# PERLA®

## OCT FIXATION

# C O N T E N T

# CONCEPT AND DESIGN

The PERLA® Occipito-Cervico-Thoracic (OCT) Fixation System has been designed with surgeons in accordance with Spineart's philosophy: Quality, Innovation, Simplicity.

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

## AT A GLANCE

Comprehensive Screw Range
Cannulated Screws
Occipital Fixation
Versatile Cross-Connectors

## INDICATIONS*

The PERLA® posterior occipito-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 cranio-cervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 to 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 occipito-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.
The occipital bone screws are limited to occipital fixation only.
The use of the multi-axial screws is limited to placement in the cervical spine (C1 to C7) and the thoracic spine (T1 to T3).

In order to achieve additional levels of fixation, the PERLA® posterior occipito-cervico-thoracic fixation system may be connected to the ROMEO®2 and Perla® TL Posterior Osteosynthesis Systems with rod connectors. Transition rods may also be used to connect the PERLA® posterior occipito-cervico-thoracic fixation system to the ROMEO®2 and Perla® TL Posterior Osteosynthesis Systems. Refer to the ROMEO®2 and Perla® TL Posterior Osteosynthesis Systems packages inserts for a list of the ROMEO®2 and Perla® TL Posterior Osteosynthesis Systems indications of use.
PERLA® posterior occipito-cervico-thoracic fixation system is indicated for skeletally mature patients.

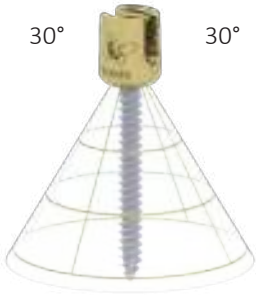
* For further informations or indications, please refer to page 57.

# IMPLANTS

## SCREWS

### POLYAXIAL SCREWS

| LENGTH | Ø3.5 | Ø4 | Ø4.5 |
|---|---|---|---|
| L08 | CPF-PS 35 08-S | CPF-PS 04 08-S | CPF-PS 45 08-S |
| L10 | CPF-PS 35 10-S | CPF-PS 04 10-S | CPF-PS 45 10-S |
| L12 | CPF-PS 35 12-S | CPF-PS 04 12-S | CPF-PS 45 12-S |
| L14 | CPF-PS 35 14-S | CPF-PS 04 14-S | CPF-PS 45 14-S |
| L16 | CPF-PS 35 16-S | CPF-PS 04 16-S | CPF-PS 45 16-S |
| L18 | CPF-PS 35 18-S | CPF-PS 04 18-S | CPF-PS 45 18-S |
| L20 | CPF-PS 35 20-S | CPF-PS 04 20-S | CPF-PS 45 20-S |
| L24 | CPF-PS 35 24-S | CPF-PS 04 24-S | CPF-PS 45 24-S |
| L28 | CPF-PS 35 28-S | CPF-PS 04 28-S | CPF-PS 45 28-S |
| L32 | CPF-PS 35 32-S | CPF-PS 04 32-S | CPF-PS 45 32-S |
| L36 | CPF-PS 35 36-S | CPF-PS 04 36-S | CPF-PS 45 36-S |
| L40 | CPF-PS 35 40-S | CPF-PS 04 40-S | CPF-PS 45 40-S |
| L44 | CPF-PS 35 44-S | CPF-PS 04 44-S | CPF-PS 45 44-S |
| L48 | CPF-PS 35 48-S | CPF-PS 04 48-S | CPF-PS 45 48-S |
| L52 | CPF-PS 35 52-S | CPF-PS 04 52-S | CPF-PS 45 52-S |




### CANNULATED POLYAXIAL SCREWS

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

# IMPLANTS

## SCREWS

### SMOOTH SHANK SCREWS

| LENGTH | SMOOTH | THREADED | Ø3.5 | Ø4 |
|---|---|---|---|---|
| L18 | 8 | 10 | CPF-SS 35 18-S | CPF-SS 04 18-S |
| L20 | 8 | 12 | CPF-SS 35 20-S | CPF-SS 04 20-S |
| L22 | 8 | 14 | CPF-SS 35 22-S | CPF-SS 04 22-S |
| L24 | 8 | 16 | CPF-SS 35 24-S | CPF-SS 04 24-S |
| L26 | 10 | 16 | CPF-SS 35 26-S | CPF-SS 04 26-S |
| L28 | 10 | 18 | CPF-SS 35 28-S | CPF-SS 04 28-S |
| L30 | 10 | 20 | CPF-SS 35 30-S | CPF-SS 04 30-S |
| L32 | 12 | 20 | CPF-SS 35 32-S | CPF-SS 04 32-S |
| L34 | 12 | 22 | CPF-SS 35 34-S | CPF-SS 04 34-S |
| L36 | 12 | 24 | CPF-SS 35 36-S | CPF-SS 04 36-S |


### CANNULATED SMOOTH SHANK SCREWS

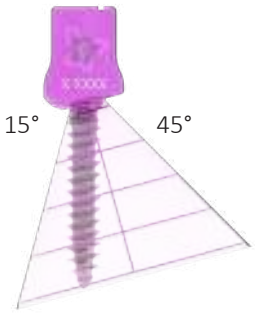
| LENGTH | SMOOTH | THREADED | Ø4 |
|---|---|---|---|
| L18 | 8 | 10 | CPF-KS 04 18-S |
| L20 | 8 | 12 | CPF-KS 04 20-S |
| L22 | 8 | 14 | CPF-KS 04 22-S |
| L24 | 8 | 16 | CPF-KS 04 24-S |
| L26 | 10 | 16 | CPF-KS 04 26-S |
| L28 | 10 | 18 | CPF-KS 04 28-S |
| L30 | 10 | 20 | CPF-KS 04 30-S |
| L32 | 12 | 20 | CPF-KS 04 32-S |
| L34 | 12 | 22 | CPF-KS 04 34-S |
| L36 | 12 | 24 | CPF-KS 04 36-S |

# IMPLANTS

## SCREWS

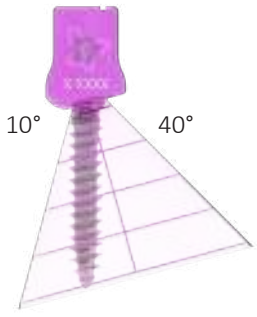
### CC PREFERRED ANGLE SCREWS

| 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 |




### CANNULATED CC PREFERRED ANGLE SCREWS

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



# IMPLANTS

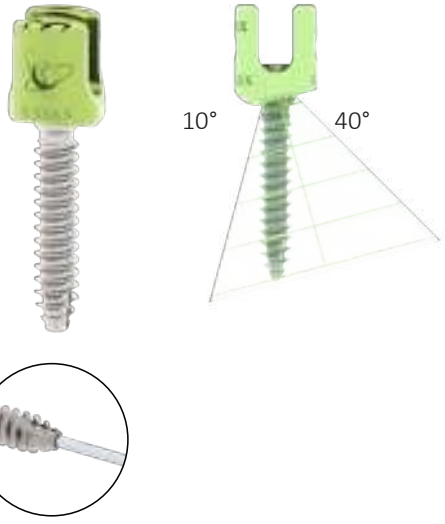
## SCREWS

### 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 |


### CANNULATED ML PREFERRED ANGLE SCREWS

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



# IMPLANTS

## OCCIPITAL PLATE

| SIZE S | CPF-OP 00 0S-S |
|---|---|

| SIZE M | CPF-OP 00 0M-S |
|---|---|

| SIZE L | CPF-OP 00 0L-S |
|---|---|

## OCCIPITAL SCREWS

| **LENGTH** | **Ø4.5** | **Ø5** |
|---|---|---|
| L06 | CPF-OS 45 06-S | CPF-OS 05 06-S |
| L08 | CPF-OS 45 08-S | CPF-OS 05 08-S |
| L10 | CPF-OS 45 10-S | CPF-OS 05 10-S |
| L12 | CPF-OS 45 12-S | CPF-OS 05 12-S |
| L14 | CPF-OS 45 14-S | CPF-OS 05 14-S |
| L16 | CPF-OS 45 16-S | CPF-OS 05 16-S |

## SET SCREW

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

* Packed with screws and plates

# IMPLANTS

## RODS

### PREBENT RODS TITANIUM Ø3,5

| LENGTH | REFERENCE |
|---|---|
| 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 | REFERENCE |
|---|---|
| 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 | REFERENCE |
|---|---|
| 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 | REFERENCE |
|---|---|
| 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

## RODS

### TRANSITION RODS TITANIUM

| Ø5,4 → | Ø3,5 | REFERENCE |
|---|---|---|
| L100 | L200 | CPF-TR T3 00-S |
| L400 | L200 | CPF-TR T6 00-S |

| Ø5,5 → | Ø3,5 | REFERENCE |
|---|---|---|
| L100 | L200 | CPF-T5 T3 00-S |
| L400 | L200 | CPF-T5 T6 00-S |

| Ø6 → | Ø3,5 | REFERENCE |
|---|---|---|
| L100 | L200 | CPF-T6 T3 00-S |
| L400 | L200 | CPF-T6 T6 00-S |

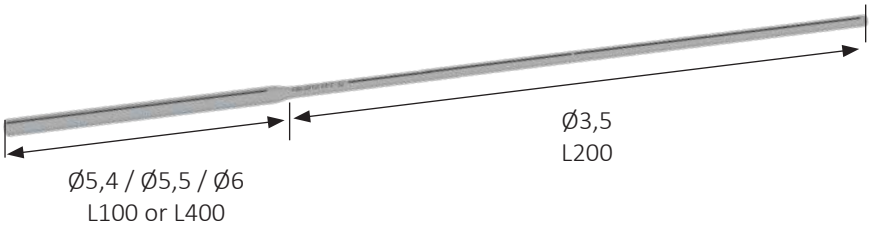
### TRANSITION RODS COBALT CHROMIUM

| Ø5,4 → | Ø3,5 | REFERENCE |
|---|---|---|
| L100 | L200 | CPF-TR C3 00-S |
| L400 | L200 | CPF-TR C6 00-S |

| Ø5,5 → | Ø3,5 | REFERENCE |
|---|---|---|
| L100 | L200 | CPF-T5 C3 00-S |
| L400 | L200 | CPF-T5 C6 00-S |

| Ø6 → | Ø3,5 | REFERENCE |
|---|---|---|
| L100 | L200 | CPF-T6 C3 00-S |
| L400 | L200 | CPF-T6 C6 00-S |

Ø5.4 Transition rods are adapted to a connection between PERLA® and ROMEO®2 systems.
Ø5.5 and Ø6 Transition rods are adapted to a connection between PERLA® and PERLA® TL systems.



# IMPLANTS

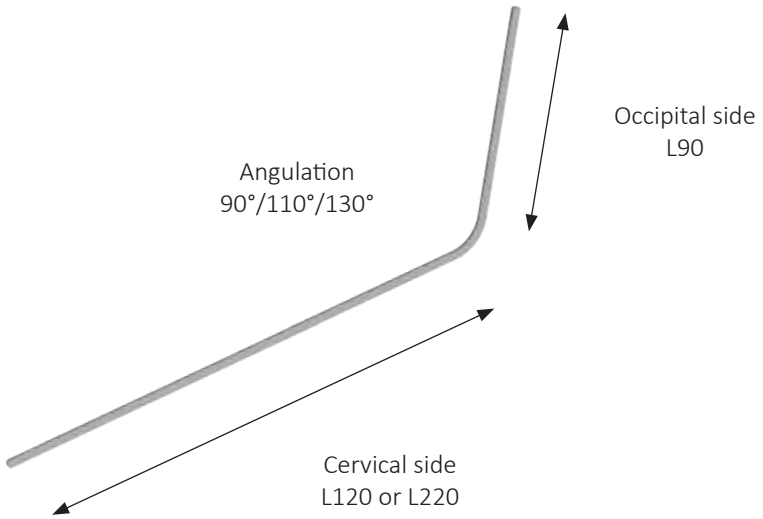
## RODS

### OCCIPITAL RODS TITANIUM

| ANGULATION | SIZE | LENGTH CERVICAL SIDE | LENGTH OCCIPITAL SIDE | REFERENCE |
|---|---|---|---|---|
| 90° | S | L120 | L90 | CPF-OR TS 90-S |
| | M | L220 | L90 | CPF-OR TM 90-S |
| 110° | S | L120 | L90 | CPF-OR TS 11-S |
| | M | L220 | L90 | CPF-OR TM 11-S |
| 130° | S | L120 | L90 | CPF-OR TS 13-S |
| | M | L220 | L90 | CPF-OR TM 13-S |

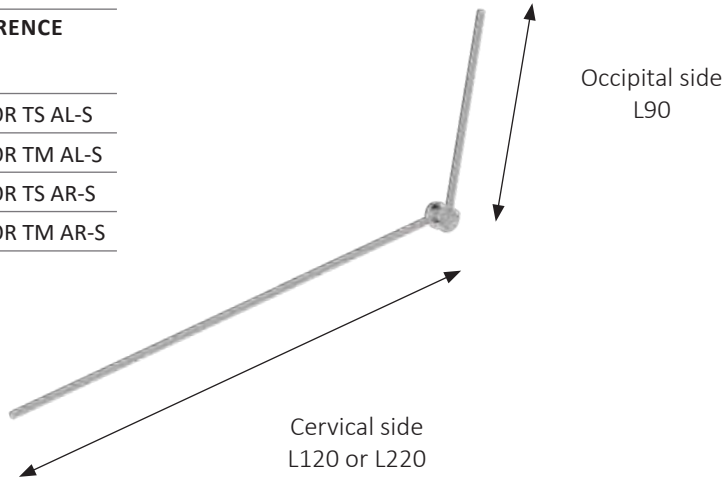
### OCCIPITAL RODS COBALT CHROMIUM

| ANGULATION | SIZE | LENGTH CERVICAL SIDE | LENGTH OCCIPITAL SIDE | REFERENCE |
|---|---|---|---|---|
| 90° | S | L120 | L90 | CPF-OR CS 90-S |
| | M | L220 | L90 | CPF-OR CM 90-S |
| 110° | S | L120 | L90 | CPF-OR CS 11-S |
| | M | L220 | L90 | CPF-OR CM 11-S |
| 130° | S | L120 | L90 | CPF-OR CS 13-S |
| | M | L220 | L90 | CPF-OR CM 13-S |




### ADJUSTABLE RODS TITANIUM

| SIDE | SIZE | LENGTH CERVICAL SIDE | LENGTH OCCIPITAL SIDE | REFERENCE |
|---|---|---|---|---|
| Left | S | L120 | L90 | CPF-OR TS AL-S |
| | M | L220 | L90 | CPF-OR TM AL-S |
| Right | S | L120 | L90 | CPF-OR TS AR-S |
| | M | L220 | L90 | CPF-OR TM AR-S |



# IMPLANTS

## HOOKS

| 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 LL-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: Ø3.5/5.4 or 5.5mm, Ø3.5/6mm, 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 |

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

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

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

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

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

| | |
|---|---|
| **PARALLEL CONNECTOR 3C-6O | CPF-PC 3C 6O-S |

| | |
|---|---|
| **PARALLEL CONNECTOR 3O-6C | CPF-PC 3O 6C-S |

| | |
|---|---|
| ***PARALLEL CONNECTOR CC-TO | CPF-PC CC TO-S |

| | |
|---|---|
| ***PARALLEL CONNECTOR CO-TC | CPF-PC CO TC-S |

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

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

* Rod connectors adapted to a connection between PERLA® Ø3,5 rods and ROMEO®2 Ø5,4 rods or PERLA® TL Ø5,5 rods.

** Rod connectors adapted to a connection between PERLA® Ø3,5 rods and PERLA® TL Ø6 rods.

*** Rod connectors adapted to a connection between PERLA® Ø3,5 rods and PERLA® TL Ø5,5 or Ø6 rods.

# IMPLANTS

## CONNECTORS

### RTR CROSS CONNECTOR

| | | |
|---|---|---|
| Size 1 | 21-23 | CPF-CR 21 23-S |
| Size 2 | 23-26 | CPF-CR 23 26-S |
| Size 3 | 26-32 | CPF-CR 26 32-S |
| Size 4 | 32-44 | CPF-CR 32 44-S |
| Size 5 | 44-56 | CPF-CR 44 56-S |

### HTH CROSS CONNECTOR

| | | |
|---|---|---|
| Size A | 20-25 | CPF-CH 20 25-S |
| Size B | 25-30 | CPF-CH 25 30-S |
| Size C | 30-35 | CPF-CH 30 35-S |
| Size D | 35-40 | CPF-CH 35 40-S |
| Size E | 40-45 | CPF-CH 40 45-S |
| Size F | 45-50 | CPF-CH 45 50-S |

## SET SCREWS

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

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

* For HTH cross connector use only

# TECHNICAL FEATURES

## COMPREHENSIVE SCREW RANGE

A variety of screws are available to address every surgical need including Polyaxial, Smooth Shank, Cranio-Caudal and Medio-Lateral preferred angle screws with 60° of polyaxiality.

## CANNULATED SCREW

Polyaxial, Smooth Shank, Cranio-Caudal and Medio-Lateral screws are also available in a cannulated version with the adapted instrumentation, to adapt to certain approaches such as the transpedicular fixation.

## OCCIPITAL FIXATION

A range of occipital plates and rods have been designed, allowing fixation to the occiput for occipito-cervical construct.

# TECHNICAL FEATURES

## VERSATILE CROSS-CONNECTORS

Choice of Adjustable Rod to Rod or Head to Head cross connectors
to accommodate different constructs and anatomical needs.

## COMPACT SETS

One compact set of intuitive instruments for posterior cervico-toracic cases.
Two additional boxes are also available for Occipital fixation procedures and the use
of cannulated screws (provided separately).

## WIDE OPTIONS

The PERLA® system has various rod options and offers a variety of rod connectors
answering to surgeons needs and allowing an easy connection with ROMEO®2 and
PERLA® TL thoraco-lumbar systems.

# INSTRUMENT SET

## CERVICAL SET

| # | 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 | 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 |
| 18 | ROCKER (UPPER) | CPF-IN 20 00-N |
| 19 | ROD HOLDER (LOWER) | CPF-IN 19 00-N |
| 20 | ROD BENDER | CPF-IN 29 00-N |
| 21 | 2.5 TORQUE LIMITING HANDLE | HAN-SI AO 26-N |
| 22 | DISTRACTION FORCEPS | CPF-IN 31 00-N |
| 23 | COMPRESSION FORCEPS | CPF-IN 32 00-N |
| 24 | REDUCER PART A | CPF-IN 21 0A-N |

| # | DESCRIPTION | REFERENCE |
|---|---|---|
| 25 | REDUCER PART B | CPF-IN 21 0B-N |
| 26 | ROD TEMPLATE L250 (UPPER) | CPF-IN 30 00-N |
| ● 27 | ROD TEMPLATE L100 (LOWER) | CPF-IN 30 01-N |
| 28 | DRIVER T20 | CPF-IN 13 00-N |
| 29 | COUNTER TORQUE | CPF-IN 23 00-N |
| 30 | PUSHER | CPF-IN 17 00-N |
| 31 | REDUCER PART C | CPF-IN 21 0C-N |
| 32 | CC SLEEVE | CPF-IN 36 00-N |
| 33 | HOOK HOLDER | CPF-IN 15 00-N |
| ● 34 | ROD GRIPPER | CPF-IN 34 00-N |
| 35 | CC CALIPER | CPF-IN 27 00-N |
| 36 | DRIVER HEXA | CPF-IN 14 00-N |
| 37 | DRIVER T15 | CPF-IN 12 00-N |
| ● 38 | SAGITTAL BENDER LEFT | CPF-IN 24 0L-N |
| ● 39 | SAGITTAL BENDER RIGHT | CPF-IN 24 0R-N |
| 40 | HOOK PREPARER | CPF-IN 16 00-N |
| ● 41 | CORONAL BENDER LEFT | CPF-IN 25 0L-N |
| ● 42 | CORONAL BENDER RIGHT | CPF-IN 25 0R-N |
| ● 43 | K-WIRE – BLUNT TIP | CPF-IN 62 00-N |
| ● 44 | SCREWDRIVER – CANNULATED | CPF-IN 63 00-N |



● : OPTIONAL

# INSTRUMENT SET

## OCCIPITAL SET

| # | DESCRIPTION | REFERENCE |
|---|---|---|
| 01 | U-JOINT OCCIPITAL TUBE | CPF-IN 50 00-N |
| 02 | U-JOINT OCCIPITAL ANGLED SLEEVE | CPF-IN 50 10-N |
| 03 | STRAIGHT OCCIPITAL DRILL Ø3.2 | CPF-IN 51 00-N |
| 04 | *STRAIGHT OCCIPITAL DRILL Ø3.2 (STERILE) | CPF-IN 51 00-S |
| 05 | U-JOINT OCCIPITAL DRILL Ø3.2 | CPF-IN 51 10-N |
| 06 | STRAIGHT OCCIPITAL TAP Ø4,2 | CPF-IN 52 10-N |
| 07 | U-JOINT OCCIPITAL TAP Ø4,2 | CPF-IN 52 20-N |
| 08 | OCCIPITAL DRILL GUIDE L6 & L8 | CPF-IN 53 00-N |
| 09 | OCCIPITAL DRILL GUIDE L10 & L12 | CPF-IN 53 10-N |
| 10 | OCCIPITAL DRILL GUIDE L14 & L16 | CPF-IN 53 20-N |
| 11 | OCCIPITAL PLATE HOLDER | CPF-IN 54 00-N |
| 12 | OCCIPITAL PLATE TEMPLATE SMALL | CPF-IN 54 10-N |
| 13 | OCCIPITAL PLATE TEMPLATE MEDIUM | CPF-IN 54 20-N |
| 14 | OCCIPITAL PLATE TEMPLATE LARGE | CPF-IN 54 30-N |
| 15 | OCCIPITAL PLATE BENDER HOLDER | CPF-IN 55 00-N |
| 16 | OCCIPITAL PLATE BENDER | CPF-IN 55 10-N |
| 17 | STRAIGHT OCCIPITAL SCREWDRIVER T15 | CPF-IN 56 00-N |
| 18 | U-JOINT OCCIPITAL SCREWDRIVER T15 | CPF-IN 56 10-N |
| 19 | U-JOINT OCCIPITAL TIGHTENER T20 | CPF-IN 56 20-N |
| 20 | OCCIPITAL COUNTER TORQUE | CPF-IN 56 30-N |
| 21 | OCCIPITAL COUNTER TORQUE FOR ADJUSTABLE ROD | CPF-IN 56 40-N |

* Under CE 1250

# INSTRUMENTS

## CERVICAL SET

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

| | |
|---|---|
| PEDICLE PROBE CURVED | CPF-IN 02 01-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 |

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

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

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

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

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

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

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

# INSTRUMENTS

## CERVICAL SET

| 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 |
|---|---|

| ROD CUTTER | CPF-IN 28 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 |
|---|---|

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

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

# INSTRUMENTS

## CERVICAL SET

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

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

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

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

## CERVICAL SET - OPTIONAL

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

| DRIVER T20 SOLID | CPF-IN 13 02-N |
|---|---|

| 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 |
|---|---|

* Under CE 1250

# INSTRUMENTS

## CERVICAL SET - OPTIONAL

DEPTH GAUGE CPF-IN 33 00-N

PROBE CPF-IN 02 00-N

*ADJUSTABLE DRILL (STERILE) CPF-IN 08 00-S

SPEED SCREWDRIVER SPE-IN 01 62-N

PERSUADER CPF-IN 37 00-N

ROD TEMPLATE L100 CPF-IN 30 01-N

ROD GRIPPER CPF-IN 34 00-N

SETSCREW HOLDER DOUBLE T20 CPF-IN 13 01-N

SPEED SCREWDRIVER SLEEVE CPF-IN 22 04-N

K-WIRE – BLUNT TIP CPF-IN 62 00-N

SCREWDRIVER – CANNULATED CPF-IN 63 00-N

* Under CE 1250

# INSTRUMENTS

## OCCIPITAL SET

| | |
|---|---|
| U-JOINT OCCIPITAL TUBE | CPF-IN 50 00-N |

| | |
|---|---|
| U-JOINT OCCIPITAL ANGLED SLEEVE | CPF-IN 50 10-N |

| | |
|---|---|
| STRAIGHT OCCIPITAL DRILL Ø3.2 | CPF-IN 51 00-N |
| *STRAIGHT OCCIPITAL DRILL Ø3.2 (STERILE) | CPF-IN 51 00-S |

| | |
|---|---|
| U-JOINT OCCIPITAL DRILL Ø3.2 | CPF-IN 51 10-N |

| | |
|---|---|
| STRAIGHT OCCIPITAL TAP Ø4,2 | CPF-IN 52 10-N |

| | |
|---|---|
| U-JOINT OCCIPITAL TAP Ø4,2 | CPF-IN 52 20-N |

| | |
|---|---|
| OCCIPITAL DRILL GUIDE L6 & L8 | CPF-IN 53 00-N |

| | |
|---|---|
| OCCIPITAL DRILL GUIDE L10 & L12 | CPF-IN 53 10-N |

| | |
|---|---|
| OCCIPITAL DRILL GUIDE L14 & L16 | CPF-IN 53 20-N |

| | |
|---|---|
| OCCIPITAL PLATE TEMPLATE - SMALL | CPF-IN 54 10-N |

| | |
|---|---|
| OCCIPITAL PLATE HOLDER | CPF-IN 54 00-N |

* Under CE 1250

# INSTRUMENTS

## OCCIPITAL SET

OCCIPITAL PLATE TEMPLATE - MEDIUM CPF-IN 54 20-N

OCCIPITAL PLATE TEMPLATE - LARGE CPF-IN 54 30-N

OCCIPITAL PLATE BENDER - HOLDER CPF-IN 55 00-N

OCCIPITAL PLATE BENDER CPF-IN 55 10-N

STRAIGHT OCCIPITAL SCREWDRIVER T15 CPF-IN 56 00-N

U-JOINT OCCIPITAL SCREWDRIVER T15 CPF-IN 56 10-N

U-JOINT OCCIPITAL TIGHTENER T20 CPF-IN 56 20-N

OCCIPITAL COUNTER TORQUE CPF-IN 56 30-N

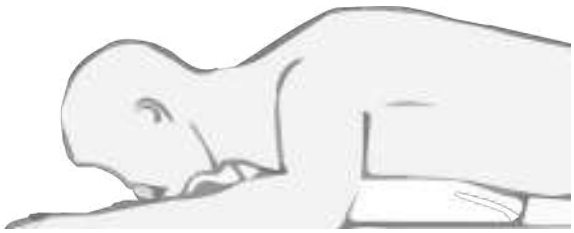
OCCIPITAL COUNTER TORQUE FOR ADJUSTABLE ROD CPF-IN 56 40-N

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

_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 |

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

### _STEP 3

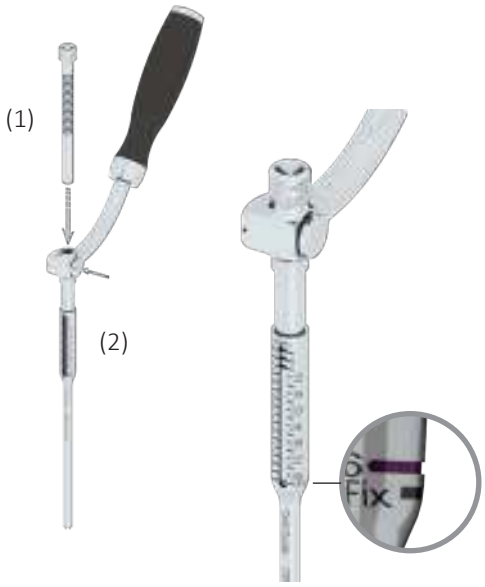
### PROBE INSERTION

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 |
|---|---|
| PEDICLE PROBE CURVED | CPF-IN 02 01-N |

### _STEP 4




### FIXED DRILL TECHNIQUE

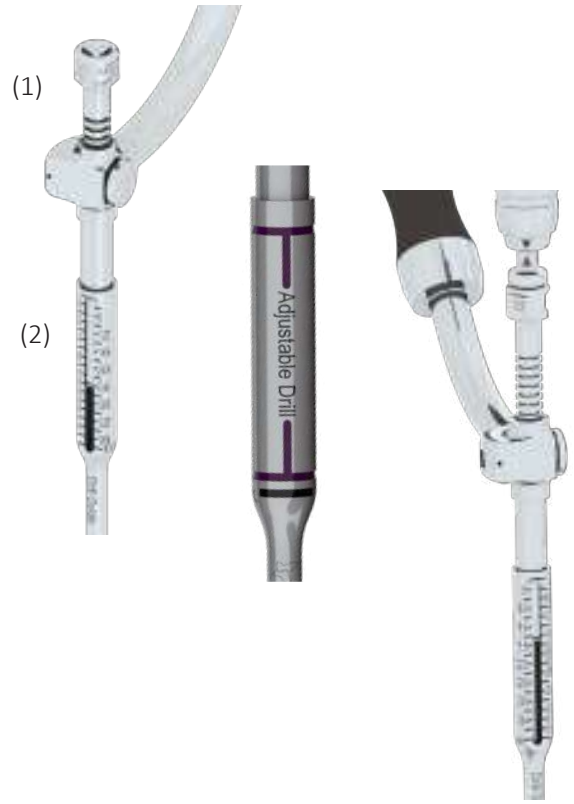
Position the Adjustable Drill Guide (1) into the Drill Guide (2) on the “FIX” position by pressing the lateral button on the Drill Guide. Choose the appropriate Fixed Drill and connect it to the Straight Handle AO Ø20. This assembly can be introduced into the Drill Guide.

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 |
| | CPF-IN 07 10-S |
| | CPF-IN 07 12-S |
| | CPF-IN 07 14-S |
| | CPF-IN 07 16-S |
| | CPF-IN 07 18-S |
| | CPF-IN 07 50-S |
| ADJUSTABLE DRILL GUIDE | CPF-IN 10 00-N |
| STRAIGHT HANDLE RATCHET AO Ø20 | HAN-RA AO 20-N |

* Under CE 1250

## _STEP 4 BIS




## 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.

⚠ **WARNING:** Care should be taken during drill insertion to avoid any involuntary button pressure of the drill guide.

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

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

### _STEP 5

## BONE HOLE VERIFICATION

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 |

## _STEP 7

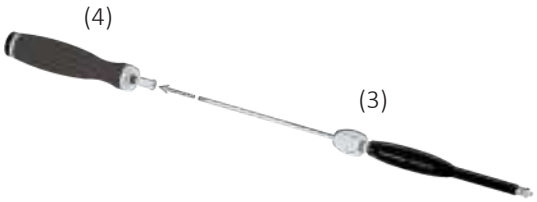
## SCREWDRIVER ASSEMBLY

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 is necessary for screwdriver assembly (Hexagonal endtip).


For assembly, slide the Screwdriver Sleeve (1), 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

## CERVICO-THORACIC FIXATION

### _STEP 8

### SCREW ATTACHMENT

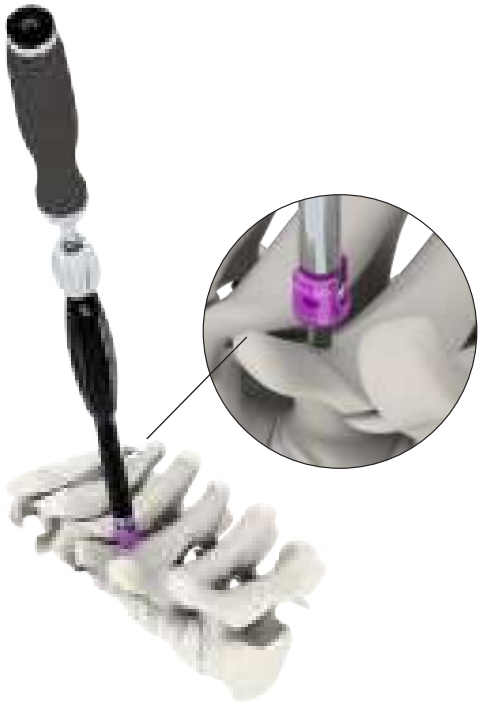
Select the proper screw and attach it on the Screwdriver assembly by aligning the Screwdriver tip into the screw shank recess.

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

**NOTE 2:** 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 |

**NOTE 3:** In case of use of cannulated screw, use the **Screwdriver - Cannulated** and the **K-Wire - Blunt Tip**.

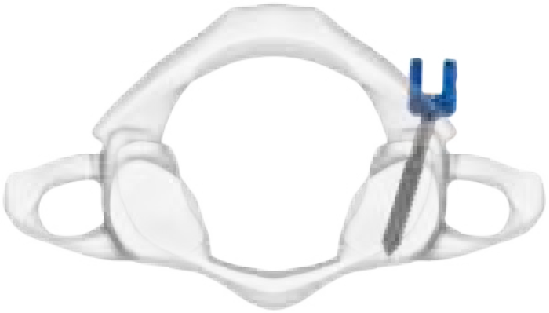
| INSTRUMENT | REFERENCE |
|---|---|
| K-WIRE - BLUNT TIP | CPF-IN 62 00-N |
| SCREWDRIVER - CANNULATED | CPF-IN 63 00-N |

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

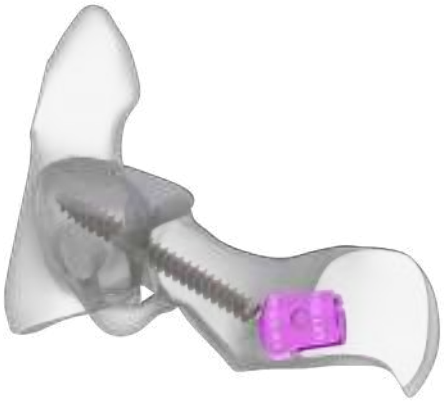
_STEP 9

## SCREW USE BY TYPE



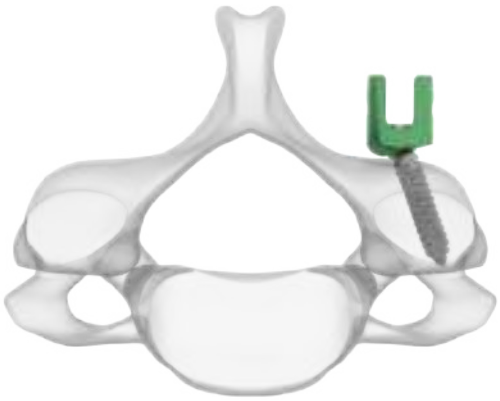
### EXAMPLE OF C1 SCREW INSERTION

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 C2 SCREW INSERTION

Cranio-caudal preferred angle screw 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

Medio-lateral preferred angle screw may be implanted in the pedicle or 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.

⚠ **WARNING:** The 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.

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

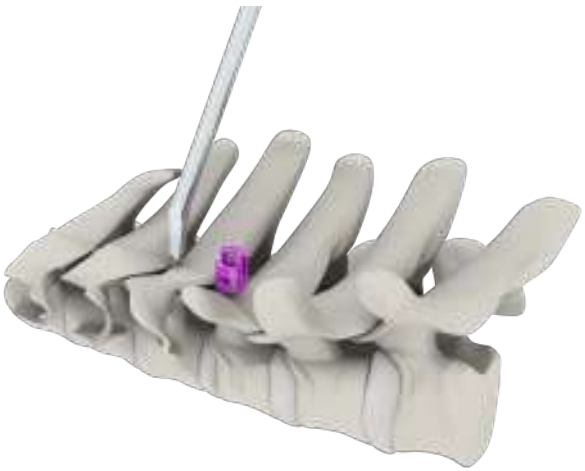
### _STEP 10

### SCREW HEAD ALIGNMENT

The Head Aligner may be used to position the 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

## CERVICO-THORACIC FIXATION

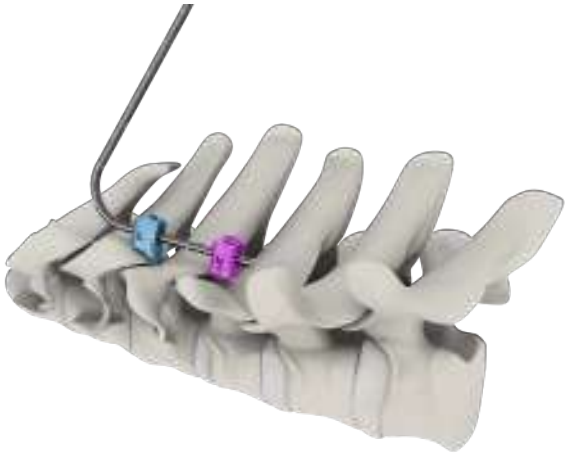
### _STEP 12

### 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 L100mm or L250mm to determine the appropriate length and contour of the rod.

| INSTRUMENT | REFERENCE |
|---|---|
| ROD TEMPLATE L250 | CPF-IN 30 00-N |
| ROD TEMPLATE L100 | CPF-IN 30 01-N |

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

### _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 intrument's handles to bend the rod.

⚠ **WARNING:** Repeated bending can weaken the rod.

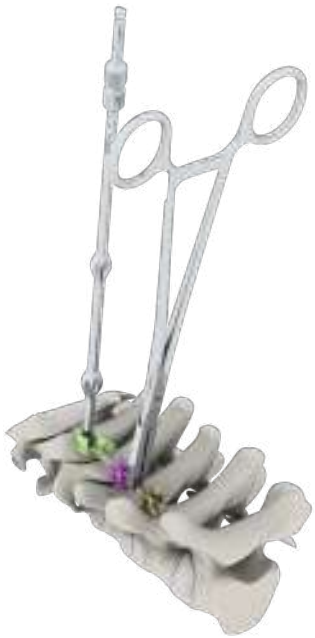
| INSTRUMENT | REFERENCE |
|---|---|
| ROD BENDER | CPF-IN 29 00-N |

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

### _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 counterclockwise 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 |
| SET SCREW HOLDER DOUBLE T20 | CPF-IN 13 01-N |

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

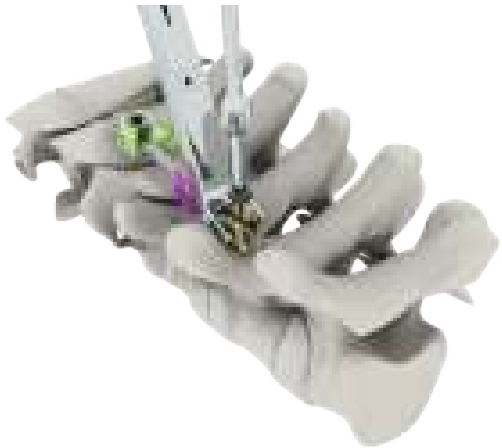
### _STEP 18

## 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

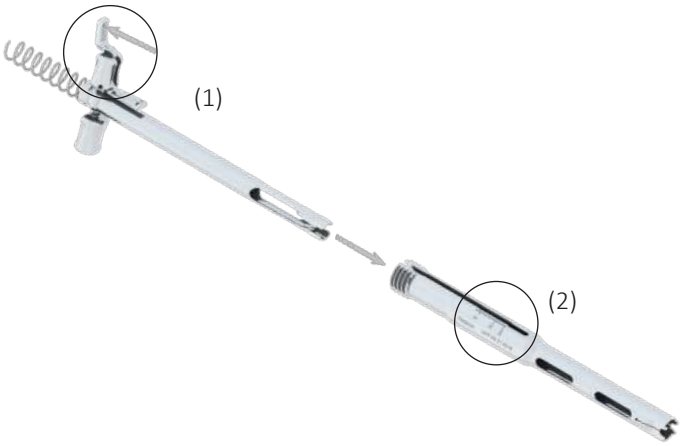
Controlled reduction can be achieved using the Rocker.

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 |

## CERVICO-THORACIC FIXATION

### _STEP 18








### OPTION 3: REDUCER

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

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

⚠ **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 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.

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

### _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.

⚠ **WARNING**: Care should be taken to check correct engagement of the rod into the benders.

| 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

## CERVICO-THORACIC FIXATION

### _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 |
| DRIVER T20 SOLID | CPF-IN 13 02-N |

_STEP 23

## ROD-TO-ROD CROSS CONNECTORS

To measure the appropriate RTR cross connector size, place the CC Caliper arms on the inner 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 | **REFERENCE** |
|---|---|
| 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 |

## CERVICO-THORACIC FIXATION

_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 ball ends into the extended set screws 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.

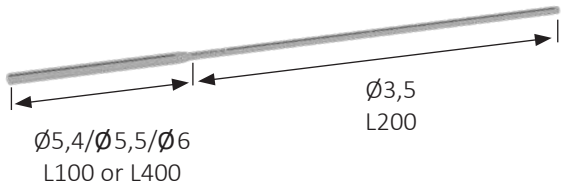
| **INSTRUMENT** | **REFERENCE** |
|---|---|
| CC CALIPER | CPF-IN 27 00-N |
| ROD HOLDER | CPF-IN 19 00-N |
| DRIVER HEXA | CPF-IN 14 00-N |
| 2.5 TORQUE LIMITING HANDLE | HAN-SI AO 26-N |

| 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

## CERVICO-THORACIC FIXATION

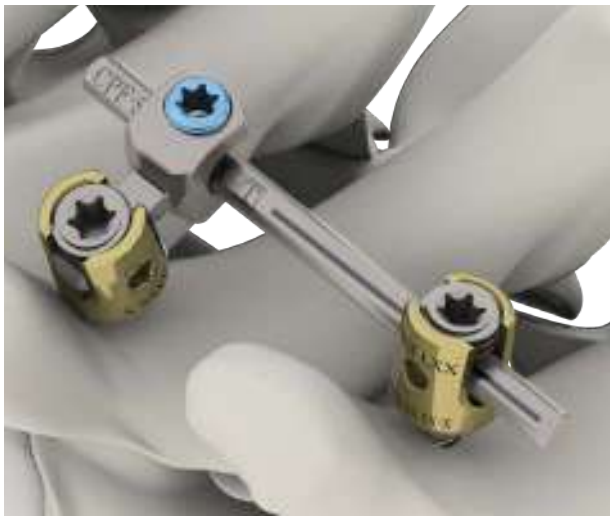
### _STEP 25




### TRANSITION RODS (OPTIONAL)

Transition Rods allow the transition from the cervical to the thoracic spine, moving from a Ø3.5mm rod to a Ø5.4/Ø5.5/Ø6mm 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 Ø5.4 or Ø5.5 or Ø6mm rods 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 |

**NOTE 1:** Lock the open part of the connector first in order to ensure a proper positionning on the rod.

**NOTE 2:** For the use of the parallel connectors CC-TO and CO-TC, the **Final Tightener** from the PERLA® TL system is needed for final tightening of the T27 grey setscrew.

Use the **Counter Torque** on the PERLA® TL Rod next to the connector, during final tightening.

| INSTRUMENT | REFERENCE |
|---|---|
| FINAL TIGHTENER | TLF-IN 05 40-N |
| COUNTER TORQUE | TLF-IN 05 30-N |

# SURGICAL TECHNIQUE

## CERVICO-THORACIC FIXATION

### _FINAL CONSTRUCT

### _REVISION

## POSTERIOR CERVICO-THORACIC FIXATION SYSTEM CONSTRUCT REMOVAL

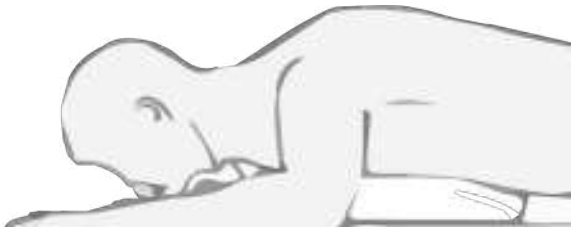
Loosen and remove all set screws using the Counter Torque and appropriate driver (Driver T15, Driver T20, or Driver Hexa) connected to the Straight Handle Ratchet AO Ø20. Remove rods. Fully secure the Screwdriver to the screw recess and turn counterclockwise to remove screws.

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

# SURGICAL TECHNIQUE

## OCCIPITAL FIXATION

### _STEP 1



### PATIENT POSITIONING AND EXPOSURE

Place the patient in the prone position with the head securely attached. Perform a standard midline incision from the External Occipital Protuberance (EOP) and continue caudally.

Extend the dissection laterally to expose the bony elements needed, allowing placement of the instrumentation.

### _STEP 2

### OCCIPITAL PLATE SELECTION

After placing screws and /or hooks to the cervical and / or thoracic spine as described in the previous section, use the **Occipital Plate Templates** to estimate the adapted size of occipital plate to select.

Connect it to the **Plate Holder** for an easier manipulation. To do so, place the tip of the **Plate Holder** in one of the two plate connectors. Orientate the handle to the desired position then tighten the extremity of the **Plate Holder** to lock the positioning.
Once the size is selected, use the corresponding Occipital Plate implant for contouring.

| INSTRUMENT | REFERENCE |
|---|---|
| OCCIPITAL PLATE HOLDER | CPF-IN 54 00-N |
| OCCIPITAL PLATE TEMPLATE - SMALL | CPF-IN 54 10-N |
| OCCIPITAL PLATE TEMPLATE - MEDIUM | CPF-IN 54 20-N |
| OCCIPITAL PLATE TEMPLATE - LARGE | CPF-IN 54 30-N |

# SURGICAL TECHNIQUE

## OCCIPITAL TECHNIQUE

### _STEP 3

### PLATE BENDING

Use the **Occipital Plate Bender** and the **Occipital Plate Bender – Holder** to bend the Occipital Plate.

1. Slide the Occipital Plate implant in the **Occipital Plate Bender**
   - Lateral side for the lateral wings
   - Midline side for the medial wing
2. Then slide the **Occipital Plate Bender - Holder** perpendicularly
3. Contour the Occipital Plate implant to fit the anatomy

Use the **Occipital Plate Holder** as described on STEP 2 for an easier manipulation of the Occipital Plate implant.

**NOTE 1:** Extreme bending over the rod attachment body travel slot will limit the amount of medial/lateral adjustment in the rod attachment body.

**NOTE 2:** Extreme bending over the screw holes will limit the ability to insert the screw properly.

⚠ **WARNING :** Reverse and/or repeated bending of the plate should not be attempted.

| INSTRUMENT | REFERENCE |
|---|---|
| OCCIPITAL PLATE BENDER – HOLDER | CPF-IN 55 00-N |
| OCCIPITAL PLATE BENDER | CPF-IN 55 10-N |
| OCCIPITAL PLATE HOLDER | CPF-IN 54 00-N |

## OCCIPITAL TECHNIQUE

### _STEP 4

### DRILLING

Using the **Occipital Plate Holder**, hold the Occipital Plate implant on the occiput at the desired position.

Connect the **Straight Occipital Drill Ø3.2** to the **Straight Handle Ratchet AO Ø20**.
Select the **Occipital Drill Guide** with the desired depth and place it on the center hole of the plate.
Slide the **Straight Occipital Drill** through the guide and drill by turning the **Straight Handle Ratchet AO Ø20** clockwise until the **Straight Occipital Drill** stop contacts the top of the **Occipital Drill Guide**.

| INSTRUMENT | REFERENCE |
|---|---|
| OCCIPITAL PLATE HOLDER | CPF-IN 54 00-N |
| STRAIGHT OCCIPITAL DRILL Ø3.2 | CPF-IN 51 00-N |
| *STRAIGHT OCCIPITAL DRILL Ø3.2 (STERILE) | CPF-IN 51 00-S |
| STRAIGHT HANDLE RATCHET AO Ø20 | HAN-RA AO 20-N |
| OCCIPITAL DRILL GUIDE L6 & L8 | CPF-IN 53 00-N |
| OCCIPITAL DRILL GUIDE L10 & L12 | CPF-IN 53 10-N |
| OCCIPITAL DRILL GUIDE L14 & L16 | CPF-IN 53 20-N |
| U-JOINT OCCIPITAL TUBE | CPF-IN 50 00-N |
| U-JOINT OCCIPITAL ANGLED SLEEVE | CPF-IN 50 10-N |
| U-JOINT OCCIPITAL DRILL Ø3.2 | CPF-IN 51 10-N |

* Under CE 1250

## OCCIPITAL TECHNIQUE

### _STEP 5

### TAPPING

Connect the **Straight Occipital Tap** to the **Straight Handle Ratchet AO Ø20**.
Slide the **Straight Occipital Tap** through the same guide used during the previous step and tap by turning the **Straight Handle Ratchet AO Ø20** clockwise until the **Straight Occipital Tap** stop contacts the top of the **Occipital Drill Guide**.

**NOTE:** A Depth Gauge is available if a double check of the depth measurement is requested.

| INSTRUMENT | REFERENCE |
|---|---|
| OCCIPITAL PLATE HOLDER | CPF-IN 54 00-N |
| STRAIGHT OCCIPITAL TAP Ø4.2 | CPF-IN 52 10-N |
| STRAIGHT HANDLE RATCHET AO Ø20 | HAN-RA AO 20-N |
| OCCIPITAL DRILL GUIDE L6 & L8 | CPF-IN 53 00-N |
| OCCIPITAL DRILL GUIDE L10 & L12 | CPF-IN 53 10-N |
| OCCIPITAL DRILL GUIDE L14 & L16 | CPF-IN 53 20-N |

## OCCIPITAL TECHNIQUE

### _STEP 6

### SCREW INSERTION

Connect the **Straight Occipital Screwdriver T15** to the **Straight Handle Ratchet AO Ø20**.
Select the size of occipital screw needed.
Align the screwdriver tip into the screw shank recess. The retention effect of the screwdriver will maintain the screw.

Position the occipital screw at the entry point through the occipital plate. Insert the screw by turning the **Straight Handle Ratchet AO Ø20** clockwise.
Repeat steps 4, 5 and 6 for the insertion of the remaining screws.

Disconnect the **Occipital Plate Holder** when needed.

**NOTE:** The Ø4.5mm screws are recommended for first intention placement. The Ø5mm screws should be used as a revision option.

| INSTRUMENT | REFERENCE |
|---|---|
| STRAIGHT OCCIPITAL SCREWDRIVER T15 | CPF-IN 56 00-N |
| STRAIGHT HANDLE RATCHET AO Ø20 | HAN-RA AO 20-N |
| OCCIPITAL PLATE HOLDER | CPF-IN 54 00-N |

# SURGICAL TECHNIQUES

## OCCIPITAL TECHNIQUE

### _STEP 7

### ROD MEASUREMENT

Use the **Rod Template L250** to determine the appropriate length and angulation of the rod.

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

### _STEP 8

### ROD BENDING AND ROD CUTTING

Select the appropriate rod material, length, type and angulation.

**NOTE:** The Adjustable Rod is available in left and right versions. Make sure to position them on the good side.

Use the **Rod Bender** to contour the rod and adapt to patient anatomy.

Use the **Rod Cutter** to shorten the rod to the desired length.

⚠ **WARNING:** Repeated bending can weaken the rod.

| INSTRUMENT | REFERENCE |
|---|---|
| ROD BENDER | CPF-IN 29 00-N |
| ROD CUTTER | CPF-IN 28 00-N |

## OCCIPITAL TECHNIQUE

### _STEP 9

### ROD INSERTION AND SET SCREW POSITIONNING

Grasp the rod with the **Rod Holder** and seat it into the occipital plate connector.

Connect the **Straight Handle Ratchet AO Ø20** to the **Driver T20** and attach a set screw on it. Insert the set screw into the occipital plate rod connector by turning clockwise the **Straight Handle Ratchet AO Ø20**.
Provisionally tighten the set screw to secure the construct.

**NOTE:** In case of use of an Adjustable Rod, tighten set screws of screws and plate first, then, set screw of the Adjustable Rod for final adjustment. To do so, use the **Straight Handle Ratchet AO Ø20** and the **Driver T15**.

| INSTRUMENT | REFERENCE |
|---|---|
| DRIVER T20 | CPF-IN 13 00-N |
| DRIVER T15 | CPF-IN 12 00-N |
| STRAIGHT HANDLE RATCHET AO Ø20 | HAN-RA AO 20-N |

# SURGICAL TECHNIQUES

## OCCIPITAL TECHNIQUE

### _STEP 10

### FINAL TIGHTENING

#### FOR PLATE SET SCREW

Connect the **Driver T20** with the **2.5 Torque Limiting Handle**.
Slide the assembly through the **Occipital Counter Torque** placed on the rod connector of the occipital plate.
Final tighten the set screw by turning the **2.5 Torque Limiting Handle** clockwise until it clicks.
Repeat the step for the second set screw of the occipital plate.

#### FOR ADJUSTABLE ROD SET SCREW

Connect the **Driver T15** with the **2.5 Torque Limiting Handle**.
Slide the assembly through the **Occipital Counter Torque for Adjustable Rod** placed on the articulated part of the Adjustable Rod.
Final tighten the set screw by turning the **2.5 Torque Limiting Handle** clockwise until it clicks.
Repeat the step for the second Adjustable Rod.

**NOTE:** Always use the **Counter Torques** during final tightening to reduce torque transfer to the spine and avoid damage to the **Drivers T20 and T15** tips.

| INSTRUMENT | REFERENCE |
|---|---|
| DRIVER T20 | CPF-IN 13 00-N |
| DRIVER T15 | CPF-IN 12 00-N |
| 2.5 TORQUE LIMITING HANDLE | HAN-SI AO 26-N |
| OCCIPITAL COUNTER TORQUE | CPF-IN 56 30-N |
| OCCIPITAL COUNTER TORQUE FOR ADJUSTABLE ROD | CPF-IN 56 40-N |

# SURGICAL TECHNIQUES

## OCCIPITAL TECHNIQUE

### _ANGLED INSTRUMENTATION

U-joint instrumentation is available for cases with strong occipital angles, where trajectories are difficult to achieve. Prefer straight instrumentation when access is not particularly challenging.

U-joint instrumentation can be used at steps 4, 5, 6, 9 and 10.

U-joint instrumentation assembly:

1. Slide the **U-Joint shaft (drill, tap or screwdriver)** through the **U-Joint Occipital Tube**.
2. Slide the **U-Joint Occipital Angled Sleeve** onto the articulated part of the **U-Joint shaft**.
3. Turn the **U-Joint Occipital Tube** counterclockwise into the **U-Joint Occipital Angled Sleeve** to lock them together.

| INSTRUMENT | REFERENCE |
|---|---|
| U-JOINT OCCIPITAL TUBE | CPF-IN 50 00-N |
| U-JOINT OCCIPITAL ANGLED SLEEVE | CPF-IN 50 10-N |
| U-JOINT OCCIPITAL DRILL Ø3.2 | CPF-IN 51 10-N |
| U-JOINT OCCIPITAL TAP Ø4.2 | CPF-IN 52 20-N |
| U-JOINT OCCIPITAL SCREWDRIVER T15 | CPF-IN 56 10-N |
| U-JOINT OCCIPITAL SCREWDRIVER T20 | CPF-IN 56 20-N |

# SURGICAL TECHNIQUES

## OCCIPITAL TECHNIQUE

### _FINAL CONSTRUCT

### _REVISION

To remove any of the implant described in the previous steps, engage set screws and / or occipital screws to the appropriate driver (**Driver T15, Driver T20**) connected to the **Straight Handle Ratchet AO Ø20**. Through the adapted **Counter Torque**, turn the handle counterclockwise for removal.

# GENERAL INFORMATION

| REFERENCE OF THE IFU | PER-IF 00 01-W | REVISION OF THE FINAL IFU | DEC-2019 |
|---|---|---|---|

## _STERILITY

The implant is provided sterile. 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.

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

The 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 occipito-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 occipito-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 occipito-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 occipito-cervico-thoracic fixation system consists of a variety of shapes and sizes of rods, hooks, screws, rod connectors and occipital plates 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 occipito-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 cranio-cervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 to 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 occipito-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.

The occipital bone screws are limited to occipital fixation only.

The use of the multi-axial screws is limited to placement in the cervical spine (C1 to C7) and the thoracic spine (T1 to T3).

In order to achieve additional levels of fixation, the PERLA® posterior occipito-cervico-thoracic fixation system may be connected to the ROMEO®2 and Perla® TL Posterior Osteosynthesis Systems with rod connectors.

Transition rods may also be used to connect the PERLA® posterior occipito-cervico-thoracic fixation system to the ROMEO®2 and Perla® TL Posterior Osteosynthesis Systems. Refer to the ROMEO®2 and Perla® TL Posterior Osteosynthesis Systems packages inserts for a list of the ROMEO®2 and Perla® TL Posterior Osteosynthesis Systems indications of use.

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

## _CONTRAINDICATIONS

The PERLA® posterior occipito-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 expected 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 metabolic 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 occipito-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.

# GENERAL INFORMATION

The rods and plates should not be repeatedly or excessively bent. The rods and plates should not be reverse bent in the same location. Bending the plate outside of the bend zone may result in cracking of the plate.

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 occipito-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 occipito-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 occipito-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.

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

**Automatic disinfection/cleaning protocol**

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

## _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.

**Sterilization trays cleaning and disinfection**

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

# GENERAL INFORMATION

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 |

**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.

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):**

Exposure time: 18 minutes

Temperature: 134°C

Drying time: 30 minutes

**Cycle 2 (USA):**

Exposure time: 4 minutes

Temperature: 132°C

Drying time: 30 minutes

"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

SPINEART

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