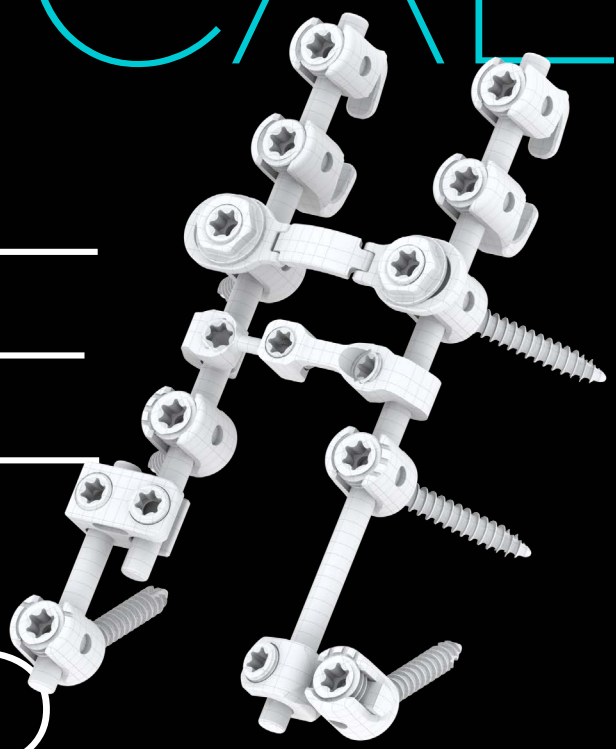
PERLA®

BY SPINEART

# CERVICAL POSTERIOR FIXATION



# CONTENT

# CONCEPT AND DESIGN

The PERLA® Posterior Cervico-Thoracic Fixation System has been designed with surgeons in accordance with Spineart's motto: Quality, Simplicity, Innovation.

The PERLA® platform consists of sterile-packed implants and streamlined instrumentation to address posterior cervico-thoracic pathologies and variable patient anatomy. Enhancing surgical flow through cutting edge technologies and Swiss-made quality, we are proud to offer to surgeons and OR staff a unique system: PERLA®.

## AT A GLANCE

- 2 TYPES OF PREFERRED ANGLE SCREWS (cranial-caudal & mediolateral)
- SMOOTH SHANK SCREWS
- COMPREHENSIVE RANGE OF HOOKS AND POLYAXIAL SCREWS
- MULTIPLE CROSS-CONNECTOR AND ROD CONNECTOR OPTIONS

# CONCEPT AND DESIGN

## 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 TI-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.

## 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.

See also CAUTION and PRECAUTION sections.

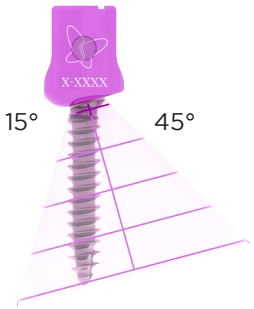
# IMPLANTS

| CC PREFERRED ANGLE SCREWS | | |
|---|---|---|
| LENGTH | Ø3.5 | Ø4 |
| L08 | CPF-CS 35 08-S | CPF-CS 04 08-S |
| L10 | CPF-CS 35 10-S | CPF-CS 04 10-S |
| L12 | CPF-CS 35 12-S | CPF-CS 04 12-S |
| L14 | CPF-CS 35 14-S | CPF-CS 04 14-S |
| L16 | CPF-CS 35 16-S | CPF-CS 04 16-S |
| L18 | CPF-CS 35 18-S | CPF-CS 04 18-S |
| L20 | CPF-CS 35 20-S | CPF-CS 04 20-S |
| L24 | CPF-CS 35 24-S | CPF-CS 04 24-S |
| L28 | CPF-CS 35 28-S | CPF-CS 04 28-S |
| L32 | CPF-CS 35 32-S | CPF-CS 04 32-S |
| L36 | CPF-CS 35 36-S | CPF-CS 04 36-S |
| L40 | CPF-CS 35 40-S | CPF-CS 04 40-S |
| L44 | CPF-CS 35 44-S | CPF-CS 04 44-S |
| L48 | CPF-CS 35 48-S | CPF-CS 04 48-S |
| L52 | CPF-CS 35 52-S | CPF-CS 04 52-S |

| ML PREFERRED ANGLE SCREWS | | |
|---|---|---|
| LENGTH | Ø3.5 | Ø4 |
| L08 | CPF-MS 35 08-S | CPF-MS 04 08-S |
| L10 | CPF-MS 35 10-S | CPF-MS 04 10-S |
| L12 | CPF-MS 35 12-S | CPF-MS 04 12-S |
| L14 | CPF-MS 35 14-S | CPF-MS 04 14-S |
| L16 | CPF-MS 35 16-S | CPF-MS 04 16-S |
| L18 | CPF-MS 35 18-S | CPF-MS 04 18-S |
| L20 | CPF-MS 35 20-S | CPF-MS 04 20-S |
| L24 | CPF-MS 35 24-S | CPF-MS 04 24-S |
| L28 | CPF-MS 35 28-S | CPF-MS 04 28-S |
| L32 | CPF-MS 35 32-S | CPF-MS 04 32-S |
| L36 | CPF-MS 35 36-S | CPF-MS 04 36-S |
| L40 | CPF-MS 35 40-S | CPF-MS 04 40-S |
| L44 | CPF-MS 35 44-S | CPF-MS 04 44-S |
| L48 | CPF-MS 35 48-S | CPF-MS 04 48-S |
| L52 | CPF-MS 35 52-S | CPF-MS 04 52-S |


CRANIAL-CAUDAL
PREFERRED ANGLE SCREWS


MEDIO LATERAL
PREFERRED ANGLE SCREWS




# IMPLANTS

| SMOOTH SHANK SCREWS | | |
|---|---|---|
| LENGTH | Ø3.5 | Ø4 |
| L18 | CPF-SS 35 18-S | CPF-SS 04 18-S |
| L20 | CPF-SS 35 20-S | CPF-SS 04 20-S |
| L22 | CPF-SS 35 22-S | CPF-SS 04 22-S |
| L24 | CPF-SS 35 24-S | CPF-SS 04 24-S |
| L26 | CPF-SS 35 26-S | CPF-SS 04 26-S |
| L28 | CPF-SS 35 28-S | CPF-SS 04 28-S |
| L30 | CPF-SS 35 30-S | CPF-SS 04 30-S |
| L32 | CPF-SS 35 32-S | CPF-SS 04 32-S |
| L34 | CPF-SS 35 34-S | CPF-SS 04 34-S |
| L36 | CPF-SS 35 36-S | CPF-SS 04 36-S |

| POLYAXIAL SCREWS | | |
|---|---|---|
| LENGTH | Ø3.5 | Ø4 |
| L08 | CPF-PS 35 08-S | CPF-PS 04 08-S |
| L10 | CPF-PS 35 10-S | CPF-PS 04 10-S |
| L12 | CPF-PS 35 12-S | CPF-PS 04 12-S |
| L14 | CPF-PS 35 14-S | CPF-PS 04 14-S |
| L16 | CPF-PS 35 16-S | CPF-PS 04 16-S |
| L18 | CPF-PS 35 18-S | CPF-PS 04 18-S |
| L20 | CPF-PS 35 20-S | CPF-PS 04 20-S |
| L24 | CPF-PS 35 24-S | CPF-PS 04 24-S |
| L28 | CPF-PS 35 28-S | CPF-PS 04 28-S |
| L32 | CPF-PS 35 32-S | CPF-PS 04 32-S |
| L36 | CPF-PS 35 36-S | CPF-PS 04 36-S |
| L40 | CPF-PS 35 40-S | CPF-PS 04 40-S |
| L44 | CPF-PS 35 44-S | CPF-PS 04 44-S |
| L48 | CPF-PS 35 48-S | CPF-PS 04 48-S |
| L52 | CPF-PS 35 52-S | CPF-PS 04 52-S |



| SET SCREW | CPF-SC 00 00-S |
|---|---|

| EXTENDED SET SCREW | CPF-SC 01 00-S |
|---|---|

| HEXAGONAL SET SCREW | CPF-SC 02 00-S |
|---|---|

# IMPLANTS

| PREBENT RODS TITANIUM Ø3,5 | |
|---|---|
| LENGTH | |
| L40 | CPF-PR T0 40-S |
| L45 | CPF-PR T0 45-S |
| L50 | CPF-PR T0 50-S |
| L55 | CPF-PR T0 55-S |
| L60 | CPF-PR T0 60-S |
| L65 | CPF-PR T0 65-S |
| L70 | CPF-PR T0 70-S |
| L75 | CPF-PR T0 75-S |
| L80 | CPF-PR T0 80-S |
| L85 | CPF-PR T0 85-S |
| L90 | CPF-PR T0 90-S |


| PREBENT RODS COBALT CHROMIUM Ø3,5 | |
|---|---|
| LENGTH | |
| L40 | CPF-PR C0 40-S |
| L45 | CPF-PR C0 45-S |
| L50 | CPF-PR C0 50-S |
| L55 | CPF-PR C0 55-S |
| L60 | CPF-PR C0 60-S |
| L65 | CPF-PR C0 65-S |
| L70 | CPF-PR C0 70-S |
| L75 | CPF-PR C0 75-S |
| L80 | CPF-PR C0 80-S |
| L85 | CPF-PR C0 85-S |
| L90 | CPF-PR C0 90-S |

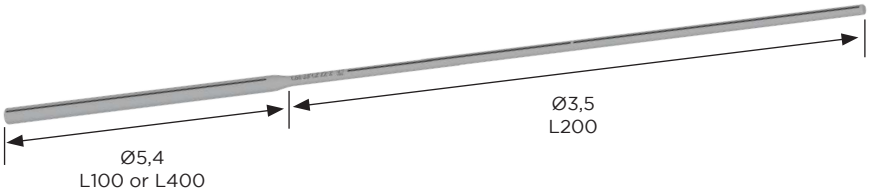

| STRAIGHT RODS TITANIUM Ø3,5 | |
|---|---|
| LENGTH | |
| L20 | CPF-SR T0 20-S |
| L25 | CPF-SR T0 25-S |
| L30 | CPF-SR T0 30-S |
| L35 | CPF-SR T0 35-S |
| L40 | CPF-SR T0 40-S |
| L45 | CPF-SR T0 45-S |
| L50 | CPF-SR T0 50-S |
| L55 | CPF-SR T0 55-S |
| L60 | CPF-SR T0 60-S |
| L65 | CPF-SR T0 65-S |
| L70 | CPF-SR T0 70-S |
| L75 | CPF-SR T0 75-S |
| L80 | CPF-SR T0 80-S |
| L85 | CPF-SR T0 85-S |
| L90 | CPF-SR T0 90-S |
| L100 | CPF-SR T1 00-S |
| L110 | CPF-SR T1 10-S |
| L120 | CPF-SR T1 20-S |
| L240 | CPF-SR T2 40-S |
| L350 | CPF-SR T3 50-S |


| STRAIGHT RODS COBALT CHROMIUM Ø3,5 | |
|---|---|
| LENGTH | |
| L20 | CPF-SR C0 20-S |
| L25 | CPF-SR C0 25-S |
| L30 | CPF-SR C0 30-S |
| L35 | CPF-SR C0 35-S |
| L40 | CPF-SR C0 40-S |
| L45 | CPF-SR C0 45-S |
| L50 | CPF-SR C0 50-S |
| L55 | CPF-SR C0 55-S |
| L60 | CPF-SR C0 60-S |
| L65 | CPF-SR C0 65-S |
| L70 | CPF-SR C0 70-S |
| L75 | CPF-SR C0 75-S |
| L80 | CPF-SR C0 80-S |
| L85 | CPF-SR C0 85-S |
| L90 | CPF-SR C0 90-S |
| L100 | CPF-SR C1 00-S |
| L110 | CPF-SR C1 10-S |
| L120 | CPF-SR C1 20-S |
| L240 | CPF-SR C2 40-S |
| L350 | CPF-SR C3 50-S |

# IMPLANTS

| TRANSITION RODS TITANIUM | | | |
|---|---|---|---|
| Ø5,4 | ⟶ | Ø3,5 | REFERENCE |
| L100 | ——— | L200 | CPF-TR T3 00-S |
| L400 | ——— | L200 | CPF-TR T6 00-S |

| TRANSITION RODS COBALT CHROMIUM | | | |
|---|---|---|---|
| Ø5,4 | ⟶ | Ø3,5 | REFERENCE |
| L100 | ——— | L200 | CPF-TR C3 00-S |
| L400 | ——— | L200 | CPF-TR C6 00-S |




## HOOKS RANGE

| HOOK OFFSET LEFT / S | CPF-HO OF SL-S |
|---|---|


| HOOK OFFSET RIGHT / S | CPF-HO OF SR-S |
|---|---|


| HOOK OFFSET LEFT / L | CPF-HO OF SL-S |
|---|---|


| HOOK OFFSET RIGHT / L | CPF-HO OF LR-S |
|---|---|


| HOOK STRAIGHT / S | CPF-HO ST 0S-S |
|---|---|


| HOOK STRAIGHT / L | CPF-HO ST 0L-S |
|---|---|

# IMPLANTS

## CONNECTORS

The PERLA® System offers rod connectors: Ø3.5/5.4mm, Ø3.5/3.5mm, axial, parallel and lateral connectors as well as adjustable, head-to-head, and rod-to-rod cross connectors to adapt to surgeon technique, and improve intraoperative surgical flow.

| AXIAL CONNECTOR 3O-5C | CPF-AC 3O 5C-S |
|---|---|

| PARALLEL CONNECTOR 3O-3C | CPF-PC 3O 3C-S |
|---|---|

| PARALLEL CONNECTOR 3C-5O | CPF-PC 3C 5O-S |
|---|---|

| LATERAL CONNECTOR / S | CPF-LC 00 0S-S |
|---|---|


| RTR CROSS CONNECTOR | |
|---|---|
| SIZE 1 | CPF-CR 21 23-S |
| SIZE 2 | CPF-CR 23 26-S |
| SIZE 3 | CPF-CR 26 32-S |
| SIZE 4 | CPF-CR 32 44-S |
| SIZE 5 | CPF-CR 44 56-S |

| AXIAL CONNECTOR 3C-5O | CPF-AC 3C 5O-S |
|---|---|

| PARALLEL CONNECTOR 3C-3C | CPF-PC 3C 3C-S |
|---|---|

| PARALLEL CONNECTOR 3O-5C | CPF-PC 3O 5C-S |
|---|---|

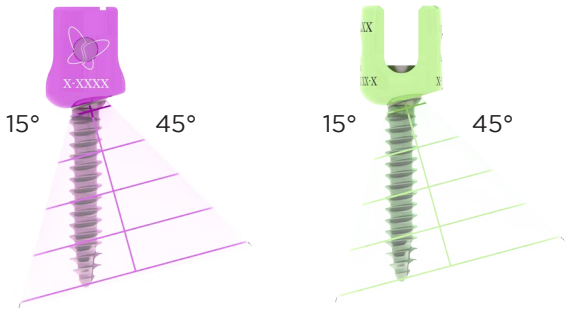
| LATERAL CONNECTOR / L | CPF-LC 00 0L-S |
|---|---|


| HTH CROSS CONNECTOR | |
|---|---|
| SIZE A | CPF-CH 20 25-S |
| SIZE B | CPF-CH 25 30-S |
| SIZE C | CPF-CH 30 35-S |
| SIZE D | CPF-CH 35 40-S |
| SIZE E | CPF-CH 40 45-S |
| SIZE F | CPF-CH 45 50-S |

# TECHNICAL FEATURES

## FEATURE 1

The PERLA® System provides preferred angle screws (cranial-caudal & medial-lateral) to adapt the various patient anatomies while simplifying rod alignment.




## FEATURE 2

The PERLA® System includes a complete range of polyaxial screw lengths and diameters featuring 60° range of motion along with multiple hook designs and sizes to adapt the patient anatomy.


| POLYAXIAL SCREW | | |
|---|---|---|
| DIAMETER | LENGTH | INCREMENT |
| 3.5mm | 8-20mm<br>24-52mm | 2mm<br>4mm |
| 4.0mm | 8-20mm<br>24-52mm | 2mm<br>4mm |

# TECHNICAL FEATURES

## FEATURE 3

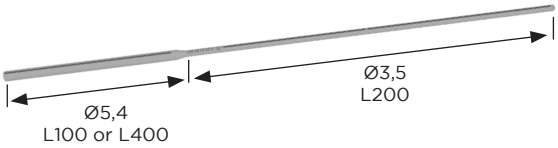
The PERLA® System offers adjustable cross connectors, head to head and rod to rod that can accommodate freedom in different planes to improve intraoperative surgical flow.

## FEATURE 4

The PERLA® System also offers a variety of rod connectors: Ø3.5/5.4mm or Ø3.5/3.5mm, axial or parallel and lateral connectors.


## FEATURE 5

The PERLA® System has various rod options. Pre-cut and pre-bent Ø3.5mm Ti and CoCr rods or Ø3.5/5.4mm Ti and CoCr transition rods.



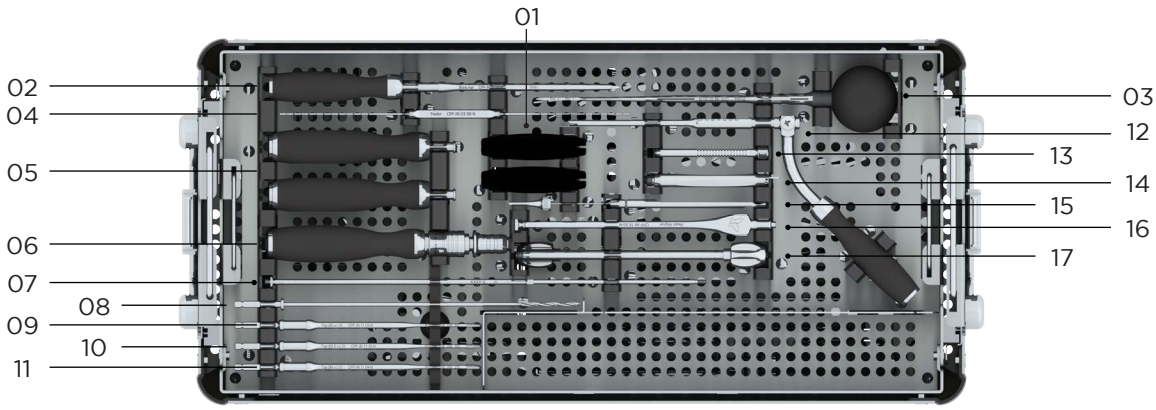

## FEATURE 6

The PERLA® System compact instrument set gives the flexibility to build a construct that meets anatomical challenges and handle the pathology being treated.

All implants in the PERLA® System are sterile packed and bar coded.

# INSTRUMENT SET

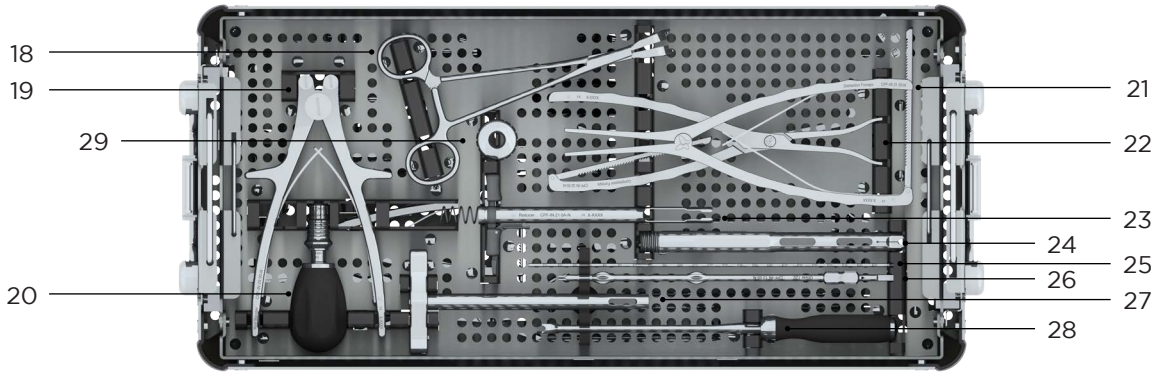
**LEVEL 1**




| # | DESCRIPTION | REFERENCE |
|---|---|---|
| 01 | SCREWDRIVER SLEEVE (x2) | CPF-IN 22 01-N |
| 02 | BONE AWL | CPF-IN 01 00-N |
| 03 | PROBE | CPF-IN 02 00-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 | CPF-IN 22 00-N |
| 08 | ADJUSTABLE DRILL | 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 | CPF-IN 10 00-N |
| 14 | FIXED DRILL | CPF-IN 33 00-N |
| 15 | DEPTH GAUGE | CPF-IN 33 00-N |
| 16 | HEAD ALIGNER | CPF-IN 18 00-N |
| 17 | SCREWDRIVER TUBE (x2) | CPF-IN 22 02-N |

# INSTRUMENT SET

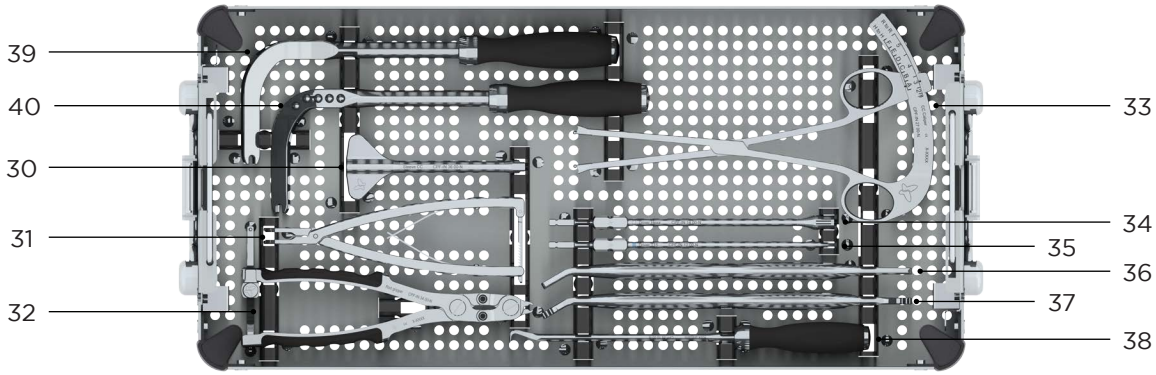
**LEVEL 2**




| # | DESCRIPTION | REFERENCE |
|---|---|---|
| 18 | ROCKER (above) | CPF-IN 20 00-N |
| 18 | ROD HOLDER (below) | CPF-IN 19 00-N |
| 19 | ROD BENDER | CPF-IN 29 00-N |
| 20 | 2.5 TORQUE LIMITER | 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 | CPF-IN 30 00-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 |

# INSTRUMENT SET

**LEVEL 3**




| # | 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 |

# INSTRUMENTS

| BONE AWL | CPF-IN 01 00-N |
|---|---|

| PROBE | CPF-IN 02 00-N |
|---|---|

| FEELER | CPF-IN 03 00-N |
|---|---|

| STRAIGHT HANDLE RATCHET AO Ø20 | HAN-RA AO 20-N |
|---|---|

| 2.5 TORQUE LIMITING HANDLE | HAN-SI AO 26-N |
|---|---|

| FIXED DRILL LXX (8 TO 50) | CPF-IN 07 XX-S |
|---|---|

| ADJUSTABLE DRILL | CPF-IN 08 00-S |
|---|---|

| DRILL GUIDE | CPF-IN 09 00-N |
|---|---|

| ADJUSTABLE DRILL GUIDE | CPF-IN 10 00-N |
|---|---|

| TAP ØX (3,0-3,5-4,0) | CPF-IN 11 XX-N |
|---|---|

| DRIVER T15 | CPF-IN 12 00-N |
|---|---|

| DRIVER T20 | CPF-IN 13 00-N |
|---|---|

| DRIVER HEXA | CPF-IN 14 00-N |
|---|---|

| HOOK HOLDER | CPF-IN 15 00-N |
|---|---|

# INSTRUMENTS

| | |
|---|---|
| HOOK PREPARER | CPF-IN 16 00-N |

| | |
|---|---|
| HEAD ALIGNER | CPF-IN 18 00-N |


| | |
|---|---|
| ROCKER | CPF-IN 20 00-N |

| | |
|---|---|
| REDUCER PART B | CPF-IN 21 0B-N |

| | |
|---|---|
| SCREWDRIVER | CPF-IN 22 00-N |

| | |
|---|---|
| SCREWDRIVER TUBE | CPF-IN 22 02-N |

| | |
|---|---|
| COUNTER TORQUE | CPF-IN 23 00-N |

| | |
|---|---|
| PUSHER | CPF-IN 17 00-N |

| | |
|---|---|
| ROD HOLDER | CPF-IN 19 00-N |

| | |
|---|---|
| REDUCER PART A | CPF-IN 21 0A-N |

| | |
|---|---|
| REDUCER PART C | CPF-IN 21 0C-N |


| | |
|---|---|
| SCREWDRIVER SLEEVE | CPF-IN 22 01-N |


| | |
|---|---|
| SCREWDRIVER HANDLE | CPF-IN 22 03-N |

| | |
|---|---|
| SAGITTAL BENDER RIGHT | CPF-IN 24 0R-N |

# INSTRUMENTS

| SAGITTAL BENDER LEFT | CPF-IN 24 0L-N |
|---|---|

| CORONAL BENDER LEFT | CPF-IN 25 0L-N |
|---|---|

| ROD CUTTER | CPF-IN 28 00-N |
|---|---|

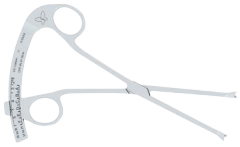
| ROD TEMPLATE L250 | CPF-IN 30 00-N |
|---|---|

| COMPRESSION FORCEPS | CPF-IN 32 00-N |
|---|---|

| ROD GRIPPER | CPF-IN 34 00-N |
|---|---|

| CORONAL BENDER RIGHT | CPF-IN 25 0R-N |
|---|---|

| CC CALIPER | CPF-IN 27 00-N |
|---|---|



| ROD BENDER | CPF-IN 29 00-N |
|---|---|

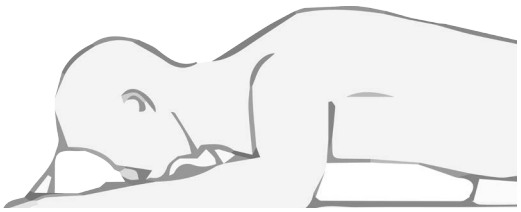
| DISTRACTION FORCEPS | CPF-IN 31 00-N |
|---|---|

| DEPTH GAUGE | CPF-IN 33 00-N |
|---|---|

| CC SLEEVE | CPF-IN 36 00-N |
|---|---|

# SURGICAL TECHNIQUE

## STEP **1**

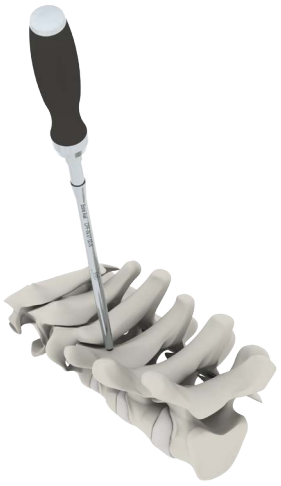


PATIENT POSITIONING AND EXPOSURE

Place the patient in the prone position with the head and neck securely aligned. Perform a standard midline dissection down to the spinous processes of the appropriate vertebrae. Extend dissection laterally to expose the facets and transverse processes.

**WARNING**: Care should be taken during bone preparation to avoid damage to the pedicle and to the surgical instruments.

## STEP **2**



HOLE PREPARATION

Use the Bone Awl or a burr to pierce cortical bone and create an entry point for each screw. The Bone Awl has a stop that limits insertion to 6mm depth.

**Note**: Fluoroscopy or image guidance can be utilized to assist the physician.

| INSTRUMENT | REFERENCE |
|---|---|
| BONE AWL | CPF-IN 01 00-N |

## STEP **3**

PROBE INSERTION

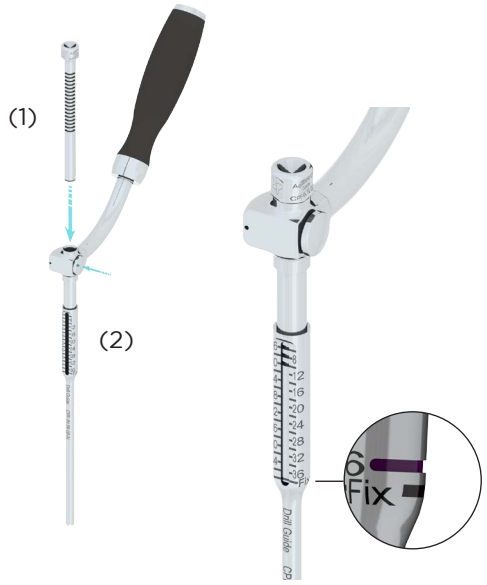
Insert the pedicle Probe in the prepared entry point and advance the pedicle Probe to the desired depth while maintaining the proper trajectory.

**Note**: check the depth markings as a guide.

| INSTRUMENT | REFERENCE |
|---|---|
| PROBE | CPF-IN 02 00-N |

# SURGICAL TECHNIQUE

## STEP **4a**



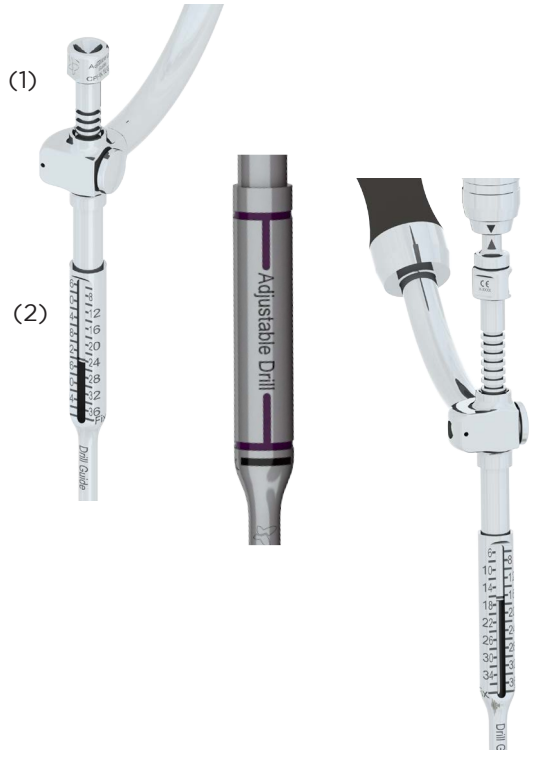

FIXED DRILL TECHNIQUE

Position the Adjustable Drill Guide (1) into the Drill Guide (2) on the “FIX” position by pressing the lateral button on the Drill Guide. Choose the appropriate Fixed Drill and connect it to the Straight Handle AO Ø20. This assembly can be introduced into the Drill Guide.

Position the Drill Guide at the entry point and advance the Fixed Drill by turning the Straight Ratchet Handle AO Ø20 clockwise.

| INSTRUMENT | REFERENCE |
|---|---|
| DRILL GUIDE | CPF- IN 09 00-N |
| FIXED DRILL | CPF-IN 07 08-S<br>CPF-IN 07 10-S<br>CPF-IN 07 12-S<br>CPF-IN 07 14-S<br>CPF-IN 07 16-S<br>CPF-IN 07 18-S<br>CPF-IN 07 50-S |
| ADJUSTABLE DRILL GUIDE | CPF-IN 10 00-N |
| STRAIGHT HANDLE RATCHET AO Ø20 | HAN-RA AO 20-N |

## STEP **4b**




ADJUSTABLE DRILL TECHNIQUE

Choose the appropriate length to be drilled by sliding the Adjustable Drill Guide (1) into the Drill Guide (2). Check the scale to control the proper length.

Connect the Adjustable Drill to the Straight Handle Ratchet AO Ø20.

Insert the Adjustable Drill into the Adjustable Drill Guide. Target the entry point with the Adjustable Drill and drill in the desired trajectory by turning the Straight Handle Ratchet AO Ø20 clockwise.

Drill until the Adjustable Drill stop contacts the top of the Adjustable Drill Guide.

| INSTRUMENT | REFERENCE |
|---|---|
| DRILL GUIDE | CPF- IN 09 00-N |
| ADJUSTABLE DRILL | CPF-IN 08 00-S |
| ADJUSTABLE DRILL GUIDE | CPF-IN 10 00-N |
| STRAIGHT HANDLE RATCHET AO Ø20 | HAN-RA AO 20-N |

# SURGICAL TECHNIQUE

## STEP **5**

BONE HOLE INTEGRITY

Verify the integrity of the screw path by using the Feeler.

The Feeler is LASER etched every 5mm to estimate hole depth and screw length.

| INSTRUMENT | REFERENCE |
|---|---|
| FEELER | CPF-IN 03 00-N |

## STEP **6**

TAPPING

PERLA® screws are self-tapping. However, if tapping is desired one may choose the appropriate Tap diameter (available in Ø3.0, Ø3.5mm and Ø4.0mm) according to the screw diameter selected.

Connect the Tap to the Straight Handle Ratchet AO Ø20. Position the Tap at the entry point and advance into bone by turning the Straight Handle Ratchet AO Ø20 clockwise.

**WARNING**: do not use a Tap with a larger diameter than the selected screw.

**Note**: Insert the Depth Gauge in the prepared hole to measure the screw length. The Depth Gauge has a scale with 1 mm increments.

| INSTRUMENT | REFERENCE |
|---|---|
| TAP Ø3.0mm | CPF-IN 11 03-N |
| TAP Ø3.5mm | CPF-IN 11 35-N |
| TAP Ø4.0mm | CPF-IN 11 04-N |
| STRAIGHT HANDLE RATCHET AO Ø20 | HAN-RA AO 20-N |
| DEPTH GAUGE | CPF-IN 33 00-N |

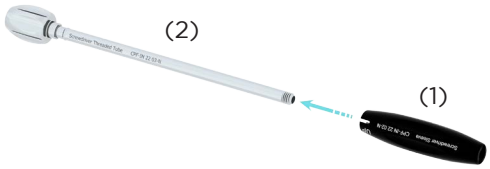
# SURGICAL TECHNIQUE

## STEP **7**

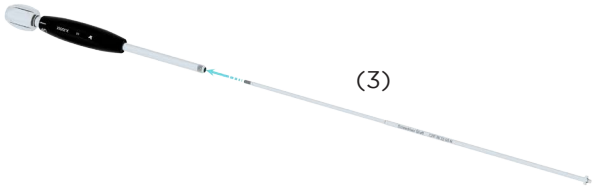
SCREWDRIVER ASSEMBLY

The Screwdriver can be disassembled to facilitate the cleaning and sterilization steps while reducing the risk of contamination. The Screwdriver is composed of the following parts:
- Screwdriver Sleeve CPF-IN 22 01-N
- Screwdriver Tube CPF-IN 22 02-N
- Screwdriver CPF-IN 22 00-N
- Screwdriver Handle CPF-IN 22 03-N

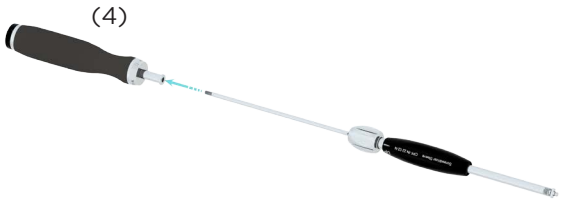
**Note**: The Head aligner CPF-IN 18 00-N is necessary for screwdriver assembly (Hexagonal endtip).




For assembly, slide the Screwdriver Sleeve (1) and clip onto the Screwdriver Tube (2) and engage the Screwdriver (3) into the Screwdriver Tube (2) from the threaded distal part.




Slide the Screwdriver Handle (4) over the remaining proximal part of the Screwdriver (3), until the hex endtip Screwdriver (3) connects to the Screwdriver Handle (4).




Tighten the assembled Screwdriver by turning the Head Aligner (5) (Hexagonal endtip) clockwise into the proximal part of the Screwdriver Handle for a secure fit.


The Screwdriver is now assembled and ready to use.

| INSTRUMENT | REFERENCE |
|---|---|
| SCREWDRIVER SLEEVE | CPF-IN 22 01-N |
| SCREWDRIVER TUBE | CPF-IN 22 02-N |
| SCREWDRIVER | CPF-IN 22 00-N |
| SCREWDRIVER HANDLE | CPF-IN 22 03-N |
| HEAD ALIGNER | CPF-IN 18 00-N |

# SURGICAL TECHNIQUE

## STEP **8**

SCREW ATTACHMENT

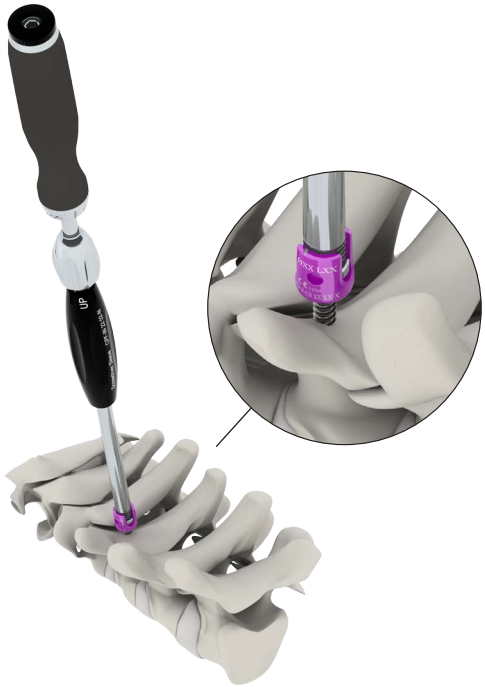
Select the proper screw and attach it on the Screwdriver assembly by aligning the Screwdriver tip into the screw shank recess.

Advance the Screwdriver Tube by rotating clockwise until the implant is securely connected to the Screwdriver.

Repeat this process to connect remaining screws.

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

## STEP **9**



SCREW INSERTION

Insert the screw by turning the Screwdriver Handle clockwise. Release the screw from the Screwdriver by turning the Screwdriver Tube (2) counter clockwise.

**Note**: Confirm screw position using lateral and A/P radiographs or fluoroscopy.

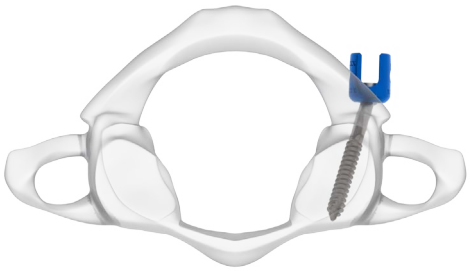
**Note**: Avoid impinging soft tissue or bone to maintain screw polyaxiality. Adjust screw depth if necessary.

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

# SURGICAL TECHNIQUE

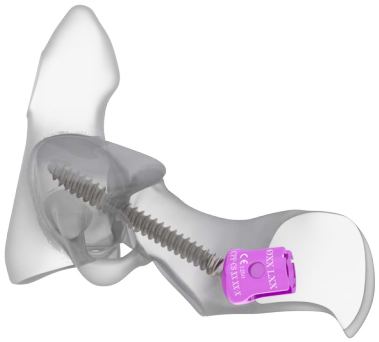
## STEP **9** (cont.)

**EXAMPLES**



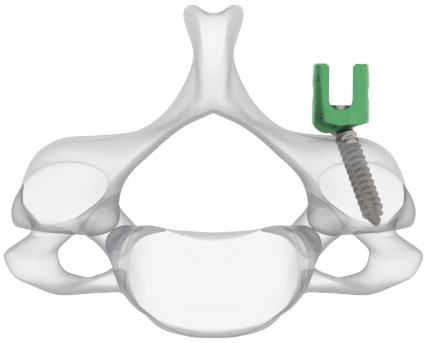
EXAMPLE OF C1 SCREW INSERTION

Smooth shank polyaxial screw may be used for C1 implantation. The threaded part of the screw is inserted in the C1 lateral mass.



EXAMPLE OF C3 TO C7 LATERAL MASS SCREW INSERTION

Cranial-caudal preferred angle screws may be implanted in C2 via pedicle targeting. The design allows up to 45° of angulation and is intended to accommodate variable patient anatomy and reduce the need for rod contouring.

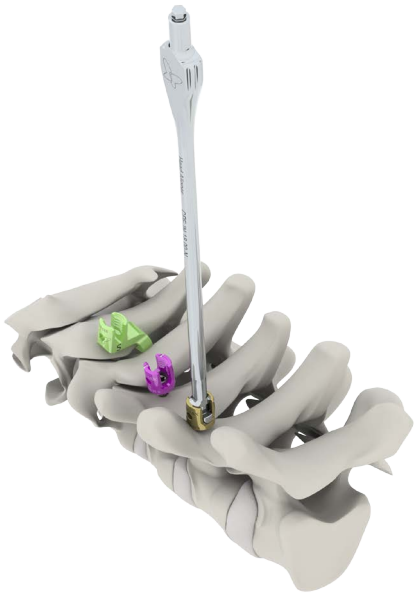


EXAMPLE OF C3 TO C7 LATERAL MASS SCREW INSERTION

Mediolateral preferred angle screws may be implanted in the lateral mass when anatomy necessitates divergent targeting. The design allows up to 45° of angulation and is intended to accommodate variable patient anatomy and reduce the need for rod contouring.

# SURGICAL TECHNIQUE

## STEP **10**

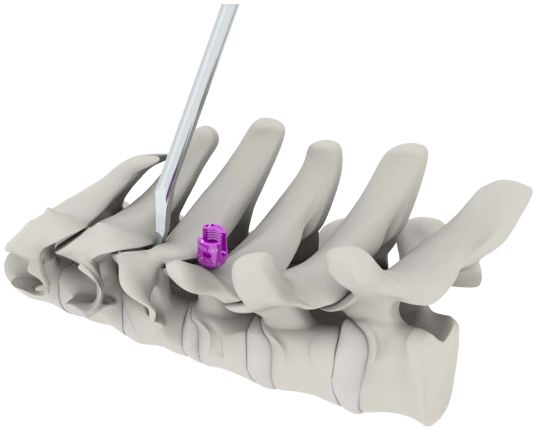


SCREW HEAD ALIGNMENT

The Head Aligner may be used to position the preferred angled screw heads to facilitate rod insertion.

| INSTRUMENT | REFERENCE |
|---|---|
| HEAD ALIGNER | CPF-IN 18 00-N |

## STEP **11**



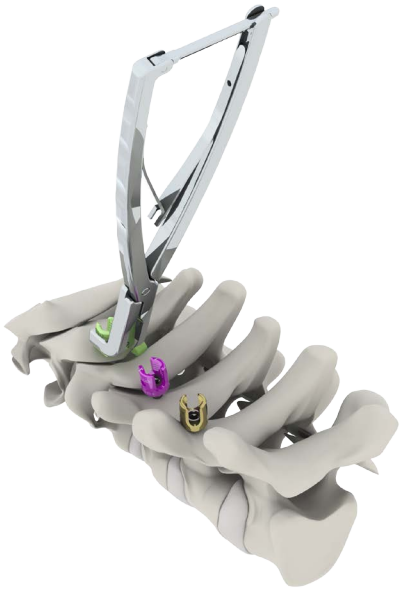
HOOK SITE PREPARATION

Identify the anatomical landmarks and remove soft tissue. Insert the Hook Preparer on the lamina to prepare the surgical site for the implant.

| INSTRUMENT | REFERENCE |
|---|---|
| HOOK PREPARER | CPF-IN 16 00-N |

# SURGICAL TECHNIQUE

## STEP **12**

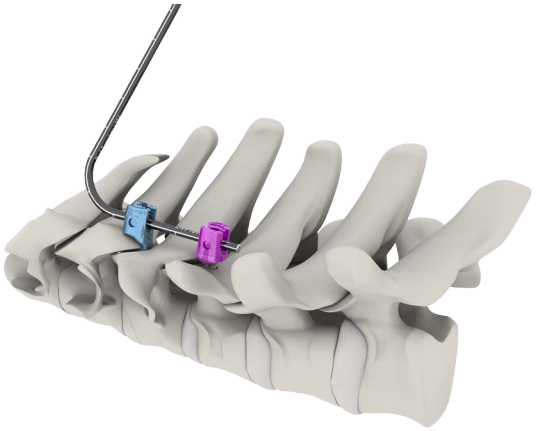


HOOK PLACEMENT

Attach the hook to the Hook Holder and insert the hook underneath the lamina, taking care not to breach the dura mater.

| INSTRUMENT | REFERENCE |
|---|---|
| HOOK HOLDER | CPF-IN 15 00-N |

## STEP **13**



ROD MEASUREMENT

Use the Rod Template L250mm to determine the appropriate length and contour of the rod.

| INSTRUMENT | REFERENCE |
|---|---|
| ROD TEMPLATE L250 | CPF-IN 30 00-N |

# SURGICAL TECHNIQUE

## STEP **14**

ROD CUTTING

Select the appropriate rod material and length.

When necessary, use the rod cutter to shorten the rod to the desired length.

| INSTRUMENT | REFERENCE |
|---|---|
| ROD CUTTER | CPF-IN 28 00-N |

## STEP **15**

ROD BENDING

To adapt to patient anatomy, the rod can be contoured using the Rod Bender. Place the rod in the appropriate orientation and squeeze the handles to bend the rod.

**Note**: Reverse bending can weaken the rod and is not recommended.

| INSTRUMENT | REFERENCE |
|---|---|
| ROD BENDER | CPF-IN 29 00-N |

# SURGICAL TECHNIQUE

## STEP **16**

ROD INSERTION

Grasp the rod with the Rod Holder and seat it into the implant heads.

| INSTRUMENT | REFERENCE |
|---|---|
| ROD HOLDER | CPF-IN 19 00-N |

## STEP **17**

SET SCREW POSITIONING

Attach T20 Driver to Set Screws and place the Set Screw in each screw or hook by rotating clockwise.

Provisionally Tighten Set Screws to secure the construct.

**Note**: If a Set Screw does not initially advance, rotate the Set Screw a quarter turn and then turn clockwise.

If a HTH Cross Connector is to be used load an extended Set Screw onto the T20 Driver and place it at the selected screws.

| INSTRUMENT | REFERENCE |
|---|---|
| DRIVER T20 | CPF-IN 13 00-N |

# SURGICAL TECHNIQUE

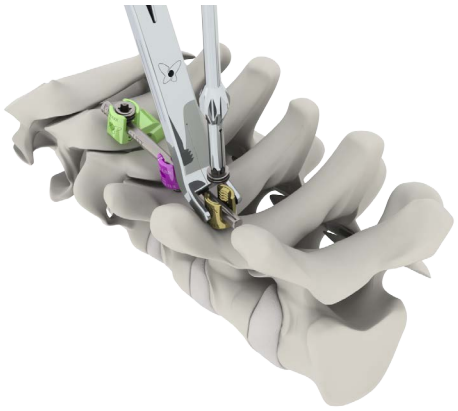
## STEP **18**

ROD REDUCTION OPTIONS

**OPTION 1: PUSHER**

The Pusher may be used to seat the rod into the implant head and facilitate Set Screw introduction. The Pusher can also be used to advance hooks.

| INSTRUMENT | REFERENCE |
|---|---|
| PUSHER | CPF-IN 17 00-N |



**OPTION 2: ROCKER**

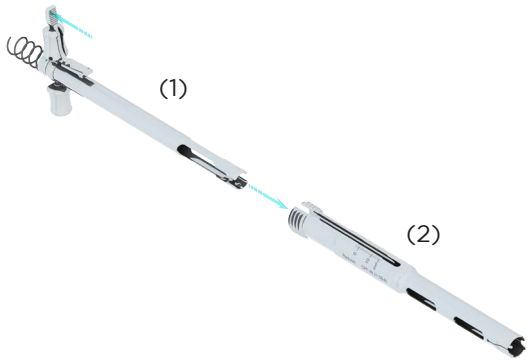
Controlled reduction can be achieved using the Rocker.

Engage the Rocker onto the notches of the implant head. Tilt the instrument over the rod to reduce the rod.

| INSTRUMENT | REFERENCE |
|---|---|
| ROCKER | CPF-IN 20 00-N |

# SURGICAL TECHNIQUE

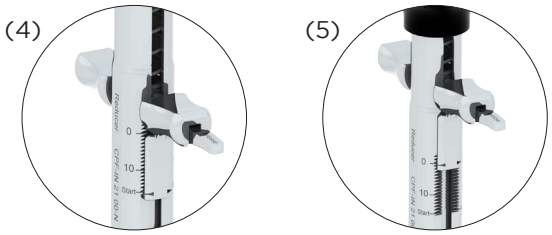
## STEP **18** (cont.)




**OPTION 3: REDUCER**

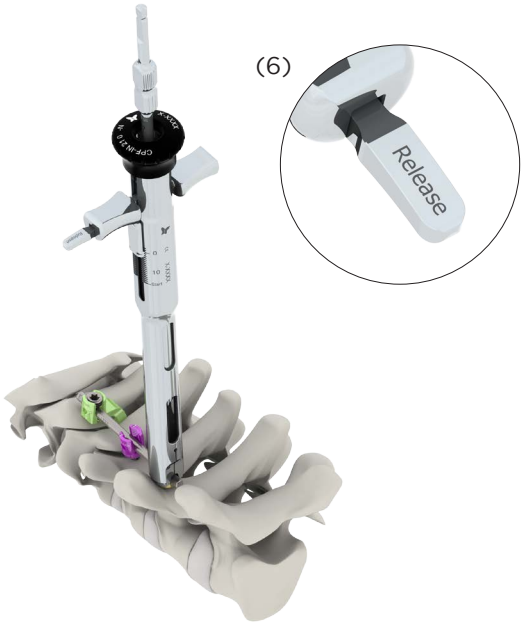
To assemble the Reducer, slide the Reducer Part A (1) into the Reducer Part B (2).


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




Position the Reducer in the start position (4) and engage the Reducer onto the implant screw head notches.

Apply downward force to persuade the rod until the Reducer indicator is at the “0” position (5) .




Once the rod is seated, introduce the Set Screw through the Reducer with the Driver T20.

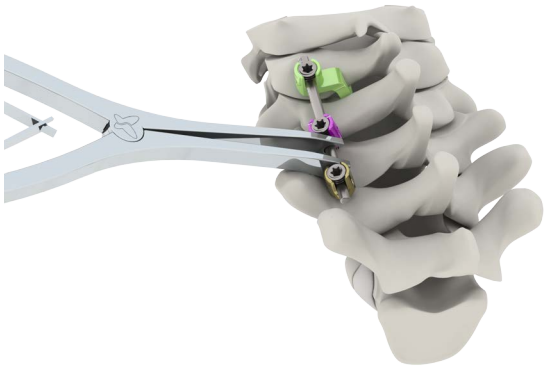
Disconnect the Reducer by pressing the release trigger (6).

**WARNING**: Extended Set Screws are NOT compatible with the Reducer. ONLY the Rocker can be used with Extended Set Screws

| INSTRUMENT | REFERENCE |
|---|---|
| REDUCER | CPF-IN 21 00-N |

# SURGICAL TECHNIQUE

## STEP **19**



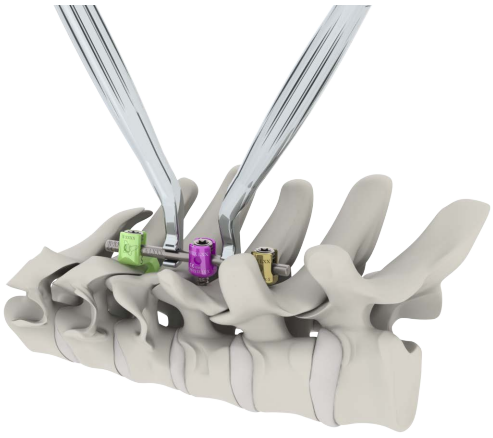
COMPRESSION / DISTRACTION MANEUVERS

Once the rod is secured, distraction and/or compression maneuvers can be applied to the construct.

After tightening one of the Set Screws, set up either the Distraction Forceps or the Compression Forceps against the implant heads and squeeze the handles to obtain distraction or compression.

| INSTRUMENT | REFERENCE |
|---|---|
| DISTRACTION FORCEPS | CPF-IN 31 00-N |
| COMPRESSION FORCEPS | CPF-IN 32 00-N |

## STEP **20**



IN-SITU BENDING

Sagittal Benders can be used to contour the rod in situ.

Coronal Benders can be used to contour the rod in situ.

| INSTRUMENT | REFERENCE |
|---|---|
| SAGITTAL BENDER LEFT | CPF-IN 24 0L-N |
| SAGITTAL BENDER RIGHT | CPF-IN 24 0R-N |
| CORONAL BENDER LEFT | CPF-IN 25 0L-N |
| CORONAL BENDER RIGHT | CPF-IN 25 0R-N |

# SURGICAL TECHNIQUE

## STEP **21**

ROD MANIPULATION

A rod gripper can be used to position the rod into screw heads.

| INSTRUMENT | REFERENCE |
|---|---|
| ROD GRIPPER | CPF-IN 34 00-N |

## STEP **22**

FINAL TIGHTENING

Connect the Driver T20 to the 2.5 Torque Limiting Handle. Slide the assembly through the Counter Torque and engage the Set Screw hexalobe recess.

Final tighten the Set Screw by turning the 2.5 Torque Limiting Handle clockwise until it clicks.

**Note**: Always use the counter torque during final tightening to reduce torque transfer to the spine and avoid damage to the Driver T20 tip.

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

# SURGICAL TECHNIQUE

## STEP **23**

ROD-TO-ROD CROSS CONNECTORS

To measure the appropriate RTR Cross Connector size, place the CC Caliper arms on the outer sides of the rods and determine the size indicated on the CC Caliper scale (1 to 5).

Engage the RTR Cross Connector with the Rod Holder and snap it over the rods.

For final tightening, connect the Driver T15 to the 2.5 Torque Limiting Handle and turn it clockwise until it clicks.

**Note**: The CC Sleeve is ONLY compatible with the central RTR Cross Connector Set Screw

| INSTRUMENT | REFERENCE |
|---|---|
| CC CALIPER | CPF-IN 27 00-N |
| ROD HOLDER | CPF-IN 19 00-N |
| DRIVER T15 | CPF-IN 12 00-N |
| 2.5 TORQUE LIMITING HANDLE | HAN-SI AO 26-N |
| CC SLEEVE | CPF-IN 36 00-N |

| RTR CROSS CONNECTOR | |
|---|---|
| SIZE 1 | CPF-CR 21 23-S |
| SIZE 2 | CPF-CR 23 26-S |
| SIZE 3 | CPF-CR 26 32-S |
| SIZE 4 | CPF-CR 32 44-S |
| SIZE 5 | CPF-CR 44 56-S |

# SURGICAL TECHNIQUE

## STEP **24**

HEAD-TO-HEAD CROSS CONNECTORS

Insert an extended Set Screw into the screw head using a Set Screw Holder.
Final tighten the extended Set Screw using the Driver T20, 2.5 Torque-Limiting Handle, and Counter Torque (See STEP 22).
Repeat these steps on the contralateral side.

Place the CC Caliper end tips into the extended Set Screw hexalobe recess and determine the size indicated on the CC caliper scale (A to F).

Engage the HTH Cross Connector with the Rod Holder and attach it to the extended Set Screws.

Connect the 2.5 Torque Limiting Handle to the Driver Hexa and insert a Hexagonal Set Screw. Introduce the Hexagonal Set Screw over the Extended Set Screw and final tighten by turning the 2.5 Torque Limiting Handle clockwise until it clicks.

| INSTRUMENT | REFERENCE |
|---|---|
| CC CALIPER | CPF-IN 27 00-N |
| ROD HOLDER | CPF-IN 19 00-N |
| DRIVER HEXA | CPF-IN 14 00-N |
| 2.5 TORQUE LIMITING HANDLE | HAN-SI AO 26-N |

| HTH CROSS CONNECTOR | |
|---|---|
| SIZE A | CPF-CH 20 25-S |
| SIZE B | CPF-CH 25 30-S |
| SIZE C | CPF-CH 30 35-S |
| SIZE D | CPF-CH 35 40-S |
| SIZE E | CPF-CH 40 45-S |
| SIZE F | CPF-CH 45 50-S |

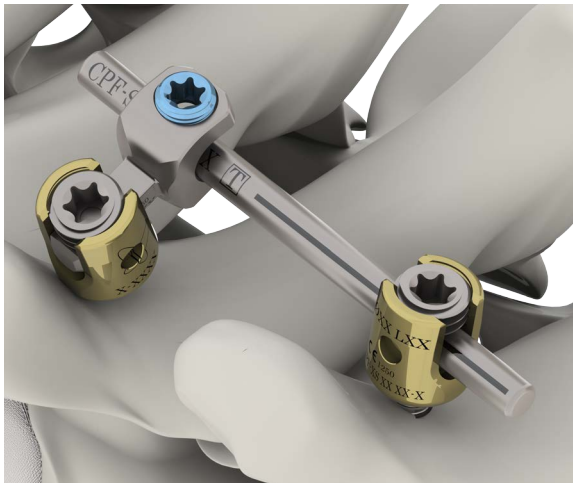
# SURGICAL TECHNIQUE

## STEP **25**


TRANSITION RODS (OPTIONAL)

Transition Rods allow the transition from the cervical to the thoracic spine, moving from a Ø3.5mm rod to a Ø5.4mm rod. Transition rods are offered in both titanium and cobalt chromium. Additional rod contouring and/or rod cutting may be performed (STEP 14 and STEP 15).

## STEP **26**



LATERAL CONNECTORS

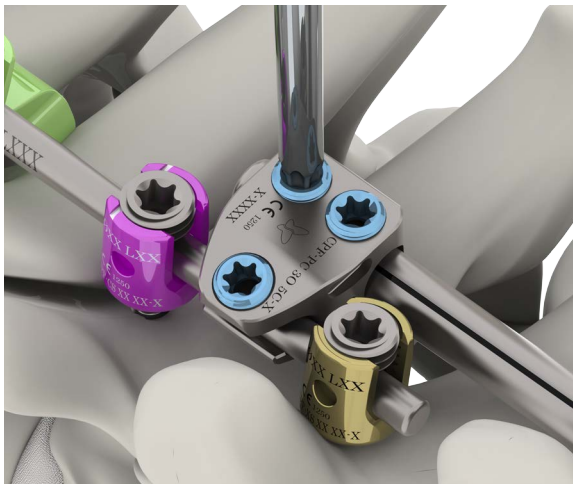
Choose the appropriate Lateral Connector size (Small or Large) and handle it with the Rod Holder.

Use the lateral connector to link a rod to a screw head.

Final tighten the construct using the Driver T15 connected to the 2.5 Torque Limiting Handle (turn clockwise until it clicks).

| INSTRUMENT | REFERENCE |
|---|---|
| ROD HOLDER | CPF-IN 19 00-N |
| DRIVER T15 | CPF-IN 12 00-N |
| 2.5 TORQUE LIMITING HANDLE | HAN-SI AO 26-N |

## STEP **27**



PARALLEL AND AXIAL CONNECTORS

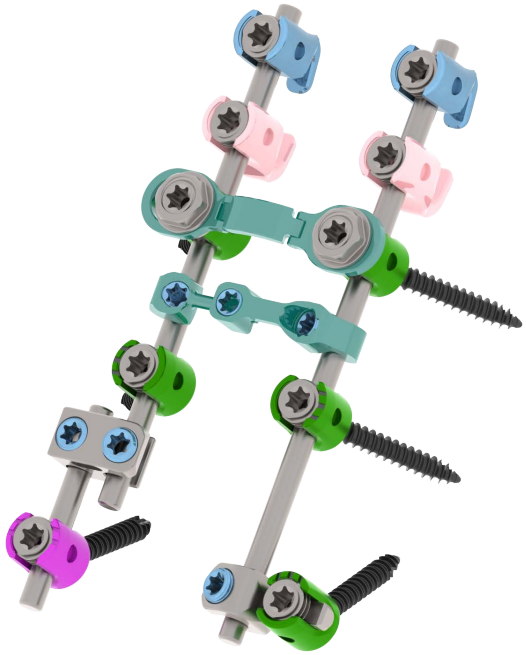
Choose the appropriate connector (parallel or axial) and secure it with the rod holder.

Connect a Ø3.5mm rod to a Ø3.5mm rod or to a Ø5.4mm rod (ROMEO®2) and final tighten the construct using the Driver T15 connected to the 2.5 Torque Limiting Handle (turn clockwise until it clicks).

| INSTRUMENT | REFERENCE |
|---|---|
| ROD HOLDER | CPF-IN 19 00-N |
| DRIVER T15 | CPF-IN 12 00-N |
| 2.5 TORQUE LIMITING HANDLE | HAN-SI AO 26-N |

# SURGICAL TECHNIQUE

## FINAL CONSTRUCT



## REVISION

POSTERIOR CERVICO-THORACIC FIXATION SYSTEM
CONSTRUCT REMOVAL

Loosen and remove all Set Screws using the Counter Torque and appropriate driver (Driver T15, Driver T20, or Driver Hexa) connected to the 2.5 Torque Limiting Handle. Remove rods. Fully secure the Screwdriver to the screw recess and turn counterclockwise to remove polyaxial screws.

| INSTRUMENT | REFERENCE |
|---|---|
| COUNTER TORQUE | CPF-IN 23 00-N |
| DRIVER HEXA | CPF-IN 14 00-N |
| DRIVER T15 | CPF-IN 12 00-N |
| DRIVER T20 | CPF-IN 13 00-N |
| 2.5 TORQUE LIMITING HANDLE | HAN-SI AO 26-N |
| SCREWDRIVER SLEEVE | CPF-IN 22 01-N |
| SCREWDRIVER TUBE | CPF-IN 22 02-N |
| SCREWDRIVER | CPF-IN 22 00-N |
| SCREWDRIVER HANDLE | CPF-IN 22 03-N |

# GENERAL INFORMATION

**INSTRUCTIONS FOR USE – IMPLANTS & INSTRUMENTS**
**PERLA® POSTERIOR CERVICO-THORACIC FIXATION SYSTEM**

## 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.

US Caution Federal law restricts these devices to be sold by or on the order of a physician.

## 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 rods associated to 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 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.

# GENERAL INFORMATION

## 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.

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: device component fracture, loss of fixation, pseudoarthrosis (i.e non-union), fracture of the vertebra, neurological injury, and vascular or visceral 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.

## PRECAUTIONS 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

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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.

Steam Sterilization at 121°C for 30 minutes in gravity autoclave has not been shown to be effective in sterilizing PERLA® instruments.

## 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

Precaution: 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

Prior to starting, the person carrying out the procedure must properly decontaminate, clean, and sterilize the instruments that will be used during surgery. The insertion is then performed with the following information in mind:

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These methods and parameters have been validated following the AAMI TIR 30 Technical Report for reusable instruments.

**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 2 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.

| WASHER-DISINFECTOR PARAMETERS | | | |
|---|---|---|---|
| STEP | SOLUTION | TEMPERATURE | TIME |
| Pre-cleaning | Water | Cold | / |
| Cleaning | Water<br>+<br>Neutral enzymatic cleaner<br>(example: Neodisher MA) | 55°C | 10 minutes |
| Rinsing | Water<br>+<br>Neutralizer<br>(example: Neodisher Z) | Cold | / |
| Rinsing | Water | Cold | / |
| Final Rinsing | Water | 93°C | 10 minutes |

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**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 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)

Minimum exposure time: 18 minutes

Minimum temperature: 134°C

Drying time: 30 minutes

This 134°C – 18 minutes sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

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.

# NOTES

spineart.com

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