TSUNAMI MEDICAL

THE WAVE OF INNOVATION

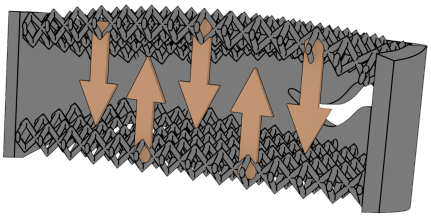
CAPRI
Cervical Fusion Cage

Surgical Technique

System Description

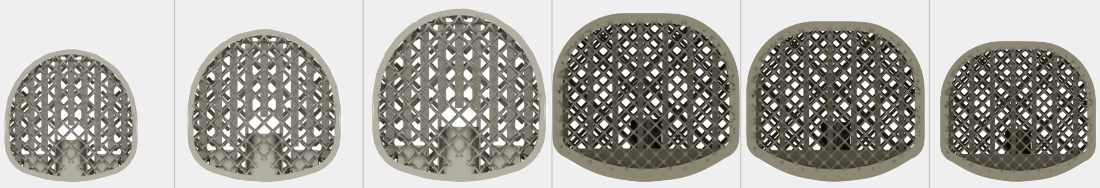
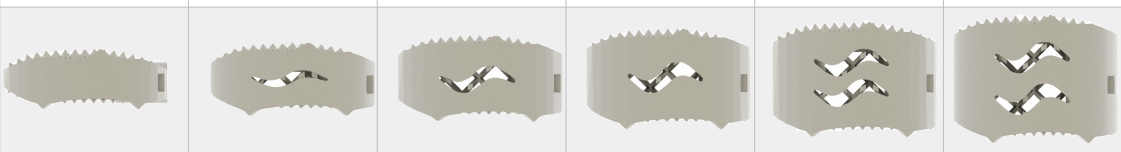
b-OK BoneInGrow™ Cervical Cage has been designed in order to promote highest quality intervertebral fusion. Novel concept of titanium processing developed by Tsunami Medical provides an excellent environment for bone fusion due to followings factors:

- osseointegration of titanium particle
- benefits of dynamic fusion process due to Wolf's Law
- open implants structure allows free flow of bone cells
- high porous surface supports settlement and growth of new bone formations.

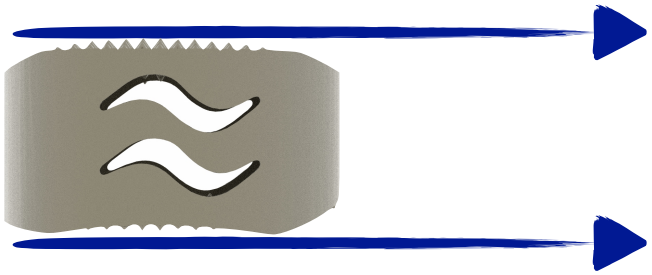


b-OK Cervical Cage System is intended to be used as bone fusion device. Please see Product Insert for indications and contraindication list. The b-OK system must be used by professionals with appropriate trainings accomplished.

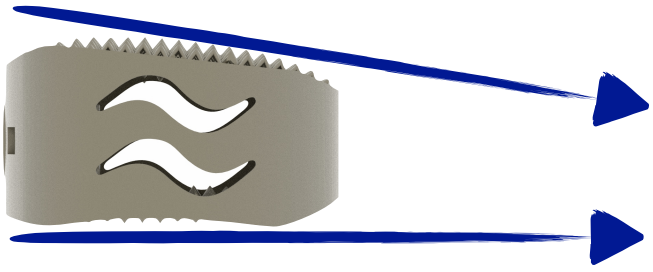
Ref. Code	**Foot Print Size**
ACC1212**00	Foot Print Size **12x12mm** - Angle **0°** Range of Heights [mm] **4, 5, 6, 7, 8, 9**
ACC1212**05	Foot Print Size **12x12mm** - Angle **5°** Range of Heights [mm] **4, 5, 6, 7, 8, 9**
ACC1414**00	Foot Print Size **14x14mm** - Angle **0°** Range of Heights [mm] **4, 5, 6, 7, 8, 9**
ACC1414**05	Foot Print Size **14x14mm** - Angle **5°** Range of Heights [mm] **4, 5, 6, 7, 8, 9**
ACC1616**00	Foot Print Size **16x16mm** - Angle **0°** Range of Heights [mm] **4, 5, 6, 7, 8, 9**
ACC1616**05	Foot Print Size **16x16mm** - Angle **5°** Range of Heights [mm] **4, 5, 6, 7, 8, 9**
ACC1412**05	Foot Print Size **14x12mm** - Angle **5°** Range of Heights [mm] **4, 5, 6, 7, 8, 9**
ACC1614**05	Foot Print Size **16x14mm** - Angle **5°** Range of Heights [mm] **4, 5, 6, 7, 8, 9**
ACC1816**05	Foot Print Size **18x16mm** - Angle **5°** Range of Heights [mm] **4, 5, 6, 7, 8, 9**

Foot Print	12mmX12mm	14mmx14mm	16mmx16mm	18mmx16mm	16mmx14mm	14mmx12mm
						
hight	4mm	5mm	6mm	7mm	8mm	9mm
						

CHIFOSI ANGLE:



0° DEGREES

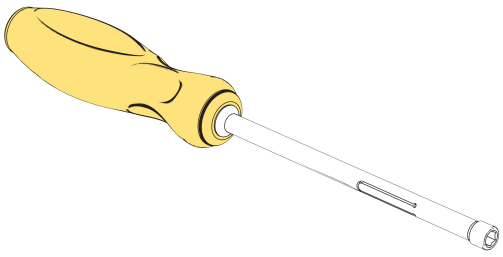


5° DEGREES

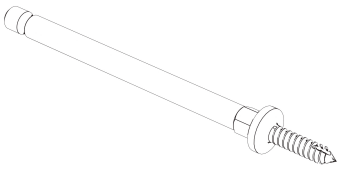
Instruments

Ref. Code	Description	Qty per Set
BOK-CS-05	Distraction Screwdriver	1
BOK-CS-12	Distraction Screw 12mm	2
BOK-CS-14	Distraction Screw 14mm	2
BOK-CS-16	Distraction Screw 16mm	2
BOK-CS-07R	Caspar Distractor Right	1
BOK-CS-07L	Caspar Distractor Left	0
BOK-CS-0405S	Trial Implant 4-5mm Small	1
BOK-CS-0607S	Trial Implant 6-7mm Small	1
BOK-CS-0809S	Trial Implant 8-9mm Small	1
BOK-CS-0405M	Trial Implant 4-5mm Medium	1
BOK-CS-0607M	Trial Implant 6-7mm Medium	1
BOK-CS-0809M	Trial Implant 8-9mm Medium	1
BOK-CS-0405L	Trial Implant 4-5mm Large	1
BOK-CS-0607L	Trial Implant 6-7mm Large	1
BOK-CS-0809L	Trial Implant 8-9mm Large	1
BOK-CS-03	Cervical Endplate Rasp	1
BOK-CS-01	Cervical Cage Holder	1
BOK-CS-02	Cervical Cage Holder - Shaft	1
BOK-CS-06	Cervical Nerve Hook	1
BOK-CS-04	Curette, Square Shaped	1
BOK-CS-08	Vertebral Body Puncturer	1
BOK-CS-09	Cage Filling Support	1
BOK-CS-LID-F	Lid Full DIN	1
BOK-CS-CTN-F	Container Full DIN	1
B-OKCC-INST02	Cervical Cage Set Full DIN	

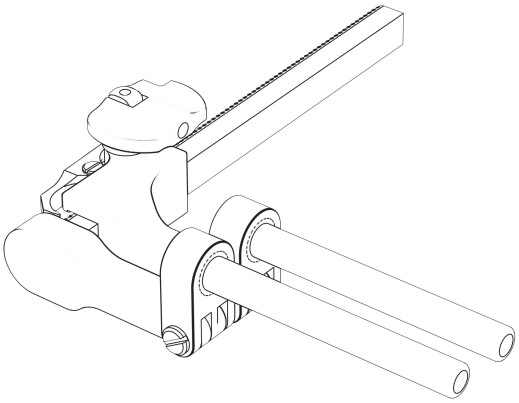
BOK-CS-05 Distraction Screwdriver



BOK-CS-xx Distraction Screw 12mm, 14mm, 16mm

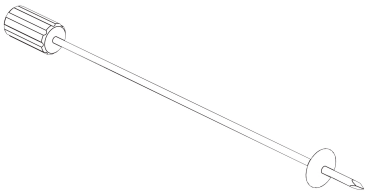


BOK-CS-07X Caspar Distractor Right / Left

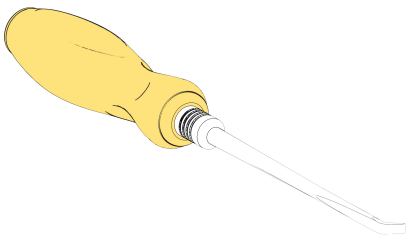


BOK-CS-09 Cage Filling Support

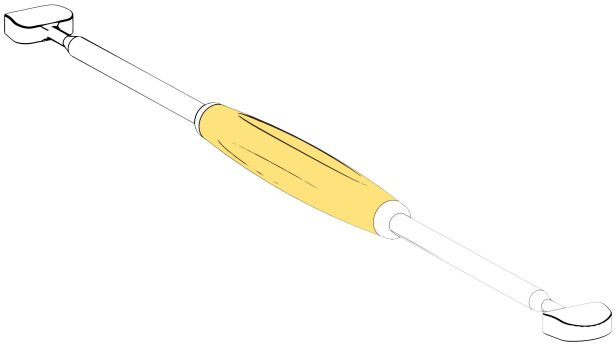
BOK-CS-08 Vertebral Body Puncturer



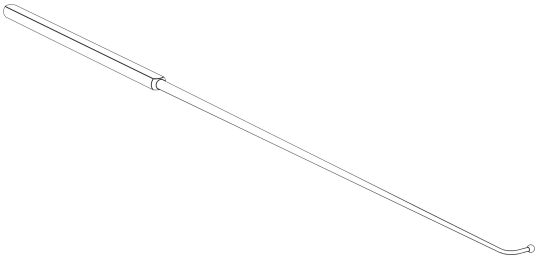
BOK-CS-04 Curette, Square Shaped



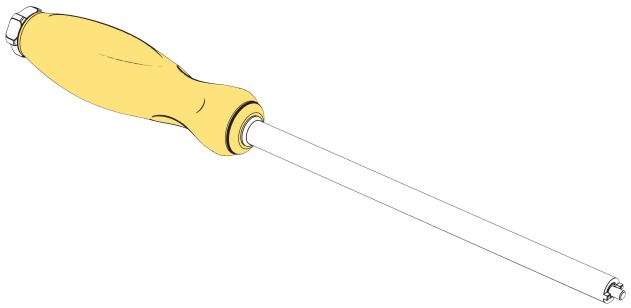
BOK-CS-XXX Trial Implants



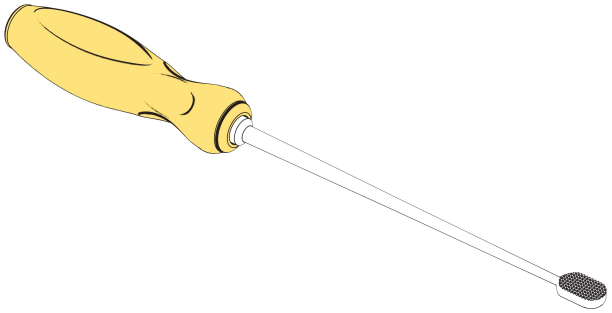
BOK-CS-06 Cervical Nerve Hook



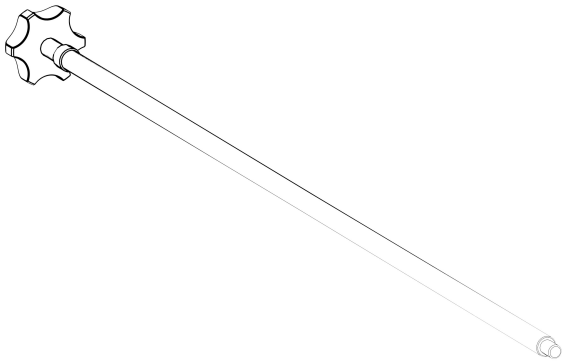
BOK-CS-01 Cervical Cage Holder



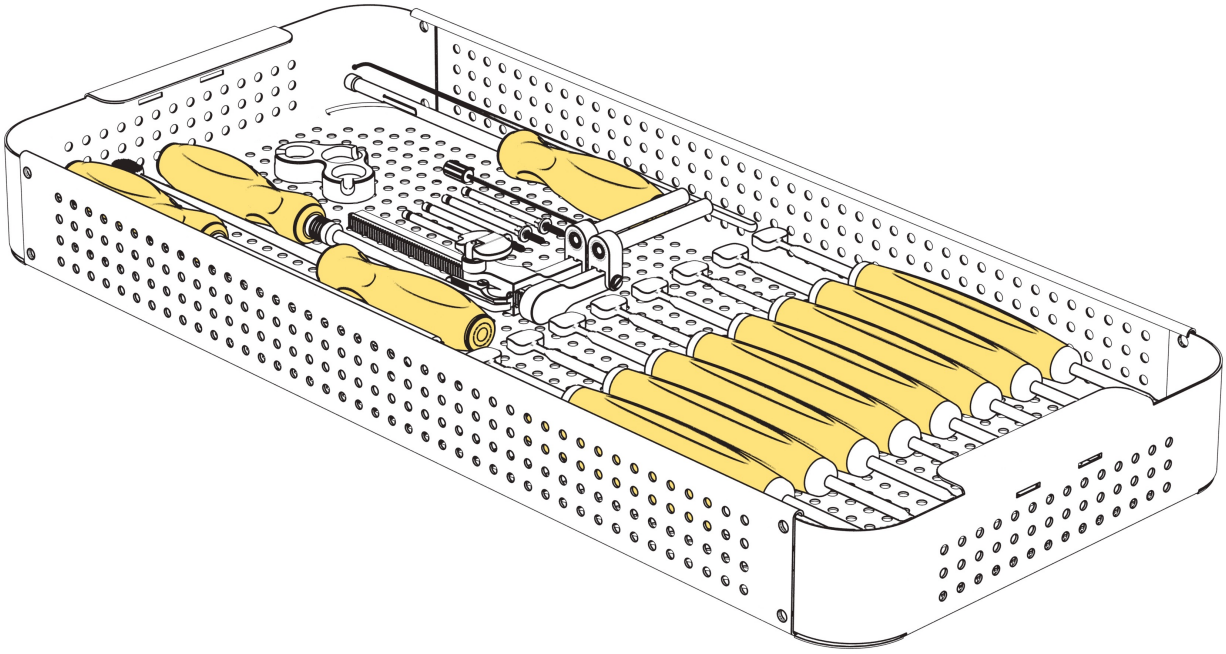
BOK-CS-03 Cervical Endplate Rasp



BOK-CS-02 Cervical Cage Holder, Shaft

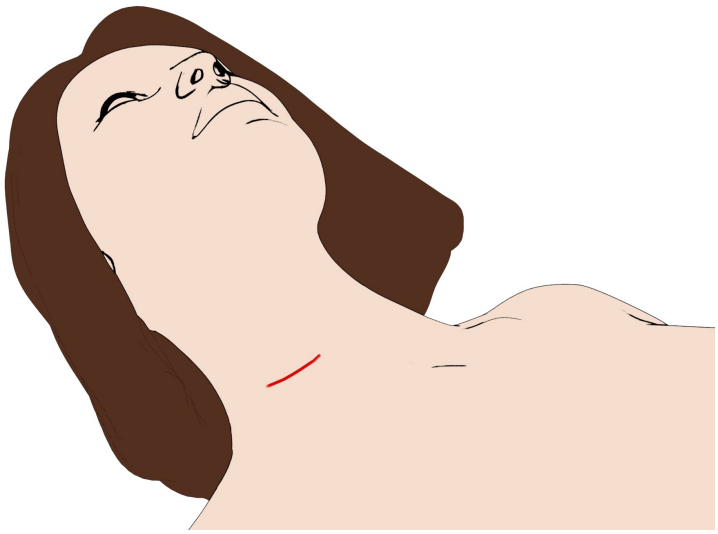


B-OKCC-INST02 Cervical Cage Set Full DIN



Patient Positioning

Patient position should expose spine level which going to be fused. Overlordosis or hyperkyphosis should be avoided. By using C-Arm proper level of cervical spine must be verified. Skin incision should allow adequate approach to stabilising spine segment(s). Additional instruments like vertebral distractor, soft tissue retractors is subject of additional space requirements.

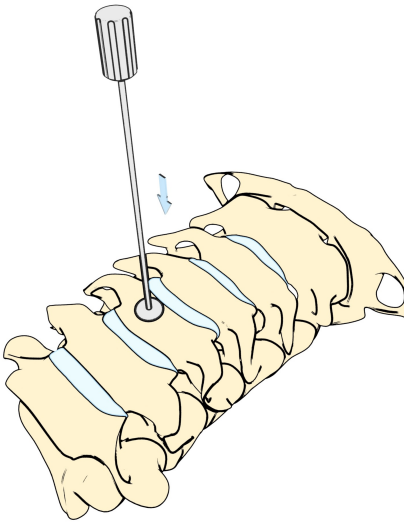


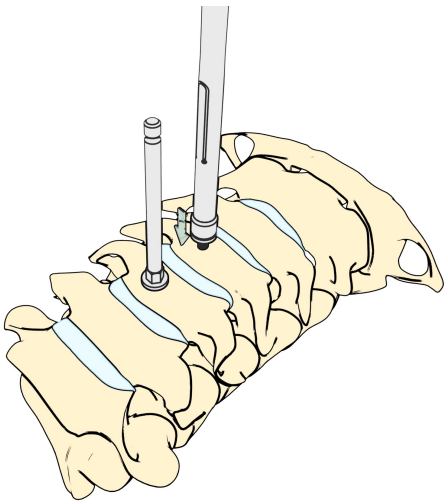
To maintain comfortable surgical field tissue retractor system is highly recommended.

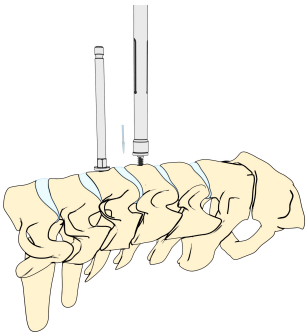
Vertebral Distraction

Determine length of Distraction Screw on lateral x-ray. Assemble appropriate Distraction Screw into Distractor Screw Driver.

Define the midline and mark up the entering point by Vertebral Body Puncturer.

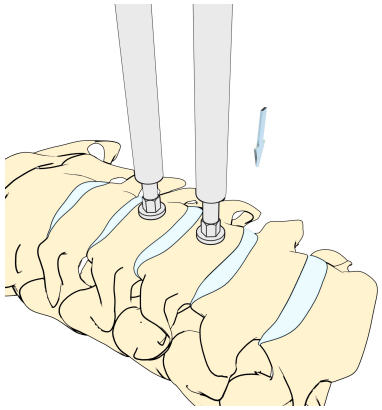


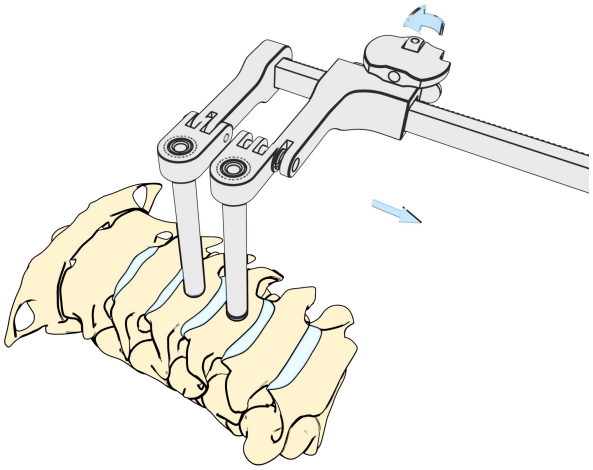




Please keep positioning Distraction Screws parallel in order to facilitates further

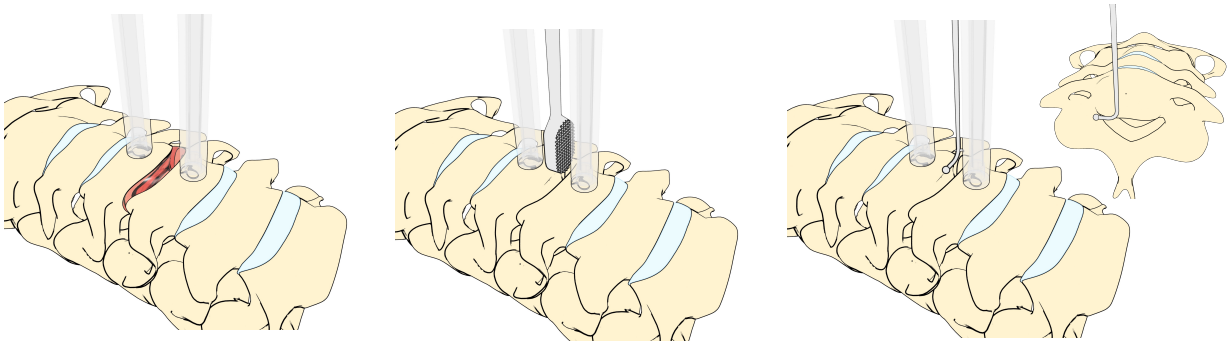
Insert the Distraction Screws, install Caspar Distractor and perform vertebral distraction.





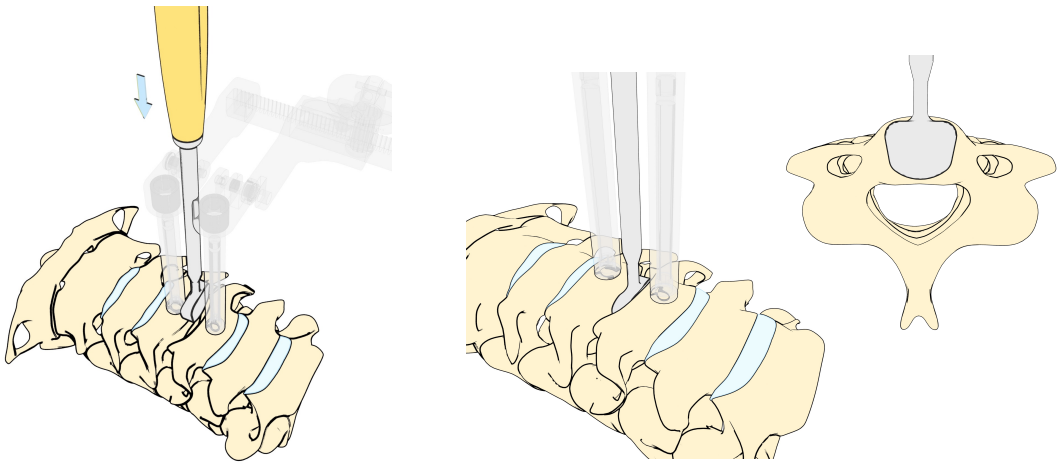
Decompression and Cage Trailing

Remove the disc and cartilage layer on the vertebral plates. Use Square Curette facilitate cartilage removal. In order to check root decompression Cervical Nerve Hook may be used.



b-OK Cervical Cage incorporates BoneInGrow™ titanium net which allows free flow of bone cells. Using Cervical Endplate Rasp is recommended when preparing the endplate in order to create efficient bone contact.

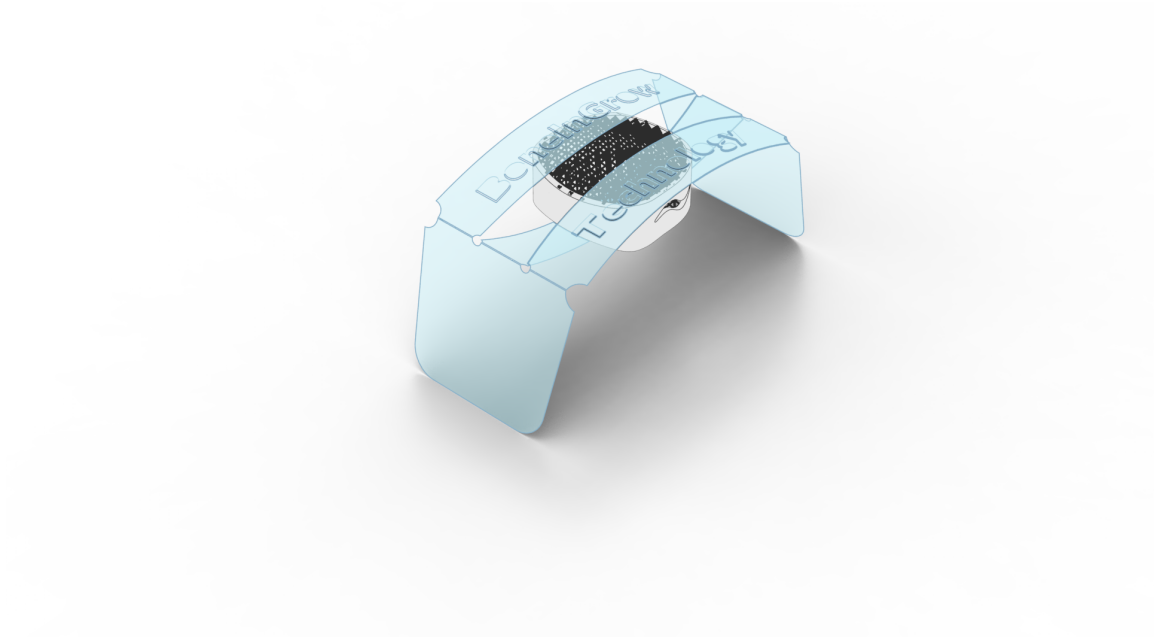
When trailing is performed lateral x-ray is highly recommended in order to asset implant's high, angulations and foot print size. Implant Trial should be inserted in middle line. Release the distraction on Caspar Distractor and check if the Implant Trial fits firmly between endplates.



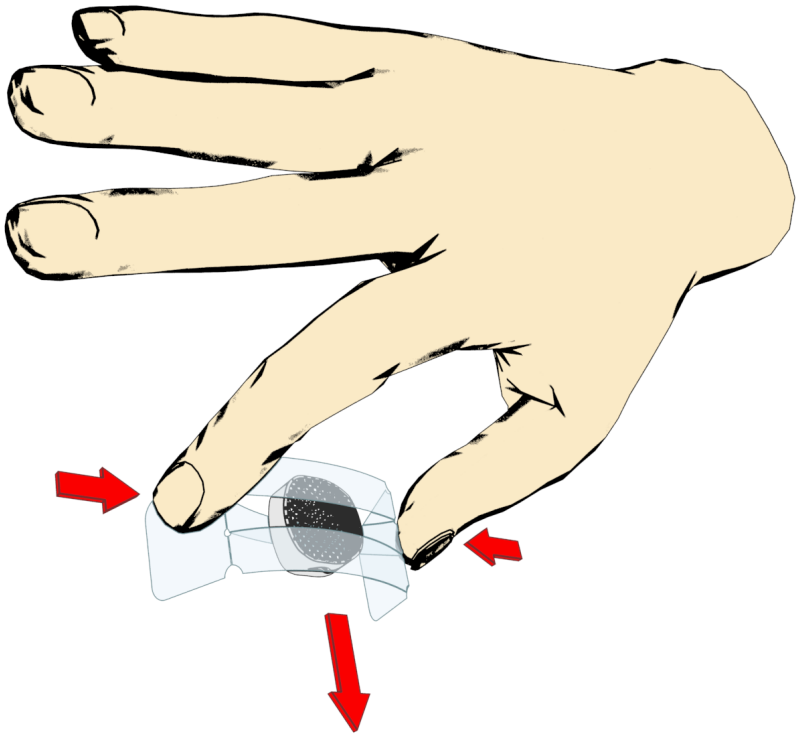
Please note that Implant Trial are designed in 0 degrees. In case of lordosis restoration is intended please select cage with 5 degrees inclination. Once appropriate size is selected please follow the implant preparation in accordance to marking on Implant Trial.

Implant Packaging

b-OK System is deliver as sterile, in double blister with special holder.



Open the blister take holder out and press as indicated below in order to release implant. Please make sure that implant will fall dow into sterile area.

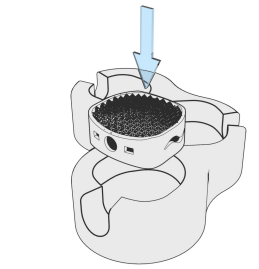


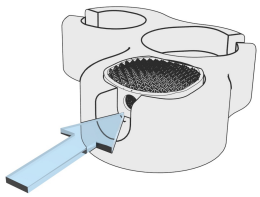
Implant Preparation

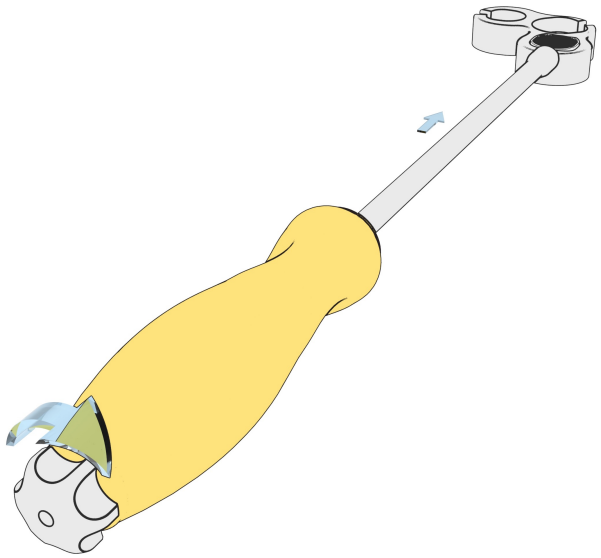
b-OK System is intended to be filled by bone substitute or harvest allograft. Both substitution should be delivered in paste like formulation. Please use Tsunami Filling System in order to secure appropriate filling. Implant can be filled before or after implantation procedure.

Please place cage into Filling Support. By using Tsunami Filling System inject the bone substitute into the cage. Please see the table with recommended volume for every size.

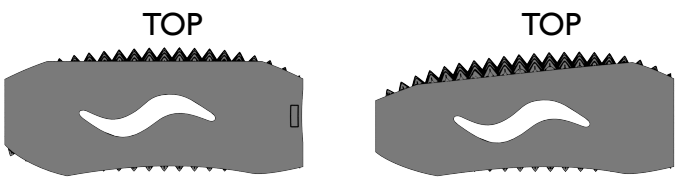
Foot Print Cage Hight	**4**	**5**	**6**	**7**	**8**	**9**
12x12	0,4cc	0,5cc	0,7cc	0,8cc	0,9cc	1cc
14x14	0,6cc	0,75cc	0,9cc	1cc	1,2cc	1,4cc
16x16	0,8cc	1cc	1,2cc	1,4cc	1,6cc	1,8cc
14x12	0,5cc	0,7cc	0,8cc	0,9cc	1,1cc	1,3cc
16x14	0,7cc	0,9cc	1,1cc	1,2cc	1,5cc	1,7cc
18x16	0,9cc	1,2cc	1,3cc	1,5cc	1,7cc	1,9cc





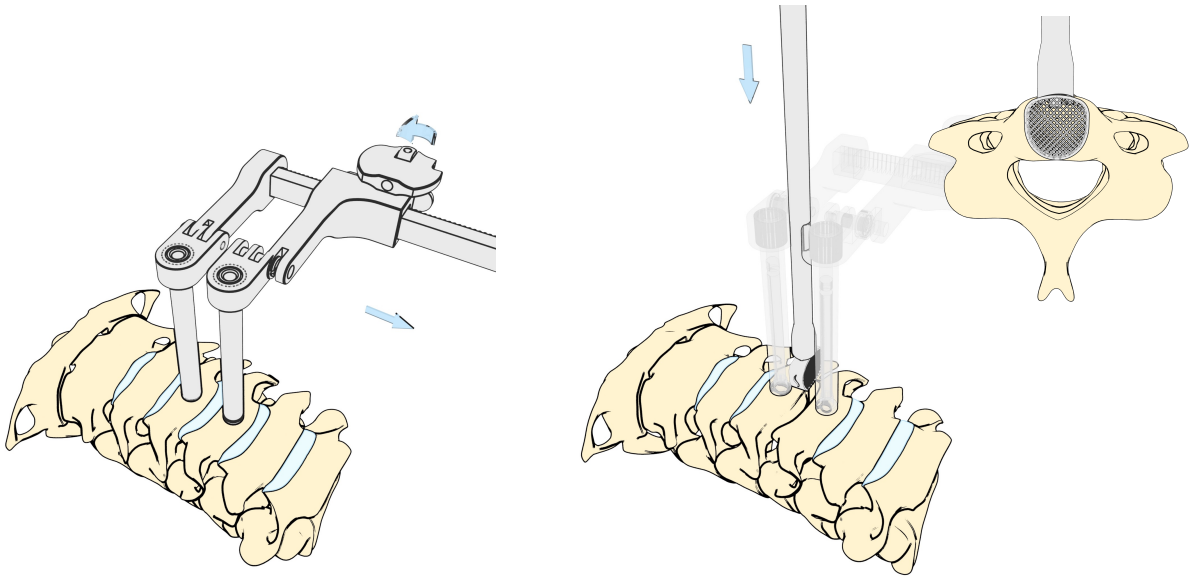


Connect the Implant Holder to Cage and secure the position by clockwise turning the knob on silicone handle. Double check is the UP sign correspond to upper side of the cages.



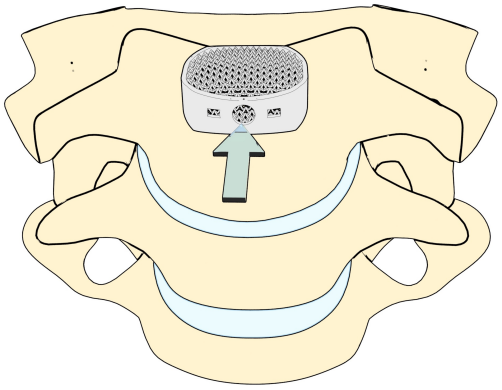
Implantation

If necessary increase distraction to facilitate device insertion. Insert cage by gentle hammering. Keep midline as guidance for insertion. Lateral x-ray is highly recommended during implantation procedure.



After final positioning has been confirmed detach the Implant Holder by turning knob counterclockwise. Remove the Implant Holder and check the implant positioning both in AP and lateral x-rays.

The b-OK Cage can be filled after the implantation by Tsunami Filling System. Please see Tsunami Filling System Brochure for details.



General Information

IMPORTANT INFORMATION ON THE B-OK CERVICAL TITANIUM CAGE SYSTEM

The B-OK Spinal System is intended recreate and maintain distance between vertebras to support biologic fusion in the cervical spine. Using additional fixation device may be appropriate.

DESCRIPTION:

The B-OK Spinal System consists of the cages in variable sizes and shapes. The composition of implants may be vary depends on anatomical conditions and physician decision.

B-OK Spinal System components must NOT be used with any other spinal systems or any other fixation systems. Do NOT never use titanium implant and stainless steel implant in the same construct. Any application of any components from B-OK Spinal System together with any other systems or other manufactures releases Tsunami for any liabilities.

All components of B-OK Spinal System should be never reused under any circumstances.

B-OK Spinal System is designed to be applied for anterior approach only.

MATERIALS:

The entire system is be made out of medical grade titanium or titanium alloy or PEEK described by ISO 5832-3 or 10993-5 or ASTM F2026 or ASTM F136 standards. Tsunami Medical sorely warrants that all devices are manufacture from one of the foregoing material specifications. No other warranties, express or implied, are made. Please see the Tsunami product brochure for further information.

INDICATIONS:

B-OK Spinal System is intended for cervical interbody fixation for the following indications:

1. Degenerative disc disease..
2. Spinal stenosis.
3. Revision surgery for failed disc surgery or progressive degenerative discopathies
4. Spinal disc or nerve compression
5. Pseudoarthrosis.
6. Instability of motion segments.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

(1) Risk of infection or infection in progress, or fever or inflammation.
(2) Obesity.
(3) Pregnancy.
(4) Mental illness.
(5) Allergy on any system components.
(6) Any anatomical, medical or surgical conditions witch may preclude potential or intentional benefits of spinal implants application.
(7) Bone, joints or ligaments conditions such but not limited as: osteopenia, bone absorption, osteomalacia. Osteoporosis is relative contraindications an must by carefully evaluated prior surgery.
(8) Implants size, shape or anchorage functionality might be not enough to achieve expected clinical results.
(9) Mixing of implants with other manufacturers or with other fixation systems.
(10) Potential risk of unexpected patients anatomy destruction, interference with neurological, functional or other deficits.
(11) Any risk of patient's unwillingness to follow postoperative instructions.
(12) Any other not described in indications.

POTENTIAL ADVERSE EVENTS

Possible adverse events which might occur after spinal surgery with or without instrumentation include, but are not limited to:

(1) Disassembly, bending, and/or breakage of any or all of the system components.
(2) Migrations any of system components.
(3) Pressure on the skin from component parts in patients with inadequate tissue coverage.
(4) Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
(5) Dura leakage, distortion or damage.
(6) Neurologic dysfunctions and/or physiological dysfunctions like paresthesia, radiculopathy, paralysis, hyperthesia, or any others related to general surgery associated to anaesthesia.
(7) Infections.
(8) Loss of urinary functions.
(9) Permanent or temporary or developing sexual dysfunctions.
(10) Postoperative change of body curvature, change of physiological range of movement.
(11) Pseudoarthrosis or non-fusion or delayed fusion.
(12) Bone loss or overgrowth, or any other bone malformations.
(13) Permanent or temporary limitation or inability to perform daily activities.
(14) Changing in mental behaviour.
(15) Permanent or temporary or developing respiratory problems.
(16) Permanent or temporary or developing cardiovascular deteriorations or dysfunctions.
(17) Death.

In some of cases additional surgery or surgeries might be necessary to correct or change potential adverse events.

WARNINGS:

The effectiveness and safety of interbody fixation is only applicable for certain conditions with significant instability which require the fusion supported by medical device. 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.

PRECAUTIONS

The B-OK Cage may be supported by additional fixation device. Is some cases additional fixation device is highly recommended. The applications of pedicle screw, cervical screws and/or interbody cages should be performed by experienced surgeons with specific training in use of B-OK Spinal System. The spinal screw fixation system and/or inter body cage system should not be considered as sole spinal support. No implants can withstand body loads without bone support. Therefore bends, breakages, loosening, disassembling may occur over the time. A successful results are not always achievable. The factors as proper preoperative and operative procedure, comprehensive knowledge of surgical techniques, proper selection of implant's size and type are considerably important in treatment process. Patients with obesity, smokers, alcohol abused are risk of non-fusion surgery. 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 the positioning of the implants or patients anatomy or any other patients or implants correction 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 design is vital to successful surgery performance. Proper implants and 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.

IMPORTANT: All necessary informations about surgery, potential risks, benefits and adverse effects should be conveyed to the patient prior to surgery.

PREOPERATIVE:

(1) Patients meet the criteria described in the indications should be only selected.
(2) Patients conditions should be checked prior surgery Any required diagnostics should be performed.
(3) The efficient and adequate implants and instruments inventory must be secured and be available during the surgery.
(4) All implants, instruments and any other components should be cleaned and sterilised before use. Any implants, instruments or components delivered as sterile must be checked due to sterility and expiration time prior surgery.
(5) Implants and instruments should be stored in certain conditions to warranty the sterility and protection from any contamination or corrosive environment.
(6) It's highly recommended that all personnel interacting with any mechanical components from the spinal system should be familiar with all components before using.

INTRAOPERATIVE:

(1) Extreme caution should be used when working close or around the spinal cord and nerve roots.
(2) Whenever possible or required intraoperative diagnostic system should be used to facilitate surgery.
(3) Breakage, bends, scratch slippage, part loosening or improper use of any implant or instrument during the surgery may cause injury to OR personal or patient.
(4) It's very important to follow carefully surgical technique. Proper application of any instrument or implant may facilitate surgery.
(5) Before closing of soft tissue double check of all implants positioning, geometrical relations, and fixing, tightening or mounting manoeuvres for all screws, nuts or other fixing parts should be performed. Image diagnostics is highly recommended at this stage.

POSTOPERATIVE:

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

(1) Detailed instructions on the use and limitations of the device should be given to the patient.
(2) The patient should be warned to avoid falls or sudden jolts in spinal position.
(3) The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilise nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
(4) As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
(5) Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, the B-OK Spinal System components should never be reused under any circumstances.

CE

Design & Quality
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