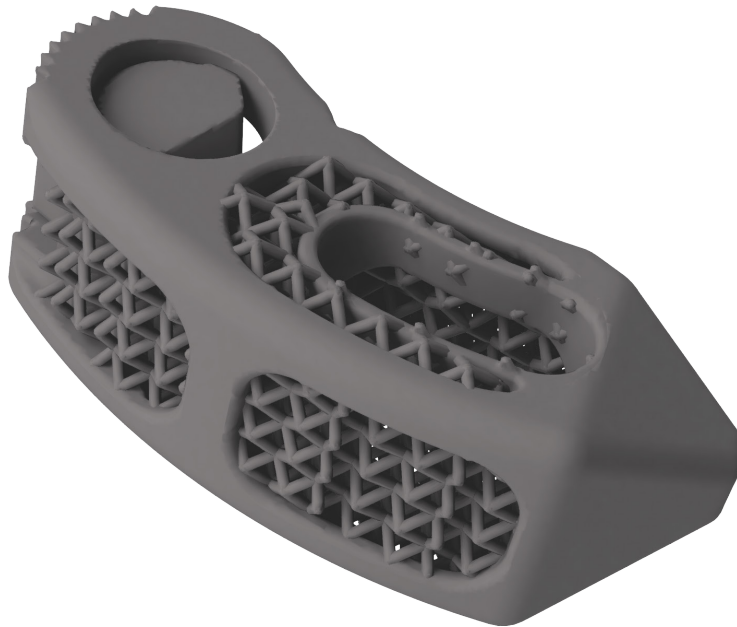


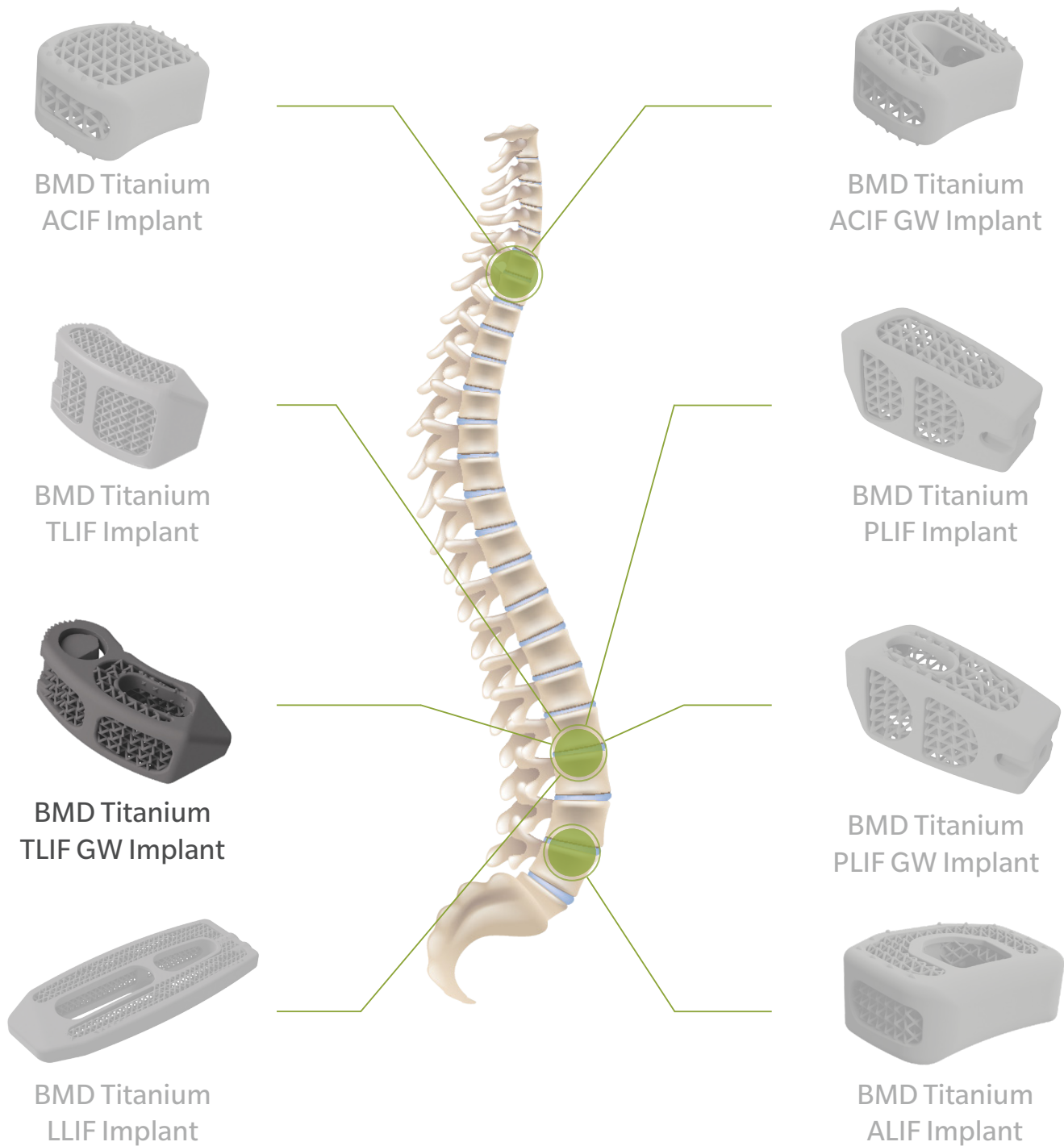


GLOBAL[®]
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The Lumbar BMD
Titanium TLIF GW Implant [®]

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 TLIF 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

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 then 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

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 to avoid over distraction. Apply the distractor parallel to the intervertebral space and turn clockwise to open up the disc space. Correct the surface if necessary with the Rasp tool (Figure 3a).



Figure 4
Trial implant

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).

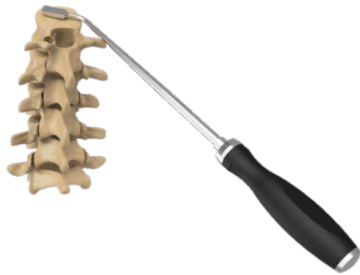


Figure 3a
Correct the surface

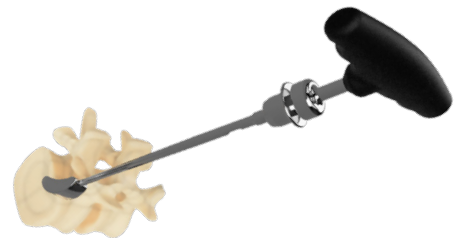


Figure 4a
Determination the implant size

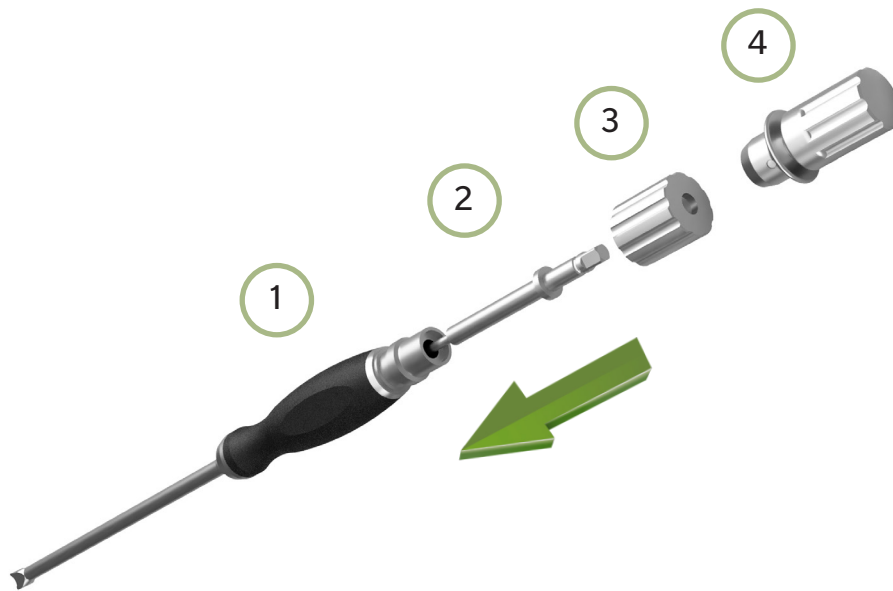


Figure 5
Tool assembly steps

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 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).

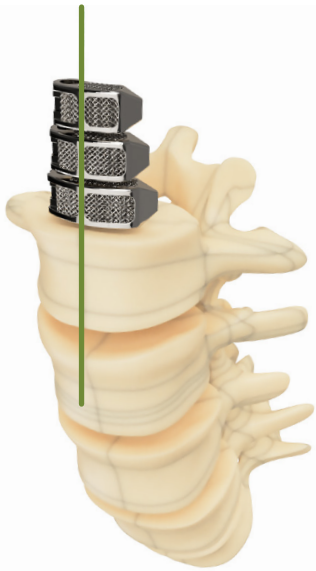


Figure 9
Centre of the implant

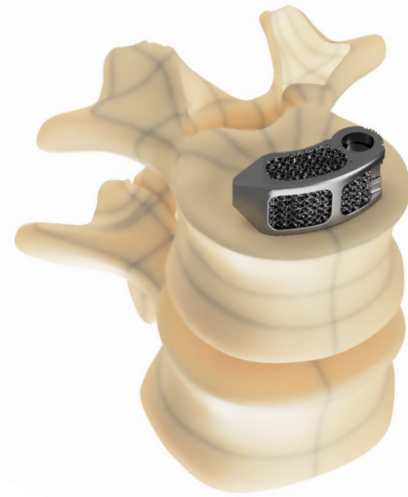



Figure 10
Final position

Detaching Implant from Holder

After the implant is in the final position, loosen the swivel-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. Then 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 GW Implant® does not require any specific postoperative care and the patient should be treated according to hospital and medical standards.



Figure 11
Implant Removal

Implant Removal

Either the Holder or Universal Removal Instrument may be 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	DESCRIPTION	L x W x H	ANGLE	CODE
TLIF GW	26mm x 10mm x 7mm	0°	BMDO26100700	TLIF GW	30mm x 11mm x 13mm	4°	BMDO30111304
TLIF GW	26mm x 10mm x 8mm	0°	BMDO26100800	TLIF GW	30mm x 11mm x 14mm	4°	BMDO30111404
TLIF GW	26mm x 10mm x 9mm	0°	BMDO26100900	TLIF GW	30mm x 11mm x 15mm	4°	BMDO30111504
TLIF GW	26mm x 10mm x 10mm	0°	BMDO26101000	TLIF GW	30mm x 11mm x 16mm	4°	BMDO30111604
TLIF GW	26mm x 10mm x 11mm	0°	BMDO26101100	TLIF GW	30mm x 11mm x 17mm	4°	BMDO30111704
TLIF GW	26mm x 10mm x 12mm	0°	BMDO26101200	TLIF GW	34mm x 12mm x 7mm	4°	BMDO34120704
TLIF GW	26mm x 10mm x 13mm	0°	BMDO26101300	TLIF GW	34mm x 12mm x 8mm	4°	BMDO34120804
TLIF GW	26mm x 10mm x 14mm	0°	BMDO26101400	TLIF GW	34mm x 12mm x 9mm	4°	BMDO34120904
TLIF GW	26mm x 10mm x 15mm	0°	BMDO26101500	TLIF GW	34mm x 12mm x 10mm	4°	BMDO34121004
TLIF GW	26mm x 10mm x 16mm	0°	BMDO26101600	TLIF GW	34mm x 12mm x 11mm	4°	BMDO34121104
TLIF GW	26mm x 10mm x 17mm	0°	BMDO26101700	TLIF GW	34mm x 12mm x 12mm	4°	BMDO34121204
TLIF GW	30mm x 11mm x 7mm	0°	BMDO30110700	TLIF GW	34mm x 12mm x 13mm	4°	BMDO34121304
TLIF GW	30mm x 11mm x 8mm	0°	BMDO30110800	TLIF GW	34mm x 12mm x 14mm	4°	BMDO34121404
TLIF GW	30mm x 11mm x 9mm	0°	BMDO30110900	TLIF GW	34mm x 12mm x 15mm	4°	BMDO34121504
TLIF GW	30mm x 11mm x 10mm	0°	BMDO30111000	TLIF GW	34mm x 12mm x 16mm	4°	BMDO34121604
TLIF GW	30mm x 11mm x 11mm	0°	BMDO30111100	TLIF GW	34mm x 12mm x 17mm	4°	BMDO34121704
TLIF GW	30mm x 11mm x 12mm	0°	BMDO30111200	TLIF GW	26mm x 10mm x 7mm	8°	BMDO26100708
TLIF GW	30mm x 11mm x 13mm	0°	BMDO30111300	TLIF GW	26mm x 10mm x 8mm	8°	BMDO26100808
TLIF GW	30mm x 11mm x 14mm	0°	BMDO30111400	TLIF GW	26mm x 10mm x 9mm	8°	BMDO26100908
TLIF GW	30mm x 11mm x 15mm	0°	BMDO30111500	TLIF GW	26mm x 10mm x 10mm	8°	BMDO26101008
TLIF GW	30mm x 11mm x 16mm	0°	BMDO30111600	TLIF GW	26mm x 10mm x 11mm	8°	BMDO26101108
TLIF GW	30mm x 11mm x 17mm	0°	BMDO30111700	TLIF GW	26mm x 10mm x 12mm	8°	BMDO26101208
TLIF GW	34mm x 12mm x 7mm	0°	BMDO34120700	TLIF GW	26mm x 10mm x 13mm	8°	BMDO26101308
TLIF GW	34mm x 12mm x 8mm	0°	BMDO34120800	TLIF GW	26mm x 10mm x 14mm	8°	BMDO26101408
TLIF GW	34mm x 12mm x 9mm	0°	BMDO34120900	TLIF GW	26mm x 10mm x 15mm	8°	BMDO26101508
TLIF GW	34mm x 12mm x 10mm	0°	BMDO34121000	TLIF GW	26mm x 10mm x 16mm	8°	BMDO26101608
TLIF GW	34mm x 12mm x 11mm	0°	BMDO34121100	TLIF GW	26mm x 10mm x 17mm	8°	BMDO26101708
TLIF GW	34mm x 12mm x 12mm	0°	BMDO34121200	TLIF GW	30mm x 11mm x 7mm	8°	BMDO30110708
TLIF GW	34mm x 12mm x 13mm	0°	BMDO34121300	TLIF GW	30mm x 11mm x 8mm	8°	BMDO30110808
TLIF GW	34mm x 12mm x 14mm	0°	BMDO34121400	TLIF GW	30mm x 11mm x 9mm	8°	BMDO30110908
TLIF GW	34mm x 12mm x 15mm	0°	BMDO34121500	TLIF GW	30mm x 11mm x 10mm	8°	BMDO30111008
TLIF GW	34mm x 12mm x 16mm	0°	BMDO34121600	TLIF GW	30mm x 11mm x 11mm	8°	BMDO30111108
TLIF GW	34mm x 12mm x 17mm	0°	BMDO34121700	TLIF GW	30mm x 11mm x 12mm	8°	BMDO30111208
TLIF GW	26mm x 10mm x 7mm	4°	BMDO26100704	TLIF GW	30mm x 11mm x 13mm	8°	BMDO30111308
TLIF GW	26mm x 10mm x 8mm	4°	BMDO26100804	TLIF GW	30mm x 11mm x 14mm	8°	BMDO30111408
TLIF GW	26mm x 10mm x 9mm	4°	BMDO26100904	TLIF GW	30mm x 11mm x 15mm	8°	BMDO30111508
TLIF GW	26mm x 10mm x 10mm	4°	BMDO26101004	TLIF GW	30mm x 11mm x 16mm	8°	BMDO30111608
TLIF GW	26mm x 10mm x 11mm	4°	BMDO26101104	TLIF GW	30mm x 11mm x 17mm	8°	BMDO30111708
TLIF GW	26mm x 10mm x 12mm	4°	BMDO26101204	TLIF GW	34mm x 12mm x 7mm	8°	BMDO34120708
TLIF GW	26mm x 10mm x 13mm	4°	BMDO26101304	TLIF GW	34mm x 12mm x 8mm	8°	BMDO34120808
TLIF GW	26mm x 10mm x 14mm	4°	BMDO26101404	TLIF GW	34mm x 12mm x 9mm	8°	BMDO34120908
TLIF GW	26mm x 10mm x 15mm	4°	BMDO26101504	TLIF GW	34mm x 12mm x 10mm	8°	BMDO34121008
TLIF GW	26mm x 10mm x 16mm	4°	BMDO26101604	TLIF GW	34mm x 12mm x 11mm	8°	BMDO34121108
TLIF GW	26mm x 10mm x 17mm	4°	BMDO26101704	TLIF GW	34mm x 12mm x 12mm	8°	BMDO34121208
TLIF GW	30mm x 11mm x 7mm	4°	BMDO30110704	TLIF GW	34mm x 12mm x 13mm	8°	BMDO34121308
TLIF GW	30mm x 11mm x 8mm	4°	BMDO30110804	TLIF GW	34mm x 12mm x 14mm	8°	BMDO34121408
TLIF GW	30mm x 11mm x 9mm	4°	BMDO30110904	TLIF GW	34mm x 12mm x 15mm	8°	BMDO34121508
TLIF GW	30mm x 11mm x 10mm	4°	BMDO30111004	TLIF GW	34mm x 12mm x 16mm	8°	BMDO34121608
TLIF GW	30mm x 11mm x 11mm	4°	BMDO30111104	TLIF GW	34mm x 12mm x 17mm	8°	BMDO34121708
TLIF GW	30mm x 11mm x 12mm	4°	BMDO30111204	TLIF GW	26mm x 10mm x 9mm	12°	BMDO26100912

DESCRIPTION	L x W x H	ANGLE	CODE
TLIF GW	26mm x 10mm x 10mm	12°	BMDO26101012
TLIF GW	26mm x 10mm x 11mm	12°	BMDO26101112
TLIF GW	26mm x 10mm x 12mm	12°	BMDO26101212
TLIF GW	26mm x 10mm x 13mm	12°	BMDO26101312
TLIF GW	26mm x 10mm x 14mm	12°	BMDO26101412
TLIF GW	26mm x 10mm x 15mm	12°	BMDO26101512
TLIF GW	26mm x 10mm x 16mm	12°	BMDO26101612
TLIF GW	26mm x 10mm x 17mm	12°	BMDO26101712
TLIF GW	30mm x 11mm x 9mm	12°	BMDO30110912
TLIF GW	30mm x 11mm x 10mm	12°	BMDO30111012
TLIF GW	30mm x 11mm x 11mm	12°	BMDO30111112
TLIF GW	30mm x 11mm x 12mm	12°	BMDO30111212
TLIF GW	30mm x 11mm x 13mm	12°	BMDO30111312
TLIF GW	30mm x 11mm x 14mm	12°	BMDO30111412
TLIF GW	30mm x 11mm x 15mm	12°	BMDO30111512
TLIF GW	30mm x 11mm x 16mm	12°	BMDO30111612
TLIF GW	30mm x 11mm x 17mm	12°	BMDO30111712
TLIF GW	34mm x 12mm x 9mm	12°	BMDO34120912
TLIF GW	34mm x 12mm x 10mm	12°	BMDO34121012
TLIF GW	34mm x 12mm x 11mm	12°	BMDO34121112
TLIF GW	34mm x 12mm x 12mm	12°	BMDO34121212
TLIF GW	34mm x 12mm x 13mm	12°	BMDO34121312
TLIF GW	34mm x 12mm x 14mm	12°	BMDO34121412
TLIF GW	34mm x 12mm x 15mm	12°	BMDO34121512
TLIF GW	34mm x 12mm x 16mm	12°	BMDO34121612
TLIF GW	34mm x 12mm x 17mm	12°	BMDO34121712

Tool List

NAME	REF	NAME	REF
Curette 45° D9L5	35-111	TLIF Trial 0°, 12 mm	55-155
Curette 15° D7L3	35-112	TLIF Trial 0°, 13 mm	55-156
Curette 15° D9L5	35-113	TLIF Trial 0°, 14 mm	55-157
Curette 45° D7L3	35-123	TLIF Trial 0°, 15 mm	55-158
Cage Holder	55-101	TLIF Trial 0°, 16 mm	55-159
Mallet	35-115	TLIF Trial 0°, 17 mm	55-160
Rasp	35-116	TLIF Trial 4°, 7 mm	55-161
Rasp 45° left	55-105	TLIF Trial 4°, 8 mm	55-162
Rast 45° right	55-106	TLIF Trial 4°, 9 mm	55-163
Removal Instrument	35-119	TLIF Trial 4°, 10 mm	55-164
T-Handle	35-114	TLIF Trial 4°, 11 mm	55-165
Distractor 7 mm	35-130	TLIF Trial 4°, 12 mm	55-166
Distractor 8 mm	35-131	TLIF Trial 4°, 13 mm	55-167
Distractor 9 mm	35-132	TLIF Trial 4°, 14 mm	55-168
Distractor 10 mm	35-133	TLIF Trial 4°, 15 mm	55-169
Distractor 11 mm	35-134	TLIF Trial 4°, 16 mm	55-170
Distractor 12 mm	35-135	TLIF Trial 4°, 17 mm	55-171
Distractor 13 mm	35-136	TLIF Trial 8°, 7 mm	55-200
Distractor 14 mm	35-137	TLIF Trial 8°, 8 mm	55-201
Distractor 15 mm	35-138	TLIF Trial 8°, 9 mm	55-202
Distractor 16 mm	35-139	TLIF Trial 8°, 10 mm	55-203
Distractor 17 mm	35-140	TLIF Trial 8°, 11 mm	55-204
Distractor Shaver 7 mm	35-101	TLIF Trial 8°, 12 mm	55-205
Distractor Shaver 8 mm	35-102	TLIF Trial 8°, 13 mm	55-206
Distractor Shaver 9 mm	35-103	TLIF Trial 8°, 14 mm	55-207
Distractor Shaver 10 mm	35-104	TLIF Trial 8°, 15 mm	55-208
Distractor Shaver 11 mm	35-105	TLIF Trial 8°, 16 mm	55-209
Distractor Shaver 12 mm	35-106	TLIF Trial 8°, 17 mm	55-210
Distractor Shaver 13 mm	35-107	TLIF Trial 12°, 9 mm	55-250
Distractor Shaver 14 mm	35-108	TLIF Trial 12°, 10 mm	55-251
Distractor Shaver 15 mm	35-109	TLIF Trial 12°, 11 mm	55-252
Distractor Shaver 16 mm	35-117	TLIF Trial 12°, 12 mm	55-253
Distractor Shaver 17 mm	35-118	TLIF Trial 12°, 13 mm	55-254
Shaver 7 mm	35-150	TLIF Trial 12°, 14 mm	55-255
Shaver 8 mm	35-151	TLIF Trial 12°, 15 mm	55-256
Shaver 9 mm	35-152	TLIF Trial 12°, 16 mm	55-257
Shaver 10 mm	35-153	TLIF Trial 12°, 17 mm	55-258
Shaver 11 mm	35-154	Trial Basket	35-120
Shaver 12 mm	35-155	Instrument Basket	55-450
Shaver 13 mm	35-156		
Shaver 14 mm	35-157		
Shaver 15 mm	35-158		
Shaver 16 mm	35-159		
Shaver 17 mm	35-160		
TLIF Trial 0°, 7 mm	55-150		
TLIF Trial 0°, 8 mm	55-151		
TLIF Trial 0°, 9 mm	55-152		
TLIF Trial 0°, 10 mm	55-153		
TLIF Trial 0°, 11 mm	55-154		

Important Information on the Global BMD Titanium TLIF 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, osteochondrosis, degenerative stenosis, pseudarthrosis
- Traumatic disc involvement – only in the absence of traumatic vertebrae 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 post-operative 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.

 **MANUFACTURER**
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Surgical Technique Guide – BMD Titanium TLIF GW Implant[®], Rev. 2021-04-21 v. 1.1