GLOBAL®
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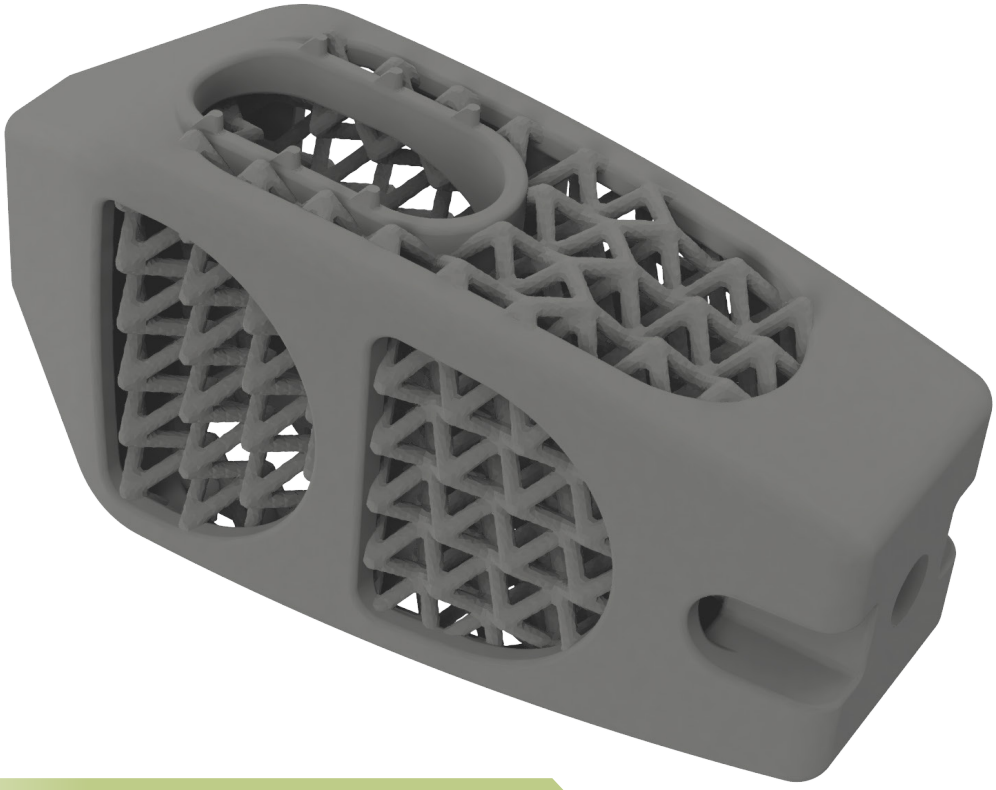
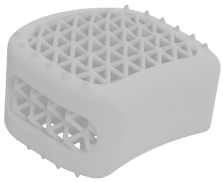
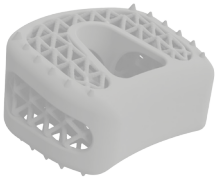


The Lumbar BMD Titanium PLIF GW Implant ®

Surgical Technique Guide

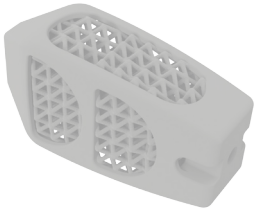


BMD Titanium
ACIF Implant



BMD Titanium
ACIF GW Implant

BMD Titanium
TLIF Implant



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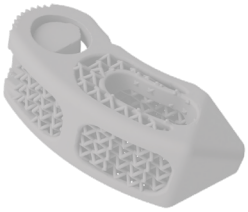
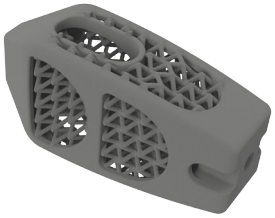
PLIF Implant

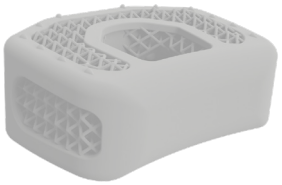


BMD Titanium
TLIF GW Implant



BMD Titanium
PLIF GW Implant

BMD Titanium
LLIF Implant



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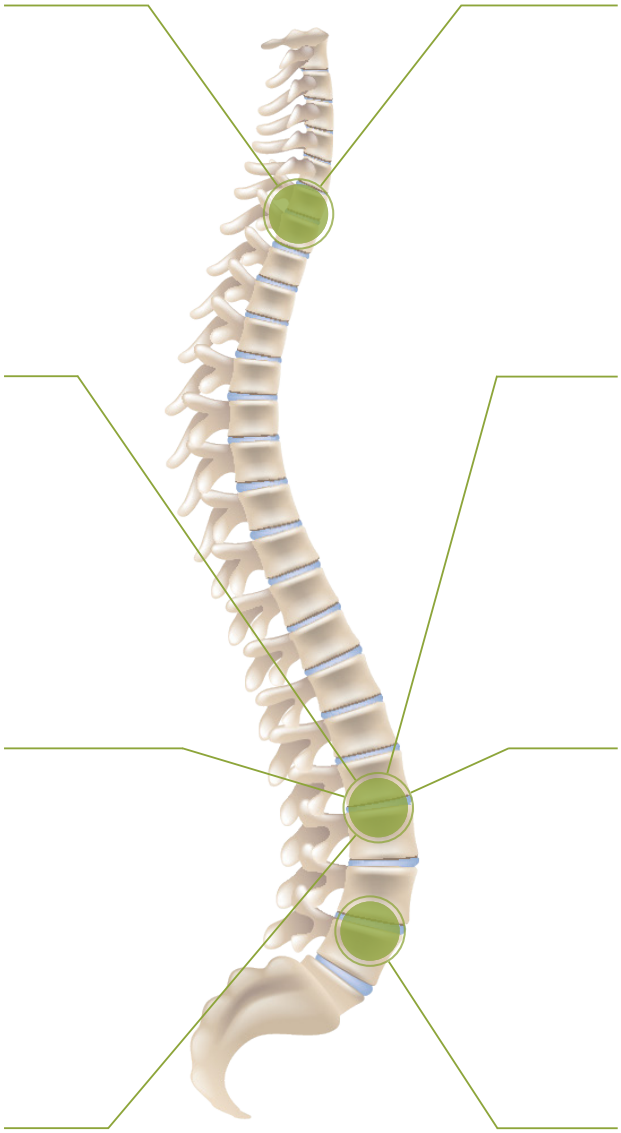

3D-printed spinal fusion Global BMD Titanium Implants®

TABLE OF CONTENTS

The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient.
Only those individuals with specialized training and experience in spinal surgery should attempt to use the BMD Titanium PLIF GW Implant ®.
Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential. Refer to the Instructions for Use (IFU) for a complete list of prescribing information. This technique guide was developed in conjunction with health care professionals. Additional information about the medical device is available from Global Biomedica s.r.o.

Figure 1
Patient positioning

Figure 2
Endplate preparation

Preparation and Approach

The patient is placed on the OR table using the standard positioning in cases of Posterior Lumbar Interbody Fusion (Figure 1). Make sure the ab domen is free positioned to avoid pressure on the large vessels and to minimize blood loss. A radiolucent OR table is recommended, as X-ray shall be used to confirm identification of the affected disc and in a later stage the position of the implant. Mark the affected segment after fluoroscopy control. A standard incision is performed over the level(s) to be instrumented. Expose the spinous process and facet joint on the affected side. Use a high-speed drill, or Kerrison rongeur Resect the necessary part of lamina and facet joint to approach the spinal canal, avoid tho completely resection of facet joint, if possibile.

Decompression and Discectomy

To ease the discectomy procedure, insertion of pedicle screws and performing a slight distraction over the pedicle screws prior to the discectomy can be advantageous. The neural foramen and spinal canal are decompressed as necessary. Dural sac is gently retracted medially using a nerve Root retractor. The posterolateral portion of the annulus is than exposed and a window is created to gain access to the intervertebral space. The dural sac and neural structures are continually protected by the nerve root retractor. After the disc is cleared, the endplate cartilage should be removed carefully, leaving the upper and lower bony endplate intact (Figure 2). Injury to the bony endplates may lead to implant subsidence.

Figure 3
Intervertebral disc space

Distraction

An adequate distraction of the intervertebral disc space is one of the preconditions for the primary stability required after cage implantation. For this purpose Distractors are available in several heights (Figure 3). Each size of Distractor has grooves, that indicate the length of 20, 24, 28 and 33 mm respectively. It should be considered to start with the smallest size Distractor to avoid over distraction. Apply the Distractor parallel to the intevertebral space and turn clockwise to open up the disc space.

Figure 4
Correct the surface

To obtain parallel distraction, proceed in the counter side with one size bigger until sufficient distraction is achieved. Correct the surface if necessary with the Rasp tool (Figure 4).

Figure 5
Determination the implant size

Determination of Implant Size

The selection of the implant trial depends on the height, width and depth of the intervertebral disc space, as well as the chosen preparation technique and the anatomy of the patient (Figure 5). Select the trial that best matches the shape of the intervertebral disc space. Chose gradually the trial that is higher and/or with higher lordosis angle until a secure position in the intervertebral disc space is achieved. Use the highest possible trial implant to ensure maximal stability. You can verify the correct position of the implant trial with help of the x-ray imaging to make sure the implant fits exactly into the intervertebral disc space. The length of the implant can be determined according to the picture below (Figure 5a).

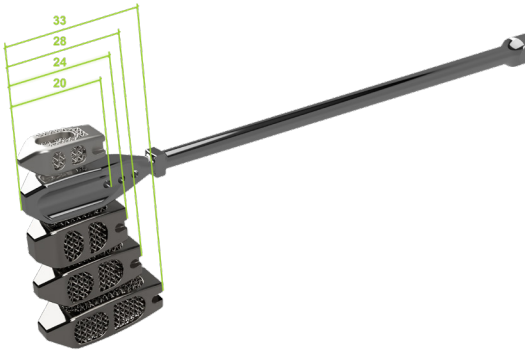

Figure 5a

Figure 6
Implant mounting

Implant Insertion

Open the sterile packaging of the implant size that was determined with the Trial. Attach the implant to the Inserter. Place the implant between the tips of the Inserter that fit into the notches on the lateral side of the implant. Screw the implant to the Inserter by final tightening of the screwcap on the back of the Inserter and tighten with hand (Figure 6). Once the implant is blocked on the instrument, it can be implanted into the intervertebral space.

Figure 7
Place the implant

It is recommended to place the implants in pairs (Figure 7). In case of implanting an oblique single implant, it is advisable to use the largest possible footprint available that fits the anatomy.
Gently tap the implant into the intervertebral disc space using the hammer provided in the instrument set. The first implant should not cross the midline in order not to interfere with the second implant.
During implantation is necessary to retract and protect neural structures by a nerve root retractor. Despite the application of smooth solid titanium surfaces, the rough porous structure potentially increases the risk of soft tissue adherence unless there is sufficient protection.
Use the Hexagonal Key to rotate the implant if it needs to be assembler (Figure 8).

Figure 8
Implant rotation

Completion of Surgery

After Implantation of the implant a final check of the position of the implant under fluososcopy is advised (Figure 9).
Posterior supplemental fixation is strongly recommended. Perform wound closure as usual. Please document which implants were used in the patient files. Patient labels are supplied with each implant for your convenience. The use of the BMD Titanium PLIF GW Implant ® does not require any specific postoperative care and the patient should be treated accordingto hospital and medical standards.

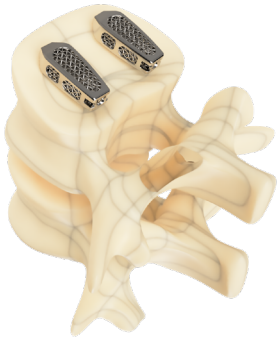

Figure 9
Final position

Figure 10
Implant removal

Implant Removal

Either the Inserter or Universal Removal Instrument may be used for Implant removal by attachment via clockwise rotation to the implant threads (Figure 10). Be careful to avoid pushing the implant posteriorly. Once the implant is firmly attached, remove the implant from the disc space. Vertebral bone overgrowth or osteophytes may beremoved to facilitate implant retrieval.

List of Implants

DESCRIPTION	L x W x H	ANGLE	CODE
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PLIF GW	20mm x 9mm x 11mm	20°	BMDH20091120
PLIF GW	20mm x 9mm x 12mm	20°	BMDH20091220
PLIF GW	20mm x 9mm x 13mm	20°	BMDH20091320
PLIF GW	20mm x 9mm x 14mm	20°	BMDH20091420
PLIF GW	20mm x 9mm x 15mm	20°	BMDH20091520
PLIF GW	20mm x 9mm x 16mm	20°	BMDH20091620
PLIF GW	20mm x 9mm x 17mm	20°	BMDH20091720
PLIF GW	24mm x 9mm x 13mm	20°	BMDH24091320
PLIF GW	24mm x 9mm x 14mm	20°	BMDH24091420
PLIF GW	24mm x 9mm x 15mm	20°	BMDH24091520
PLIF GW	24mm x 9mm x 16mm	20°	BMDH24091620
PLIF GW	24mm x 9mm x 17mm	20°	BMDH24091720
PLIF GW	24mm x 10mm x 13mm	20°	BMDH24101320
PLIF GW	24mm x 10mm x 14mm	20°	BMDH24101420
PLIF GW	24mm x 10mm x 15mm	20°	BMDH24101520
PLIF GW	24mm x 10mm x 16mm	20°	BMDH24101620
PLIF GW	24mm x 10mm x 17mm	20°	BMDH24101720
PLIF GW	28mm x 9mm x 15mm	20°	BMDH28091520
PLIF GW	28mm x 9mm x 16mm	20°	BMDH28091620
PLIF GW	28mm x 9mm x 17mm	20°	BMDH28091720
PLIF GW	28mm x 10mm x 15mm	20°	BMDH28101520
PLIF GW	28mm x 10mm x 16mm	20°	BMDH28101620
PLIF GW	28mm x 10mm x 17mm	20°	BMDH28101720

Tool List

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Distractor shaver 9 mm	35-103
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Shaver 8 mm	35-151
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Shaver 11 mm	35-154
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Shaver 13 mm	35-156
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Shaver 16 mm	35-159
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PLIF Trial 0°, 7 mm	45-750
PLIF Trial 0°, 8 mm	45-751
PLIF Trial 0°, 9 mm	45-752
PLIF Trial 0°, 10 mm	45-753
PLIF Trial 0°, 11 mm	45-754
PLIF Trial 0°, 12 mm	45-755

NAME	REF
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PLIF Trial 0°, 14 mm	45-757
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PLIF Trial 4°, 8 mm	45-760
PLIF Trial 4°, 9 mm	45-761
PLIF Trial 4°, 10 mm	45-762
PLIF Trial 4°, 11 mm	45-763
PLIF Trial 4°, 12 mm	45-764
PLIF Trial 4°, 13 mm	45-765
PLIF Trial 4°, 14 mm	45-766
PLIF Trial 4°, 15 mm	45-767
PLIF Trial 4°, 16 mm	45-768
PLIF Trial 4°, 17 mm	45-769
PLIF Trial 8°, 7 mm	45-770
PLIF Trial 8°, 8 mm	45-771
PLIF Trial 8°, 9 mm	45-772
PLIF Trial 8°, 10 mm	45-773
PLIF Trial 8°, 11 mm	45-774
PLIF Trial 8°, 12 mm	45-775
PLIF Trial 8°, 13 mm	45-776
PLIF Trial 8°, 14 mm	45-777
PLIF Trial 8°, 15 mm	45-778
PLIF Trial 8°, 16 mm	45-779
PLIF Trial 8°, 17 mm	45-780
PLIF Trial 12°, 9 mm	45-781
PLIF Trial 12°, 10 mm	45-782
PLIF Trial 12°, 11 mm	45-783
PLIF Trial 12°, 12 mm	45-784
PLIF Trial 12°, 13 mm	45-785
PLIF Trial 12°, 14 mm	45-786
PLIF Trial 12°, 15 mm	45-787
PLIF Trial 12°, 16 mm	45-788
PLIF Trial 12°, 17 mm	45-789
PLIF Trial 16°, 11 mm	45-790
PLIF Trial 16°, 12 mm	45-791
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PLIF Trial 16°, 14 mm	45-793
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Important Information on the Global BMD Titanium PLIF GW Implant ®

Device Description and Materials

Global Biomedica offers spinal surgery implants with excellent biocompatibility and bioactivity. We use the latest innovative technologies to create a line of spinal BMD Titanium Implant ®. These are implant for interbody fusion of biocompatible titanium (Ti64ELI). Internal and surface grid structure with optimum pore size of 700µm (Cube vertex centroid - lattice) with reinforced edges ensures not only high stability and resistance to deformation of the implant, or immersion in the vertebral body, but also bioactivity - potentiates the formation of bone in the area of contact surfaces and thus the formation of a strong connection between the implant and bone, the risk of developing non union (pseudoarthrosis) is thus minimized.

Indication for Use

The lumbar BMD Titanium Implant ® is indicated for lumbar interbody fusion for the following indications:

- Degenerative and postoperative spinal involvement in term of rupture, ostechondrosis, degenerative stenosis, pseudarthrosis
- Traumatic disc involvement – only in the absence of traumatic vertebras involvement and significant ligament instability of posterior column

Contraindications

The lumbar BMD Titanium Implant ® should not be used in patients with any of the following contraindications (Contraindications include, but are not limited). Infection or progressive infection, fever or inflammation.

- Obesity
- Insanity
- Allergy for any of system components
- Any anatomical, medical or surgical conditions that may prevent the potential or intentional benefits of using spinal implants
- Bone, joint or ligament conditions such as: Osteolytic involvement, bone absorption, osteomalacia. Osteopenia and osteoporosis is a relative contraindication and a thorough assessment of the situation is required before performing surgery
- Implant size, shape or functionality of the anchor may not be sufficient to achieve the expected clinical results
- Any risk of patient unwillingness to follow postoperative instructions
- Any other than described indications

Warnings And Precautions

- The effectiveness and safety of interbody fusion is only applicable for certain conditions with significant instability which require the fusion supported by medical device.
- Correct placement and appropriate size selection are crucial to achieve optimal results.
- The device might be supportive for such mechanical instability like deformity, fracture, listhesis, dislocation, tumor, pseudoarthrosis. The effectiveness and safety for any other conditions are unknown.
- BMD Titanium Implant ® may be supported by additional fixation device. In some cases additional fixation device is highly recommended.
- The contemporary applications of pedicular fixation must be performed by experienced surgeons with specific training in usage BMD Titanium Implant ®.
- The spinal screw fixation system and/or interbody cage system should not be considered as sole spinal support. No implants can withstand body loads without bone support.
- Over the time bends, breakages, loosening, migration may occur. Successful results are not always achievable. The factors as proper preoperative and operative procedure, comprehensive knowledge or surgical techniques, proper selection of implant's size and type are considerably important in treatment process.
- Patients with obesity, smokers, alcohol abused are enhanced risk of non-fusion. Also patients in weak muscle or bone conditions, nervous system dysfunctions are poor candidates for spinal fusion.
- Prior or during or after the surgery in order to evaluate or check positioning of the implants or patients anatomy or any other patients or implants X-ray or CT or any other invasive diagnostic examinations may be necessary to be performed.
- The proper, patient's individual implants selection in terms of type, size, shape or instruments handling is crucial.
- Extensive bending or contouring should be avoided.
- Sharp edges cutting, reversed bending, scratching or notching may generate internal stressing which may weak the implants or construct.

Potential Adverse Effects

Potential adverse events which may occur after the spinal surgery with or without instrumentation include, but are not limited:

- Breaking, bending, and/or breakage of any or all of the system components.
- Migrations of any system components.
- Pressure on the skin from component parts in patients with inadequate tissue coverage.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Damage and leakage of the hard arachnoid, leakage of coeliolymph.
- Neurological dysfunctions such as paresthesia, radiculopathy, paralysis, hyperesthesia or any others related to general surgery associated to anesthesia.
- Infections.
- Loss of urinary and defaecate functions.
- Permanent or temporary or developing sexual dysfunctions.
- Postoperative change in body curvature, change of physiological range of movement.
- Pseudarthrosis or non-fusion or delayed fusion.
- Loss of bone or overgrowth.
- Permanent or temporary limitation or inability to perform daily activities.
- Changing in mental behavior.
- Permanent or temporary or developing respiratory problems.
- Permanent or temporary or developing cardiovascular deteriorations or dysfunctions.
- Death.

In some cases additional surgery or surgeries might be necessary to correct or change potential adverse events.

IMPORTANT NOTICE: All necessary information on surgery, potential risks, benefits and adverse effects must be reported to the patient prior to surgery.

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Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is recommendations. Because this information does not purport to constitute any diagnostics or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.

⚠ Caution: Please see the product Instructions for Use for a complete listing of the indications, contraindications, precautions, warnings and adverse effects.

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