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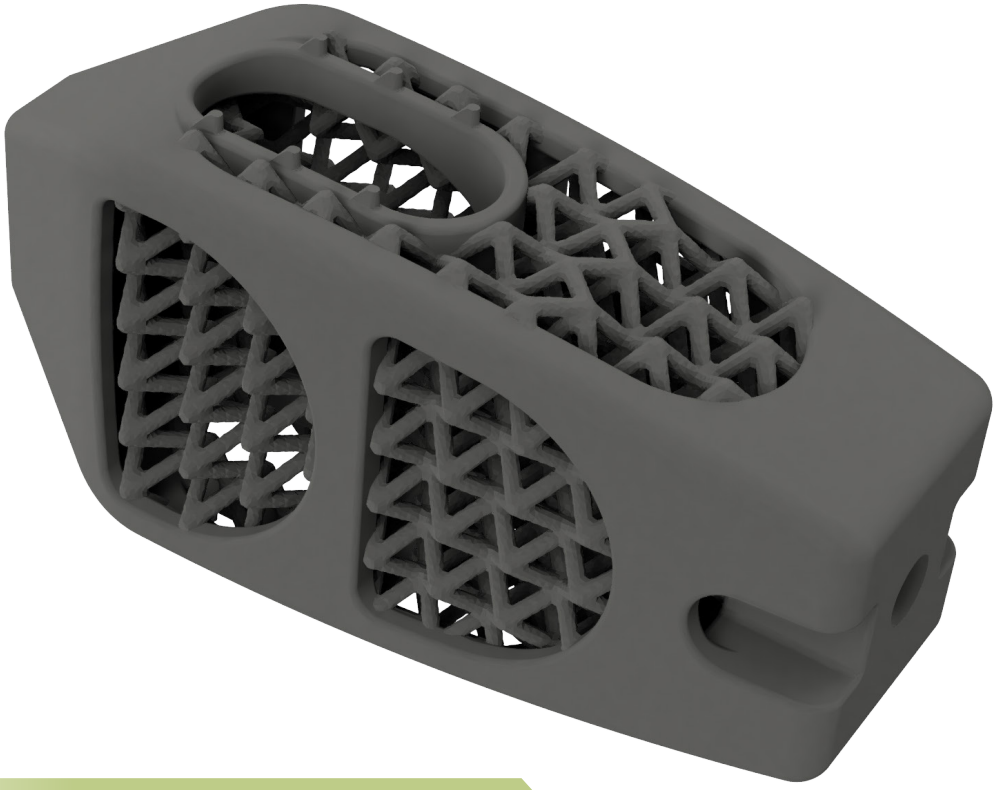
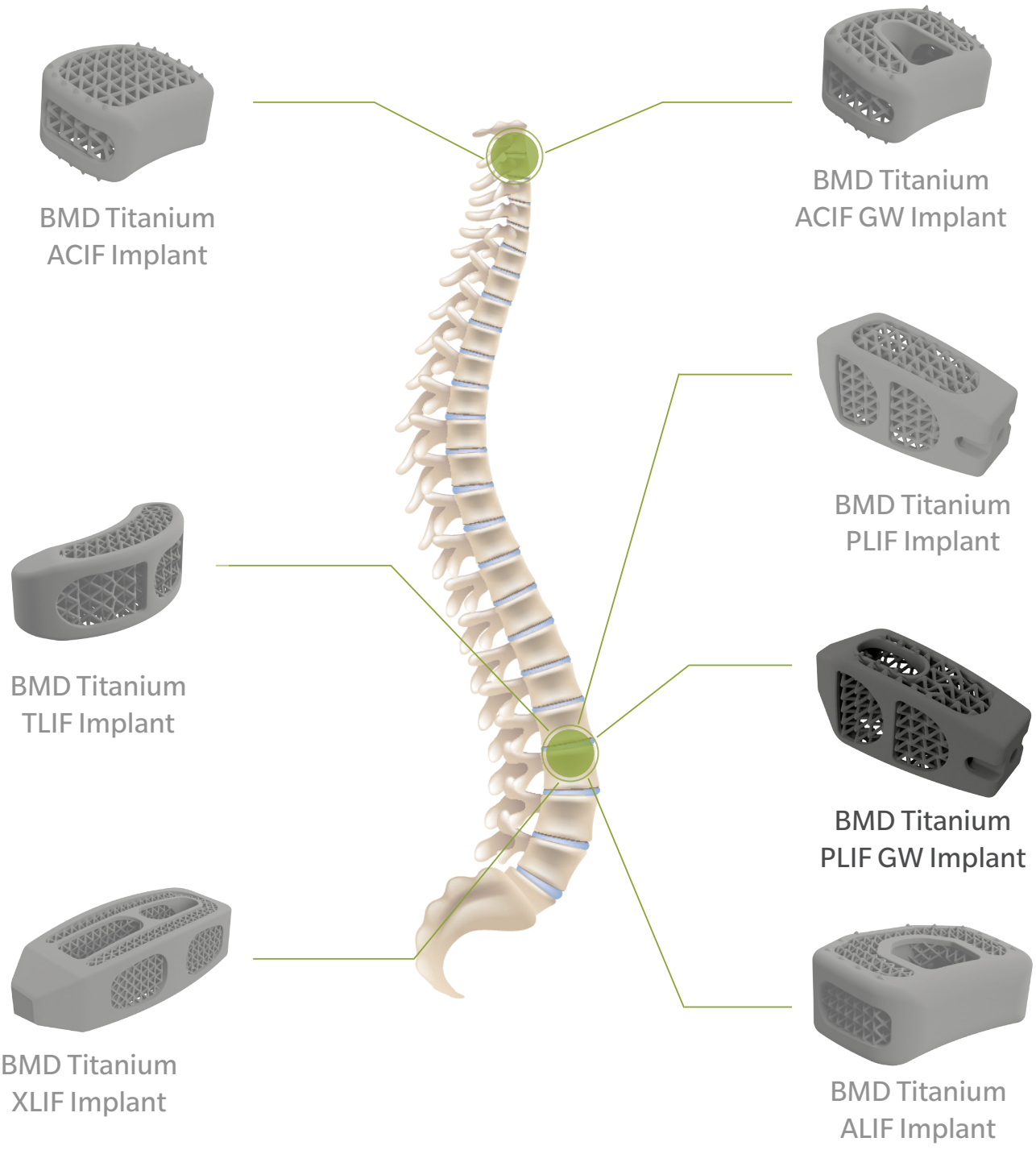


The Lumbar BMD Titanium PLIF GW Implant ®

Surgical Technique Guide



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 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 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

Selection of the trial implant depends on the height, width and depth of intervertebral space and the way of patient preparation and anatomy (Figure 5). Choose a test implant that best matches the shape of enterverte-bral space and insert it into the Trial Holder. Use X-Ray to check the correct position of the test implant, which should fit tightly and accurately into intervertebral space.

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 Implant ® does not require any specific postoperative care and the patient should be treated accordingto hospital and medical standards.

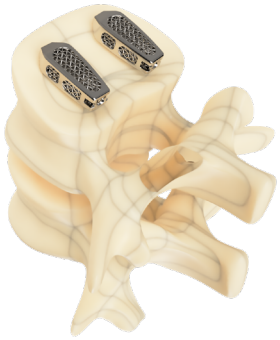

Figure 9
Final position

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, D x H x W,		4°	PART NUMBER
PLIF,	24mm x 7mm x 10mm,	4°	BMDH24100704
PLIF,	24mm x 8mm x 10mm,	4°	BMDH24100804
PLIF,	24mm x 9mm x 10mm,	4°	BMDH24100904
PLIF,	24mm x 10mm x 10mm,	4°	BMDH24101004
PLIF,	24mm x 11mm x 10mm,	4°	BMDH24101104
PLIF,	24mm x 12mm x 10mm,	4°	BMDH24101204
PLIF,	24mm x 13mm x 10mm,	4°	BMDH24101304
PLIF,	24mm x 14mm x 10mm,	4°	BMDH24101404
PLIF,	24mm x 15mm x 10mm,	4°	BMDH24101504
PLIF,	28mm x 7mm x 10mm,	4°	BMDH28100704
PLIF,	28mm x 8mm x 10mm,	4°	BMDH28100804
PLIF,	28mm x 9mm x 10mm,	4°	BMDH28100904
PLIF,	28mm x 10mm x 10mm,	4°	BMDH28101004
PLIF,	28mm x 11mm x 10mm,	4°	BMDH28101104
PLIF,	28mm x 12mm x 10mm,	4°	BMDH28101204
PLIF,	28mm x 13mm x 10mm,	4°	BMDH28101304
PLIF,	28mm x 14mm x 10mm,	4°	BMDH28101404
PLIF,	28mm x 15mm x 10mm,	4°	BMDH28101504
PLIF,	33mm x 9mm x 12mm,	4°	BMDH33120904
PLIF,	33mm x 11mm x 12mm,	4°	BMDH33121104
PLIF,	33mm x 13mm x 12mm,	4°	BMDH33121304
PLIF,	33mm x 15mm x 12mm,	4°	BMDH33121504

DESCRIPTION, D x H x W,		8°	PART NUMBER
PLIF,	24mm x 7mm x 10mm,	8°	BMDH24100708
PLIF,	24mm x 8mm x 10mm,	8°	BMDH24100808
PLIF,	24mm x 9mm x 10mm,	8°	BMDH24100908
PLIF,	24mm x 10mm x 10mm,	8°	BMDH24101008
PLIF,	24mm x 11mm x 10mm,	8°	BMDH24101108
PLIF,	24mm x 12mm x 10mm,	8°	BMDH24101208
PLIF,	24mm x 13mm x 10mm,	8°	BMDH24101308
PLIF,	24mm x 14mm x 10mm,	8°	BMDH24101408
PLIF,	24mm x 15mm x 10mm,	8°	BMDH24101508
PLIF,	28mm x 7mm x 10mm,	8°	BMDH28100708
PLIF,	28mm x 8mm x 10mm,	8°	BMDH28100808
PLIF,	28mm x 9mm x 10mm,	8°	BMDH28100908
PLIF,	28mm x 10mm x 10mm,	8°	BMDH28101008
PLIF,	28mm x 11mm x 10mm,	8°	BMDH28101108
PLIF,	28mm x 12mm x 10mm,	8°	BMDH28101208
PLIF,	28mm x 13mm x 10mm,	8°	BMDH28101308
PLIF,	28mm x 14mm x 10mm,	8°	BMDH28101408
PLIF,	28mm x 15mm x 10mm,	8°	BMDH28101508
PLIF,	33mm x 9mm x 12mm,	8°	BMDH33120908
PLIF,	33mm x 10mm x 12mm,	8°	BMDH33121008
PLIF,	33mm x 11mm x 12mm,	8°	BMDH33121108
PLIF,	33mm x 12mm x 12mm,	8°	BMDH33121208
PLIF,	33mm x 13mm x 12mm,	8°	BMDH33121308
PLIF,	33mm x 14mm x 12mm,	8°	BMDH33121408
PLIF,	33mm x 15mm x 12mm,	8°	BMDH33121508

DESCRIPTION, D x H x W,		12°	PART NUMBER
PLIF,	24mm x 9mm x 10mm,	12°	BMDH24100912
PLIF,	24mm x 10mm x 10mm,	12°	BMDH24101012
PLIF,	24mm x 11mm x 10mm,	12°	BMDH24101112
PLIF,	24mm x 12mm x 10mm,	12°	BMDH24101212
PLIF,	24mm x 13mm x 10mm,	12°	BMDH24101312
PLIF,	24mm x 14mm x 10mm,	12°	BMDH24101412
PLIF,	24mm x 15mm x 10mm,	12°	BMDH24101512
PLIF,	24mm x 16mm x 10mm,	12°	BMDH24101612
PLIF,	24mm x 17mm x 10mm,	12°	BMDH24101712
PLIF,	28mm x 11mm x 10mm,	12°	BMDH28101112
PLIF,	28mm x 12mm x 10mm,	12°	BMDH28101212
PLIF,	28mm x 13mm x 10mm,	12°	BMDH28101312
PLIF,	28mm x 14mm x 10mm,	12°	BMDH28101412
PLIF,	28mm x 15mm x 10mm,	12°	BMDH28101512
PLIF,	28mm x 16mm x 10mm,	12°	BMDH28101612
PLIF,	28mm x 17mm x 10mm,	12°	BMDH28101712
PLIF,	33mm x 11mm x 12mm,	12°	BMDH33121112
PLIF,	33mm x 12mm x 12mm,	12°	BMDH33121212
PLIF,	33mm x 13mm x 12mm,	12°	BMDH33121312
PLIF,	33mm x 14mm x 12mm,	12°	BMDH33121412
PLIF,	33mm x 15mm x 12mm,	12°	BMDH33121512
PLIF,	33mm x 16mm x 12mm,	12°	BMDH33121612
PLIF,	33mm x 17mm x 12mm,	12°	BMDH33121712

DESCRIPTION, D x H x W,		16°	PART NUMBER
PLIF,	24mm x 11mm x 10mm,	16°	BMDH24101116
PLIF,	24mm x 12mm x 10mm,	16°	BMDH24101216
PLIF,	24mm x 13mm x 10mm,	16°	BMDH24101316
PLIF,	24mm x 14mm x 10mm,	16°	BMDH24101416
PLIF,	24mm x 15mm x 10mm,	16°	BMDH24101516
PLIF,	24mm x 16mm x 10mm,	16°	BMDH24101616
PLIF,	24mm x 17mm x 10mm,	16°	BMDH24101716
PLIF,	28mm x 13mm x 10mm,	16°	BMDH28101316
PLIF,	28mm x 14mm x 10mm,	16°	BMDH28101416
PLIF,	28mm x 15mm x 10mm,	16°	BMDH28101516
PLIF,	28mm x 16mm x 10mm,	16°	BMDH28101616
PLIF,	28mm x 17mm x 10mm,	16°	BMDH28101716

DESCRIPTION, D x H x W,		20°	PART NUMBER
PLIF,	24mm x 13mm x 10mm,	20°	BMDH24101320
PLIF,	24mm x 14mm x 10mm,	20°	BMDH24101420
PLIF,	24mm x 15mm x 10mm,	20°	BMDH24101520
PLIF,	24mm x 16mm x 10mm,	20°	BMDH24101620
PLIF,	24mm x 17mm x 10mm,	20°	BMDH24101720
PLIF,	28mm x 15mm x 10mm,	20°	BMDH28101520
PLIF,	28mm x 16mm x 10mm,	20°	BMDH28101620
PLIF,	28mm x 17mm x 10mm,	20°	BMDH28101720

Tool list

DESCRIPTION D x W x H,	QTY	PART NUMBER
Distractor 7, 1/4	1	35-101
Distractor 8, 1/4	1	35-102
Distractor 9, 1/4	1	35-103
Distractor 10, 1/4	1	35-104
Distractor 11, 1/4	1	35-105
Distractor 12, 1/4	1	35-106
Distractor 13, 1/4	1	35-107
Distractor 14, 1/4	1	35-108
Distractor 15, 1/4	1	35-109
Curette D9L5	1	35-110
Curette 45° D9L5	1	35-111
Curette 15° D5L3	1	35-112
Curette 15° D9L5	1	35-113
T-Handle	2	35-114
Mallet	1	35-115
Rasp	1	35-116
Distractor 16, 1/4	1	35-117
Distractor 17, 1/4	1	35-118
Trial Basket	1	35-120
Final Impactor	1	45-101
Hexagonal Key	1	45-102
Cage Holder	2	45-103
Cage Slider 1/4	1	45-104
PLIF Trial 4° 1/4, 10 x 7 mm	1	45-680
PLIF Trial 4° 1/4, 10 x 8 mm	1	45-681
PLIF Trial 4° 1/4, 10 x 9 mm	1	45-682
PLIF Trial 4° 1/4, 10 x 10 mm	1	45-683
PLIF Trial 4° 1/4, 10 x 11 mm	1	45-684
PLIF Trial 4° 1/4, 10 x 12 mm	1	45-685
PLIF Trial 4° 1/4, 10 x 13 mm	1	45-686
PLIF Trial 4° 1/4, 10 x 14 mm	1	45-687
PLIF Trial 4° 1/4, 10 x 15 mm	1	45-688

DESCRIPTION D x W x H,	QTY	PART NUMBER
PLIF Trial 8° 1/4, 10 x 7 mm	1	45-689
PLIF Trial 8° 1/4, 10 x 8 mm	1	45-690
PLIF Trial 8° 1/4, 10 x 9 mm	1	45-691
PLIF Trial 8° 1/4, 10 x 10 mm	1	45-692
PLIF Trial 8° 1/4, 10 x 11 mm	1	45-693
PLIF Trial 8° 1/4, 10 x 12 mm	1	45-694
PLIF Trial 8° 1/4, 10 x 13 mm	1	45-695
PLIF Trial 8° 1/4, 10 x 14 mm	1	45-696
PLIF Trial 8° 1/4, 10 x 15 mm	1	45-697
Instrument Basket	1	45-400
Trial Basket PLIF	1	45-401
PLIF Trial 12° 1/4, 10 x 9 mm	1	45-698
PLIF Trial 12° 1/4, 10 x 10 mm	1	45-699
PLIF Trial 12° 1/4, 10 x 11 mm	1	45-700
PLIF Trial 12° 1/4, 10 x 12 mm	1	45-701
PLIF Trial 12° 1/4, 10 x 13 mm	1	45-702
PLIF Trial 12° 1/4, 10 x 14 mm	1	45-703
PLIF Trial 12° 1/4, 10 x 15 mm	1	45-704
PLIF Trial 12° 1/4, 10 x 16 mm	1	45-705
PLIF Trial 12° 1/4, 10 x 17 mm	1	45-706
PLIF Trial 16° 1/4, 10 x 11 mm	1	45-707
PLIF Trial 16° 1/4, 10 x 12 mm	1	45-708
PLIF Trial 16° 1/4, 10 x 13 mm	1	45-709
PLIF Trial 16° 1/4, 10 x 14 mm	1	45-710
PLIF Trial 16° 1/4, 10 x 15 mm	1	45-711
PLIF Trial 16° 1/4, 10 x 16 mm	1	45-712
PLIF Trial 16° 1/4, 10 x 17 mm	1	45-713
PLIF Trial 20° 1/4, 10 x 13 mm	1	45-714
PLIF Trial 20° 1/4, 10 x 14 mm	1	45-715
PLIF Trial 20° 1/4, 10 x 15 mm	1	45-716
PLIF Trial 20° 1/4, 10 x 16 mm	1	45-717
PLIF Trial 20° 1/4, 10 x 17 mm	1	45-718

Important information on the Global BMD Titanium 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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