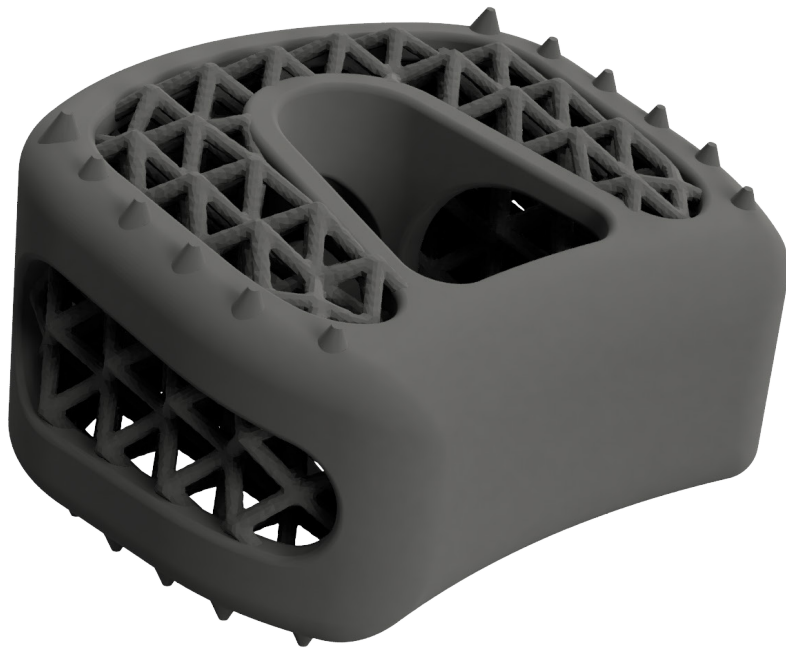


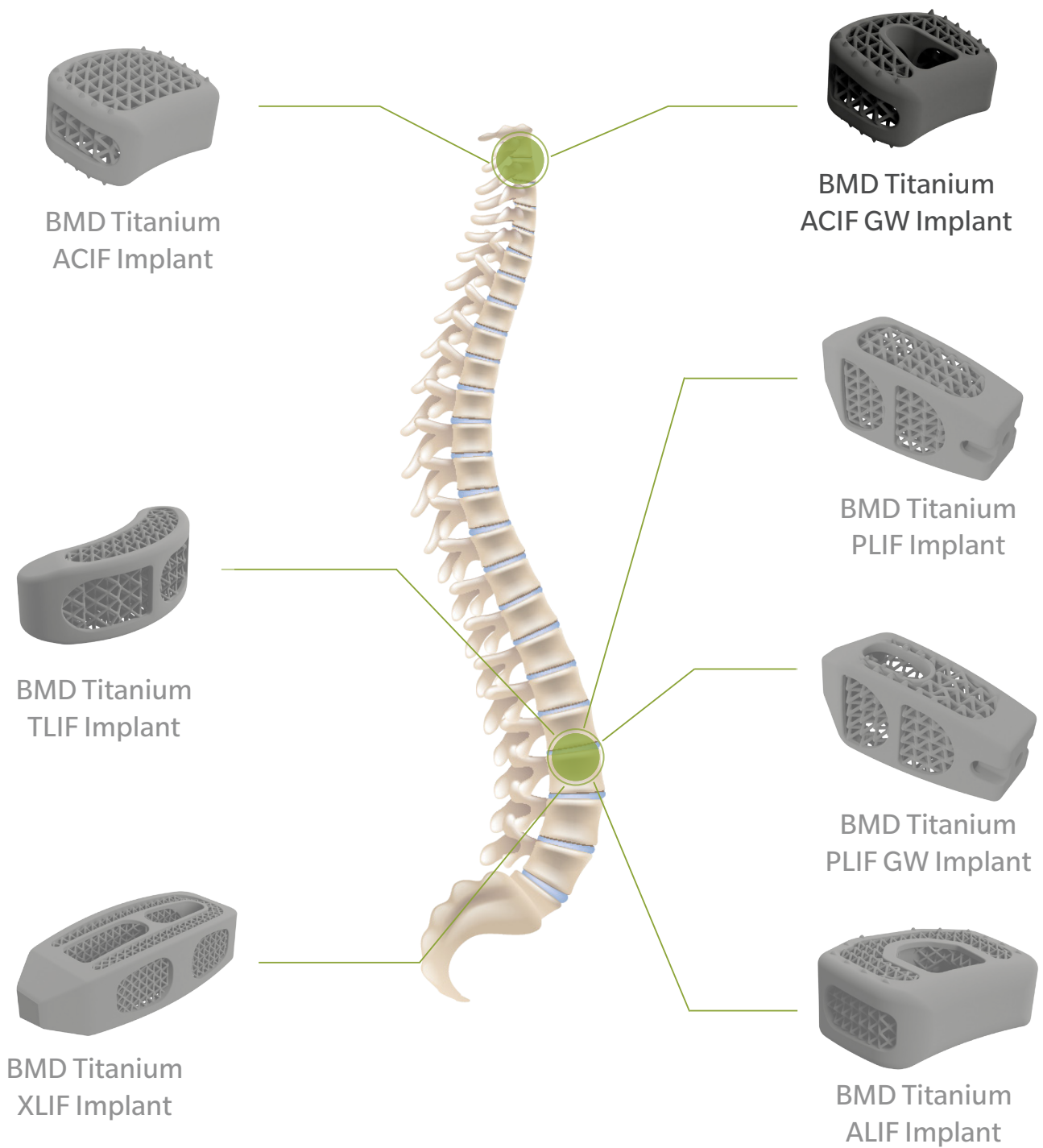


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The Cervical BMD  
Titanium ACIF GW Implant<sup>®</sup>

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 ACIF GW Implant<sup>®</sup>. 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

## Positioning of the patient

The patient is positioned on his back and the head is fixed. Cervical spine should be in physiological lordotic position. The incision should target the area of the operation. Expose the intervertebral disc and the adjacent vertebral body with a standard anterior approach to cervical spine (Figure 1).

The incision should enable relevant access for the stabilization of the spine segment.

A radiolucent operating 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.



Figure 2  
Mount the Distraction Pin

Mount the Distraction Pin on the Pin Holder and insert it into the vertebral body adjacent to the disc (Figure 2). Should insertion prove difficult, pre-drill a hole for the Pin. Repeat this for the second Pin.

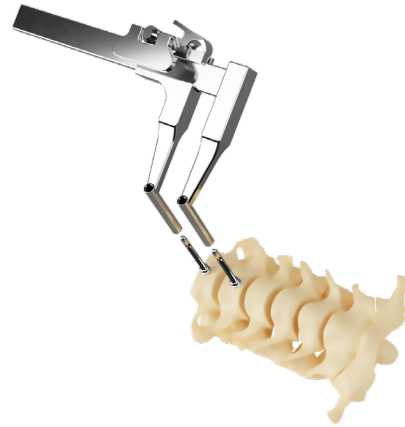


Figure 3  
Distraction of operative level

## Installation of the Caspar Distractor

Place the Caspar Distractor over the Pins and perform the distraction (Figure 3). The distraction is crucial in order to restore the disk height as well as to ensure optimal access into the intervertebral space.

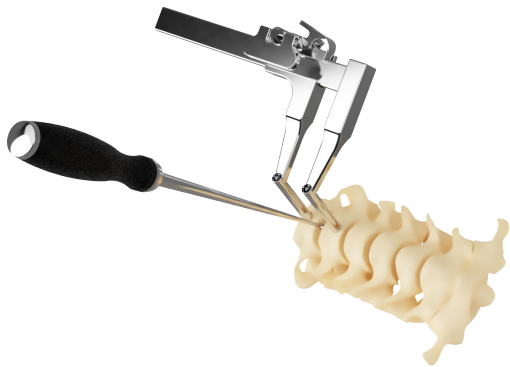


Figure 4  
Perform a complete discectomy

## Discectomy

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To ensure smooth assembly, fair stability and fast fusion after the implantation, it is necessary to remove the full intervertebral disc including the cartilaginous endplates and expose the bleeding bony endplates (Figure 4).



Figure 5  
Trial selection

## Determination of Implant Size

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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). Make sure that the side with appropriate lordosis is selected before inserting  
Use X-Ray to check the correct position of the test implant, which should fit tightly and accurately into intervertebral space.



**Figure 6**  
Mount the selected implant

## Implant installation

Open the sterile packaging of the implant size that was determined with the Trial implant. Mount the selected implant on the Implant Holder and tighten with hand (Figure 6). Make sure that locking pins, which determine the implant position are correctly positioned before tightening the Implant Holder.



**Figure 7**  
Implant insertion

Once the implant is fixed on the instrument, it can be inserted into the intervertebral space. Ensure proper insertion of the implant, „UP” mark on the instrument (Figure 7).

After insertion and proper placement of the implant in the intervertebral space, release the instrument (T-Handle can be used). Use X-Ray to check the correct position of the implant that should fit tightly and accurately into intervertebral space.



**Figure 8**  
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 8). 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 be removed to facilitate implant retrieval.

## List of implants

DESCRIPTION, D x H x W,	0°	PART NUMBER	DESCRIPTION, D x H x W,	10°	PART NUMBER
ACIF, 10mm x 4mm x 12mm,	0°	BMDC10120400	ACIF, 12mm x 5mm x 14mm,	10°	BMDC12140510
ACIF, 10mm x 5mm x 12mm,	0°	BMDC10120500	ACIF, 12mm x 6mm x 14mm,	10°	BMDC12140610
ACIF, 10mm x 6mm x 12mm,	0°	BMDC10120600	ACIF, 12mm x 7mm x 14mm,	10°	BMDC12140710
ACIF, 10mm x 7mm x 12mm,	0°	BMDC10120700	ACIF, 12mm x 8mm x 14mm,	10°	BMDC12140810
ACIF, 10mm x 8mm x 12mm,	0°	BMDC10120800	ACIF, 12mm x 9mm x 14mm,	10°	BMDC12140910
ACIF, 10mm x 9mm x 12mm,	0°	BMDC10120900	ACIF, 12mm x 10mm x 14mm,	10°	BMDC12141010
ACIF, 12mm x 4mm x 14mm,	0°	BMDC12140400	ACIF, 14mm x 5mm x 16mm,	10°	BMDC14160510
ACIF, 12mm x 5mm x 14mm,	0°	BMDC12140500	ACIF, 14mm x 6mm x 16mm,	10°	BMDC14160610
ACIF, 12mm x 6mm x 14mm,	0°	BMDC12140600	ACIF, 14mm x 7mm x 16mm,	10°	BMDC14160710
ACIF, 12mm x 7mm x 14mm,	0°	BMDC12140700	ACIF, 14mm x 8mm x 16mm,	10°	BMDC14160810
ACIF, 12mm x 8mm x 14mm,	0°	BMDC12140800	ACIF, 14mm x 9mm x 16mm,	10°	BMDC14160910
ACIF, 12mm x 9mm x 14mm,	0°	BMDC12140900	ACIF, 14mm x 10mm x 16mm,	10°	BMDC14161010
ACIF, 14mm x 4mm x 16mm,	0°	BMDC14160400	ACIF, 16mm x 5mm x 18mm,	10°	BMDC16180510
ACIF, 14mm x 5mm x 16mm,	0°	BMDC14160500	ACIF, 16mm x 6mm x 18mm,	10°	BMDC16180610
ACIF, 14mm x 6mm x 16mm,	0°	BMDC14160600	ACIF, 16mm x 7mm x 18mm,	10°	BMDC16180710
ACIF, 14mm x 7mm x 16mm,	0°	BMDC14160700	ACIF, 16mm x 8mm x 18mm,	10°	BMDC16180810
ACIF, 14mm x 8mm x 16mm,	0°	BMDC14160800	ACIF, 16mm x 9mm x 18mm,	10°	BMDC16180910
ACIF, 14mm x 9mm x 16mm,	0°	BMDC14160900	ACIF, 16mm x 10mm x 18mm,	10°	BMDC16181010

DESCRIPTION, D x H x W,	5°	PART NUMBER
ACIF, 10mm x 4mm x 12mm,	5°	BMDC10120405
ACIF, 10mm x 5mm x 12mm,	5°	BMDC10120505
ACIF, 10mm x 6mm x 12mm,	5°	BMDC10120605
ACIF, 10mm x 7mm x 12mm,	5°	BMDC10120705
ACIF, 10mm x 8mm x 12mm,	5°	BMDC10120805
ACIF, 10mm x 9mm x 12mm,	5°	BMDC10120905
ACIF, 12mm x 4mm x 14mm,	5°	BMDC12140405
ACIF, 12mm x 5mm x 14mm,	5°	BMDC12140505
ACIF, 12mm x 6mm x 14mm,	5°	BMDC12140605
ACIF, 12mm x 7mm x 14mm,	5°	BMDC12140705
ACIF, 12mm x 8mm x 14mm,	5°	BMDC12140805
ACIF, 12mm x 9mm x 14mm,	5°	BMDC12140905
ACIF, 14mm x 4mm x 16mm,	5°	BMDC14160405
ACIF, 14mm x 5mm x 16mm,	5°	BMDC14160505
ACIF, 14mm x 6mm x 16mm,	5°	BMDC14160605
ACIF, 14mm x 7mm x 16mm,	5°	BMDC14160705
ACIF, 14mm x 8mm x 16mm,	5°	BMDC14160805
ACIF, 14mm x 9mm x 16mm,	5°	BMDC14160905
ACIF, 16mm x 5mm x 18mm,	5°	BMDC16180505
ACIF, 16mm x 6mm x 18mm,	5°	BMDC16180605
ACIF, 16mm x 7mm x 18mm,	5°	BMDC16180705
ACIF, 16mm x 8mm x 18mm,	5°	BMDC16180805
ACIF, 16mm x 9mm x 18mm,	5°	BMDC16180905
ACIF, 16mm x 10mm x 18mm,	5°	BMDC16181005

## Tool list

DESCRIPTION, D x W x H,	QTY	PART NUMBER	DESCRIPTION, D x W x H,	QTY	PART NUMBER
Spoon Curette	1	25-101	ACIF Trial 5°, 12 x 14 x 6 mm	1	25-208
Open Curette	1	25-103	ACIF Trial 5°, 12 x 14 x 7 mm	1	25-209
Cage Holder	1	25-110	ACIF Trial 5°, 12 x 14 x 8 mm	1	25-210
Cage Holder with Stopper	1	25-111	ACIF Trial 5°, 12 x 14 x 9 mm	1	25-211
Final Impactor	1	25-112	ACIF Trial 5°, 14 x 16 x 4 mm	1	25-212
Caspar Right	1	25-113	ACIF Trial 5°, 14 x 16 x 5 mm	1	25-213
Pins Holder	1	25-114	ACIF Trial 5°, 14 x 16 x 6 mm	1	25-214
Pin for Caspar 14mm	2	25-115	ACIF Trial 5°, 14 x 16 x 7 mm	1	25-215
Pin for Caspar 16mm	2	25-116	ACIF Trial 5°, 14 x 16 x 8 mm	1	25-216
Caspar Left	1	25-117	ACIF Trial 5°, 14 x 16 x 9 mm	1	25-217
ACIF Trial 0°, 10 x 12 x 4 mm	1	25-150	ACIF Trial 5°, 16 x 18 x 5 mm	1	25-218
ACIF Trial 0°, 10 x 12 x 5 mm	1	25-151	ACIF Trial 5°, 16 x 18 x 6 mm	1	25-219
ACIF Trial 0°, 10 x 12 x 6 mm	1	25-152	ACIF Trial 5°, 16 x 18 x 7 mm	1	25-220
ACIF Trial 0°, 10 x 12 x 7 mm	1	25-153	ACIF Trial 5°, 16 x 18 x 8 mm	1	25-221
ACIF Trial 0°, 10 x 12 x 8 mm	1	25-154	ACIF Trial 5°, 16 x 18 x 9 mm	1	25-222
ACIF Trial 0°, 10 x 12 x 9 mm	1	25-155	ACIF Trial 5°, 16 x 18 x 10 mm	1	25-223
ACIF Trial 0°, 12 x 14 x 4 mm	1	25-156	ACIF Trial 10°, 12 x 14 x 5 mm	1	25-224
ACIF Trial 0°, 12 x 14 x 5 mm	1	25-157	ACIF Trial 10°, 12 x 14 x 6 mm	1	25-225
ACIF Trial 0°, 12 x 14 x 6 mm	1	25-158	ACIF Trial 10°, 12 x 14 x 7 mm	1	25-226
ACIF Trial 0°, 12 x 14 x 7 mm	1	25-159	ACIF Trial 10°, 12 x 14 x 8 mm	1	25-227
ACIF Trial 0°, 12 x 14 x 8 mm	1	25-160	ACIF Trial 10°, 12 x 14 x 9 mm	1	25-228
ACIF Trial 0°, 12 x 14 x 9 mm	1	25-161	ACIF Trial 10°, 12 x 14 x 10 mm	1	25-229
ACIF Trial 0°, 14 x 16 x 4 mm	1	25-162	ACIF Trial 10°, 14 x 16 x 5 mm	1	25-230
ACIF Trial 0°, 14 x 16 x 5 mm	1	25-163	ACIF Trial 10°, 14 x 16 x 6 mm	1	25-231
ACIF Trial 0°, 14 x 16 x 6 mm	1	25-164	ACIF Trial 10°, 14 x 16 x 7 mm	1	25-232
ACIF Trial 0°, 14 x 16 x 7 mm	1	25-165	ACIF Trial 10°, 14 x 16 x 8 mm	1	25-233
ACIF Trial 0°, 14 x 16 x 8 mm	1	25-166	ACIF Trial 10°, 14 x 16 x 9 mm	1	25-234
ACIF Trial 0°, 14 x 16 x 9 mm	1	25-167	ACIF Trial 10°, 14 x 16 x 10 mm	1	25-235
ACIF Trial 5°, 10 x 12 x 4 mm	1	25-200	ACIF Trial 10°, 16 x 18 x 5 mm	1	25-236
ACIF Trial 5°, 10 x 12 x 5 mm	1	25-201	ACIF Trial 10°, 16 x 18 x 6 mm	1	25-237
ACIF Trial 5°, 10 x 12 x 6 mm	1	25-202	ACIF Trial 10°, 16 x 18 x 7 mm	1	25-238
ACIF Trial 5°, 10 x 12 x 7 mm	1	25-203	ACIF Trial 10°, 16 x 18 x 8 mm	1	25-239
ACIF Trial 5°, 10 x 12 x 8 mm	1	25-204	ACIF Trial 10°, 16 x 18 x 9 mm	1	25-240
ACIF Trial 5°, 10 x 12 x 9 mm	1	25-205	ACIF Trial 10°, 16 x 18 x 10 mm	1	25-241
ACIF Trial 5°, 12 x 14 x 4 mm	1	25-206	Instrument Basket	1	25-250
ACIF Trial 5°, 12 x 14 x 5 mm	1	25-207	Trial Basket	1	35-120



# 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 cervical BMD Titanium Implant® is indicated for cervical 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 cervical 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, lysis, dislocation, tumor, pseudoarthrosis. The effectiveness and safety for any other conditions are unknown.
- BMD Titanium Implant<sup>®</sup> 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<sup>®</sup>.
- 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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 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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