PERLA®

CERVICAL POSTERIOR FIXATION

LAUNCH MASTERFILE

C O N T E N T

04
CERVICAL SPINE OVERVIEW

05
CERVICAL SPINE BIOMECHANICS

06
CERVICAL SPINE ANATOMY

07
SUB-AXIAL CERVICAL SPINE ANATOMY

08
AXIAL CERVICAL SPINE ANATOMY

09
CERVICAL SPINE FIXATION

13
INDICATIONS / CONTRAINDICATIONS

14
PRODUCT POSITIONING

15
PRODUCT DESCRIPTION

24
ENGINEERING CORNER

27
COMPETITIVE ANALYSIS

30
KIT SETUP

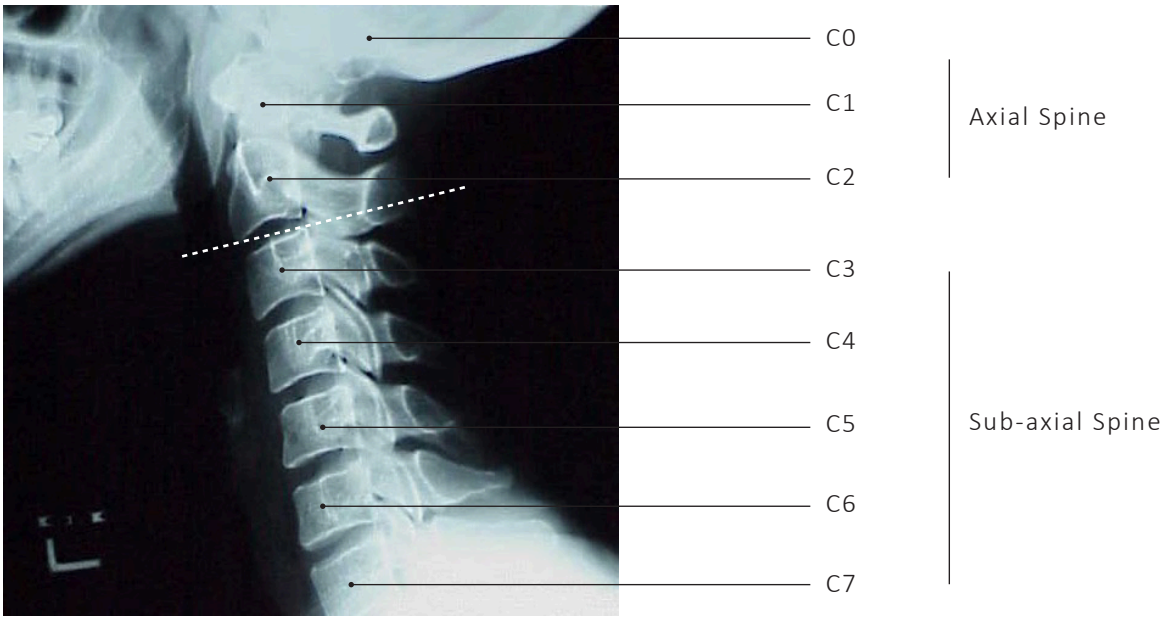
34
INSTRUMENTS

43
TIPS AND TRICKS

45
FAQS

48
GENERAL INFORMATION

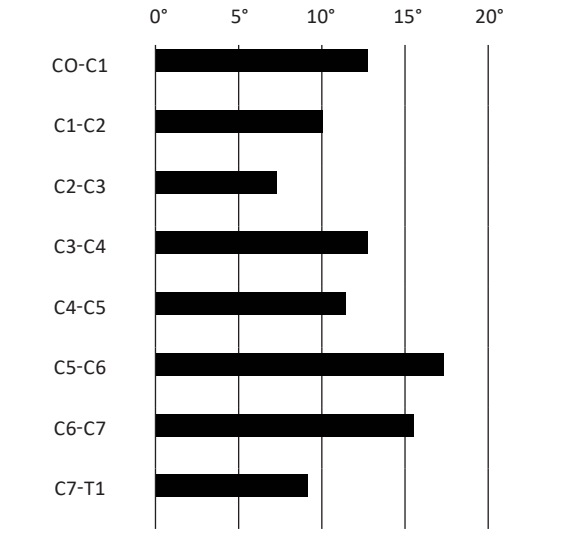
CERVICAL SPINE OVERVIEW



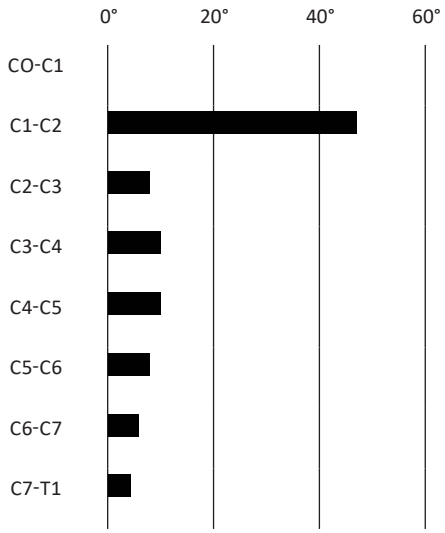
- The axial cervical spine is composed of C1 (Atlas) and C2 (Axis) vertebrae.
- Sometimes the Occiput is also considered as part of the cervical spine and described as C0.
- The sub-axial spine is composed of C3 to C7 vertebrae. C3 to C6 are similarly shaped while C7 (prominent vertebra) is shaped differently.

CERVICAL SPINE BIOMECHANICS

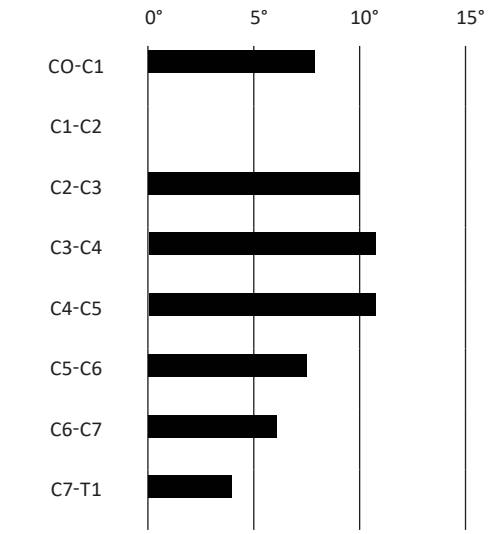
FLEXION / EXTENSION



AXIAL ROTATION



LATERAL BENDING



- The axial cervical spine (C1-C2) provides the greatest range of motion in term of combined axial rotation with flexion/extension.
- The sub-axial spine (C3-C7) provides the same range of motion as the lumbar spine.

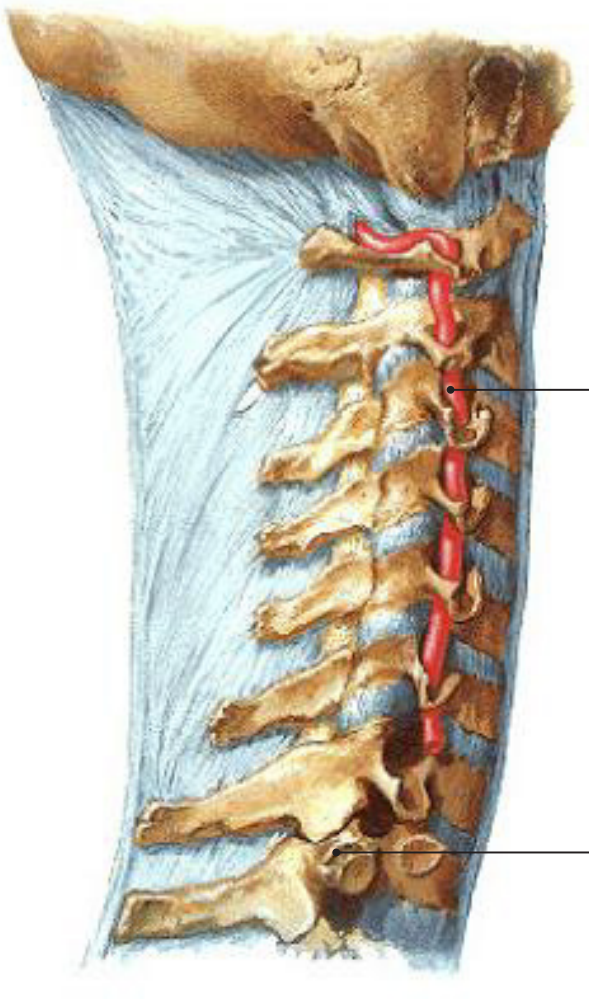
CLINICAL BIOMECHANICS OF THE SPINE, A. WHITE, M. PANJABI, 1978, PAGES 65, 71 AND 84.

CERVICAL SPINE ANATOMY

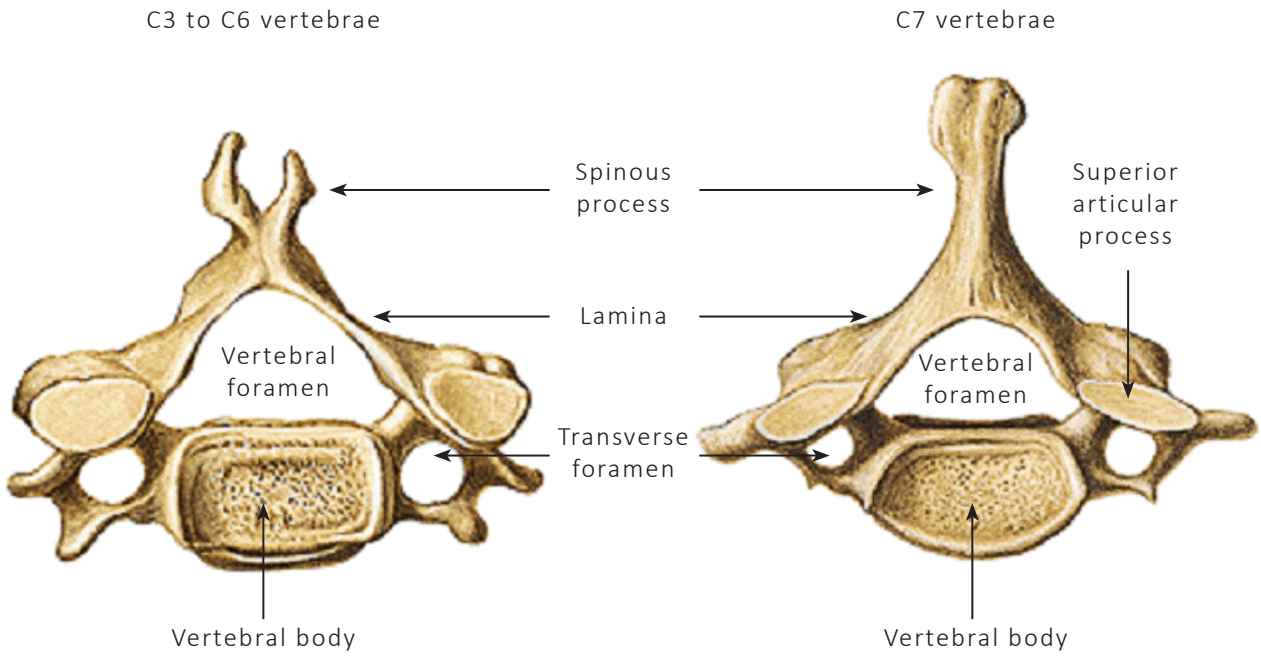
LATERAL VIEW

The cervical spine has various shapes of vertebrae:

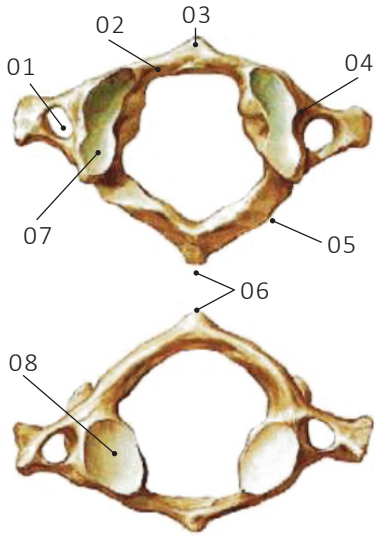
- C1: anterior and posterior arches (no lamina and no pedicle), no vertebral body
- C2: odontoïd process that fits into C1 vertebral foramen
- C3 to C6: similarly shaped without any specificity
- C7: similar to C3/C6 vertebrae but with bigger spinous process and smaller lateral masses
- For all of them, the vertebral artery is going through their transverse foramen



SUB-AXIAL CERVICAL SPINE ANATOMY

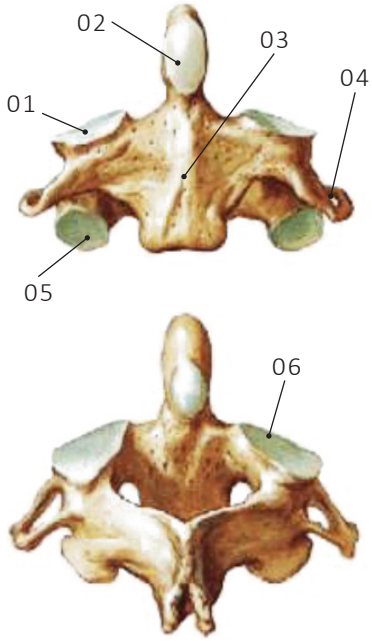


AXIAL CERVICAL SPINE ANATOMY



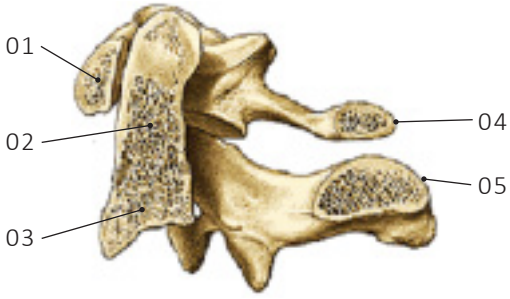
C1 OR ATLAS

01 Transverse foramen
02 Anterior arch
03 Anterior tubercule
04 Lateral mass
05 Posterior arch
06 Posterior tubercule
07 Superior articular surface of lateral mass for occipital condyle
08 Inferior articular surface of lateral mass axis



C2 OR ATLAS

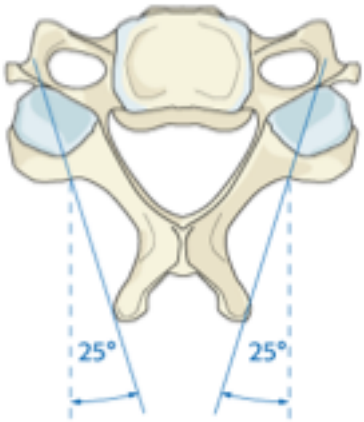
01 Superior articular facet for atlas
02 Odontoid process / dens
03 Vertebral body
04 Transverse process
05 Inferior articular facet for C3
06 Superior articular facet for atlas

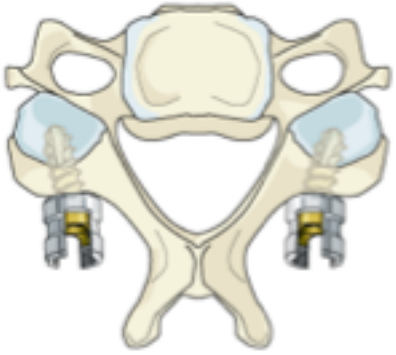


C1-C2 VIEW OF A CUT IN THE SAGITTAL PLANE

01 C1 Anterior arch
02 Odontoid process / dens
03 C2 Vertebral body
04 C1 Posterior arch
05 C2 Posterior arch

CERVICAL SPINE FIXATION



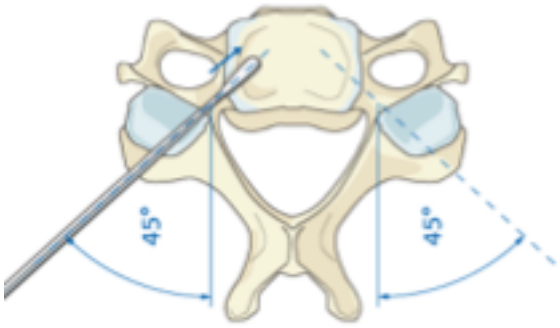


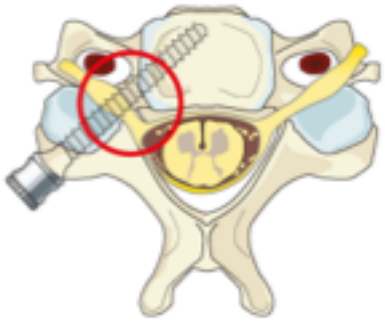
LATERAL MASS FIXATION - MARGEL TECHNIQUE

This is the most commonly used fixation technique for cervical spine. It allows a safe and secure approach, away from the vertebral artery and the spinal canal.
The screw trajectory is around **25° laterally** to avoid the vertebral artery which is located directly anterior to the entry point.

The ANDERSON technique has the same approach but with a reduced angulation of **10° laterally**.

Lateral Mass Fixation technique is mostly used from C3 to C6 levels and also C1 for HARMS Technique (see p10).



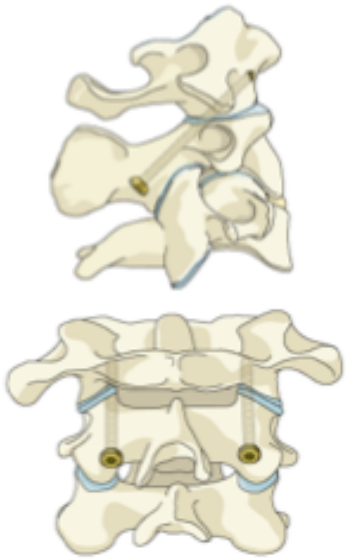


PEDICLE FIXATION

In the cervical area, this is a seldomly used technique as it is more challenging. The screw needs to be inserted in the pedicle, between the vertebral artery and the cervical cord. Even minor screw malposition can result in severe neurovascular injury.
The main advantage of this technique is that it provides 4 times greater pullout resistance compared to the lateral mass fixation. This is why this approach is mainly used in patients with poor bone quality.
Depending on the exact location of the starting point, the insertion angle of the screw is around **45° medially**. That is why the inserted screw needs a great medio-lateral angulation.

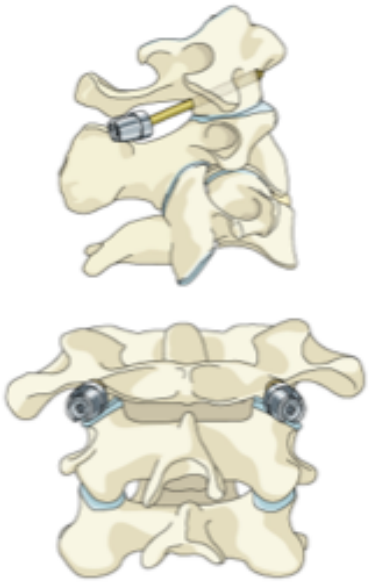
Pedicle Fixation technique is mainly used on C2 for HARMS Technique (see p10) and C7 due to its limited lateral masses.

CERVICAL SPINE FIXATION



TRANSARTICULAR FIXATION - MAGERL TECHNIQUE (C1-C2)

The «transarticular» name is due to the approach of the screw as it goes through the C1-C2 facet articulation.
The insertion angle is around **45° cephalad** in the sagittal plane. The screw needs a high cranio-caudal angulation.



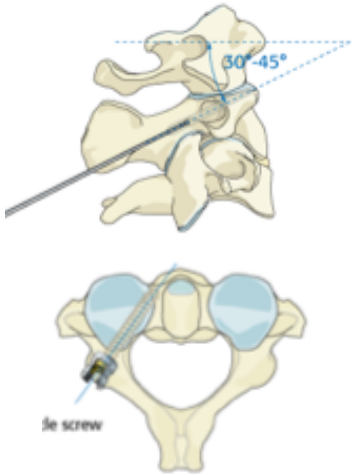
HARMS TECHNIQUE (C1-C2)

This technique separates the fixation of C1 and C2:

- C1: lateral mass fixation

_ Starts just caudal or on top of the posterior arch:

- **Caudal of the posterior arch:** a part of the bone screw will stay out of the bone, so the use of a partially threaded screw is needed.
- **Top of the posterior arch:** the posterior arch needs to be thick enough to allow for the screw insertion.



- C2: pedicle fixation (laminar and pars fixation are also possible but less practised)

_ The angulation of the screw is approximatively **30°-45° craniocaudally**. The pedicle of C2 has a higher ascendance than the other vertebrae. A screw with a great cranio-caudal angulation is needed.

CERVICAL SPINE FIXATION

Medscape® www.medscape.com

	Roy-Camille Screw Length				Magerl Screw Length			
	Males		Females		Males		Females	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
C3	11.7	1.5	11.0	1.5	14.0	1.7	13.2	1.7
C4	12.6	1.5	11.5	1.3	15.1	1.7	13.8	1.4
C5	12.9	1.5	11.4	1.4	15.6	1.8	13.9	1.4
C6	12.4	1.5	11.1	1.6	15.6	2.1	14.0	2.1
C7	9.8	1.3	8.5	1.2	11.4	1.8	9.6	1.5

Source: Spine © 2008 Lippincott Williams & Wilkins

QUANTITATIVE ANATOMY OF SUBAXIAL CERVICAL LATERAL MASS: AN ANALYSIS OF SAFE SCREW LENGTHS FOR ROY-CAMILLE AND MAGERL TECHNIQUES. Brian D. Stemper, PhD; Satyajit V. Marawar, MD; Narayan Yoganandan, PhD; Barry S. Shender, PhD; Raj D. Rao, MD. Spine. 2008;33(8):893-897.

SCREW SIZES

12 and 14mm screw lenghts are commonly used for most levels. 10mm lenght screws are typically used at C7.

24 to 28mm screw lenghts are commonly used for pedicle screw fixation.

SCREW PULLOUT RESISTANCE

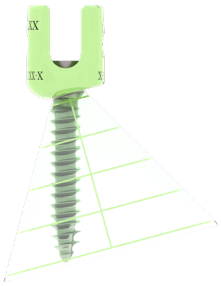
Studies have shown pedicle screw fixation provides 4 times greater pullout resistance compared to lateral mass screws.*

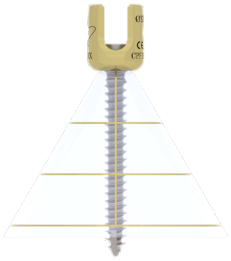
However, due to vertebral artery and spinal cord proximity, pedicle screw placement is risky, limiting the technique to instances where greater pullout resistance is necessary.

For example, pedicle screw placement may be necessary in patients with poor bone quality.

**CERVICAL PEDICLE SCREWS VS. LATERAL MASS SCREWS: UNIPLANAR FATIGUE ANALYSIS AND RESIDUAL PULLOUT STRENGTHS. Johnston TL , Karaikovic EE, Lautenschlager EP, Marcu D. Spine. 2006;6(6):667-72*

CERVICAL SPINE FIXATION





SCREW OPTIONS

Once anatomical specificities and fixation techniques are known, you can fit the approach with the adapted screw:

- Polyaxial Screw (PS)
  _ 30° polyaxiality
  _ Adapted to lateral mass approach
- Smooth Shank Screw (SS)
  _ 30° polyaxiality
  _ Partially threaded
  _ Adapted to C1 lateral mass fixation starting caudally from the posterior arch
- Cranio-Caudal Preferred Angle (CC)
  _ 45° polyaxiality on cranio-caudal plan
  _ 30° polyaxiality on medio-lateral plan
  _ Adapted to C1/C2 transarticular approach and pedicle fixation on C2
- Medio-Lateral Preferred Angle (ML)
  _ 45° polyaxiality on medio-lateral plan
  _ 30° polyaxiality on cranio-caudal plan
  _ Adapted to pedicle fixation from C3 to C7

The chart below resumes instrumented level / fixation technique / screw type association.

VERTEBRA	FIXATION TECHNIQUE		
	LATERAL MASS	PEDICLE	TRANSARTICULAR
C1	SS (caudal of the posterior arch)		
	PS (on top of the posterior arch)		
C2		CC	
C1/C2			CC
C3 to C6	PS		
		ML	
C7		ML	

INDICATIONS CONTRAINDICATIONS

INDICATIONS

The PERLA® posterior cervico-thoracic fixation system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from Tl-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The PERLA® posterior cervico-thoracic fixation system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the PERLA® posterior cervico-thoracic fixation system may be connected to the ROMEO® Posterior Osteosynthesis System with rod connectors. Transition rods may also be used to connect the PERLA® posterior cervico-thoracic fixation system to the ROMEO® Posterior Osteosynthesis System. Refer to the ROMEO® Posterior Osteosynthesis System package insert for a list of the ROMEO® Posterior Osteosynthesis System indications of use.

Perla posterior cervico thoracic fixation system is indicated for skeletally mature patients.

CONTRAINDICATIONS

The PERLA® posterior cervico-thoracic fixation system is not designed or sold for any use except as indicated.

DO NOT USE THE PERLA® SYSTEM IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.

Contraindications include, but are not limited to:

- Overt infection or distant foci of infections.
- Local inflammation, with or without fever or leukocytosis.
- Pregnancy.
- Morbid obesity.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
- Suspected or documented metal allergy or intolerance.
- Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
- Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
- Use in displaced, non-reduced fractures with bone loss.
- The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
- Poor prognosis for good wound healing (e.g., decubitis ulcer, end-stage diabetes, severe protein deficiency, and/or malnutrition).
- Any case not needing a bone graft or fusion.
- Any case not described in the indications.

PRODUCT POSITIONING

SEGMENT GROWTH

Revenues for the Posterior Cervical Fixation are growing faster than anterior fixation with a 2015-2018 CAGR of 5.0% vs only 3.7% for anterior fixation.

PROCEDURE GROWTH

Posterior Cervical Fixation procedures are growing faster than anterior fixation with a 2015-2018 CAGR of 6.4% vs only 5.3% for ante-rior fixation.

PROCEDURE PROFILE

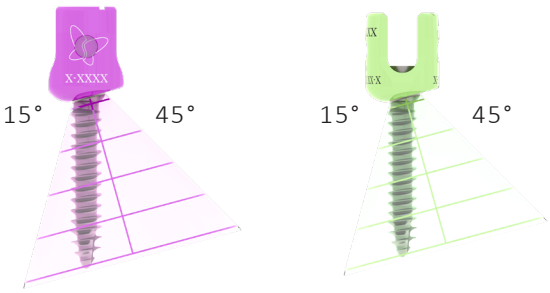
C3-T1 no fixation at C7
4 levels
10 screws
2 rods
2 Cross connectors

AVERAGE SELLING PRICE (ASP)

Posterior Cervical Fixation ASP is 2.6 higher than anterior fixation.

Data from: MRG non-fusion 2012 / iData ASP07 / iDtaLASP13 / Global data 2013 / iDataEU12 / iDataEUOB13 / MRG EUMI2010 / Global Data US 2015

PRODUCT DESCRIPTION



PREFERRED ANGLE SCREWS

Cranial-caudal and Medio-lateral preferred angle screws available to adapt to various patients anatomy and to simplify rod placement. These screws feature 45 º of polyaxiality in the preferred direction.

POLYAXIAL SCREWS, SMOOTH SHANK SCREWS & HOOKS

Polyaxial and Smooth Shank screws provide 60º range of motion (+- 30º). Multiple hook designs provide additional fixation options.

RODS

Rods are available pre-bent and straight with titanium and cobalt chromium options. Transition rods (ø3.5/5.4mm) offer link to ROMEO®2 constructs.

PRODUCT DESCRIPTION

CROSS CONNECTORS

Rod to Rod and Head to Head cross connectors increase torsional and lateral stability*. Rod to rod connectors are adjustable in 3 axes.

ROD CONNECTORS

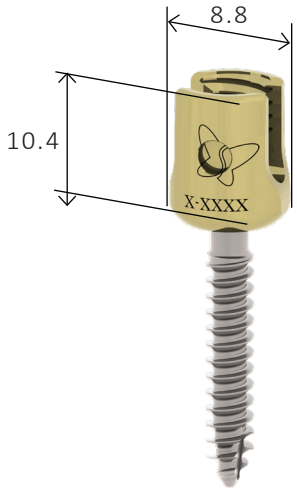
9 different connector designs to link Ø3.5 and Ø5.4mm rod constructs and provide intraoperative flexibility.

STREAMLINED INSTRUMENTATION

Intuitive instrumentation in 1 compact set.

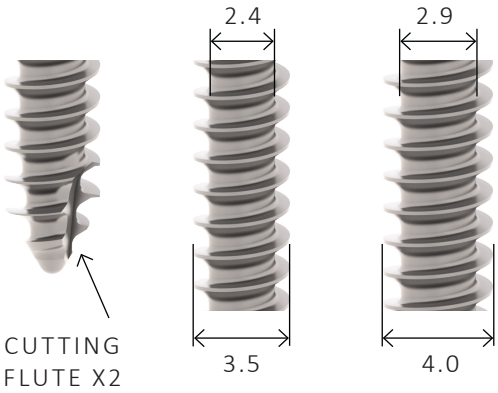
** BIOMECHANICAL ANALYSIS OF THE C2 INTRALAMINAR FIXATION TECHNIQUE USING A CROSS-LINK AND OFFSET CONNECTOR FOR AN UNSTABLE ATLANTOAXIAL JOINT. LEHMAN RA JR1, DMITRIEV AE, WILSON KW. SPINE J. 2012 FEB;12(2):151-6. DOI: 10.1016/J. SPINE.2012.01.020.*

PRODUCT DESCRIPTION



HEAD DESIGN

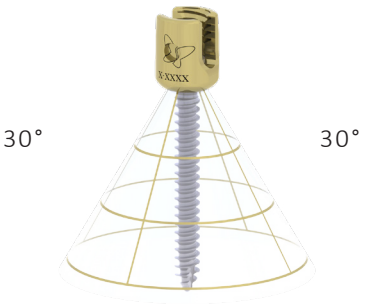
- Color coded by screw type
- Reduced screw head volume



THREAD DESIGN

- Cylindrical core & thread
- Streamlined tip
- Cortical thread type
- Self tapping
- Blunt tip

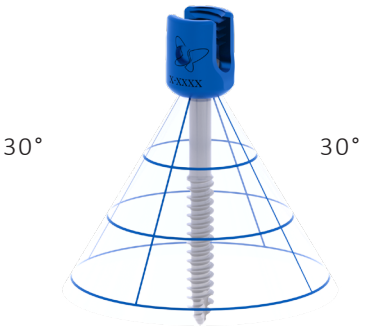
PRODUCT DESCRIPTION



POLYAXIAL SCREW

- Yellow tulip
- 2 per box
- ±30° polyaxiality

Ø	3,5		4.5	
LENGTH (MM)	8 to 20	20 to 52	8 to 20	20 to 52
INCREMENT (MM)	2	4	2	4

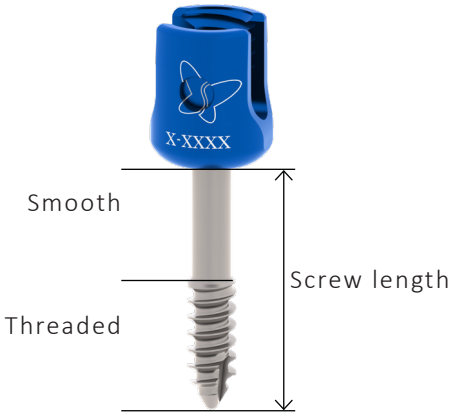


THREAD DESIGN

- Blue tulip
- 1 per box
- ±30° polyaxiality
- Inner and outer diameter are the same as polyaxial screws
- Smooth and threaded parts vary according to screw length

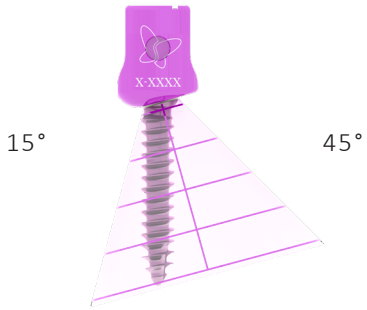
Ø	3,5	4.0
LENGTH (MM)	18 to 36	18 to 36
INCREMENT (MM)	2	2

Example of C1 screw insertion



SCREW LENGTH (MM)	SMOOTH (MM)	THREADED (MM)
18	8	10
20	8	12
22	8	14
24	8	16
26	10	16
28	10	18
30	10	20
32	12	20
34	12	22
36	12	24

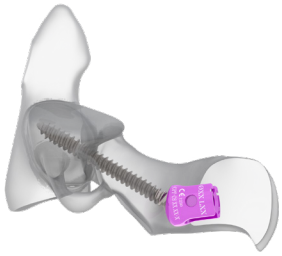
PRODUCT DESCRIPTION



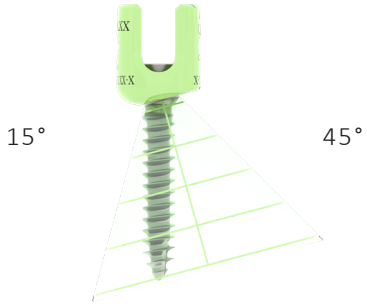
Ø	3,5		4.0	
LENGTH (MM)	8 to 20	20 to 52	8 to 20	20 to 52
INCREMENT (MM)	2	4	2	4

CC PREFERRED ANGLE SCREW

- CC = Cranio-caudal -15°/+45°
- Mediolateral ±30°
- Pink tulip
- 1 per box



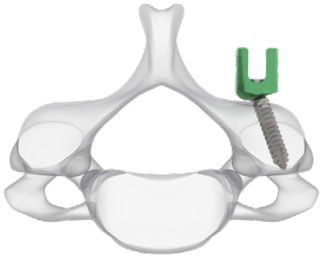
Example of transpedicular C2 screw insertion



Ø	3,5		4.0	
LENGTH (MM)	8 to 20	20 to 52	8 to 20	20 to 52
INCREMENT (MM)	2	4	2	4

ML PREFERRED ANGLE SCREW

- ML = Medio-lateral -15°/+45°
- Cranial-caudal ±30°
- Green tulip
- 1 per box



Example of C3-C7 lateral mass screw insertion

PREFERRED ANGLE IDENTIFICATION

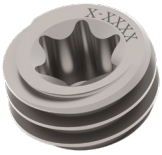
Laser etched grooves indicate preferred angle in cranio-caudal and medio-lateral orientation.

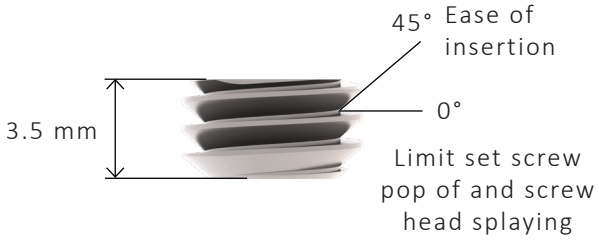
PRODUCT DESCRIPTION

	OFFSET LEFT	OFFSET RIGHT	STRAIGHT
LARGE 6x2.8			
SMALL 4.5x2			

HOOKS

- Full range
- Serrated for initial stability
- 1 per box

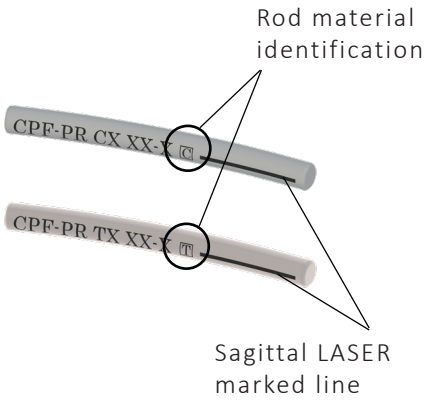




SET SCREWS

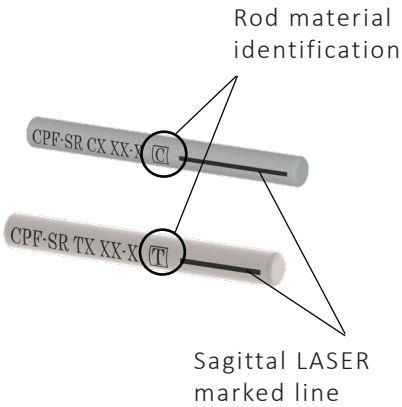
- Buttress thread
- Used for any type of screws and hooks
- Hexalobe T20 = grey
- Torque limiting tightener 22 lbf.in / 2.5 Nm
- Packed with screws/hooks

PRODUCT DESCRIPTION



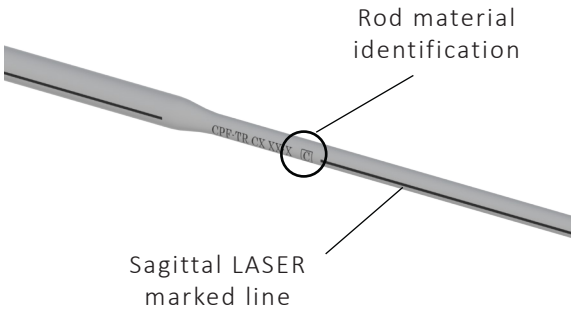
PREBENT ROD

- Ø3.5mm
- 2 rod materials: Ti alloy & CoCr alloy
- Length:
  _ L40 to L90 with 5mm increment
- 2 per box



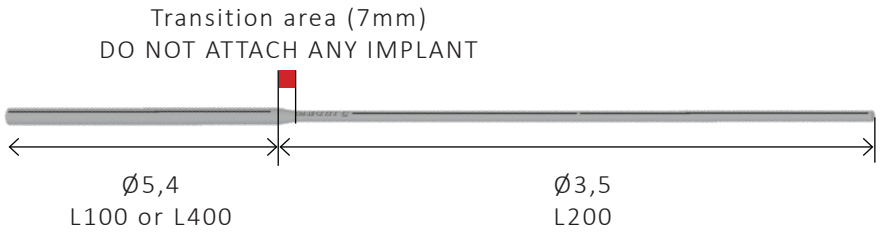
STRAIGHT ROD

- Ø 3.5mm
- 2 rod materials: Ti alloy & CoCr alloy
- Length:
  _ L40 to L90 with 5mm increment
  _ L90 to L120 with 10mm increment
  _ L240
  _ L350
- 2 per box

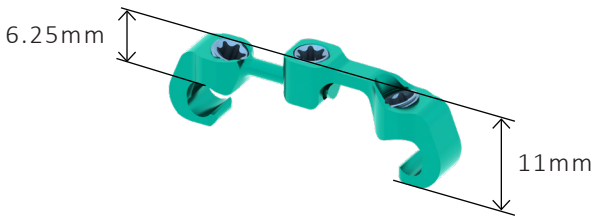


TRANSITION ROD

- ø3.5mm and ø5.4mm portions
- 2 rod materials: Ti alloy & CoCr alloy



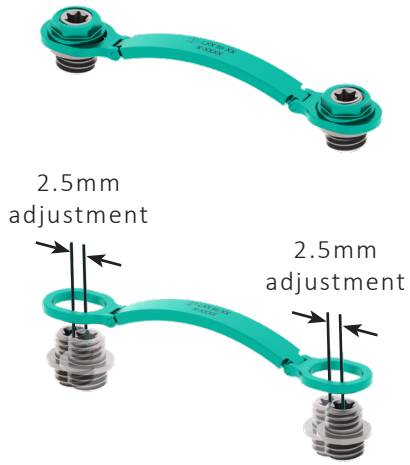
PRODUCT DESCRIPTION



SIZE	1	2	3	4	5
LENGTH (MM)	21-23	23-26	26-32	32-44	44-56

RTR (ROD TO ROD) CROSS CONNECTOR

- Rod to rod
- Pre–assembled
- Captive set screws Hexalobe T15 = blue
- Torque limiting tightener 22 lbf.in / 2.5 Nm
- Pivot, rotate and telescopic
- Low profile: 6.25mm above the rods
- For ø3,5 rods
- 1 per box



SIZE	A	B	C	D	E	F
LENGTH (MM)	20-25	25-30	30-35	35-40	40-45	45-50

HTH (HEAD TO HEAD) CROSS CONNECTOR

- Top loading
- Low profile
- Extended set screws & locking nuts
- Eyelets provide angulation
- Eyelets allow for 2.5mm translation
- 1 box for the connector
- 1 box for 2 extended set screws + 2 hexagonal set screws (locking nuts)

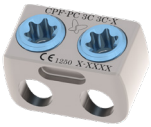
HTH (HEAD TO HEAD) CROSS CONNECTOR

- Hexagonal set screw = green
- Torque limiting tightener 22 lbf.in / 2.5 Nm

- Extended set screws Hexalobe T20
- Hexalobe T20 = grey
- Buttress thread 0°/45°
- 1 packaging for 2 extended setscrew & 2 hexagonal set screws

PRODUCT DESCRIPTION

3.5/3.5 close/open
3C-3O



3.5/3.5 close/close
3C-3C

3.5/5.4 close/open
3C-5O

5.4/3.5 close/open
5C-3O

PARALLEL ROD CONNECTORS

- Captive set screws Hexalobe T15 = Blue
- Torque limiting tightener 22 lbf.in/2.5 Nm
- 2 set screws used to secure ø5.4mm rods
- 1 per box

3.5/5.4 open/close
3O-5C

5.4/3.5 open/close
5O-3C

AXIAL ROD CONNECTORS

- Captive set screws Hexalobe T15 = Blue
- Torque limiting tightener 22 lbf.in / 2.5 Nm
- 1 per box

LATERAL CONNECTORS

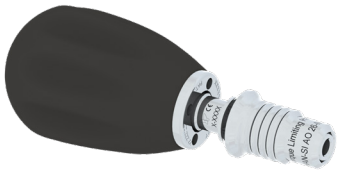
- Captive set screws Hexalobe T15 = Blue
- Torque limiting tightener 22 lbf.in / 2.5Nm
- Flat portion
- 2 lengths
- 1 per box

ENGINEERING CORNER

SET SCREW INTERFACE AND FINAL TIGHTENING

DEVICE				
DESCRIPTION	SET SCREW	EXTENDED SET SCREW	HEXAGONAL SET SCREW	CROSS CONNECTOR SET SCREW
REF.	CPF-SC 00 00-S	CPF-SC 01 00-S	CPF-SC 02 00-S	CPF-AC XX XX-S CPF-PC XX XX-S CPF-RC XX XX-S
INTERFACE	TORX T20	TORX T20	HEXA 7	TORX T15
TORQUE	22 LBF.IN / 2.5NM			

TORQUE LIMITING HANDLE

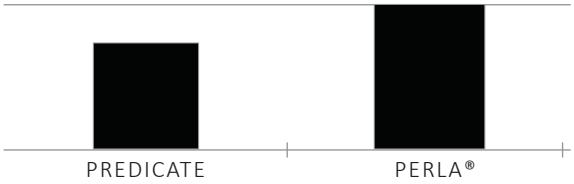


Torque limit: 2.5 Nm or 22 inch pounds
Calibrated for 1 year use

ENGINEERING CORNER

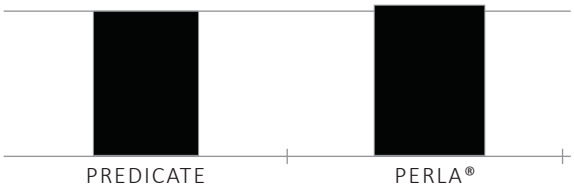
STATIC COMPRESSION OF CORPECTOMY MODEL

PERLA® result: 10% superior to predicate.*



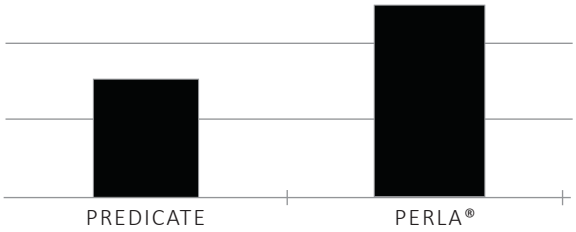
STATIC TORSION OF CORPECTOMY MODEL

PERLA® result: 1.6% superior to predicate.*



DYNAMIC COMPRESSION OF CORPECTOMY MODEL

PERLA® result: 70% superior to predicate.*



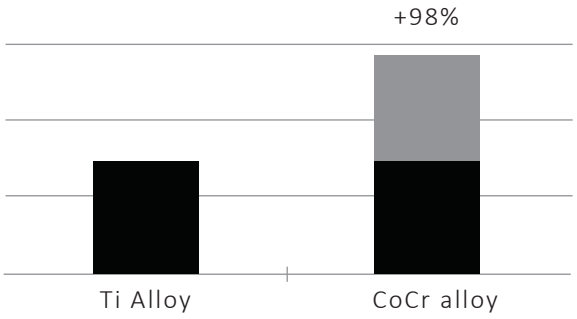
* Internal data

ENGINEERING CORNER

ROD MATERIAL AND MECHANICAL BEHAVIOUR

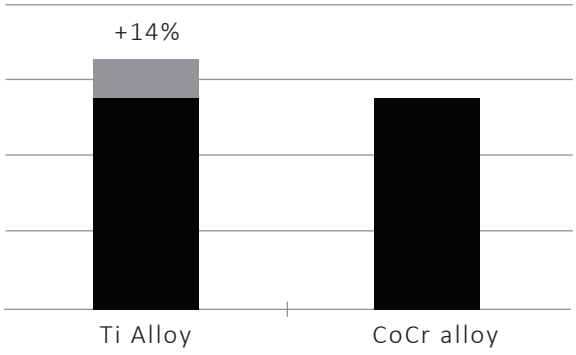
STIFFNESS

Stiffness is a property that indicates material rigidity in a specific design. A stiff rod is needed to correct a deformity. The spine is reduced to the rod and not the rod bending to the spine.



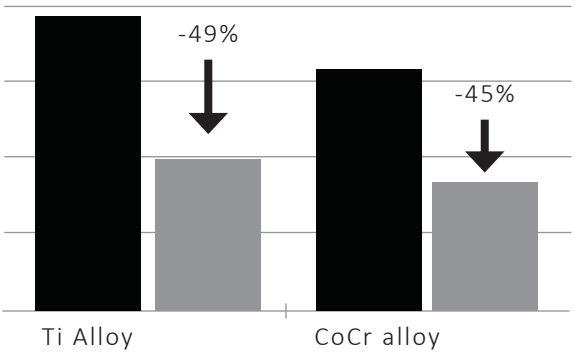
ROD YIELD RESISTANCE

The higher the Rod Yield Resistance, the greater the ability for the rod to maintain the deformity correction over time. This is key to avoid loss of correction post op.



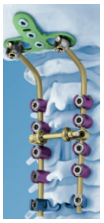
INFLUENCE OF ROD BENDING

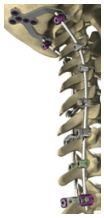
Intra-operative rod bending decreases rod strength. The greater amount of intra-operative bending negatively influences construct resistance. Pre-bent rods decrease the amount of intra-operative rod bending.
The graph below shows loss of resistance after a 40° bending.



INFLUENCE OF ROD CONTOURING ON ROD STRENGTH AND STIFFNESS IN SPINE SURGERY. Satoru Demura, MD; Hideki Murakami, MD; Hiroyuki Hayashi, MD; Satoshi Kato, MD; Katsuhito Yoshioka, MD; Noriaki Yokogawa, MD; Takayoshi Ishii, MD; Takashi Igarashi, MD; Xiang Fang, MD; Hiroyuki Tsuchiya, MD.

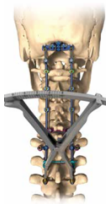
COMPETITIVE ANALYSIS

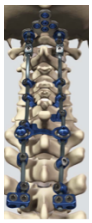


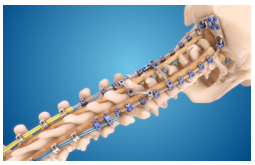


		SPINEART PERLA®	MEDTRONIC VERTEX SELECT	SYNTHES SYNAPSE	STRYKER OASYS
SCREWS	DIAMETER	3.5mm 4.0mm 4.5mm (only for multi-axial screw)	3.5mm 4.0mm 4.5mm	3.5mm 4.0mm 4.5mm	3.5mm 4.0mm (except for smooth shank) 4.5mm (only for non-biased screw)
	ANGULATION	±30° up to 45°	±30° up to 45°	±50° (±40° for 4.5mm diameter screw) ±40° for Smooth Shank screw	±30° up to 55°
	PREFERRED ANGLE	CC and ML	3 relief notches with 45°	-	CC, ML and Smooth Shank
	SMOOTH SHANK	✓	✓	✓ (constant 10mm unthreaded length throughout all screw length)	✓ (constant 10mm unthreaded length throughout all screw length)
RODS	MATERIAL	Ti Alloy CoCr	Ti Alloy Chromaloy	Ti Alloy	Vitalium Ti Alloy Pure Titanium
	DIAMETER	3.5mm	3.2mm 3.5mm	3.5mm 4.0mm (compatible with 4.0mm diameter screw only)	3.5mm
	SHAPE	Straight and Pre-bent	Straight	Straight and Pre-bent	Straight
	TRANSITION	✓	✓	✓	✓
CONNECTORS	ROD TO ROD	✓	✓	✓	✓
	HEAD TO HEAD	✓	✓	✓	✓
	AXIAL	✓	✓	-	✓
	PARALLEL	✓	✓	✓	✓
	LATERAL	✓	✓	✓	✓
	COMPETITIVE WEAKNESSES		Fixed notches for preferred angle screws. No pre-bent rod.	No CoCr rod. No axial connector	Fixed Rod to Rod Cross Connector. No pre-bent rod. No CoCr rod.

COMPETITIVE ANALYSIS







		NUVASIVE VUE POINT II	ZIMMER VIRAGE	MEDTRONIC INFINITY	ULRICH NEON3
SCREWS	DIAMETER	3.5mm 4.0mm 4.5mm (only for multi-axial screw)	3.5mm 4.0mm 4.5mm (except Smooth Shank screw) 5.0mm (except Smooth Shank screw)	3.0mm 3.5mm 4.0mm 4.5mm 5.5mm	3.5mm 4.0mm 4.5mm 5.5mm
	ANGULATION	±40° up to 55°	±32° up to 56°	Up to 60°	±48° up to 55°
	PREFERRED ANGLE	CC and Smooth Shank	1 orientable notch with 56°	1 orientable notch with 60°	CC and ML
	SMOOTH SHANK	✓ (constant 10mm unthreaded length throughout all screw length + only available with 3.5mm diameter screw)	✓ (length of the smooth portion varies with differetn screw lengths)	✓ (constant 10mm unthreaded length throughout all screw length)	✓ (constant 13mm unthreaded length throughout all screw length)
RODS	MATERIAL	Ti Alloy CoCr	Ti Alloy CoCr	Ti Alloy Chromaloy	Ti Alloy Pure Titanium CoCr
	DIAMETER	3.5mm	3.5mm	3.2mm 3.5mm	4.0mm
	SHAPE	Straight and Pre-bent	Straight and Pre-bent	Straight and Pre-bent	Straight
	TRANSITION	✓	✓	✓	-
CONNECTORS	ROD TO ROD	✓	✓	✓	✓
	HEAD TO HEAD	✓	✓	✓	✓
	AXIAL	✓	-	✓	✓
	PARALLEL	✓	✓	✓	✓
	LATERAL	✓	✓	✓	✓
	COMPETITIVE WEAKNESSES	No ML screw option.	No Axial Rod Connector. Preferred angle hard to find.	Preferred angle hard to find.	No transition rod. Thicker rod (+0.5mm)

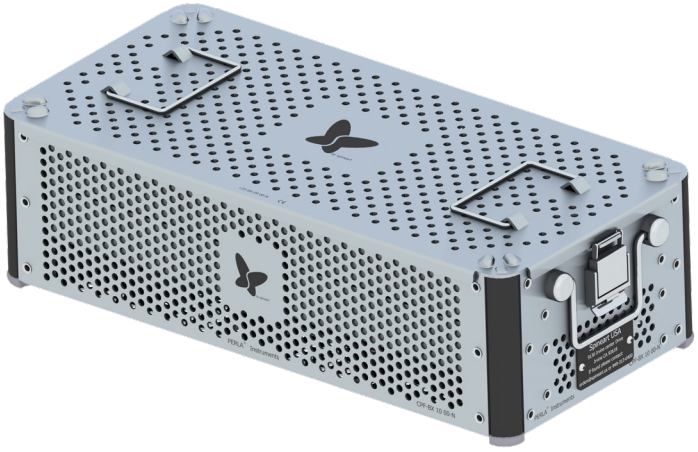
COMPETITIVE ANALYSIS

SCREW HEAD DIMENSION

SPINEART	PERLA®	8.8	10.4

COMPANY	SYSTEM	DIAMETER (MM)	HEIGHT (MM)
ALPHATEC	Solanas	8.2	9.6
DEPUY SYNTHES	Mountaineer	8.5	11
DEPUY SYNTHES	Summit	9	11
DEPUY SYNTHES	Synapse	9	10.8
DEPUY SYNTHES	Axon	9	11
MEDTRONIC	Vertex Select	8.5	10
NUVASIVE	Vuepoint2	8.5	9.3
SEASPINE	Sierra	7.8	10.6
STRYKER	Oasys	8	10
ZIMMER	Virage	8.5	10.5

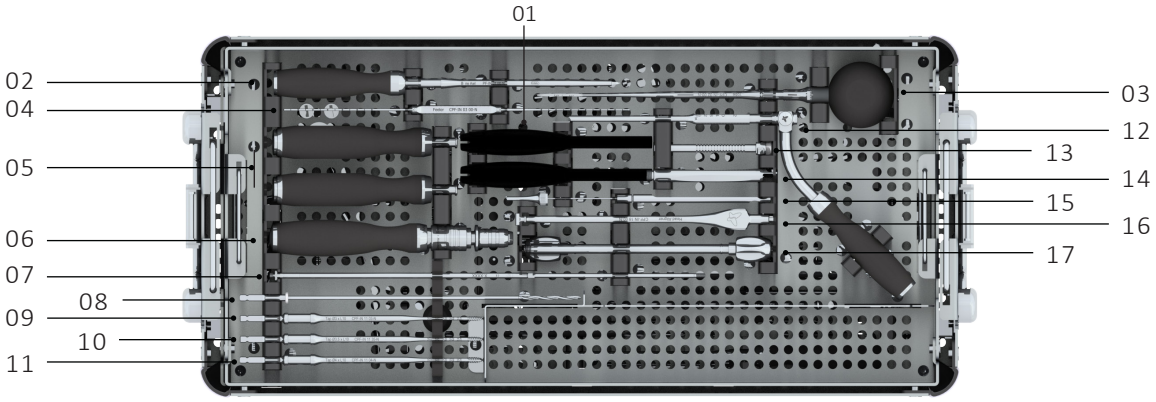
KIT SETUP



DESCRIPTION	REFERENCE
CONTAINER BASE	CPF-BX 10 00-N
UPPER TRAY	CPF-BX 10 01-N
MIDDLE TRAY	CPF-BX 10 02-N
CONTAINER LID	LID-BX 09 00-N

KIT SETUP

UPPER LEVEL

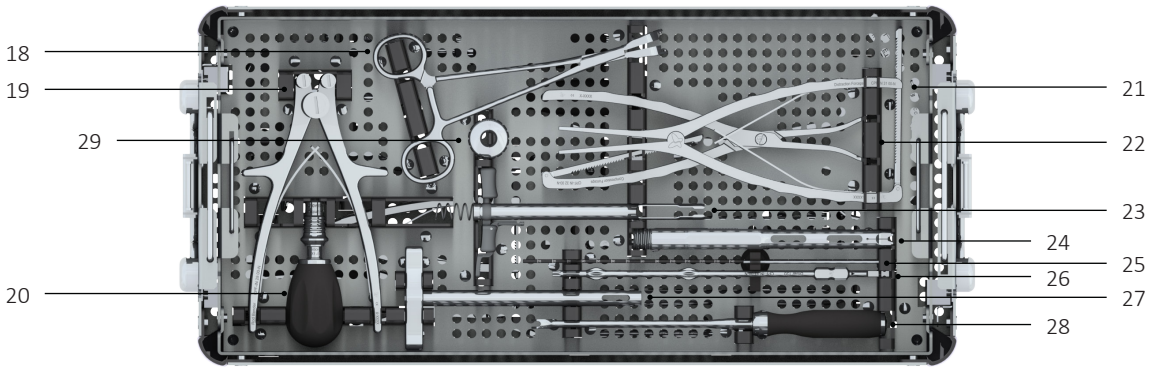


	#	DESCRIPTION	REFERENCE
	01	SCREWDRIVER SLEEVE (X2)	CPF-IN 22 01-N
	02	BONE AWL	CPF-IN 01 00-N
	03	PEDICLE PROBE CURVED	CPF-IN 02 01-N
	04	FEELER	CPF-IN 03 00-N
	05	SCREWDRIVER HANDLE (X2)	CPF-IN 22 03-N
	06	STRAIGHT HANDLE RATCHET AO Ø20	HAN-RA AO 20-N
	07	SCREWDRIVER (X2)	CPF-IN 22 00-N
	08	ADJUSTABLE DRILL (X2)	CPF-IN 08 00-N
	09	TAP Ø3	CPF-IN 11 03-N
	10	TAP Ø3.5	CPF-IN 11 35-N
	11	TAP Ø4	CPF-IN 11 04-N
	12	DRILL GUIDE	CPF-IN 09 00-N
	13	ADJUSTABLE DRILL GUIDE (X2)	CPF-IN 10 00-N
●	14	DEPTH GAUGE (PART 1)	CPF-IN 33 00-N
●	15	DEPTH GAUGE (PART 2)	CPF-IN 33 00-N
	16	HEAD ALIGNER	CPF-IN 18 00-N
	17	SCREWDRIVER TUBE (X2)	CPF-IN 22 02-N

● : OPTIONAL

KIT SETUP

MIDDLE LEVEL

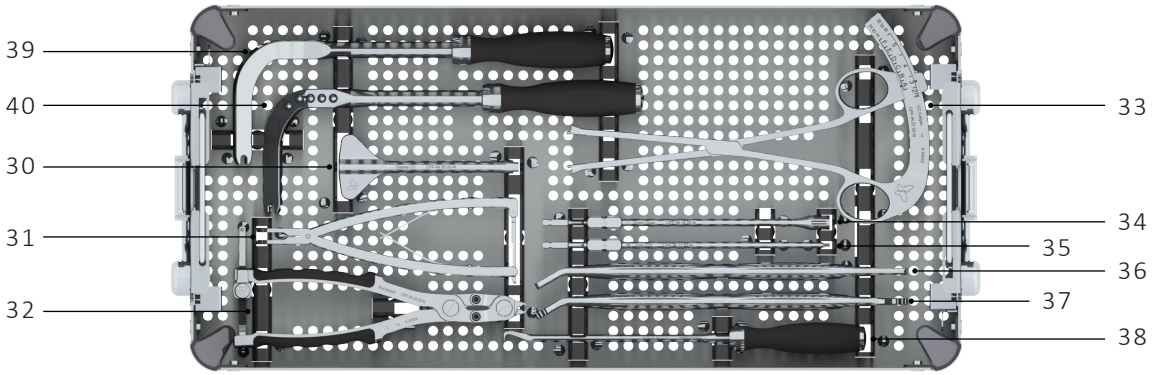


#	DESCRIPTION	REFERENCE
18	ROCKER (UPPER)	CPF-IN 20 00-N
18	ROD HOLDER (LOWER)	CPF-IN 19 00-N
19	ROD BENDER	CPF-IN 29 00-N
20	2.5 TORQUE LIMITING HANDLE	HAN-SI AO 26-N
21	DISTRACTION FORCEPS	CPF-IN 31 00-N
22	COMPRESSION FORCEPS	CPF-IN 32 00-N
23	REDUCER PART A	CPF-IN 21 0A-N
24	REDUCER PART B	CPF-IN 21 0B-N
25	ROD TEMPLATE L250 (UPPER)	CPF-IN 30 00-N
●	ROD TEMPLATE L100 (LOWER)	CPF-IN 30 01-N
26	DRIVER T20	CPF-IN 13 00-N
27	COUNTER TORQUE	CPF-IN 23 00-N
28	PUSHER	CPF-IN 17 00-N
29	REDUCER PART C	CPF-IN 21 0C-N

● : OPTIONAL

KIT SETUP

LOWER LEVEL



	#	DESCRIPTION	REFERENCE
	30	CC SLEEVE	CPF-IN 36 00-N
	31	HOOK HOLDER	CPF-IN 15 00-N
●	32	ROD GRIPPER	CPF-IN 34 00-N
	33	CC CALIPER	CPF-IN 27 00-N
	34	DRIVER HEXA	CPF-IN 14 00-N
	35	DRIVER T15	CPF-IN 12 00-N
●	36	SAGITTAL BENDER LEFT	CPF-IN 24 0L-N
●	37	SAGITTAL BENDER RIGHT	CPF-IN 24 0R-N
	38	HOOK PREPARER	CPF-IN 16 00-N
●	39	CORONAL BENDER LEFT	CPF-IN 25 0L-N
●	40	CORONAL BENDER RIGHT	CPF-IN 25 0R-N

● : OPTIONAL

INSTRUMENTS

INSTRUMENT	REFERENCE
BONE AWL	CPF-IN 01 00-N
PROBE	CPF-IN 02 00-N
PEDICLE PROBE CURVED	CPF-IN 02 01-N
FEELER	CPF-IN 03 00-N
TAPS Ø3	CPF-IN 11 03-N
TAPS Ø3.5	CPF-IN 11 35-N
TAPS Ø4	CPF-IN 11 04-N
STRAIGHT HANDLE RATCHET AO Ø20	HAN-SI AO 20-N
DEPTH GAUGE	CPF-IN 33 00-N

BONE PREPARATION

The PERLA® instrumentation set includes:

Bone awl
The surgeon can use the bone awl to perforate the outer bone cortex once the entry point of the screw is located.

Straight & Curved Pedicle Probe
The probes can be used to prepare the screw path. The curved pedicle probe has a profile adapted to pedicle screw preparation and the straight probe has a design more adapted to lateral mass screw preparation.
Each probe has a straight line LASER marked on the shaft which corresponds to the flat side of the endtip.

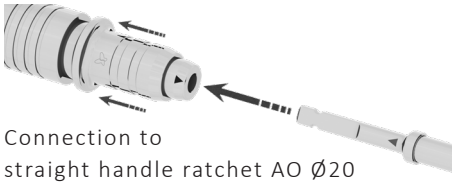
Feeler
The feeler allows to check the integrity of the prepared screw path.

Taps & Straight handle ratchet AO Ø20
When connected to the straight ratchet handle, the taps can be used to prepare the pedicle. They are available in Ø3, 3.5 and 4mm.
Straight handle ratchet AO Ø20 is connected by pulling the proximal ring and by aligning the 2 arrows (on shaft and on handle). Ratcheting mechanism has 3 positions: forward, backward and fixed in “0” position.

Depth Gauge
The depth gauge determines the depth of the bone hole which determines the length of the screw.

The instruments are made of stainless steel and the handles are made of silicone.

NOTE 1



Connection to
straight handle ratchet AO Ø20

NOTE 2

TAPS

TAPS Ø	3.0mm	3.5mm	4.0mm
INNER Ø	2.3mm	2.6mm	3.1mm

INSTRUMENTS

INSTRUMENT	REFERENCE
DRILL GUIDE	CPF-IN 09 00-N
FIXED DRILL L08 to L50	CPF-IN 07 08-N to CPF-IN 07 50-N
ADJUSTABLE DRILL GUIDE	CPF-IN 10 00-N
ADJUSTABLE DRILL	CPF-IN 08 00-S/N
STRAIGHT HANDLE RATCHET AO Ø20	HAN-RA AO 20-N

DRILLING OPTIONS

To ensure a safe introduction of the screw, surgeons can drill the hole before introducing the implant:

- Drill guide
- Fixed drills 8-18mm lengths (2mm increments) and 50mm length
- Adjustable drill guide
- Adjustable drill
- Straight handle ratchet AO Ø20

Two options are available for drilling:

1– The surgeon can use the adjustable drill (purple ring) combined with the adjustable drill guide to drill depths from 6 to 36mm with a 2mm increment. To translate the adjustable drill guide until the appropriate length, the user has to press on the lateral button. Once released, the selected length is secured by a stop mechanism.

2– The surgeon can use the fixed option by using the drill guide with the adjustable drill guide in fixed position. The surgeon selects the appropriate fixed drill (black ring) from 8 to 18mm (2mm increments) or 50mm.

Each type of drill can be quick connected to the straight handle ratchet AO Ø20 by pulling the proximal ring and by aligning the 2 arrows (on shaft and on handle). Ratcheting mechanism has 3 positions: forward, backward and fixed in “0” position.

The instruments are made of stainless steel and the handles are made of silicone.

NOTE 1

Purple ring : Adjustable Drill

NOTE 2

Black ring : Fixed Drill

INSTRUMENTS

INSTRUMENT	REFERENCE
SCREWDRIVER	CPF-IN 22 00-N
SCREWDRIVER SLEEVE	CPF-IN 22 01-N
SCREWDRIVER TUBE	CPF-IN 22 02-N
SCREWDRIVER HANDLE	CPF-IN 22 03-N

SCREW IMPLANTATION

The screwdriver is used to facilitate the positioning of the screw. It is made of 4 parts and needs to be assembled before connecting it to the implant (see page 43 for assembly details):

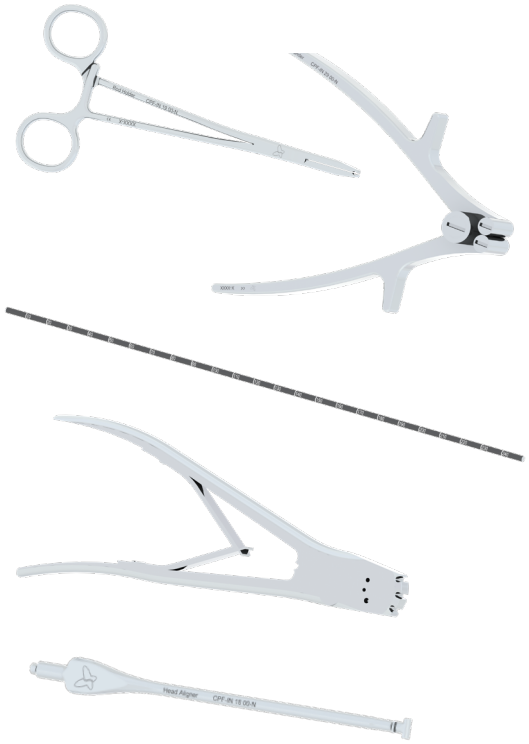
- Screwdriver
- Screwdriver sleeve
- Screwdriver tube
- Screwdriver handle

Start by introducing the shaft into the bone screw, then turn the screwdriver tube clockwise to tighten the screw tulip head. This transforms all polyaxial, CC and ML into a rigid assembly.
The sleeve is designed to allow the surgeon to implant the screw, protect soft tissue, and avoid inadvertent loosening of the implant.

The plastic free-spinning cap on the top of the handle allows the surgeon to safely keep his hand in place while rotating the screwdriver handle. It acts very closely as a ratchet handle.

The instruments are made of stainless steel and the handle is made of silicone. Screwdriver sleeve is made of radel.

INSTRUMENTS



INSTRUMENT	REFERENCE
ROD TEMPLATE L100	CPF-IN 30 01-N
ROD TEMPLATE L250	CPF-IN 30 00-N
ROD CUTTER	CPF-IN 28 00-N
ROD BENDER	CPF-IN 29 00-N
ROD HOLDER	CPF-IN 19 00-N
HEAD ALIGNER	CPF-IN 18 00-N

ROD PREPARATION

Rod template
The rod template is available in two lengths 100 and 250mm. It has to be shaped in the screw head and helps approximate the rod curvature. The laser marking also indicates the rod length.

Rod cutter
The rod cutter can be used to adjust the rod length.

Rod bender
Allows surgeon to contour the rod.

Rod holder
The surgeons can introduce the rod with the rod holder.

Head aligner
Used to align screw heads prior to rod introduction. It is also used to assemble and disassemble the screwdriver (see page 41)

The instruments are made of stainless steel and the rod template is made of soft aluminum.

NOTE
Rod holder can also be used to hold the cross connectors & rod connectors

INSTRUMENTS

INSTRUMENT	REFERENCE
DRIVER T20	CPF-IN 13 00-N
SET SCREW HOLDER DOUBLE	CPF-IN 13 01-N

SET SCREW MANIPULATIONS

Set screw can be inserted into the tulip head with following instruments:

Driver T20
It can be used as implant holder without any connecting handle. Small outgrowth diameter can be used as handles. The hexalobe distal end is split which gives its retentive capacity.

Set screw Holder Double
It is used as implant holder for set screw and can hold 2 set screws: one at each side. The hexalobe distal ends are both split which give their retentive capacity.

The instruments are made of stainless steel.

INSTRUMENTS

INSTRUMENT	REFERENCE
ROCKER	CPF-IN 20 00-N
REDUCER PART A, B & C	CPF-IN 21 0A-N CPF-IN 21 0B-N CPF-IN 21 0C-N
DISTRACTION FORCEPS	CPF-IN 31 00-N
COMPRESSION FORCEPS	CPF-IN 32 00-N
ROD GRIPPER	CPF-IN 34 00-N
SAGITTAL BENDER LEFT & RIGHT	CPF-IN 24 0R-N CPF-IN 24 0L-N
CORONAL BENDER LEFT & RIGHT	CPF-IN 25 0R-N CPF-IN 25 0L-N

ROD MANOEUVERS

There are various instruments available for rod handling.

Rocker
Reduction of rod can be done with the rocker if the length is <5mm. The small holes manufactured on hooks or tulip heads can be captured by the rocker.

Reducer
The reducer is more appropriate for reduction <16mm. The instrument need to be set in “start position” which is the position where the instrument clip on the tulip head. Then he can persuade until “0” position. The small “V” shape machined on the endtip helps to suppress any splay. After insertion and pre-tightening of set screw through the reducer, the surgeon can remove it by pulling the “release” button.

Distraction & compression forceps
Distraction or compression manoeuvers could be achieved with stroke of compression or distraction respectively around 45mm and 30mm.

Rod Gripper
Rod gripper is used for derotation manoeuvers. The release button safely secures the ratchet in place, and when pressed releases the ratchet.

Sagittal & coronal benders Left and Right
Sagittal and coronal benders can be used to bend the rod in sagittal plane or in coronal plane. Sagittal bender can also be used as a rod bender ex-vivo thanks to holes manufactured on the endtips.

The instruments are made of stainless steel. Rod gripper handles are over-molded with silicone to enhance ergonomic and comfort during manoeuvers. Reducer caps is in radel for better comfort and to lighten the instrument weight. Handles of coronal benders are made of silicone.

INSTRUMENTS

FINAL TIGHTENING

Final tighten the construct using the following instruments:

- Driver T20
- Driver T20 solid
- 2.5 Torque limiting handle
- Counter torque

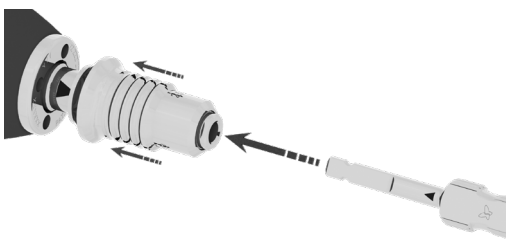
Connect the 2.5 Torque limiting handle to the Driver T20 or Driver T20 solid by pulling the proximal ring and aligning the 2 arrows (on the shaft and on the handle). Place the Counter torque over the screw head and mate the Driver T20 tip to the set screw recess. Turn the handle clockwise until the handle “clicks.”

The instruments are made of stainless steel. The handle is made of silicone”

INSTRUMENT	REFERENCE
DRIVER T20	CPF-IN 13 00-N
DRIVER T20 SOLID	CPF-IN 13 01-N
2.5 TORQUE LIMITING HANDLE	HAN-SI AO 26-N
COUNTER TORQUE	CPF-IN 23 00-N

NOTE

Connection to 2.5 Torque limiting handle



INSTRUMENTS

HOOK ACCESSORIES

Hooks are also available and can be used with the :

Hook preparer
Hook preparer can be used to prepare hook site. Only one type of preparer is used for all type of hooks.

Hook holder
Surgeon uses the Hook holder to insert the appropriate hook.

Pusher
The pusher is positioned on the rod and allows a hook to be positioned into place.

The instruments are made of stainless steel.
Handles are made of silicone

INSTRUMENT	REFERENCE
HOOK PREPARER	CPF-IN 16 00-N
HOOK HOLDER	CPF-IN 15 00-N
PUSHER	CPF-IN 17 00-N

INSTRUMENTS

INSTRUMENT	REFERENCE
CC CALIPER	CPF-IN 13 00-N
DRIVER T15	CPF-IN 13 01-N
DRIVER HEXA	HAN-SI AO 26-N
CC SLEEVE	CPF-IN 23 00-N
2.5 TORQUE LIMITING HANDLE	HAN-SI AO 26-N

CONNECTORS ACCESSORIES

Specific Instruments are available for connector placement.

CC Caliper
The caliper is common to the two types of cross connectors and present 2 scales relative to each type of implant:
Scale A to F → HTH cross connector
Scale 1 to 5 → RTR cross connector

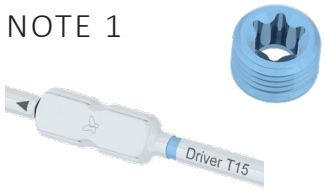
Driver T15
When connected to the 2.5 Torque limiting handle, the Driver T15 (blue ring) is dedicated to the final tightening of the blue set screws on all types of connectors.

CC Sleeve
The CC sleeve is used to final tight the middle set screw of the RTR cross connector.

Driver Hexa
The Driver Hexa (green ring) is dedicated to the hexagonal set screw of HTH cross connectors. Driver Hexa has the double function of holder and final tightener when connected to the 2.5 Torque limiting handle.

The instruments are made of stainless steel. Handles are made of silicone.

NOTE 1



Blue ring: Blue set screws

NOTE 2

Green ring: Green Hexagonal set screws

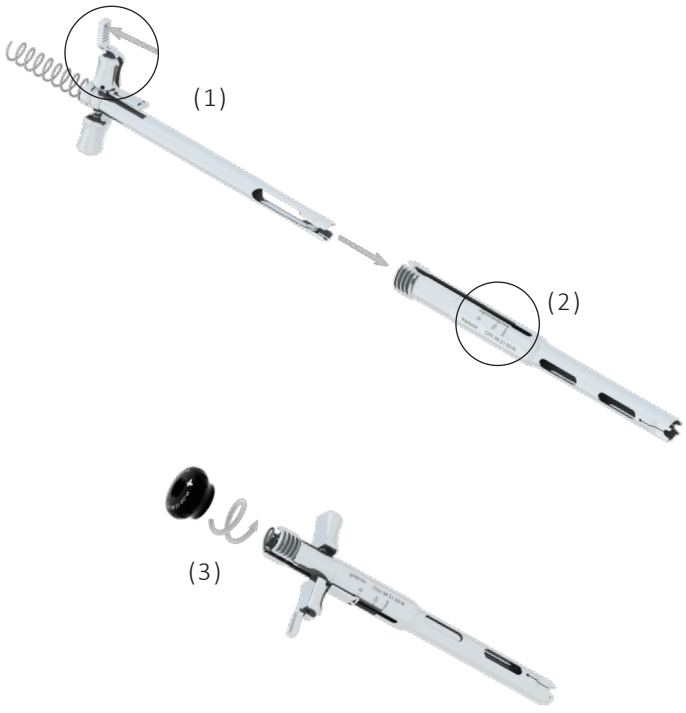
TIPS AND TRICKS

HOW TO ASSEMBLE THE SCREWDRIVER ?

For assembly, slide the Screwdriver sleeve and clip onto the Screwdriver tube and engage the screwdriver into the Screwdriver tube from the threaded distal part.

Slide the screwdriver handle over the remaining proximal part of the Screwdriver, until the hex endtip Screwdriver connects to the Screwdriver handle.

Tighten the assembled Screwdriver by turning the head aligner (Hexagonal Endtip) clockwise into the proximal part of the Screwdriver Handle for a secure fit.



HOW TO ASSEMBLE THE REDUCER ?

To assemble the Reducer, slide the Reducer part A (1) into the Reducer part B (2).

WARNING: Make sure the release button of the Part A (1) slides through the graduated scale of the Part B (2).

Thread the reducer Part C (3) clockwise into the reducer Part B over the reducer Part A (2) spring.

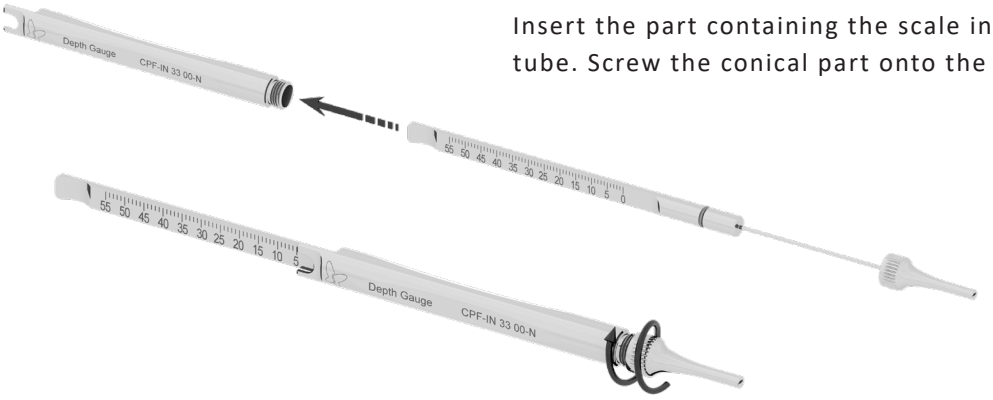
TIPS AND TRICKS

HOW TO ASSEMBLE THE DRILL GUIDE ?

Position the Adjustable drill guide into the Drill guide by pressing the lateral button on the Drill Guide. Choose the appropriate Fixed drill and connect it to the straight handle AO Ø 20. This assembly can be introduced into the Drill guide.

HOW TO ASSEMBLE THE DEPTH GAUGE ?

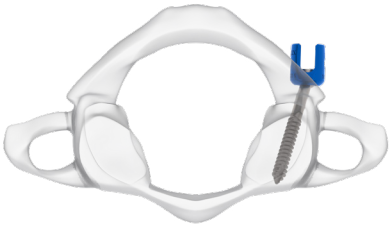
Insert the part containing the scale into the tube. Screw the conical part onto the tube.



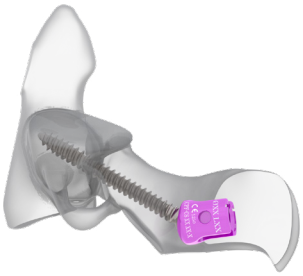
FAQs

WHY DO WE HAVE 4 TYPES OF SCREWS ?

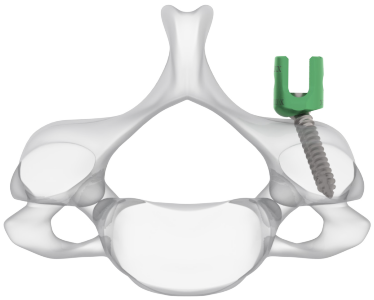
To better adapt to anatomy and implantation technique, we developed a full range of screws. Anatomy of cervical vertebrae could require lateral mass approach due to very small size or lack of pedicle.



Smooth shank screw – Blue Tulip
Smooth shank screw has a smooth shank part to protect root from any injury in C1 level.



CC prefered angle screw – Pink Tulip
Cranio-caudal screw presents a preferred angle in the cranial-caudal plane to allow implantation in the pedicle of C2.



ML prefered angle screw – Green Tulip
Medio-lateral preferred angle screws are designed to be implanted in the pedicle or offset lateral mass of the vertebrae between C3 and C7 thanks to the preferred angle oriented into the medio-lateral plane.

Polyaxial Screw– Yellow Tulip
Polyaxial screws are the most versatile one that could be implanted in the pedicle or the lateral mass.

F A Q s

WHY DO WE HAVE 2 TYPES OF CROSS CONNECTORS ?

RTR Cross connector – Rod To Rod fixation
RTR connector is the most versatile one. It's designed to be fixed onto the two longitudinal rods.

HTH Cross connector – Head To Head fixation
HTH connector is designed to be fixed onto the two screw heads when space between the two screws is too short to place a RTR cross connector.

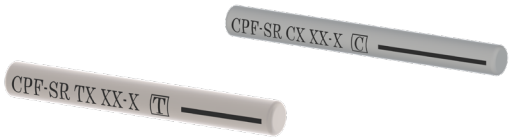
HOW CAN WE CONNECT THE PERLA® TO THE ROMEO®2 SYSTEM ?

Different options are available to connect the two posterior fusion systems :

Transition rods
Transition rods have two diameters Ø5.4 and Ø3.5 to connect a ROMEO®2 screw and a PERLA® screw.

Rod connectors
4 types of Rod connectors are available to make the transition between the 2 systems. Parallel ones and axial ones, each available in two versions Ø3.5 open/Ø5.4 closed and vice versa.

F A Q s



WHY DO WE HAVE 2 TYPE OF MATERIAL FOR RODS ?

Stiffness is the property to be rigid and have the spine going to the rod and not the rod flexing to the deformity. The CoCr alloy is stiffer than the Titanium alloy so the surgeon can use this material if anatomy requires a stiffer construct.

WHY HAVING TAPS IF SCREWS ARE SELF TAPPING ?

Taps are proposed as options for surgeons who feel more comfortable with an intermediate step of preparation. This step helps to prepare pedicle and lateral mass with an intermediate diameter, decreasing stress on bone, and limiting risk of anatomy injury.

Taps are available with the same diameter of screw. It’s recommended to under tap the hole and so to use tap Ø3 for screw Ø3.5 and tap Ø3.5 for screw Ø4. Ø4 is also available for surgeons who like to tap with the same diameter of screw.

WHY PERLA ?

The first definition of the italian word PERLA is the spherical mass, typically iridescent, formed within the shell of an oyster. Most commonly, the word PERLA is used to signify a precious thing or the finest example of something. PERLA symbolizes simplicity and effortless elegance.

REFERENCE OF THE IFU	PER-IF 00 01-W	REVISION OF THE FINAL IFU	DEC-2018

_STERILITY

The implant is provided sterile. Implants are packaged in a first polyethylene pouch, included in a second polyethylene pouch. This packaging is labeled and an IFU is included.

_CAUTION

If the implant or its packaging seems to be damaged, if the expiry date is exceeded or if the sterility cannot be guaranteed for any reason, the implant mustn't be used. The re-sterilization of the gamma sterilized implant is forbidden. The PERLA® implant must not be used with implant other than PERLA® range. Never use stainless steel and titanium components in the same construct. Medical titanium alloy, and/or medical grade cobalt chromium may be used together. The PERLA® Implant must only be used with the PERLA® instruments. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the posterior osteosynthesis system.

The safety and effectiveness of the posterior cervico-thoracic fixation system have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion instrumentation. These conditions are significant mechanical instability or deformity of the cervico-thoracic, spine secondary to degenerative disc disease (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors. The safety and effectiveness of these devices for any others conditions are unknown.

_DESCRIPTION

PERLA® posterior cervico-thoracic fixation 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 PERLA® posterior cervico-thoracic fixation system consists of a variety of shapes and sizes of rods, hooks, multi-axial screws, which can be rigidly locked to the rod. In order to obtain a maximal stiffness, transverse connectors are also available. PERLA® implants are made of titanium alloy, some rods are also available in cobalt chromium alloy.

_INDICATIONS

The PERLA® posterior cervico-thoracic fixation system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis);

tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The PERLA® posterior cervico-thoracic fixation system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the PERLA® posterior cervico-thoracic fixation system may be connected to the ROMEO® Posterior Osteosynthesis System with rod connectors. Transition rods may also be used to connect the PERLA® posterior cervico-thoracic fixation system to the ROMEO® Posterior Osteosynthesis System. Refer to the ROMEO® Posterior Osteosynthesis System package insert for a list of the ROMEO® Posterior Osteosynthesis System indications of use.

PERLA® posterior cervico-thoracic fixation system is indicated for skeletally mature patients.

_CONTRAINDICATIONS

The PERLA® posterior cervico-thoracic fixation system is not designed or sold for any use except as indicated. DO NOT USE THE PERLA® SYSTEM IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.

Contraindications include, but are not limited to :

1. Overt infection or distant foci of infections.
2. Local inflammation, with or without fever or leukocytosis.

3. Pregnancy.
4. Morbid obesity.
5. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
6. Suspected or documented metal allergy or intolerance.
7. Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
8. Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
9. Use in displaced, non-reduced fractures with bone loss.
10. The presence of marked bone absorption or severe etabolic bone disease that could compromise the fixation achieved.
11. Poor prognosis for good wound healing (e.g., decubitis ulcer, end-stage diabetes, severe protein deficiency, and/or malnutrition).
12. Any case not needing a bone graft or fusion.
13. Any case not described in the indications

See also CAUTION and PRECAUTION sections.

_SIDE EFFECTS

Per operative:

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

Post operative:

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

Specific to implant:

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

Potential risk identified with the use of this cervico-thoracic spinal fixation system, which may require additional surgery, include: Screw misplacement, device component fracture, loss of fixation, pseudoarthrosis (i.e non-union), fracture of the vertebra, kyphosis of the subaxial spine, neurological injury, and vascular injury.

_PRE-OP PLANNING

Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

_PRECAUTION FOR USE

An in-depth discussion of all possible complications associated with spine stabilization with implants is beyond the scope of these instructions.

The implantation of spinal fixation systems should be performed only by experienced spinal surgeons with specific training in the use of these spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant diameter and length.

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.

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 cervico-thoracic fixation procedure may not meet the patient's expectations, thus requiring more surgery to replace or remove the implant, or other types of procedures. Surgeons should therefore take several factors into consideration, in order to achieve optimal results for each patient. It is therefore essential that each patient who must undergo this type of procedure be informed, with the supporting documentation available, of the potential complications.

The PERLA® posterior cervico-thoracic fixation system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of PERLA® posterior cervico-thoracic fixation

system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

_HANDLING

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

Careful preparation of the surgical site and choosing an implant of the right size will increase the chances of a successful reconstruction. Surgeons are advised not to remove the device from its sterile packaging until after the implant site has been properly prepared and precise measurements have been taken.

_SURGERY METHODS

The implantation of pedicle screw spinal systems 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. We strongly recommend that excessive force should not be applied when installing any of the PERLA® implants.

A handbook on surgical techniques, describing the standard implant procedure, is available.

_PATIENT CARE FOLLOWING TREATMENT

Detailed instructions on the use and limitations of the device should be given to the patient. Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician. The patient should be instructed regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient.

_STORAGE CONDITION

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

_INSTRUMENTATION

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

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

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

_DECONTAMINATION, CLEANING, AND STERILIZATION

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

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

The PERLA®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.

GENERAL INFORMATION

Manual disinfection/cleaning protocol

- Rinse soiled devices under running cold tap water for 1 minute, using soft-bristled brush to assist in the removal of gross soil debris. Devices that have been assembled during the surgery, must be disassembled before cleaning.
- Soak devices in a bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and manually clean for 5 minutes using soft-bristled brush, at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minute.
- Use a syringe to flush the devices with cannulation with 2x20 ml of neutral enzymatic cleaner at room temperature (+15/+25°C).
- Soak devices in a freshly prepared bath of neutral enzymatic cleaner (as example: ANIOSYME DD1) and clean ultrasonically for 10 minutes at room temperature (+15/+25°C).
- Rinse devices under running cold water for 1 minutes. Devices with mobile parts must be manipulated through their full range of motion 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 must be manipulated through their full range of motion 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. Devices that have been assembled during the surgery, 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 must be manipulated through their full range of motion 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 must be manipulated through their full range of motion during rinsing.
- Load devices into the washer-disinfector.
- Visually inspect devices.
- Dry using a soft, lint free cloth.

Sterilization trays cleaning and disinfection

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

Cleaning recommendations

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

WASHER-DISINFECTOR PARAMETERS

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

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 then recommended, using an autoclave and steam, and following a protocol that meets the minimum requirements or more, and is in compliance with current legislation (e.g., 134°C – 18 minutes) to obtain a guaranty of sterility of 10^{-6}.The validation for sterilization have been done according to overkill/half cycle method as described in the ISO 17664, ISO 17665 standards and of AAMI TIR 12 Technical Report.

_STERILIZATION PARAMETERS

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

Cycle 1 (EU):

Minimum exposure time: 18 minutes

Minimum temperature: 134°C

Drying time: 30 minutes

Cycle 2 (USA):

Minimum exposure time: 4 minutes

Minimum temperature: 132°C

Drying time: 30 minutes

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

_FURTHER INFORMATION

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

N O T E

N O T E

S P I N E A R T

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AUG-2019 - REF.:PER-MF 01 31-E CE 0088