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4CIS® AUGUSTA

ALIF PEEK Cage

Surgical Technique

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SYSTEM OVERVIEW

Introduction

The 4CIS® Augusta PEEK ALIF Cage is single component devices used to restore height of disc space by anterior approach and to facilitate lumbar interbody fusion with maintaining physiological lordotic angulation of lumbar spine.
To allow maximum preservation and ensure ample contact surfaces with bony endplate, a variety of shapes and sizes are available and each device has two tantalum (ASTMF560) markers for ease of visualization on radiographs.
The vertical square teeth on the top and the bottom surface prevent subsidence of the cage into the vertebral body while they increase the anchoring and prevent slipping or expulsion.
To make solid fusion of intervertebral body, hollow space in the implant allows bone graft material to be filled. The implant has safety proven structure and material (Polyetheretherketone, ASTM F2026) to promote biological synostosis and assures mechanical safety against load.

Indication

The 4CIS® Augusta PEEK ALIF Cage is an intervertebral body fusion devices intended for use to skeletally mature patients with Degenerative Disk Disease (DDD) of the lumbar spine with Spondylolisthesis and it is designed for treatment of instability in disk and vertebra, and in case second operation of spine.
The 4CIS® Augusta PEEK ALIF Cage is indicated to be used with autologous bone graft to facilitate fusion and are intended to be used with supplemental fixation.
The device is to be used in patients who have had six months of non-operative treatment.

OPERATIVE TECHNIQUE

STEP 1 : Approach

Patient should be placed in a supine position appropriate for an anterior approach. Identify the affected level using anterior and posterior fluoroscopic imaging. Determine surgical approach based on the surgeons preference. Mark and create the appropriate incisions. Dissect and retract soft tissues to reach the bony anatomy. For access to the target disc space, create an appropriately sized window through the anterior longitudinal ligament and the annulus fibrosus.

STEP 2 : Preparing the Disc Space

Proceed with Discectomy. The 4CIS® curette can be used to remove the affected disc while maintaining the integrity of the endplates.

Note : Removing the superficial layers of the cartilaginous endplates exposes bleeding bone. Adequate preparation of the endplates is important to facilitate vascular supply to the bone graft. Excessive cleaning, however, may weaken the endplate due to removal of bone underlying the cartilaginous layers.

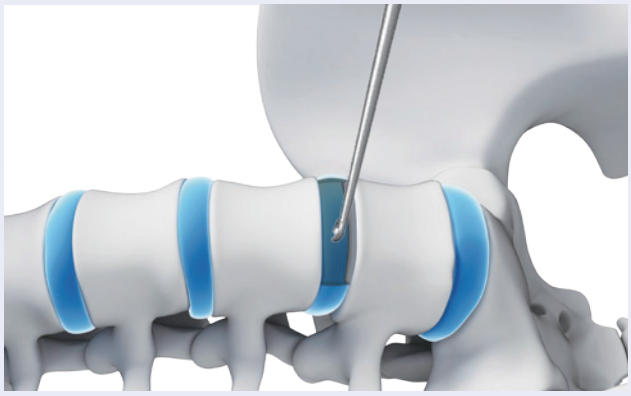


Figure 1

The Rasp and Shavers can be used to prepare the endplates by removing any remaining cartilage.

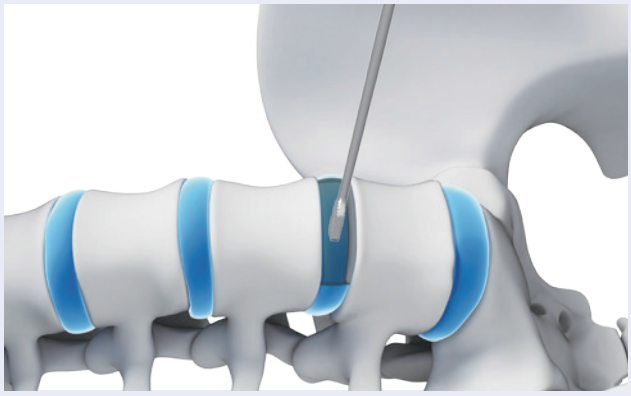


Figure 2

STEP 3 : Determine implant size

Select appropriate sized Trial and insert the Trial into the intervertebral disc space using gentle impaction.
Check fit and positioning with anterior/posterior and lateral flouroscopy. Fluoroscopy can assist in confirming the fit and geometry of the trial spacer. Repeat until the desired fit is achieved to identify the optimal Trial profile.
If the Trial appears too small or too tight, try the next larger or smaller size until the most secure fit is achieved. It is essential to use the tallest clinically reasonable implant to maximize segment stability.
The Slap Hammer can be used to help remove the Trial.

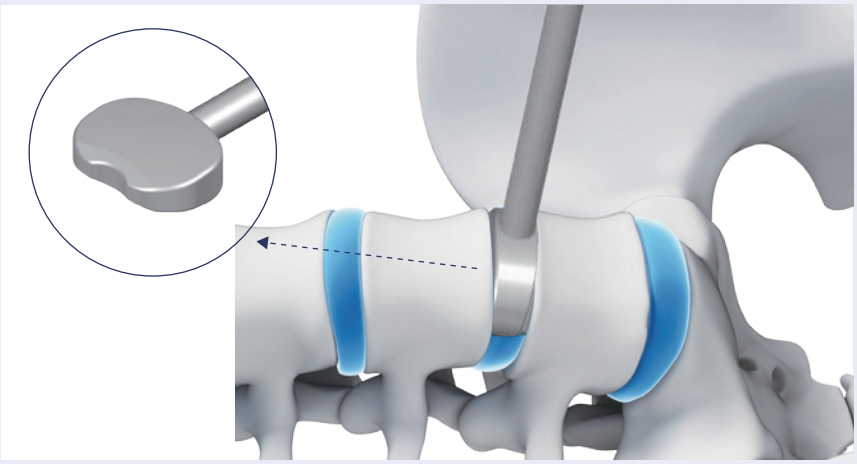


Figure 3

Figure 4

STEP 4 : Preparing the Cage

Select the cage profile that corresponds to the selected Trial. Lower the cage by hand into the corresponding space in the Bone Graft Block. Fill the graft window with the desired graft material, and use the Tamp to secure the content in place.

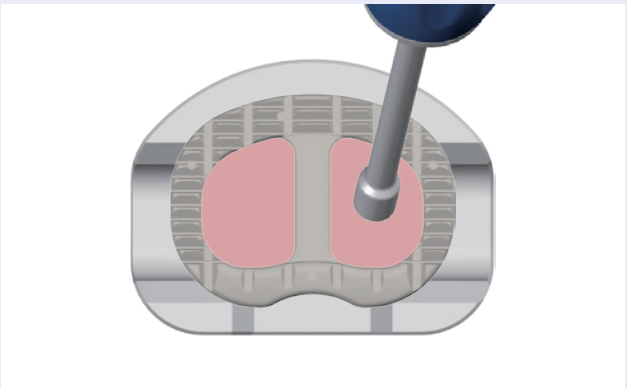


Figure 5

STEP 5 : Insertion

Option 1: Using Squid Inserter

To insert the cage by using Squid Inserter, attach the Square T-Handle to the Inserter first.

Take the cage from the Graft Station and guide it to the threaded prong of the Inserter.
To secure the cage onto the Inserter, turn the tightening knob while holding the cage in place.
Place the tips of the instrument into the disc space so the depth stops on the spring ramps touch the anterior rim of the vertebral body.

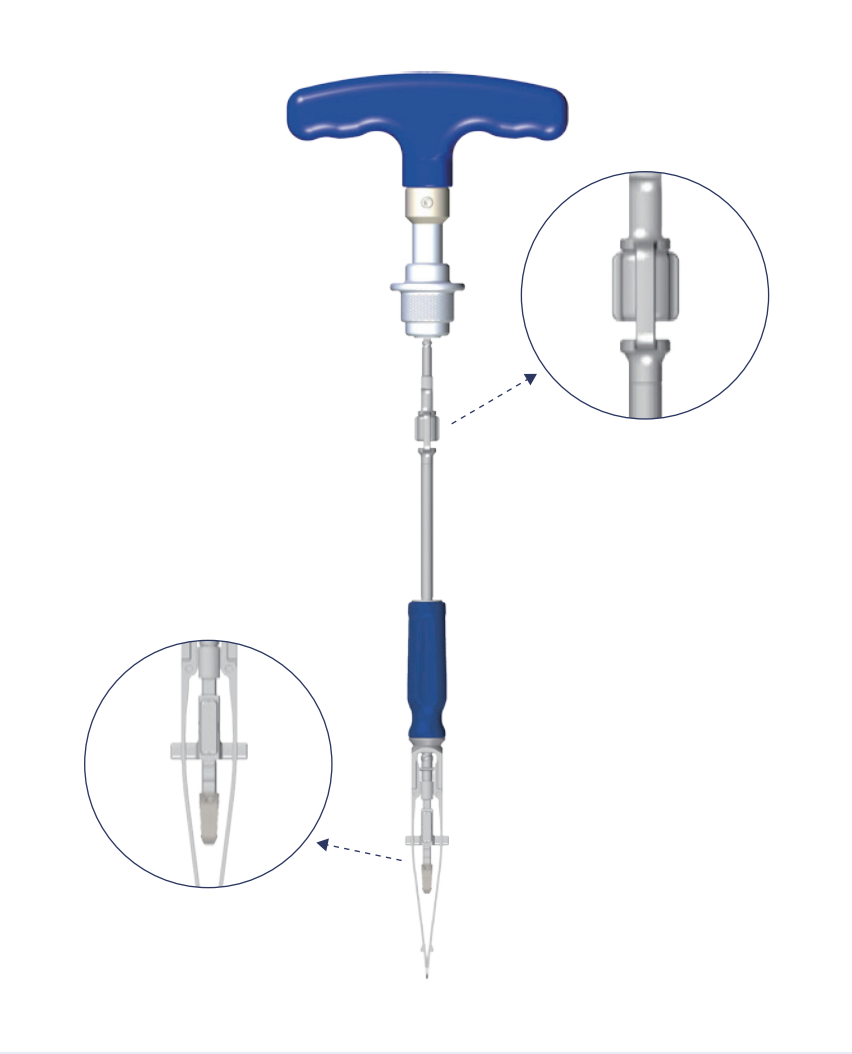


Figure 6

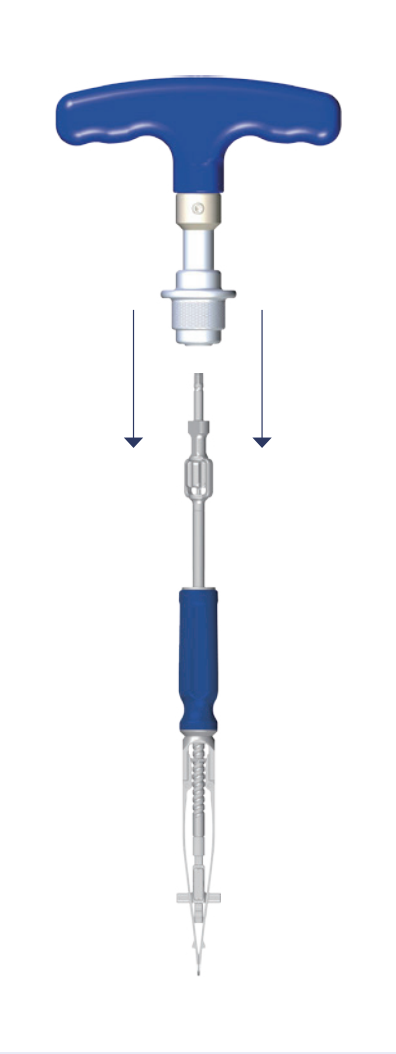


Figure 7

Guide the tips of the Inserter through the annulotomy window into the intervertebral space. Ensure the tips are seated flush against the vertebral bodies. Firmly grip the central handle and apply even counterpressure to keep the Inserter secure and stable during insertion. Gradually drive the cage forward through the Inserter blades and into the intervertebral space. The blades will automatically distract the vertebrae to allow impact-free insertion.

Figure 8

Figure 9

Figure 10

Turn the tightening knob of the inserter counter clockwise to release the cage, and remove the Inserter. Once cage has been inserted, confirm final positioning with anterior/posterior and lateral fluoroscopy.

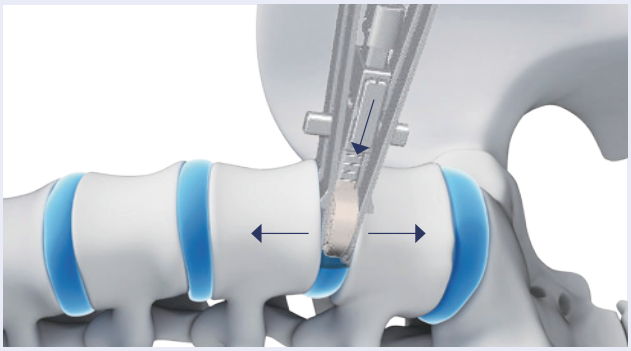


Figure 11

Option 2 : Using Implant Inserter and Impactor

Insert the implant using the ALIF implant inserter, ensuring that the tallest side of the implant lies against the inserter. The implant inserter aligns with the preformed grooves or slot on the implant for easy insertion. Aligning with the implant inserter and the preformed slot on the implant can prevent the fastened product from being separated. Ensure that the implant is held flush against the inserter. Attach the cage to the thread of inserter and turn the inserter to firmly secure the instrument jaws against the implant. Introduce the spacer into the intervertebral disc space until the implant is flush or slightly recessed. Slight implaction on the implant inserter may be necessary. Release the implant inserter by loosening the locking screw and use the impactor to fully seat the implant.

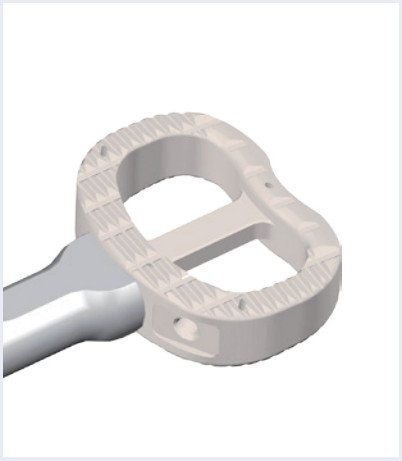


Figure 12

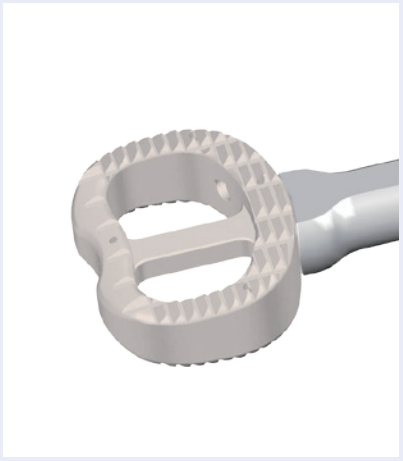


Figure 13

Figure 14

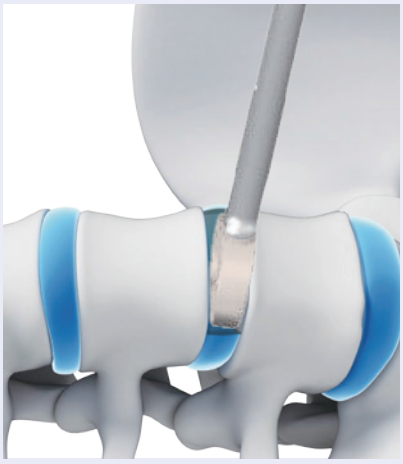


Figure 15

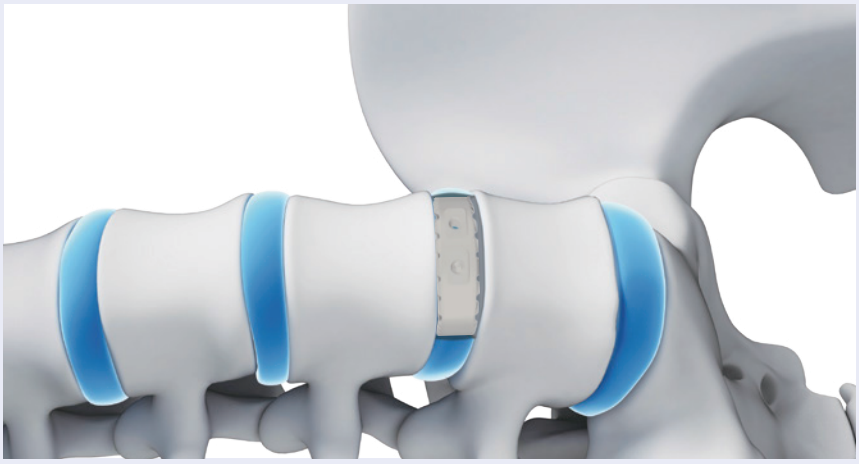
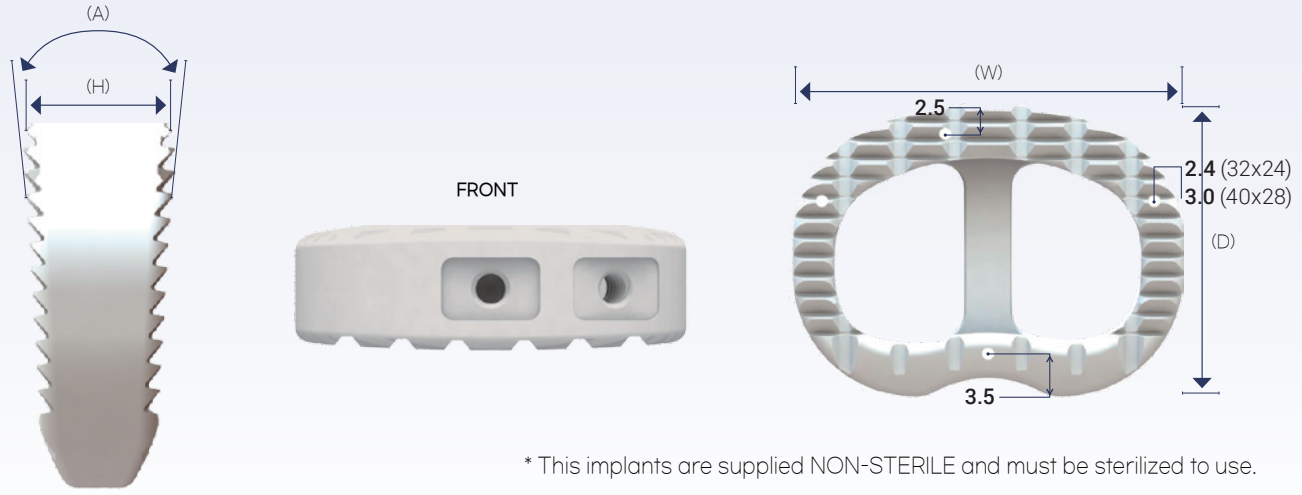


Figure 16

4CIS® AUGUSTA ALIF PEEK CAGE



* This implants are supplied NON-STERILE and must be sterilized to use.

Catalog No.	Description (W x D x H x A°, unit: mm)
APU6-32QA	32 x 24 x 10 x 6°
APU6-32QC	32 x 24 x 12 x 6°
APU6-32QE	32 x 24 x 14 x 6°
APU6-32QG	32 x 24 x 16 x 6°
APU6-32QJ	32 x 24 x 18 x 6°
APU6-32QL	32 x 24 x 20 x 6°
APUC-32QA	32 x 24 x 10 x 12°
APUC-32QC	32 x 24 x 12 x 12°
APUC-32QE	32 x 24 x 14 x 12°
APUC-32QG	32 x 24 x 16 x 12°
APUC-32QJ	32 x 24 x 18 x 12°
APUC-32QL	32 x 24 x 20 x 12°
APUL-32QC	32 x 24 x 12 x 20°
APUL-32QE	32 x 24 x 14 x 20°
APUL-32QG	32 x 24 x 16 x 20°
APUL-32QJ	32 x 24 x 18 x 20°
APUL-32QL	32 x 24 x 20 x 20°

Catalog No.	Description (W x D x H x A°, unit: mm)
APU6-40UA	40 x 28 x 10 x 6°
APU6-40UC	40 x 28 x 12 x 6°
APU6-40UE	40 x 28 x 14 x 6°
APU6-40UG	40 x 28 x 16 x 6°
APU6-40UJ	40 x 28 x 18 x 6°
APU6-40UL	40 x 28 x 20 x 6°
APUC-40UA	40 x 28 x 10 x 12°
APUC-40UC	40 x 28 x 12 x 12°
APUC-40UE	40 x 28 x 14 x 12°
APUC-40UG	40 x 28 x 16 x 12°
APUC-40UJ	40 x 28 x 18 x 12°
APUC-40UL	40 x 28 x 20 x 12°
APUL-40UC	40 x 28 x 12 x 20°
APUL-40UE	40 x 28 x 14 x 20°
APUL-40UG	40 x 28 x 16 x 20°
APUL-40UJ	40 x 28 x 18 x 20°
APUL-40UL	40 x 28 x 20 x 20°

INSTRUMENTS

5901-0462	4CIS® Augusta Trial, W32 x D24, H10, 6°
5901-0463	4CIS® Augusta Trial, W32 x D24, H12, 6°
5901-0464	4CIS® Augusta Trial, W32 x D24, H14, 6°
5901-0465	4CIS® Augusta Trial, W32 x D24, H16, 6°
5901-0466	4CIS® Augusta Trial, W32 x D24, H18, 6°
5901-0467	4CIS® Augusta Trial, W32 x D24, H20, 6°
5901-0468	4CIS® Augusta Trial, W32 x D24, H10, 12°
5901-0469	4CIS® Augusta Trial, W32 x D24, H12, 12°
5901-0470	4CIS® Augusta Trial, W32 x D24, H14, 12°
5901-0471	4CIS® Augusta Trial, W32 x D24, H16, 12°
5901-0472	4CIS® Augusta Trial, W32 x D24, H18, 12°
5901-0473	4CIS® Augusta Trial, W32 x D24, H20, 12°
5901-0474	4CIS® Augusta Trial, W32 x D24, H12, 20°
5901-0475	4CIS® Augusta Trial, W32 x D24, H14, 20°
5901-0476	4CIS® Augusta Trial, W32 x D24, H16, 20°
5901-0477	4CIS® Augusta Trial, W32 x D24, H18, 20°
5901-0478	4CIS® Augusta Trial, W32 x D24, H20, 20°
5901-0479	4CIS® Augusta Trial, W40 x D28, H10, 6°
5901-0480	4CIS® Augusta Trial, W40 x D28, H12, 6°
5901-0481	4CIS® Augusta Trial, W40 x D28, H14, 6°
5901-0482	4CIS® Augusta Trial, W40 x D28, H16, 6°
5901-0483	4CIS® Augusta Trial, W40 x D28, H18, 6°
5901-0484	4CIS® Augusta Trial, W40 x D28, H20, 6°
5901-0485	4CIS® Augusta Trial, W40 x D28, H10, 12°
5901-0486	4CIS® Augusta Trial, W40 x D28, H12, 12°
5901-0487	4CIS® Augusta Trial, W40 x D28, H14, 12°
5901-0488	4CIS® Augusta Trial, W40 x D28, H16, 12°
5901-0489	4CIS® Augusta Trial, W40 x D28, H18, 12°
5901-0490	4CIS® Augusta Trial, W40 x D28, H20, 12°
5901-0491	4CIS® Augusta Trial, W40 x D28, H12, 20°
5901-0492	4CIS® Augusta Trial, W40 x D28, H14, 20°
5901-0493	4CIS® Augusta Trial, W40 x D28, H16, 20°
5901-0494	4CIS® Augusta Trial, W40 x D28, H18, 20°
5901-0495	4CIS® Augusta Trial, W40 x D28, H20, 20°

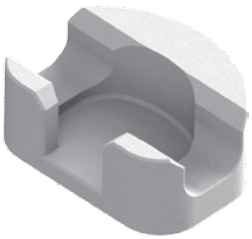
5901-0230 4CIS® Augusta Cage Inserter, Straight

5901-0231 4CIS® Augusta Impactor, Straight

5901-0234 4CIS® Augusta Rasp

5901-0461 4CIS® Curette

5901-0226 4CIS® Augusta Bone Graft Block, D24 x W32
5901-0228 4CIS® Augusta Bone Graft Block, D28 x W40



4901-7021 Square Handle (T-Type)

5901-0229 4CIS® Augusta Bone Temp

5901-0132 4CIS® Slap Hammer

5901-0235 4CIS® Augusta Squid Inserter

WARNING AND CAUTIONS

Warning

01. Do not use this product other than its indication. Cannot be inserted other than indicated area and cervical vertebrae is not allowed.
02. Never use a damaged, explanted implant or one which has been used erroneously when it has come into contact with tissues, even after cleaning. The implant must be discarded.
03. This product is one time use only and can never be re-used in any occasions. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time, and may result in premature rupture. Such reuse may also result in infection in the patient.
04. Non-sterilized implants and instruments must be cleaned, sterilized and decontaminated prior to surgical use as instructed by the manufacturer.
05. Sterilized product must be checked the sterilized expiration date before used.
06. Transplant should only be performed by physicians/surgeons who have full understanding of Solco Biomedical Co., Ltd. surgical technique and surgical instrument usage. And Solco product needs to be handled based on its proper surgical technique manual or operational literature.
07. A wrong choice of implant size may cause damage to the product and may be the reason of unsuccessful surgery. Therefore, product's design and size should be selected after full consideration of patient's weight, amount of exercise, and area of vertebral checked by X-ray. Please refer to "the choice of implant".
08. It cannot be used with other product without validation regarding safety and effectiveness. If it is used with other product, Solco biomedical Co., Ltd do not take any responsibility.
09. Where material oversensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
10. It is important for surgeon and medical staff to be well-informed of the following information and give it to patient before the procedure, in order to be warned of the potential consequences and ensure success of the surgical implantation:
    - Clinical data show that patients who smoke tend to have less optimum bony consolidation, as well as patients who are undernourished, alcoholic, obese, or patients with muscle weakness or nerve paralysis.
    - To aid bone healing it is important to limit use of nicotine and non-steroidal medicinal products (ex.: aspirin).
    - The implanted device must not be subjected to exposure to unwanted forces such as mechanical vibrations. Consequently, the patient must be informed of limiting his or her physical activity (athletic and occupational), especially in the cases of lifting, twisting and crushing.
    - Throughout the period of consolidation, the patient must follow the surgeon's instructions and recommendations.
    - These implants do not present any known risk of interference with other medical equipment.
    - Safety and compatibility of the device in the setting of magnetic resonance (imaging) have not been evaluated. No thermal test or test of migration has been performed on the device in this setting.

Caution

01. A condition of senility, mental illness, or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

02. Compliance with pre-operative and perioperative procedures, including knowledge of the surgical technique, as well as the proper selection and positioning of implants are important factors in success of use of the system by the surgeon. Knowledge and experience in spinal surgery are pre-requisites.

03. Furthermore, appropriate selection of patients, as well as the patient's cooperation, greatly affect results.

04. Non-Sterilized Implants must be placed on a tray for use.

05. The compatibility needs to be verified before use with other product.

06. The products must be stored away from contact with metal or abrasive materials to prevent cracks or scratches. The product maybe damaged from loads due to scratches not visible with naked eyes.

07. The use of implants may interfere with the anatomical structure or physiological performance of the patient. It should be reviewed carefully about radiological diagnosis and its side effects before the procedure.

08. The 4CIS® Augusta PEEK ALIF Cage has not been evaluated for safety and compatibility in the MR environment. The 4CIS®Augusta PEEK ALIF Cage has not been tested for heating or migration in the MR environment.

09. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

4CIS®
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