

CONTENT

CONCEPT AND DESIGN	PAGE 04
IMPLANTS	PAGE 05
TECHNICAL FEATURES	PAGE 07
INSTRUMENTS SET	PAGE 08
INSTRUMENTS	PAGE 11
SURGICAL TECHNIQUE	PAGE 18

1

CONCEPT AND DESIGN

Since 2005 SpineArt has been following its motto: quality, innovation, simplicity, by developing highly performant systems for the treatment of spinal pathologies.

The ROMEO®2 posterior fixation system incorporates smart technologies and simplicity.

SpineArt is innovating again offering an expanded platform to address complex spine cases. The unique ROMEO[®]2 25D screw features a semi-polyaxial design, providing the versatility of a classic polyaxial screw and the rigidity of a monoaxial screws for reduction maneuvers.

The combination of ROMEO[®]2 25D screw with the powerful QR reducer allows multi-segmental vertebral derotation.

ROMEO[®]2 is a complete posterior fixation system with unique and efficient technologies that offers alternative solutions to the surgeons and their patients.

AT A GLANCE

DEFORMITY PLATFORM STREAMLINED SCREW TIP SEMI-POLYAXIAL 25D SCREW LOW PROFILE HEAD

QUICK RELEASE REDUCER



INDICATIONS

ROMEO[®]2 lumbar posterior osteosynthesis system is intended to provide immobilization and stabilization of thoraco-lumbo-sacral spine in skeletally mature patients for the following indications: DDD (degenerative disc disease), spondylolisthesis, trauma, spinal stenosis, curvatures, tumor, pseudoarthrosis and failed previous fusion.



Monoaxial Screws

LENGTH / DIAMETER	Ø4	Ø5	Ø6	Ø7	Ø8	
L25	ELL-MS 04 25-S					2
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	- 2
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	-
-						-

Polyaxial Screws

LENGTH / DIAMETER	Ø4	Ø5	Ø6	Ø7	Ø8
L25	ELL-PS 04 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 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

25D Screws

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

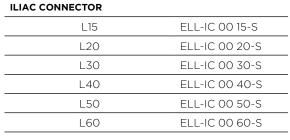
Reduction Screws

LENGTH / DIAMETER	Ø5	Ø6	Ø7
L30	ELL-SS 05 30-S	ELL-SS 06 30-S	ELL-SS 07 30-S
L35	ELL-SS 05 35-S	ELL-SS 06 35-S	ELL-SS 07 35-S
L40	ELL-SS 05 40-S	ELL-SS 06 40-S	ELL-SS 07 40-S
L45	ELL-SS 05 45-S	ELL-SS 06 45-S	ELL-SS 07 45-S
L50	ELL-SS 05 50-S	ELL-SS 06 50-S	ELL-SS 07 50-S



SETSCREW	ELL-SC 00 00-S
	1
ROD CONNECTOR AXIAL	ELL-RC AX 00-S

RODS / STRAIGHT ø5,4	
L100	ELL-RD 21 00-S
L120	ELL-RD 21 20-S
L140	ELL-RD 21 40-S
L160	ELL-RD 21 60-S
L180	ELL-RD 21 80-S
L200	ELL-RD 22 00-S
L220	ELL-RD 22 20-S
L240	ELL-RD 22 40-S
L350	ELL-RD 23 50-S
L500	ELL-RD 25 00-S
L550	ELL-RD 25 50-S



THE REAL PROPERTY OF

ELL-RC PA 00-S

ROD CONNECTOR

PARALLEL



RODS / COBALT CHROMIUM / STRAIGHT ø5,4

•	
L100	ELL-RD 11 00-S
L120	ELL-RD 11 20-S
L140	ELL-RD 11 40-S
L160	ELL-RD 11 60-S
L180	ELL-RD 11 80-S
L200	ELL-RD 12 00-S
L220	ELL-RD 12 20-S
L240	ELL-RD 12 40-S
L350	ELL.RD 13 50-S
L500	ELL-RD 15 00-S
L550	ELL-RD 15 50-S





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



CROSS CONNECTORS / MULTIAXIAL	
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



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



TECHNICAL FEATURES

STANDARD SCREWS

- Streamlined tip
- Polyaxial & Monoaxial & Reduction Screws
- Low profile implants
- Sterile packaged



25D SCREWS

- Unique implant head design
- Semi polyaxiality
- Coronal & axial correction
- Clear marking identification
- Streamlined tip
- Sterile packaged



Clear LASER marking to identify the locked area



ROMEO[®]2

INSTRUMENT SET



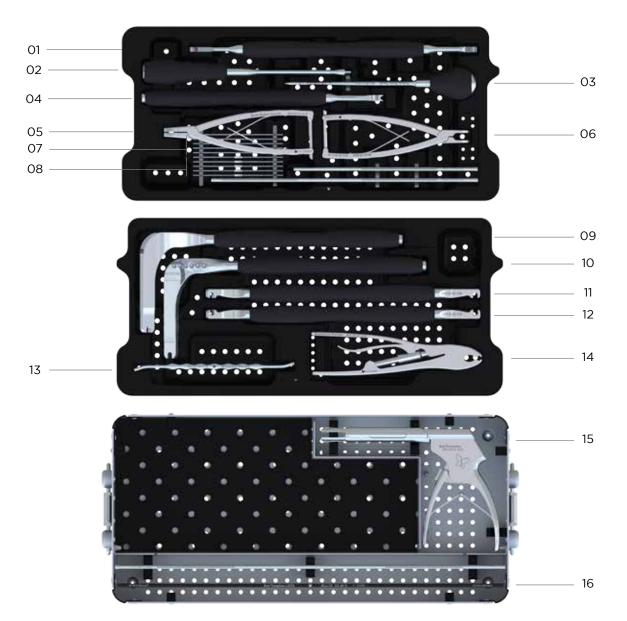
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#	DESCRIPTION	REFERENCE
01	PEDICLE SOUNDER	ELL-IN 01 02-N
02	SETSCREW TUBE	ELL-IN 01 15-N
03	SETSCREW HOLDER	ELL-IN 01 10-N
04	SETSCREW TIGHTENER	ELL-IN 04 06-N
05	SCREWDRIVER SHAFT PS	ELL-IN 01 03-N
06	SCREWDRIVER SHAFT MS	ELL-IN 01 20-N
07	SCREWDRIVER 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 01 22-N
11	BONE AWL	ELL-IN 02 01-N
12	STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N
13	T-HANDLE	HAN-SI MD TE-N

#	DESCRIPTION	REFERENCE
14	COUNTER TORQUE	ELL-IN 01 11-N
15	ROD BENDER	ELL-IN 00 09-N
16	DYNAMOMETRIC TIGHTENER	ELL-IN 03 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
	INSTRUMENTS CONTAINER	ROM-BX 10 01-N

ROMEO[®]2

INSTRUMENT SET



٠S.

01	LAMINA PREPARER HOOK PUSHER	ELL-IN 00 30-N ELL-IN 00 32-N
02	HOOK PUSHER	ELL-IN 00 32-N
03	PEDICLE PROBE SMALL	ELL-IN 01 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

#	DESCRIPTION	REFERENCE
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
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	ROD TEMPLATE L500	ELL-IN 01 28-N
	INSTRUMENTS CONTAINER	ROM-BX 40 01-N

QUICK RELEASE REDUCER

The QR REDUCER is a versatile instrument that can be used for:

- Rod persuasion into a screw head. •
- controlled • Bilateral, powerful and spondylolisthesis reduction.
- Deformity reduction, with multilevel sequential use.
- Vertebral body derotation through • application of a cantilever force on the screw.



The QR reducer ELL-IN 10 34-N is composed of:

- Part A: Handle ٠
- Part B: Tube
- Part C: Shaft
- Part D: T Handle

The QR reducer handle design:

- Quick Release ring
 Quick Release door
- 3. Locking ring



QUICK RELEASE REDUCER

1- Insert the shaft into the reducer tube. The extremity of the shaft has to be slightly squeezed to ease the insertion.



2- Connect the handle to the tube. Firmly screw the locking ring of the handle.



3- Push the shaft 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 shaft is aligned with the «start» LASER marking of the tube.







LAMINA PREPARER ELL-IN 00 30-N HOOK PUSHER ELL-IN 00 32-N PEDICLE PROBE SMALL PEDICLE PREPARER ELL-IN 01 23-N ELL-IN 00 29-N HOOK HOLDER LATERAL ELL-IN 01 31-N HOOK HOLDER ELL-IN 00 31-N Fair Contraction of the local division of th And and it was St. State MARKER LEFT ELL-IN 00 25-N MARKER RIGHT ELL-IN 00 24-N 40

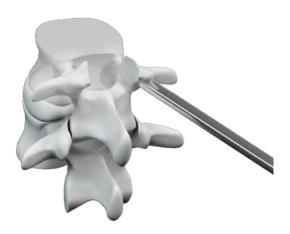




CROSS CONNECTORS SYSTEM 2 INSTRUMENTS



STEP 1



PEDICLE PREPARATION

PEDICLE SOUNDING

X-ray control.

After determining the entry point in 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 Ø4mm screw, it is **mandatory** to use the pedicle probe small.

For Ø5, Ø6, Ø7 and Ø8mm use the pedicle probe.

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

Insert the pedicle sounder to verify the integrity of the screw path. Markers "left & right" can be used during

STEP 2



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

STEP 3

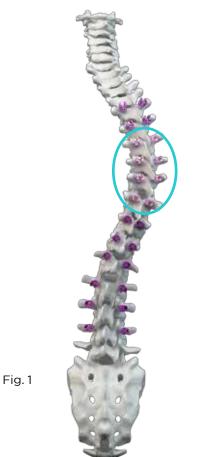
SCREWDRIVER ASSEMBLING

- 01. Insert the screwdriver tube into the screwdriver sleeve through the hole with the LASER mark "UP", until a "click" is heard.
- O2. Select the screwdriver shaft PS and slide it into the distal end of the screwdriver tube until it clicks.
- 03. Connect the assembly to a handle option, e.g. straight handle ratchet.



INSTRUMENT	REFERENCE
SCREWDRIVER SHAFT PS	ELL-IN 01 03-N
SCREWDRIVER TUBE	ELL-IN 21 03-N
SCREWDRIVER SLEEVE	ELL-IN 20 03-N
STRAIGHT HANDLE RATCHET	HAN-SI RA ST-N

STEP 4



SCREW INSERTION

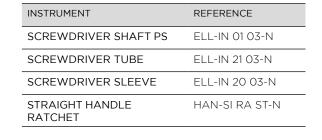
Connect the screw to the screwdriver and proceed to implantation.

Repeat this step for each screw.

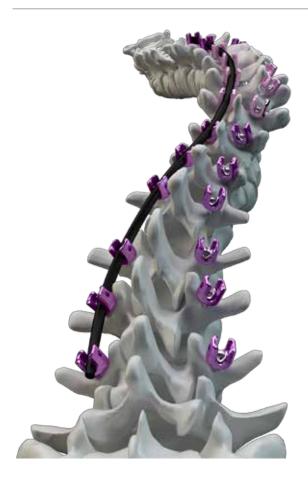
The 25D screws can selectively be implanted in the vertebrae that need to be directly derotated.

As shown in fig. 1, Thoracic vertebrae 7 to 10 are instrumented with 25D screws, i.e. targeted vertebra that will need coronal and axial corrections, located at the apex of the curvature.





STEP 5



ROD SELECTION & CONTOURING

Determine the appropriate contour and length of the rod using the rod template L500.

Perform rod contouring using the rod bender.

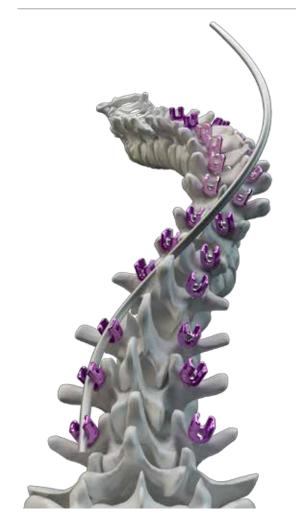
Note: ROMEO^{*}2 rods are Ø5.4mm. To contour a Titanium rod, the radius selector of the bender can be positioned on 5, 6, 7 or 8. When a cobalt chromium needs to be contoured, we recommend to position the radius selector of the bender on 7 or 8.

Once bent, rods should not be bent back again. Repeated bending can weaken the rod.



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

STEP 6



ROD PLACEMENT

According to 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

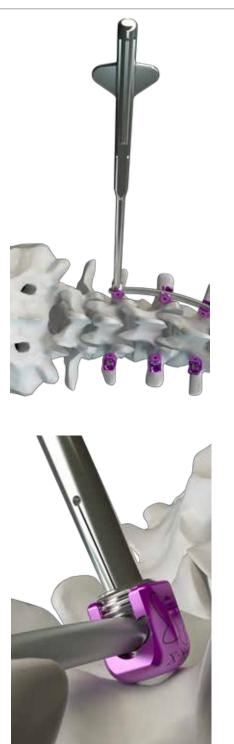
This surgical technique describes the approach based on one rod placed in the concavity.

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 higher than 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 7



ROD PLACEMENT

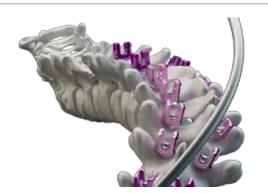
Start inserting the setscrews from the caudal part of the construct. The setscrews should not be firmly locked at this stage, to allow movement of the rod in the screw heads.

Connect the setscrew to the setscrew holder. three different setscrew holders are available.

To ensure the placement of the setscrew and avoid any cross threading, the setscrew tube can be used.

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

STEP 8



ROD PLACEMENT

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

The LASER marking **must** be orientated medially for the screws seating in the concavity, and laterally for the screws seating in the convexity.

STEP 9





ROD PERSUASION

Persuade the rod into the implant head by turning the handle part of the QR reducer or the QR T handle. Sequential manipulation of the QR reducer can be performed for multilevel rod reduction.

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.

In addition to easing the insertion of the contoured rod into the implant heads, the 25D screws help in reducing the stress that could be transmitted from the rod to the vertebrae.

If the rod is fully seated in the implant heads, setscrew can be inserted through the QR reducer.

INSTRUMENT	REFERENCE
QR REDUCER	ELL-IN 10 34-N
QR REDUCER T HANDLE	HAN-SS TY 14-N
SETSCREW HOLDER W	ELL-IN 03 10-N



STEP 10



The rod rotation maneuver will be achieved using the

Thanks to the hexagonal tip at the rod extremity, the hexagonal wrench can additionally be used.

STEP 11



SPINE DEROTATION

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

Once the rotation of the rod is complete, release the derotation forceps. Firmly tighten the setscrews. You may use the counter torque and the setscrew tightener connected to a T-Handle.

Start at the caudal part of the construct and progressively advance to the vertebrae instrumented with the 25D screws.

Do not tighten the setscrews of the 25D screws before any vertebral body derotation maneuvers.

REFERENCE
ELL-IN 01 11-N
ELL-IN 04 06-N
HAN-SI MD TE-N

STEP 12



VERTEBRAL BODY DEROTATION

Further correction can be achieved via vertebral body derotation.

The vertebral body derotation maneuver is performed by applying a cantilever force on the QR reducer placed on the 25D screws. The force will be directly transmitted to make the vertebrae rotate.

Continue vertebral body derotation until neutral position is reached. Increase the setscrew tightening. Repeat sequentially this process along the spine on each 25D instrumented vertebra.

Variation: to maintain the bone-screw interface during maneuvers, the cantilever force can be shared on both pedicles by connecting a second QR reducer on the same vertebra.

Variation: loss of rotational correction due to spine spring back can be minimized by following the steps described above after insertion of the second rod.

INSTRUMENT	REFERENCE
DEROTATION FORCEPS	ELL-IN 01 18-N
QR REDUCER	ELL-IN 10 34-N

STEP **13**



FINE-TUNING AND FINAL TIGHTENING

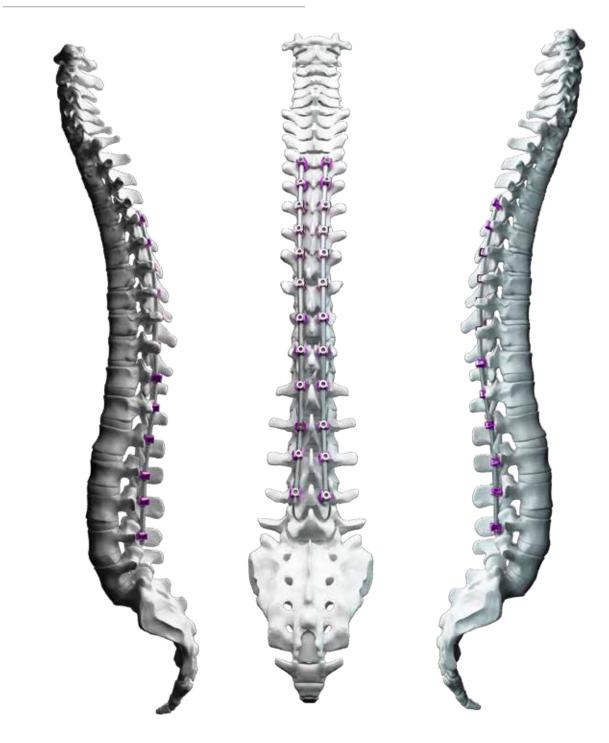
Remove the QR reducers.

If needed, fine-tune the correction by performing compression and distraction and/or in situ bending.

Proceed to the final tightening of the construct using the counter torque and the dynamometric tightener.

INSTRUMENT	REFERENCE
DISTRACTION FORCEPS	ELL-IN 00 07-N
COMPRESSION FORCEPS	ELL-IN 00 08-N
SAGITTALBENDER LEFT/ RIGHT	ELL-IN 00/01 26-N
CORONAL BENDER LEFT/ RIGHT	ELL-IN 00/01 27-N
COUNTER TORQUE	ELL-IN 01 11-N
DYNAMOMETRIC TIGHTENER	ELL-IN 03 06-N

FINAL CONSRUCT



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