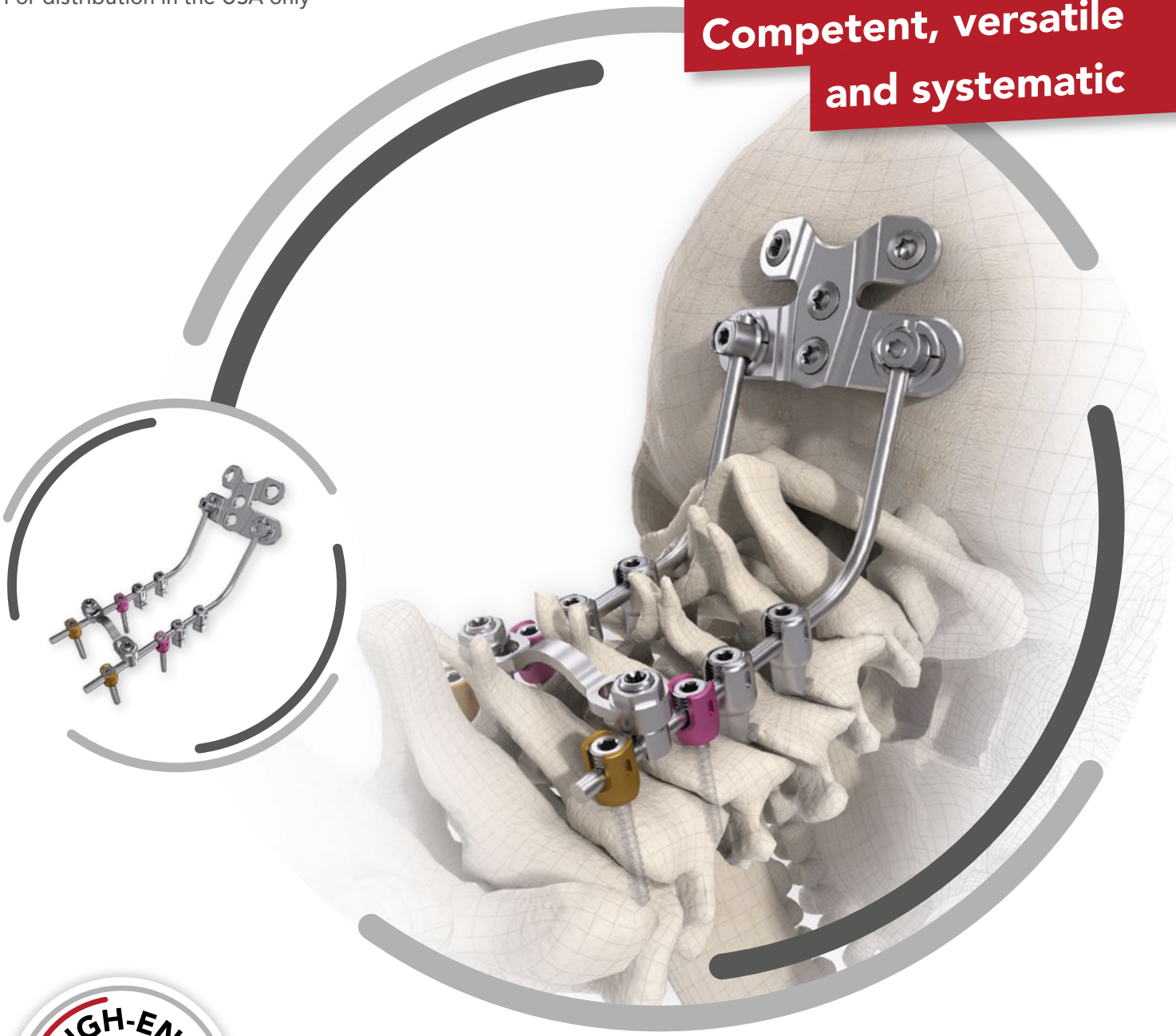
PRODUCT INFORMATION | OCTS | US

COSY®

Cervicothoracic Occipital Rod-Screw System

For distribution in the USA only

Competent, versatile and systematic



HIGH-END MADE IN GERMANY

www.signus.com

SIGNUS The Spine Sign®


HIGH-END
MADE IN GERMANY

CONTENTS

ABOUT SIGNUS

SIGNUS – THE SIGN FOR SPINE:

PASSIONATE! DYNAMIC! WORLDWIDE!

Innovative high-end implants made in Germany: For more than 30 years, SIGNUS has been the experienced specialist for comprehensive solutions in the surgical spine care sector. Founded in 1994 in Germany's Lower Franconian city of Alzenau by Susanne and Uwe Siedler, our family-owned company currently has staff of approx. 80 at sites in Germany, Australia, Switzerland and USA. SIGNUS offers the comprehensive product range of cervical spine to SIG sacroiliac joints, which are predominately manufactured at the nearby production site of ProCon Medizintechnik. In addition to Europe (CE) and the USA (FDA), we sell our certified implants throughout the world on every continent. Target-oriented further development of the products in connection with the continuous exchange with the users as well as international further education and hospitalisation programs make SIGNUS a reliable global partner.

The entire SIGNUS Portfolio with detailed information and descriptions are available for you online at www.signus.com

ADDITIONAL PRODUCTS

DIPLOMAT® – Posterior instrumentation

- Modular system with in-situ exchangeable tulips
- Open, minimally invasive and percutaneous application
- Screws from 5.5 mm cannulated and fenestrated

CONCEPT – ROD-SCREW SYSTEM

COSY® is a occiputal cervical-thoracic system (OCTS) for posterior surgical immobilisation, stabilisation and correction of malpositions of the human cervical spine and the cervicothoracic junction, including the occipito-cervical junction if necessary. The implants are available in various lengths, diameters and sizes to enable adaptation to different patient anatomies.

The COSY® system comprises rods, hooks, screws, polyaxial screws, fixation screws, connecting pieces, occipital plates and occipital screws in various sizes that can be firmly connected to a rod in various configurations. The system includes transition rods (hybrid rods) from 3.5 mm to 5.5 or 6.0 mm in diameter and parallel rod-to-rod connectors. For stabilisation and fusion of the occipitocervical junction the system provides occipital plates with corresponding screws and rods in various sizes. The fixation of the occiput can be extended to the thoracolumbar area with the transition rods.

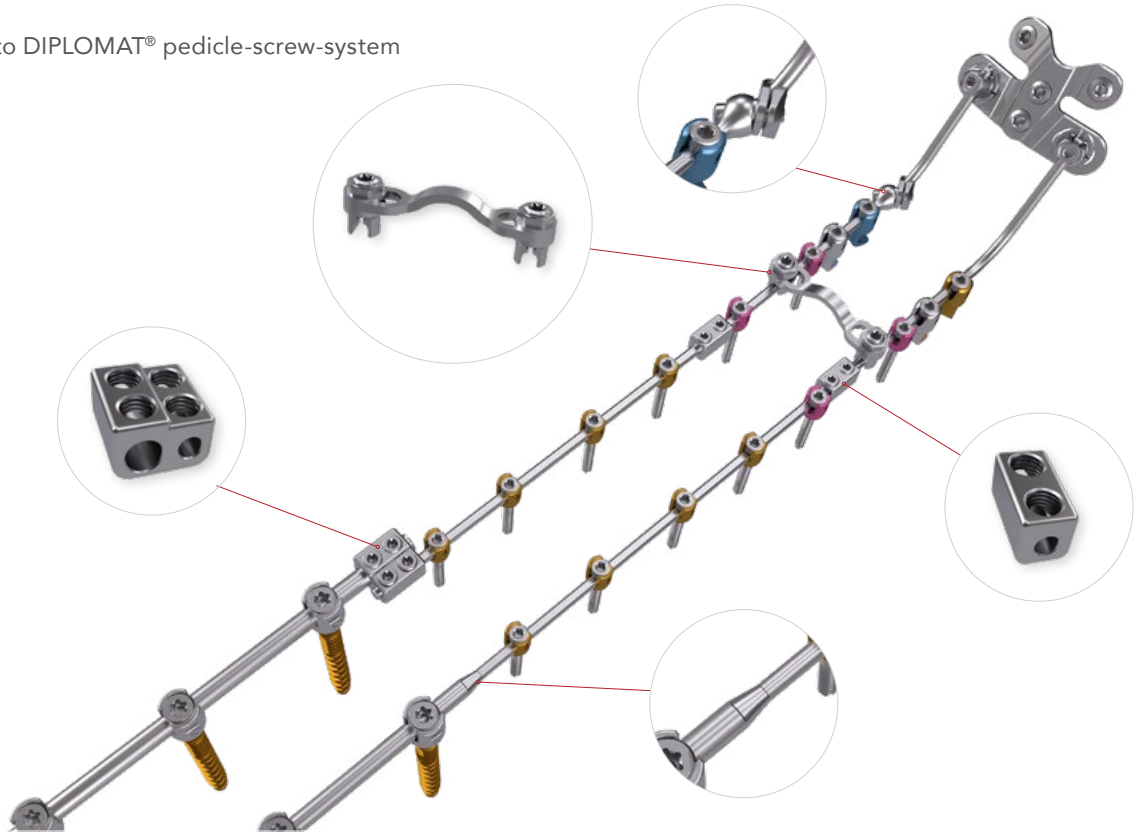
These components are intended to allow connection of the COSY® Cervicothoracic Occipital Rod-Screw System to a thoracolumbosacral pedicle screw system (DIPLOMAT®). The implants are made from a titanium alloy (Ti-6Al-4V). Rods are available in versions made from a titanium or a cobalt-chrome alloy.

NOTE

The use of the thoracolumbosacral pedicle screw systems (DIPLOMAT®) are not described. They can be found in the corresponding product information.

Optional Fixation of Occiput

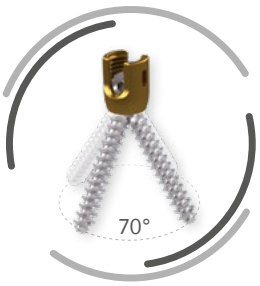
Connection to DIPLOMAT® pedicle-screw-system



CONCEPT – ROD-SCREW SYSTEM

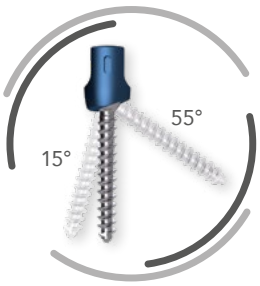
Polyaxial screws with tulips

Variable angle



70° angulation

Fixed angle



15° / 55° angulation

Colour coded tulips

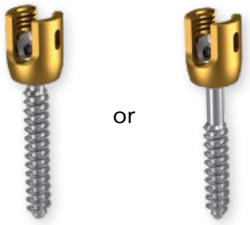
Ø 3.5 mm
magenta

Ø 4.0 mm
gold

Ø 4.5 mm
silver

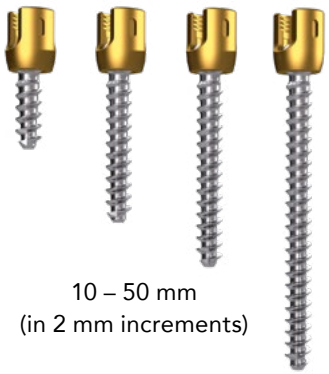
Ø 3.5 and Ø 4.0 mm
blue

Also available as smooth shank screw



Also available as self drilling screw

Variety of screw lengths available



10 – 50 mm
(in 2 mm increments)

20 – 44 mm
(in 2 mm increments)

All screws have a low profile, are cannulated and maintain position.

CONCEPT – ROD-SCREW SYSTEM

Connection to Occiput

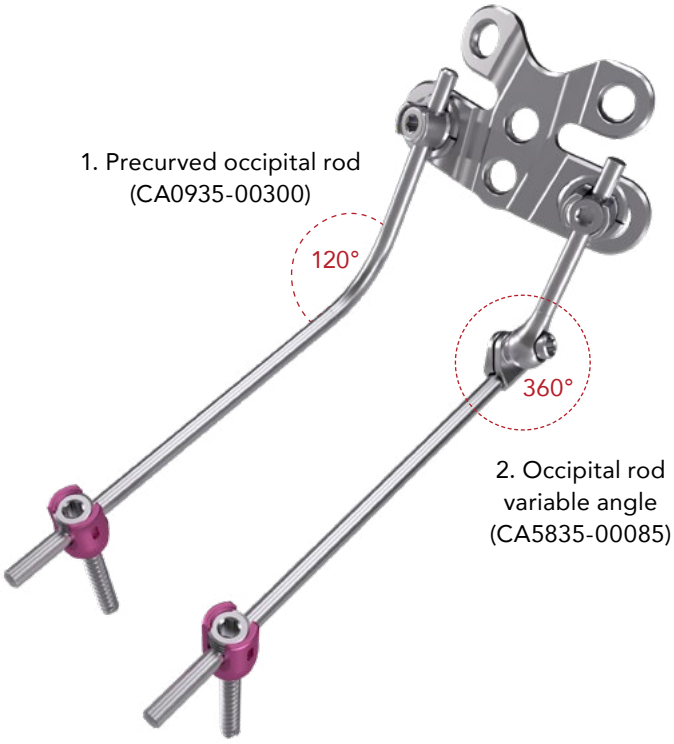
Occiput plate

Occipital screws

Ø 4.5 mm Ø 5.0 mm

Regular and rescue screw, 6 – 16 mm length

2 Options for connection

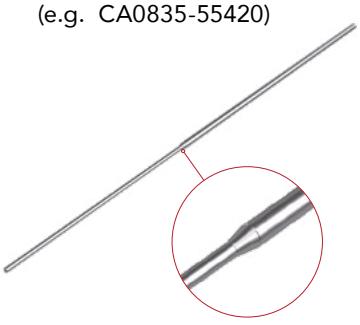


Cervical-thoracic connection

From Ø 3,5 mm to Ø 5,5 / Ø 6,0 mm with

Parallel connector closed
(e.g. CA0150-35055)

Transitionrod straight
(e.g. CA0835-55420)



or

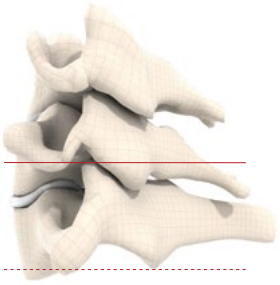
Parallel connector open
(e.g. CA0152-35055)

COSY® connectable to DIPLOMAT® pedicle-screw system

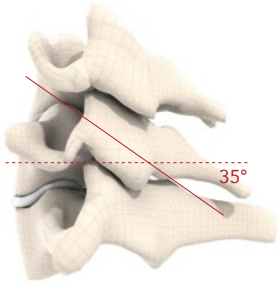
CONCEPT – ROD-SCREW SYSTEM

Lateral mass screw fixation techniques

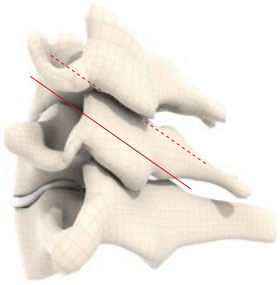
There are several techniques for screw fixation. All of which can be achieved with the COSY® System by choosing the corresponding screw:



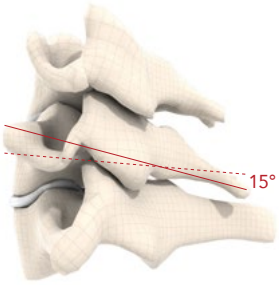
Roy-Camille



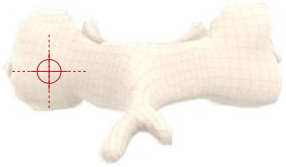
Anderson

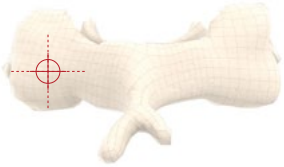


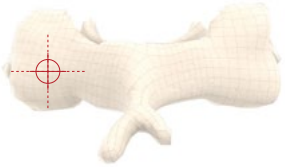
Magerl

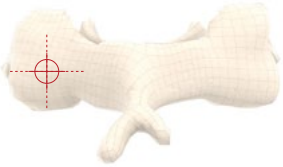


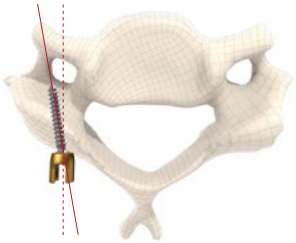
Ann

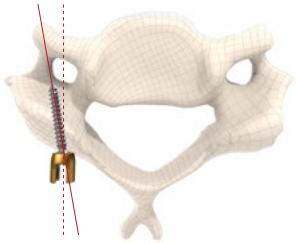


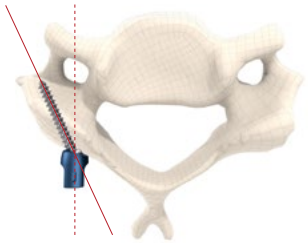


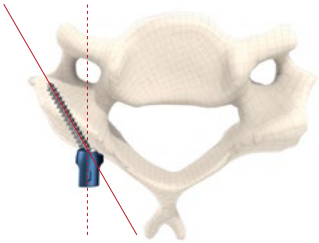


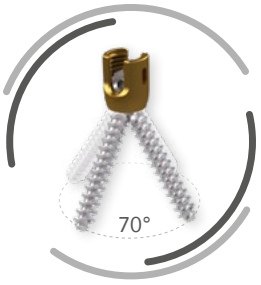




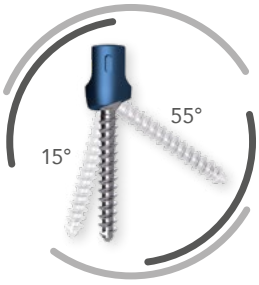








Variable angle tulip



Fixed angle tulip

PRODUCT-SPECIFIC ADVANTAGES

- **Seamless Fixation from Occiput to Thoracic Spine**
  - Enables fixation from occiput to thoracic spine for comprehensive stabilization
- **Versatile Screw and Tulip Options for Tailored Solutions**
  - Large range of screw sizes and types for different surgical requirements
  - Ability to customize fixation to patient needs
  - Facilitates use in different surgical approaches and techniques
- **Optimized screw design**
  - Cannulated screws for simplified Insertion
  - Low profile design minimizes pressure points, enhancing patient comfort
  - Polyaxial screws that maintain position for stable rod placement and construct assembly
- **High Flexibility and Stability with Variable Screws**
  - Angulation up to 70° for greater flexibility in screw placement
- **Extensive Configuration Options with Connector Family**
  - Variety of connectors allows for complex constructs and versatile solutions
  - Facilitates creation of tailored constructs for specific anatomical challenges
- **Compatible with DIPLOMAT® screw-rod system**
  - Transition rods and connectors provide transition between cervical and thoracolumbar constructs

IMPLANTS – ROD-SCREW SYSTEM

Screw, cannulated, polyaxial

Art. no. CA1221-35010 – CA1221-35034
Ø 3.5 × 10 mm – Ø 3.5 × 34 mm,
2 mm increments

Art. no. CA1221-40010 – CA1221-40034
Ø 4.0 × 10 mm – Ø 4.0 × 34 mm,
2 mm increments

OPTIONAL

Art. no. CA1221-35036– CA1221-35040
Ø 3.5 × 36mm – Ø 3.5 × 40mm,
2 mm increments

Art. no. CA1221-40036– CA1221-40040
Ø 4.0 × 36mm – Ø 4.0 × 40mm,
2 mm increments

Pedicle screw, cannulated, polyaxial

Art. no. CA1221-45020 – CA1221-45050
Ø 4.5 × 20 mm – Ø 4.5 × 50 mm,
5 mm increments

Shank screw, cannulated, polyaxial

Art. no. CA1721-40022 – CA1721-40040
Ø 4.0 × 22 mm – Ø 4.0 × 40 mm,
2 mm increments

OPTIONAL

Art. no. CA1721-35022– CA1721-35040
Ø 3.5 × 22mm – Ø 3.5 × 40 mm,
2 mm increments

Screw, angled, cannulated, polyaxial

Art. no. CA3221-35020 – CA3221-35032
Ø 3.5 × 20 mm – Ø 3.5 × 32 mm,
2 mm increments

OPTIONAL

Art. no. CA3221-40020 – CA3221-40032
Ø 4.0 × 20 mm – Ø 4.0 × 32 mm,
2 mm increments

Screw, angled, cannulated, self-drilling, polyaxial

Art. no. CA3220-40034 – CA3220-40044
Ø 4.0 × 34 mm – Ø 4.0 × 44 mm,
2 mm increments

OPTIONAL

Art. no. CA3220-35034 - CA3220-35050
Ø 3.5 × 24 mm – Ø 3.5 × 50 mm,
2 mm increments

Set screw

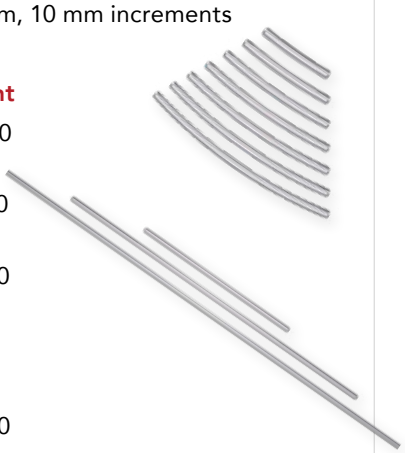
Art. no. CA0140-35000
T15 / Ø 6.5 x 3 mm

For polyaxial screw, screw with angled tulip, shank screw, hook, offset connector

TITANIUM Rod curved

Art. no. CA0935-00030 – CA0935-00090
Ø 3.5 × 30 mm to 90 mm, 10 mm increments

TITANIUM Rod straight



Art. no. CA0835-00080
Ø 3.5 x 80 mm

Art. no. CA0835-00120
Ø 3.5 x 120 mm

Art. no. CA0835-00240
Ø 3.5 x 240 mm

OPTIONAL

Art. no. CA0835-00360
Ø 3.5 x 360 mm

TITANIUM Transitionrod straight

Art. no. CA0835-55420
Ø 3.5 / 5.5 x 420 mm

Art. no. CA0835-60420
Ø 3.5 / 6.0 x 420 mm

OPTIONAL

Art. no. CA0835-55600
Ø 3.5 / 5.5 x 600 mm

Art. no. CA0835-60600
Ø 3.5 / 6.0 x 600 mm

IMPLANTS – ROD-SCREW SYSTEM

Inferior lamina hook

Art. no. CA0157-35006/SX
Inferior lamina hook short

Art. no. CA0157-35007/SX
Inferior lamina hook long

Atlas hook

Art. no. CA0157-35008/S2
Ø 3.5 mm × 100 mm

Cross connector

Art. no. CA0155-22030/S
22–30 mm

Art. no. CA0155-26036/S
26–36 mm

Art. no. CA0155-32042/S
32–42 mm

Tulips cross connector

Art. no. CA0160-22030/SX
22–30 mm

Art. no. CA0160-26036/SX
26–36 mm

Art. no. CA0160-32042/SX
32–42 mm

Set screw tulips cross connector

Art. no. CA0160-00100
T15, Ø 6.1 x 8.0 mm

OPTIONAL
Set screw tulips cross connector, reduction

Art. no. CA0160-00300
T15 Ø 6,1 x 20.3 mm

Retaining nut tulips cross connector

Art. no. CA0160-00200

OPTIONAL
Offset connector

Art. no. CA0156-35012
Ø 3.5 x 12 mm

Art. no. CA0156-35015
Ø 3.5 x 15 mm

OPTIONAL
Hook

Art. no. CA0157-35001/SX
Hook straight

Art. no. CA0157-35002/SX
Hook left

Art. no. CA0157-35003/SX
Hook right

OPTIONAL
Set screw parallel/inline connector

Art. no. CA0150-00100
T15, Ø 6.1 x 8 mm

Inline connector

Art. no. CA0151-35035
Ø 3.5 mm / 3.5 mm

Parallel connector closed

Art. no. CA0150-35055
Ø 3.5 mm / 5.5 mm

Art. no. CA0150-35060
Ø 3.5 mm / 6.0 mm

Parallel connector open

Art. no. CA0152-35055
Ø 3.5 mm / 5.5 mm

Art. no. CA0152-35060
Ø 3.5 mm / 6.0 mm

NOTE

Additional sizes, diameters, lenghts upon request and availability.

According to availability and on request, the implants are available sterile.

IMPLANTS – OCCIPITAL PLATE – OPTIONAL

Occiput plates

Art. no. CA0004-32056
4-hole 32 x 56 mm

Art. no. CA0005-32056
5-hole 32 x 56 mm

Occiput set screw

Art. no. CA0140-35000
T15 Ø 6.5 x 3 mm

Occipital screw

Art. no. CA0101-45006
Ø 4.5 x 6 mm

Art. no. CA0101-45008
Ø 4.5 x 8 mm

Art. no. CA0101-45010
Ø 4.5 x 10 mm

Art. no. CA0101-45012
Ø 4.5 x 12 mm

Art. no. CA0101-45014
Ø 4.5 x 14 mm

Art. no. CA0101-45016
Ø 4.5 x 16 mm

Revision occipital screw

Art. no. CA0100-50006
Ø 5.0 x 6 mm

Art. no. CA0100-50008
Ø 5.0 x 8 mm

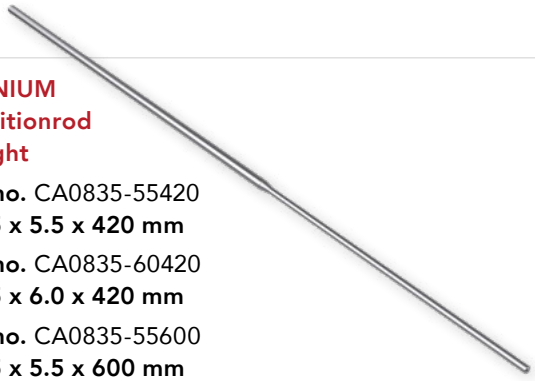
Art. no. CA0100-50010
Ø 5.0 x 10 mm

Art. no. CA0100-50012
Ø 5.0 x 12 mm

Art. no. CA0100-50014
Ø 5.0 x 14 mm

Art. no. CA0100-50016
Ø 5.0 x 16 mm

TITANIUM Transitionrod straight



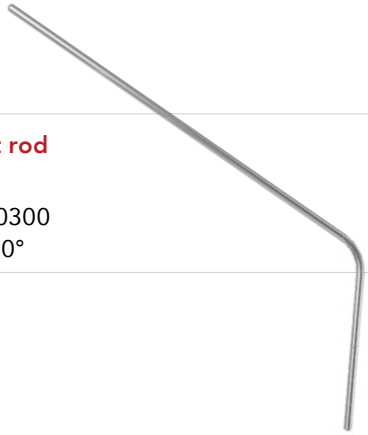
Art. no. CA0835-55420
Ø 3.5 x 5.5 x 420 mm

Art. no. CA0835-60420
Ø 3.5 x 6.0 x 420 mm

Art. no. CA0835-55600
Ø 3.5 x 5.5 x 600 mm

Art. no. CA0835-60600
Ø 3.5 x 6.0 x 600 mm

TITANIUM Occiput rod curved



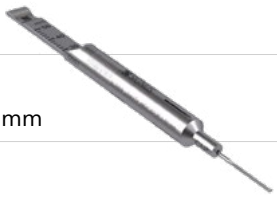
Art. no. CA0935-00300
Ø 3.5 x 300 mm, 120°

TITANIUM Occiput rod variable angle

Art. no. CA5835-00085
Ø 3.5 x 85 mm

INSTRUMENTS – ROD-SCREW SYSTEM

Art. no. CB0022
Awl Ø 1.75 mm
with palm-handle

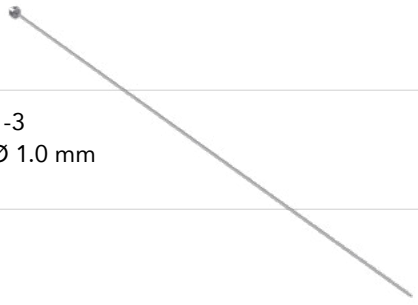


Art. no. CB0026-1/-2/-3
Screw length indicator 0–50 mm

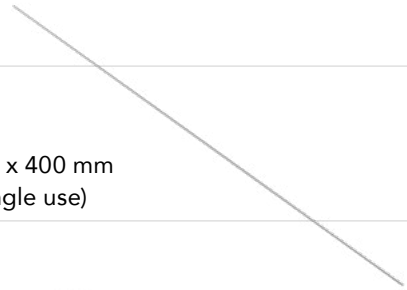
Art. no. CB0021
Awl Ø 2.5 mm, cannulated,
AO-connection

Art. no. CB0101-1
Palm-handle for obturator,
with ratchet, AO-connection

Art. no. CB0101-2
Obturator knob



Art. no. CB0101-3
Obturatorwire Ø 1.0 mm
(single use)

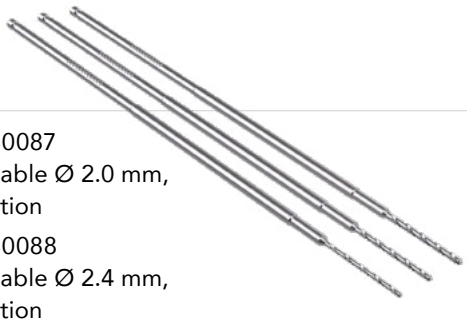


OPTIONAL
Art. no. CB0144
Guide wire Ø 1.0 x 400 mm
round/round (single use)

OPTIONAL
Art. no. CB0146
Screw length indicator 0–50 mm,
for guide wire

Art. no. CB0023
Pedicle sensor straight

Art. no. CB0086
Depth stop variable



Art. no. CB0087
Drill bit variable Ø 2.0 mm,
AO-connection

Art. no. CB0088
Drill bit variable Ø 2.4 mm,
AO-connection

Art. no. CB0089
Drill bit variable Ø 2.7 mm,
AO-connection

INSTRUMENTS – ROD-SCREW SYSTEM

OPTIONAL

Art. no. CB0102
Drill Ø 2.0 x 12 mm,
AO-connection

Art. no. CB0112
Drill Ø 2.4 x 12 mm,
AO-connection

Art. no. CB0122
Drill Ø 2.7 x 12 mm,
AO-connection

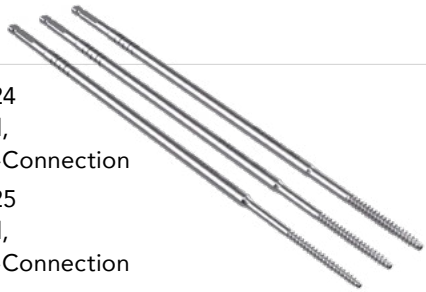
Art. no. CB0069
Screwdriver polyaxial,
cannulated,
AO-connection, T15

OPTIONAL

Art. no. CB0064
Screwdriver, cannulated,
AO-connection, T15

Art. no. CB0030
Drill guide polyaxial screw

Art. no. CB0051
Rod template bendable
Ø 3.5 x 400 mm



Art. no. CB0024
Tap cannulated,
Ø 3.5 mm, AO-Connection

Art. no. CB0025
Tap cannulated,
Ø 4.0 mm, AO-Connection

Art. no. CB0076
Tap cannulated,
Ø 4.5 mm, AO-Connection

OPTIONAL

Art. no. CB0048
Rod cutter

Art. no. CB0038
Rod bender Ø 3.5 mm

Art. no. CB0068
Reamer polyaxial screw

OPTIONAL

Art. no. CB0039/-40
In-situ rod bender,
left + right Ø 3.5 mm

INSTRUMENTS – ROD-SCREW SYSTEM

Art. no. CB0043
Rod forceps

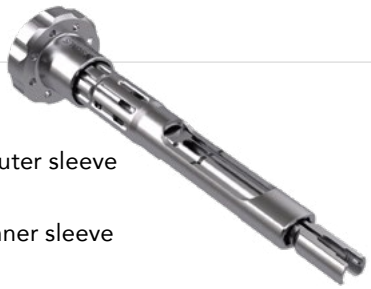
OPTIONAL
Art. no. CB0147
Rod holder

Art. no. CB0067
Tulip adjuster

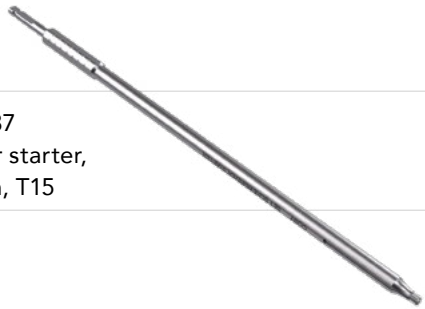
OPTIONAL
Art. no. CB0080
Rodfork

OPTIONAL
Art. no. CB0084
Persuader 0–9 mm

Art. no. CB0049
Persuader

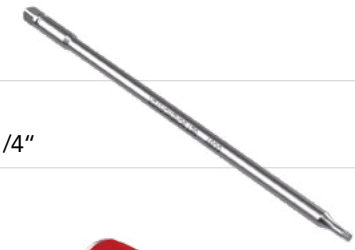


OPTIONAL
Art. no. CB0070-1
Reduction tower – outer sleeve
Art. no. CB0070-2
Reduction tower – inner sleeve
Art. no. CB0071
Reduction tower – rotary knob



Art. no. CB0037
Set screwdriver starter,
AO-connection, T15

Art. no. CB0073-1
T-Handle, torque limiter
3 Nm, 1/4“



Art. no. CB0073-2
Set screwdriver T15, 1/4“

Art. no. CB0081
Counter torque

INSTRUMENTS – ROD-SCREW SYSTEM

Art. no. CB0045
Compressor Ø 3.5 mm

Art. no. CB0046
Distractor Ø 3.5 mm

Art. no. CB0073-3
Screwdriver cross connector SW7, 1/4“

Art. no. CB0062
Screwdriver cross connector, starter

OPTIONAL
Art. no. CB0055
Hook holder

OPTIONAL
Art. no. CB0056
Bender cross connector

OPTIONAL
Art. no. CB0145
Dilator

NOT SHOWN

Art. no. CB01AY
Instrument tray BASIC

Art. no. CB01AZ
Instrument tray BASIC - insert

Art. no. CB02AY
Instrument tray additional

INSTRUMENTS – OCCIPITAL PLATE – OPTIONAL

Instruments for fixation of the occiput:

Art. no. CB0006
Occiput, drill AO,
Ø 3,5 x 12 mm

Art. no. CB0009-1
Occiput plate holder

Art. no. CB0003
Occiput, screwdriver,
occipital screw T20, AO

Art. no. CB0009-2
Occiput plate bender

Art. no. CB0007
Occiput, screwdriver,
set screw T15, 1/4”

Art. no. DZ-0101-A
Holding forceps

Art. no. CB0008
Occiput counter torque

Art. no. CB0002
Occiput drill guide

NOT SHOWN

Art. no. CB03AY
Occiput, Instrument tray

Art. no. CB0004
Occiput, tap, AO, Ø 4.5 mm

INDICATIONS, CONTRAINDICATIONS, WARNINGS AND MRI

INDICATIONS

The COSY® Cervicothoracic Occipital Rod-Screw 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 craniocervical junction, the cervical spine (C1 – C7), and the thoracic spine from T1 – T3:

- Traumatic spinal fractures and / or traumatic dislocations
- Instabilities or deformity
- Failed previous fusions (e.g. pseudoarthrosis)
- Tumours involving the cervical spine
- Degenerative disease including intractable radiculopathy and / or myelopathy
- Neck and / or arm pain of discogenic origin as confirmed by radiographic studies
- Degenerative disease of the facets with instability

The COSY® Cervicothoracic Occipital Rod-Screw 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 advance stage tumours involving the cervical spine in whom life expectancy is of limited duration to permit achievement of fusion. In order to achieve additional levels of fixation, the COSY® Cervicothoracic Occipital Rod-Screw System may be connected to the components of the DIPLOMAT® System or MONOPOLY™ System using the rod-to-rod connectors or transition rods.

CONTRAINDICATIONS

- Anomalous bone density, osteoporosis or osteomalacia that prevents stable anchorage of the implant
- Infectious processes in, on or in adjacent regions of the spine
- Allergy or intolerance to the implant material
- Surgical conditions that rule out any potential benefit from spinal surgery (such as severe damage to bone structures at the implantation site, badly distorted anatomy due to anomalies)
- Medical conditions that could prevent successful implantation (e.g. obesity, mental disorders, pregnancy, patients in poor general health, systemic or metabolic diseases, lack of patient compliance)
- Surgery precluded due to the physical condition of the patient, e.g. fever or leucocytosis
- Patients whose tissue cover above the surgical site or whose bone mass or bone quality at the surgical site is inadequate
- Patients in whom placement of an implant would influence the anatomic structures or the anticipated physiological performance
- Patient stature too small or too large for the range of instruments and implants
- The use of different metals or components not belonging to the screw system is not permitted
- Cases that are not mentioned under Indications

WARNINGS

The spinal implants are intended for single use only and are not reusable. Reuse can result in infection and / or loss of function, including patient death.

- SIGNUS implants may only be inserted with the instruments provided for this purpose. If the implants are inserted using other instruments, correct implantation cannot be guaranteed.
- The indication, selection and implantation are the responsibility of the surgeon performing the procedure, which must be experienced and instructed in performing spinal surgery.
- Unless otherwise stated, SIGNUS products must not be directly connected to the materials / components of other systems.
- Inspection of the implant for scratches or other obvious damage. A damaged implant must not be used.
- Due to potential damage, the implant must not be reinserted after removal from the site.
- When inserting the implant, special attention should be paid to protecting the nerve structures and blood vessels, and refraining from using excessive force.
- The final fixation of the locking screws must be carried out with the SIGNUS torque limiter.
- Metallic implants may pose a risk of heating of the device when exposed to a high magnetic field such as an MRI. High heating could lead to patient injury.
- Metallic implants may generate image artifacts when exposed to a high magnetic field, such as an MRI, which could lead to difficulty in reading the MRI.

Follow-up care and follow-up examinations must be individually tailored to the patient and defined by the attending physician. After the operation, the patient should only be allowed to exercise to a very limited extent for an appropriate post-operative period. This applies in particular to lifting loads, rotating movements and any type of sport. Falls or sudden jerky movements of the operated region should be avoided.

USA: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

MRI SAFETY INFORMATION:

The COSY® Cervicothoracic Occipital Rod-Screw System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the COSY® Cervicothoracic Occipital Rod-Screw System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

NOTE

Please note the instructions for use
(current version: eifu.signus.com)

1 PREPARATION

The patient is most commonly placed in a prone position with the head held securely in position with a Mayfield head holder or a halo (Image 1).

Prior to instrumentation via direct visualisation, it must be made sure that the patient postion is anatomically aligned in an acceptable flexion, extension, translation or rotation position. This is particularly most important if the occiput must be connected and fixed to the cervical and thoracic spine.

The physiological alignment and fixation of the position must be checked and established with X-ray imaging. Physiological alignment may not always be possible.

Excessive skin and neck folds in the operative field should be pulled using adhesive tape. All other extremities should also be well cushioned and securely positioned.

Care should be taken to avoid injury to the spinal cord, vertebral arteries, and C2 nerve roots in the upper cervical spine, the facet capsules and interspinous ligaments. Facet joints that are not included in the planned fusion should remain untouched. Exposing additional facets can lead to disruption and instability of the facets.

1

2

Preparation of the screw entry point and length determination

OPTION 1: Non cannulated approach

Opening of the surgical field in the usual manner a central skin incision in the neck, the musculature is pushed aside and the spinal column is exposed. After identification of the segment, the non-cannulated awl (CB0022) can be used for this purpose (Image 2).

To detemine the screw length the screw length indicator (CB0026-1/-2/-3) can be used (Image 3).

It is inserted into the screw entry point. The indicator has a little hook which will stick on the bone wall. By pulling the instrument until it doesn´t go further, the length can be taken from the marking. Before implantation of the screw, it has proven useful to check the integrity of the bone wall using the pedicle sensor (CB0023).

3

OPTION 2: Cannulated approach

To open the cortex the cannulated obturator awl with matching handle (CB0021 combined with CB0101-1/-2/-3) can be used (Image 1).

1

Exposing the cortical bone (CB0021 combined with CB0101-1/-2/-3)

How to use the awl with obturator wire

1. The awl (CB0021) is connected to the palm handle (CB0101-1) (Image 2).
2. The obturator wire (CB0101-3) is inserted into the knob (CB0101-2). The wire has a flat and a rounded side. By pressing the rounded side of the wire into the side opening of the knob, the wire is connected to the knob (Image 3).
3. The knob with the wire is firmly connected to the palm handle by turning clockwise to the stop position (Image 4).
4. The obturator wire is removed in the reverse order.

CAUTION

The wire is a single-use item and must be replaced after every operation.

2

3

4

After opening the cortex, the awl is removed and the appropriate screw length is determined with the screw length indicator.

The obturator wire (CB0101-3) is removed and replaced by a guide wire (CB0144). Next the length indicator (CB0146) is placed over the guide wire. The marking on the guide wire indicates the screw length to be used (Image 5).

Before implantation of the screw, it has proven useful to check the integrity of the bone wall using the pedicle sensor (CB0023) (Image 6).

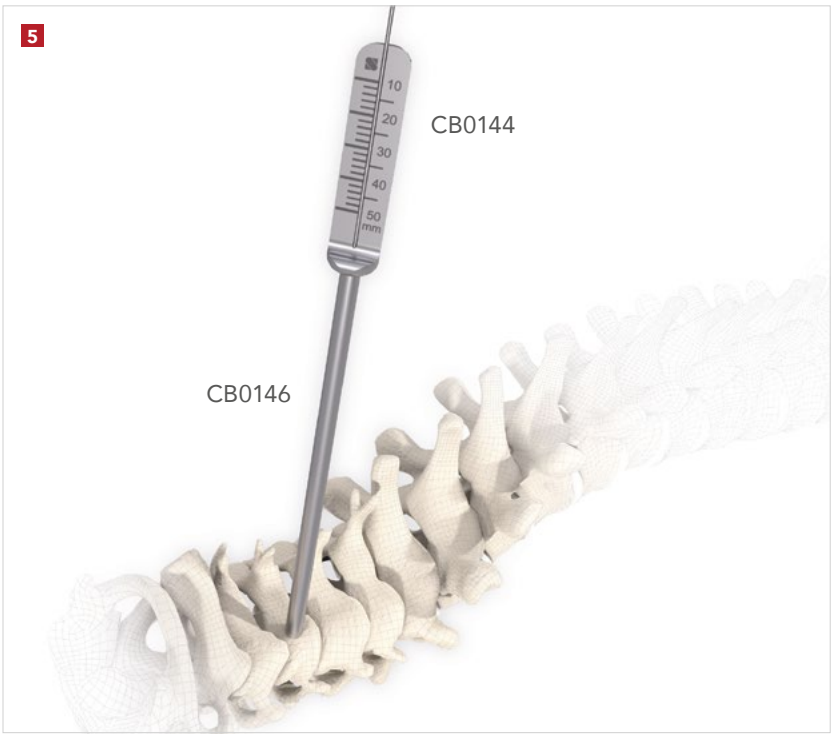
NOTE

Optionally, a drill can be used to open the screw entry point (Follow page 23).

NOTE

When a different angle of the entry point is required, the instrument should first be removed and repositioned. This also prevents unintentional bending of the awl.

5



Guide wire in screw length indicator.

6

CB0023
Pedicle sensor straight

SURGICAL TECHNIQUE – ROD-SCREW SYSTEM

Using a drill

There are variable drills available corresponding to the required screw diameter. The variable drill provides a drilling depth that ranges from 8 to 30 mm in 2 mm increments. The depth of the drill hole is determined by the position of the drill stop (CB0086). The drill stop is set by pressing the locking button on the drill and engages when released. The drill stop hooks into the grooves on the drills (Image 1).

Following drills are available:

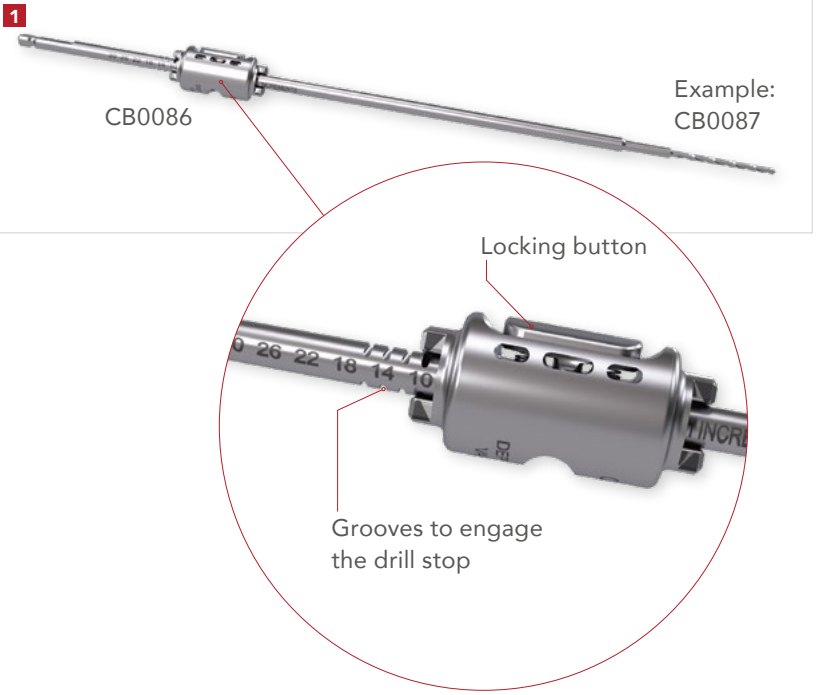
- Drill with AO connector variable, Ø 2.0 mm for Ø 3.5 mm screws (CB0087)
- Drill with AO connector variable, Ø 2.4 mm for Ø 4.0 mm screws (CB0088)
- Drill with AO connector variable, Ø 2.7 mm for Ø 4.5 mm screws (CB0089)

NOTE

The teeth on the drill guide prevent unintentional slipping and help maintain the trajectory.

1. The matching drill is fitted with a handle (CB0101-1) and adjusted to the required drilling depth by applying the drill stop (CB0086).
2. The drill is inserted into the drill guide (CB0030) up to the drill stop. The visible length of the drill is then checked (Image 2).
3. Placing the drill guide on the desired site and drilling until the depth stop of the drill makes contact (Image 3).

1



2

3

Using taps

If necessary, a cannulated tap can be used prior to implanting the screw (Image 1). The following cannulated taps are available:

- Tap, AO-Connection Ø 3.5 mm for Ø 3.5 mm screws (CB0024)
- Tap, AO-Connection Ø 4.0 mm for Ø 4.0 mm screws (CB0025)
- Tap, AO-Connection Ø 4.5 mm for Ø 4.5 mm screws (CB0076)

NOTE

The diameter of the tap is 0.5 mm less than the diameter of the screw. For the best possible grip, for monocortical and bicortical anchorage, it has proven optimal to cut a thread in the first 2–3 mm despite the self-tapping screw tip. The taps have a depth marking for guidance.

1. If required, a thread can be cut. For this purpose, the tap (CB0024 / CB0025 / CB0076) is inserted through the drill guide (CB0030).
2. While maintaining the correct trajectory, the thread is cut in the drill channel. Length markings are provided on the proximal part of the instrument. The length marking shows how far the tap has already been screwed in (Image 2).

NOTE

Drilling and tapping is performed the same way for all screws.

1

2

2 SCREW IMPLANTATION

OPTIONAL: Before implanting the screws the reamer (CB0068) can be used to make room for the screw head and tulip.

1. Connecting the screwdriver (CB0069) with a palm handle (CB0101-1).
2. Selecting the suitable screw size and connecting it to the screwdriver (Image 1).
3. The tip of the screwdriver is inserted into the tulip. It must be ensured that the teeth of the screwdriver are correctly inserted into the corresponding indentations on the screw (Image 2).
4. By rotating the locking wheel clockwise, the screw is fixed to the screwdriver (Image 3).
5. The screwdriver is ready for implanting the screws (Image 4).

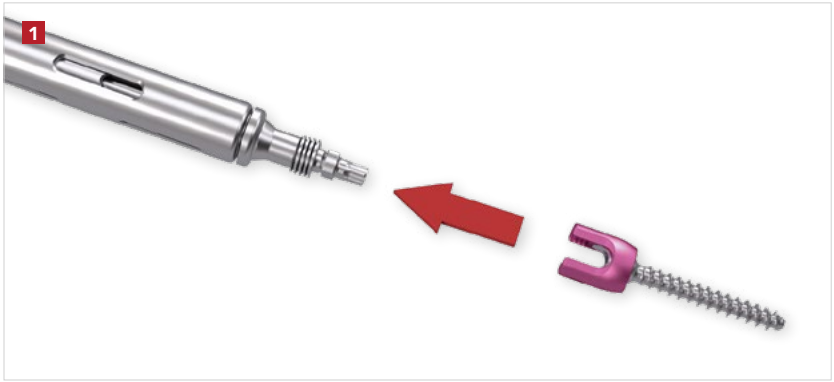
NOTE

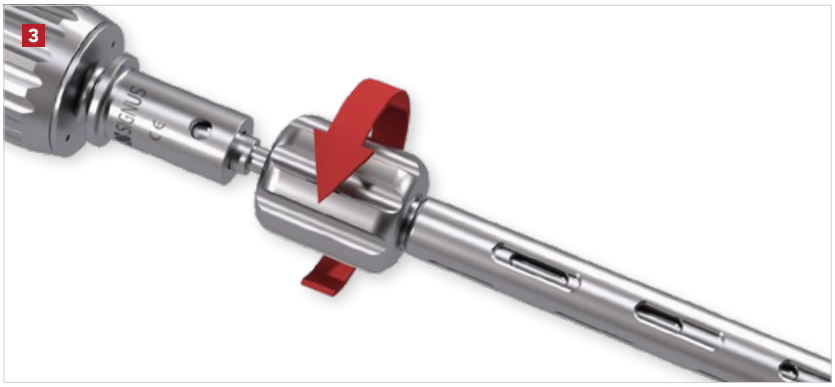
The screwdriver is a single piece and cannot be disassembled. It has numerous flushing holes that enable optimal and safe cleaning of the instrument.

6. The instrument is disconnected from the screw in the reverse order by turning the locking wheel counterclockwise.

NOTE

All polyaxial screws are inserted in the same manner. Hooks can be used as an alternative to screws.





Completely assembled screw driver with attached screw.

3 INSERTING THE ROD

Rods are available in precut lengths. Using the bendable rod template (CB0051), the required rod length can be determined, preshaped and used for contouring the final rod.

OPTIONAL:
Shortening and bending the rod

The rod length can be shortened using a rod cutter (CB0048) (Image 1). The required contour of a rod can be premodeled with the help of a rod bender (CB0038) and applied to the rod to be inserted (Image 2).

1

CB0048

2

CB0038

In-situ rod benders (CB0039/-40) can be used to achieve additional contouring of rods that have already been inserted (Image 3).

3

CB0039/-40

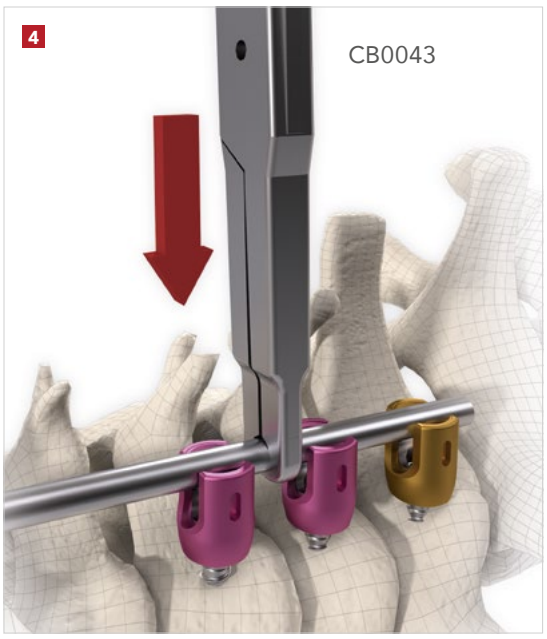
Rods are inserted into the screw (or hook) with the rod forceps (CB0043) (Image 4).

NOTE

If the tulips are not lined up, the tulip adjuster (CB0067) can be used to turn them in the appropriate direction (Image 5).

When additional rotation of the rod in-situ is needed, the rod holder (CB0147) can be used.

4



CB0043

5

CB0067

SURGICAL TECHNIQUE – ROD-SCREW SYSTEM

Pushing the Rod into the tulip

There are several possibilities to push the rod into the tulip, depending on the force needed.

OPTION A: Using the Tulip adjuster

The Tulip adjuster (CB0067) is designed to be also usable as a rod pusher (Image 1).

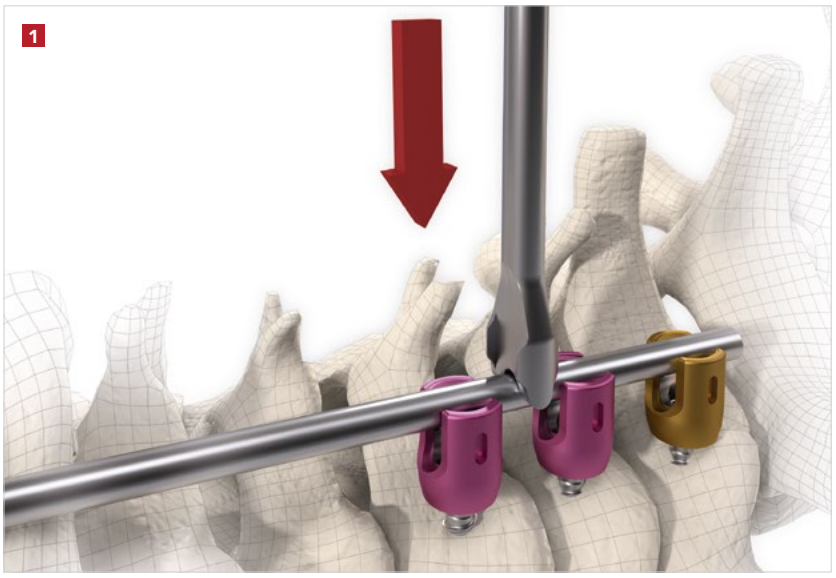
OPTION B: Using the Rodfork

The Rodfork (CB0080) can be used to push the rod into the tulips (Image 2).

OPTION C: Using Persuader Type 1

The Persuader (CB0084) can also be used (Image 3).

1



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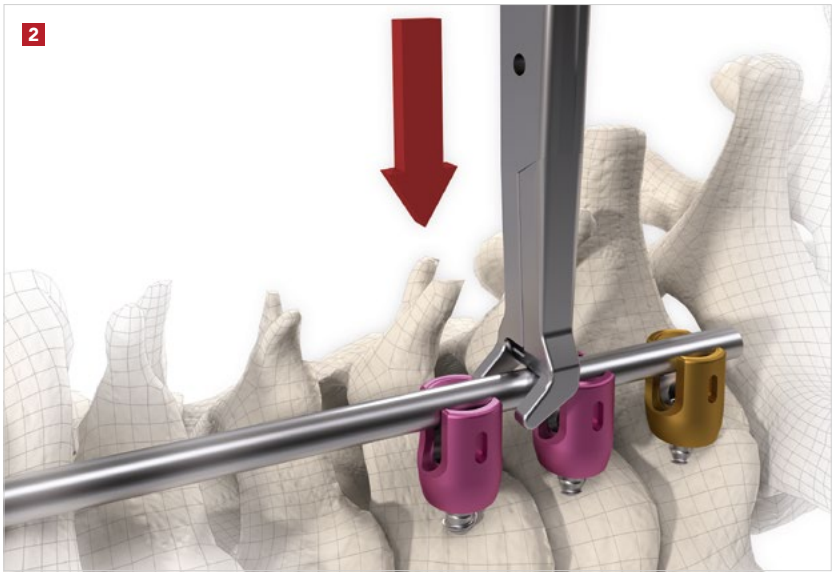


3

OPTION D: Using Persuader Type 2

The persuader (CB0049) is used to push the rod into the tulip (Image 1).

1. Pressing the handle together, the rod is pushed into the tulip. It stays in position until the rod is fixed by applying the set screw (Image 2).
2. This procedure can be repeated for all screws.

1

CB0049

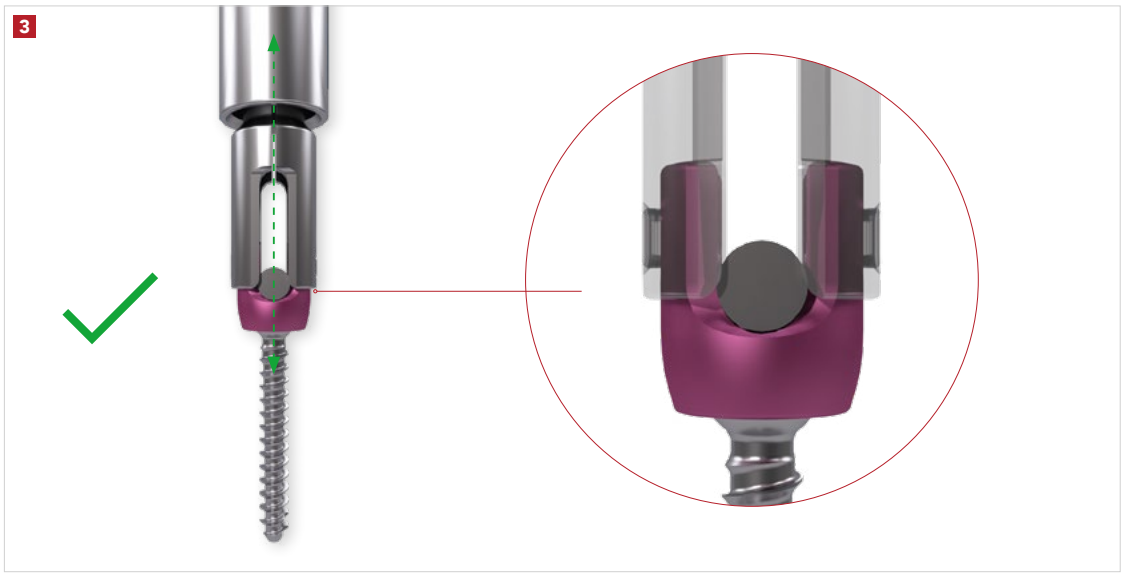
2

Inserting the set screw with the set screwdriver (CB0037).

Alignment of the persuader

The persuader and the screw need to be straight aligned to securely attach the tulip (Image 3).

3



Persuader correctly aligned.

OPTION E: Using a reduction tower

The reduction tower (CB0070-1 / -2, CB0071) is used to push the rod into the screw (Image 1).

1. Positioning of the reduction tower on the tulip (or hook).
2. Rotating the reduction tower knob clockwise until the rod is securely positioned in the screw.
3. Holding the rod in position until the rod is fixed with the set screw (Image 2).
4. This procedure can be repeated for all screws.

1

CB0070-1 / -2, CB0071

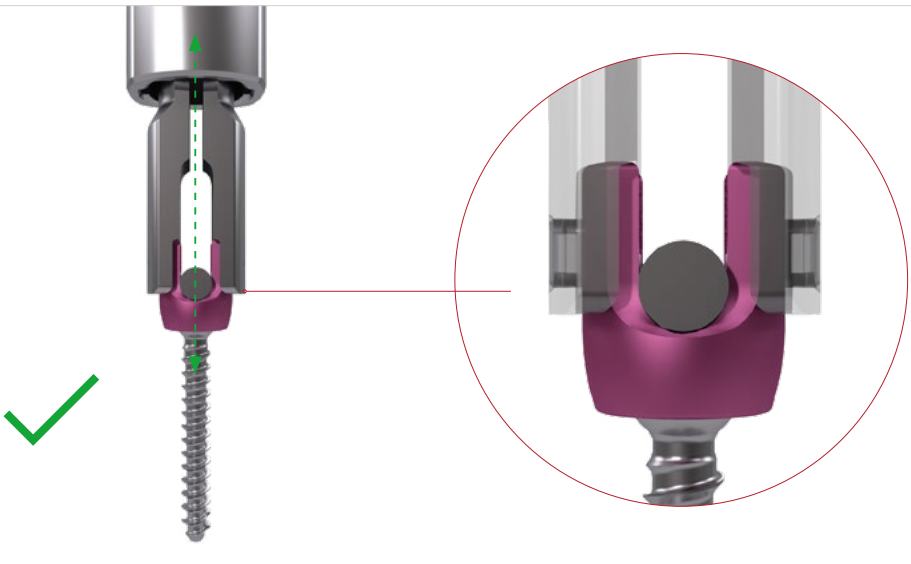
2

Inserting the set screw with the set screwdriver (CB0037).

Alignment of the reduction tower

The reduction tower and the screw need to be straight aligned to securely attach the tulip (Image 3).

3



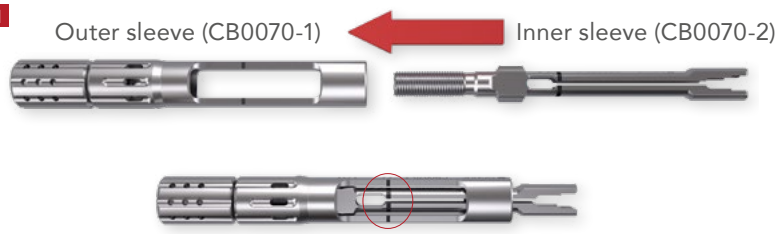
Reduction tower correctly aligned.

How to assemble the reduction tower

The outer and inner sleeve are provided with markings to ensure a proper handling.

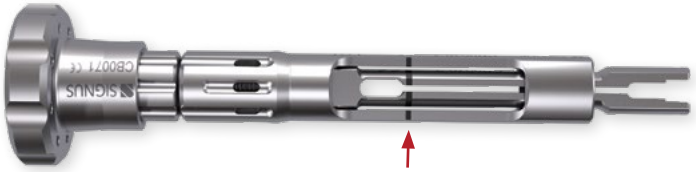
1. The inner sleeve is inserted into the outer sleeve and screwed in, up to the marking (Image 1).
2. Grooves on the inner sleeve and notches on the outer sleeve guide to the correct assembly (Image 2).
3. The reduction tower is ready for use as soon as the markings are at the same level and the adjustment knob has been attached (Image 3).

1



2

3



CB0071

4 INSERTING THE SET SCREW

1. The set screws for the polyaxial screws are picked up with the self-retaining set screwdriver starter (CB0037).
2. Initially they are applied clockwise handtight into the tulip.
3. Final fixation of the polyaxial screws with 3 Nm is performed using the T-Handle with torque limiter (CB0073-1) in connection with final set screwdriver (CB0073-2) (Image 1 + 2).

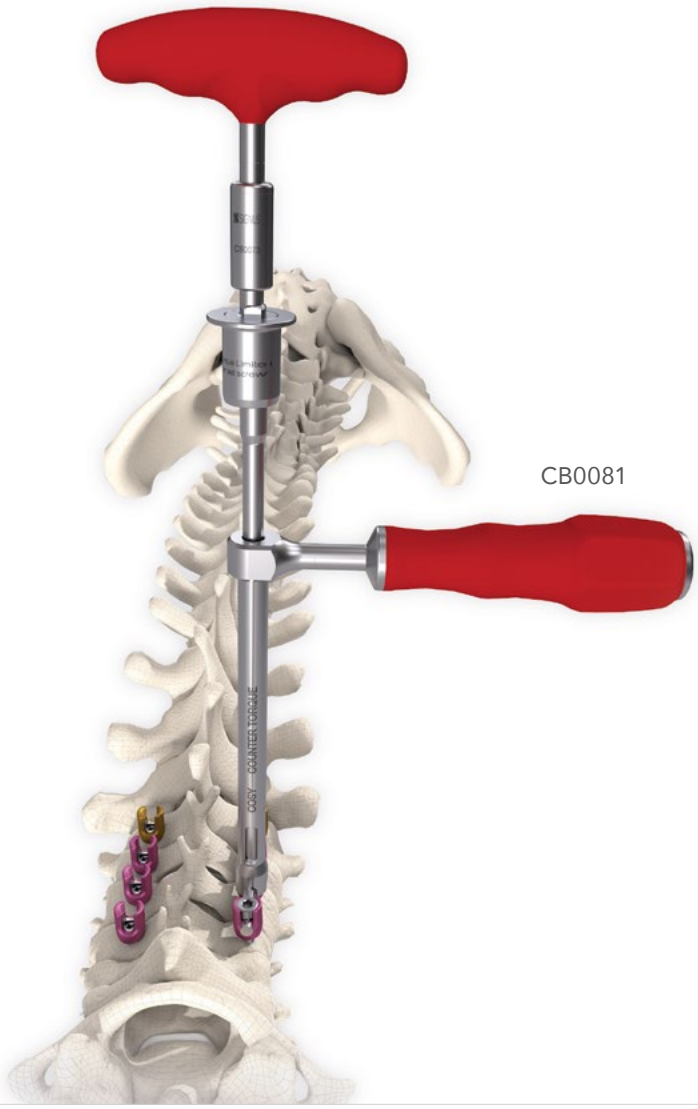
NOTE

Same procedure for screws applies for hooks and offset connectors.

4. Attachment of the counter torque (CB0081) on the tulip. This allows to place the set screw correct aligned.
5. The set screwdriver is inserted through the counterpart. The screw is rotated clockwise until an audible click indicates that the necessary torque 3 Nm is reached.

2

1



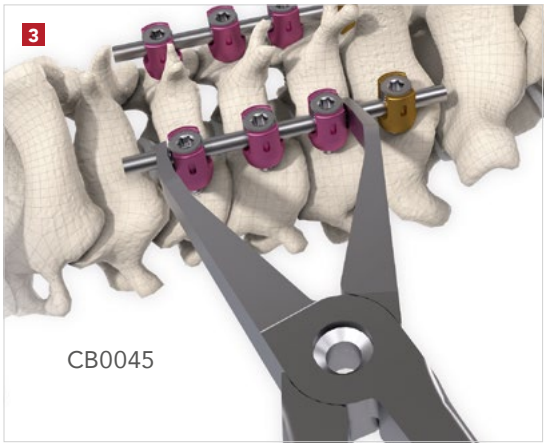
Compression and Distraction

Segmental compression or distraction can be carried out with the compressor (CB0045) (Image 3) or distractor (CB0046) (Image 4).

NOTE

For performing a compression or distraction, a "flexible" counter bearing must be created. This is achieved in fixing the set screws just handtight. After compression or distraction is achieved, the set screws must be fully tightened (See above).

3



Compression

4

Distractor

5 ADDITIONAL OPTIONS

Responding to the requirements of various indications and difference in patient anatomy, additional options are available for the COSY® Cervicothoracic Occipital Rod-Screw System.

- Cross connector: For additional stabilisation of instrumentation.
- Offset connector: For counteracting a distance between a rod and a screw.
- Parallel / Inline connector: For joining adjacent fixations.
- Transition rod: For transitional fixation from the cervical to the thoracic / lumbar region.
- Hook: To connect the rod with the vertebral arch.
- Atlas and Lamina Hook: To connect the posterior atlas arch to the rod (See page 39 "Atlas claw").


Cross connector


Offset connector


Parallel connector closed


Inline connector


Transitionrod


Hook


Atlas and Lamina Hook

Cross connector

If additional stability is required a cross connector can be inserted. The COSY® Cervicothoracic Occipital Rod-Screw System provides two different cross connector options:

1. Cross connector: Rod to rod (Image 1).
2. Cross connector: Tulip to tulip (Image 2).

1

2

SURGICAL TECHNIQUE – ROD-SCREW SYSTEM

Cross connector: Rod to rod

The cross connector is fixed directly from rod to rod.
This achieves additional stabilisation.

1. To fix the connector, the screwdriver cross connector (CB0073-3) is used with the T-Handle (CB0073-1) (Image 1 + 2).
2. With the Rod forceps (CB0043) or the rod holder (CB0147) the rod is held in place of the cross connector and turned in a clockwise direction until an audible click indicates that the necessary torque 3 Nm is reached (Image 3).
3. The opposite side of the cross connector is fixed in the same way.

CAUTION

The described steps must be adhered. Otherwise there is a danger that the cross connector is not correctly fixed.

3

1

Screw driver for cross connector

2

Cross connector tulip to tulip

With screw heads that are close together, the use of a rod-to-rod cross connector is sometimes not possible. In this case a tulip-to-tulip cross connector can be used. The tulips of the polyaxial screws are used as fixation points.

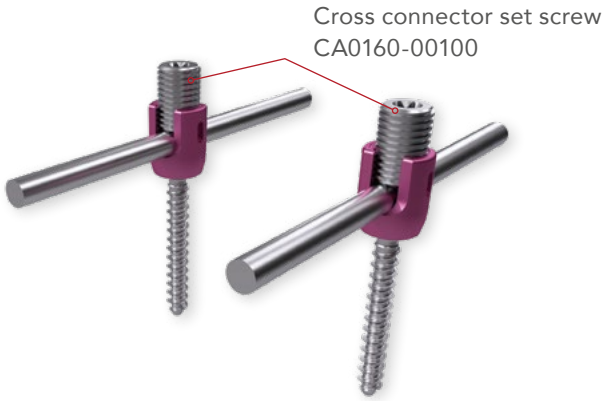
CAUTION

To position the tulip to tulip cross connector, a special set screw (CA0160-00100) for the cross connector and a special connecting nut (CA0160-00200) are needed for each side. Ensure that the steps are followed and the torque 3 Nm is applied.

1. The torque limiter 3 Nm (CB0073-1) is connected to the set screwdriver (CB0073-2) and the tulip-to-tulip cross connector set screws (CA0160-00100) are implanted and fixed with 3 Nm (Image 1 and Image 2)
2. After final fixation of the set screws the tulip-to-tulip cross connector is placed over the cross connector set screws (Image 3).

   If needed, the tulip-to-tulip cross connector can be further shaped using the rod benders (CB0039/-40) (Image 4).

1



Fixation with 3 Nm.

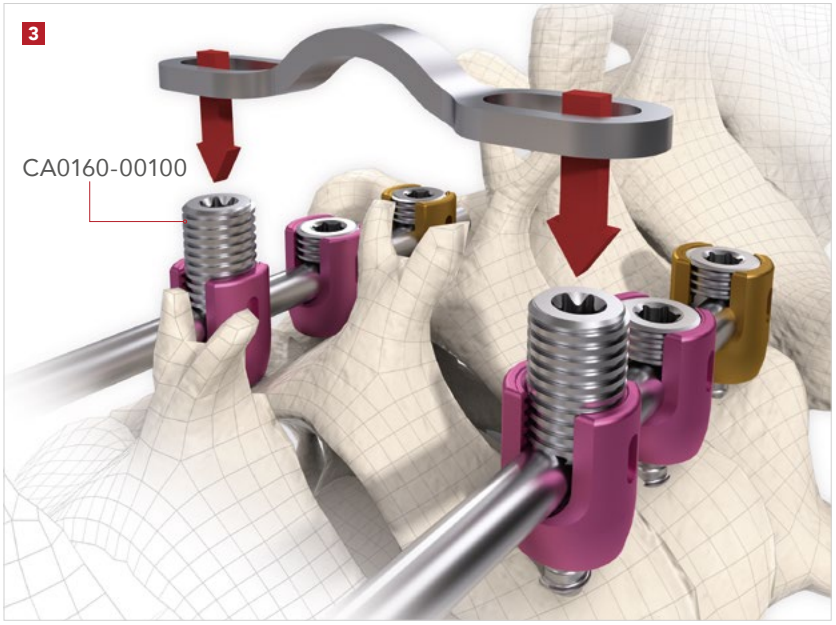
2

Connect the T-Handle with torque limiter 3 Nm with the set screwdriver.

4

Optional bending of tulip connector

3



Positioning of the cross connector.

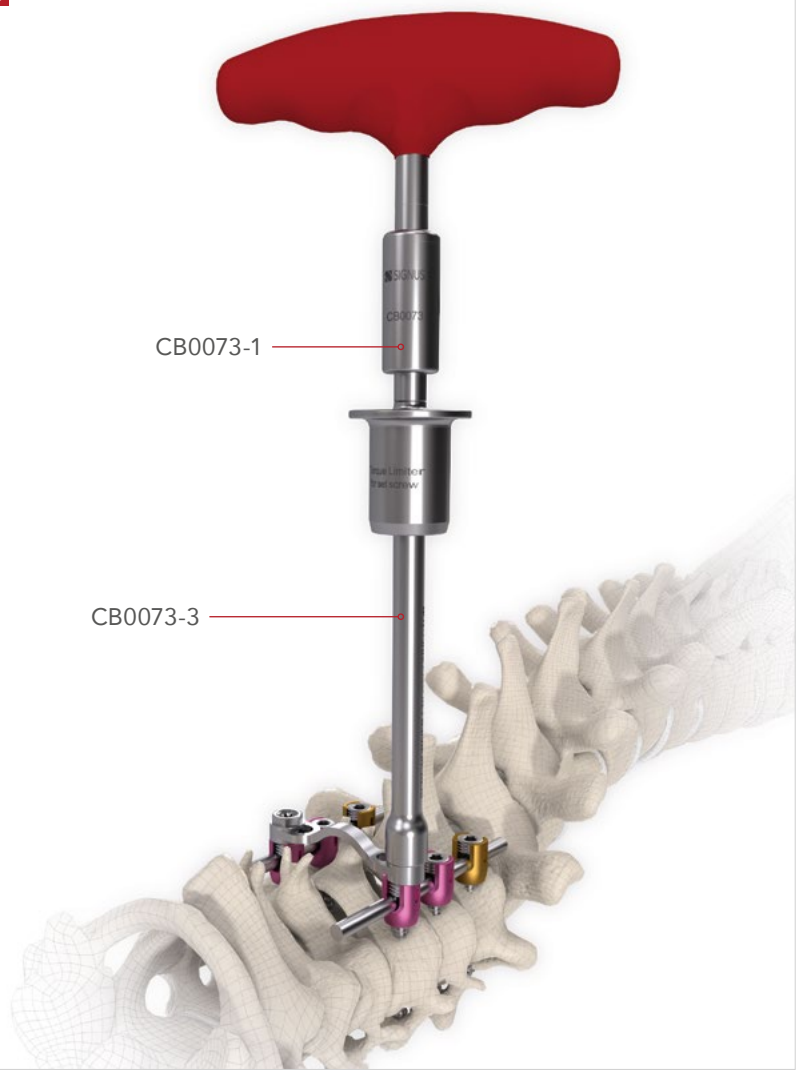
CAUTION

For shaped tulip-to-tulip cross connectors it is mandatory to make sure both rings of the cross connector are flush with the base of the tulip. Otherwise applying a torque to the cross connector nut can cause problems with the inner set screw.

3. The retaining nut for the cross connector (CA0160-00200) can be pre-fixed with the screwdriver cross connector starter (CB0062) (Image 5).
4. The screw driver for cross connector (CB0073-3) is connected to the T-Handle (CB0073-1) and the retaining nut cross connector is screwed onto the screw plug of the tulip to tulip cross connector. Final fixation is performed with 3 Nm (Image 6 and 7).

5

6



7

SURGICAL TECHNIQUE – ROD-SCREW SYSTEM

Offset connector

The offset connector for joining adjacent fixations is inserted into the tulip of the screw and fixed with a set screw. The standard rod is then placed in the offset connector and also fixed with a set screw. After checking the correct positioning, both set screws are firmly tightened with 3 Nm (Image 1).

NOTE

For fixation of the offset connector and rod, the set screw CA0140-35000 is used.

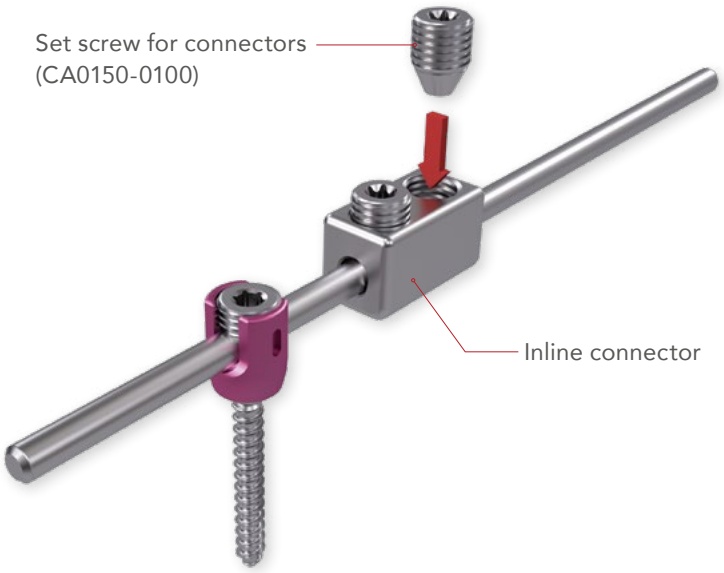
1

Inline connector

The inline connector enables a connection instrumentation with a rod diameter of Ø 3.5 mm without having to remove the existing construct.

It is recommended to first pretension the inline connector on the new rod and provisionally tighten it with the set screw of the connector. After checking the correct positioning, all connector set screws are firmly tightened with 3 Nm (Image 2).

2



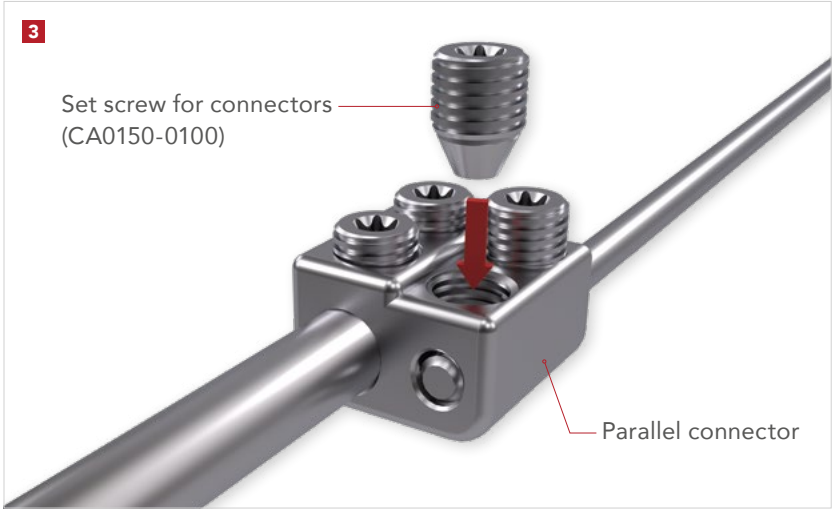
Parallel connector

The closed and open parallel connectors enable a connection instrumentation with rod combinations of Ø 3.5 × 5.5 mm and Ø 3.5 × 6.0 mm without having to remove the existing construct (Image 3).

NOTE

For fixation of the parallel / inline connector with the rod, the set screw CA0150-0100 is used. The set screws of the inline and parallel connectors are smaller compared to the set screws of the offset connectors, offset hooks, polyaxial screws, hooks and occipital plate. They are not interchangeable.

3



SURGICAL TECHNIQUE – ROD-SCREW SYSTEM

Transition rod

Transition rods (Image 1) enable fixation from the cervical to the thoracic-lumbar region. They are available in the following versions:

- Ø 3.5/5.5 mm × 420 mm/600 mm
- Ø 3.5/6.0 mm × 420 mm/600 mm

Screws are first placed in the cervical region and thoracolumbar region prior to insertion of the hybrid rod.

NOTE

The screw implantation is performed according to the described surgical technique of the SIGNUS system used (COSY®, DIPLOMAT®).

- A suitable transition rod is selected, which can be adapted in length and shape to the patient's anatomy. The flexible rod template (CB0051) can be used as an aid for the correct shape.
- The hybrid rod is inserted into the tulips.
- After a final position check, the transition rod is pre-fixed with the appropriate set screws. Final torque tightening is performed as described in the surgical techniques.

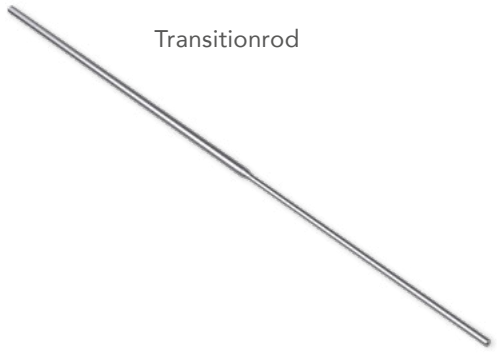
NOTE

Final fixation of the set screws: COSY® 3 Nm / DIPLOMAT® 11 Nm

CAUTION

Screws, hooks or connectors must not be placed in the transition zone of the transition rod because this can lead to incomplete fixation of the implants on the rod (Image 2).

1



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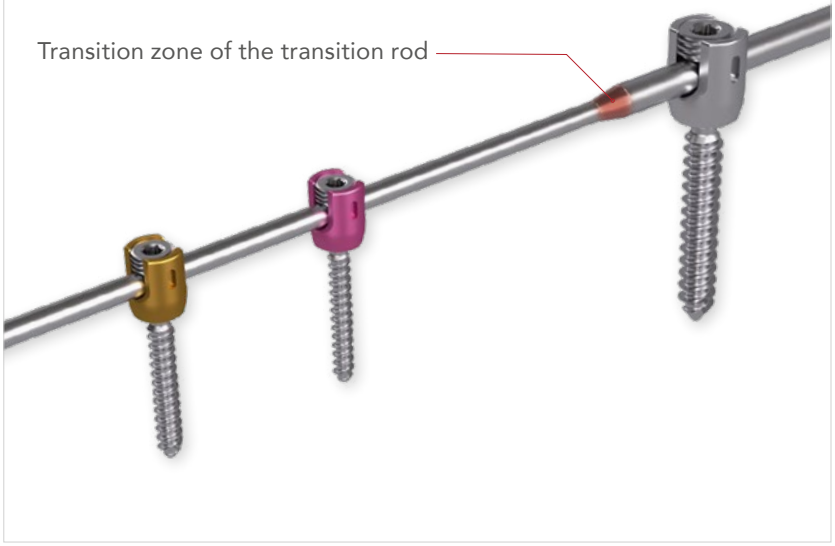


SURGICAL TECHNIQUE – ROD-SCREW SYSTEM – OPTIONAL

Hook Implantation

If the anatomy or the quality of the bone does not permit the placement of screws, hooks can be used as an alternative.

Five different lamina hook types are available:

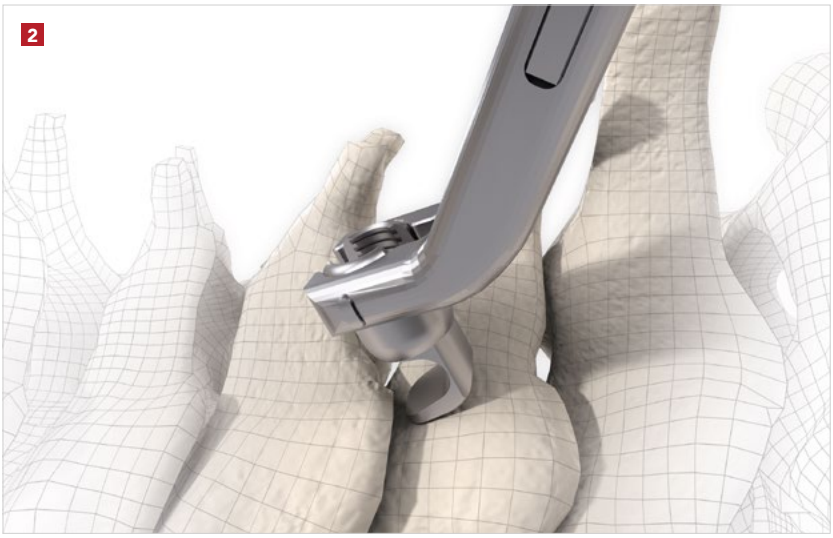
- Hook, straight
- Hook, left
- Hook, right
- Hook for offset connector, right
- Hook for offset connector, left

1

Surgical technique for hooks

1. First the orientation points to place the cervical hooks need to be determined.
2. Removing just a sufficient amount of soft tissue and ligamentous structures to allow a good view of the entire lamina and the edges of the spinal canal.
3. Selecting the suitable hook size based on the anatomy.
4. Clamping the desired hook into the hook holder (CB0055) by ensuring that the teeth of the instrument grab into the small recesses on the external head of the hook (Image 1).
5. Placing the hook, below the superior or inferior lamina (Image 2). The hook can be aligned either in a cranial or caudal position.
6. Attaching the rod after all hooks are placed.
7. Fixation of the rod with set screws using the set screwdriver starter (CB0037). Pre-tighten of the set screws in clockwise direction (Image 3).
8. Final tightened with 3 Nm (CB0073-1 + CB0073-2).

2



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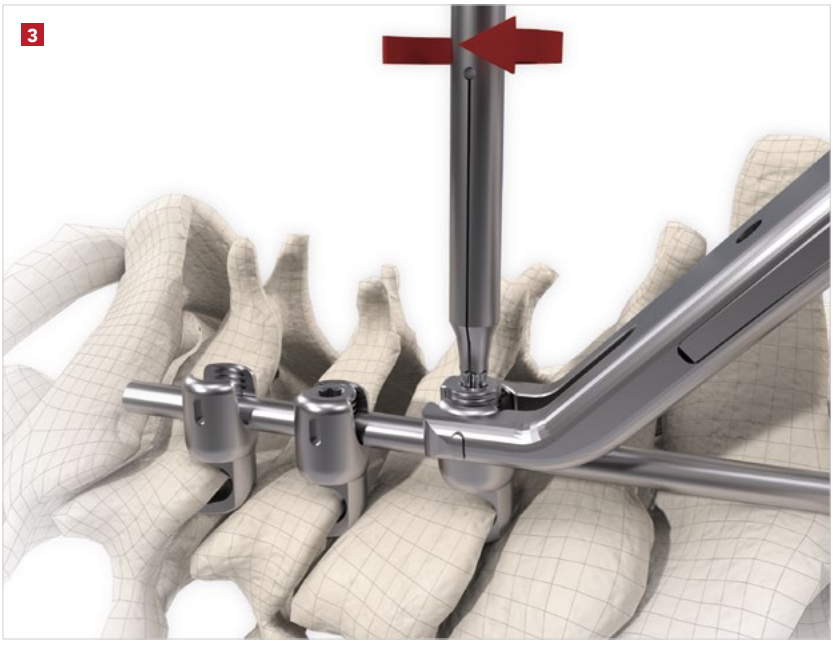


Atlas and Lamina Hook: Implanting the atlas claw

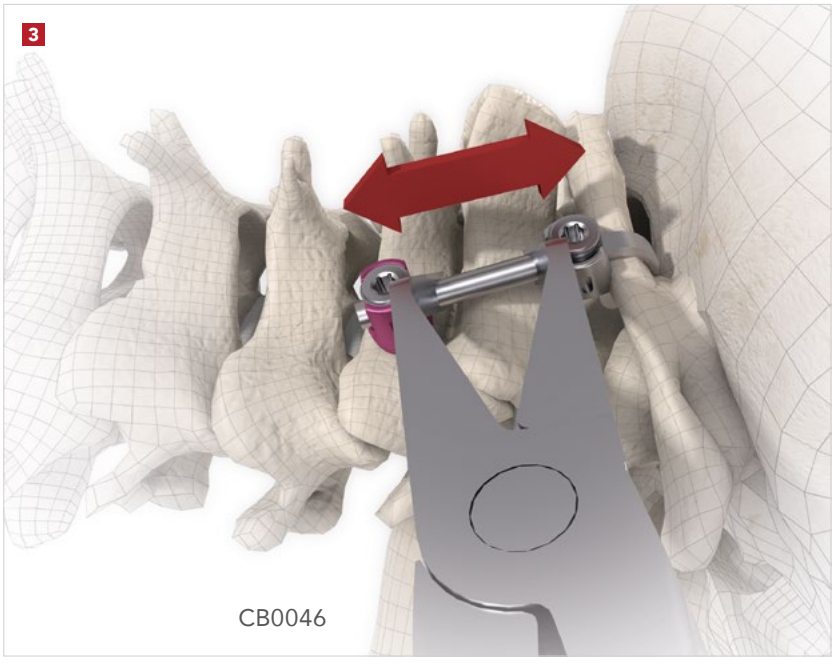
To create an atlas claw the inferior lamina hook (CA0157-35006/007) and the atlas hook rod (CA0157-35008) are combined. The inferior lamina hook is available in two lengths: long (CA0157-35007) and short (CA0157-35006).

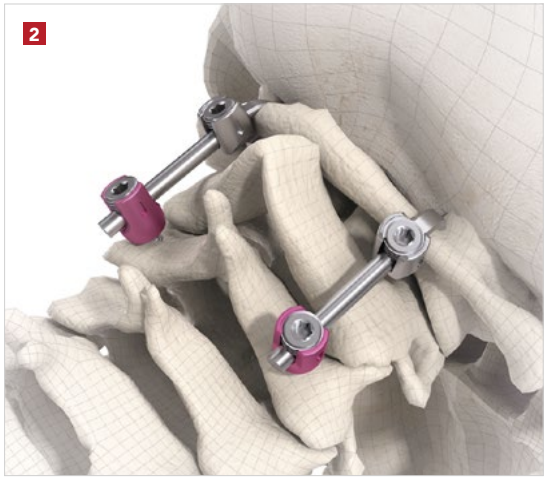
The Ø 3.5 mm atlas hook (CA0157-35008) might need to be shortened prior implantation.

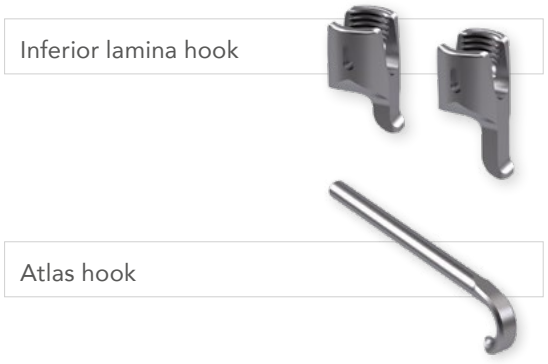
1. The inferior lamina hook is pushed onto the end of the atlas hook rod and prefixed with a set screw. To fix the set screw, the set screwdriver starter (CB0037) for lamina hook T15 is used (Image 1).
2. The atlas hook is mounted on the vertebral arch of the atlas and the inferior lamina hook is pushed beneath the arch of the atlas. Reaching the correct position the prefixed set screw must be firmly tightened (Image 2).
3. For a secure anchorage of the atlas hook in combination with the inferior lamina hook, a distractor should be placed between the atlas hook and the inferior lamina hook. To do so, the set screw of the placed screw must be fixed with 3 Nm while the inferior lamina hook must still be able to be moved (Image 3).
4. The inferior lamina hook is now pushed beneath the caudal end of the atlas vertebral arch by spreading the distractor, thus anchoring the atlas hook. The inferior lamina hook must be fixed with 3 Nm after positioning is complete.

CAUTION

To prevent injuries to the vertebral artery, the atlas hook should not be fixed too far laterally from the midline. Freshening the joint arch and surfaces of C1 / 2 and depositing bone chip helps with fusion.







1 PREPARING THE OCCIPITAL PLATE

Preoperative planning

The Os occipitale thickness is highly variable and should be measured using imaging procedures prior to the surgery. Determining in advance the length of the occipital bicotical screws to be inserted acts as a safety factor.

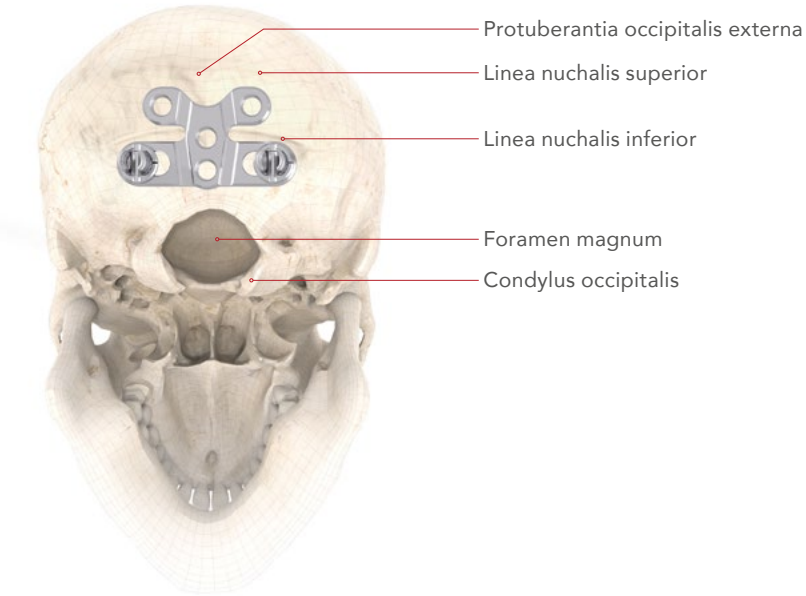
The best postioning for the plate is at the occiput midline as the bone is most pronounced in this area. Lateral to the midline the bone starts to become much thinner. In order to be able to use the longest possible screws, the cranial end of the occiput plate should be placed directly below the protuberantia occipitalis externa (Image 1 and Image 2).

In the area of the protuberantia occipitalis externa the confluens sinuum is positioned (interior of the cranium) therefore, bicortical screws must not be used, when drilling the screw entrance points, it must be ensured that the drill does not damage the brain after perforating the inner cortical bone.

NOTE

COSY® provides a variable drill guide sleeve with a drill depth stop that limits drilling to a predefined depth. The drilling depth is extended until the inner cortical bone is perforated. Each drilling process requires checking the screw length.

1



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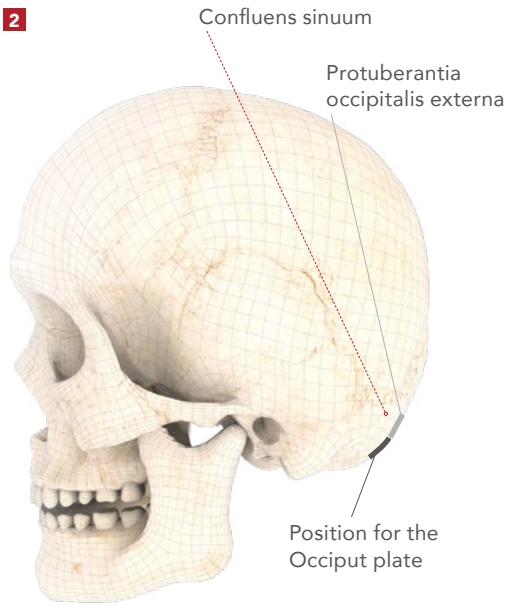


SURGICAL TECHNIQUE – OCCIPITAL PLATE

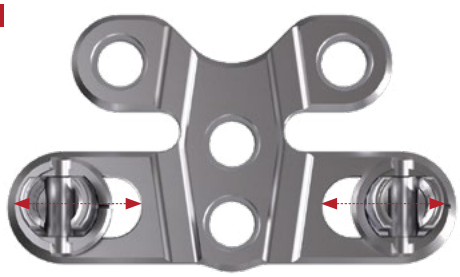
Plate positioning

The COSY® Cervicothoracic Occipital Rod-Screw System has a 4-hole occipital plate ensuring the best possible attachment on the occiput. (A 5-hole plate is available on request) The plate can be adapted to the anatomy of the occiput via the intended bending zones (Image 1).

Rods are required to connect the occiput plate to the cervical pedicle screws. They have a diameter of Ø 3.5 mm. The rods are inserted into the tulips of the occipital plate. The distance of the tulips could be moved lateral in a range of 30 – 42 mm to simplify the insertion of the rods (Image 2).

1

2



Adjustable tulips from 30–42 mm width

2 PREPARATION

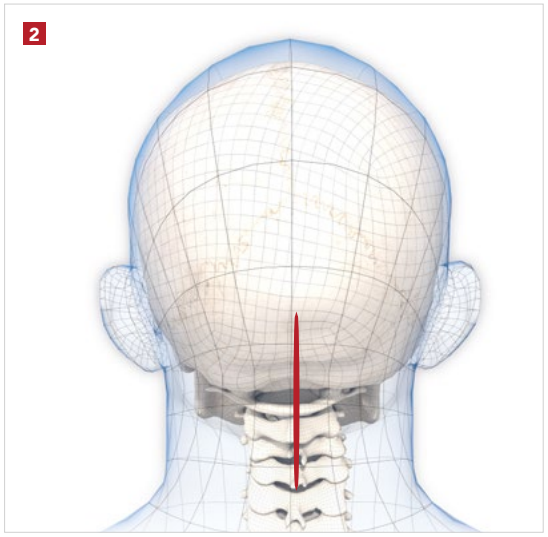
The patient is most commonly placed in a prone position with the head held securely in position with a Mayfield head holder or a halo (Image 1 + 2).

Prior to instrumentation via direct visualisation, it must be made sure that the patient postion is anatomically aligned in an acceptable flexion, extension, translation or rotation position. This is particularly most important if the occiput must be connected and fixed to the cervical and thoracic spine.

The physiological alignment and fixation of the position must be checked and established with X-ray imaging. Physiological alignment may not always be possible.

Excessive skin and neck folds in the operative field should be pulled using adhesive tape. All other extremities should also be well cushioned and securely positioned.

Care should be taken to avoid injury to the spinal cord, vertebral arteries, and C2 nerve roots in the upper cervical spine, the facet capsules and interspinous ligaments. Facet joints that are not included in the planned fusion should remain untouched. Exposing additional facets can lead to disruption and instability of the facets.



Example of incision

3 IMPLANTING THE OCCIPITAL PLATE

The posterior approach and the exposure of the occiput are carried out using the usual surgical procedure. The COSY® occipital plate can be implanted after all adjustments to the patient anatomy have been made and the area for implantation has been prepared accordingly.

NOTE

The occipital plate should sit flat against the bone. It may be necessary to slightly smooth out irregular bony protuberances while also ensuring that significant parts of the cortical bone remain, particularly in areas in which the screw will be inserted. Due to the thickness of the occipital bone, it is recommended to cut a thread before inserting the screw. The preoperatively measured drilling depth must be carefully drilled to prevent nerve damage.

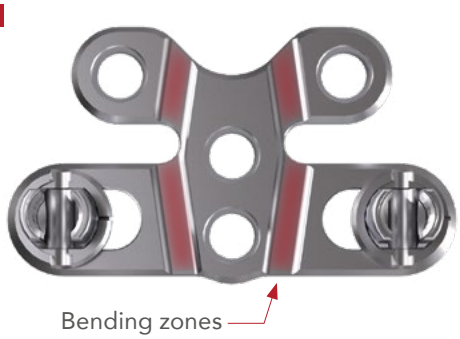
Occipital plate holder

Occipital plate bender

Preparing the occipital plate

The COSY® occipital plate can be adapted to the anatomy of the occiput by using the occipital plate holder (CB0009-1) and the occipital plate bender (CB0009-2). The plate may ONLY be bent between the screw holes and the movable tulips (Image 1: bending zones red marked). The bending of the plate is carried out in increments with respecting of bending each zone one after the other. Each bending zone can only be manipulated once, back-bending is not allowed. The plate holder and plate bender must always be used together. They are suitable for using on both sides to make a bend. The occiput plate holder is positioned on the middle section of the plate onto the 2 vertically aligned drill holes. The occipital plate bender is attached on the opposing side (Image 2).

1



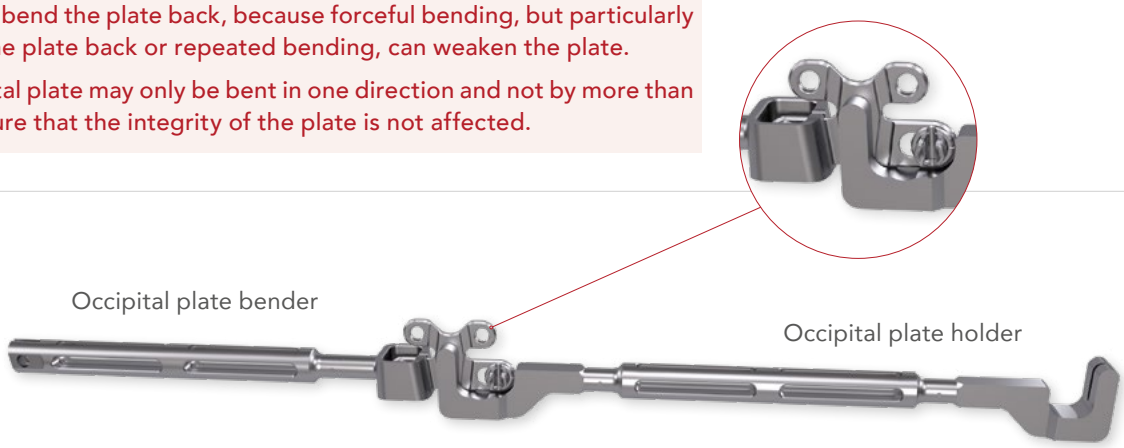
Bending zones

CAUTION

The COSY occipital plate must only be bent around the zones specifically marked for this purpose. Under no circumstances may the plate be bent at the level of the screw holes. Improper bending can impair the mechanical stability of the plate and compromise the secure fit of the screws. It is not allowed to bend the plate back, because forceful bending, but particularly bending the plate back or repeated bending, can weaken the plate.

The occipital plate may only be bent in one direction and not by more than 15° to ensure that the integrity of the plate is not affected.

2



Occipital plate bender

Occipital plate holder

SURGICAL TECHNIQUE – OCCIPITAL PLATE

Preparing the screw holes

1. The plate is attached to the holding forceps (DZ-0101-A) and held onto the occiput (Image 1).
2. Under X-ray control and always using the drill guide (CB0002) the screw hole can be prepared (Image 2).
3. A tap (CB0004) and a drill (CB0006) are available. They need to be attached to an AO handle (e.g. CB0101-1) and are inserted through the plate hole to open the screw entry point (Image 3).

NOTE

The variable drill guide is used for both drilling and cutting threads. The drill guide allows an angle of 8°.

CAUTION

The tap diameters for the Ø 4.5 mm screws are 0.2 mm less than the diameter of the screws. Ø 5.0 mm screws are self-tapping revision screws. A thread does not have to be cut.

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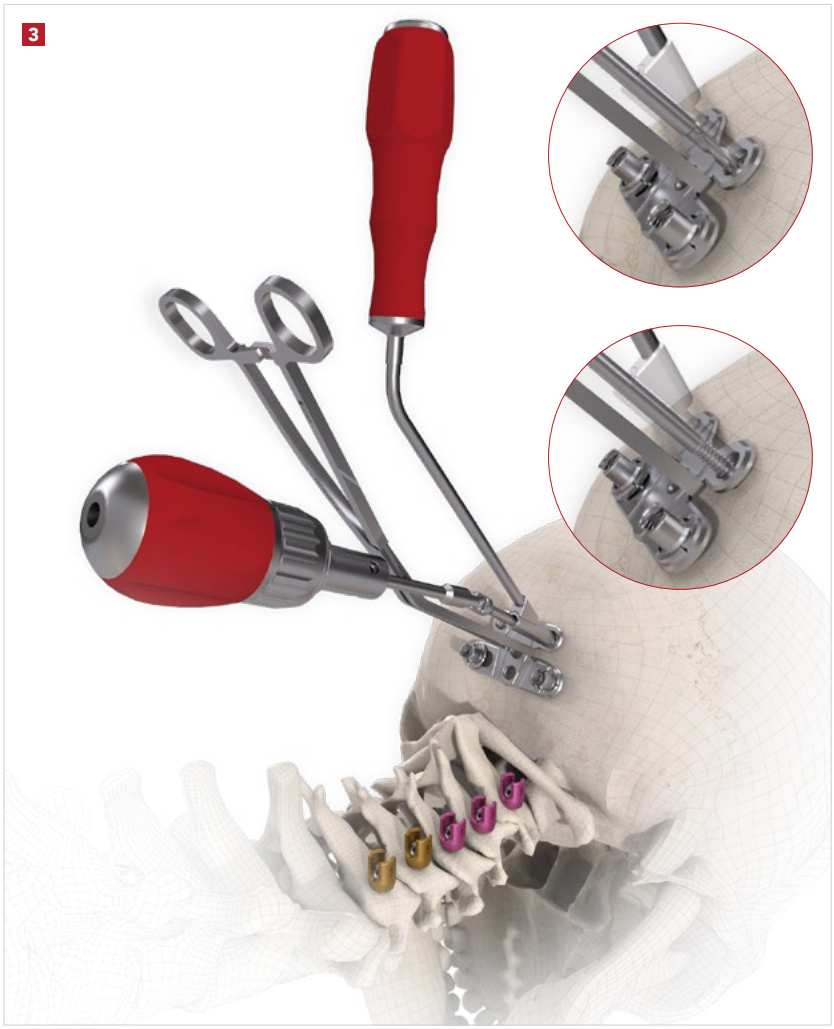


SURGICAL TECHNIQUE – OCCIPITAL PLATE

Implanting the screws

With the COSY® occipital plate attached to the holding forceps and optionally the drill guide sleeve attached, the middle screws is implanted first.

The following screws are available:
Two screw types are available of 6 – 16 mm, in 2 mm increments (Image 1).
Ø 4.5 mm standard screws
Ø 5.0 mm Revision screws (green).

The selected screw is picked up on the self-holding screwdriver (CB0003). The tip of the screwdriver has a clamping taper and holds the screw securely (Image 2).

2

CB0003

Attaching the screw to the screwdriver.

The screws should be inserted completely until they are flush with the plate.

After inserting the middle screws the drill guide and the plate inserter can be removed (Image 3). Then the remaining screws are placed an tightened. It is recommended to provide ALL plate holes with screws.

CAUTION

To prevent the occipital plate from shifting or bending, it is recommended to carefully hand-tighten all screws in the first step. When the plate is correctly positioned, all screws can be finally tightened.

TIP

The first screw should be placed medially, as the bone is most pronounced on the external occipital protuberance (POE). To facilitate the further steps, it is helpful to use the drill guide sleeve together with the occipital holding forceps when placing and drilling the first central screw.

1

3

4 CONNECTING THE OCCIPITAL PLATE TO THE ROD-SCREW SYSTEM

Option 1: Using a variable rod

The variable angle rod Ø 3.5 mm × 85 mm (CA5835-00085) in combination with a straight rod can be used (Image 1).

The variable angle occipital rod can be adjusted to the anatomical situation due to its adjustable angle.

Between the two ends of the rod there is an adjustment unit that is used to set and fix any angle between the two rod ends.

1. Adapting the variable occiput rod to the right lenght.
2. Inserting the variable rod into the occipital plate and hand-tighten the set screws.
3. Placing the straight rod into the rod clamp of the variable rod and into the tulips of the implanted screws (Image 2).

Using the Occiput Screwdriver Occipital screw (CB0003)

4. Hand-tighten the fixing screw from the variable rod and hand-tighten of all implanted screws (Image 3).
5. Final fixation of all set screws with 3 Nm if the occipital plate, screws and rods are correct placed.

CAUTION

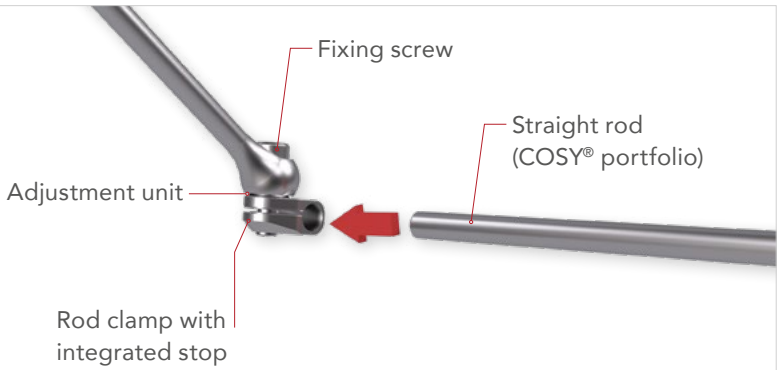
The rod clamp of the variable occiput rod with adjustment unit has a **receptacle for straight** rods. The rod must be inserted up to the prescribed stop, only in this way a correct connection with the variable occiput rod and the straight rod for the screws guaranteed.

NOTE

To facilitate the rod placement, the connecting tulips can be adjusted **by means of a movable area.** It ranges from 30 – 42 mm (Image 4).

1

2



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SURGICAL TECHNIQUE – OCCIPITAL PLATE

Option 2:
Using a 120° precurved rod

To connect the occipital plate with the cervical spine, a 120° precurved Ø 3.5 mm rod can be used (Image 1).

NOTE

To facilitate the rod placement, the connecting tulips can be adjusted by means of a movable area. It ranges from 30 – 42 mm.

Inserting the precurved rod the rod holder (CB0043) is used. To determine the required length and shape of the rod a phantom rod (CB0051) can be used.

It can be useful to mark the rod where it should be shortened. The rod cutter (CB0048) is used to cut the rod (Image 2).

The phantom rod is placed along the instrumentation and bent as required for the anatomy or the desired curve. The rod is then adjusted accordingly using the rod bender (CB0038) (Image 3).

CAUTION

To maintain the intactness and integrity of the rod, it must not be bent back and forth repeatedly.

1. Adapting the pre-curved rod to the right length and shape.

NOTE

Additional rod adjustment can be carefully contoured with the in-situ bender.

2. Inserting the pre-curved rod into the occipital plate tulips and implanted pedicle screws.
3. Hand-tighten of all set screws.
4. Final fixation of all set screws with 3 Nm if the occipital plate, screws and rods are correctly placed.

1

2

3

SURGICAL TECHNIQUE – OCCIPITAL PLATE

Final fixation of the rods and screws

1. The screwdriver set screw (CB0007) with the T-Handle torque limiter (CB0073-1) is connected to the set screw (Image 1).
2. The set screws are placed into the tulips of the occipital plate and the implanted pedicle screws. They are provisionally hand-tightened by rotating the screwdriver clockwise.

NOTE

Before final fixation of the occipital plate, the rod and the implanted screws, it must be checked again that the correct anatomical alignment has been created.

3. For the final fixation of all set screws, the counter torque (CB0008) must be attached. (Image 3 and Image 4).
4. One after the other, all set screws are final tightened clockwise until an audible "click" indicates that the necessary torque (3 Nm) is reached (Image 5).

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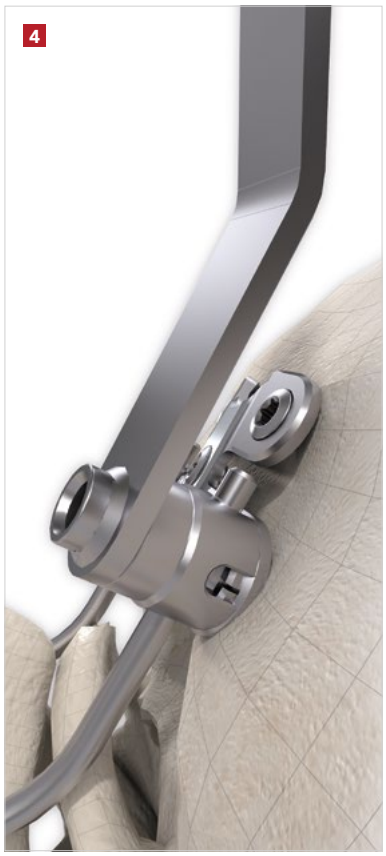

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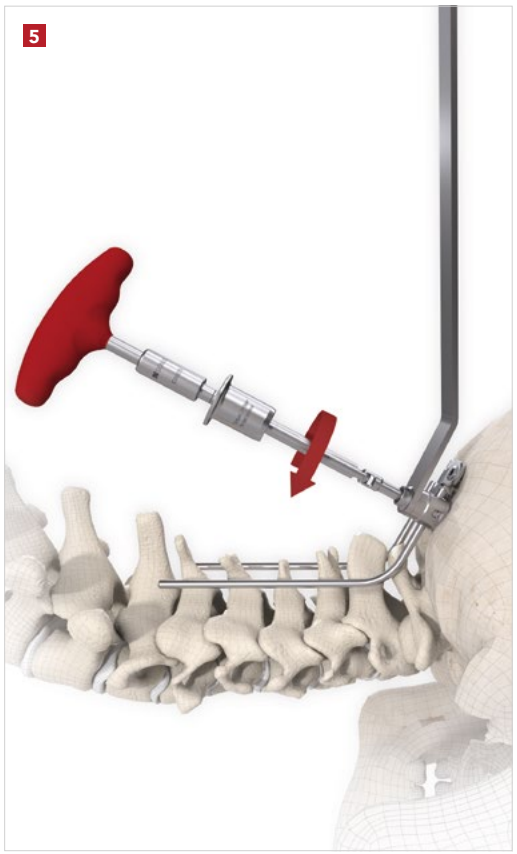

SURGICAL TECHNIQUE – OCCIPITAL PLATE

Final instrumentation

NOTES

NOTES

NOTE: This document was written by the technical department at SIGNUS Medizintechnik GmbH. Despite being reviewed by trained personnel, the sole purpose of this brochure is to provide an explanation of the technical aspects of handling the product described.
This document, in particular the description of the surgical procedure, should not be considered medical scientific literature.

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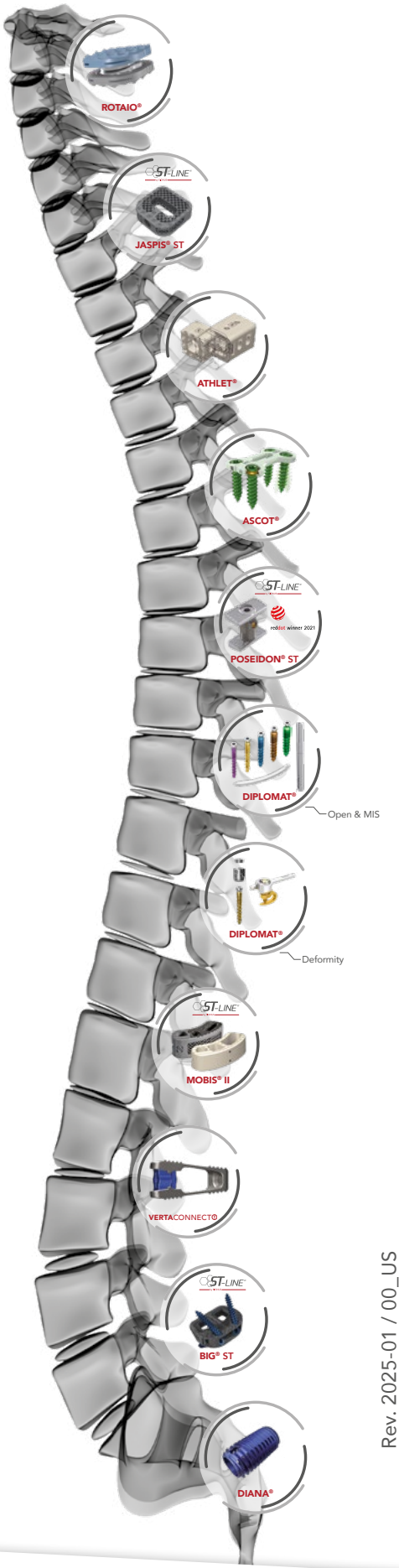

SIGNUS key visual. Not all products are available in the US market and have FDA approval.

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