaBone Sternal was developed by PAJUNK® for simple and safe aspiration of bone marrow from the pelvic and sternum region.

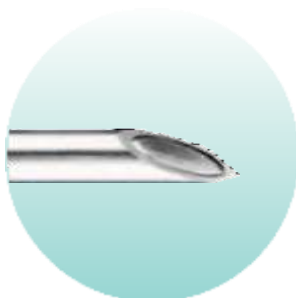
The ergonomically shaped handle and the extremely sharp cannula tip guarantees ease of use during puncture and aspiration.

The essential features at a glance:

- ➔ anatomically shaped handle
- ➔ extremely sharp cannula tip
- ➔ puncture cannula made of stainless steel with high stability
- ➔ safe sample extraction by specially shaped cannula shaft
- ➔ aspiration connection with LuerLock connector



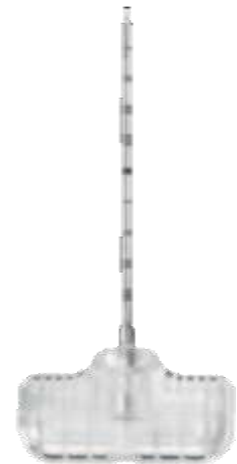
Cannula tip with sharp grind



Precise fit grind between outer cannula and stylet

TrokaCut

Product	Size	Art. No.	PU
Set for bone marrow biopsy with bevelled hollow tip	13 G x 100 mm (2.4 mm)	1147-1C010	5
	11 G x 100 mm (3.0 mm)	1147-1E010	5
	11 G x 150 mm (3.0 mm)	1147-1E015	5
	8 G x 100 mm (4.0 mm)	1147-1I010	5
	8 G x 150 mm (4.0 mm)	1147-1I015	5
Set for bone marrow biopsy with bevelled hollow tip and inner cannula	11 G x 100 mm (3.0 mm)	1147-6E010	5
	8 G x 100 mm (4.0 mm)	1147-6I010	5



TrokaBone

Product	Size	Bevelled hollow tip Trocar tip		PU
		Art. No.	Art. No.	
Set for bone marrow biopsy	13 G x 100 mm (2.4 mm)	1145-1C010	1145-2C010	5
	11 G x 100 mm (3.0 mm)	1145-1E010	1145-2E010	5
	11 G x 150 mm (3.0 mm)	1145-1E015	1145-2E015	5
	8 G x 100 mm (4.0 mm)	1145-1I010	1145-2I010	5
	8 G x 150 mm (4.0 mm)	1145-1I015	1145-2I015	5
Set for bone marrow biopsy with inner cannula	11 G x 100 mm (3.0 mm)	1145-6E010		5
	8 G x 100 mm (4.0 mm)	1145-6I010		5



TrokaBone Sternal

Working length 5-25 mm

Product	Size	Art. No.	PU
Set for bone marrow biopsy in sternum region	18 G x 50 mm (1.2 mm)	1146-1D025	5
	17 G x 50 mm (1.5 mm)	1146-1G025	5
	15 G x 50 mm (1.8 mm)	1146-1K025	5
	14 G x 50 mm (2.0 mm)	1146-1M025	5



PAJUNK GmbH
 Medizintechnologie
 Karl-Hall-Strasse 1
 D-78187 Geisingen/Germany
 Telefon +49 (0) 77 04/92 91-0
 Telefax +49 (0) 77 04/92 91-6 00
www.pajunk.com

SQS as a conformity assessment body identification number 1250 herewith certifies the organisation

Spineart SA
Chemin du Pré-Fleuri 3
1228 Plan-les-Ouates
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II

Directive 93/42/EEC (without section 4)

This approval is based on the report dated January 6, 2020.

The scope of validity covers the products

Sterile and non sterile spine instruments

The following CE label can be applied to the products mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Reg. no. 45886

Validity 24.01.2020–25.05.2024
Issue 24.01.2020

Approved Medical Responsible
24.01.2020



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



sqs.ch

Swiss Association for Quality
and Management Systems (SQS)
Bernstrasse 103, 3052 Zollikofen, Switzerland



ANNEX II

Directive 93/42/EEC (without section 4)

This Appendix is valid only in connection with the following certificate:

Registration Number 45886

Validity from January 24, 2020 up to and including May 25, 2024

This approval includes the following Medical Device/s:

Classe IIa

Vertebral body elevation TEKTONA instrumentation range

Appendix Issue: January 24, 2020



SQS as a conformity assessment body identification number 1250 herewith certifies the organisation

Spineart SA
Chemin du Pré-Fleuri 3
1228 Plan-les-Ouates
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II

Directive 93/42/EEC (without section 4)

This approval is based on the report dated January 6, 2020.

The scope of validity covers the products

Sterile and non sterile spine implants

The following CE label can be applied to the products mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Reg. no. 33159

Validity 24.01.2020–25.05.2024
Issue 24.01.2020

Approved Medical Responsible
24.01.2020



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



sqs.ch

Swiss Association for Quality
and Management Systems (SQS)
Bernstrasse 103, 3052 Zollikofen, Switzerland



ANNEX II**Directive 93/42/EEC (without section 4)**

This Appendix is valid only in connection with the following certificate:

Registration Number 33159

Validity from January 24, 2020 up to and including May 25, 2024

This approval includes the following Medical Devices:

Class IIb

TRYPTIK 2 C-Plate Anterior Cervical Plate System

Lumbar osteosynthesis ROMEO2 range

Lumbar osteosynthesis ROMEO2 MIS (Minimal Invasive Surgery)

Lumbar cage JULIETpo PEEK

Lumbar cage JULIETan PEEK

JULIET LL PEEK and JULIET LL-T lateral lumbar cage

Cervical disc prosthesis BAGUERAc range

Intersomatic cervical cage TRYPTIKca and TRYPTIKcc

Intersomatic cervical modular cage TRYPTIKmc, modular plate TRYPTIKmp and cervical screw TRYPTIKcs

Cervical cage SCARLET AC-T range

Intersomatic lumbar cage JULIETtl PEEK

Intersomatic lumbar cage JULIETol PEEK

Intersomatic lumbar cage SCARLET AL-T

Posterior axial device ROMEO2 PAD range

Intersomatic lumbar cage JULIET Ti PO

Intersomatic lumbar cage JULIET Ti OL

Intersomatic lumbar cage JULIET Ti TL

Class IIa

Single use surgical instruments STERILE packaged

Appendix Issue: January 24, 2020



EC CERTIFICATE AT SERTİFİKA

According to Annex II of the Directive 93/42/EEC on Medical Devices
93/42/AT Tıbbi Cihaz Yönetmeliği Ek II'ye göre

Full Quality Assurance System Tam Kalite Güvencesi

Certificate Number: 2195-MED-1404201
Sertifika Numarası

Manufacturer: TRİA SPİNE MEDİKAL LTD. ŞTİ.
Üretici
Head Office/Merkez: 1551. Sok. No:35/33 İvedik OSB Yenimahalle Ankara TÜRKİYE
Factory/Fabrika: 1551. Sok. No:35/21 İvedik OSB Yenimahalle Ankara TÜRKİYE

Product(s): Sterile and Non-Sterile Spinal System Implants
Ürün(ler)
Steril ve Steril Olmayan Spinal Sistem İmplantları

Model(s): Product specifications are given on the second page.
Model(ler)
Ürün detayları ikinci sayfada verilmiştir.

Reference Report No: MM0572-P005-R01, MM0572-P005-R02, MM0572-P005-R03
Referans Rapor No

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

2195 kimlik numaralı Onaylanmış Kuruluş Szutest, yukarıda belirtilen üreticinin 93/42/AT Tıbbi Cihaz Yönetmeliği EK II(madde 4 hariç) madde 3'üne göre bir kalite yönetim sistemi uyguladığını, bu yönetim sisteminin yönetmeliğin sadece bahsi geçen ürünün üretiminin güvenlik koşullarını sağlama ve devam ettirme ile ilgili gerekliliklerin karşıladığını beyan eder. Onaylanan bu kalite yönetim sistemi, 93/42/AT Tıbbi Cihaz Yönetmeliği EK II, Madde 5'e göre periyodik olarak gözetime ve habersiz saha denetimlerine tabidir.

Üretici, ürünlerinin tasarımında ve yapısında gerçekleştirdiği önemli değişiklikleri Szutest'e bildirmek zorundadır. Steril kondisyondaki sınıf I ürünler için kalite yönetim sistemi değerlendirmesi üretimin steril kondisyonun sağlanması ve korunmasıyla limitlidir. Ölçüm fonksiyonlu sınıf I ürünler için Kalite yönetim sistemi değerlendirmesi üretimin cihazların metrolojik şartlara uyumunu sağlamasıyla limitlidir.

This EC certificate is valid till 2024-05-26.

Bu AT Sertifikası 2024-05-26 tarihine kadar geçerlidir.

Issue Date/Yayın Tarihi: 2014-02-11
Revision No./ Revizyon No.: 05 Recertification/Yeniden Belgelendirme
Revision Date/ Revizyon Tarihi: 2020-03-27



Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company



HumanTech Spine GmbH

Gewerbestr. 5
71144 Steinenbronn
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Cervical Plate Screw Fixation System	class IIb
Spinal Screw Rod Fixation System	class IIa and IIb
Anterior Cervical Interbody Devices	class IIa and IIb
Lumbar Interbody Devices	class IIb
Cement Applicator	class IIa
Vertebral Body Replacement Devices	class IIb

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	540287 MR2
Certificate unique ID	170727894
Effective date	2018-11-01
Expiry date	2023-10-31
Frankfurt am Main	2018-11-01

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
PAJUNK GmbH Medizintechnologie

Karl-Hall-Straße 1, 78187 Geisingen, Germany

Certified location:

Karl-Hall-Straße 1, 78187 Geisingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 51268-Z3-00, the decision dated 2018-03-20 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-03-22 to 2023-03-21

Registration No.: 51268-16-02



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-03-20
Notified Body ID-number: 0124



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de

ZLG-BS-295.10.02



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 11 0673 QS/NB

The quality system of manufacturer

Samay Surgical

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):


Orthopaedic Implants, Spinal Implants

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2016-08-09
Valid until: 2021-08-08
First Issued: 2011-08-09
Revision: b

Date: 2016-08-09




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 11 0673 QS/NB

issued for manufacturer:


Samay Surgical

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, NH-8B, Veraval
(Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

4.5 mm L-Buttress Plates for Right Leg
4.5 mm L-Buttress Plates for Left Leg
3.5 mm Cloverleaf Plates
4.5 mm Condylar Buttress (C.B.P) Plates for Right Leg
4.5 mm Condylar Buttress (C.B.P) Plates for Right Leg
4.5 mm Lateral Tibia Buttress Plates for Right Leg
4.5 mm Lateral Tibia Buttress Plates for Left Leg
3.5 mm Hook Plates
DHS Barrel Plate Round Hole 120° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 125° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 130° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 135° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 140° (Barrel Length 25MM & 38mm)
DHS Barrel Plate Round Hole 145° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 120° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 125° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 130° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 135° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 140° (Barrel Length 25MM & 38mm)
DHS Barrel Plate DCP Hole 145° (Barrel Length 25MM & 38mm)
95° DCS Barrel Plate Round Hole
95° DCS Barrel Plate Round Hole
DHS Lag Screw
DHS Compression Screw
Condylar Angled Blade plate 95° (Round Hole) 50mm blade
Condylar Angled Blade plate 95° (Round Hole) 55mm blade

Date: 2016-08-09




RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. **G1 18 06 05033 001**

Manufacturer:**OSARTIS GmbH**

Lagerstraße 11-15
64807 Dieburg
GERMANY

**Facility(ies):**

OSARTIS GmbH
Lagerstraße 11-15, 64807 Dieburg, GERMANY

OSARTIS GmbH
Nordring 29, 64807 Dieburg, GERMANY

OSARTIS GmbH
Benzstraße 4, 64807 Dieburg, GERMANY

Product**Category(ies):**

**Mixing and delivery devices for bone cements
and sterile accessories (class IIa), bone substitute
materials (class III), bone cements (class IIb + class III),
and collagen products (class III)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

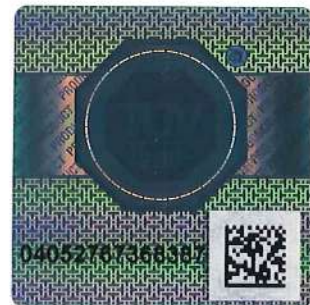
713127557

Valid from:

2018-07-02

Valid until:**2022-07-01****Date,** 2018-07-02

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1

EMKI

EMKI

EMKI

EMKI

EMKI

EMKI

EC CERTIFICATE
Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-776-200-1509

The Directorate of Device Testing and Clinical Engineering (EMKI)
certifies that the manufacturer:

Biotech GmbH
Hagenauer Str. 17-19
65203 Wiesbaden
Germany

for the products / product category:

Sterile and non-sterile orthopaedic implant systems

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-066-2007**

This certificate is valid together with EC Design-Examination Certificates according to Directive 93/42/EEC on Medical Devices, Annex II (4) No. **5-777-204-1509** and No. **5-778-204-1509**.

This certificate is valid until **22-09-08** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 5

First issued: 2015-09-09

Budapest, 2018-05-16

Head of EMKI



EMKI 2007

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33
E-mail: cert@emki.hu, Web: www.emki.hu
H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

EMKI



Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the standard specified below.



Spineart SA
Chemin du Pré-Fleuri 3
1228 Plan-les-Ouates
Switzerland

Scope of certification

According to appendix

Field of activity

Design, manufacturing and sales of sterile and non-sterile spine medical devices

Normative base

**EN ISO 13485:2016 Medical devices –
Quality Management System**

Validity 03. 10. 2017 – 02. 2022
Issue 27. 06. 2018

Reg. no. H31786

X. Edelmann, President SQS

R. Glauser, CEO SQS



sqs.ch



Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland



CERTIFICATE



Medical Devices Quality Management System
CERTIFICATE NO: 31910501

Tria Spine Medical Ltd. Şti.

Head Office : 1551. Sok. No:35 / 33 İvedik OSB Yenimahalle, Ankara TÜRKİYE

Factory : 1551. Sok. No:35 / 21 İvedik OSB Yenimahalle, Ankara TÜRKİYE

EN ISO 13485:2016

**Design, Production and Sales of Sterile and Non-Sterile Neurosurgery
and Non-Sterile Trauma Implants and Spinal Surgical Instruments**

Approves that the Medical Devices Quality Management System implemented for above scope.

Issue Date 15.04.2019
Expiry Date 14.04.2023



TÜRKAK BDS NO
YS-79CB-B206



Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on <http://public.szutest.com.tr> or by using BDS No on <https://tdbs.turkak.org.tr>.



Product Service

CERTIFICATE

No. Q5 18 06 05033 002

Holder of Certificate: OSARTIS GmbH

Lagerstraße 11-15
64807 Dieburg
GERMANY

Facility(ies):

OSARTIS GmbH
Lagerstraße 11-15, 64807 Dieburg, GERMANY

OSARTIS GmbH
Nordring 29, 64807 Dieburg, GERMANY

OSARTIS GmbH
Benzstraße 4, 64807 Dieburg, GERMANY



Certification Mark:



Scope of Certificate:

Design and development, production and distribution of bone cements, mixing and delivery devices for bone cements (including accessories), bone substitute materials including application devices, collagen products

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

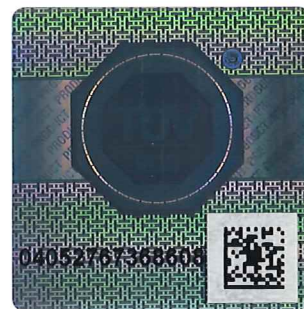
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713127557

Valid from: 2018-07-02
Valid until: 2022-07-01

Date, 2018-07-02

Stefan Preiß



Page 1 of 1





Management System Certificate

Certificate No. **MD-QMS/91/R/1933**

This is to certify that

Samay Surgicals

**Survey No. 212, Plot No. 6, Nr. Patidar Plastic, Nh-8b,
Veraval (Shapar) – 360 024, Dist. Rajkot, Gujarat, India**

has been found to conform to the requirements of
Medical Devices - Quality Management System Standard :

ISO 13485:2016

This certificate is valid for the following scope :

**Design, Manufacture & Supply of Orthopedic Implants,
Spinal Implant & related Instruments.**

Initial Certification : 20th August, 2011
Re-certification : 20th August, 2017
Valid until : 19th August, 2022



UK

Authorised Signatory

This Certificate is valid when confirmed by data listed in the International Register of Quality Assessed Organisations <www.irqao.org>. Further clarification regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the certified organization. Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid.

Zenith Quality Assessors Pvt. Ltd.

(Management System Certification Division, MSCD002)

306, 4th Floor, Sai Apex, Near Datta Mandir, Viman Nagar, Pune - 411 014, Maharashtra, India.
www.zenith-worldwide.com

Accreditation Body : ACCREDITATION SERVICE FOR CERTIFYING BODIES (EUROPE) Ltd.

6, Ferris Place, Bournemouth, Dorset, BH8 0AU, United Kingdom.

www.ascb.co.uk

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-492-135-1809

The **Directorate of Device Testing and Clinical Engineering (EMKI)**
as a Certification Body with ID No. NAH-4-0096/2016
accredited by the National Accreditation Authority for management system certification
certifies that the quality management system applied by

BIOTECH GmbH
Hagenauer Str. 17-19, 65203 Wiesbaden
Germany
and
Magyarországi Fióktelepe
Petőfi Sándor utca 43-47, 2049 Diósd
Hungary

meets the requirements of standard

EN ISO 13485:2016

in the field:

**Design, development, manufacture and distribution
of non active surgical implant systems;**
**Design, development, manufacture and distribution
of surgical instrument systems**

Registry number of the related audit report: **43-066-2007**

This certificate is valid until **2021-09-08** supposed that the results of the regular yearly
surveillance audits are satisfactory.

Budapest, 2018-09-09



Head of EMKI



EMKI 2092

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

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