ATHLET®

VBR in PEEK-OPTIMA®

For distribution in the USA only

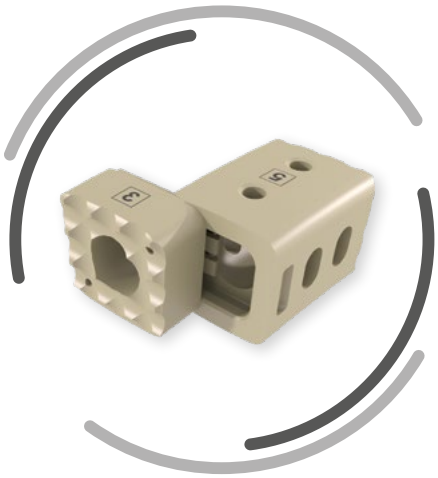
The real winner

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

CONCEPT

A vertebral body replacement requires top performance

- Simple intra- and postoperative control
- Anatomic adaptation
- Economic product concept and simple handling

ATHLET (athlitis = Greek for "the contestant") meets this challenge! Its unique concept combines all required characteristics in one product making it a real winner.

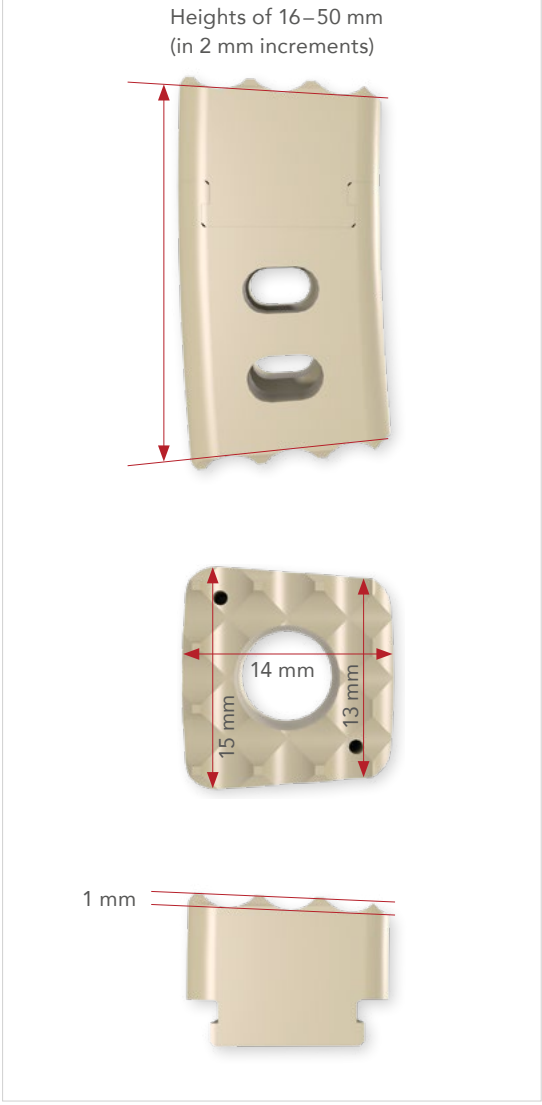
IMPLANTS

ATHLET® is a vertebral body replacement. Along with simple implantation, the large supporting surface and the generous fenestration encourage stability as well as osseointegration of the implant. The lordotic implant angle ensures optimal reconstruction of the natural spinal anatomy.

Nine implant components and four instruments enable both efficiency in the OR and individual patient requirements to be satisfied thanks to fine height gradations of 16 to 50 mm. The simple click mechanism ensures that the implant components are securely fixed.

Material details

PEEK-OPTIMA® is a biocompatible polymer offering a number of benefits for this indication. In its strength it is comparable to cortical bone and due to its excellent MRI compatibility permits artefact-free follow-up examinations. The titanium alloy markers are used with X-ray or CT during and after surgery to check that the implant is correctly positioned.

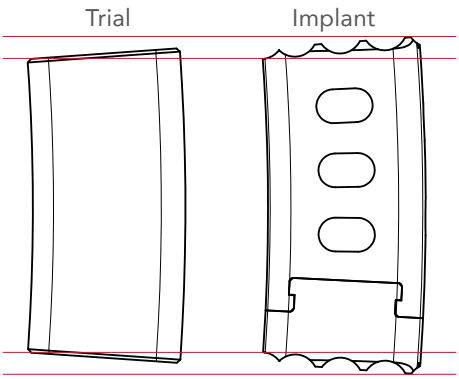


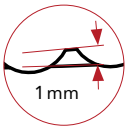
IMPLANTS

Basic body	
Height* (mm)	**Art. no.**
12	AT0412
18	AT0518
24	AT0624
30	AT0730
36	AT0836
42	AT0942

End body	
Height* (mm)	**Art. no.**
4	AT0104
6	AT0206
8	AT0308

Accessories	
Description	**Art. no.**
Connection screw VBR, sterile (L = 9 mm, Ø = 3 mm)	ATM309





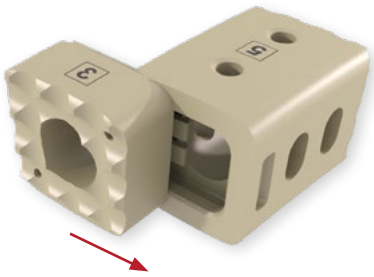
* Implant height without teeth height

All implants are in individual sterile packaging for immediate use.

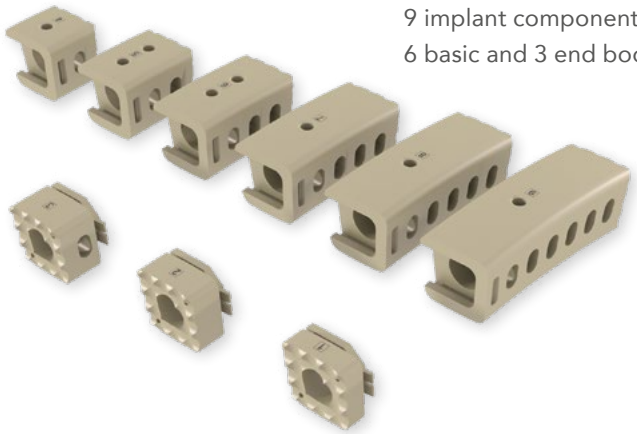
Width: 13 mm (posterior) – 15 mm (anterior)
Length: 14 mm

Just starting out? We'll help you with our clearly arranged starter kit: your mobile storehouse with all implant components.

1 treatment = 1 basic body + 1 end body



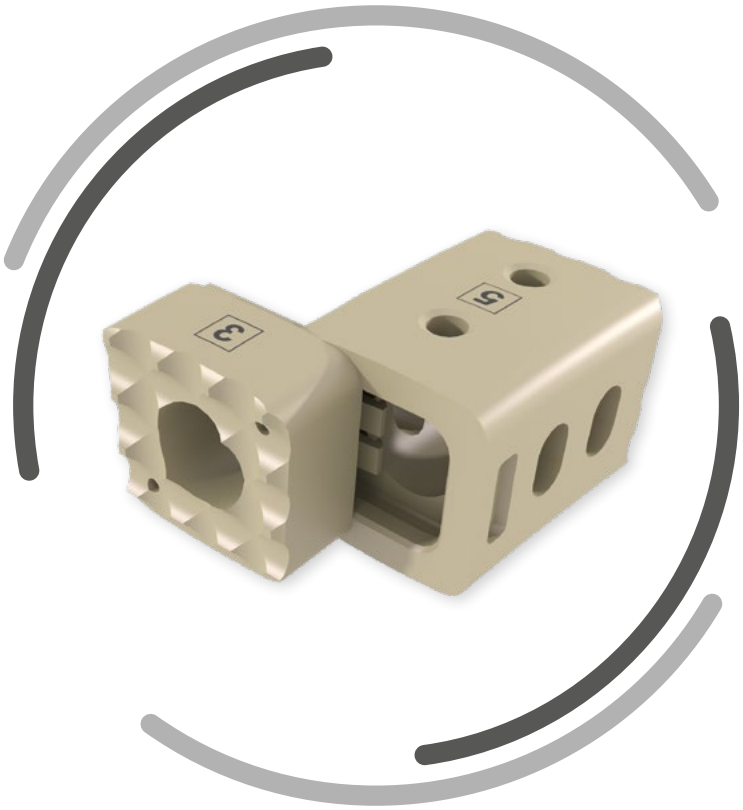
Click mechanism for secure fixation of the implant components



9 implant components, 18 heights: 6 basic and 3 end bodies

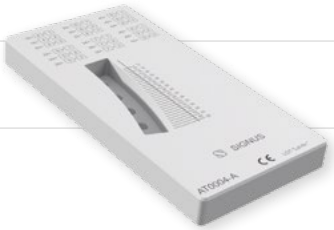
PRODUCT-SPECIFIC ADVANTAGES

- **Manufactured from PEEK-OPTIMA®**
  - Easy positioning and postoperative control
- **Lordotic angulation**
  - Natural reconstruction of the spine
- **Generous implant fenestration**
  - Optimal provision for bony in-growth
- **Large contact area, toothed endplates**
  - High primary and secondary stability
- **Heights from 16–50 mm**
  - Applicable for a broad range of indications and patient anatomies
- **Clearly arranged instrumentation**
  - Easy handling reduces the risk of complications



INSTRUMENTS

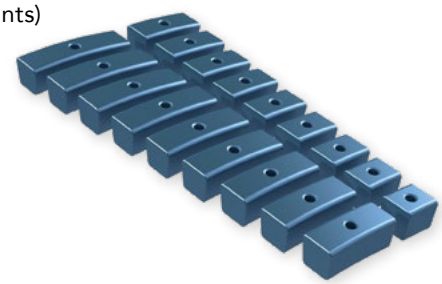
Art. no. AT0004-A
Template



Art. no. AT1100
Inserter for trials

Art. no. AT0003
Disconnector

Art. no. AT1016–AT1050
Trial 16–50 mm
(2 mm increments)

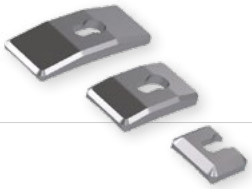


Art. no. AT0001
Inserter

Art. no. AT0005
Inserter plate small
(for basic bodies with 12 mm and 18 mm height)

Art. no. AT0006
Inserter plate medium
(for basic bodies with 24 mm and 30 mm height)

Art. no. AT0007
Inserter plate large
(for basic bodies with 36 mm and 42 mm height)



NOT SHOWN

Art. no. AT01AZ
Tray for inserter plates

Art. no. GB0002
Positioner

Art. no. AT001AY
Instrument tray

Art. no. AT002AY
Tray for Trials

INDICATIONS, CAUTION AND CONTRAINDICATIONS

INDICATIONS FOR USE

The ATHLET™ VBR System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The ATHLET™ VBR System is intended for use with supplemental fixation and should be implanted in pairs.

CAUTION

- These implants are intended for single use only and should not be re-implanted.
- Federal law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS

- Advanced osteoporosis
- Specific metal allergy (Titanium Only)
- Infection

NOTE

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

SURGICAL TECHNIQUE

1 PREPARATION

Preoperative planning

The extent of the resection and therewith the height of the vertebral body replacement can be estimated as usual with the preoperative radiographs and CT /MRI scans.

Performing the corpectomy and preparing the endplates

After preparation the corpectomy is performed. To achieve an optimal fusion result the exposed vertebral body endplates are cleaned carefully.

CAUTION

Avoid excessive cleaning or complete removal of the cortical bone. This may weaken the endplates which leads to an increased risk of implant subsidence into the adjacent vertebral bodies.

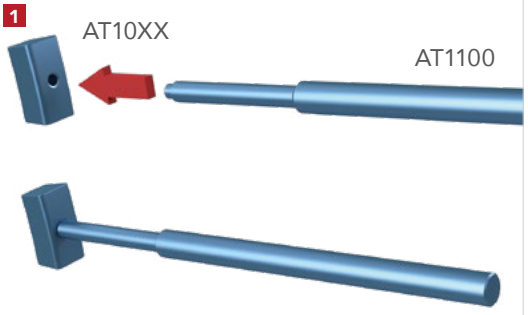
2 IMPLANTATION

Determining the implant height

To determine the height, use the Trials (AT1016–AT1050). Attach the Trial to the Inserter (AT1100) (Image 1) and carefully insert it into the defect under lateral fluoroscopy.

The Trial must be seated firmly in the intervertebral space. To verify this try to pull the Trial out after release of the distraction. If the Trial is seated loosely or can even be withdrawn, then the next greater height must be selected.

1



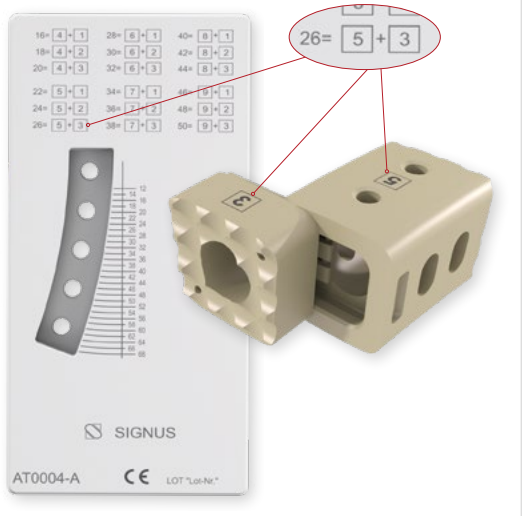
Assembly of the implant components

For simple identification all implant components are provided with a number from 1 – 9 (according to the height). On the Template (AT0004-A) you will find an overview of all the heights that can be bridged with ATHLET® and the implant combinations to achieve these heights (Image 2).

Assemble the main body and end body required for the construct.

The implant components are connected together by a latch mechanism that engages with an audible click.

2



SURGICAL TECHNIQUE

Disassembly of the implant components

The connected implant components can only be disassembled with the Disconnector (AT0003). Hold the instrument with the labeling upwards. Place the implant between the jaws of the instrument so that the protrusion fits into the window below the latch mechanism. By pressing the release button, the implant components are separated from each other (Image 3).

CAUTION

Ensure the implant is correctly oriented during the disassembly process otherwise the implant can be damaged.

3

Distraction and implantation

Distract the spinal segment to the desired height with a suitable spreader. Select the appropriate Inserter Plate (AT0005, AT0006, AT0007) for the implant and slide this onto the tip of the Inserter (AT0001). The implant heights and the corresponding Inserter Plates are listed in the instrument description.

4

Assembly

1. Place the tip of the Inserter into the wide portion of the opening in the Inserter Plate (Image 4)
2. Make sure that the slot in the tip of the Inserter is aligned as shown (Image 5)
3. Push the tip of the Inserter into the narrower opening of the Inserter Plate (Image 6)

The assembled implant is threaded onto the Inserter by rotating the blue thumb wheel.

The vertebral body replacement ATHLET® can now be introduced into the situs of the patient. The final position of ATHLET® has been reached when the Implant is flush with the ventral edge of the vertebral body and does not protrude into the spinal canal. The insertion of the implant is performed under imaging control.

5

NOTE

To improve the fusion result it is recommended to place bone graft and/or a bone substitute into and around the implant.

6

Additional fixation

As with all vertebral body replacements, ATHLET® requires supplemental fixation.

3 REVISION

ATHLET® can be revised, if necessary. Select the described approach in section **"1 Preparation"** and prepare the implant. To remove the implant, reattach it to the inserter.

CAUTION

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

NOTES

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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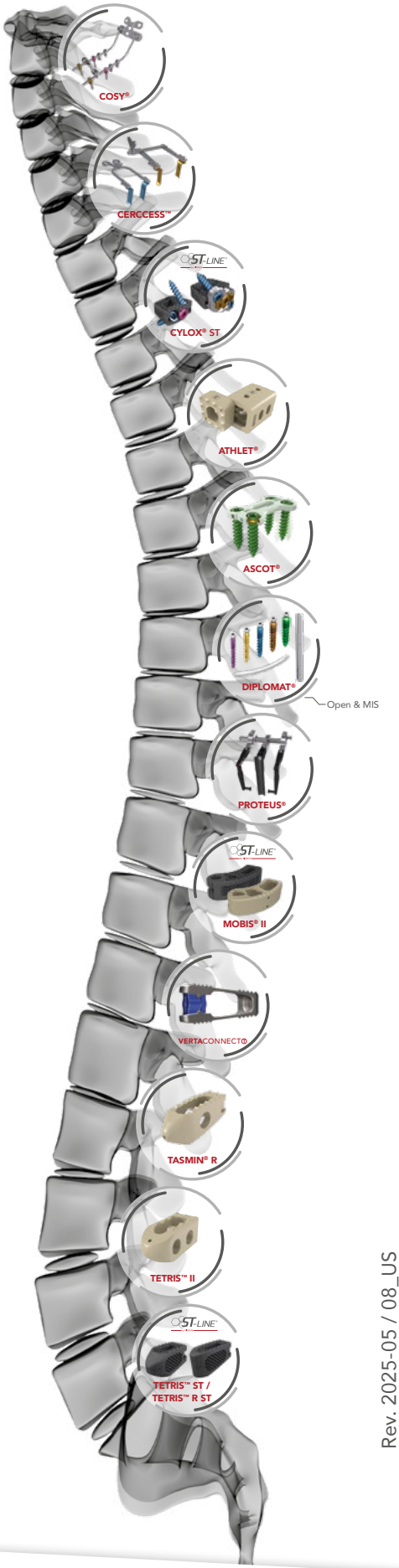

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