WOMBAT®

ST and PEEK – Transforaminal Lumbar Interbody Fusion

Easy implantation – maximum support

HIGH-END MADE IN GERMANY

www.signus.com

SIGNUS The Spine Sign®

SIGNUS Medizintechnik GmbH thanks the following surgeons for their collaboration:

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University Hospital Greifswald

Dr. Frank Hassel
Loretto Hospital Freiburg

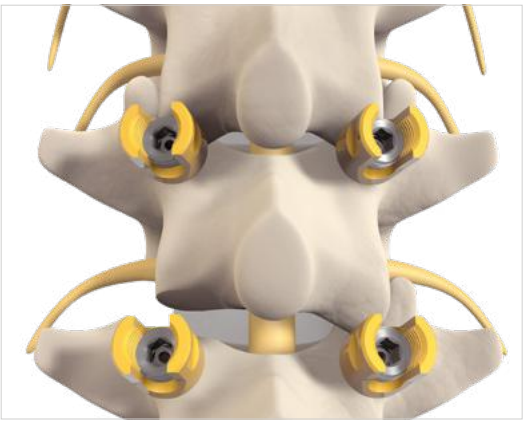
Dr. Frank Schröder
Hans-Susemihl Hospital Emden

CONTENT

Concept	4
Implants	4
Product-specific advantages	7
Instruments	8
Indications, contraindications and cautions	9
Surgical technique	10
1 Preparation	10
2 Implantation	11
3 Revision	14
Notes	15

CONCEPT

Due to protection of the spinal canal and the stabilizing posterior structures, the transforaminal fusion technique has meanwhile become increasingly widespread. With WOMBAT, we offer a TLIF implant that, by contrast to the classic banana-shaped cages, is positioned diagonally in the intervertebral space. Bilateral support is thereby achieved in spite of the unilateral access - and that with in just one surgical step!



IMPLANTS

Besides the simple implantation technique, the bone-implant contact area and the filling volume can in addition be maximized by utilization of the entire diagonal diameter of the vertebral body.

The large fenestration in the implant permits the cage to be packed with natural or synthetic bone graft substitute such as KAINOS® Inject.

Due to its biconvex design, the implant can be aligned perfectly with the curvature of the vertebral body and so is ideally suited for unilateral, posterior access (TLIF) in the L1-S1 region of the spine.

Combined with an additional posterior instrumentation and toothed endplate, the inserted cage ensures high primary stability and optimal conditions for vertebral body fusion.

Restoration of the intervertebral space can be guaranteed by a large selection of implants that at the same time offer a high degree of intraoperative flexibility. In addition to plane-parallel implants, the WOMBAT cage is also available with a 6° lordotic angle.

IMPLANTS

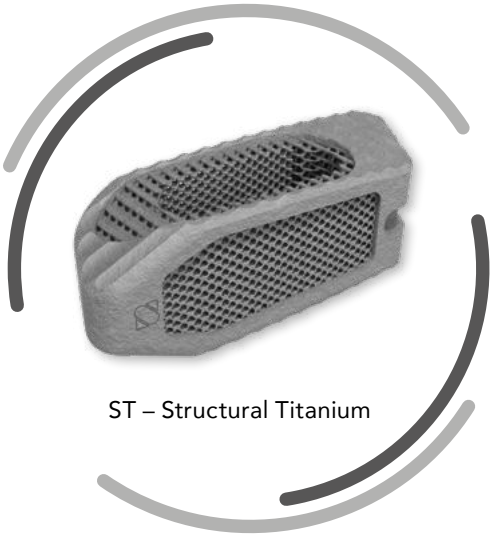
WOMBAT ST

The implant is made of the proven material titanium (Ti6Al4V).

"ST" Structural Titanium - is an open-pore titanium grid structure with anatomic parameters designed to optimize intercorporal fusion.

The structured interior with defined porosity offers the bone an ideal "anchor" for ingrowth of blood vessels and bone cells.

With good to excellent fusion results, porous implants have become established as the gold standard for endoprosthetics.[1] With our WOMBAT ST fusion implant, we are now building on these results for use in the spine. WOMBAT ST consists of a titanium grid structure that, with its defined pore design, imitates the architecture of natural bone. The interconnectivity of the pores ensures optimal oxygen and nutrient supply, creating an optimized basis for bony ingrowth. The implant also offers more room for fusion, with 70 % of WOMBAT ST consisting of pores. The roughness of the implant - in addition to its proven SIGNUS teeth design - optimizes the primary stability and counteracts migration of the implant. In addition, the lateral surfaces are embedded in a smooth frame in order to keep the amount of preparation needed low and to protect the nerval structures during implantation.

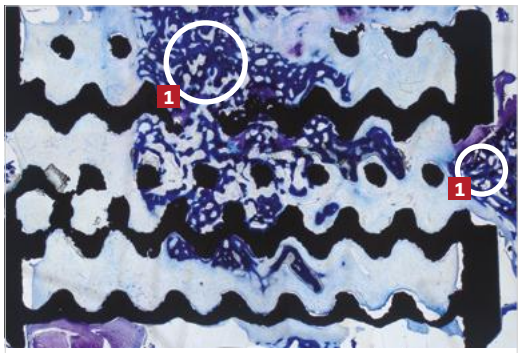


ST – Structural Titanium

ST-LINE ADVANTAGES

- **Greater contact area thanks to defined surface topology**
  - Secure anchoring in the bone owing to high primary stability
  - Reduced risk of implant migration
- **Open, macroporous titanium structure**
  - Resembles natural cancellous architecture
  - Enables not only growing-on, but also growing-in of bone
- **70 % pores**
  - Little foreign material - more room for fusion
  - Artifact-free postoperative imaging

Further information on the ST Line can be obtained from the product information or your SIGNUS representative.



Microscopic histological image of the cross-section of a structured titanium implant removed from an ovine model after 12 weeks. In the pore volume of the diamond grid structure of the implant, there is evidence of the formation of a large area of spongiosa bone structure 1, extending from the central area of the cross-section to the superior margin. (Histological findings from a formalin-fixed titanium lattice cage removed from an ovine model; Foundation: Hannover Veterinary Medicine School)

WOMBAT PEEK

PEEK-OPTIMA® is a biocompatible polymer offering a number of benefits in such indications. In its strength it is comparable to cortical bone and due to its excellent MRI compatibility permits artifact-free imaging.

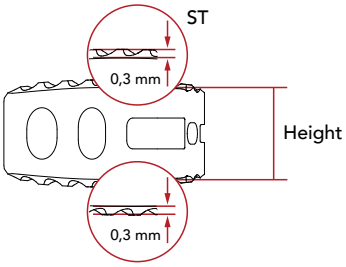
PEEK-OPTIMA

1 Rader CP; Hendrich C; Löw S; Walther M; Eulert J. Unfallchirurg 103, 846-852, 2000. Selmitsch M. In: Zweymüller K (Hrsg): 10 Jahre Zweymüller-Hüftendoprothese; S. 14-19, 1990

IMPLANTS

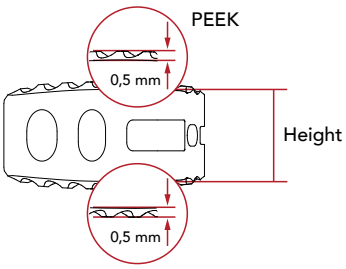
WOMBAT ST

	0° Lordosis		6° Lordosis	
Height (mm)	Length 32 mm	Length 36 mm	Length 32 mm	Length 36 mm
7	KUL000732	KUL000736		
8	KUL000832	KUL000836	KUL060832	KUL060836
9	KUL000932	KUL000936	KUL060932	KUL060936
10	KUL001032	KUL001036	KUL061032	KUL061036
11	KUL001132	KUL001136	KUL061132	KUL061136
12	KUL001232	KUL001236	KUL061232	KUL061236
13	KUL001332	KUL001336	KUL061332	KUL061336



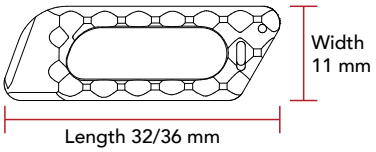
WOMBAT PEEK

	0° Lordosis		6° Lordosis	
Height (mm)	Length 32 mm		Length 32 mm	
7	KU000732			
8	KU000832		KU060832	
9	KU000932		KU060932	
10	KU001032		KU061032	
11	KU001132		KU061132	
12	KU001232		KU061232	
13	KU001332		KU061332	



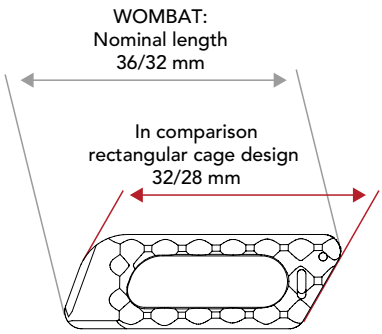
All implants are in individual sterile packaging for immediate use.

Width: 11 mm
Additional sizes available upon request.



Define the correct WOMBAT size

	WOMBAT	Rectangular design
Length (mm)	32	28
	36	32



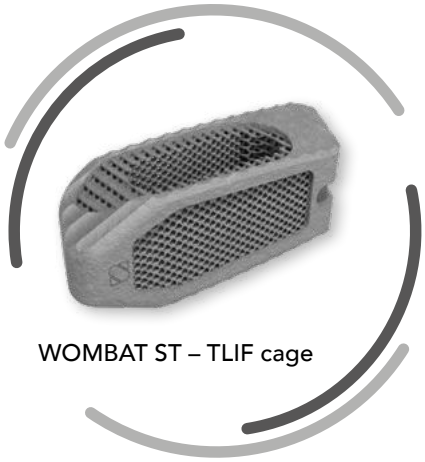
Just starting out? We'll help you with our clearly arranged starter kit: your mobile storehouse with all implant components.

You will be supplied with the implants at your hospital in a clearly arranged starter kit containing the standard portfolio.

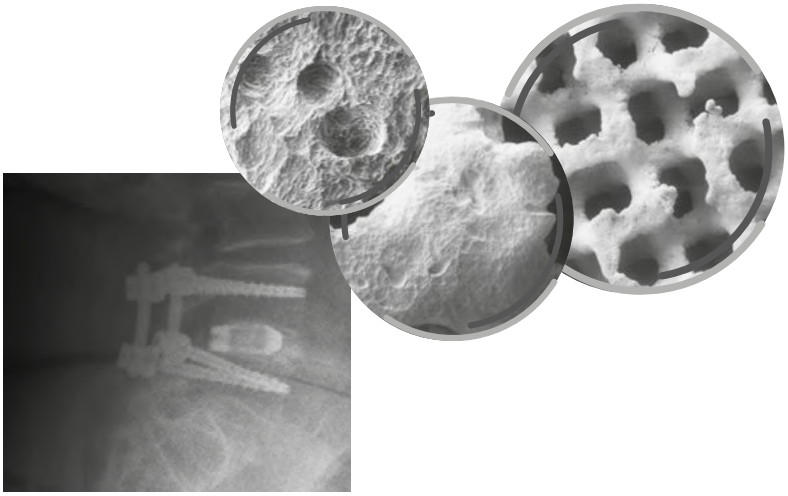
PRODUCT-SPECIFIC ADVANTAGES

- **Diagonal implant placement**
  - Easy and rapid implantation in a single surgical step
  - No complicated turning of the implant as needed for banana-shaped cages
- **Flattened implant apex**
  - Easier implantation with self-distracting design
  - No removal of the posterior edges of vertebral bodies
- **Large contact area with the vertebral body**
  - Secure implant positioning
  - Reduced risk of subsidence
- **Biconvex design with or without lordosis**
  - Anatomical adaptation in the intervertebral space
  - Optimal restoration of the sagittal alignment
- **Smooth lateral surfaces**
  - Less preparation required
  - Protection of nerve roots
- **Open, macroporous titanium structure***
  - Resembles natural cancellous architecture
  - Enables both growing-on and growing-in of bone
- **Increased roughness* in conjunction with proven SIGNUS toothed cage design**
  - Secure anchoring in the bone owing to high primary stability
  - Reduced risk of implant migration

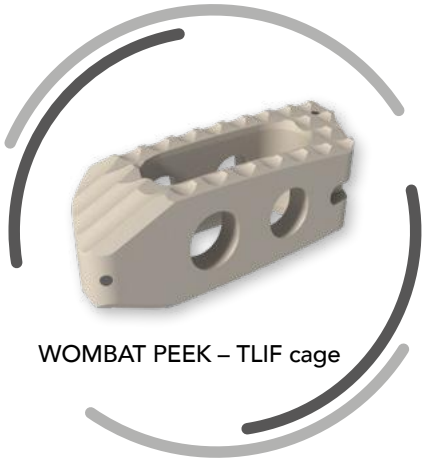
**Only related to WOMBAT ST*



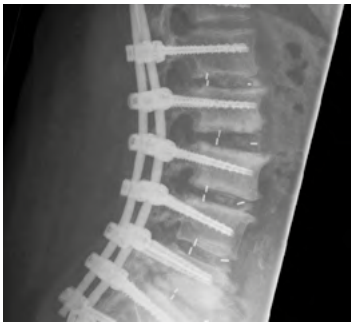
WOMBAT ST – TLIF cage



A perfect team:
WOMBAT ST and DIPLOMAT

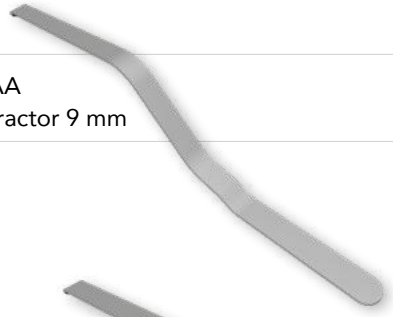


WOMBAT PEEK – TLIF cage

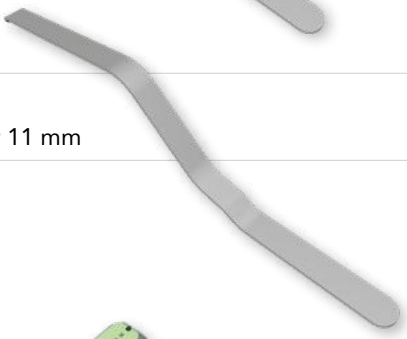


A perfect team:
WOMBAT PEEK and DIPLOMAT

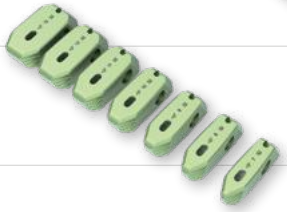
INSTRUMENTS



Art. Nr. P041AA
Nerve root retractor 9 mm



Art. Nr. P042AA
Nerve root retractor 11 mm



Art. Nr. KC000732 - KC001332
Trials 32 mm, 0°, 7-13 mm

Art. Nr. KC0003
Graft loading platform

Art. Nr. T029AHA
Graft impactor with base plate

Art. Nr. KC0001
Inserter

Art. Nr. KC0002
Positioner

Art. Nr. T003AQ
Slotted mallet

Art. Nr. T240AH
Slap hammer

Art. Nr. 500012
Release instrument

NOT SHOWN
Art. Nr. KC01AY
Instrument tray

Art. Nr. KC02AZ
Trial tray

OPTIONAL – NOT SHOWN
Art. Nr. KC000632
Trial 32 mm, 0°, 6 mm

Art. Nr. KC001432
Trial 32 mm, 0°, 14 mm

INDICATIONS, CONTRAINDICATIONS AND CAUTIONS

WOMBAT is used in the following lumbar diseases (L1-S1):

INDICATIONS

- Degenerative disc diseases
- Mechanical instability
- Osteochondrosis
- Disc herniation
- Spondylolisthesis
- Spinal canal stenosis

CONTRAINDICATIONS

- Infections
- Massive osteoporosis
- Specific metal allergy
  (titanium implants, titanium or tantalum markers)
- Myelopathic focus in the fused segment
  (only for titanium alloy implants)
- Medical conditions that could prevent successful implantation
- Cases not mentioned under indications

CAUTIONS

- The spinal implants are intended for use once only and may not be re-used. The re-use of an implant may result in its failure, in infection and/or death.
- Implants must be considered as potentially infectious after use. Therefore they need to be disposed of (hazardous medical waste) according to the applicable hygiene and waste disposal guidelines.

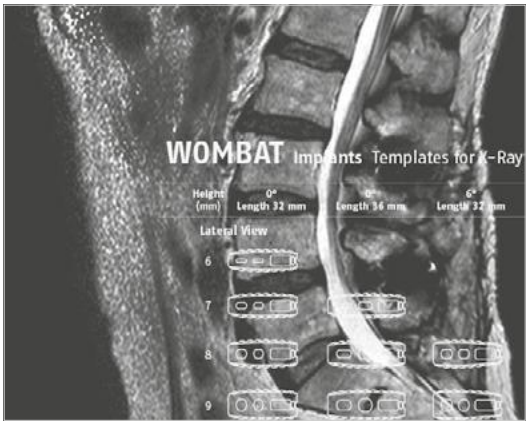
USA: Federal law restricts this device to sale by or on the order of a physician.

SURGICAL TECHNIQUE

1 PREPARATION

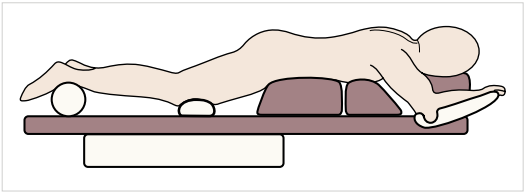
Preoperative planning

Once the indication has been established, templates can be used during preoperative planning to estimate the optimal size of the WOMBAT Cage. They can be used with a variety of imaging procedures (X-ray, CT and MRI).



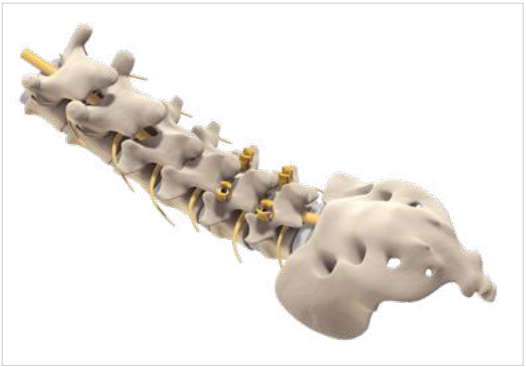
Patient positioning

Place the patient in a prone position, with physiological lordosis restored. Make sure that the abdomen is not overloaded in such a position so as to counteract venous stasis. The patient should be positioned on a radiolucent operating table that permits free movement of the C arm at the sagittal and AP level.



Approach

Perform a vertical skin incision in the midline or 2 to 3 fingerbreadths lateral to the spine at the level of the segment to be treated. Then perform a unilateral partial facetectomy or foraminotomy for transforaminal insertion of the cage on the symptomatic side. To protect the neural structures, it is advisable to use nerve root retractors during all further steps of the procedure.

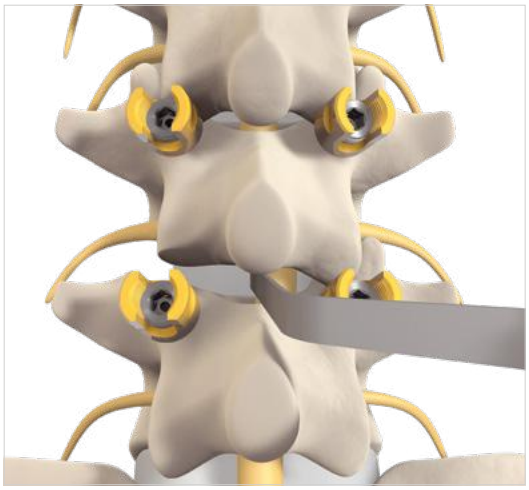


Posterior instrumentation

After exposing the segment to be treated, first position the pedicle screws of the posterior instrumentation. To begin with, the desired anatomical correction to the position can be undertaken and secured.

Discectomy and preparation of the endplates

Determine the entry site in the lateral disc space depending on the decompression and the patient's pathology. After unilateral decompression, the epidural space and neural structures should be adequately exposed. Decompression should involve both the affected disc and further space-occupying structures (e.g. posterior osteophytes), preserving only the anterior and lateral segments of the anulus fibrosus.



NOTE

The extracted bone material can later be used for implant packing, interbody impaction and adhesion.

To achieve optimal fusion results, freshen the exposed vertebral endplates.

NOTE

Excessive or complete removal of the cortical endplates should be avoided, since this can weaken them and thus lead to subsidence of the implant into the adjacent vertebral body.

The SIGNUS lumbar preparation set (refer to the brochure ***'Lumbar preparation'***) can be used for resecting the disc and endplate preparation.

2 IMPLANTATION

Distraction and implant selection

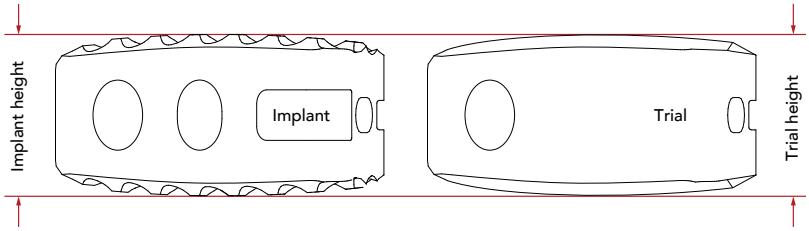
Thanks to their tapered design, in addition to estimating the implant size needed later, the trials can also be used for distraction.

NOTE

Optionally, segmental distraction can also be performed with the posterior instrumentation.

NOTE

The trials correspond to the implant height (including teeth).

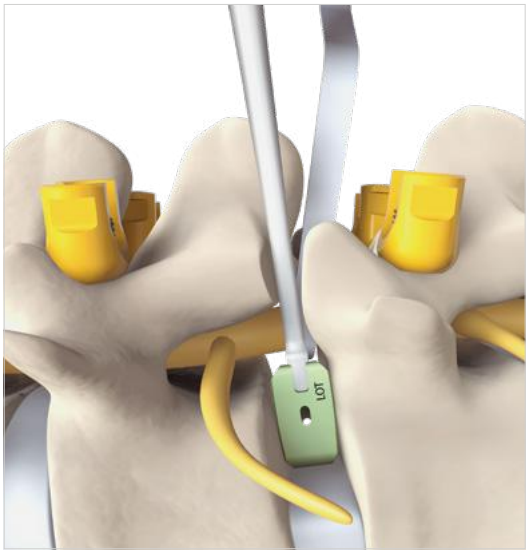


SURGICAL TECHNIQUE

Start with a somewhat smaller trial than preoperatively estimated. Place the trial in the inserter and fixate it. Insert the selected trial into the intervertebral space. The "medial / lateral" label on the inserter indicates how to insert the trial in the intervertebral space. The final position of the trial is around 3 mm behind the anterior longitudinal ligament.

A lateral beam path (reference = height of adjacent intervertebral disc spaces) and tactile inspection should ensure that the trial is positioned securely. If the trial is loose or can even be removed, the next size up should be selected.

Once the desired height has been determined the trial can be removed from the intervertebral space. If the trial is too tightly positioned, it can be removed with the slap hammer.



NOTE

With a view to secure positioning of the implant and the clinical outcome, over-distraction should be avoided.

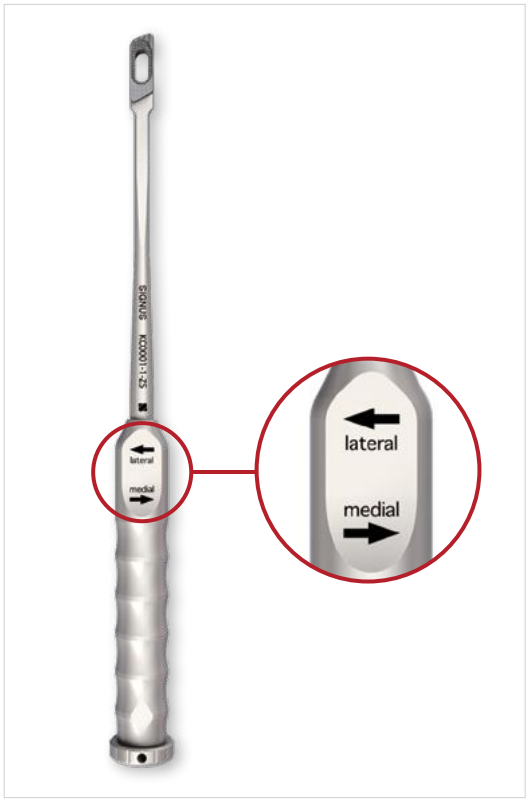
Implant insertion

After determining the correct implant height and lordosis, remove the appropriate implant from the sterile packaging.

NOTE

The implant must be kept in its original packaging. The packaging must be stored in a dry place, protected from sunlight. It should only be opened immediately prior to use of the implant. Check expiry date and intactness of the sterile packaging before use. All of the packaging must be removed.

The implant must likewise be checked for integrity before being implanted. The size indicated on the implant must be compared with the size determined using the trial implant.

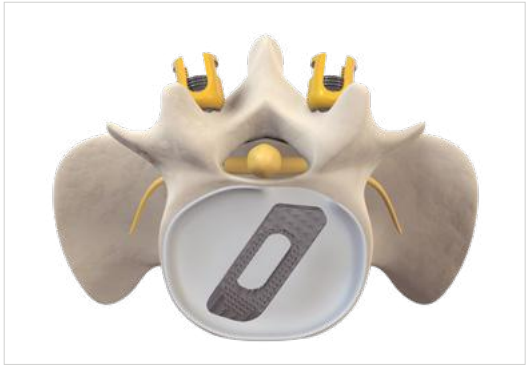


The implant can now be attached to the inserter via the screw thread and can be inserted in the intervertebral space. Here too, the "medial / lateral" label on the inserter indicates how to insert the trial in the intervertebral space.

If WOMBAT is to be placed in final position, the positioner can now be used to do this.

Adhesion of bone material

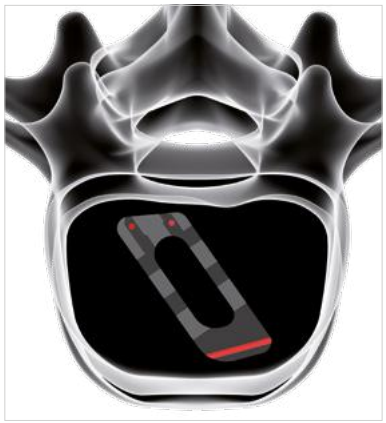
To improve the fusion outcome it is advisable to insert bone graft in and around the implant.



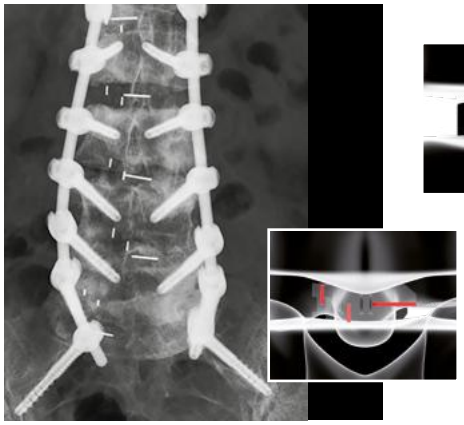
VERIFICATION IMAGE X-RAY / CT – WOMBAT WITH DIPLOMAT

WOMBAT PEEK

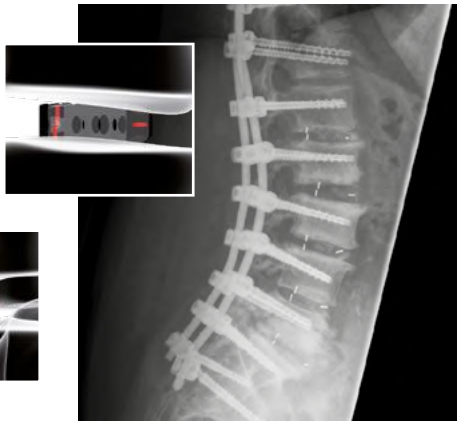
Axial view



AP

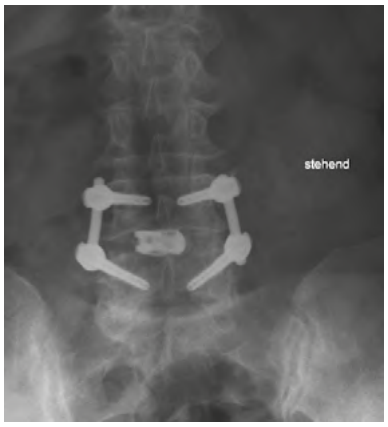


Lateral

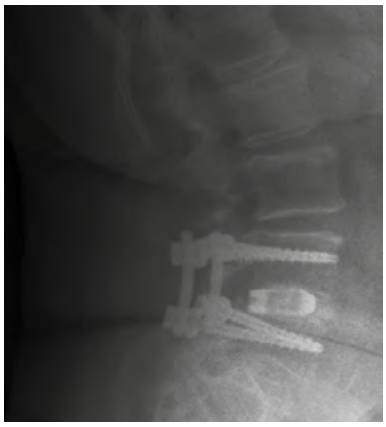


WOMBAT ST

AP

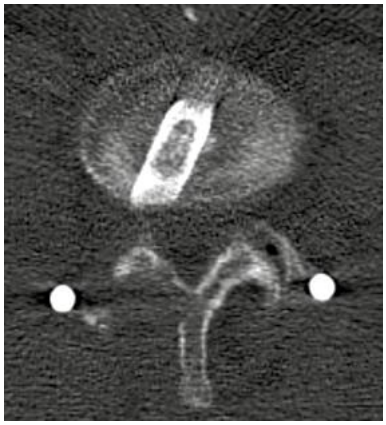


Lateral



WOMBAT ST

Axial view



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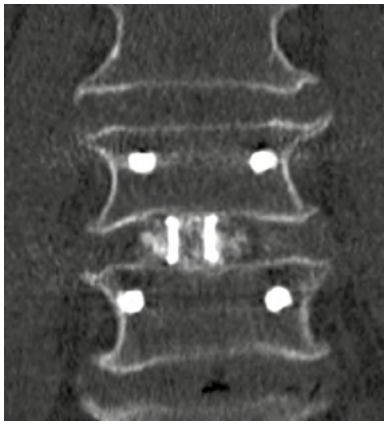
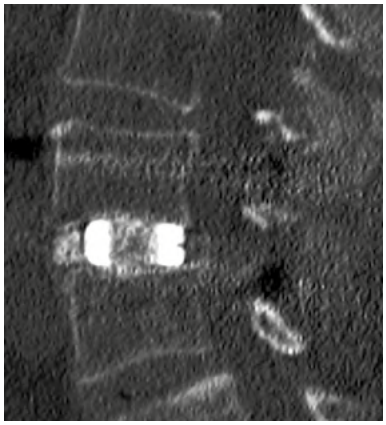


Lateral



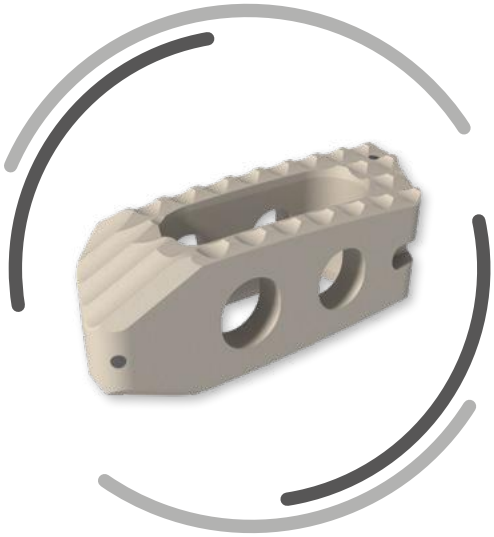
Source: Dr. Jan-Uwe Müller, Universitätsklinikum Greifswald

3 REVISION

WOMBAT can be revised, if necessary. To do so, take the approach described above and expose the implant. Special attention should be paid to preparation of the nerve tissue and the scar tissue that has already developed. To extract the implant, the tissue must first be removed. To remove the implant, reattach it to the inserter. Using the slap hammer, remove the implant from the disc space. While doing so, ensure that the integrity of the nerve structures is preserved.

CAUTION

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



NOTE

The surgical steps should be carried out in the same way as for WOMBAT PEEK.

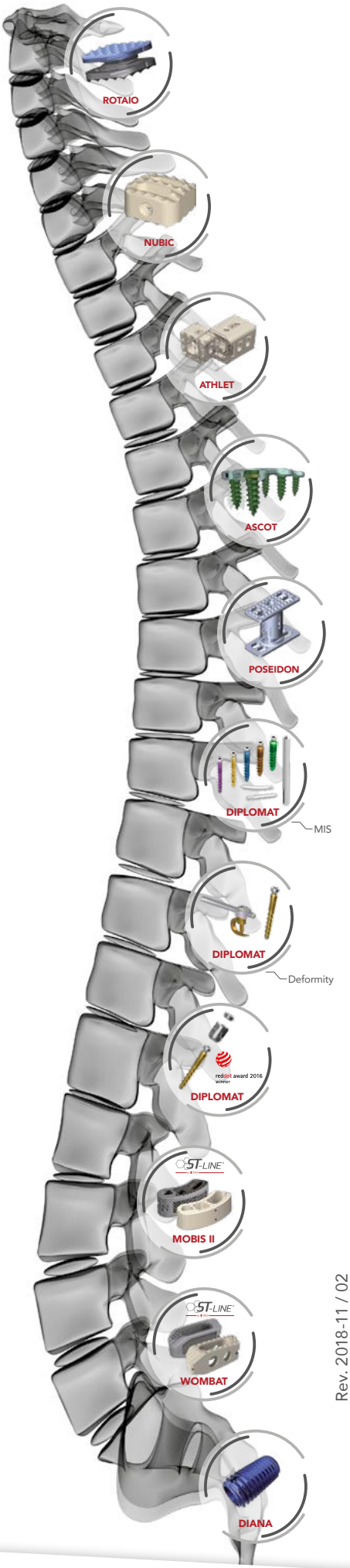
NOTES

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.

SIGNUS – THE SIGN FOR SPINE

PASSIONATE!
DYNAMIC!
WORLDWIDE!

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



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