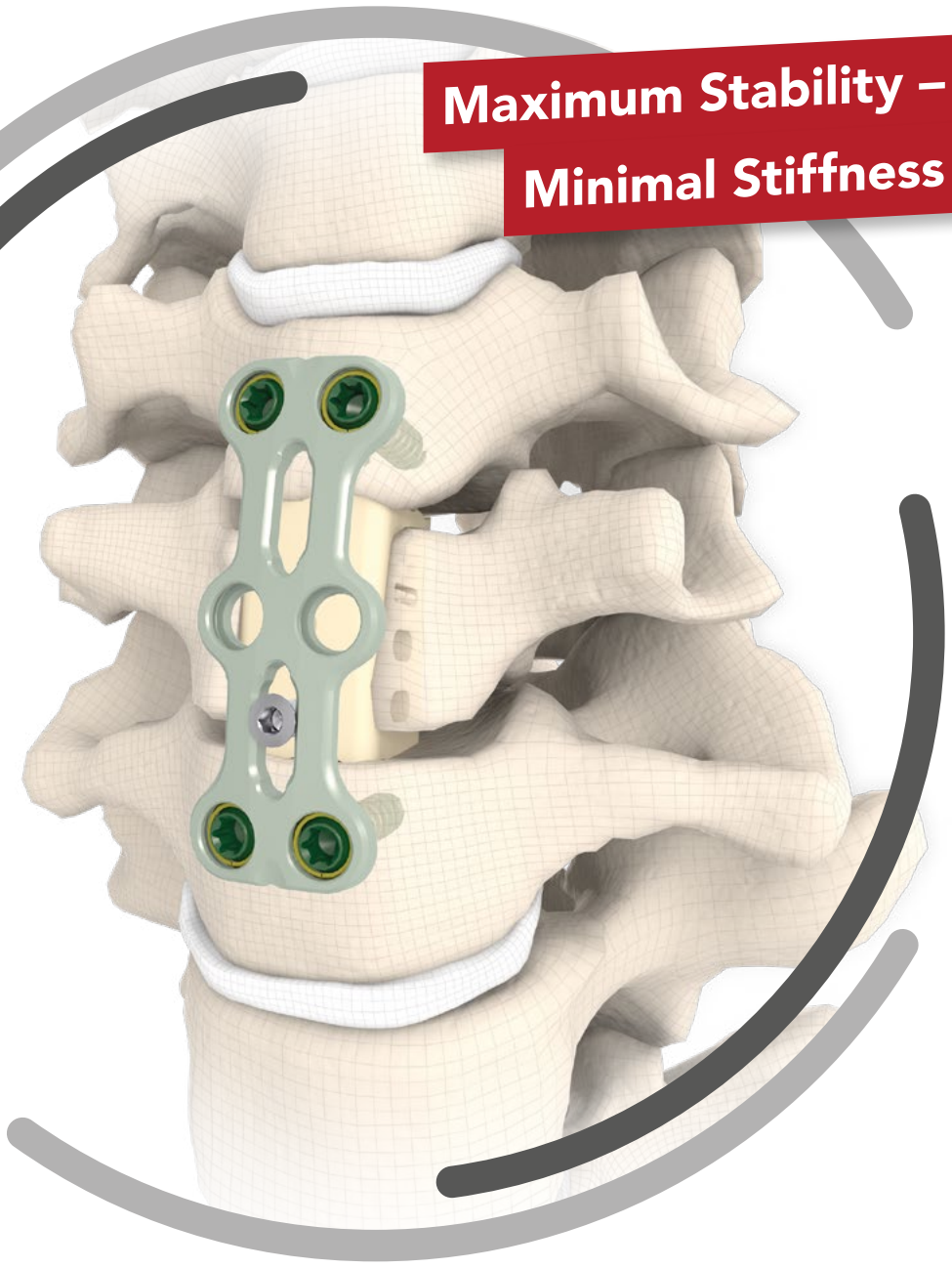
ASCOT®

Anterior Cervical Stabilization

For distribution in the USA only

Maximum Stability – Minimal Stiffness



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:

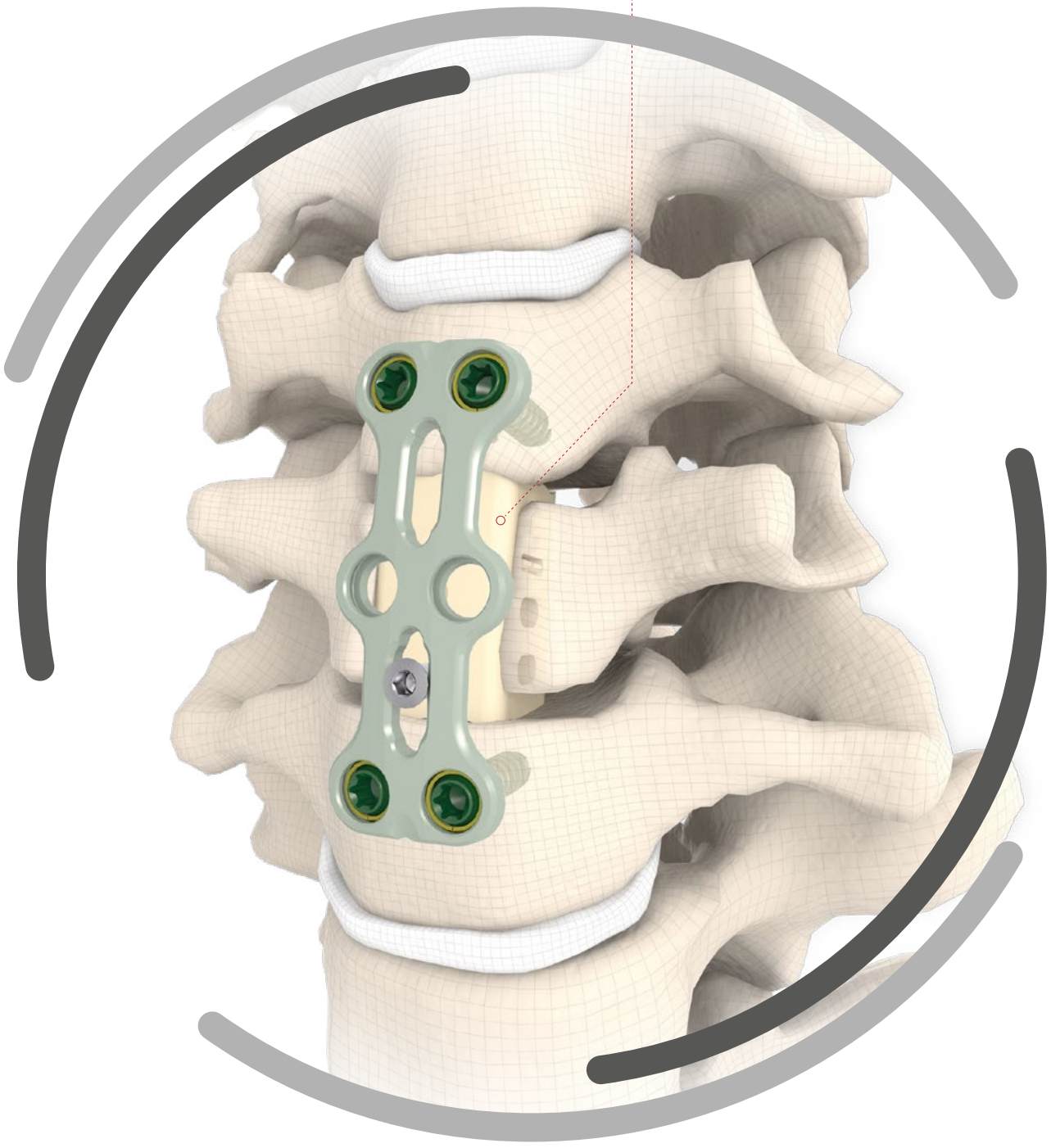
PASSIONATE! DYNAMIC! WORLDWIDE!

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

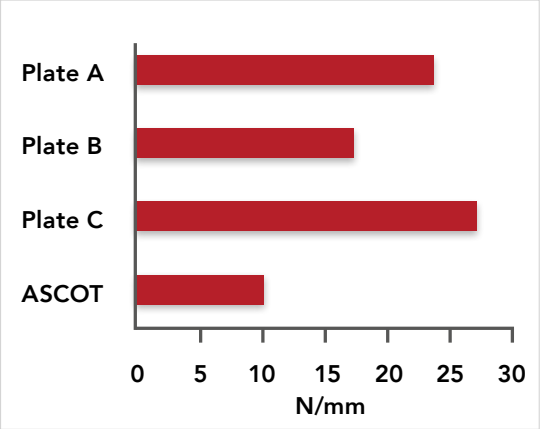
ADDITIONAL PRODUCTS

ATHLET® – The real winner
Cervical Vertebral Body Replacement



CONCEPT

A cervical plate and screw system is used to temporarily stabilize the cervical spine from C2 to C7 during solid stiffening of bone (fusion). The system should be integrated into the biomechanical system of the cervical spine as unobtrusively as possible. ASCOT® achieves this balance between maximal stabilization on the one hand with minimal stiffness on the other. This allows for optimal load transmission onto the bone (Wolff's law), thereby supporting segment fusion.
Thanks to its angular variability, ASCOT® can optimally adapt to the changing anatomic situation over the course of the healing process. An integrated locking mechanism and self-drilling screws enable screw placement and locking in a single step, making the system efficient to handle and safe for the patient.

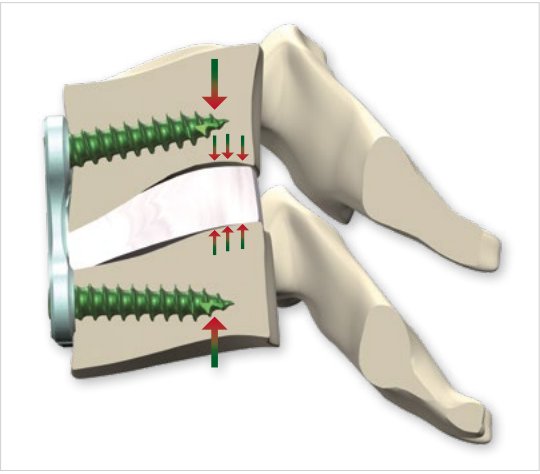


Minimal stiffness for optimal load transmission

IMPLANTS

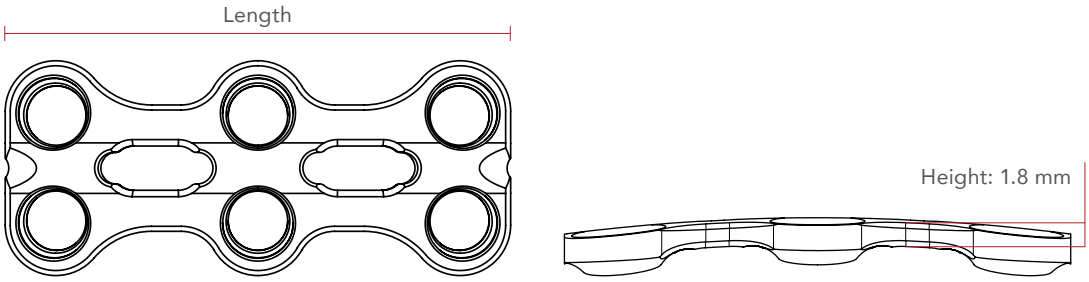
ASCOT® offers the user a high degree of flexibility for ventral stabilization of C2–C7. The pre-lordosed plate is available in different lengths for one to four segment constructs. With a thickness of barely 1.8 mm, ASCOT® is one of the thinnest plates on the market. The self-drilling and self-tapping screws are available in different lengths and diameters both with an angle 10° of angular variability and fixed angle version. In addition ASCOT® can be fixed with a connector screw to the SIGNUS cervical vertebral body replacement implants such as ATHLET®, as well as to a bone graft to ensure a secure construct.

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

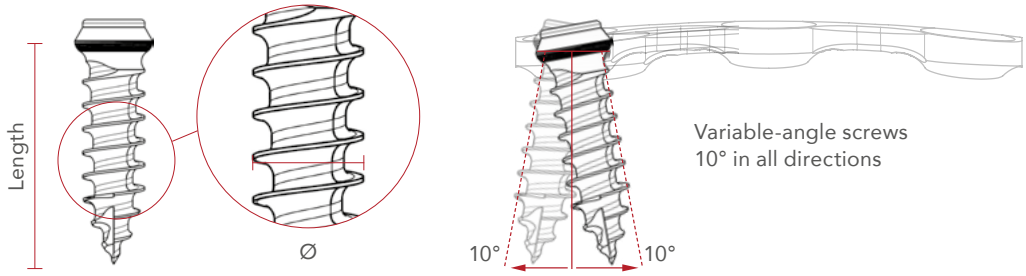

Variable screws support physiological subsidence.

IMPLANTS

Plates			
Description	**Length (mm)**	**Increments (mm)**	**Art. no.**
1-segment plates	22–36	2	H1-022–H1-036
2-segment plates	38–54	2	H2-038–H2-054
3-segment plates	50–71	3	H3-050–H3-071
4-segment plates	68–80	4	H4-068–H4-080



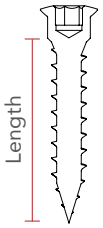
Locking screws				
Description	**Ø diameter (mm)**	**Length (mm)**	**Increments (mm)**	**Art. no.**
Variable-angle screw, self-drilling	4	14–18	2	HB-4014–HB-4018
	4.35	14–18	2	HB-4314–HB-4318



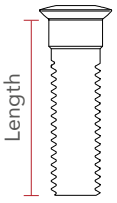
Optional				
Description	**Ø diameter (mm)**	**Length (mm)**	**Increments (mm)**	**Art. no.**
1-segment plate	–	20	–	H1-020
4-segment plates	–	84–100	4	H4-084–H4-100
Fixed-angle screw, self-tapping*	4	14–18	2	HX-4014–HX-4018
	4.35	14–18	2	HX-4314–HX-4318
Cervical graft screw, sterile	2.7	14	–	DC-2714/S[1]
Cervical connection screw VBR, sterile	3	9	–	ATM309[3]

[1] For use with bone graft, [2] For use with ATHLET®

*Article availability upon request



Cervical graft screw



Cervical connection screw VBR (ATHLET®)

PRODUCT-SPECIFIC ADVANTAGES

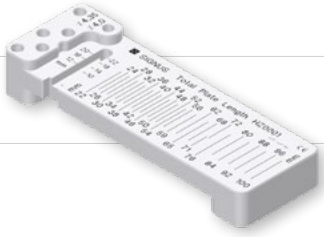
- **Thin, semi-rigid plate design**
  - Minimized stress-shielding effect
  - Optimal load transmission and promotion of fusion (Wolff's law)
  - Support of physiological subsidence ("graft settling")
- **Automatic locking mechanism***
  - Reliable protection from postoperative screw migration
  - No additional surgical step
  - Visible locking for optimal control
- **Wide range of pre-lordosed mono- and poly-segmental plates**
  - Optimal adaptation to patient anatomy
  - In most cases implantable without additional bending
- **Self-drilling variable-angle[1] and self-tapping fixed-angle locking screws**
  - No need for pre-drilling or tapping
  - Wide 10°[1] angular variability
- **Color coding**
  - Simple size identification

** U.S. Patent No.: 7,524,325. Altus Spine*

INSTRUMENTS

Art. no. DZ-0101-A
Plate holder

Art. no. DZ-0901-B
Caliper



Art. no. HZ0001
Template

Art. no. DZ-1001-A
Plate bender

Art. no. RZ0002
Pin driver

Art. no. HZ0003
Variable guide

Art. no. HZ0004-1-B
Punch outer part

Art. no. RZ0004-2-B
Punch inner part

Art. no. HZ0005
Drill with handle
Ø 2.4 mm, 12–22 mm

Art. no. HZ0007
Tap with handle
Ø 4.0 mm, 12–22 mm

Art. no. HZ0015
Screwdriver

Art. no. RZ0030
Cervical handle with AO-connector

INSTRUMENTS

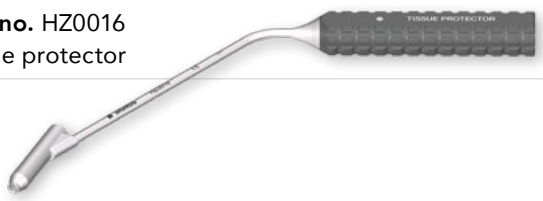
Art. no. HZ0017-1
Revision screwdriver - Outer part

Art. no. HZ0017-2
Revision screwdriver - Inner part

Art. no. HZ0017-4
Revision screwdriver - Ring release

Art. no. FZ-1201-C
Cervical screwdriver hexagon AF2

Art. no. FZ-1202
Cervical screwdriver hexagon AF2, bushing



Art. no. HZ0016
Tissue protector

OPTIONAL

Art. no. RZ1609
Fixation pin, 2x sterile
(for single use)

OPTIONAL

Art. no. HZ0009
Fixed universal guide, right

OPTIONAL

Art. no. HZ0010
Fixed universal guide, left

NOT SHOWN

Art. no. RZ20AY
Instrument tray

Art. no. HZ30AZ
Instrument tray - Insert

Art. no. RZ10AY
Implant tray

Art. no. HZ12AY
Screw caddy

Art. no. RZ11AY
Plate caddy

INDICATIONS, CONTRAINDICATIONS, WARNINGS AND MRI

INDICATIONS

The ASCOT® 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.

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 ASCOT® 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 ASCOT® 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

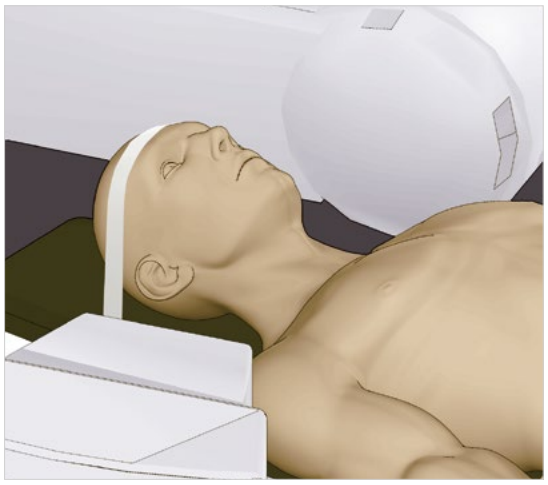
1 PREPARATION

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.

NOTE

The lateral image of the cervicothoracic transition may be overlaid by the inferior CS mobile segment 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

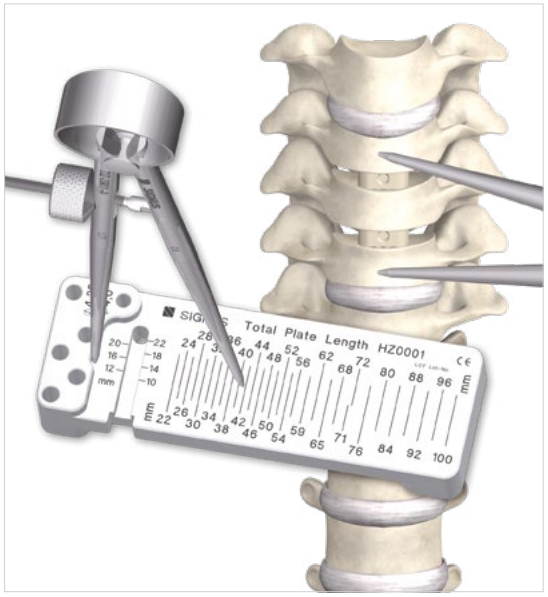
After complete decompression, the anterior section of the vertebral body is carefully smoothed to provide an optimal seat for the plate.

Plate selection and preparation

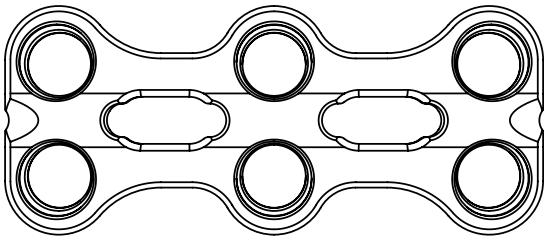
Use the caliper to measure on the vertebrae the required length of the plate and then place it on the template to read the plate length. Please note that the numbers on the plates always refer to their total length.

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.



Length



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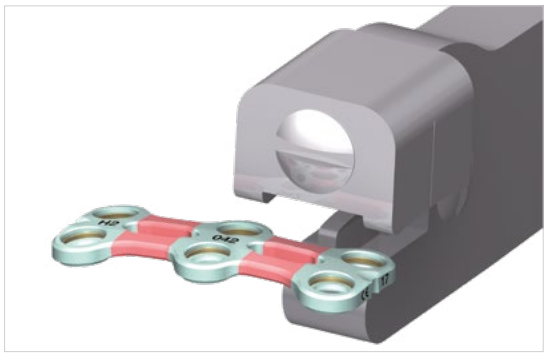
SURGICAL TECHNIQUE

The implanted plate should have the largest possible contact area with the bone. For this reason, the ASCOT® 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 in the bending zones intended for this purpose.

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 ASCOT® locking 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.



Further lordosis in the area indicated (marked in red)

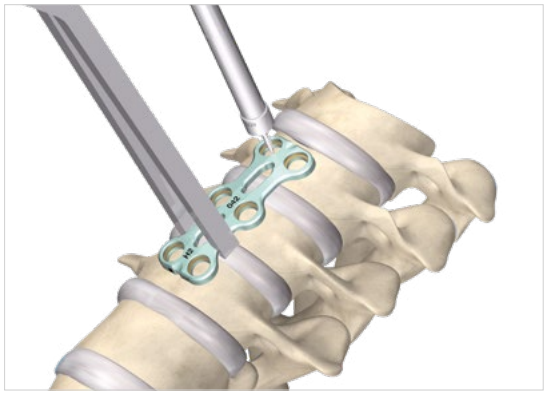
2 IMPLANTATION

Plate positioning

The plate holder is 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 is used to screw fixation pins into two of the cranial/caudal plate holes and thus attach the plate to the vertebral bodies.

CAUTION

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



Screwing in of the fixation pins

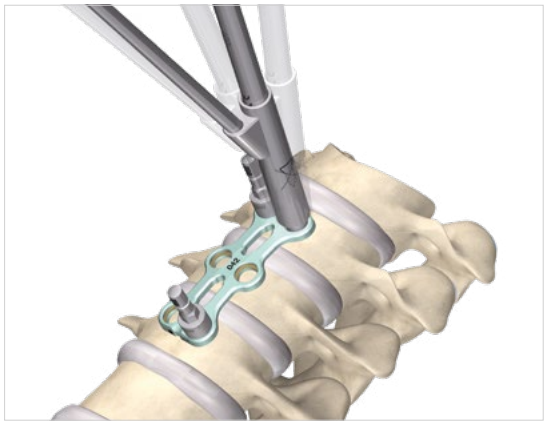
Screw hole preparation

Use the variable universal 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 ASCOT® locking screws, to centre the entry of the screw into the plate hole and to prevent potential contact of the screws in the vertebral body.

Variable universal guide

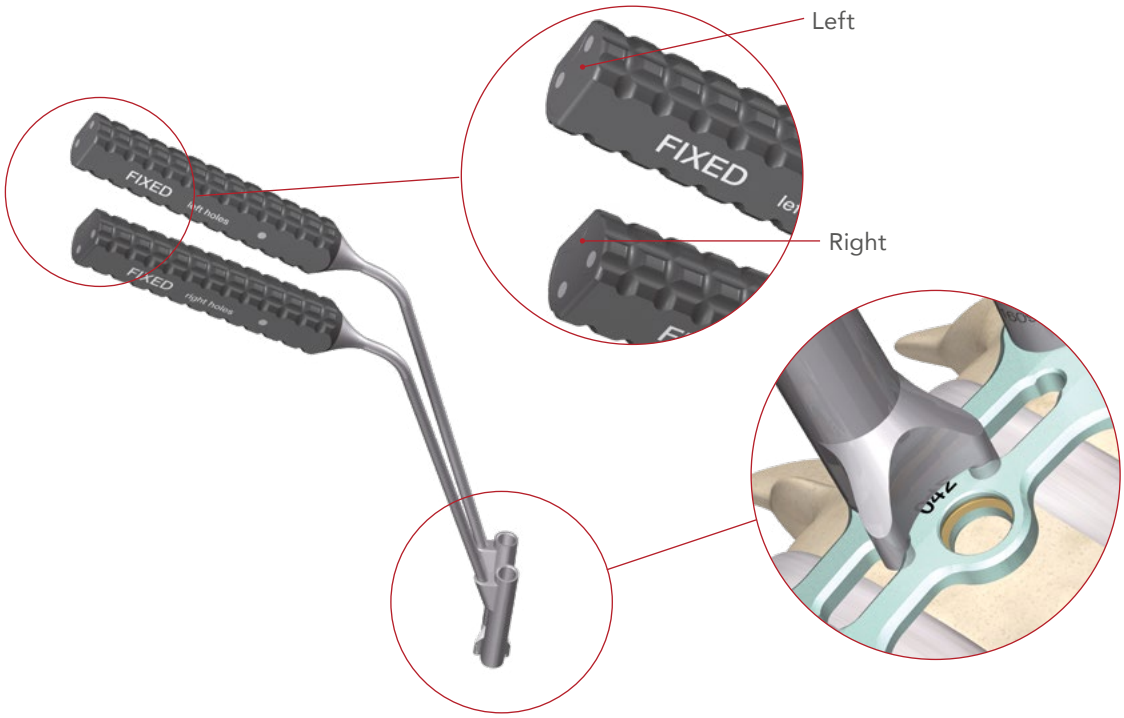
The variable universal guide is inserted directly into the plate hole and has a stop that can be felt at 10°, which corresponds to the angular variability of the ASCOT® locking screws. The guide can be used for the following surgical steps:

- Drilling
- Tapping



Preparation of the screw hole using the guide

SURGICAL TECHNIQUE



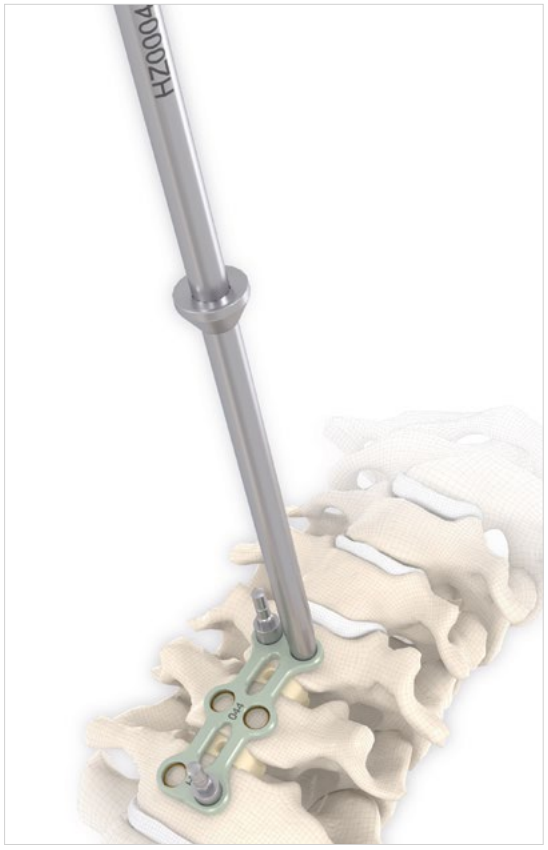
OPTIONAL:
Fixed universal guide

When using the fixed universal guide, the locking screw has 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. The craniocaudal screw angle depends on the plate's degree of lordosis. The fixed universal guide is inserted into the plate's slots and is held securely in place by means of small 'tabs'. The following surgical steps can be performed with the fixed universal guide:

- Punch use
- Drilling
- Tapping

Use of the punch

When the punch is used, the entry site of the locking screw is centred in the plate hole. To penetrate the cortical bone, the punch must be simultaneously pressed down and turned under visualization. The punch has a stop that can be felt at 10° and can therefore be used without a variable guide. The punch depth is limited by a depth stop at a maximum of 7 mm.



Use of the punch

SURGICAL TECHNIQUE

OPTIONAL:
Drilling and tapping

Since the ASCOT® locking screws are self-drilling, it is not necessary to drill or tap the holes. A drill with a handle and a tapper are available on the instrument tray if you wish to perform these steps anyway. These surgical steps must be conducted with one of the guides indicated under visualization. This protects the tissue, and the markings on the instruments display the corresponding depth.

Drill with depth stop

Tapper

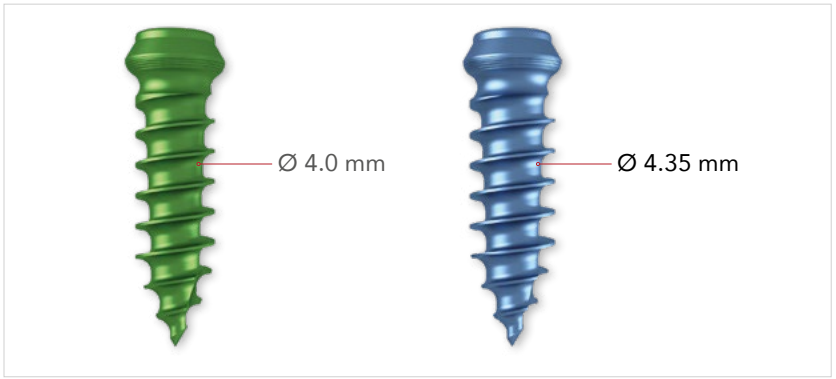
Implantation of the locking screw

Once the suitable screw has been selected, it is removed from the implant tray with the screwdriver.
For easier identification, the screws are color coded:

- Locking screw Ø 4.0 mm = green
- Locking screw Ø 4.35 mm = blue

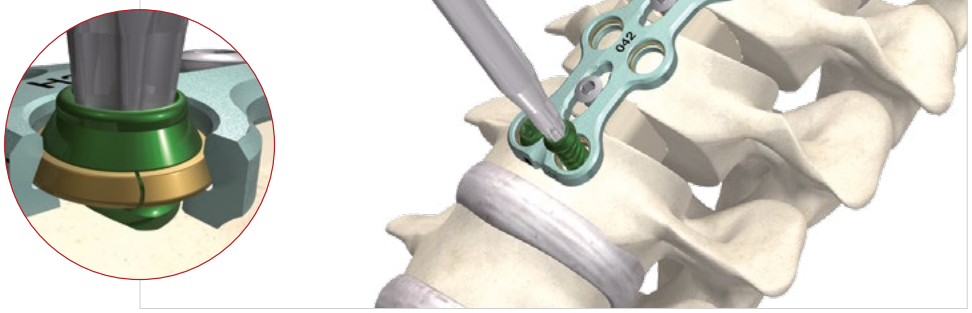
NOTE

The screw lengths listed here refer to the length below the plate (without the head). We recommend that you choose a screw length that penetrates two-thirds of the vertebral body depth.



SURGICAL TECHNIQUE

The screw can now be anchored in the vertebral body under visualization. While the screw is being screwed in, the locking ring is briefly expanded in the plate hole and then contracts back into its original position. This counteracts post-operative screw migration.

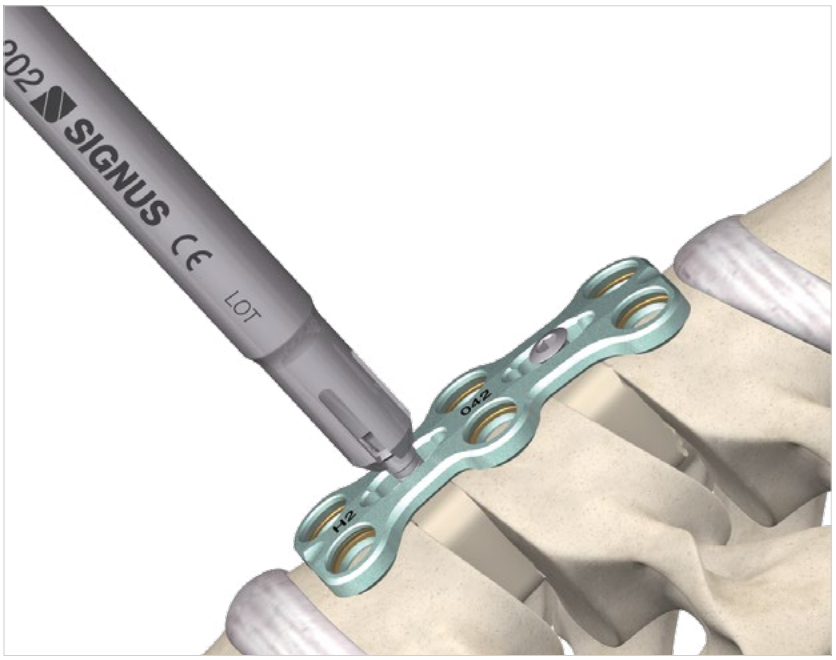


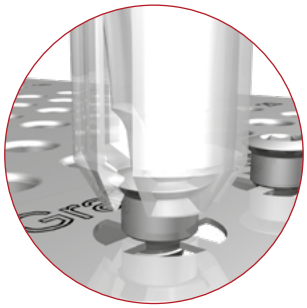
OPTIONAL:

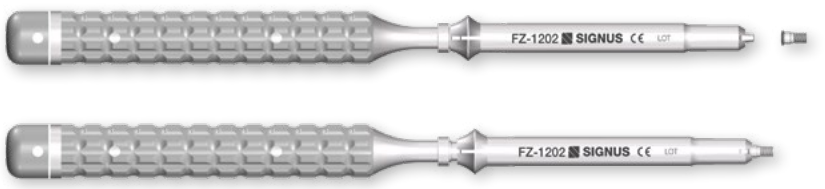
Using a connector / graft screw

Two different connector screws are available to connect ASCOT® with the cervical SIGNUS vertebral body replacements ATHLET®. ASCOT® 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 sleeve over the screwdriver up to the stop and place the screwdriver on the screw. By pressing the sleeve downward, the connector or graft screw is fixed on the screwdriver and can now be screwed into the cage thread / bone graft through the plate slot. The sleeve on the screwdriver must be pulled back again for final tightening of the screw.

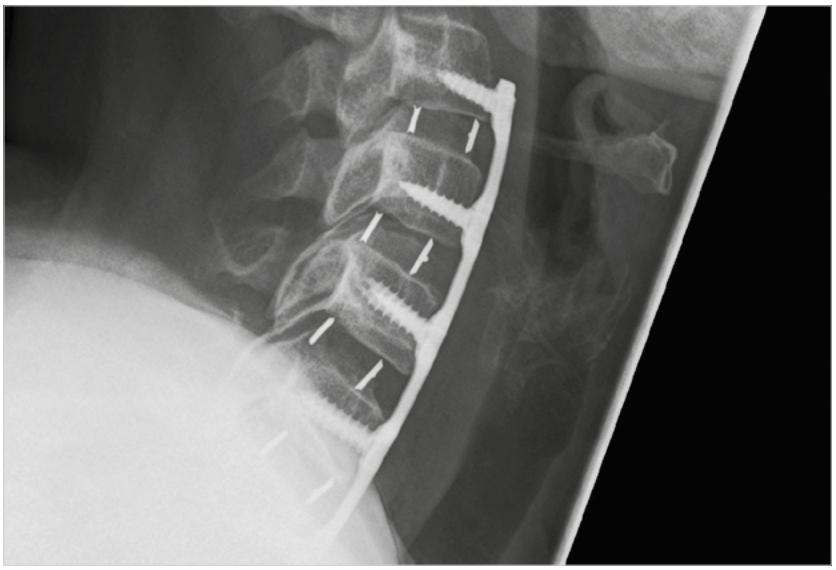






Radiographic guidance

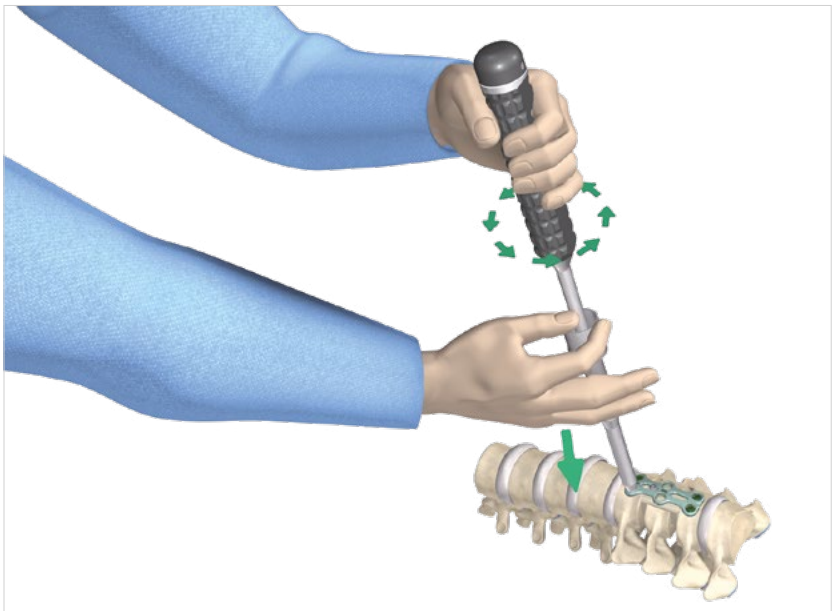
After implanting all screws, they are checked again to ensure that they are seated properly. Final visualization is performed to document the correct positioning of ASCOT®. The wound is then closed.



3 REVISION

If bone quality is good, the screwdriver and the ring release may be used for revision. To this end, slide the ring release onto the screwdriver and place the instrument on the screw. With one hand, press down the ring release and keep it pressed down. Turn the screwdriver to the left in order to unscrew the screw from the vertebral body.

If bone quality is poor, it may not be possible to unscrew the screw due to the absence of bone material beneath the screw. In this case, the revision screwdriver should be used. Its spreadable tip enables it to exert tensile force on the screw that need to be replaced.



SURGICAL TECHNIQUE

The revision screwdriver consists of four parts:

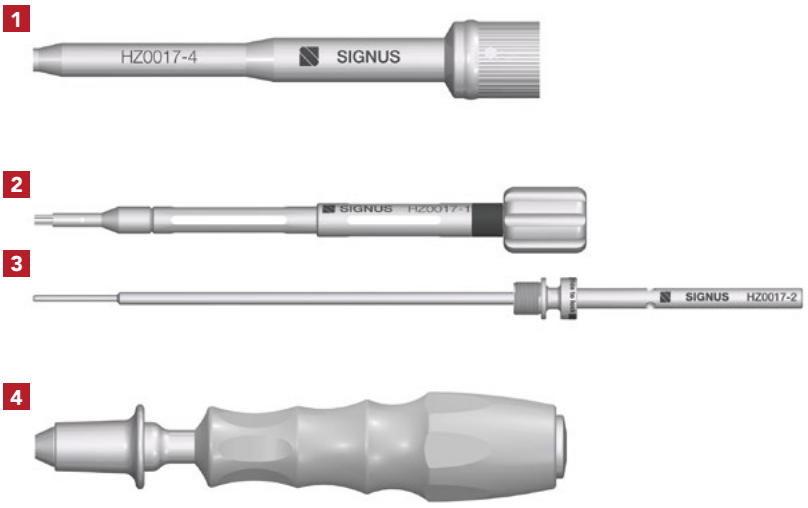
1 Ring release

Presses the locking ring down in the plate hole and releases the screw locking in the process.

2 3 Revision screwdriver

Consists of two parts. When the two parts are screwed into each other, the slotted screwdriver tip spreads apart.

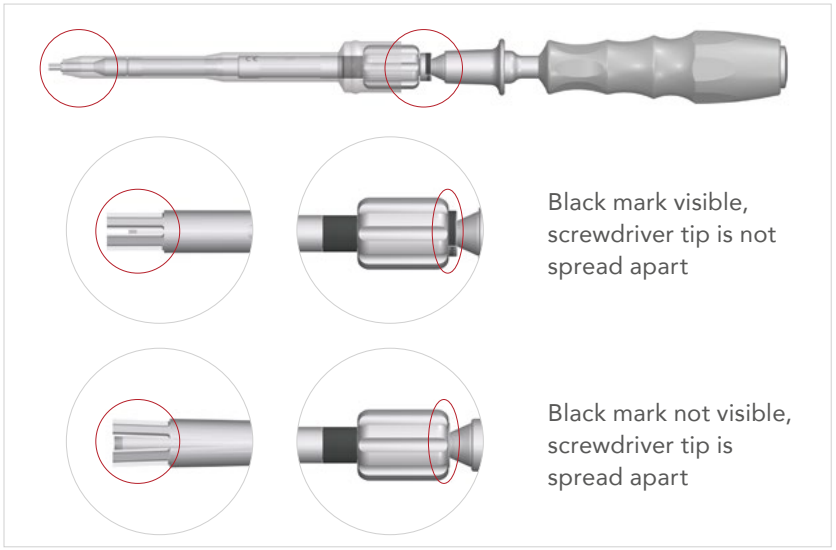
4 Handle

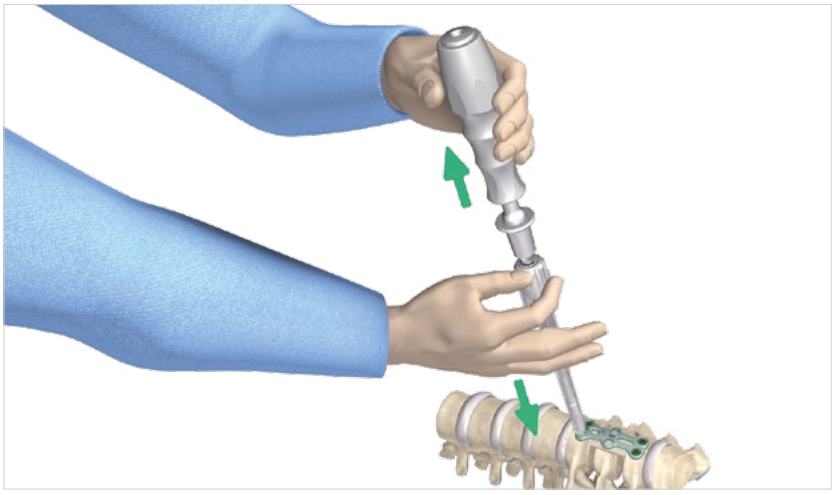


Place the two parts of the screwdriver into each other and screw them together loosely by turning to the left so that the black mark remains visible. Now place the handle on the distal end and slide the ring release at the proximal end over the screwdriver.

Place the revision screwdriver in the screw. Turn the handle to the left until you can no longer see the black mark. The tip of the screwdriver is now spread apart. Be sure to hold onto the outer part of the revision screwdriver while turning in order to prevent it from turning at the same time.

Now press the ring release with one hand and keep it pressed and with the other hand, turn the screwdriver in order to remove the screw from the vertebral body.





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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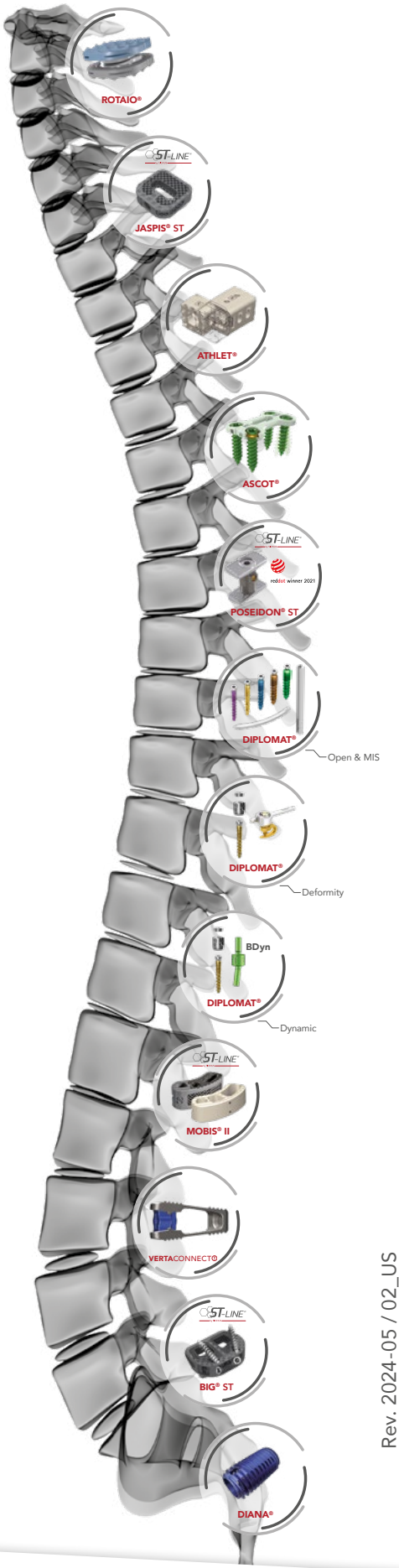

SIGNUS key visual. Not all products are available in the US market and have FDA approval.

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Rev. 2024-05 / 02_US

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