



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.

\* Not available in the US



## AT A GLANCE

Streamlined Tip  
Polyaxial Head  
Low Profile Implants  
Compact Set

## INDICATIONS

The ROME02 system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (painful degeneration of the disc), spondylolisthesis, trauma, spinal stenosis, deformities (i.e. scoliosis, kyphosis, or lordosis), tumor and failed previous fusion (pseudarthrosis).

The ROME02 system is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ROME02 system is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.

The ROME02 system is indicated to be used in conjunction with bone cement to augment fixation in vertebrae with compromised bone quality.

The ROME02 system is intended to be used with autograft and/or allograft.

# 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



SETSCREW

ELL-SC 00 00-S



SETSCREW HEXALOBE

ELL-SC 01 00-S



# 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



## 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 / 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



## 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 TRANSVERSE HOOKS

ELL-TC 00 00-S



# IMPLANTS

## 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 51 00-S
L110	ELL-RD 51 10-S
L120	ELL-RD 51 20-S
L130	ELL-RD 51 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 PO 00-S



LAMINAR THORACIC SUPRA

ELL-HO LT SU-S



LAMINAR INFRA

ELL-HO LT IN-S



ANGLED LEFT

ELL-HO AN 0L-S

ANGLED RIGHT

ELL-HO AN 0R-S



OFFSET LEFT

ELL-HO OF 0L-S

OFFSET RIGHT

ELL-HO OF 0R-S



# IMPLANTS (Non-Sterile)

## POLYAXIAL SCREWS

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



## REDUCTION SCREWS

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



# I M P L A N T S (Non-Sterile)

## 25D SCREWS

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



## MONOAXIAL SCREWS

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



# IMPLANTS (Non-Sterile)

ROD CONNECTOR PARALLEL

ELL-RC PA 00-N



ROD CONNECTOR AXIAL

ELL-RC AX 00-N



ILIAC CONNECTORS

L15 ELL-IC 00 15-N

L20 ELL-IC 00 20-N

L30 ELL-IC 00 30-N

L40 ELL-IC 00 40-N

L50 ELL-IC 00 50-N

L60 ELL-IC 00 60-N



ROD CONNECTOR PARALLEL OPEN

ELL-RC PA 01-N



ILIAC T CONNECTOR

ELL-RC TE 00-N



OPEN ILIAC CONNECTORS

L15 ELL-IC 01 15-N

L20 ELL-IC 01 20-N

L30 ELL-IC 01 30-N

L40 ELL-IC 01 40-N

L50 ELL-IC 01 50-N

L60 ELL-IC 01 60-N



SETSCREW

ELL-SC 00 00-N



SETSCREW HEXALOBE

ELL-SC 01 00-N



# IMPLANTS (Non-Sterile)

## CROSS CONNECTORS /MULTIAXIAL

L30 to L31	ELL-CC-MU 30-N
L31 to L33	ELL-CC-MU 31-N
L33 to L36	ELL-CC MU 33-N
L36 to L43	ELL-CC MU 36-N
L43 to L55	ELL-CC MU 43-N
L55 to L80	ELL-CC MU 55-N



## CROSS CONNECTORS / MULTIAXIAL PREBENT

L33 to L36	ELL-CC MP 33-N
L36 to L43	ELL-CC MP 36-N
L43 to L55	ELL-CC MP 43-N
L55 to L80	ELL-CC MP 55-N



## CROSS CONNECTORS / STRAIGHT

L18	ELL-CC ST 18-N
L21	ELL-CC ST 21-N
L24	ELL-CC ST 24-N
L27	ELL-CC ST 27-N
L30	ELL-CC ST 30-N



## TRANSVERSE ROD CONNECTORS

L20	ELL-TR 00 20-N
L30	ELL-TR 00 30-N
L40	ELL-TR 00 40-N
L50	ELL-TR 00 50-N
L60	ELL-TR 00 60-N
L70	ELL-TR 00 70-N
L80	ELL-TR 00 80-N



## CROSS CONNECTORS TRANSVERSE HOOKS

ELL-TC 00 00-N



# I M P L A N T S (Non-Sterile)

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



RODS PRE-BENT Ø5.4MM TITANIUM ALLOY	
L30	ELL-RD 00 30-N
L35	ELL-RD 00 35-N
L40	ELL-RD 00 40-N
L45	ELL-RD 00 45-N
L50	ELL-RD 00 50-N
L55	ELL-RD 00 55-N
L60	ELL-RD 00 60-N
L70	ELL-RD 00 70-N
L80	ELL-RD 00 80-N
L90	ELL-RD 00 90-N
L100	ELL-RD 51 00-N
L110	ELL-RD 51 10-N
L120	ELL-RD 51 20-N
L130	ELL-RD 51 30-N



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



# I M P L A N T S (Non-Sterile)

LAMINAR LUMBAR SMALL

ELL-HO LL 0S-N



LAMINAR LUMBAR LARGE

ELL-HO LL 0L-N



LAMINAR LUMBAR  
EXTENDED

ELL-HO LL-EX-N



PEDICULAR

ELL-HO PO 00-N



LAMINAR THORACIC SUPRA

ELL-HO LT SU-N



LAMINAR INFRA

ELL-HO LT IN-N



ANGLED LEFT

ELL-HO AN 0L-N

OFFSET LEFT

ELL-HO OF 0L-N

ANGLED RIGHT

ELL-HO AN 0R-N

OFFSET RIGHT

ELL-HO OF 0R-N



# TECHNICAL FEATURES

## COMPLETE TL FIXATION PLATFORM



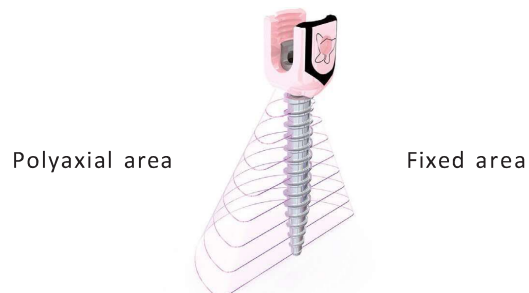
Complete range of polyaxial, semi-polyaxial, monoaxial, reduction screws, transverse connectors and rod connectors provide versatile options to treat numerous pathologies from T1 to the ilium.

## 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.

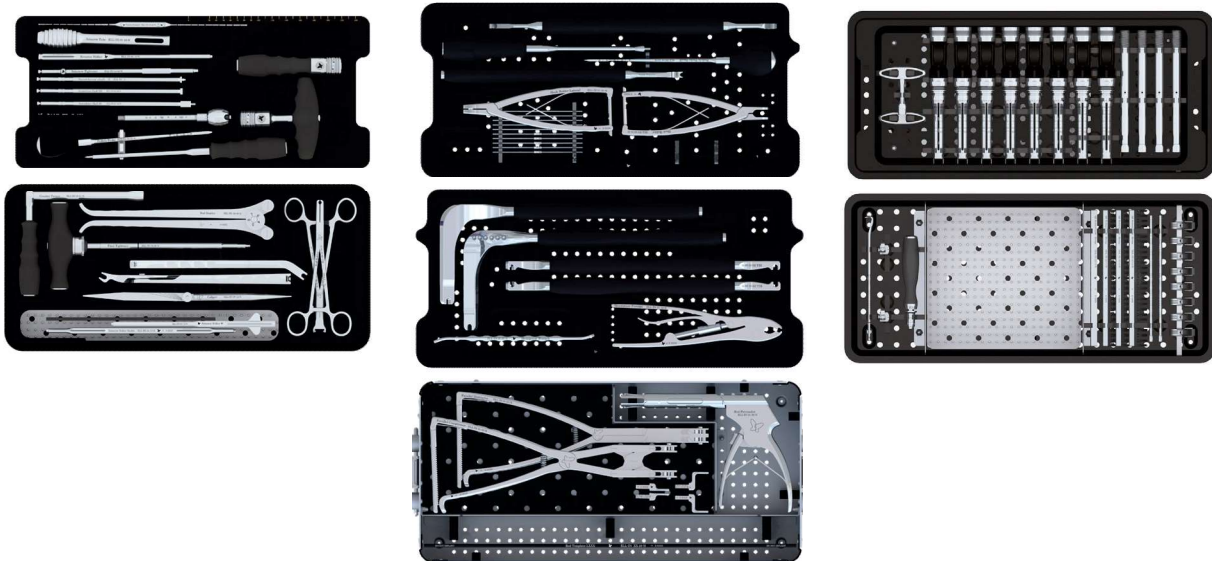
# TECHNICAL FEATURES

## HOOKS



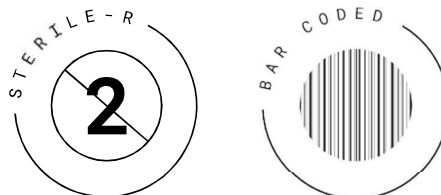
A full range of hooks with various sizes is available with ROMEO®2. Their autostatic teeth enhance their stability once impacted

## 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



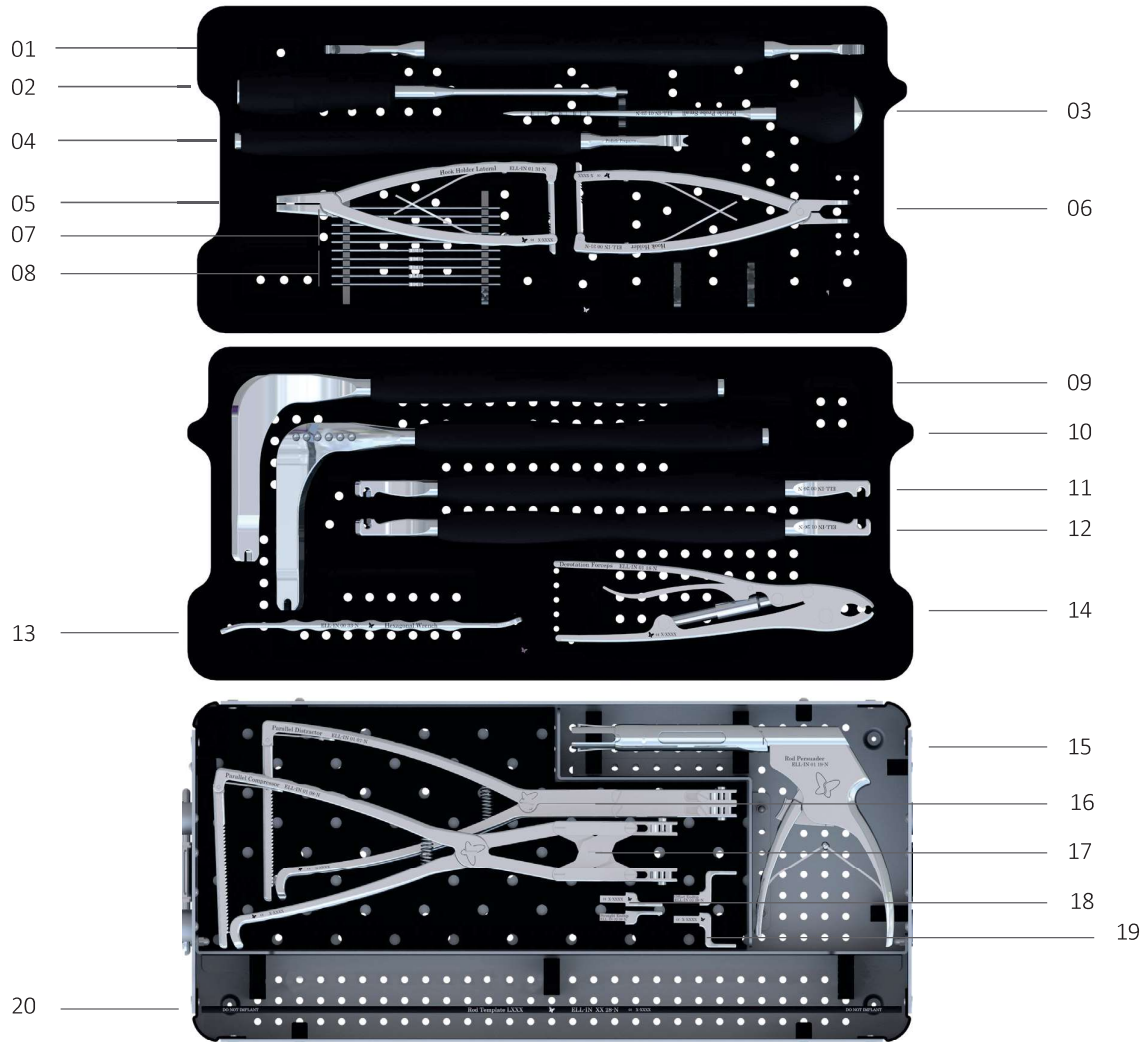
#	DESCRIPTION	REFERENCE
01	PEDICLE SOUNDER	ELL-IN 01 02-N
02	SETSCREW TUBE	ELL-IN 01 15-N
• 03	SETSCREW HOLDER	ELL-IN 01 10-N
04	SETSCREW TIGHTENER	ELL-IN 04 06-N
05	SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
06	SCREWDRIVER SHAFT MS	ELL-IN 01 20-N
07	SCREWDRIVER SHAFT SS	ELL-IN 01 16-N
08	SCREWDRIVER SLEEVE	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	SETSCREW HOLDER DOUBLE	ELL-IN 02 10-N
24	SETSCREW HOLDER W	ELL-IN 03 10-N
•	TAB BREAKER	ELL-IN 00 43-N
	INSTRUMENTS CONTAINER	ROM-BX 10 01-N

• : OPTIONAL

# INSTRUMENT SET

## LONG CONSTRUCT KIT



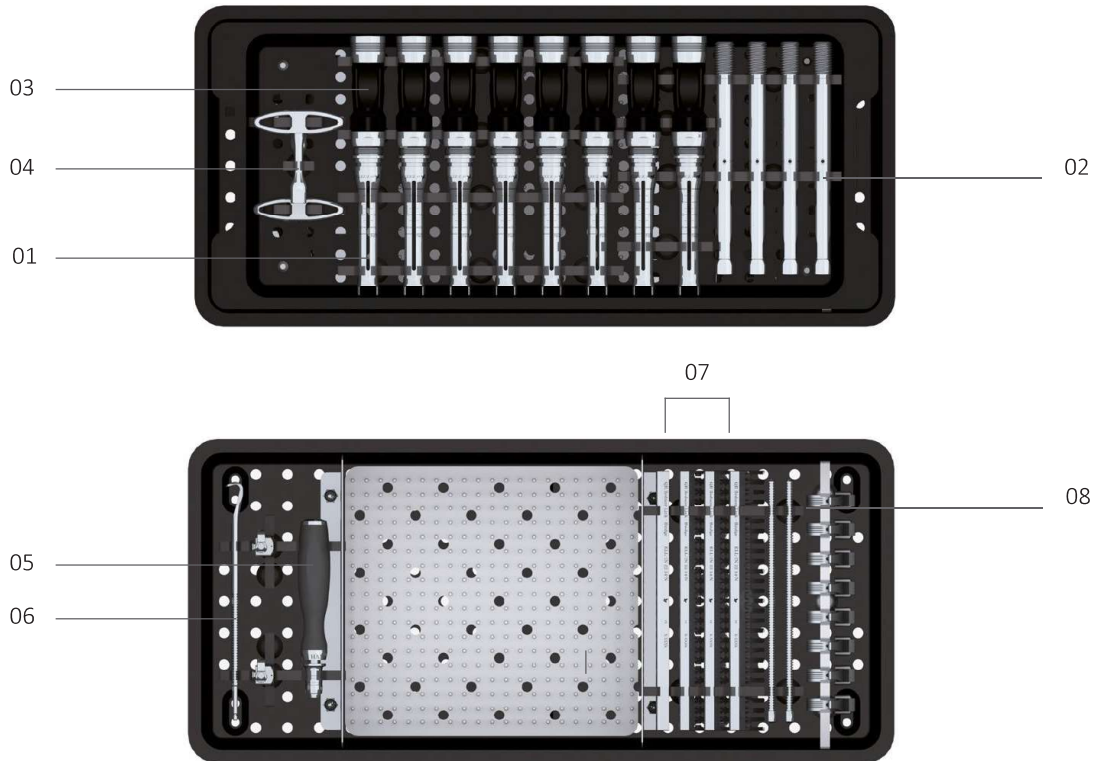
#	DESCRIPTION	REFERENCE
01	LAMINA PREPARER	ELL-IN 00 30-N
02	HOOK PUSHER	ELL-IN 00 32-N
03	PEDICLE PROBE SMALL	ELL-IN 02 23-N
04	PEDICLE PREPARER	ELL-IN 00 29-N
05	HOOK HOLDER LATERAL	ELL-IN 01 31-N
06	HOOK HOLDER	ELL-IN 00 31-N
07	MARKER LEFT	ELL-IN 00 25-N
08	MARKER RIGHT	ELL-IN 00 24-N
09	CORONAL BENDER LEFT	ELL-IN 00 27-N
10	CORONAL BENDER RIGHT	ELL-IN 01 27-N
11	SAGITTAL BENDER LEFT	ELL-IN 00 26-N

#	DESCRIPTION	REFERENCE
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
●	J-HOOK	ELL-IN 00 40-N
	INSTRUMENTS CONTAINER LC	ROM-BX 40 01-N

● : 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 R RIBAC L	SPE-IN 01 42-N SPE-IN 01 43-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

● : OPTIONAL

\* Not available in the US

# 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  $\varnothing$  (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



## SET SCREW INSERTION

SETSCREW HOLDER W

ELL-IN 03 10-N



SETSCREW TUBE

ELL-IN 01 15-N



SETSCREW TIGHTENER

ELL-IN 04 06-N



# INSTRUMENTS

## SET SCREW INSERTION - OPTION

SETSCREW HOLDER DOUBLE

ELL-IN 02 10-N



SETSCREW HOLDER

ELL-IN 01 10-N



## 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\*



## QR LINK INSTRUMENTS - OPTION

RIBAC R SPE-IN 01 42-N  
RIBAC L SPE-IN 01 43-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 \*\*\*



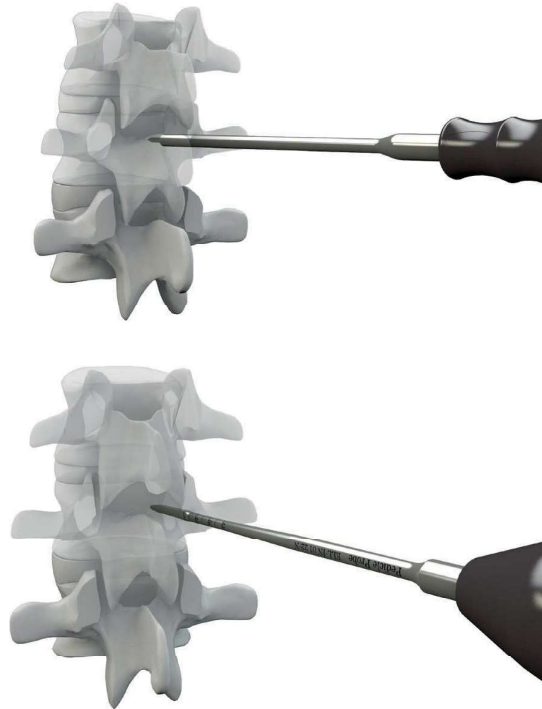
TAB BREAKER ELL-IN 00 43-N



- \* Not available in the US
- \*\* Not compatible with extended tabs of reduction screws.  
Break the tabs or use the optional counter torque version (ENLARGED EXTREMITY) ELL-IN 02 11-N
- \*\*\* 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  $\varnothing 4$ mm Screw, it is mandatory to use the **Pedicle Probe Small**. For  $\varnothing 5$ ,  $\varnothing 6$ ,  $\varnothing 7$  and  $\varnothing 8$ 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

ROME0®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



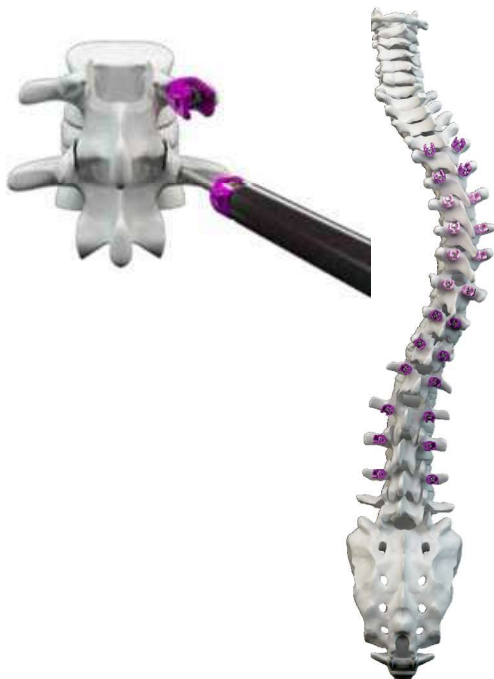
## SCREWDRIVER ASSEMBLY

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

Penetrate into the cancellous bone with the **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 **Setscrew** introduced with the **Setscrew Holder W**.

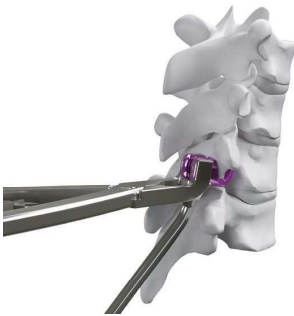
If an iliac connection is not needed, link the rod directly to the screw seated in the iliac bone.



INSTRUMENT	REFERENCE
IMPLANT HOLDER	ELL-IN 01 04-N
SETSCREW 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.

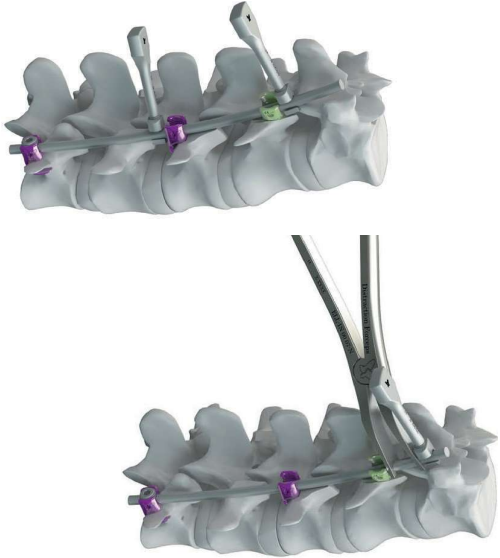
Attach the selected laminar hook to the **Hook Holder**.

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

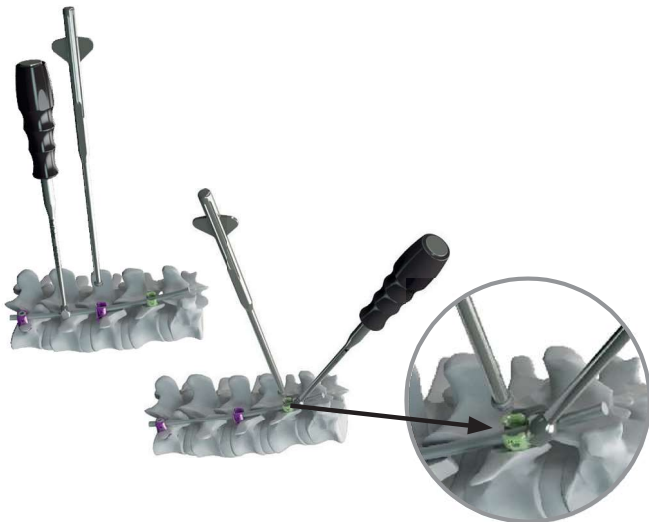


The **J-Hooks** can be placed and tightened with only one hand on the  $\varnothing 5.4\text{mm}$  rod in order to keep the hook in position and prevent back-out of the hook during in-situ maneuvers as rod rotation or bending maneuvers.

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 (OPTIONAL)	ELL-IN 00 40-N

## HOOK OPTIONAL INSTRUMENTS 2



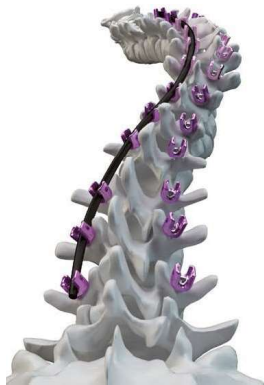
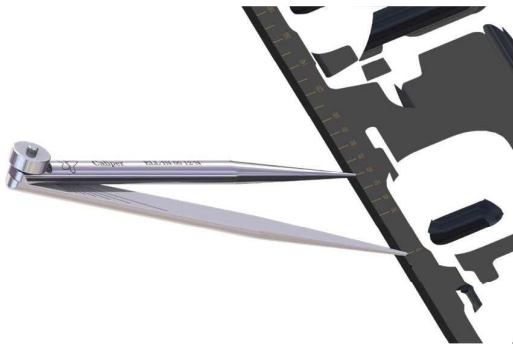
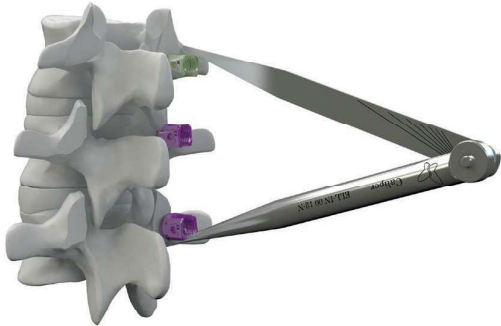
The **Rod Pusher** is a bi-functional instrument due to its specific design and provides intuitive and simple solution during hook surgeries. It can be simply use to push down the rod towards the implant head and ease the insertion of the setscrew.

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 decontoured. Repeated bending can weaken the rod.

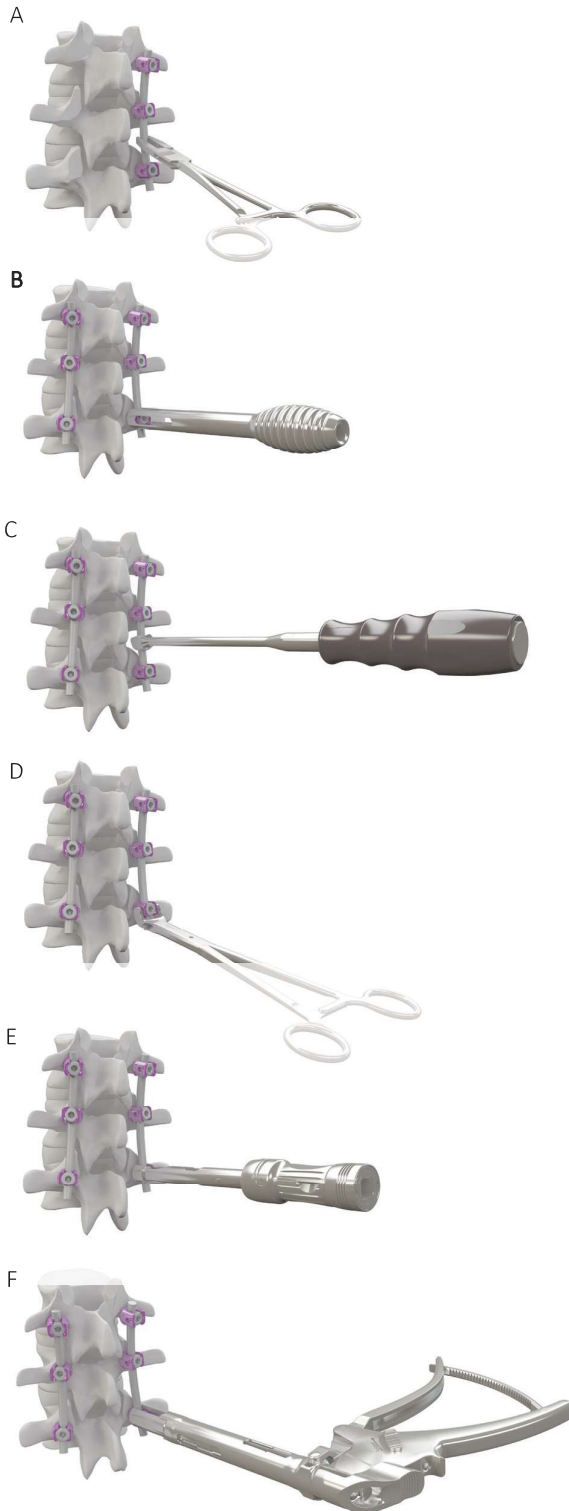
INSTRUMENT	REFERENCE
CALIPER	ELL-IN 00 12-N
ROD TEMPLATE L250	ELL-IN 00 28-N
ROD TEMPLATE L500	ELL-IN 01 28-N
ROD BENDER	ELL-IN 00 09-N

# SURGICAL TECHNIQUE

## \_STEP 9

## ROD PLACEMENT- DEGENERATIVE CASE

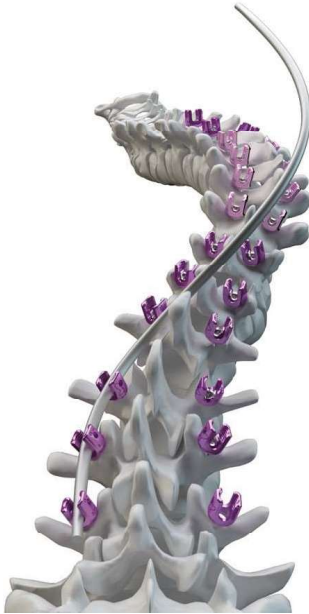
Attach the selected rod to the **Implant Holder** and place into screw heads. Multiple instrument options are available for rod reduction (see table). The use of one of these instruments is **MANDATORY**.



INSTRUMENT	REFERENCE
A. IMPLANT HOLDER	ELL-IN 01 04-N
B. SETSCREW 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 (OPTIONAL))	ELL-IN 00 40-N
HOOK HOLDER LATERAL	ELL-IN 01 31-N

## \_STEP 12



## SET SCREW INSERTION

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

Align the tip of the **Setscrew Holder** with the recess of the setscrew and firmly attach.

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

INSTRUMENT	REFERENCE
SETSCREW HOLDER W	ELL-IN 03 10-N
SETSCREW HOLDER (OPTIONAL)	ELL-IN 01 10-N
SETSCREW HOLDER DOUBLE (OPTIONAL)	ELL-IN 02 10-N
SETSCREW TUBE	ELL-IN 01 15-N

# SURGICAL TECHNIQUE

## \_STEP 13

### CHOICE OF THE REDUCTION TECHNIQUE

ROME0®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

\* Not available in the US

# SURGICAL TECHNIQUE

## \_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

# S U R G I C A L   T E C H N I Q U E

## \_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 **Setscrew 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
SETSCREW HOLDER W	ELL-IN 03 10-N
SETSCREW HOLDER (OPTIONAL)	ELL-IN 01 10-N
SETSCREW HOLDER DOUBLE (OPTIONAL)	ELL-IN 02 10-N

# SURGICAL TECHNIQUE

## \_STEP 17

### CREATE APICAL CLUSTER

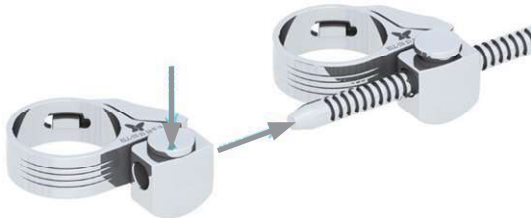
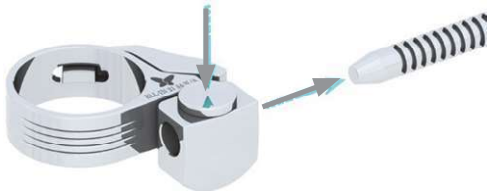
Position the **QR Reducer** on the screws. At least one rod should be introduced, but still free to move within the screw head. Start creating the apical cluster.

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.



<u>INSTRUMENT</u>	<u>REFERENCE</u>
QR REDUCER LINK	ELL-IN 21 34-N

# S U R G I C A L   T E C H N I Q U E

## \_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.

<u>INSTRUMENT</u>	<u>REFERENCE</u>
QR REDUCER LINK BRIDGE	ELL-IN 22 34-N*

*\*QR REDUCER LINK BRIDGE (ref. ELL-IN 22 34-N)  
not available in the US.*

# 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.

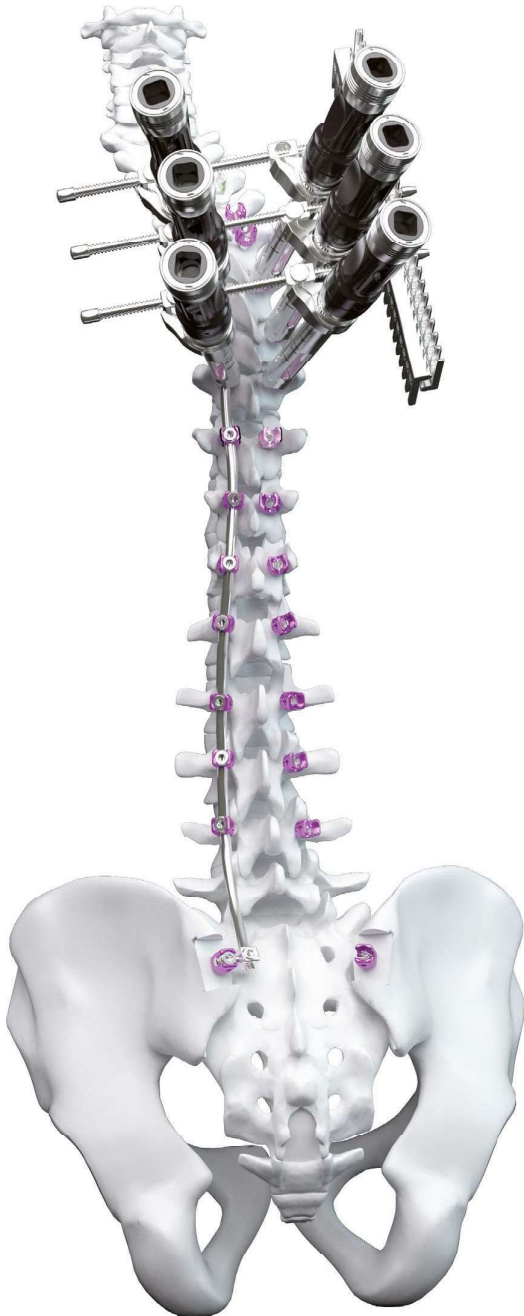
Derotate the rod to have its curvature moving from the frontal plane to the sagittal plane.

**NOTE:** Make sure to have all the Setscrews 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 Setscrews of the most proximal screw.

Tightening is achieved with the **Setscrew Tightener** attached to the **T-handle Ratchet Handle**.

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

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

*NOTE: QR REDUCER LINK BRIDGE  
(ref. ELL-IN 22 34-N) not available in the US.*

# 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 Setscrews of the construct. Insert the second rod following the steps 8 to 11.

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

\* Not available in the US.

# SURGICAL TECHNIQUE

## \_STEP 22



## CROSS CONNECTOR SYSTEM 1

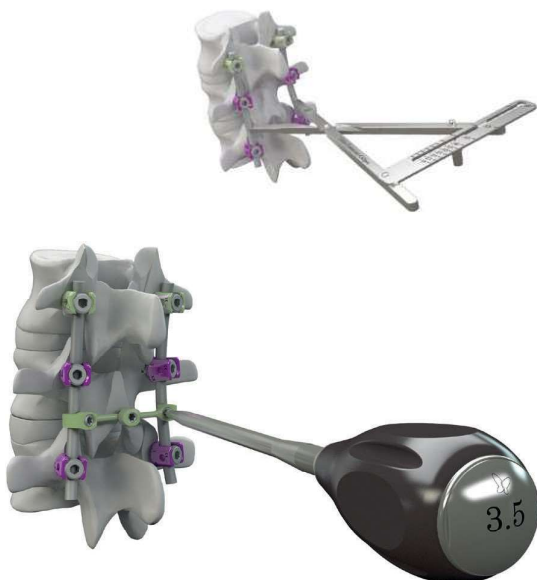
For long construct, it is recommended to add transverse connectors to increase the rotational stability of the construct. Hold the transverse hooks with the **Implant Holder** and place them onto the rod. The length of the transverse rod is measured by using the **Caliper**.

**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 setscrew 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.

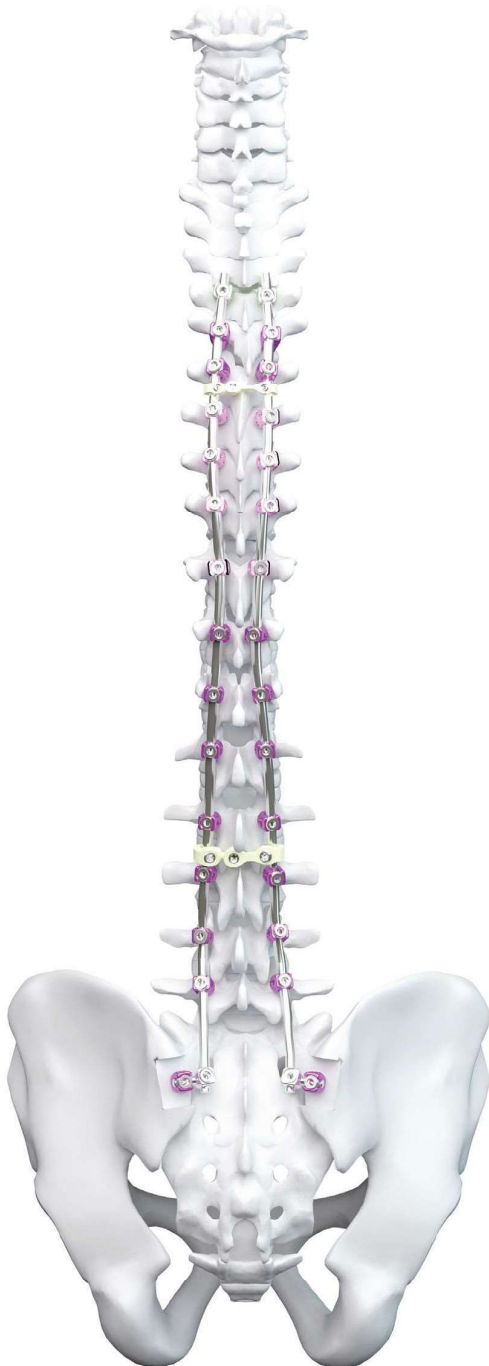
Once the cross connector is positioned, use the **3.5 Tightener** to final tighten.

**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 setscrew 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 setscrew 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



## \_REVISION

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

INSTRUMENT	REFERENCE
SETSCREW TIGHTENER	ELL-IN 04 06-N
T-HANDLE RATCHET	HAN-SI RA TE-N
COUNTER TORQUE	ELL-IN 03 11-N
SCREWDRIVER SHAFT PS	ELL-IN 05 03-N
SCREWDRIVER SLEEVE	ELL-IN 20 03-N
SCREWDRIVER TUBE	ELL-IN 21 03-N
STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N

# GENERAL INFORMATION

REFERENCE OF THE IFU

ROM-TL-IF-WW

REVISION OF THE FINAL IFU

JAN-2020

## \_STERILITY

The implant is provided sterile or non sterile.

The sterile packed instruments are for single use.

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

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

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

The re-sterilization of the gamma sterilized implant is forbidden.

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

Please refer to the individual package labeling.

## \_DESCRIPTION

The ROMEO®2 spine system was designed to ensure the best possible adaptation to patient’s anatomic variations. This system has been designed to correct and stabilize the spine.

The ROMEO®2 spine system range consists of:

- Solid pedicle screws of various lengths and diameters
- Cannulated pedicle screws of various lengths and diameters which can be used with k-wires
- Perforated pedicle screws of various lengths and diameters through which cement can be injected in the vertebrae
- Cortical bone trajectory screws of various lengths and diameters
- Spinal Hooks

All the above implants receive longitudinal rods. In order to obtain additional stiffness, transverse connectors are also available.

All ROMEO®2 implants are made of titanium alloy. Rods are also available in cobalt chromium alloy.

## \_INDICATIONS

The ROMEO®2 system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (painful degeneration of the disc), spondylolisthesis, trauma, spinal stenosis, deformities (i.e. scoliosis, kyphosis, or lordosis), tumor and failed previous fusion (pseudarthrosis).

The ROMEO®2 system is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ROMEO®2 system is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis.

The ROMEO®2 system is indicated to be used in conjunction with bone cement to augment fixation in vertebrae with compromised bone quality.

The ROMEO®2 system is intended to be used with autograft and/or allograft.

## \_CONTRAINDICATIONS

The ROMEO®2 system is not intended for any other use than indications above. Include but not limited to:

- Mental illness
- Infection
- Severely damaged bone structures that could prevent stable implantation of the implant
- Neuromuscular or vascular disorders or illness
- Inadequate activity
- Pregnancy
- Signs of local inflammation
- Patients with known sensitivity to the materials implanted

## \_SIDE EFFECTS

### Per operative:

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

# GENERAL INFORMATION

## **Post operative:**

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

## **Specific to implant:**

Implant migration, adhesion and fibrosis, limited range of movement, secondary fractures.

Potential risks identified with the use of this posterior osteosynthesis system, which may require additional surgery, include: device component fracture, loss of fixation, pseudarthrosis (i.e non-union), fracture of the vertebra, neurological injury, vascular or visceral injury, metal sensitivity or allergic reaction to a foreign body, incidental durotomy, dural tear, adjacent level degeneration, decrease in bone density due to stress shielding, paralysis, death.

**Additional potential adverse events for pediatric patients:** Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions and/or distorted anatomy); Pedicle screw malpositioning, with or without neurological or vascular injury; Proximal or distal junctional kyphosis.

**Additional potential adverse events for cement injection:** Cement leakage occurs in a high percentage of patients treated with PMMA cement for vertebral augmentation. Such leakage is asymptomatic in the majority of cases. However, the benefits of the additional stabilization should be carefully weighed against the additional risks with cement injection. Cement leakage may result in serious complications including: Radiating pain; Paralysis; Death by embolism.

## **\_WARNINGS**

Because this is a technically demanding procedure presenting a risk of serious injury to the patient, only experienced surgeons with adequate training should perform posterior osteosynthesis. Every surgeon who uses these implants must take each patient's clinical state and medical status into consideration, and be fully familiar with procedures involving the use of this type of implant and the potential complications in each case. Abnormal use of the device may lead to risks of serious injury and/or health deterioration of the patient.

The soft tissue and the adjacent bones may deteriorate over time, or may not be in an adequate state to support

the implant, thus causing instability and/or malformation. The benefits of this posterior osteosynthesis procedure may not meet the patient's expectations, thus requiring more surgery to replace or remove the implant, or requiring other types of procedures. Patients undergoing posterior osteosynthesis shall, therefore, be informed.

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

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

The ROMEO®2 implant must not be used with implant other than ROMEO®2 range. The ROMEO®2 Implant must only be used with the ROMEO®2 instruments.

The ROMEO®2 system has not been evaluated for safety and compatibility in the MR environment. The ROMEO®2 system has not been tested for heating, migration, or image artifact in the MR environment. The safety of ROMEO®2 system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury."

## **\_SURGERY METHODS**

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

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

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

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

# GENERAL INFORMATION

## HANDLING

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

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

An implant site can become infected, painful, swollen, or inflamed. Significant weight on the implant, an implant of inadequate size, and patient hyperactivity or a misuse will increase the risk of complications, including wear and tear or rupture.

When handling these implants, blunt instruments should be used in order to avoid scratching, cutting, or nicking the device. Sharp-edged, serrated or toothed instruments should not be used.

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

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

## STORAGE CONDITION

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

## INSTRUMENTATION

The instruments were specifically designed for use when installing the ROMEO®2 implants.

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

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

## DECONTAMINATION, CLEANING, AND STERILIZATION

Point-of-instruction: The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described below.

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

The ROMEO®2 instruments have been designed in order to avoid disassembly manipulation prior decontamination, cleaning and sterilization processes.

These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments and not sterile implants.

### **Manual disinfection/cleaning protocol**

- Rinse soiled devices under running cold tap water for 1 minute, using soft-bristled brush to assist in the removal of gross soil debris. The devices which can be disassembled must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 5 minutes using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute.
- Use a syringe to flush the devices with cannulation with 2x20 ml of neutral enzymatic cleaner at room temperature (+15/+25°C).
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1

### WASHER-DISINFECTOR PARAMETERS

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

# GENERAL INFORMATION

minutes. Devices with mobile parts will be activated during rinsing.

- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 2 minutes using soft-bristled brush at room temperature (+15/+25°C).
- Use a syringe to flush the devices with cannulation with 2x20 ml of deionized water at room temperature (+15/+25°C).
- Rinse thoroughly the devices with deionized water for 2 minutes. Devices with mobile parts will be activated during rinsing.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

## Automatic disinfection/cleaning protocol

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

## Sterilization trays cleaning and disinfection

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

## Cleaning recommendations

- Remove all the instruments from the trays,

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

## Disinfection recommendations

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

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

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

## Sterilization parameters:

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

### Cycle 1 (EU):

Exposure time: 18 minutes

Temperature: 134°C

Drying time: 30 minutes

### Cycle 2 (USA):

Exposure time: 4 minutes

Temperature: 132°C

Drying time: 30 minutes

# GENERAL INFORMATION

“Do not stack trays during sterilization”

The instruments must, immediately after use, be decontaminated, cleaned, and sterilized as described above, particularly before they are returned to Spineart®.

## \_MAINTENANCE AND REPAIR

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

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

## \_FURTHER INFORMATION

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



SPINEART

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