4CIS®
TORREY PINES
PEEK TLIF CAGE

Surgical Technique

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4CIS® TORREY PINES PEEK TLIF CAGE

Surgical Technique

SYSTEM OVERVIEW

Introduction

The 4CIS® Torrey Pines PEEK TLIF Cage is single component device used to restore height of disc space by transforaminal 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 (ASTM F560) markers for easy visualization on radiographs.
The vertical square teeth on the top and the bottom surface prevents 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® Torrey Pines PEEK TLIF 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® Torrey Pines PEEK TLIF 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 : Exposition

The patient is placed in the prone position.
A slightly arcuate fascial incision 1.5cm from the midline is performed. This allows a firm hold of the speculum and counter retractor, facilitating the exposure of the individual segment.

Exposure and blunt dissection of the paraspinal muscles are progressed.

Ultimately, the object of the transmuscular approach is to perform a laminotomy, medical facetectomy, foraminotomy, TLIF or pedical screw insertion in a minimally invasive fashion.

STEP 2 : Distraction

Prepare a window of transforaminal approach, using the osteotomes to remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra.

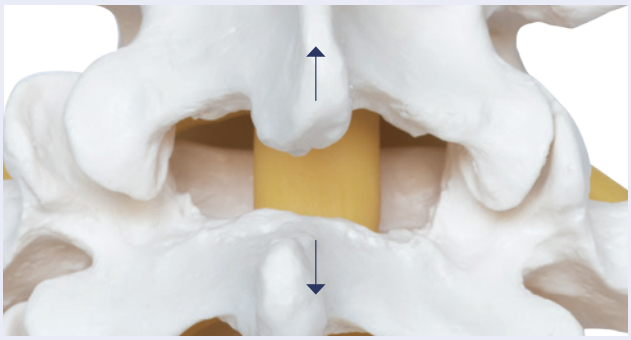


Figure 1

Using 4CIS® Durameter Retractor, the caudal equina and nerve are mobilized to expose the annulus of the disc.

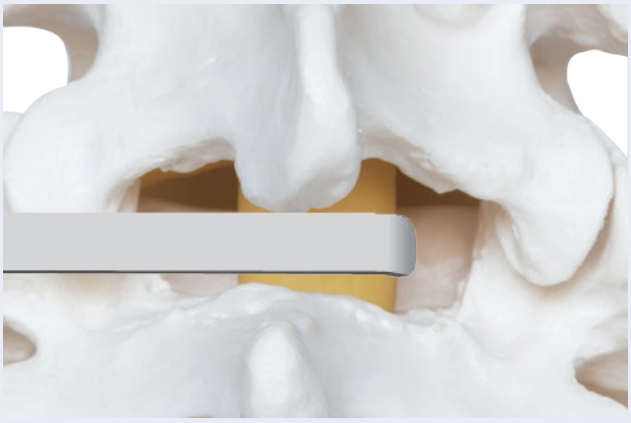


Figure 2

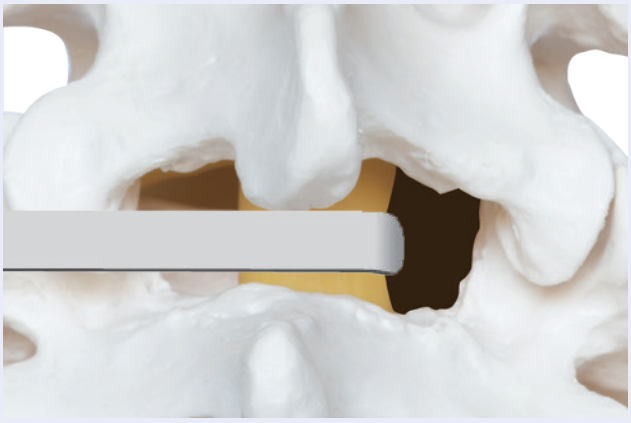


Figure 3

STEP 3 : Discectomy

Using scalpel, an incision is made to the Annulus of the disc, and the discectomy is performed as needed using appropriate other discectomy instruments. The disc space is cleared and the cartilaginous endplates are refreshed using curettes, rakes, reamers and rasp.

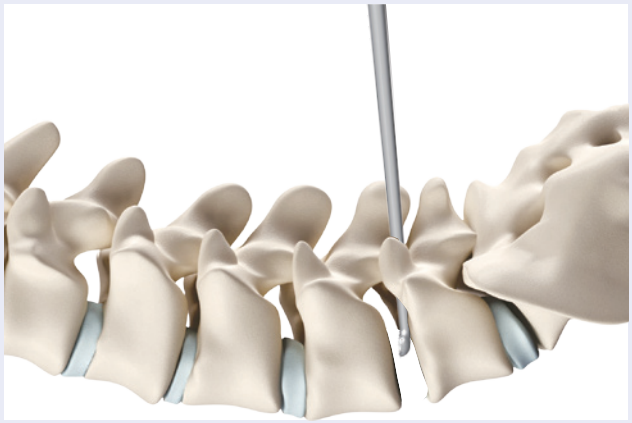


Figure 4

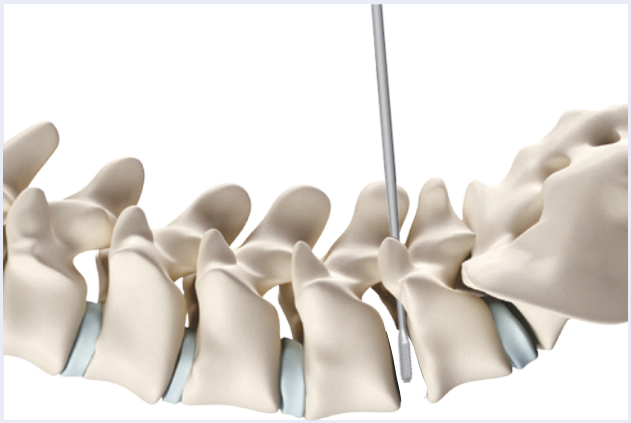


Figure 5

STEP 4 : Distraction

Gradually distract the disc space using the 4CIS® Peddle Distractor Blunt, available in 1mm increments. The final disc Height achieved should be consistent with disc height of the adjacent levels.

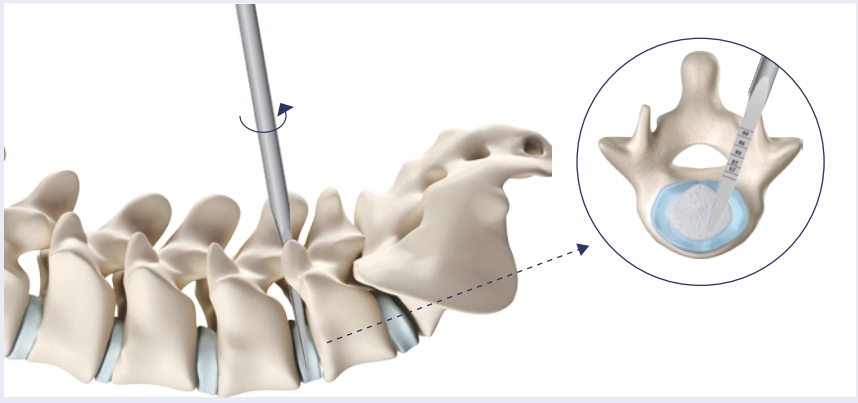


Figure 6

Figure 7

STEP 5 : Cage Size Selection

Trials are included to aid in initial test, fitting and size confirmation of the Implant.

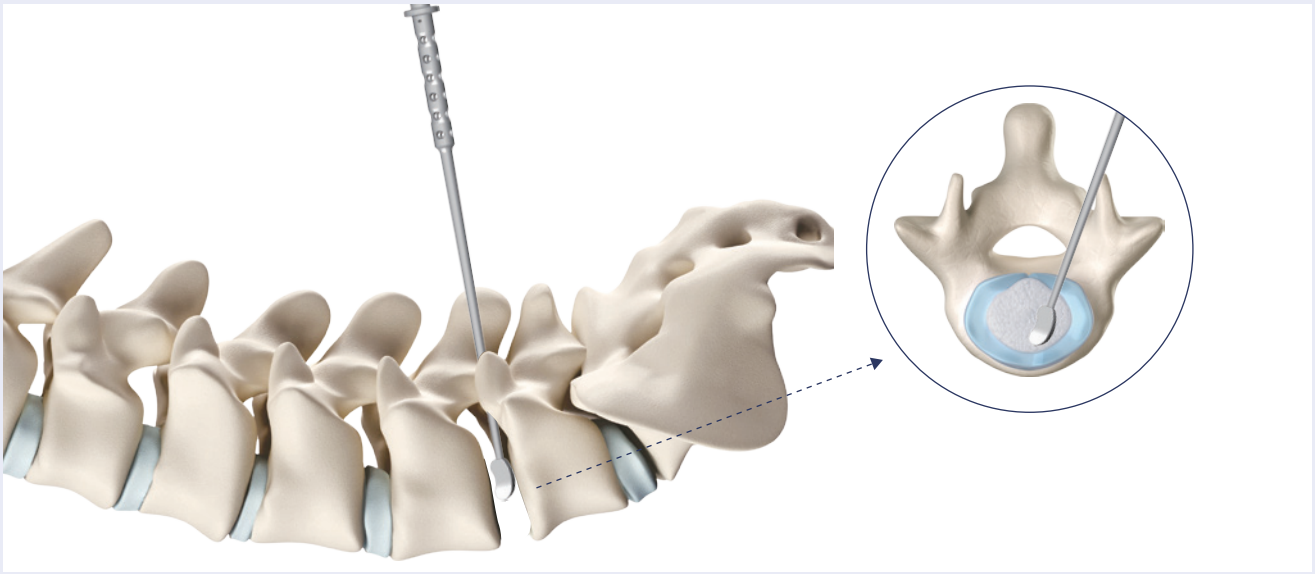


Figure 8

STEP 6 : Cage Preparation

Place bone graft in the fusion chamber of TLIF cage and compact it with the 4CIS□ Graft Compactor.

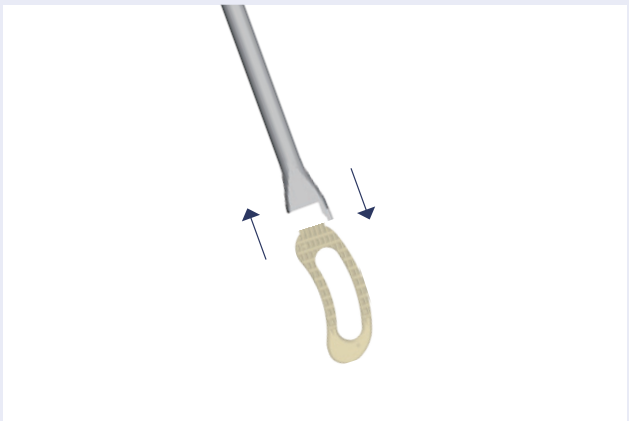


Figure 9

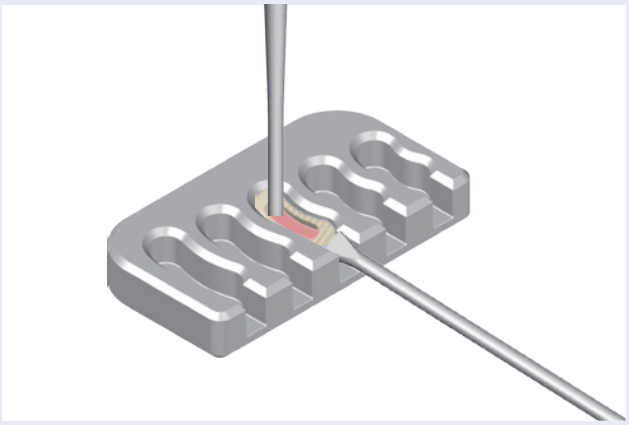


Figure 10

STEP 7 : Cage Insertion

Bone graft can be inserted anteriorly into the disc space before insertion and placement of the cage using the Anterior Graft Pusher.

TLIF Cage is inserted using 4CIS® Torrey Pines TLIF Cage Holder through transforamianal approaching. Position the cage in the inter-vertebral space as close as possible to the final position.

After separating the 4CIS® Torrey Pines TLIF Cage Holder from the implant, use the proper shape of 4CIS® Torrey Pines Final Impactor to place the cage in its final position (anterior, and centered on the vertebral endplate).

It is possible to fill the inter-vertebral space posterior to the cage with bone graft using the Anterior Graft Pusher.

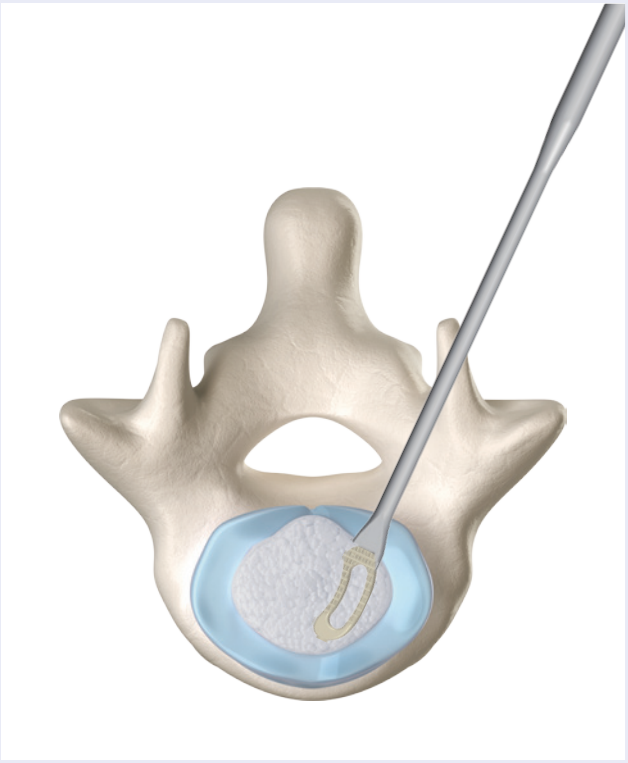


Figure 11

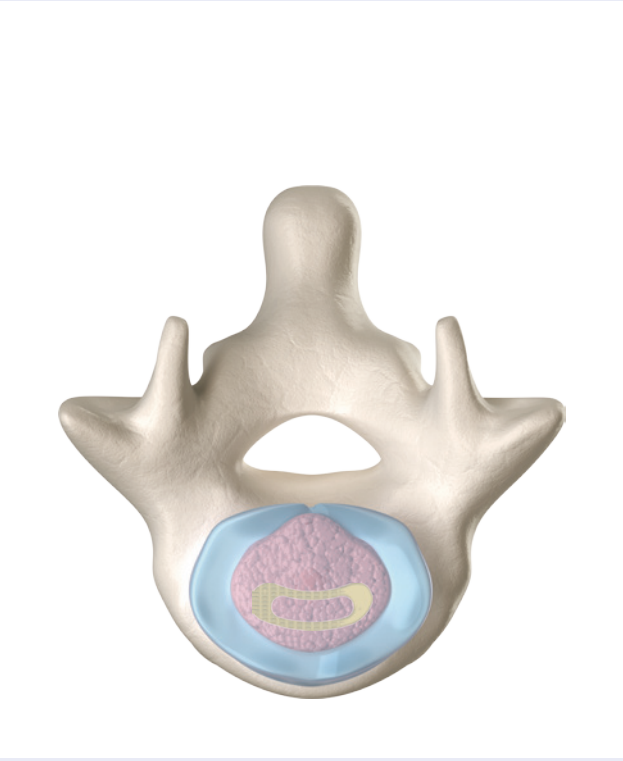


Figure 12

4CIS® TORREY PINES PEEK TLIF CAGE

(NON-STERILIZED)

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

Catalog No.	Description (W x D x H x A°, unit: mm)
TPU0-2696	26 x 9 x 6 x 0°
TPU0-2697	26 x 9x 7 x 0°
TPU0-2698	26 x 9 x 8 x 0°
TPU0-2699	26 x 9 x 9 x 0°
TPU0-269A	26 x 9 x 10 x 0°
TPU0-269B	26 x 9 x 11 x 0°
TPU0-269C	26 x 9 x 12 x 0°
TPU0-269D	26 x 9 x 13 x 0°
TPU0-269E	26 x 9 x 14 x 0°
TPU0-269F	26 x 9 x 15 x 0°
TPU0-269G	26 x 9 x 16 x 0°
TPU0-3296	32 x 9 x 6 x 0°
TPU0-3297	32 x 9 x 7 x 0°
TPU0-3298	32 x 9 x 8 x 0°
TPU0-3299	32 x 9 x 9 x 0°
TPU0-329A	32 x 9 x 10 x 0°
TPU0-329B	32 x 9 x 11 x 0°
TPU0-329C	32 x 9 x 12 x 0°

Catalog No.	Description (W x D x H x A°, unit: mm)
TPU0-329D	32 x 9 x 13 x 0°
TPU0-329E	32 x 9 x 14 x 0°
TPU0-329F	32 x 9 x 15 x 0°
TPU0-329G	32 x 9 x 16 x 0°
TPU5-2696	26 x 9 x 6 x 5°
TPU5-2697	26 x 9 x 7 x 5°
TPU5-2698	26 x 9 x 8 x 5°
TPU5-2699	26 x 9 x 9 x 5°
TPU5-269A	26 x 9 x 10 x 5°
TPU5-269B	26 x 9 x 11 x 5°
TPU5-269C	26 x 9 x 12 x 5°
TPU5-269D	26 x 9 x 13 x 5°
TPU5-269E	26 x 9 x 14 x 5°
TPU5-269F	26 x 9 x 15 x 5°
TPU5-269G	26 x 9 x 16 x 5°
TPU5-3296	32 x 9 x 6 x 5°
TPU5-3297	32 x 9 x 7 x 5°

Catalog No.	Description (W x D x H x A°, unit: mm)
TPU5-3298	32 x 9 x 8 x 5°
TPU5-3299	32 x 9 x 9 x 5°
TPU5-329A	32 x 9 x 10 x 5°
TPU5-329B	32 x 9 x 11 x 5°
TPU5-329C	32 x 9 x 12 x 5°
TPU5-329D	32 x 9 x 13 x 5°
TPU5-329E	32 x 9 x 14 x 5°
TPU5-329F	32 x 9 x 15 x 5°
TPU5-329G	32 x 9 x 16 x 5°
TPU0-26B6	26 x 11 x 6 x 0°
TPU0-26B7	26 x 11x 7 x 0°
TPU0-26B8	26 x 11 x 8 x 0°
TPU0-26B9	26 x 11x 9 x 0°
TPU0-26BA	26 x 11 x 10 x 0°
TPU0-26BB	26 x 11 x 11 x 0°
TPU0-26BC	26 x 11 x 12 x 0°
TPU0-26BD	26 x 11 x 13 x 0°
TPU0-26BE	26 x 11 x 14 x 0°
TPU0-26BF	26 x 11 x 15 x 0°
TPU0-26BG	26 x 11 x 16 x 0°
TPU0-32B6	32 x 11 x 6 x 0°
TPU0-32B7	32 x 11 x 7 x 0°
TPU0-32B8	32 x 11 x 8 x 0°
TPU0-32B9	32 x 11 x 9 x 0°
TPU0-32BA	32 x 11 x 10 x 0°
TPU0-32BB	32 x 11 x 11 x 0°
TPU0-32BC	32 x 11 x 12 x 0°
TPU0-32BD	32 x 11 x 13 x 0°
TPU0-32BE	32 x 11 x 14 x 0°

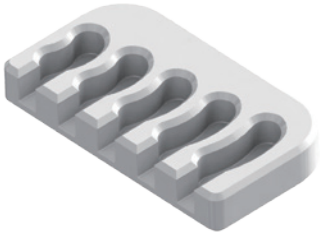
Catalog No.	Description (W x D x H x A°, unit: mm)
TPU0-32BF	32 x 11 x 15 x 0°
TPU0-32BG	32 x 11 x 16 x 0°
TPU5-26B6	26 x 11 x 6 x 5°
TPU5-26B7	26 x 11 x 7 x 5°
TPU5-26B8	26 x 11 x 8 x 5°
TPU5-26B9	26 x 11 x 9 x 5°
TPU5-26BA	26 x 11 x 10 x 5°
TPU5-26BB	26 x 11 x 11 x 5°
TPU5-26BC	26 x 11 x 12 x 5°
TPU5-26BD	26 x 11 x 13 x 5°
TPU5-26BE	26 x 11 x 14 x 5°
TPU5-26BF	26 x 11 x 15 x 5°
TPU5-26BG	26 x 11 x 16 x 5°
TPU5-32B6	32 x 11 x 6 x 5°
TPU5-32B7	32 x 11 x 7 x 5°
TPU5-32B8	32 x 11 x 8 x 5°
TPU5-32B9	32 x 11 x 9 x 5°
TPU5-32BA	32 x 11 x 10 x 5°
TPU5-32BB	32 x 11 x 11 x 5°
TPU5-32BC	32 x 11 x 12 x 5°
TPU5-32BD	32 x 11 x 13 x 5°
TPU5-32BE	32 x 11 x 14 x 5°
TPU5-32BF	32 x 11 x 15 x 5°
TPU5-32BG	32 x 11 x 16 x 5°

INSTRUMENTS

5901-0173	4CIS® Reamer Sharp 8mm
5901-0174	4CIS® Reamer Sharp 9mm
5901-0175	4CIS® Reamer Sharp 10mm
5901-0176	4CIS® Reamer Sharp 11mm
5901-0177	4CIS® Reamer Sharp 12mm
5901-0178	4CIS® Reamer Sharp 13mm
5901-0179	4CIS® Reamer Sharp 14mm

5901-0505	4CIS® Peddle Distractor Blunt 6mm
5901-0506	4CIS® Peddle Distractor Blunt 7mm
5901-0507	4CIS® Peddle Distractor Blunt 8mm
5901-0508	4CIS® Peddle Distractor Blunt 9mm
5901-0509	4CIS® Peddle Distractor Blunt 10mm
5901-0510	4CIS® Peddle Distractor Blunt 11mm
5901-0511	4CIS® Peddle Distractor Blunt 12mm
5901-0512	4CIS® Peddle Distractor Blunt 13mm
5901-0513	4CIS® Peddle Distractor Blunt 14mm
5901-0514	4CIS® Peddle Distractor Blunt 15mm
5901-0515	4CIS® Peddle Distractor Blunt 16mm

5901-0192	4CIS® Trout Bone Grafting Block



5901-0193	4CIS® Graft Compactor

5901-0187	4CIS® Durameter Retractor W6mm
5901-0188	4CIS® Durameter Retractor W8mm (Option)
5901-0189	4CIS® Durameter Retractor W10mm (Option)

5901-0185 4CIS® Torrey Pines TLIF Cage Holder

5901-0027 Cancellous Bone Funnel

5901-0051 Cancellous Bone Impactor

5901-0181 4CIS® Rasp Bayonet Rigid

5901-0434 4CIS® Cup Curette Bayonet Straight

5901-0182 4CIS® Torrey Pines Final Impactor Straight Rigid

5901-0183 4CIS® Torrey Pines Final Impactor Straight Angled

5901-0132 4CIS® Slap Hammer

5901-0218 4CIS® Slap Hammer Adaptor

4901-7021 T-Handle

5901-3160	4CIS® Torrey Pines Trial 0° 26x9x6	5901-3259	4CIS® Torrey Pines Trial 0° 26x11x6
5901-3161	4CIS® Torrey Pines Trial 0° 26x9x7	5901-3260	4CIS® Torrey Pines Trial 0° 26x11x7
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5901-3163	4CIS® Torrey Pines Trial 0° 26x9x9	5901-3262	4CIS® Torrey Pines Trial 0° 26x11x9
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5901-3246	4CIS® Torrey Pines Trial 5° 32x9x15	5901-3345	4CIS® Torrey Pines Trial 5° 32x11x15
5901-3247	4CIS® Torrey Pines Trial 5° 32x9x16	5901-3346	4CIS® Torrey Pines Trial 5° 32x11x16

WARNING AND CAUTIONS

Warning

01. Do not use this product other than its indication. Insertion 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. Reuse of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performance over time, and may result in premature rupture. Reuse may also result in infection in the patient.

04. Must check the sterilized expiration date before use.

05. Non-sterilized implants and instruments must be cleaned, sterilized and decontaminated prior to surgical use as instructed by the manufacturer.

06. Transplant should only be performed by physicians/surgeons who have full understanding of Solco Biomedical Co., Ltd. surgical technique and surgical instrument usage. Solco's 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 surgeries. 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 products without validation regarding safety and effectiveness. If it is used with other products, 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 the surgeon and medical staff to be well-informed of the following information and give it to the 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, have 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 successful 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® Torrey pines PEEK TLIF Cage has not been evaluated for safety and compatibility in the MR environment. The 4CIS® Torrey pines PEEK TLIF 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®
TORREY PINES

SOLCO.

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