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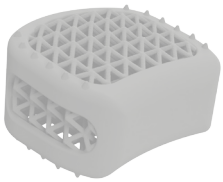
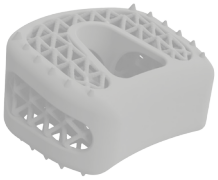
The Lumbar BMD Titanium TLIF Implant ®

Surgical Technique Guide

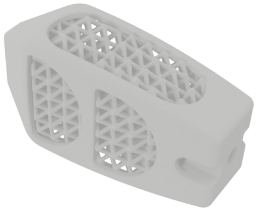


BMD Titanium
ACIF Implant



BMD Titanium
ACIF GW Implant

BMD Titanium
TLIF Implant



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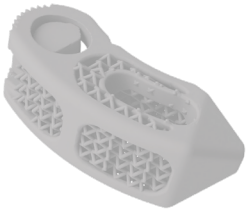
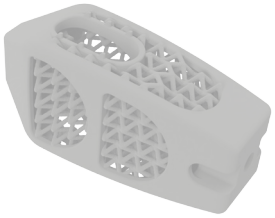
PLIF Implant

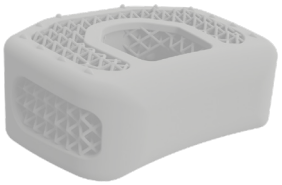


BMD Titanium
TLIF GW Implant

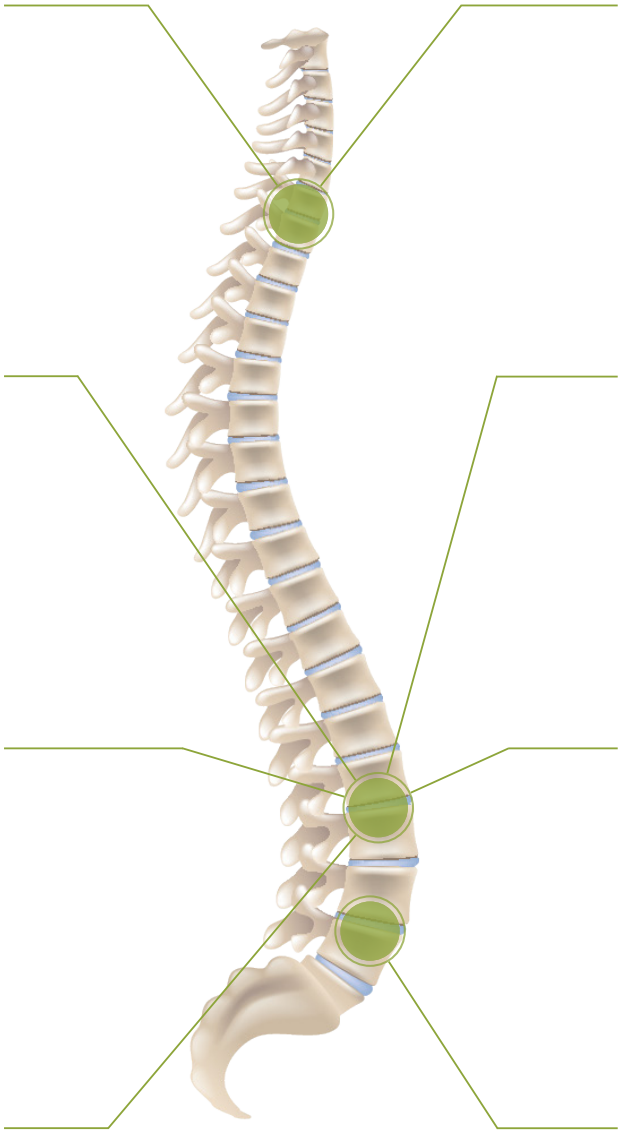


BMD Titanium
PLIF GW Implant

BMD Titanium
LLIF Implant



BMD Titanium
ALIF Implant



3D-printed spinal fusion Global BMD Titanium Implants®

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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 TLIF 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

Preparation and Approach

The patient is placed on the OR table using the standard positioning in cases of posterior approach (Figure 1). Make sure the abdomen is well 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 midline or paramedian incision is performed over the level(s) to be instrumented. Expose the facet joint on the affected side. Use a high-speed drill, or Kerrison Rongeur and resect the necessary part of lamina and facet joint to approach the foramen, avoid the complete resection of facet joint.

Figure 2
Endplate preparation

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 foramen is decompressed, as necessary. 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 the nerve root are continually protected by the nerve root retractor. After the disc is completely removed, the cartilaginous endplate should be resected 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

Figure 4
Trial implant

Distraction

An adequate distraction of the intervertebral disc space is one of the preconditions for the primary stability required after implant implantation. For this purpose distractors are available in several heights (Figure 3). It should be considered to start with the smallest size distractor toavoid over distraction. Apply the distractor parallelly to the intervertebral space and turn clockwise to open up the disc space. Correct the surface if necessary with the Rasp tool (Figure 3a).

Determination of Implant Size

The selection of the correct implant size depends on height, lordosis, depth and width of the intervertebral space, method of preparation of the patient, his anatomy and the chosen surgical access into the intervertebral space. Choose an Trial implant (Figure 4) that fits the best the height and lordosis of the intervertebral space and attach T-handle to the trial. The Trial implant should tightly and firmly fit into the intervertebral space (Figure 4a).

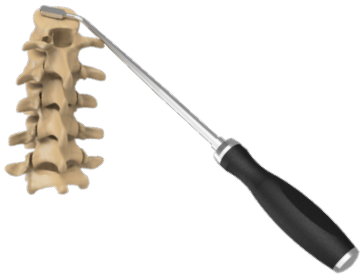

Figure 3a
Correct the surface

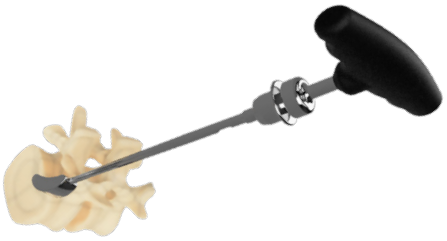

Figure 4a
Determination the implant size

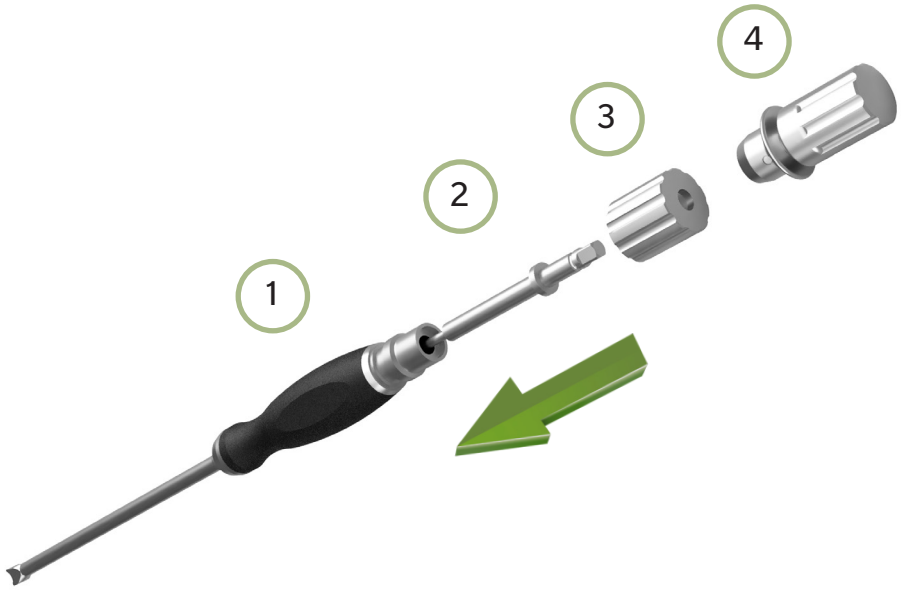

Figure 5
Tool assembly steps

Preparation of the TLIF Cage Holder

Insert the inner shaft into the instrument body with the silicone handle (Figure 5 – mark 1 & mark 2). Put the swivel-nut on the upper part of the instrument body and tighten the nut to the position UNLOCKED, according to the sign on the instrument (Figure 5 – mark 3). In the end attach the adapter to the top of the instrument (Figure 5 – mark 4). View of the complete instrument after assembly (Figure 6).

Figure 6
Complete Cage Holder

Figure 7
Put the implant

Attach the Implant to the Holder

Open sterile packaging with the size of implant determined by the trial. Put the implant into the holder in a position showed on the holder bottom part (Figure 7). *(WARNING: reverse position of the implant should be strictly avoided as the instrument could be damaged or it can malfunction).* Carefully start tightening the inner shaft with the adapter until the implant is tightly fastened on the shaft and thus securely attached to the holder (Figure 7). Set the desired initial position of the implant (Figure 8). To secure the initial position tighten the swivel-nut to the position LOCKED 🔒, according to the sign on the instrument (Figure 8). As soon as the implant is locked in the selected position and securely attached to the holder, it can be inserted into the intervertebral space. Insert the implant with gentle taps on the holder back part.

Figure 8
Initial position
Locked & Unlocked

When the implant is fully submerged in the intervertebral space it can be positioned into the its final position by its rotation. The rotation can be achieved by: unlocking the swivel-nut to its UNLOCKED 🔓 position and rotate the holder medially into the desired position. Lock the implant in its new position by turning the swivel-nut to the upper LOCKED 🔒 position (Figure 8). Before next insertion of the implant make sure the implant is firmly locked to the holder and by the lateral movement of the holder rotation of the implant is achieved. Continue until the final position of the implant in the intervertebral space is achieved. The final implant position should be checked by fluoroscopy. The final implant position can also be verified by the marker that shows exact centre of the implant (Figure 9).

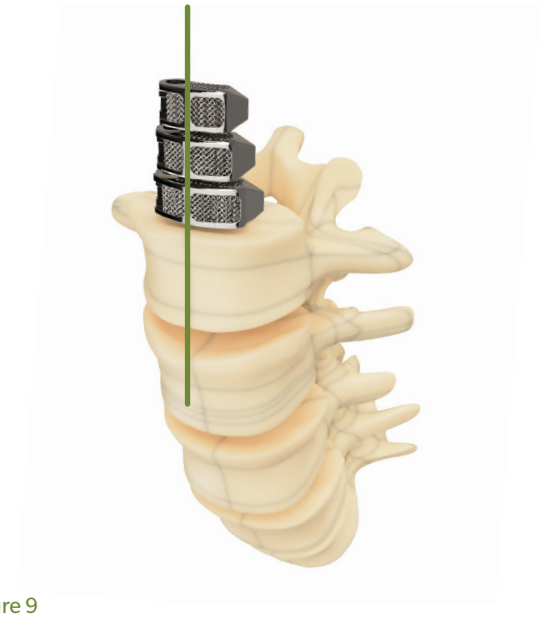

Figure 9
Centre of the implant

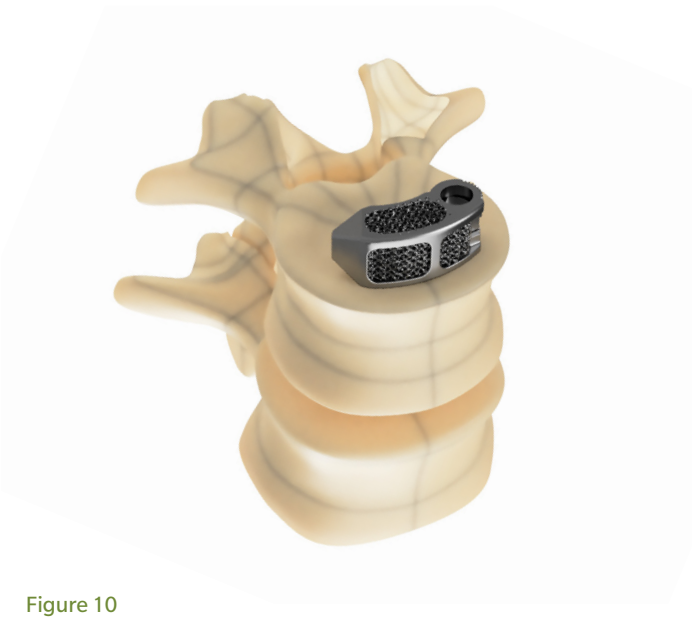

Figure 10
Final position

Detaching Implant from Holder

After the implant is in the final position, loosen theswivel-nut by rotating it to the UNLOCKED position and slowly start loosening also the adapter in the upper part of the instrument until the inner shaft is completely removed from the implant. Than carefully withdraw the instrument from the intervertebral space. Depending on surgical preference, the disc space can be filled prior to and after implant implantation, respectively ventral and/or lateral posterior, with remaining autograft or other suitable bonegraft material.

Completion of Surgery

After implantation of the implant a final check of the position of the implant under fluoroscopy is advised (Figure 10). 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 TLIF Implant® does not require any specific postoperative care and the patient should be treated accordingto hospital and medical standards.

Figure 11
Implant Removal

Implant Removal

Either the Holder or Universal Removal Instrument maybe used for Implant Removal by attachment via clockwise rotation to the implant threads (Figure 11).
Be careful to avoid pushing the implant posteriorly. Once the implant is firmly attached, remove the implant from the disc space.

List of Implants

DESCRIPTION	L x W x H	ANGLE	CODE
TLIF	26mm x 10mm x 7mm	0°	BMDT26100700
TLIF	26mm x 10mm x 8mm	0°	BMDT26100800
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Tool List

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Curette 45° D9L5	35-111
Curette 15° D7L3	35-112
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T-Handle	35-114
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Distractor 8 mm	35-131
Distractor 9 mm	35-132
Distractor 10 mm	35-133
Distractor 11 mm	35-134
Distractor 12 mm	35-135
Distractor 13 mm	35-136
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TLIF Trial 12°, 16 mm	55-257
TLIF Trial 12°, 17 mm	55-258
Trial Basket	35-120
Instrument Basket	55-450

Important Information on the Global BMD Titanium TLIF 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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