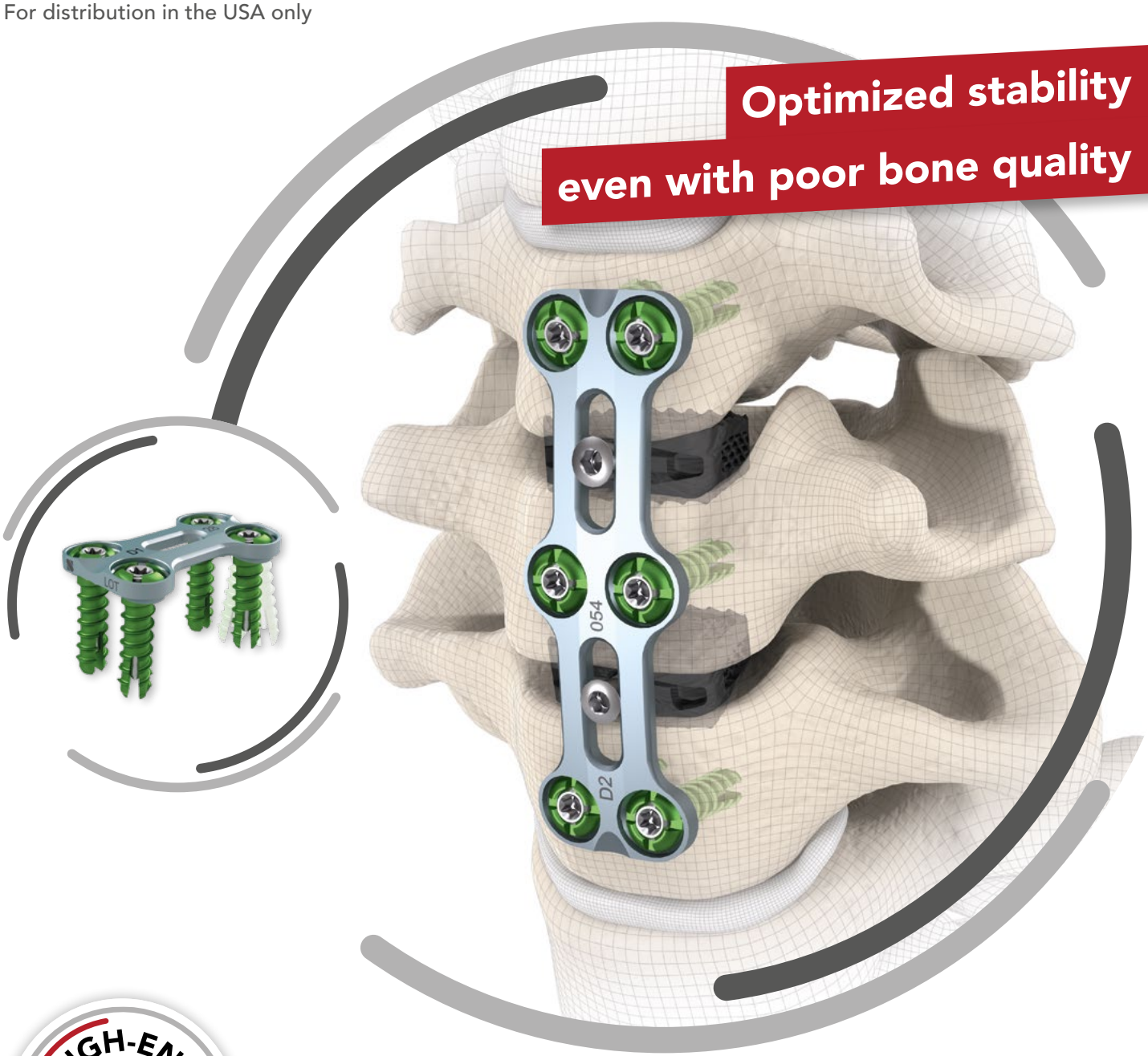
PRODUCT INFORMATION | ACF | US

TOSCA® Expansion

Anterior Cervical Stabilization

For distribution in the USA only

Optimized stability
even with poor bone quality



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 hospitalization 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

CYLOX® ST – Empower Fusion choices – stand alone or plate
Anterior Cervical Fusion

CONCEPT

Stabilization in cases requiring multi-level treatment and/or with poor bone quality continues to present a challenge in anterior cervical surgery. TOSCA® Expansion was specifically developed for this purpose. The expansion screws are anchored in the bone in the same way as a dowel. This achieves increased primary stability for monocortical anchorage that is comparable to that achieved with bicortical screw attachment. In spite of optimised stabilization, TOSCA® Expansion, with its extremely thin plate design and semi-rigid screw attachment, allows for optimal load transmission onto the bone (Wolff's law), thereby supporting segment fusion.

IMPLANTS

TOSCA® offers the user a high degree of flexibility for anterior stabilization of C2 to C7. The pre-lordosed plate is available for monosegmental to four-segment treatment each in various lengths. The self-tapping expansion screws are available in different lengths and diameters – both as variable angle with an angle of 5° in all directions and as fixed angle. With a thickness of barely 1.6 mm, TOSCA® is one of the flattest plates on the market. TOSCA® can also be fixed with a connector screw to the SIGNUS cervical vertebral body replacement implants such as ATHLET®, all SIGNUS cervical disc replacement implants such as CYLOX® ST as well as to a bone graft to ensure secure placement.

Material details

Manufactured from a biocompatible titanium alloy (Ti-6Al-4V) with proven strength.

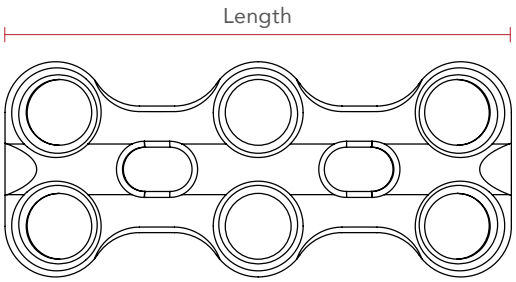
The expansion screw

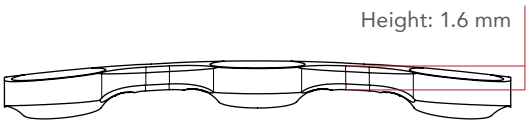
Prior to expansion

After expansion

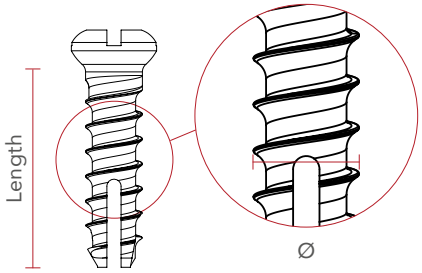
IMPLANTS

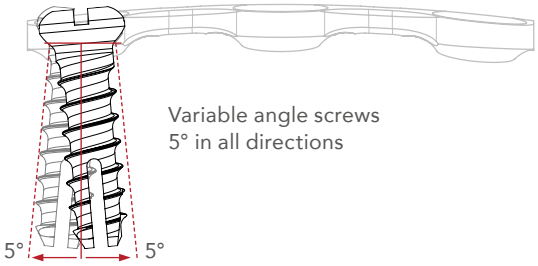
Plates			
Description	**Length (mm)**	**Increments (mm)**	**Art. no.**
1-segment plates	22–36	2	D1-022–D1-036
2-segment plates	38–54	2	D2-038–D2-054
3-segment plates	50–71	3	D3-050–D3-071
4-segment plates	68–80	4	D4-068–D4-080





Expansion screws				
Description	**Ø diameter (mm)**	**Length (mm)**	**Increments (mm)**	**Art. no.**
Variable angle screws	4	12–16	2	DV-4012–DV-4016
	4.5	12–16	2	DV-4512–DV-4516



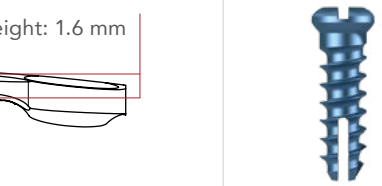


Variable angle screws
5° in all directions

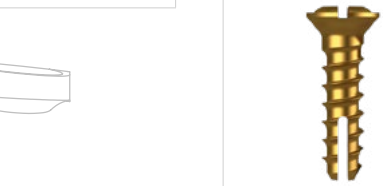
Optional				
Description	**Ø diameter (mm)**	**Length (mm)**	**Increments (mm)**	**Art. no.**
Fixed angle screws	4	12–14	2	DX-4012–DX-4014
	4.5	12–14	2	DX-4512–DX-4514
Cervical graft screw [1]	2.7	14	–	DC-2714 [1]
Cervical connection screw cage, sterile [2]	3	4.3	–	TM3043 [2]
Cervical connection screw VBR, sterile [3]	3	9	–	ATM309 [3]

[1] For use with bone graft, [2] For use with RABEA®, NUBIC® and CYLOX® ST, [3] For use with ATHLET®

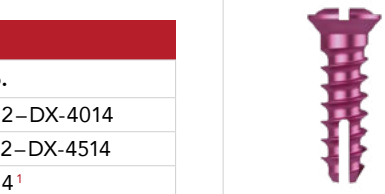
Variable angle screw,
Ø 4.0 mm - green



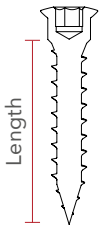
Variable angle screw,
Ø 4.5 mm - blue



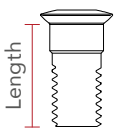
Fixed angle screw,
Ø 4.0 mm - yellow



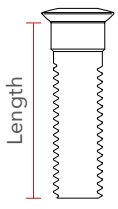
Fixed angle screw,
Ø 4.5 mm - magenta



Cervical
graft screw



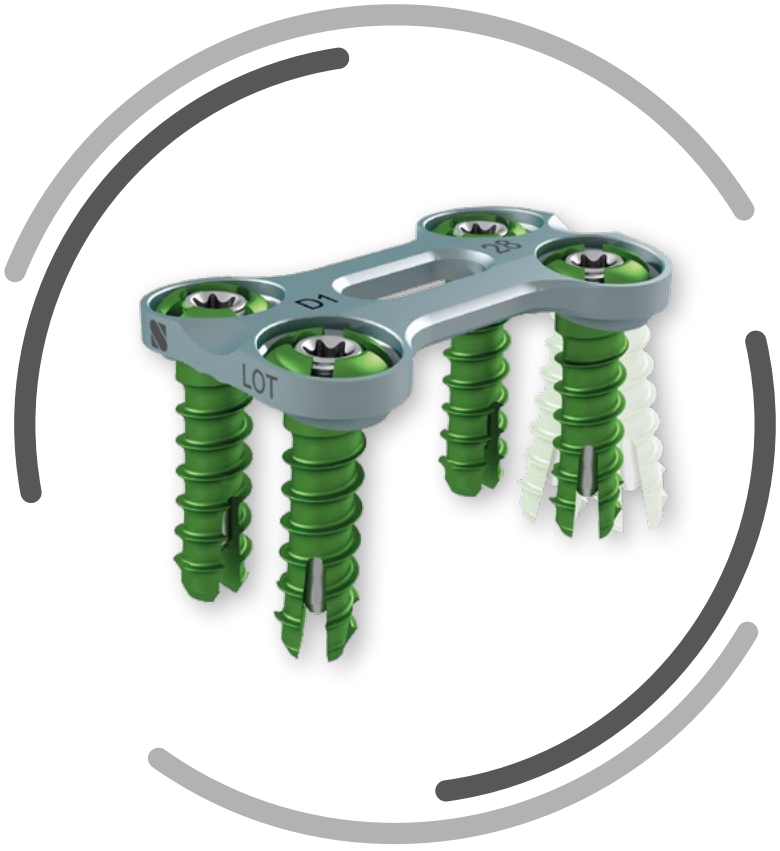
Cervical connection screw cage
(RABEA®/NUBIC®/CYLOX® ST)



Cervical connection screw VBR
(ATHLET®)

PRODUCT-SPECIFIC ADVANTAGES

- **Flat, semi-rigid plate design**
  - Minimised stress-shielding effect
  - Optimal load transmission to the bone and stimulation of fusion (Wolff's law)
  - Promotion of physiological subsidence (graft settling)
- **Wide range of pre-lordosed mono- and poly-segmental plates**
  - Optimal adaptation to patient anatomy
  - In most cases implantable without further pre-bending
- **Self-tapping variable- and fixed-angle expansion screws**
  - Primary stability as for bicortical screws
  - No danger of possible dura injury
  - Reliable stabilization with poor bone quality and multi-level treatments
  - No need for tapping
  - Application for diverse anatomic situations
- **Color coding**
  - Easy size identification



INSTRUMENTS

Art. no. DZ-0101-A
Holding forceps

OPTIONAL
Art. no. RZ0009-H
Universal guide fix right

Art. no. SN0004
Handle straight AO

Art. no. RZ0004-H
Awl, AO

Art. no. RZ0002-H
Pindriver, AO

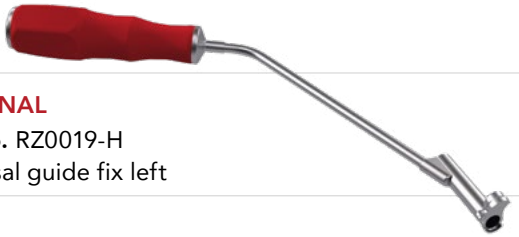
Art. no. RZ0012-H
Drill, AO,
Ø 2.4 x 10 - 26 mm

Art. no. RZ0003-H
Drill guide variable

Art. no. CB0086
Depth stop variable

Art. no. RZ0010-H
Universal guide fix doubled

Art. no. RZ0013-H
Tap, AO,
Ø 4.0 x 12 - 26 mm

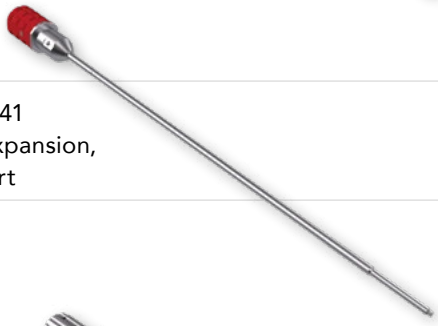


OPTIONAL
Art. no. RZ0019-H
Universal guide fix left

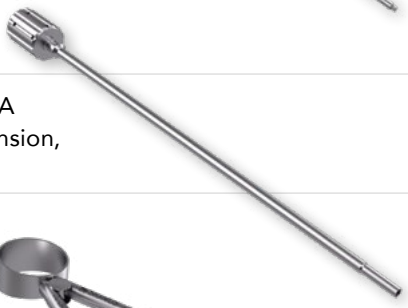
OPTIONAL
Art. no. RZ0014-H
Tap, AO,
Ø 4.5 x 12 - 26 mm

INSTRUMENTS

Art. no. DZ-0840-B
Screwdriver, expansion



Art. no. DZ-0841
Screwdriver, expansion,
spreading insert



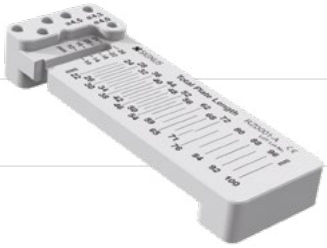
Art. no. DZ-0842-A
Screwdriver, expansion,
sleeve

Art. no. DZ-0901-B
Caliper

Art. no. DZ-1001-A
Plate bender

Art. no. FZ-1201-H
Screwdriver SW2

OPTIONAL
Art. no. FZ-1202
Screwdriver, sleeve



Art. no. RZ0001-A
Template

OPTIONAL
Art. no. RZ1609
Fixation pin Ø 1.6 x 9 mm, 2x sterile
(For single use only)

NOT SHOWN

Art. no. RZ40AY
Tray, basic, Instruments

Art. no. RZ41AZ
Tray, insert, instruments, expansion

Art. no. RZ12AY-A
Rack, screws, expansion

Art. no. RZ11AY
Rack, plates

INDICATIONS, CONTRAINDICATIONS, WARNINGS AND MRI

INDICATIONS

The TOSCA® Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, and trauma (i.e. fracture or dislocation), spinal stenosis, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

The TOSCA® II Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis and failed previous fusion.

WARNING: The TOSCA® II Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CONTRAINDICATIONS

- Severe osteoporosis, osteopenia and other cases of insufficient bone quality at the site of surgery
- Active infectious processes at the site of surgery
- Surgical conditions which 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 illness, pregnancy, patients in poor general health, lack of patient compliance)
- Allergy or intolerance to implant material
- Cases not mentioned under Indications

WARNINGS

- The spinal implants are intended for single use only and may not be re-used. Re-use can cause implant failure, infections and/or death.
- The attending physician is responsible for establishing the indication, selecting the implant and carrying out the implantation procedure, and must be experienced as well as trained in the requisite surgical technique.
- Implant components and instruments not belonging to the system must not be used.
- Instruments specially developed by SIGNUS are available for application of the implants. These ensure safe application.
- Prior to surgery, ensure that all implants and instruments belonging to the system are sterile and fit for purpose.
- Prior to implantation, examine the implant for integrity and check the given size with the instruments for comparison.
- Before surgery, the patient must be informed of all possible risks and complications that can arise in connection with the intervention itself and from use of the implant, as well as of postoperative behavior.
- The operation must be carried out under fluoroscopy. The correct position of the implant system used must be verified radiographically.
- The plates must only be bent in the zones designated for this purpose. Over-curving, bending back or excessive repeat bending can weaken the plates. The SIGNUS product information brochure contains detailed information on this.
- The implant must not be scratched or notched, as this can lead to a reduction in mechanical stability.
- Prior to wound closure the positioning of all screws in the plate should be checked once again to ensure that they have not loosened.
- All implant components used must be documented in the patient file with item numbers, name and lot number.
- Aftercare must be tailored to the individual patient's requirements and must be determined by the treating physician. After the intervention, the patient should be allowed only very limited physical activity. This applies in particular to the lifting of loads, rotating movements and all kinds of sporting activities. Falls and sudden jerking movements of the spine must be avoided.
- In the postoperative phase, special care must be taken to ensure that the patient is given all the necessary information by the treating physician according to his individual requirements.

MRI SAFETY INFORMATION

Non-clinical trials demonstrated that the TOSCA® implants are 'MRI conditional'. A patient with this implant can be safely examined in an MRI environment that complies with the following criteria:

- Static magnetic field strength of 1.5 T
- Maximum spatial magnetic field gradient of 700 Gauss/cm or less
- Maximum mean whole-body specific absorption rate (SAR) stated by the MRI system of 4 W/kg

Under these examination conditions a temperature increase in the implant of max 3.2°C (1.5 T) can be expected during a continuous examination over 15 minutes.

In non-clinical trials the image distortion caused by the product extended to about 15 mm around the TOSCA® implants when using a gradient echo sequence and a 3 T MRI system.

NOTE

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

SURGICAL TECHNIQUE

1 PREPARATION

Patient positioning

The patient should be placed in a supine position with the head secured in a slightly reclined position on a radiolucent table. The image converter is positioned so that fluoroscopy in both sagittal and frontal planes is possible (Image 1).

NOTE

In the lateral image of the cervicothoracic transition the inferior CS mobile segment may be overlaid by superimposed shoulder soft tissues. Pulling down and fixing the arm in the inferior direction can correctly image the complete examination area.

Approach

The section that is to be implanted is exposed by an anterior approach to the cervical spine using either the Cloward or the Smith-Robinson technique. For the soft tissue retraction, the CERCCESS™ cervical retractor system can be used.

Decompression and vertebral body preparation

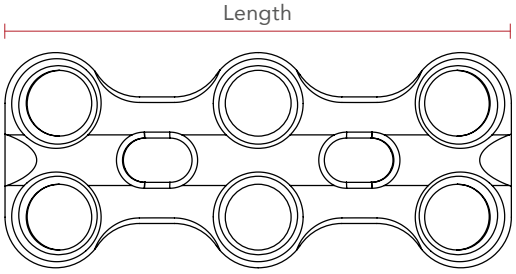
After complete decompression, the anterior section of the vertebral body is carefully smoothed to provide an optimal seat for the plate.

Plate selection and preparation

Place the measuring compass (DZ-0901-B) in the surgical site on the area to be fused (Image 2) and then place it on the reference plate (RZ0001-A) in order to read the required plate length. Please note that the numbers on the plates always refer to their total length (Image 3).

NOTE

When selecting the plate length, care should be taken to ensure that enough distance is maintained to the adjacent intact discs and that the cranial / caudal screw hole pairs are centred in the vertebral bodies.



SURGICAL TECHNIQUE

The implanted plate should have the largest possible contact area with the bone. For this reason, the TOSCA® plates are pre-shaped so that they ideally adapt to the natural lordosis of the cervical spine, therefore enabling them to be implanted without pre-bending in most cases. If it should be necessary to pre-bend the plates, this needs to be performed carefully with the plate bending forceps (DZ-1001-A) in the bending zones intended for this purpose (Image 1).

CAUTION

The plates must only be bent around the zones specifically marked for this purpose. Under no circumstances may the plates 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 TOSCA® expansion screws. The plate bending forceps permit only additional lordosis of the plate. It is not possible to use the instrument to bend the plate back, because forceful bending, but particularly bending the plate back or repeated bending, can weaken the plate.

1

Further lordosis in the intended bending zone (marked in red)

2 IMPLANTATION

Plate positioning

The plate holder forceps are used to place the plate in the desired position in the surgical site and the position is confirmed under visualization. In order to prevent the plate from slipping, the pin screwdriver (RZ0002-H + SN0004) is used to screw fixation pins (RZ1609) into two of the cranial / caudal plate holes and thus attach the plate to the vertebral bodies (Image 2).

CAUTION

The fixation pins are intended for single use only. Repeated use can cause the fine pin tip to break.

2

Screwing in of the fixation pins

Screw hole preparation:

1. Variable-angle insertion of the screws

Use the variable drill guide located in the tray in each case to prepare the screw holes. Along with protecting the tissue, it is used to adhere to the appropriate angular variability of the TOSCA® expansion screw, to centre the entry of the screw into the plate hole and to prevent potential contact of the screws in the vertebral body (Image 3).

Variable drill guide

The variable drill guide (RZ0003-H) is inserted directly into the plate hole and has a stop position that can be felt at 5°, which corresponds to the angular variability of the TOSCA® expansion screw. The drill guide can be used for the following surgical steps:

- Awl use
- Drilling
- Tapping

3

Preparation of the screw hole using the drill guide

SURGICAL TECHNIQUE

OPTIONAL:

Screw hole preparation:

2. Fixed-angle insertion of the screws

The fixed-angle TOSCA® expansion screws have a defined angle of 0° to the plate. This means that the screws of a screw hole pair can converge toward each other in each direction due to the 5° mediolateral bending of the plate and therefore are only available in lengths up to 14 mm. The craniocaudal screw angle depends on the plate's degree of lordosis. To ensure that the screws are seated securely, only the fixed universal guide may be used. The fixed universal guide is inserted into the plate's slots and is held securely in place by means of small "pins" (Image 1).

The following surgical steps can be performed with the fixed universal guide:

- Awl use
- Drilling
- Tapping
- Implantation of the expansion screw

1

RZ0010-H –
Fixed universal guide, double

Awl use

When the awl is used, the entry site of the expansion screw is centred in the plate hole. After placing the variable or fixed universal guide into the plate hole, the awl is inserted into the universal guide. Under visualization the awl is pushed downward while also being rotated to penetrate the cortical bone layer. The awl depth is limited here to a maximum of 8 mm by a depth stop (Image 2).

2

SN0004

RZ0004-H

SURGICAL TECHNIQUE

Drilling

After removing the awl, the drill (RZ0012-H) can be used. This is fitted with an AO connection and is used with the corresponding handle (SN0004). The variable depth stop (CB0086) should always be used when using the drill. This is pushed onto the drill from the back before attaching the handle. The desired drilling depth can be set by pushing the depth stop until the desired depth can be read (Image 1).

1

OPTIONAL:
Tapping

Because the TOSCA® expansion screws are self-tapping, there is no need to tap beforehand. However, if this is still desired, a tap (RZ0013-H / RZ0014-H + SN0004) is available on the instrument tray, which is screwed in up to the desired depth using the universal guide. The markings on the instrument indicate the corresponding depth (Image 2).

2

SURGICAL TECHNIQUE

Implantation of the expansion screw

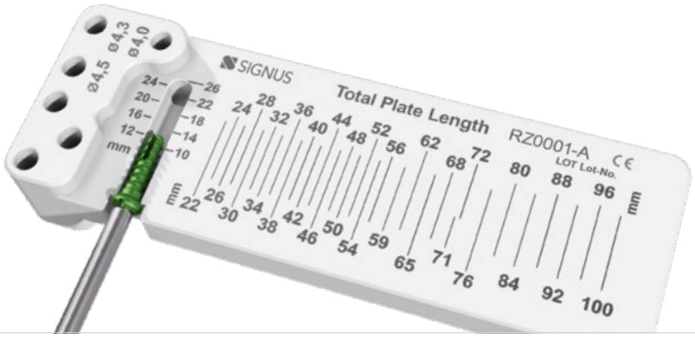
Once the suitable screw has been selected, it is screwed into the vertebral body using the screwdriver (DZ-0840-B) under visualization and spread open.

The reference plate (RZ0001-A) can be used to check the screw length (Image 1).

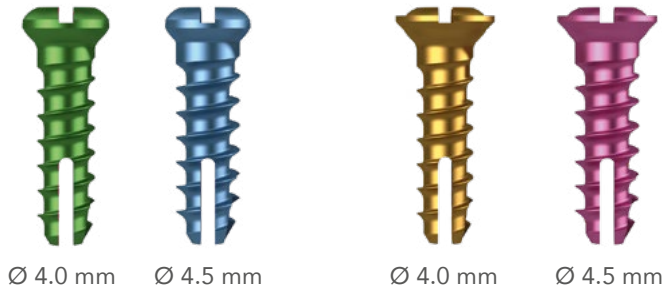
For easier identification, the screws are color coded (Image 2):

- Variable-angle screw, Ø 4.0 mm – green
- Variable-angle screw, Ø 4.5 mm – blue
- Fixed-angle screw Ø 4.0 mm – yellow
- Fixed-angle screw Ø 4.5 mm – magenta

1



2



Using the screwdriver

Insert expansion screw with expansion core

The retaining sleeve (DZ-0842-A) is used with the screwdriver to insert the expansion screw together with the expansion core.

1. Fix screw, including the expansion core, to the instrument

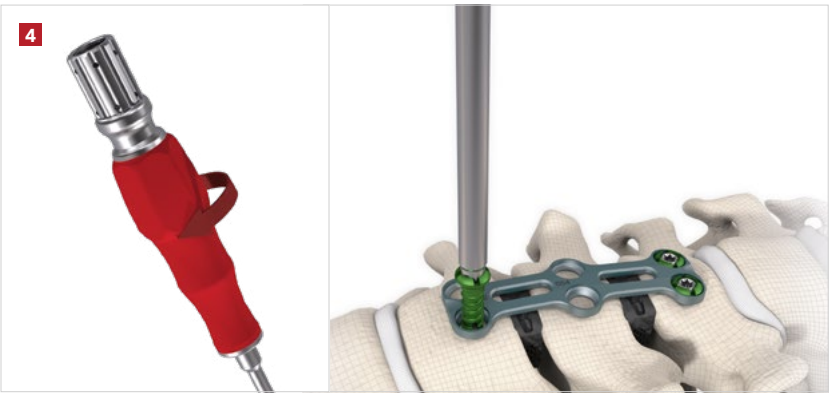
Insert the retaining sleeve (DZ-0842-A) into the screwdriver (DZ-0840) and take up the bone screw including the expansion core by engaging the crown on the proximal end of the screwdriver in the screw head. Then fix the screw by turning the holding sleeve clockwise (Image 3).

3

SURGICAL TECHNIQUE

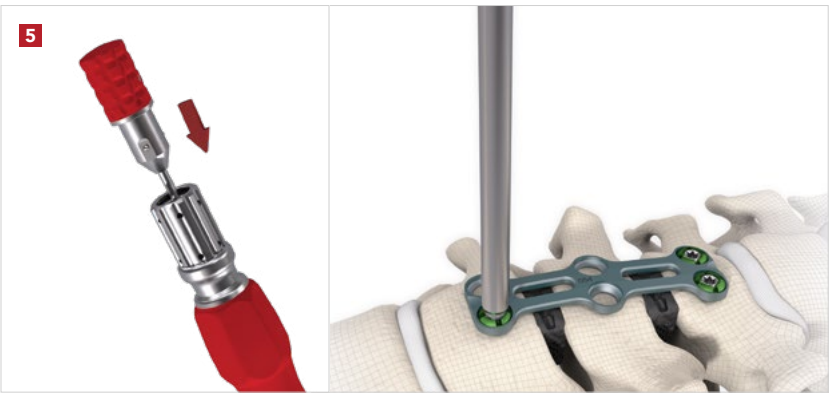
2. Screw the bone screw into the vertebral body

The bone screw is screwed into the vertebral body under radiographic control (Image 4).



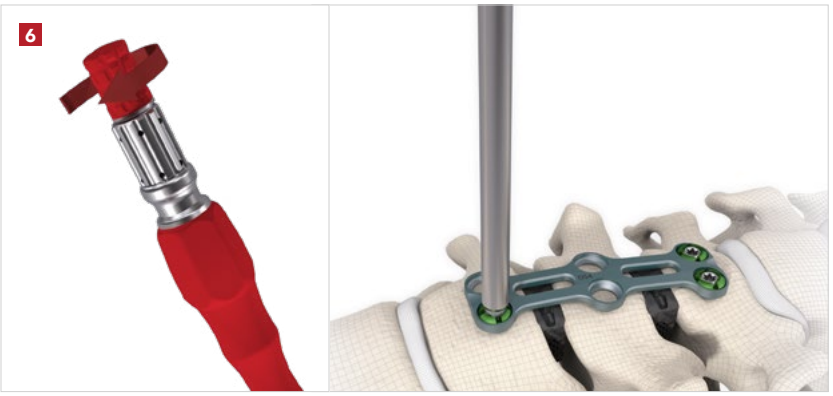
3. Insert the screwdriver for the expansion core through the cannulation

The screwdriver for the expansion core (DZ-0841) is inserted into the retaining sleeve from the back (Image 5).

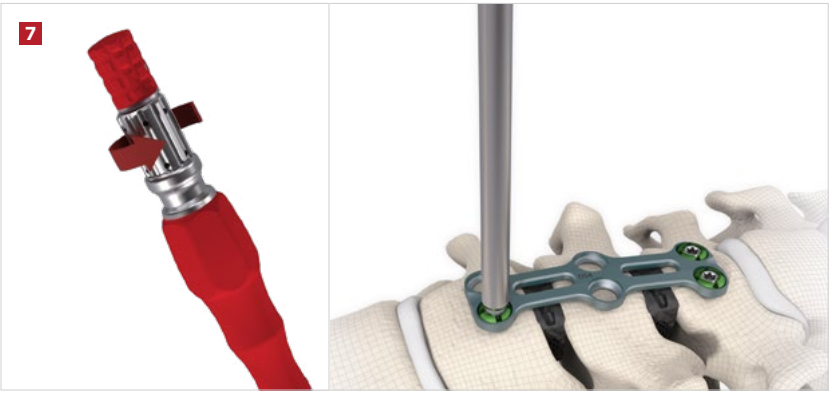


4. Expand bone screw in the vertebral body

The screwdriver for the expansion core is rotated clockwise, causing the expansion core to be screwed forward and thus expand the bone screw (Image 6).



To release the instrument, rotate the retaining sleeve (DZ-0842-A) anticlockwise (Image 7).



SURGICAL TECHNIQUE

OPTIONAL:

Using a connector/graft screw

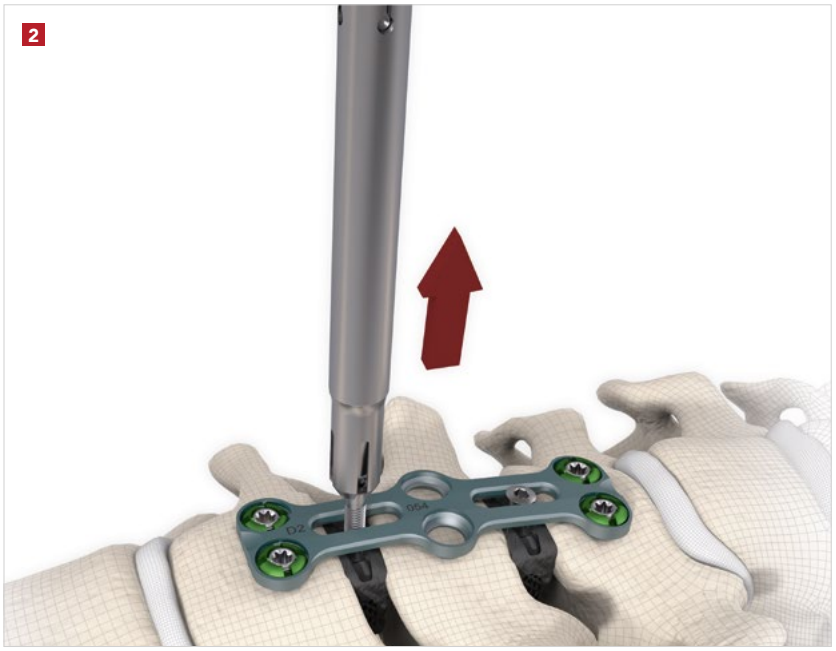
Two different connector screws are available to connect TOSCA® with the cervical SIGNUS vertebral body replacements ATHLET® as well as the disc replacement implants RABEA®, NUBIC® and CYLOX® ST. TOSCA® can also be connected to a bone graft with the help of the cervical bone graft screw.

For insertion, the sterile connector or graft screw is removed from its packaging and placed in the space provided for it in the screw tray. To pick up the screw, slide the retaining sleeve (FZ-1202) over the screwdriver (FZ-1201-H) up to the stop position and place the screwdriver on the screw. The connecting or graft screw is inserted through the middle elongated slot of the plate. By pressing the retaining sleeve downwards, the connector or graft screw is fixed on the screwdriver and can now be screwed into the cage thread/bone graft (Image 1). The retaining sleeve on the screwdriver must be pulled back again for final tightening of the screw (Image 2).

1

Slide the retaining sleeve forward to pick up the connecting screw

2

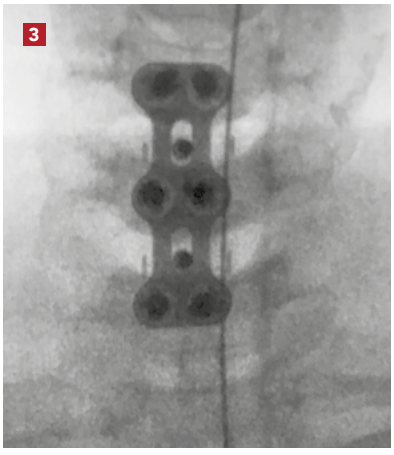


Pull back the retaining sleeve for final tightening

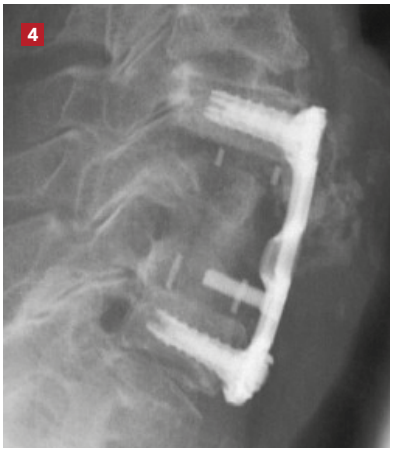
Radiographic check

After implanting all screws, they are checked again to ensure that they are seated properly. Final visualization is performed to document the correct positioning of the TOSCA®. The wound is then closed (Images 3 + 4).

3



4



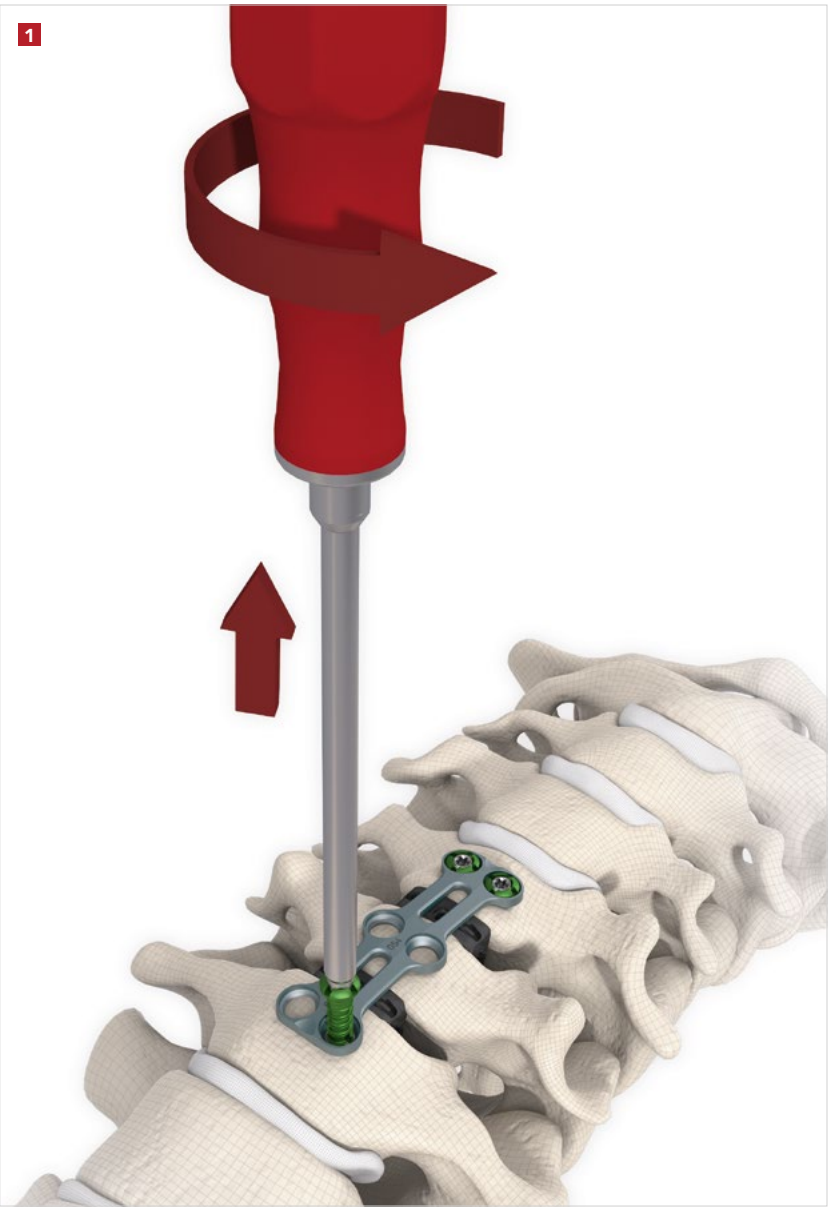
3 REVISION

TOSCA® can be revised, if necessary. Select the described access in section **'1 Preparation'** and prepare the implant. To remove the expansion screws, the expansion core must first be loosened. Only then can the bone screw be unscrewed. To do this, the instruments are used in reverse order, as described in the Section "Using the screwdriver for expansion screws" (p. 16) (Image 1).

CAUTION

Since the implant may have been damaged, do not reinsert the implant after it has been removed from the site.

1



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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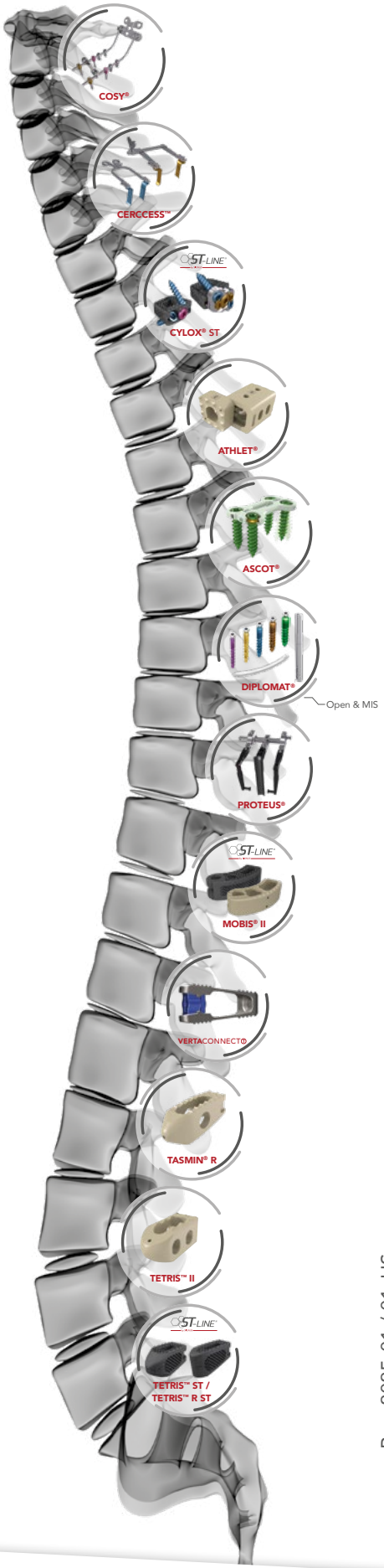

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