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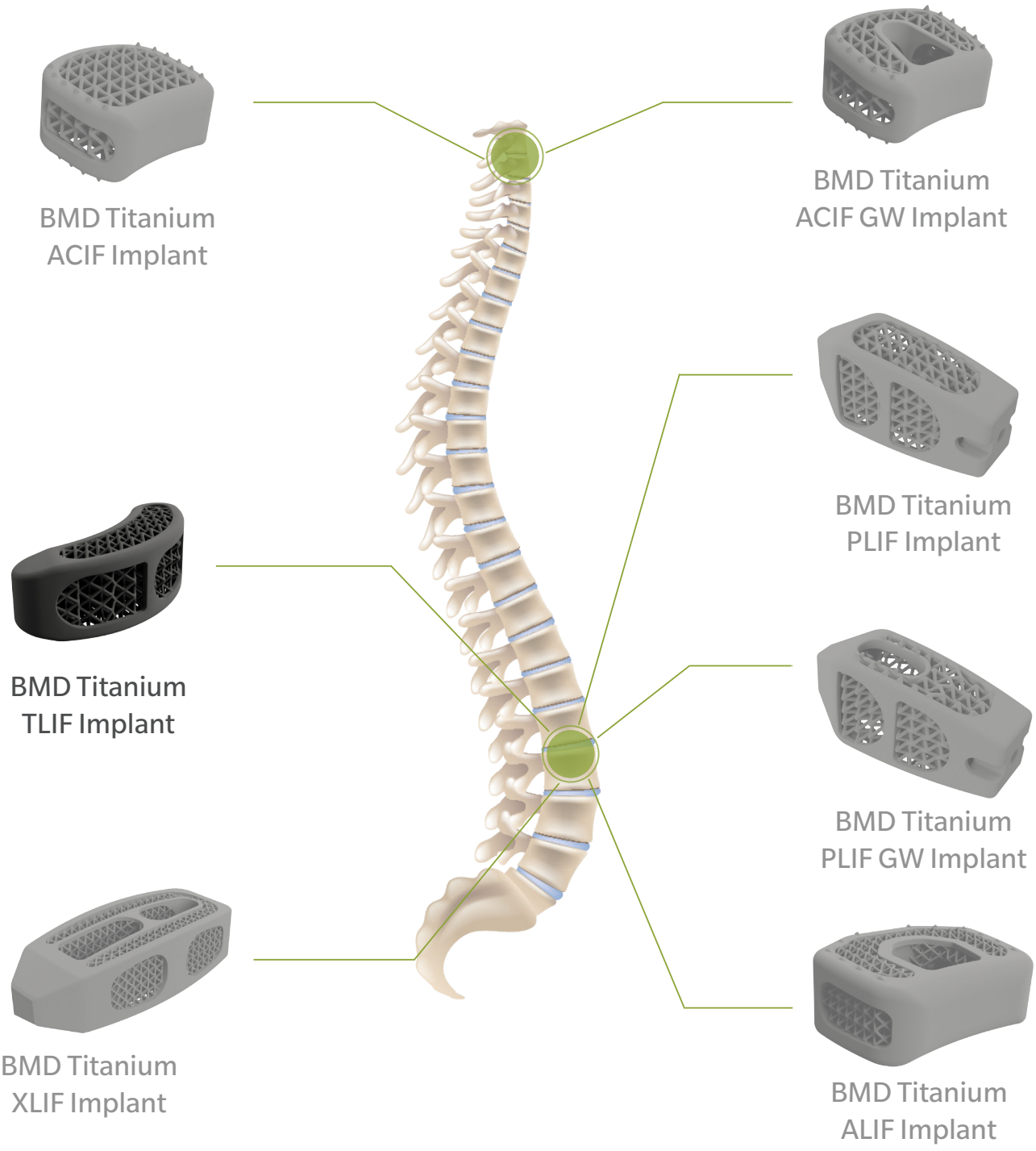
The Lumbar BMD Titanium TLIF Implant ®

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 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 - according to patient and indication the surgeon may choose a more lateral (extraforaminal) approach, leaving the facet joint intact.

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 implant implantation. For this purpose Distractors are available in several heights (Figure 3). Each size of Distractor has grooves, that indicate the length of 26, 30 and 34 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:
Make sure the Inserter is properly assembled by inserting the Inner Shaft into the Inserter Tube. The components are gripped by tightening the screwcap on the end of the handle (Figure 6).

Figure 7
Implant implantation

Once the implant is blocked on the instrument, it can be inserted into the intervertebral space (Figure 7).
The stable longitudinal alignment of the Implant and the Inserter ensures a straight introduction of the Implant along the transforaminal route. Insert the Implant with gentle taps on the back of the Inserter. The position of the Inserter relative to the Implant can be changed by unlocking the screwcap and moving the Inserter (Figure 8). The Implant should be positioned as anterior as possible in the anterior- posterior alignment. Fluoroscopy should be used to check the final position of the Implant. 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 bone graft material.

Figure 8
Moving the implant

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

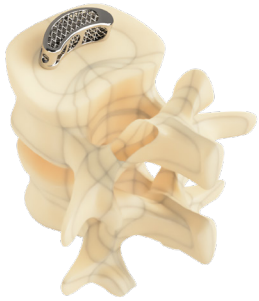

Figure 9
Implant position

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
TLIF,	26mm x 7mm x 12mm,	4°	BMDT26120704
TLIF,	26mm x 8mm x 12mm,	4°	BMDT26120804
TLIF,	26mm x 9mm x 12mm,	4°	BMDT26120904
TLIF,	26mm x 10mm x 12mm,	4°	BMDT26121004
TLIF,	26mm x 11mm x 12mm,	4°	BMDT26121104
TLIF,	26mm x 12mm x 12mm,	4°	BMDT26121204
TLIF,	26mm x 13mm x 12mm,	4°	BMDT26121304
TLIF,	26mm x 14mm x 12mm,	4°	BMDT26121404
TLIF,	26mm x 15mm x 12mm,	4°	BMDT26121504
TLIF,	30mm x 7mm x 12mm,	4°	BMDT30120704
TLIF,	30mm x 8mm x 12mm,	4°	BMDT30120804
TLIF,	30mm x 9mm x 12mm,	4°	BMDT30120904
TLIF,	30mm x 10mm x 12 mm,	4°	BMDT30121004
TLIF,	30mm x 11mm x 12mm,	4°	BMDT30121104
TLIF,	30mm x 12mm x 12mm,	4°	BMDT30121204
TLIF,	30mm x 13mm x 12mm,	4°	BMDT30121304
TLIF,	30mm x 14mm x 12mm,	4°	BMDT30121404
TLIF,	30mm x 15mm x 12mm,	4°	BMDT30121504
TLIF,	34mm x 7mm x 12mm,	4°	BMDT34120704
TLIF,	34mm x 8mm x 12mm,	4°	BMDT34120804
TLIF,	34mm x 9mm x 12mm,	4°	BMDT34120904
TLIF,	34mm x 10mm x 12mm,	4°	BMDT34121004
TLIF,	34mm x 11mm x 12mm,	4°	BMDT34121104
TLIF,	34mm x 12mm x 12mm,	4°	BMDT34121204
TLIF,	34mm x 13mm x 12mm,	4°	BMDT34121304
TLIF,	34mm x 14mm x 12mm,	4°	BMDT34121404
TLIF,	34mm x 15mm x 12mm,	4°	BMDT34121504

DESCRIPTION D x H x W,		8°	PART NUMBER
TLIF,	26mm x 7mm x 12mm,	8°	BMDT26120708
TLIF,	26mm x 8mm x 12mm,	8°	BMDT26120808
TLIF,	26mm x 9mm x 12mm,	8°	BMDT26120908
TLIF,	26mm x 10mm x 12mm,	8°	BMDT26121008
TLIF,	26mm x 11mm x 12mm,	8°	BMDT26121108
TLIF,	26mm x 12mm x 12mm,	8°	BMDT26121208
TLIF,	26mm x 13mm x 12mm,	8°	BMDT26121308
TLIF,	26mm x 14mm x 12mm,	8°	BMDT26121408
TLIF,	26mm x 15mm x 12mm,	8°	BMDT26121508
TLIF,	30mm x 7mm x 12mm,	8°	BMDT30120708
TLIF,	30mm x 8mm x 12mm,	8°	BMDT30120808
TLIF,	30mm x 9mm x 12mm,	8°	BMDT30120908
TLIF,	30mm x 10mm x 12mm,	8°	BMDT30121008
TLIF,	30mm x 11mm x 12mm,	8°	BMDT30121108
TLIF,	30mm x 12mm x 12mm,	8°	BMDT30121208
TLIF,	30mm x 13mm x 12mm,	8°	BMDT30121308
TLIF,	30mm x 14mm x 12mm,	8°	BMDT30121408
TLIF,	30mm x 15mm x 12mm,	8°	BMDT30121508
TLIF,	34mm x 7mm x 12mm,	8°	BMDT34120708
TLIF,	34mm x 8mm x 12mm,	8°	BMDT34120808
TLIF,	34mm x 9mm x 12mm,	8°	BMDT34120908
TLIF,	34mm x 10mm x 12mm,	8°	BMDT34121008
TLIF,	34mm x 11mm x 12mm,	8°	BMDT34121108
TLIF,	34mm x 12mm x 12mm,	8°	BMDT34121208
TLIF,	34mm x 13mm x 12mm,	8°	BMDT34121308
TLIF,	34mm x 14mm x 12mm,	8°	BMDT34121408
TLIF,	34mm x 15mm x 12mm,	8°	BMDT34121508

Tool list

DESCRIPTION D x W x H,	QTY	PART NUMBER
Distractor 7	1	35-101
Distractor 8	1	35-102
Distractor 9	1	35-103
Distractor 10	1	35-104
Distractor 11	1	35-105
Distractor 12	1	35-106
Distractor 13	1	35-107
Distractor 14	1	35-108
Distractor 15	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	35-117
Distractor 17	1	35-118
Trial Basket	1	35-120
Cage Holder	2	55-101
Hook	1	55-102
TLIF Trial 4° 1/4, 26 x 12 x 07 mm	1	55-150
TLIF Trial 4° 1/4, 26 x 12 x 08 mm	1	55-151
TLIF Trial 4° 1/4, 26 x 12 x 09 mm	1	55-152
TLIF Trial 4° 1/4, 26 x 12 x 10 mm	1	55-153
TLIF Trial 4° 1/4, 26 x 12 x 11 mm	1	55-154
TLIF Trial 4° 1/4, 26 x 12 x 12 mm	1	55-155
TLIF Trial 4° 1/4, 26 x 12 x 13 mm	1	55-156
TLIF Trial 4° 1/4, 26 x 12 x 14 mm	1	55-157
TLIF Trial 4° 1/4, 26 x 12 x 15 mm	1	55-158
TLIF Trial 4° 1/4, 30 x 12 x 07 mm	1	55-200
TLIF Trial 4° 1/4, 30 x 12 x 08 mm	1	55-201
TLIF Trial 4° 1/4, 30 x 12 x 09 mm	1	55-202
TLIF Trial 4° 1/4, 30 x 12 x 10 mm	1	55-203
TLIF Trial 4° 1/4, 30 x 12 x 11 mm	1	55-204
TLIF Trial 4° 1/4, 30 x 12 x 12 mm	1	55-205
TLIF Trial 4° 1/4, 30 x 12 x 13 mm	1	55-206
TLIF Trial 4° 1/4, 30 x 12 x 14 mm	1	55-207
TLIF Trial 4° 1/4, 30 x 12 x 15 mm	1	55-208
TLIF Trial 4° 1/4, 34 x 12 x 07 mm	1	55-250
TLIF Trial 4° 1/4, 34 x 12 x 08 mm	1	55-251
TLIF Trial 4° 1/4, 34 x 12 x 09 mm	1	55-252
TLIF Trial 4° 1/4, 34 x 12 x 10 mm	1	55-253
TLIF Trial 4° 1/4, 34 x 12 x 11 mm	1	55-254
TLIF Trial 4° 1/4, 34 x 12 x 12 mm	1	55-255
TLIF Trial 4° 1/4, 34 x 12 x 13 mm	1	55-256
TLIF Trial 4° 1/4, 34 x 12 x 14 mm	1	55-257
TLIF Trial 4° 1/4, 34 x 12 x 15 mm	1	55-258
TLIF Trial 8° 1/4, 26 x 12 x 07 mm	1	55-300
TLIF Trial 8° 1/4, 26 x 12 x 08 mm	1	55-301
TLIF Trial 8° 1/4, 26 x 12 x 09 mm	1	55-302
TLIF Trial 8° 1/4, 26 x 12 x 10 mm	1	55-303
TLIF Trial 8° 1/4, 26 x 12 x 11 mm	1	55-304
TLIF Trial 8° 1/4, 26 x 12 x 12 mm	1	55-305
TLIF Trial 8° 1/4, 26 x 12 x 13 mm	1	55-306
TLIF Trial 8° 1/4, 26 x 12 x 14 mm	1	55-307
TLIF Trial 8° 1/4, 26 x 12 x 15 mm	1	55-308
TLIF Trial 8° 1/4, 30 x 12 x 07 mm	1	55-350
TLIF Trial 8° 1/4, 30 x 12 x 08 mm	1	55-351
TLIF Trial 8° 1/4, 30 x 12 x 09 mm	1	55-352
TLIF Trial 8° 1/4, 30 x 12 x 10 mm	1	55-353
TLIF Trial 8° 1/4, 30 x 12 x 11 mm	1	55-354
TLIF Trial 8° 1/4, 30 x 12 x 12 mm	1	55-355
TLIF Trial 8° 1/4, 30 x 12 x 13 mm	1	55-356
TLIF Trial 8° 1/4, 30 x 12 x 14 mm	1	55-357
TLIF Trial 8° 1/4, 30 x 12 x 15 mm	1	55-358
TLIF Trial 8° 1/4, 34 x 12 x 07 mm	1	55-400
TLIF Trial 8° 1/4, 34 x 12 x 08 mm	1	55-401
TLIF Trial 8° 1/4, 34 x 12 x 09 mm	1	55-402
TLIF Trial 8° 1/4, 34 x 12 x 10 mm	1	55-403
TLIF Trial 8° 1/4, 34 x 12 x 11 mm	1	55-404
TLIF Trial 8° 1/4, 34 x 12 x 12 mm	1	55-405
TLIF Trial 8° 1/4, 34 x 12 x 13 mm	1	55-406
TLIF Trial 8° 1/4, 34 x 12 x 14 mm	1	55-407
TLIF Trial 8° 1/4, 34 x 12 x 15 mm	1	55-408
Instrument Basket	1	55-450

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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