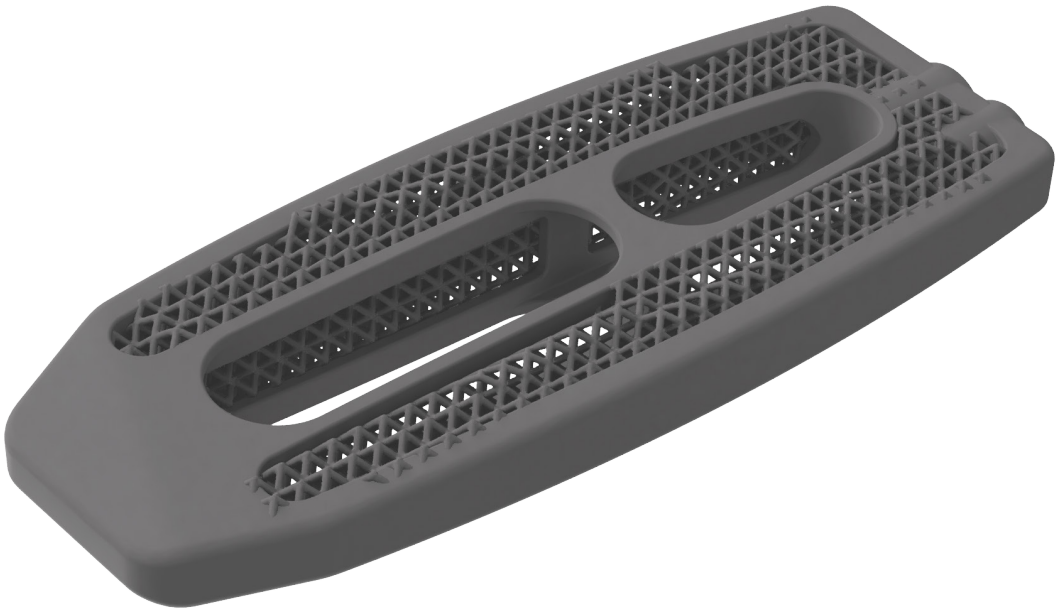
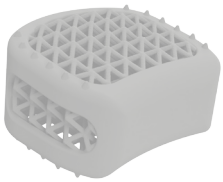
GLOBAL®
biomedica

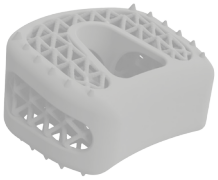


The Lumbar BMD Titanium LLIF Implant ®

Surgical Technique Guide

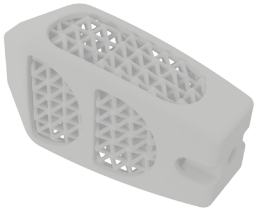


BMD Titanium
ACIF Implant

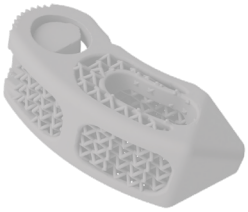


BMD Titanium
ACIF GW Implant

BMD Titanium
TLIF Implant



BMD Titanium
PLIF Implant



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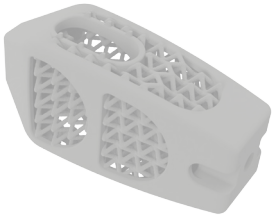
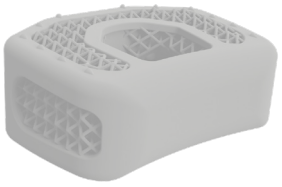
TLIF GW Implant

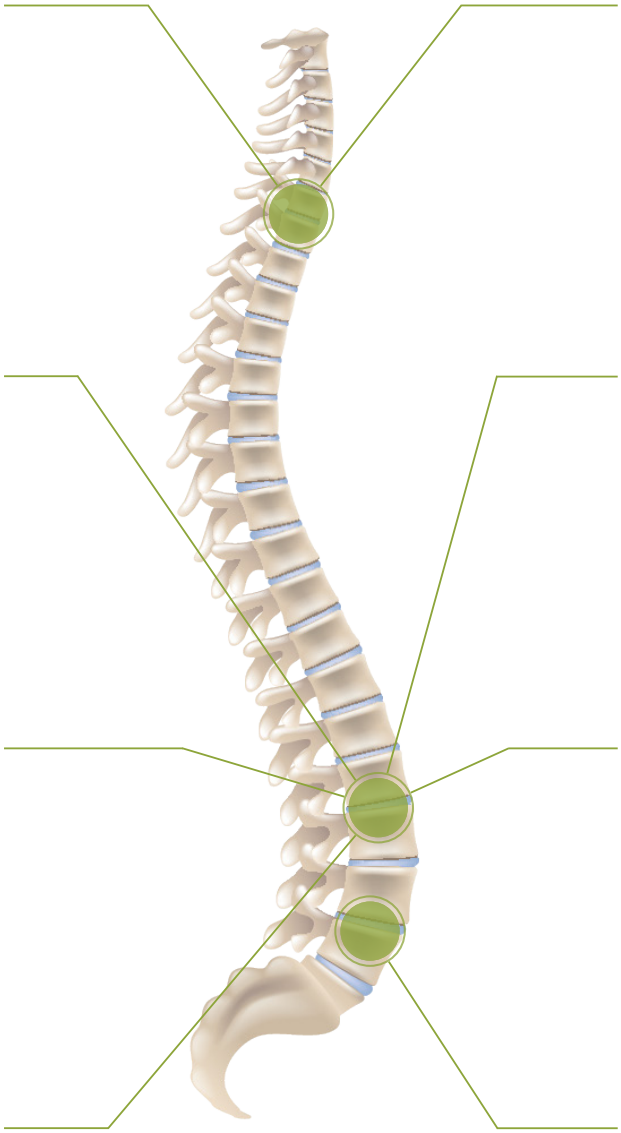


BMD Titanium
PLIF GW Implant

BMD Titanium
LLIF Implant



BMD Titanium
ALIF Implant



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 LLIF 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.

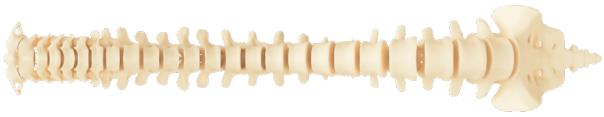


Figure 1
Patient positioning

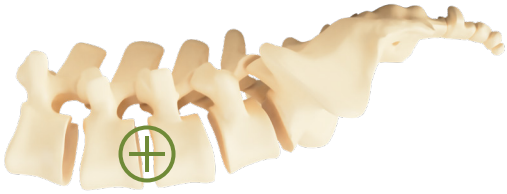


Figure 2
Designation of access point

Preparation and Approach

The patient is placed on a flexible surgical table in a true 90° right lateral decubitus position so that the iliac crest is just over the table break (Figure 1). Place pillows under the head, between the knees and under the upper arm. The patient is then secured to the table.
Note: It is also recommended to flex the table, to aid in opening the space between the twelfth rib and iliac crest.

Dilation and Retractor Insertion

Localize the disc space of surgical interest by laying two crossed Guidewires on the skin above the surgical site and lateral fluoroscopy (Figure 2). Make a small skin incision on the lateral side of patient's body. Perform blunt dissection through 3 muscle layers of abdominal wall and through transversalis fascia to retroperitoneal space. Once the psoas muscle is identified, the index finger is used to guide dilation through the access incision. Dilators will be used to direct the path to the affected disc space while monitoring the local nerves. Once the optimal path has been determined, a retractor will be utilized to hold the skin incision open, providing access and visibility to the affected area.
Note: We recommend using neuromonitoring, to avoid damage of plexus nerves through pressure of the retractor.

Figure 3
Intervertebral disc space

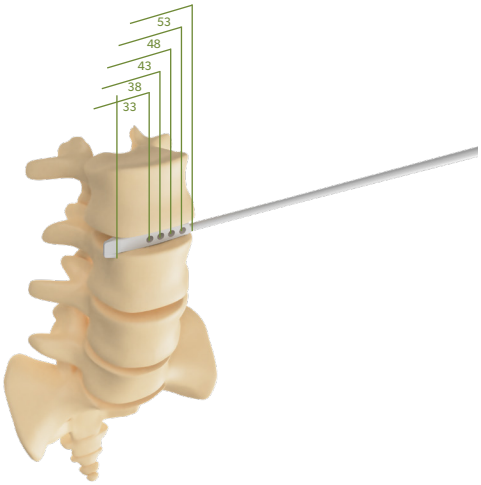


Figure 4
Determination the implant size

Disc Space Preparation and Distraction

Leaving the posterior and anterior annulus intact. Remove the intervertebral disc and osteophytes as needed. Curettes, Scrapers and Rasps are available for disc removal and endplate preparation (Figure 3). If the disc is severely collapsed, use the distractor and recreate the normal disc height and open the neuroforamen. Use Reamer Distractors. Insert the smallest Distractor into the disc space parallel to the disc space, while monitoring the insertion under fluoroscopic imaging. Continue in the same way until the required distraction is achieved and the lordosis is restored. When the discectomy is complete, use the rasp to remove the superficial cartilaginous layers of the endplates and to expose the bleeding bone.
Note: Excessive removal of the subchondral bone may weaken the vertebral endplate. If the entire endplate is removed, subsidence and a loss of segmental stability may result.

Determination of Implant Size

To determine the appropriate implant size for the desired segment, insert the smallest Trial into the disc space, moving to larger trials as needed. Selection of the test implant depends on the height, width and depth of intervertebral space and the way of patient preparation and anatomy (Figure 4). Use X-Ray to check the correct position of the test implant, which should fit tightly and accurately into intervertebral space. These grooves can be visualized under fluoroscopic imaging and may be used as a guide to determine what length of implant to select.
Note: The trial implants are available in all heights, all lordosis angles and in single width of 18mm. The lengths of the implant are on the trial marked with grooves at 40mm, 45mm, 50mm, 55mm, 60mm.

Figure 5a

Figure 5b

Figure 5
Attach the implant

Implant Insertion

Open the sterile packaging of the implant size that was determined with the Trial. Attach the implant to the Cage Holder (Figure 5a): Place the implant between the tips of the Cage Holder that fit into the notches on the lateral side of the implant. Screw the implant to the Cage Holder by final tightening of the screw cap on the back of the Inserter and tighten with hand (Figure 5b). Once the implant is blocked on the instru it can be implanted into the intervertebral space (Figure 5). Pack the interior of the implant with bone graft substitute. Gently tap the implant into the interver-disc space using the hammer provided in the instrument set.

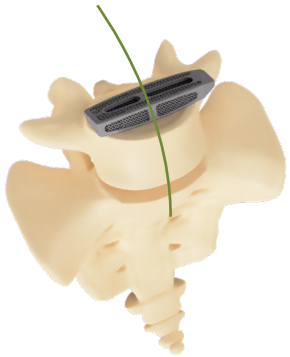


Figure 6
Final position

Implant Positioning

After insertion and proper placement of the implant in the intervertebral space, loosen the instrument. Use X-Ray to check the correct position of the implant that should fit tightly and accurately into intervertebral space (Figure 6). Adjust with the Final Impactor as necessary.
Note: The Implant is recommended for use with fixation supplement. A combination of screws and plates that are attached to adjacent vertebrae may be used. Your surgeon will determine what fixations are necessary during the procedure.

Completion of Surgery

Remove all used instruments and do a final check. After Implantation of the cages a final check of the position of the cages under fluoroscopy is advised. 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 LLIF Implants does not require any specific postoperative care and the patient should be treated according to hospital and medical standards.

Figure 7
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 7). 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
LLIF	40mm x 18mm x 7mm	0°	BMDX40180700
LLIF	40mm x 18mm x 9mm	0°	BMDX40180900
LLIF	40mm x 18mm x 11mm	0°	BMDX40181100
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LLIF	60mm x 22mm x 17mm	12°	BMDX60221712

Tool List

NAME	REF
Cage Holder	75-101
Rasp	75-102
Spoon Curette 45°	75-104
Spoon Curette 85°	75-105
Curette 45° D9L5	75-106
Removal Instrument	75-107
Final Impactor	75-108
T-Handle	35-114
Mallet	35-115
Distractor Shaver 7 mm	75-120
Distractor Shaver 8 mm	75-121
Distractor Shaver 9 mm	75-122
Distractor Shaver 10 mm	75-123
Distractor Shaver 11 mm	75-124
Distractor Shaver 12 mm	75-125
Distractor Shaver 13 mm	75-126
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Distractor Shaver 15 mm	75-128
Distractor Shaver 16 mm	75-129
Distractor Shaver 17 mm	75-130
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LLIF Trial 0°, 9 mm	75-141
LLIF Trial 0°, 11 mm	75-142
LLIF Trial 0°, 13 mm	75-143
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LLIF Trial 10°, 15 mm	75-160
LLIF Trial 10°, 17 mm	75-161
LLIF Trial 12°, 7 mm	75-162
LLIF Trial 12°, 9 mm	75-163
LLIF Trial 12°, 11 mm	75-164
LLIF Trial 12°, 13 mm	75-165
LLIF Trial 12°, 15 mm	75-166
LLIF Trial 12°, 17 mm	75-167
Trial Basket	35-124
Instrument Basket	75-450

Important Information on the Global BMD Titanium LLIF 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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