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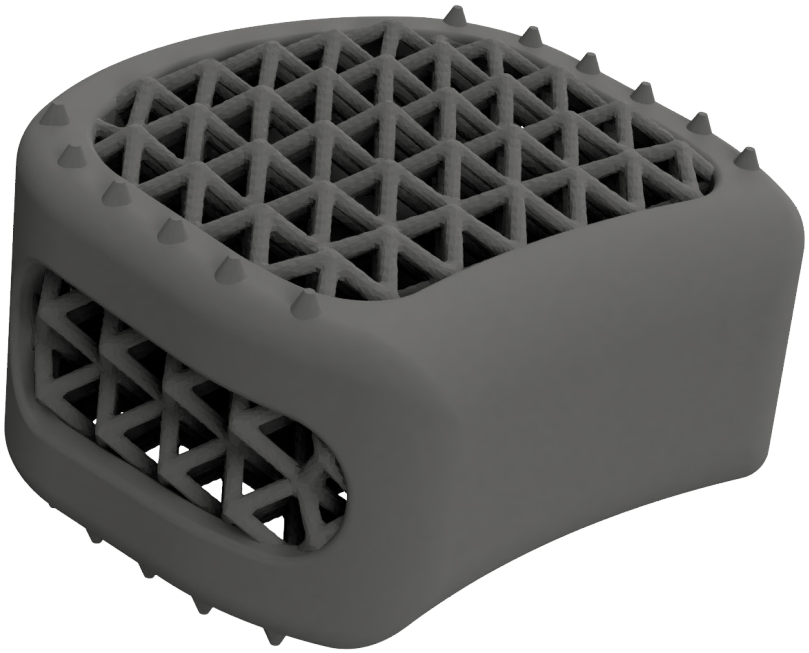
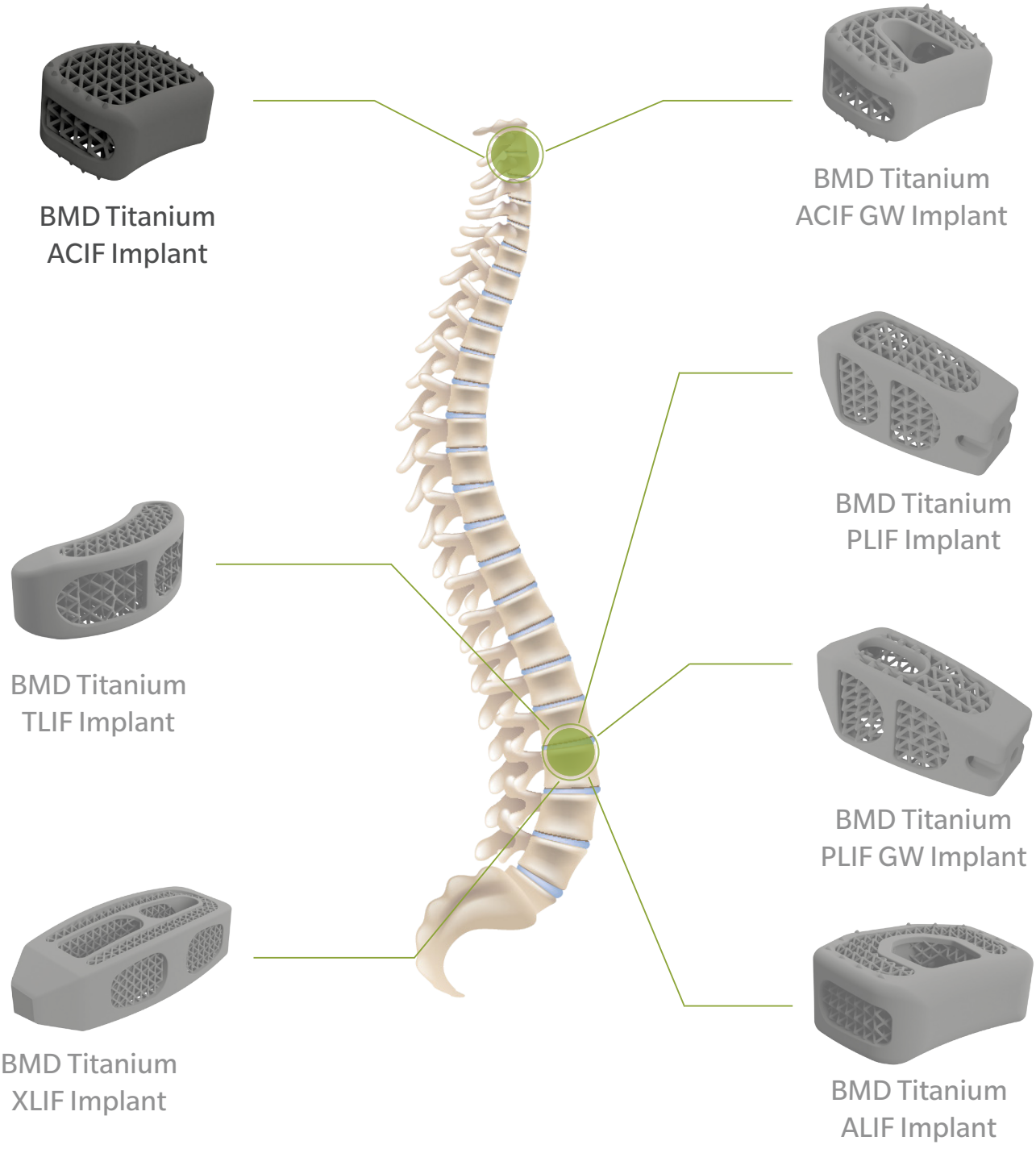


The Cervical BMD Titanium ACIF Implant ®

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 ACIF 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

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 stabilisation 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.

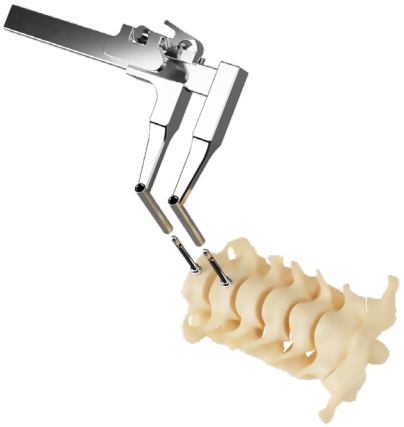

Figure 3
Distraction of operative level

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.

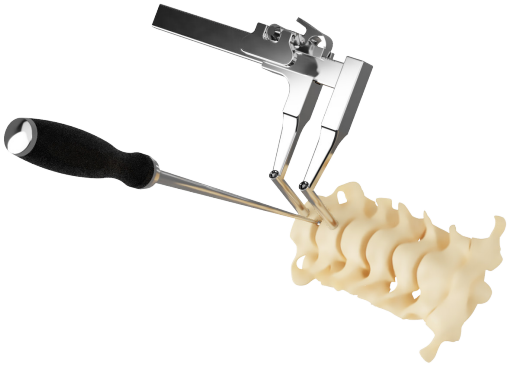

Figure 4
Perform a complete discectomy

Discectomy

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

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.

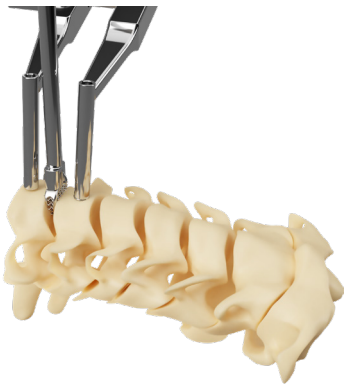

Figure 7
Implant insertion

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 beremoved to facilitate implant retrieval.

List of implants

DESCRIPTION, D x H x W,	0°	PART NUMBER
ACIF, 10mm x 4mm x 12mm,	0°	BMDA10120400
ACIF, 10mm x 5mm x 12mm,	0°	BMDA10120500
ACIF, 10mm x 6mm x 12mm,	0°	BMDA10120600
ACIF, 10mm x 7mm x 12mm,	0°	BMDA10120700
ACIF, 10mm x 8mm x 12mm,	0°	BMDA10120800
ACIF, 10mm x 9mm x 12mm,	0°	BMDA10120900
ACIF, 12mm x 4mm x 14mm,	0°	BMDA12140400
ACIF, 12mm x 5mm x 14mm,	0°	BMDA12140500
ACIF, 12mm x 6mm x 14mm,	0°	BMDA12140600
ACIF, 12mm x 7mm x 14mm,	0°	BMDA12140700
ACIF, 12mm x 8mm x 14mm,	0°	BMDA12140800
ACIF, 12mm x 9mm x 14mm,	0°	BMDA12140900
ACIF, 14mm x 4mm x16mm,	0°	BMDA14160400
ACIF, 14mm x 5mm x 16mm,	0°	BMDA14160500
ACIF, 14mm x 6mm x 16mm,	0°	BMDA14160600
ACIF, 14mm x 7mm x 16mm,	0°	BMDA14160700
ACIF, 14mm x 8mm x 16mm,	0°	BMDA14160800
ACIF, 14mm x 9mm x 16mm,	0°	BMDA14160900

DESCRIPTION, D x H x W,	10°	PART NUMBER
ACIF, 12mm x 5mm x 14mm,	10°	BMDA12140510
ACIF, 12mm x 6mm x 14mm,	10°	BMDA12140610
ACIF, 12mm x 7mm x 14mm,	10°	BMDA12140710
ACIF, 12mm x 8mm x 14mm,	10°	BMDA12140810
ACIF, 12mm x 9mm x 14mm,	10°	BMDA12140910
ACIF, 12mm x 10mm x 14mm,	10°	BMDA12141010
ACIF, 14mm x 5mm x 16mm,	10°	BMDA14160510
ACIF, 14mm x 6mm x 16mm,	10°	BMDA14160610
ACIF, 14mm x 7mm x 16mm,	10°	BMDA14160710
ACIF, 14mm x 8mm x 16mm,	10°	BMDA14160810
ACIF, 14mm x 9mm x 16mm,	10°	BMDA14160910
ACIF, 14mm x 10mm x 16mm,	10°	BMDA14161010
ACIF, 16mm x 5mm x 18mm,	10°	BMDA16180510
ACIF, 16mm x 6mm x 18mm,	10°	BMDA16180610
ACIF, 16mm x 7mm x 18mm,	10°	BMDA16180710
ACIF, 16mm x 8mm x 18mm,	10°	BMDA16180810
ACIF, 16mm x 9mm x 18mm,	10°	BMDA16180910
ACIF, 16mm x 10mm x 18mm,	10°	BMDA16181010

DESCRIPTION, D x H x W,	5°	PART NUMBER
ACIF, 10mm x 4mm x 12mm,	5°	BMDA10120405
ACIF, 10mm x 5mm x 12mm,	5°	BMDA10120505
ACIF, 10mm x 6mm x 12mm,	5°	BMDA10120605
ACIF, 10mm x 7mm x 12mm,	5°	BMDA10120705
ACIF, 10mm x 8mm x 12mm,	5°	BMDA10120805
ACIF, 10mm x 9mm x 12mm,	5°	BMDA10120905
ACIF, 12mm x 4mm x 14mm,	5°	BMDA12140405
ACIF, 12mm x 5mm x 14mm,	5°	BMDA12140505
ACIF, 12mm x 6mm x 14mm,	5°	BMDA12140605
ACIF, 12mm x 7mm x 14mm,	5°	BMDA12140705
ACIF, 12mm x 8mm x 14mm,	5°	BMDA12140805
ACIF, 12mm x 9mm x 14mm,	5°	BMDA12140905
ACIF, 14mm x 4mm x 16mm,	5°	BMDA14160405
ACIF, 14mm x 5mm x 16mm,	5°	BMDA14160505
ACIF, 14mm x 6mm x 16mm,	5°	BMDA14160605
ACIF, 14mm x 7mm x 16mm,	5°	BMDA14160705
ACIF, 14mm x 8mm x 16mm,	5°	BMDA14160805
ACIF, 14mm x 9mm x 16mm,	5°	BMDA14160905
ACIF, 16mm x 5mm x 18mm,	5°	BMDA16180505
ACIF, 16mm x 6mm x 18mm,	5°	BMDA16180605
ACIF, 16mm x 7mm x 18mm,	5°	BMDA16180705
ACIF, 16mm x 8mm x 18mm,	5°	BMDA16180805
ACIF, 16mm x 9mm x 18mm,	5°	BMDA16180905
ACIF, 16mm x 10mm x 18mm,	5°	BMDA16181005

Tool list

DESCRIPTION, D x W x H,	QTY	PART NUMBER
Spoon Curette	1	25-101
Open Curette	1	25-103
Cage Holder	1	25-110
Cage Holder with Stopper	1	25-111
Final Impactor	1	25-112
Caspar Right	1	25-113
Pins Holder	1	25-114
Pin for Caspar 14mm	2	25-115
Pin for Caspar 16mm	2	25-116
Caspar Left	1	25-117
ACIF Trial 0°, 10 x 12 x 4 mm	1	25-150
ACIF Trial 0°, 10 x 12 x 5 mm	1	25-151
ACIF Trial 0°, 10 x 12 x 6 mm	1	25-152
ACIF Trial 0°, 10 x 12 x 7 mm	1	25-153
ACIF Trial 0°, 10 x 12 x 8 mm	1	25-154
ACIF Trial 0°, 10 x 12 x 9 mm	1	25-155
ACIF Trial 0°, 12 x 14 x 4 mm	1	25-156
ACIF Trial 0°, 12 x 14 x 5 mm	1	25-157
ACIF Trial 0°, 12 x 14 x 6 mm	1	25-158
ACIF Trial 0°, 12 x 14 x 7 mm	1	25-159
ACIF Trial 0°, 12 x 14 x 8 mm	1	25-160
ACIF Trial 0°, 12 x 14 x 9 mm	1	25-161
ACIF Trial 0°, 14 x 16 x 4 mm	1	25-162
ACIF Trial 0°, 14 x 16 x 5 mm	1	25-163
ACIF Trial 0°, 14 x 16 x 6 mm	1	25-164
ACIF Trial 0°, 14 x 16 x 7 mm	1	25-165
ACIF Trial 0°, 14 x 16 x 8 mm	1	25-166
ACIF Trial 0°, 14 x 16 x 9 mm	1	25-167
ACIF Trial 5°, 10 x 12 x 4 mm	1	25-200
ACIF Trial 5°, 10 x 12 x 5 mm	1	25-201
ACIF Trial 5°, 10 x 12 x 6 mm	1	25-202
ACIF Trial 5°, 10 x 12 x 7 mm	1	25-203
ACIF Trial 5°, 10 x 12 x 8 mm	1	25-204
ACIF Trial 5°, 10 x 12 x 9 mm	1	25-205
ACIF Trial 5°, 12 x 14 x 4 mm	1	25-206
ACIF Trial 5°, 12 x 14 x 5 mm	1	25-207

DESCRIPTION, D x W x H,	QTY	PART NUMBER
ACIF Trial 5°, 12 x 14 x 6 mm	1	25-208
ACIF Trial 5°, 12 x 14 x 7 mm	1	25-209
ACIF Trial 5°, 12 x 14 x 8 mm	1	25-210
ACIF Trial 5°, 12 x 14 x 9 mm	1	25-211
ACIF Trial 5°, 14 x 16 x 4 mm	1	25-212
ACIF Trial 5°, 14 x 16 x 5 mm	1	25-213
ACIF Trial 5°, 14 x 16 x 6 mm	1	25-214
ACIF Trial 5°, 14 x 16 x 7 mm	1	25-215
ACIF Trial 5°, 14 x 16 x 8 mm	1	25-216
ACIF Trial 5°, 14 x 16 x 9 mm	1	25-217
ACIF Trial 5°, 16 x 18 x 5 mm	1	25-218
ACIF Trial 5°, 16 x 18 x 6 mm	1	25-219
ACIF Trial 5°, 16 x 18 x 7 mm	1	25-220
ACIF Trial 5°, 16 x 18 x 8 mm	1	25-221
ACIF Trial 5°, 16 x 18 x 9 mm	1	25-222
ACIF Trial 5°, 16 x 18 x 10 mm	1	25-223
ACIF Trial 10°, 12 x 14 x 5 mm	1	25-224
ACIF Trial 10°, 12 x 14 x 6 mm	1	25-225
ACIF Trial 10°, 12 x 14 x 7 mm	1	25-226
ACIF Trial 10°, 12 x 14 x 8 mm	1	25-227
ACIF Trial 10°, 12 x 14 x 9 mm	1	25-228
ACIF Trial 10°, 12 x 14 x 10 mm	1	25-229
ACIF Trial 10°, 14 x 16 x 5 mm	1	25-230
ACIF Trial 10°, 14 x 16 x 6 mm	1	25-231
ACIF Trial 10°, 14 x 16 x 7 mm	1	25-232
ACIF Trial 10°, 14 x 16 x 8 mm	1	25-233
ACIF Trial 10°, 14 x 16 x 9 mm	1	25-234
ACIF Trial 10°, 14 x 16 x 10 mm	1	25-235
ACIF Trial 10°, 16 x 18 x 5 mm	1	25-236
ACIF Trial 10°, 16 x 18 x 6 mm	1	25-237
ACIF Trial 10°, 16 x 18 x 7 mm	1	25-238
ACIF Trial 10°, 16 x 18 x 8 mm	1	25-239
ACIF Trial 10°, 16 x 18 x 9 mm	1	25-240
ACIF Trial 10°, 16 x 18 x 10 mm	1	25-241
Instrument Basket	1	25-250
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, ostechondrosis, degenerative stenosis, pseudarthrosis
- Traumatic disc involvement – only in the absence of traumatic vertebras 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, 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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