Internal use only

NOVOMAX
FUSION

Cervical Interbody Fusion Device

- Osteo-active
- Anti-Migration
- Minimize Subsidence Risk

SURGICAL TECHNIQUE

CGBIO
CELL & GROWTH FACTOR
BIOTECHNOLOGY

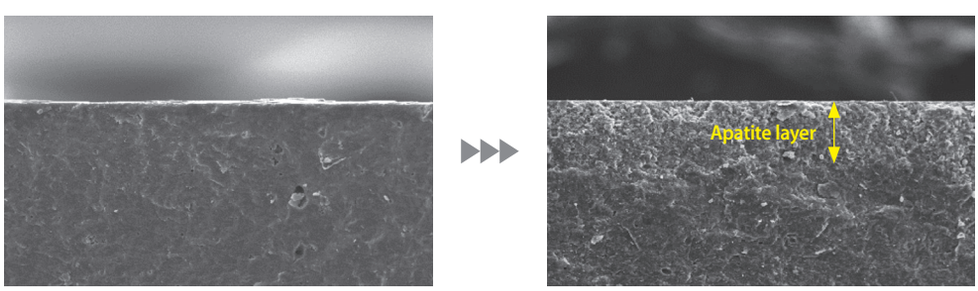
NOVOMAX
FUSION

Osteo-Active Cage

NOVOMAX-FUSION® is the spinal implant for the stabilization of the cervical spondylodesis.
It is made of CaO-SiO_2-P_2O_5-B_2O_3 based crystallized-glass (BGS-7) which has high mechanical strength, makes direct bone fusion and is biocompatible

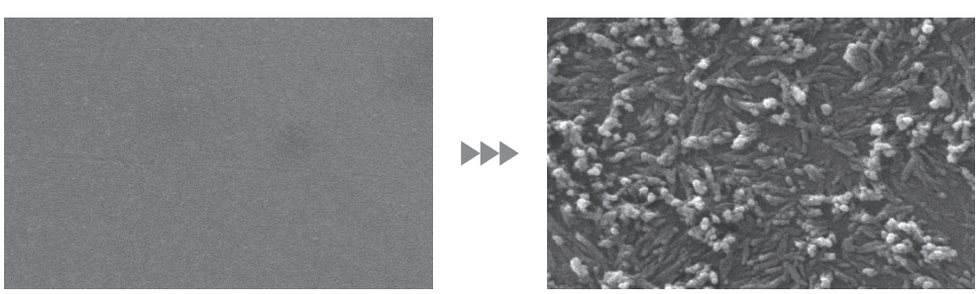
OSTEO-ACTIVATION OF THE BGS-7 GLASS CERAMIC

01. Cross-section



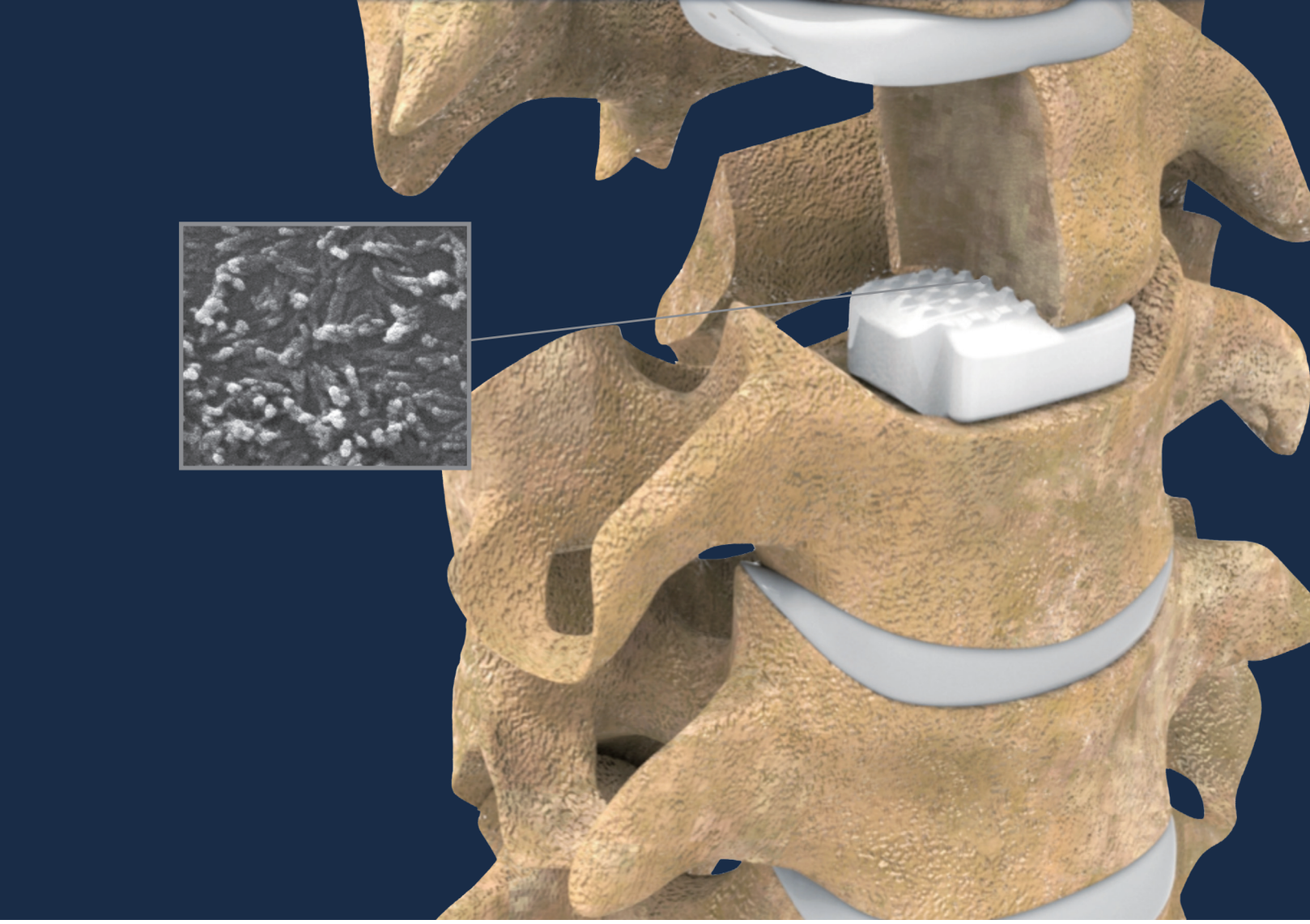
Initial | After 30D Soaking in SBF

02. Surface

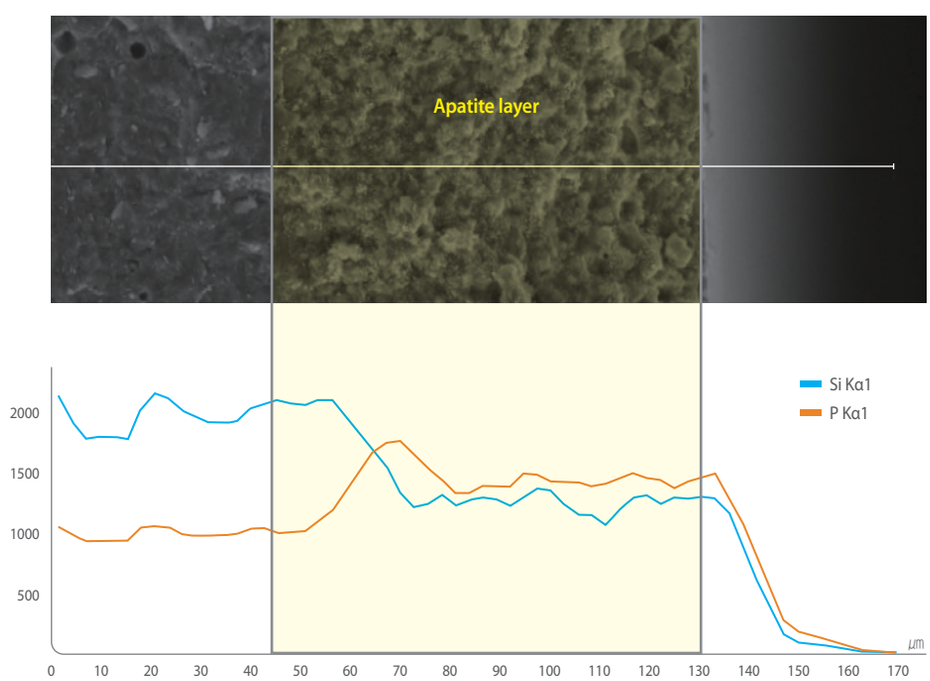


Initial | After 30D Soaking in SBF

The trans-formation of the bone-like apatite layer at the surface of the BGS-7 through the reaction of the BGS-7 and body fluids



03. Apatite layer



An increase in phosphorus and a decrease in silicon elements at the surface of the BGS-7 means the formation of the apatite layer at the surface.

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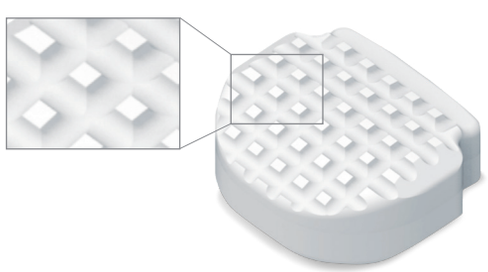
IMPLANT OVERVIEW

BGS-7 OSTEO-ACTIVE GLASS CERAMIC

- Promote direct bony fusion at the interface between bone and implant by forming bone-like apatite layer at the surface immediately after implantation
- Secures fast and strong fusion
- Provide strong compressive strength

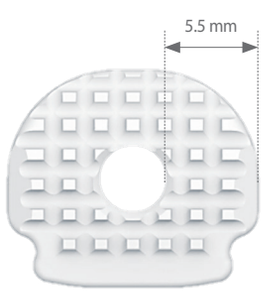
MIGRATION RESISTANCE

- Keel of pyramid type on the surface
- Provide initial stability to promote direct bony fusion at the surface



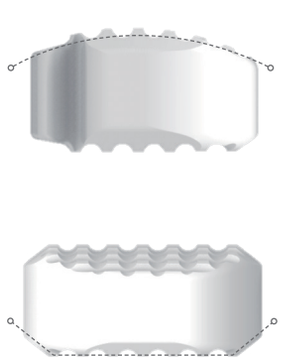
MINIMIZE SUBSIDENCE RISK

- Wide contact area between implant and bone



ANATOMICAL SHAPE

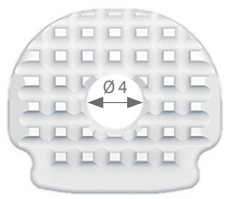
- Rounded upper endplate design that preserves the natural anatomical profile of the cervical spine
- Chamfer at the lateral edge of the cage to fit with the uncovertebral joint of the cervical vertebral body



IMPLANT SPECIFICATION

TYPES

- **No hole type**
  The fusion is secured by the bone on-growth at the surface of the BGS-7



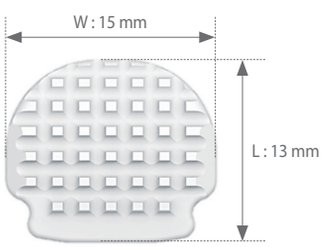
- **Hole type** (Diameter : 4 mm)
  The fusion is secured by the bone on-growth and the bone in-growth at the hole of the cage.
  And the additional grafting is possible at the hole

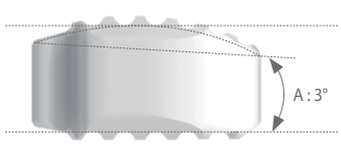
NO HOLE TYPE	
Reference code	Description (W x L x H / A)
NMNF3535	15 x 13 x 5 mm / 3°
NMNF3536	15 x 13 x 6 mm / 3°
NMNF3537	15 x 13 x 7 mm / 3°
NMNF3538	15 x 13 x 8 mm / 3°
NMNF3539	15 x 13 x 9 mm / 3°
NMNF3530	15 x 13 x 10 mm / 3°

HOLE TYPE	
Reference code	Description (W x L x H / A)
NMCF3535	15 x 13 x 5 mm / 3°
NMCF3536	15 x 13 x 6 mm / 3°
NMCF3537	15 x 13 x 7 mm / 3°
NMCF3538	15 x 13 x 8 mm / 3°
NMCF3539	15 x 13 x 9 mm / 3°
NMCF3530	15 x 13 x 10 mm / 3°

SIZE (W X L X A)

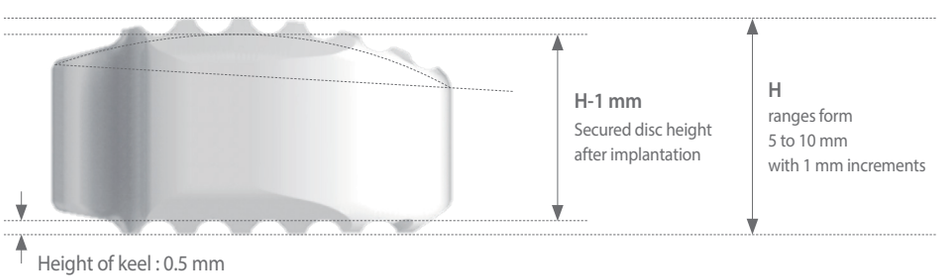
• Width(W) : 15 mm • Length(L) : 13 mm • Lordotic 3°





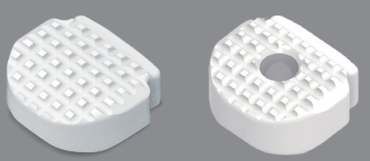
HEIGHT(H)

- Ranges from 5 mm to 10 mm (with 1 mm increments)
- The height is measured at the end point of the keel. After implantation, the keel may be embedded in the cancellous bone. Therefore, the disc height may be secured at the height minus 1 mm of the cage spec. (keel height : 0.5 mm x 2)



NOVOMAX
FUSION

SURGICAL TECHNIQUE



PREPARATION AND APPROACH

Using the standard surgical approach, expose the vertebral bodies to be fused. Traditional cervical retractors may be used. Prepare the fusion site following the appropriate technique for the specific indication.

DISCECTOMY & ENDPLATE PREPARATION

Using the ronguer or appropriate surgical instruments, Remove the disc material through the surgical channel to place the intervertebral cage. Careful attention is needed to remove all disc and bone tissues that compress the nervous structure. (Figure 1)

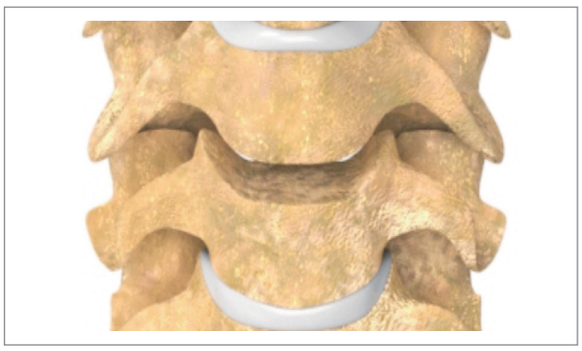


Figure 1

Prepare the disc space by using the combination of currettes, rasps, and shavers to remove cartilaginous structure at the endplate properly. (Figure 2a)

Pay attention to preserve the anatomical shape of the intervertebral disc space to ensure the perfect cage fit. Concave upper shape and flat lower shape in sagittal cross-sectional plane is needed to maximize contact area between bone and the Novomax Fusion. (Figure 2b)

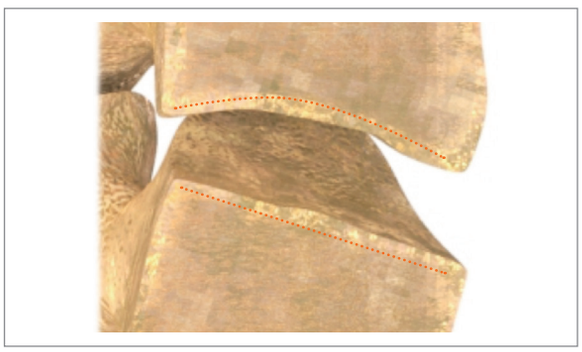


Figure 2a

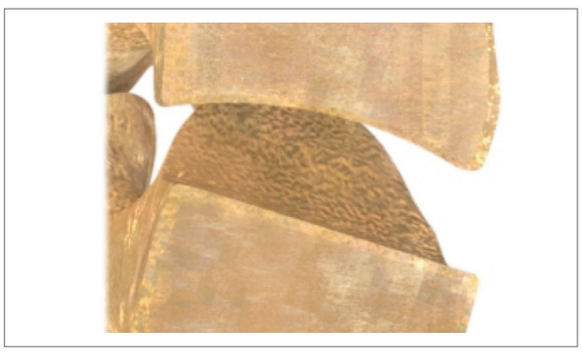


Figure 2b

*** CAUTION**

Aggressive preparation of the endplate may remove excessive bone and weaken the endplate causing subsidence.

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TRIAL AND CERVICAL TRIAL / CAGE HOLDER PREPARATION

Connect the Novomax Fusion C trial and the cervical trial holder by turning the handle clock wise.
The initial trial to match with disc height of the patients may be predicted by surgeon before inserting the trial.

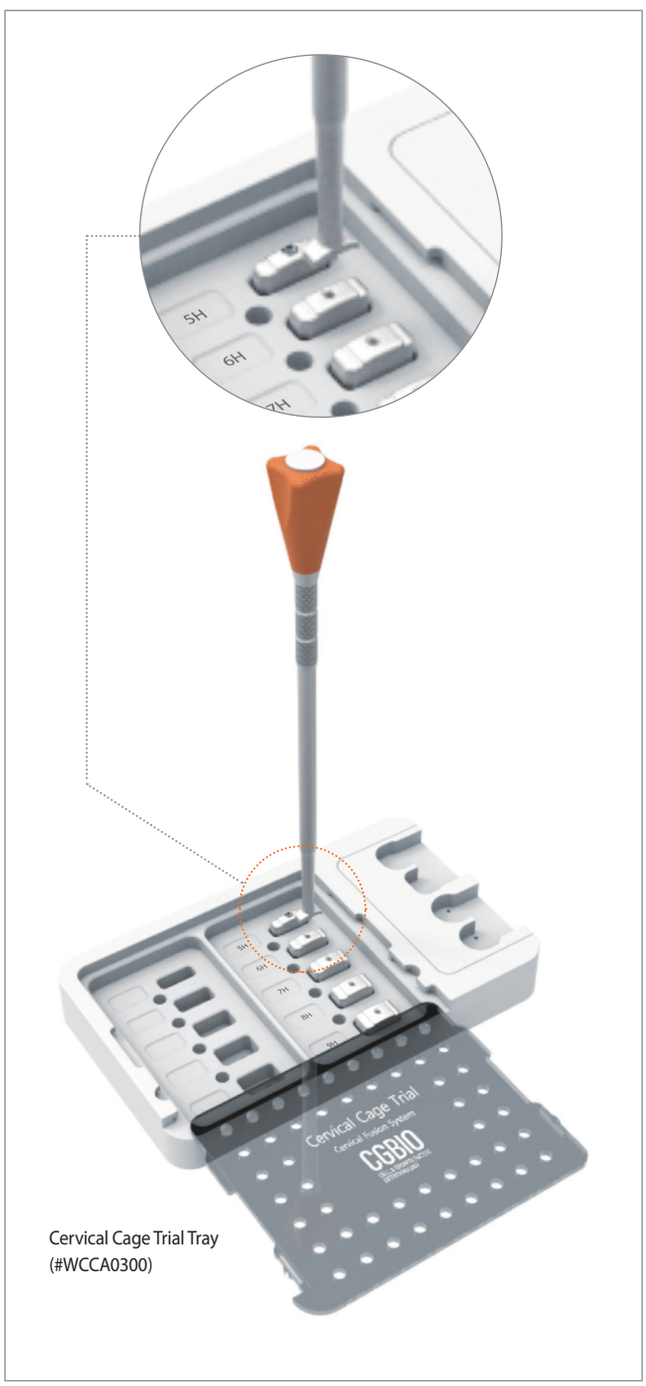


Figure 3

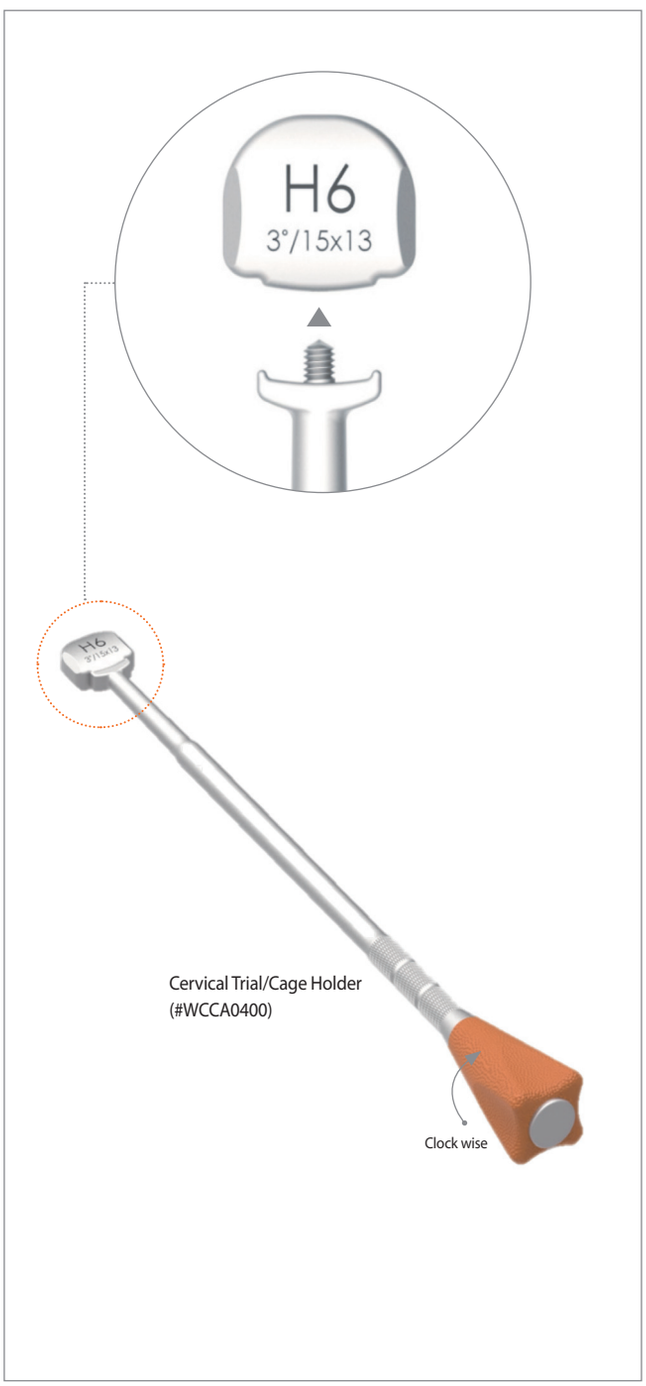
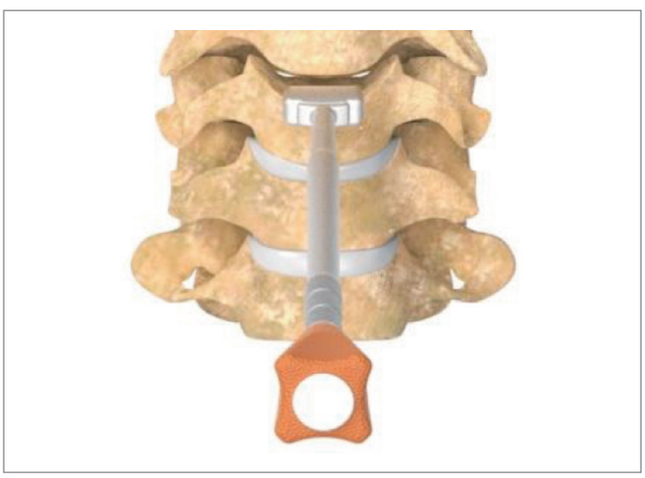
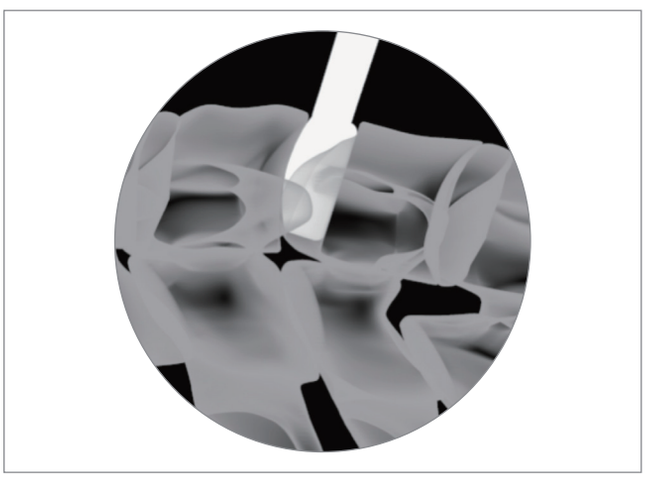


Figure 4

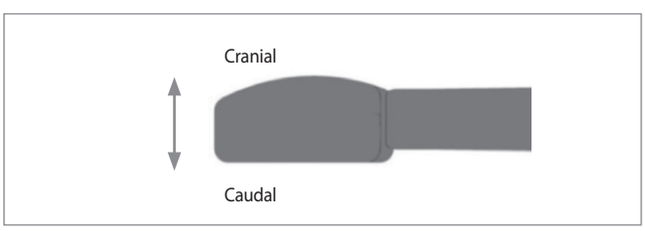
DETERMINATION OF CAGE SIZE

Insert the trial into the disc space. If it is needed, apply gentle impaction by using mallet at the metallic end of the handle. To confirm the interference fit between trial and disc space, use lateral radiographic imaging. By several trialing, the trial producing tightly interference fit, enough height restoration and good segmental stability should be determined finally.

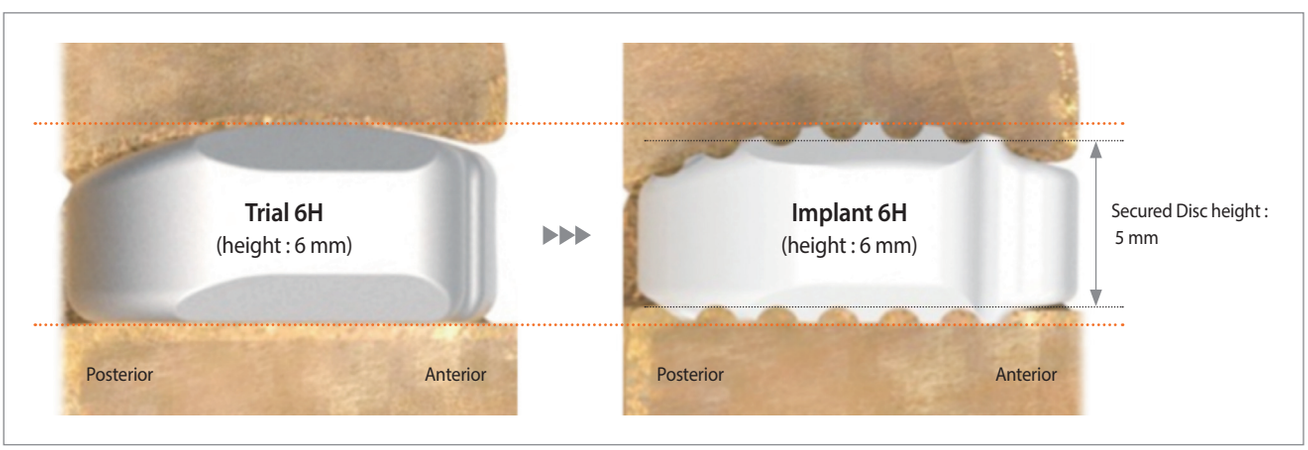




Check the shape of the trial to confirm cranial and caudal direction before inserting trials



The height of the trials corresponds to the height of the Novomax Fusion including keel height which is labelling spec. of the product. If finally determined trial produces slight loosely fit with the vertebral bodies, the Novomax Fusion of 1mm higher height than the determined trial height should be considered to secure strong stability.



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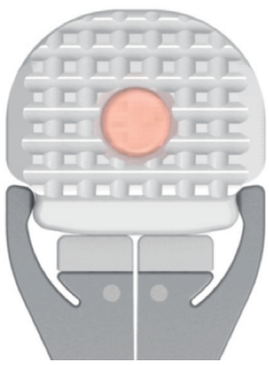
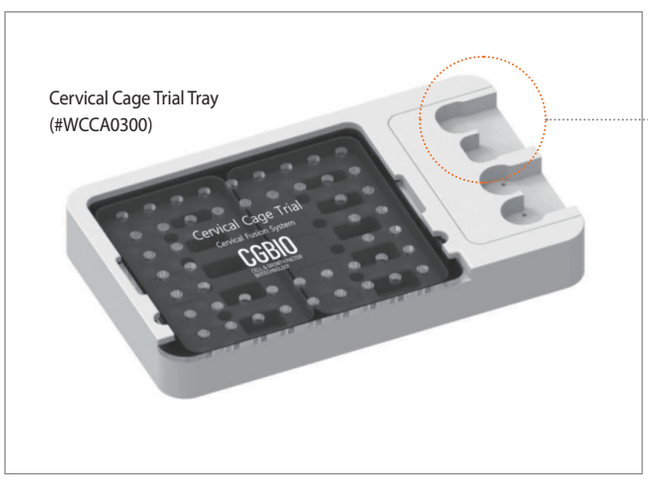
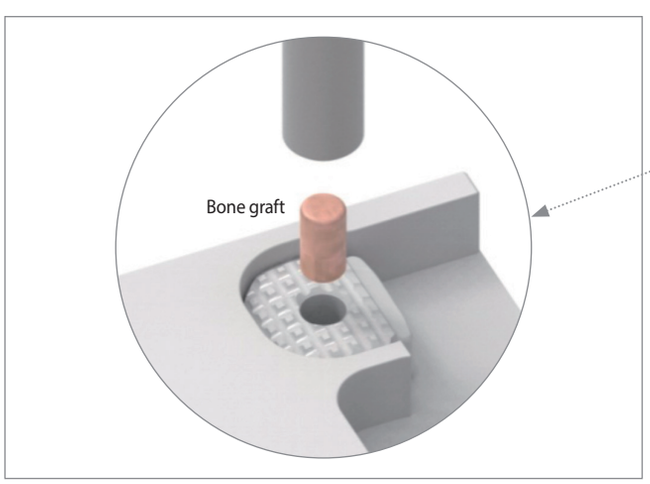
NOVOMAX FUSION PREPARATION

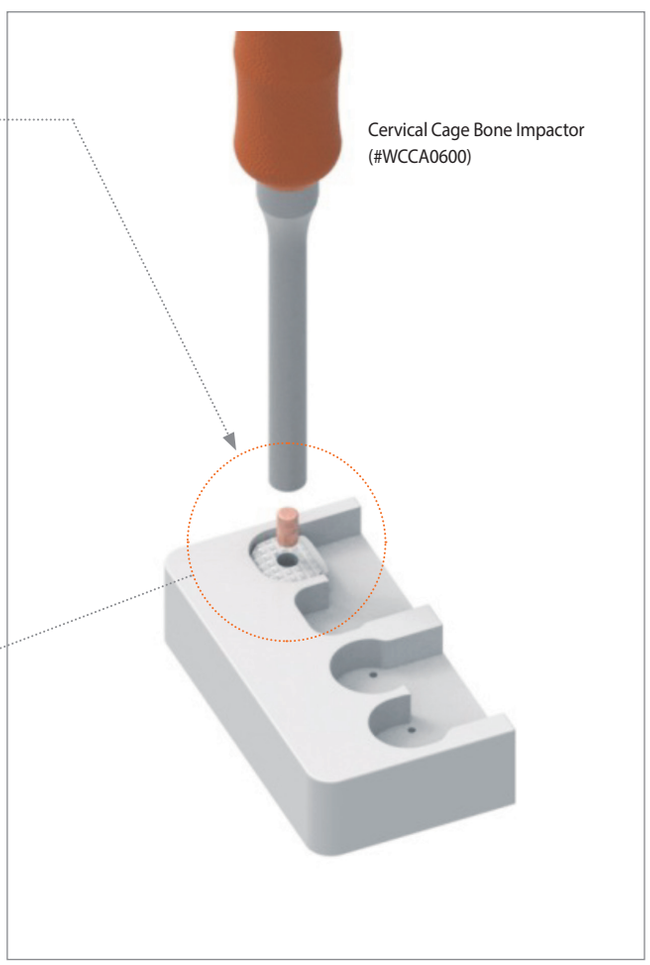
Prepare the Novomax Fusion of the finally determined height. If the Novomax Fusion having hole for the placement of bone graft (Hole Type) is selected, use the packing block of the cervical cage trial tray and the cervical cage bone impactor.



Novomax® Fusion
(Hole Type)

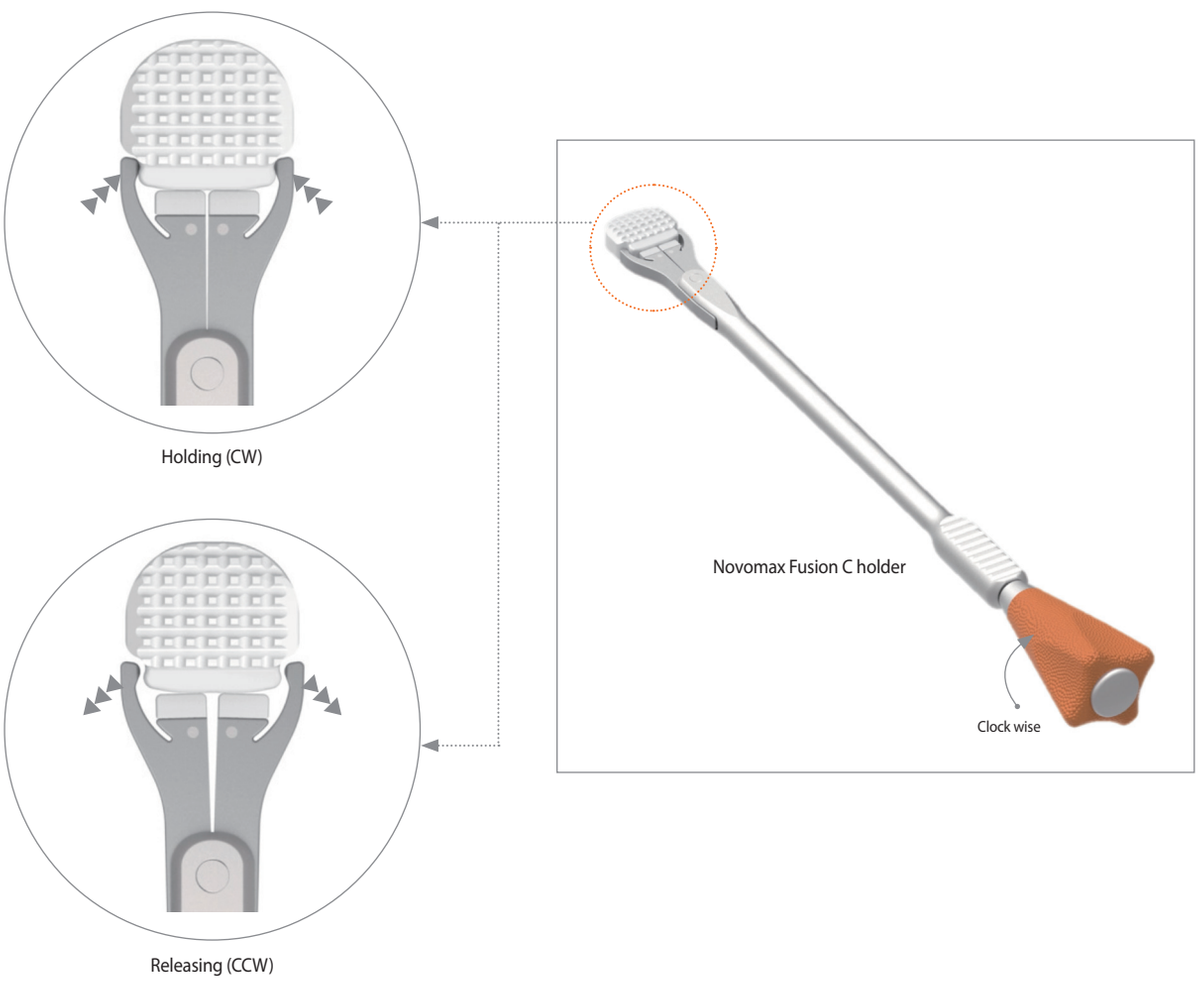


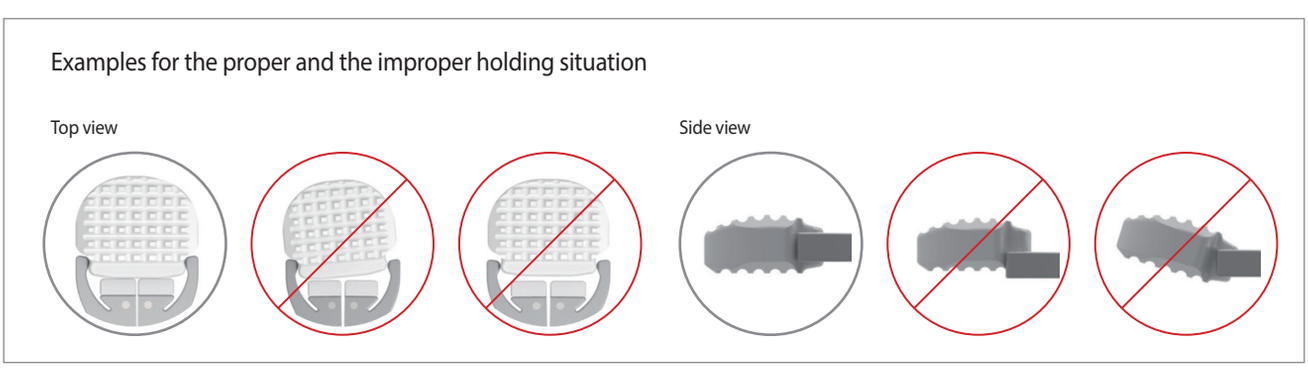




NOVOMAX FUSION & HOLDER PREPARATION

Hold the Novomax Fusion by using the Novomax Fusion C holder by rotating the handle clock wise. To prevent the separation of the implant from the holder while impacting to insert the implant, the fish tail shape of the Novomax Fusion should be restrained completely by the forceps portion of the holder as shown in the examples below.





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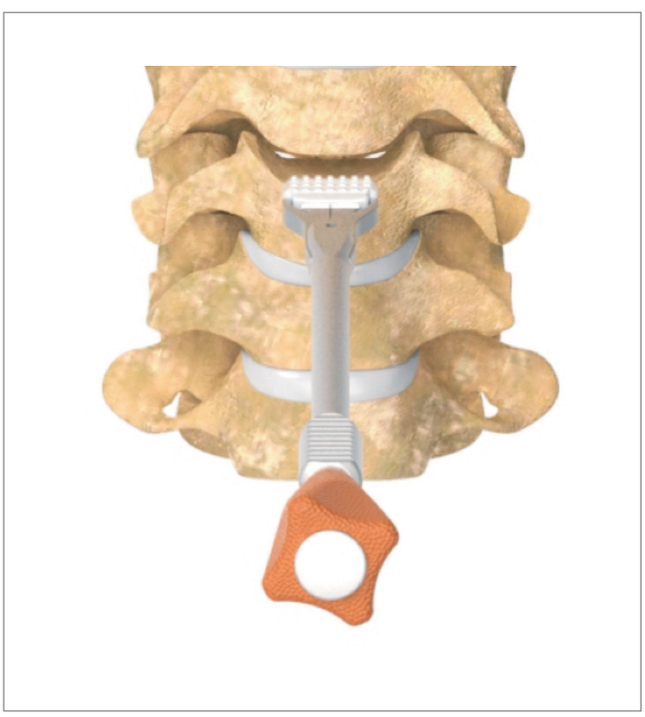
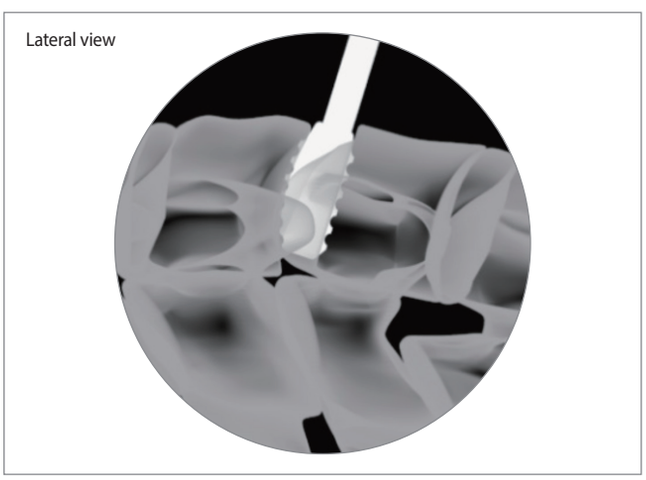
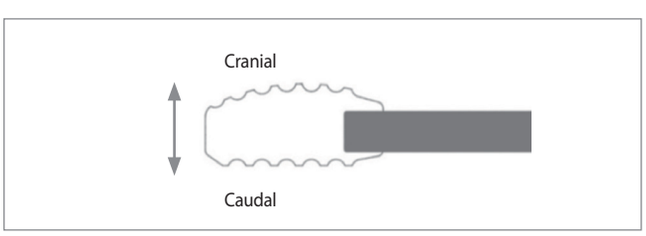
NOVOMAX FUSION INSERTION

Insert the Novomax Fusion into the disc space carefully. Check the orientation of the implant and holder in the correct cranial/caudal alignment before insertion. To confirm the interference fit between implant and disc space, use lateral radiographic imaging. The implant should produce tight interference fit, enough height restoration and good segmental stability.



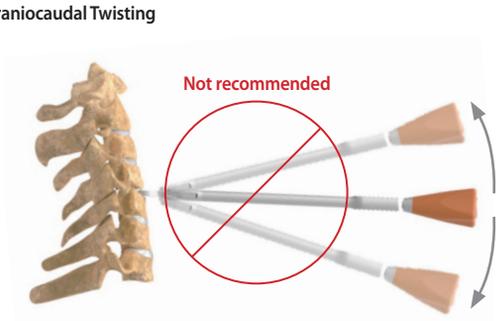




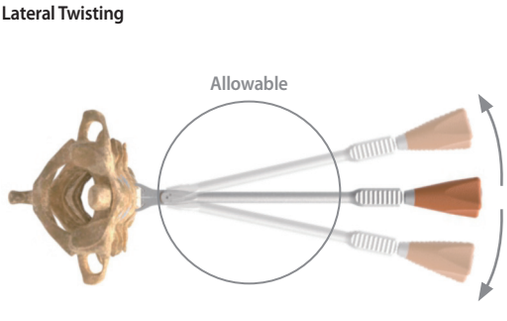
As positioning the implant, the holder should be controlled in proper motion as shown in below examples. Motion of the holder in cranial/caudal direction could cause detaching of the implant due to the specially designed mechanism of the holder to prevent ceramic implant breakage. On the other hand, motion in lateral direction is allowable.

Examples for allowable and not recommended handling motion

Craniocaudal Twisting

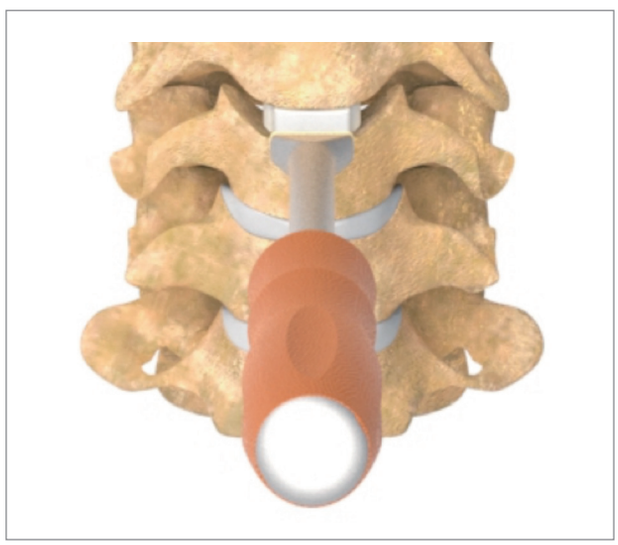


Lateral Twisting



NOVOMAX FUSION IMPACTION

If it is needed, apply gentle impaction by using the cage impactor and the mallet for positioning the implant.



*** CAUTION**

Excessive impaction could be the cause of the implant breakage

NOVOMAX
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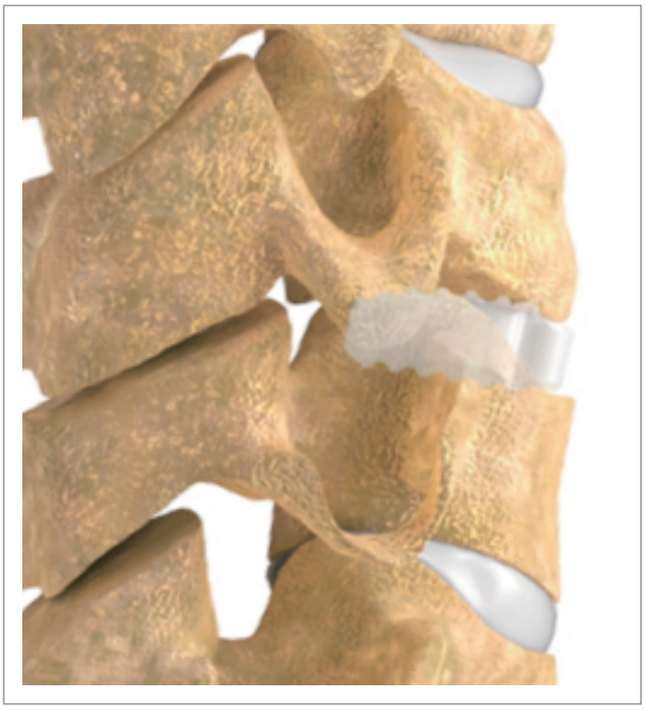
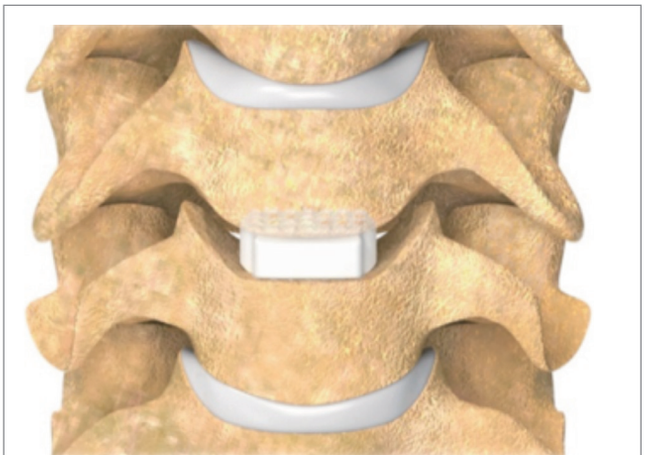
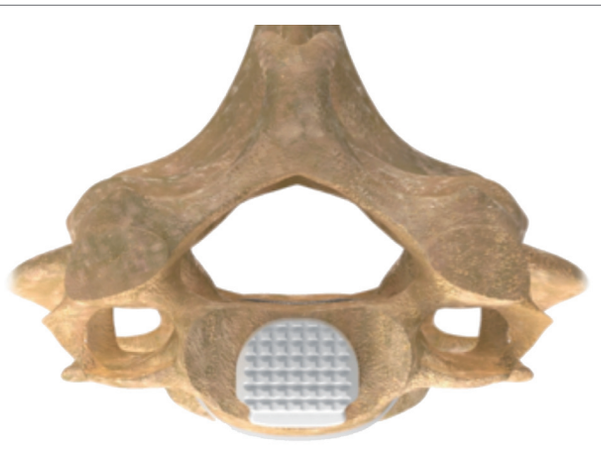
FINAL POSITION

The optimal position of the implant is centered within the periphery of the vertebrae end plates. The implant should be positioned in harmony with the anterior profile of the cervical vertebrae and the concave upper end plate of the disc space, and should not be positioned excessively posterior to prevent compression on the nervous structure.



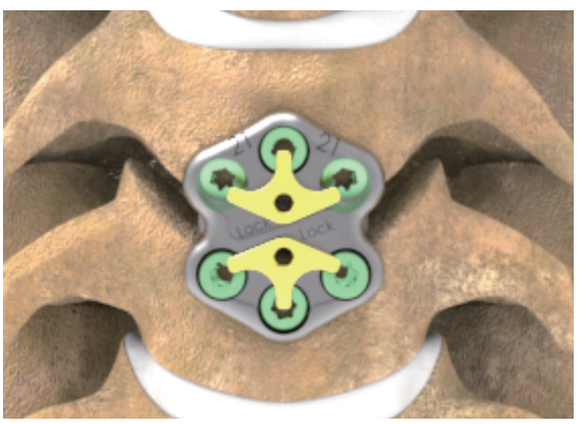


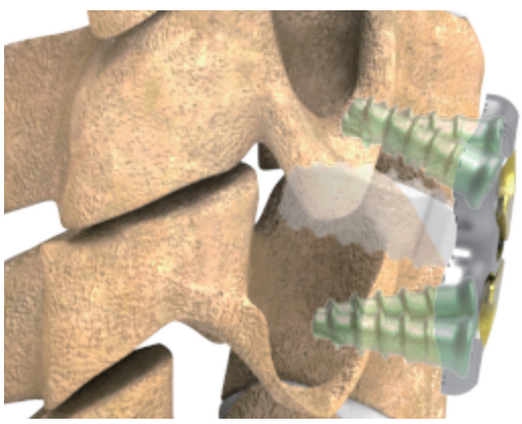


ANTERIOR CERVICAL PLATE

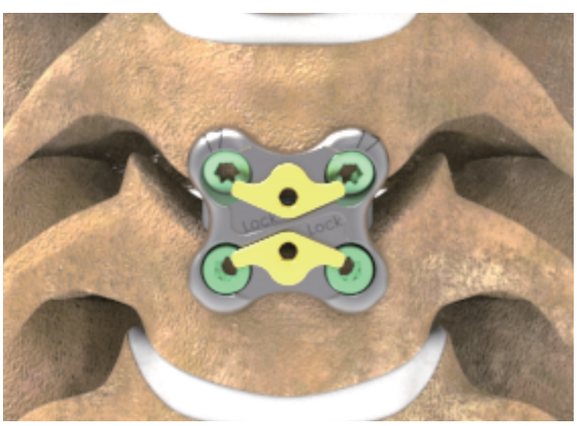
To secure the best stability of the surgically treated levels of the cervical, the anterior plate is recommended. Stability of the treated levels may helpful to drive the fast fusion. The hyper-angulation technique of the screw may compress the disc space, and could make the optimal stability.

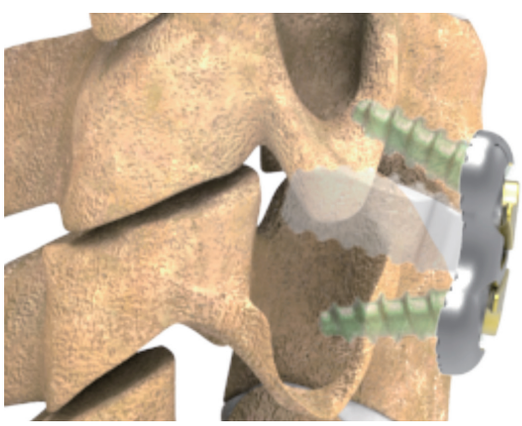
TriSecure® (3 Hole Type)





TriSecure® (2 Hole Type)

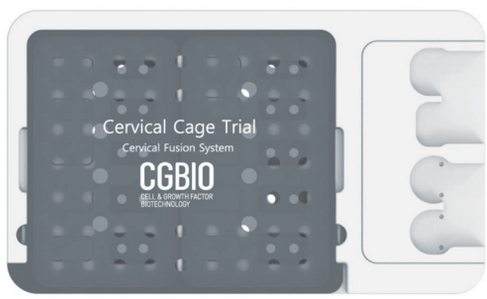
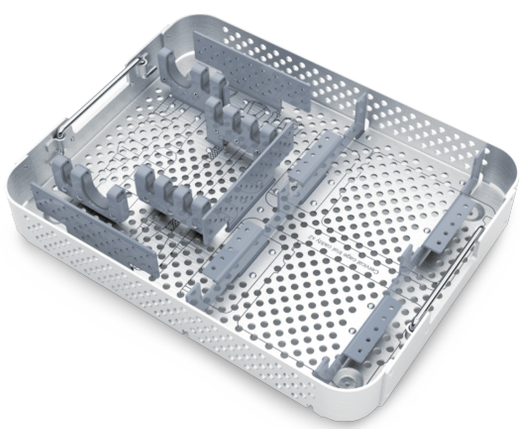




NOVOMAX
FUSION

INSTRUMENT OVERVIEW

Reference #	Description	
320400A (WCCA0300)	Cervical Trial & Cage holder	
300105D (NMCD0105)	Novomax Fusion C Trial 5H	
300106D (NMCD0106)	Novomax Fusion C Trial 6H	
300107D (NMCD0107)	Novomax Fusion C Trial 7H	
300108D (NMCD0108)	Novomax Fusion C Trial 8H	
300109D (NMCD0109)	Novomax Fusion C Trial 9H	
300240C (NMCC0240)	Novomax Fusion C holder	
320600A (WCCA0600)	Bone Impactor	
320500A (WCCA0500)	Cervical Implant Impactor	

Reference #	Description	
320300A (WCCA0300)	Cervical Trial Caddy	
320700A (WCCA0700)	Cervical Middle Tray	
320700B (WCCB0700)	Cervical Cage Tray	

NOVOMAX
FUSION

INSTRUCTIONS FOR USE

DESCRIPTION

NOVOMAX FUSION is developed as implants for the stabilization of the lumbar spinal column and anterior cervical spondylodesis. NOVOMAX FUSION is made of CaO-SiO_2-P_2O_5-B_2O_3 based crystallized-glass (BGS-7) which has high mechanical strength, makes direct bone fusion and is biocompatible.
NOVOMAX FUSION is provided sterile for single use.

INDICATIONS FOR USE

NOVOMAX Cervical Interbody Fusion Devices are indicated for use in patients with degenerative disc disease (DDD) of the cervical spine accompanying radicular symptoms at one level from C3 to T1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
These patients should be skeletally mature and have six (6) weeks of non-operative therapy.
NOVOMAX Cervical Interbody Fusion Devices are to be implanted via an anterior approach.
NOVOMAX Lumbar Interbody Fusion Devices are indicated for use in patients with degenerative disc disease (DDD) of the lumbar spine at one level or two contiguous levels from L1 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of non-operative therapy.
NOVOMAX Lumbar Interbody Fusion Devices are to be implanted via a posterior approach. NOVOMAX Lumbar Interbody Fusion Devices are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems).

CONTRAINDICATIONS

General contraindications include, but are not limited to:

- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Suspected or documented allergy to any of the implant materials.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any case not described in the indications.
- Any patient unwilling to co-operate with postoperative instructions.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth. Contraindications of this device are consistent with those of other spinal systems.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results.
This device system is not intended to be the sole means of spinal support.
NOVOMAX FUSION must be used with additional anterior or posterior instrumentation to augment stability. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.
Consider preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good reduction prior to surgery. Only perform installation and positional adjustment of implants with special equipment and instruments specific to these devices. Do not use other instruments unless specifically recommended by CGBIO because other instruments may be incompatible.
Never reuse an internal fixation device under any circumstances. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage to the connection mechanism will reduce instrument stability.
Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.
Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

Preoperative

The selection of the proper size, shape and design of the implant for each patient is crucial to planning the success of the procedure. Ceramic implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

- Use care in handing and storing these components. Do not scratch or damage them. Protect implants and instruments during storage especially from corrosive environments.
- Since mechanical parts are involved, be familiar with the various components before using the equipment and personally assemble the devices to verify that all parts and necessary instruments are present before surgery.
- Determine the type of construct to be assembled for the case prior to surgery. Have an adequate inventory of implant sizes available at the time of surgery, including sizes larger and smaller than those expected to be used.
- Unless packaged sterile, clean and sterilize all parts before use. Have additional sterile components available in case of an unexpected need.

Intraoperative

- Carefully follow the instructions in any available applicable surgical technique manual.
- At all times, use extreme caution around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- The heat generated from the curing process may also cause neurologic damage and bone necrosis.

Postoperative

Postoperative directions and warnings to the patient and patient compliance are extremely important.

- Give the patient detailed instructions on the device's use and limitations.
  If partial weight bearing is recommended or required prior to firm bony union, warn the patient that device bending, loosening, or breakage can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation maybe increased if the patient is active or if the patient is debilitated, demented, or otherwise unable to use crutches or other weight supporting devices.
  Warn the patient to avoid falls or sudden jolts in spinal position.
- For optimal surgical results, do not expose the patient or device to mechanical vibrations that may loosen the device construct. Warn the patient of this possibility, and instruct the patient to limit physical activities, especially lifting and twisting motions and any type of sport participation. Advise the patient not to smoke or consume excess alcohol during the bone graft healing process.
- Advise the patient not to bend at the point of spinal fusion, and teach the patient to compensate for this permanent physical restriction in body motion.
- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By fatigue, these stresses can cause eventual loosening, or breakage of the device. It is important that union immobilization is established and confirmed by roentgenographic examination. Where there is a non-union, or if the device loosens and/or breaks, the device should be revised immediately before serious injury occurs.

INSTRUCTIONS FOR USE

These instructions are intended as guidelines for the use of NOVOMAX FUSION as a part of established surgical techniques. They are not intended to replace or change standard procedures of treatment. Only experienced physicians, who have had appropriate training and experience in the field of implant materials and implant surgery, should use NOVOMAX FUSION.

Preoperative Preparation

Preoperative Planning

The appropriate device size must be estimated prior to surgery. With the segment fully distracted, the implants must fit tightly and accurately between the endplates. To achieve maximum segment stability, it is essential to implant the largest possible devices. The final choice of size will be made with the help of a trial implant during surgery.

Patient Positioning

Place the patient in an appropriate position. Radiographic equipment can assist in confirming the precise intraoperative position of the patient.

Surgical Procedure

1. Incise and expose disc.
2. Prepare disc and endplates.
   Using the bone curette, remove the disc through the window. Using the bone rasp, remove the superficial layers of the entire cartilaginous endplates to expose bleeding bone
3. Distract segment.
   Distraction of the segment is essential for restoring disc height and for providing good access to the intervertebral space. The tension of the longitudinal ligaments and annulus fibrosus contribute to the stability of the inserted implant, hence care must be taken not to overdistract the segment(s).
4. Determine trial implant size.
   Select the size of the trial implant as estimated during preoperative planning. Attach the trial implant to the instrument. Insert the trial implant assembly into the disc space applying gentle impaction. Use fluoroscopy and tactile feedback to confirm the fit of the trial implant. If the trial implant appears too loose or too tight, try the next larger or smaller size until a secure fit is achieved. Select the implant corresponding to the correct trial implant. Remove the trial implant assembly.
5. Determine size and prepare implant.
   Select the appropriate NOVOMAX FUSION size according to the trial implant size determined in step 4. Perfuse the implant with autologous blood or bone marrow aspirate.
6. Insert implant.
   Grasp the selected implant using the implant inserters. Introduce the correctly oriented implant into the disc space. Slight impaction will be necessary. Once the implant is in the desired position, remove the implant inserters.
   NOVOMAX FUSION should be implanted into intervertebral disc and directly contacted with the adjacent host bone.
7. Verify implant position.
   Check the implant position with X-rays.

Stabilization and Postoperative Care

Stabilization

After insertion of NOVOMAX FUSION, upper and lower spines should be fixed with internal fixation system such as pedicle screws and rods.

Postoperative Care

Take X-rays to ensure correct positioning of the implants and screws before mobilization of the patient. Bed rest must be observed for a three-day period and a corset should be worn for three months for PLIF and a light brace for at least four weeks for ACIF restrict excessive movement, such as bending, stooping, lifting, climbing, or digging.

POTENTIAL ADVERSE EVENTS

The following conditions could cause nonunion or delayed union, it is recommended to be used with supplemental fixation.

- Surgery and fixation in the excessive load bearing area
- Involvement of 3 or more levels
  It may cause a bony density reduction for the stress shielding phenomenon.

HOW SUPPLIED

1EA/PACK.

Provided in multiple footprints, lordotic angles and heights to fit a wide range of patient anatomies.

SHELF LIFE, STORAGE and HANDLING

The shelf life is 3 years form the date of manufacture. NOVOMAX FUSION is supplied sterile and is for single use only. Do not use this device if the packaging is compromised. The device should not be used beyond the stated expiration date on the package label. Do not re-sterilize.

Store at room temperature (1℃ to 30℃), in a clean, dry place.

Caution: The device is restricted to sale, distribution, and use by or on the order of a physician.

FURTHER INFORMATION

If further information is needed or required, please contact CGBIO.

NOVOMAX
FUSION

CGBIO CELL & GROWTH FACTOR BIOTECHNOLOGY

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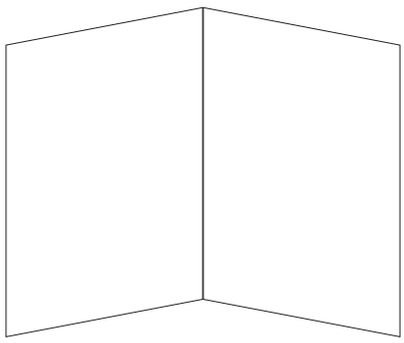

품목명	노보맥스 퓨전 서지컬 테크닉
디자인담당자	고용석 010-9060-3107
규격	210 x 297 mm / 20페이지
종이	스노우화이트 200g
인쇄	양면 4도 + 별색 1도 (Pantone 877c)
코팅	표지 무광 코팅
접지	O
접착 (양면테이프)	없음
제본	중철제본
오시 (줄수)	O
절취선 (미싱/줄수)	없음
돌출코팅 (에폭시)	없음
형압 (사이즈)	없음
박 (사이즈)	없음
기타	없음