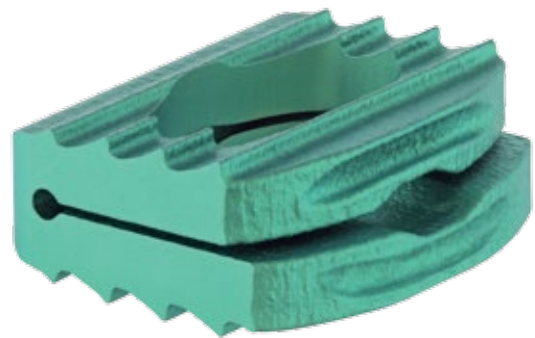




PARADIGM SPINE
the movement in spine care



Anterior Cervical Fusion Cage ***OptiStrain™ C***

Cervical Interbody Fusion

DESIGN RATIONALE

The *OptiStrain™ C** interbody fusion cage follows well established biomechanical principles: The slot design of the implant allows for reduced stress shielding and therefore enables load transfer through the device. Cyclic loading of bone stimulates bone growth in accordance to Wolff's Law and thus supports the fusion process mechanically.

OptiStrain™ C is made out of titanium alloy. Its roughened surface provides an optimal environment for a successful osteogenesis.

Optimized Load Transfer

- Reduced stress shielding
- Micro-motion through slot design
- Cyclic loading of bone
- Large central fenestration can be filled with bone graft or bone substitutes

Reduced Risk of Subsidence

- Optimized stiffness of the implant
- Endplate protection through soft stop technology
- Maximized contact surface for optimal load distribution

Biocompatible Titanium Alloy

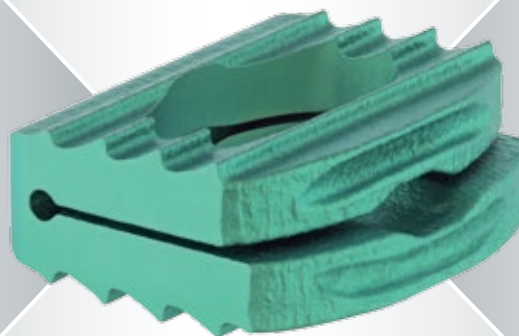
- Angiogenic and osteogenic characteristics support osseointegration
- Roughened titanium surface provides excellent primary and secondary stability

Additional Product Features

- Enhanced primary stability through teeth on implant surface
- 9 anatomical sizes
- Color coded instruments and implants

Excellent Osseointegration

- Angiogenic and osteogenic material characteristics
- Roughened titanium surface for good primary and enhanced secondary stability



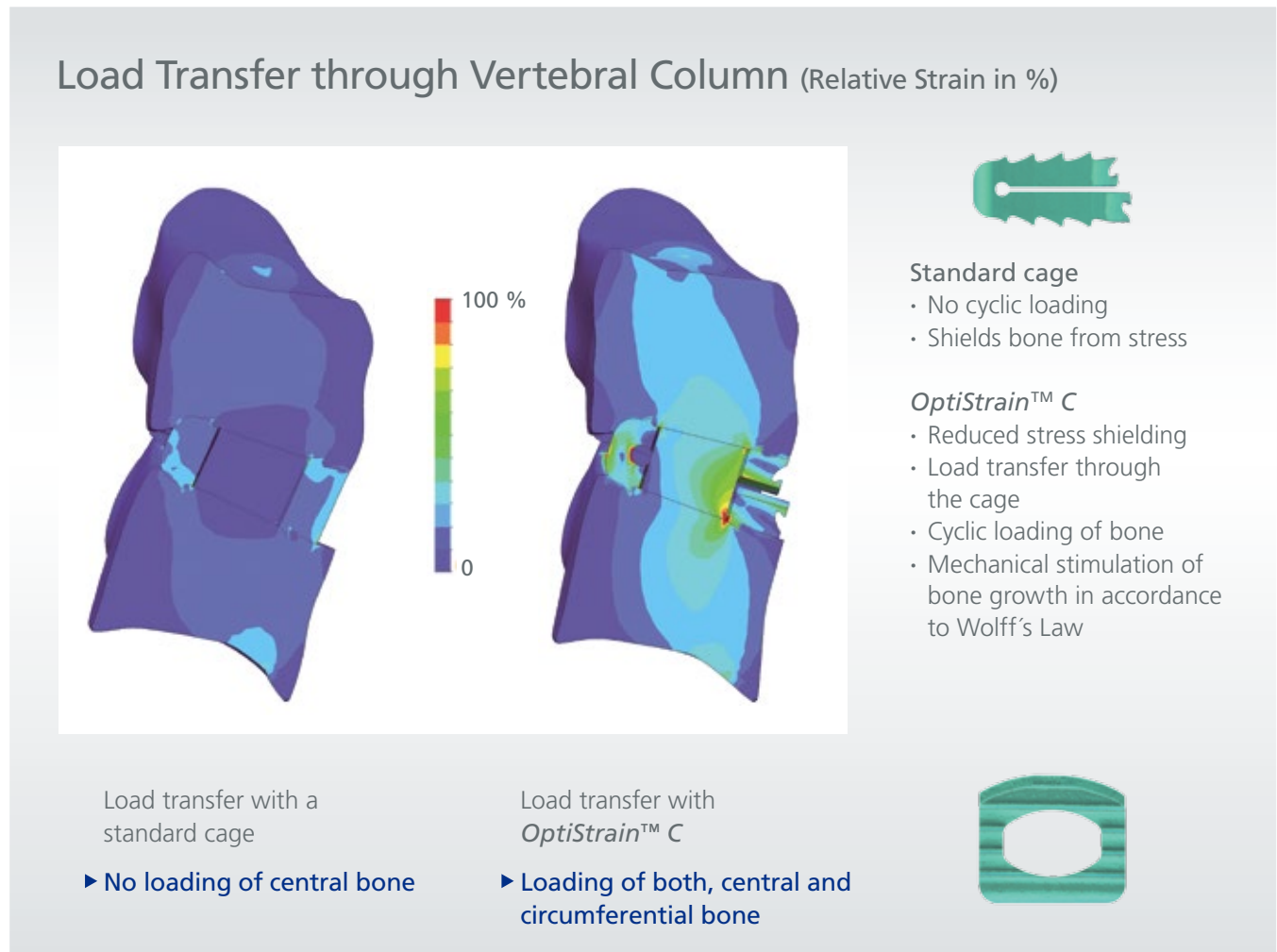
Optimized Load Transfer

- Slot allows for micro-motion
- Cyclic loading of bone
- Stress shielding can be effectively reduced
- Reduced risk of subsidence

* Strain: The unit strain derives from the Mechanostat model (Harold Frost, Utah; Paradigm of Skeletal Physiology, 1960). The model describes how bone growth and loss are stimulated by elastic deflection under loads. The deflection of bone is measured in μStrain ($1000 \mu\text{Strain} = 0,1 \%$ change in length).

Optimized Load Transfer for Optimized Bony Fusion

The slot in the *OptiStrain*[™] C design allows for micro-motion and reduces stress shielding. The optimized load transfer feature enables cyclic loading of the bone and thus actively supports osteogenesis.



Indication

The *OptiStrain*[™] C cage is intended for permanent implantation in the anterior area of the cervical spine (intervertebral) following cervical discectomy on one to three levels from C3 to C7. The implant can be filled with autologous bone or bone substitutes to facilitate fusion.

The implant can be utilized for pathologies of the cervical spine that indicate segmental arthrodesis, e.g.:

- Degenerative disc disease and instabilities
- Spinal disc herniations
- Pseudarthrosis or failed spondylodesis

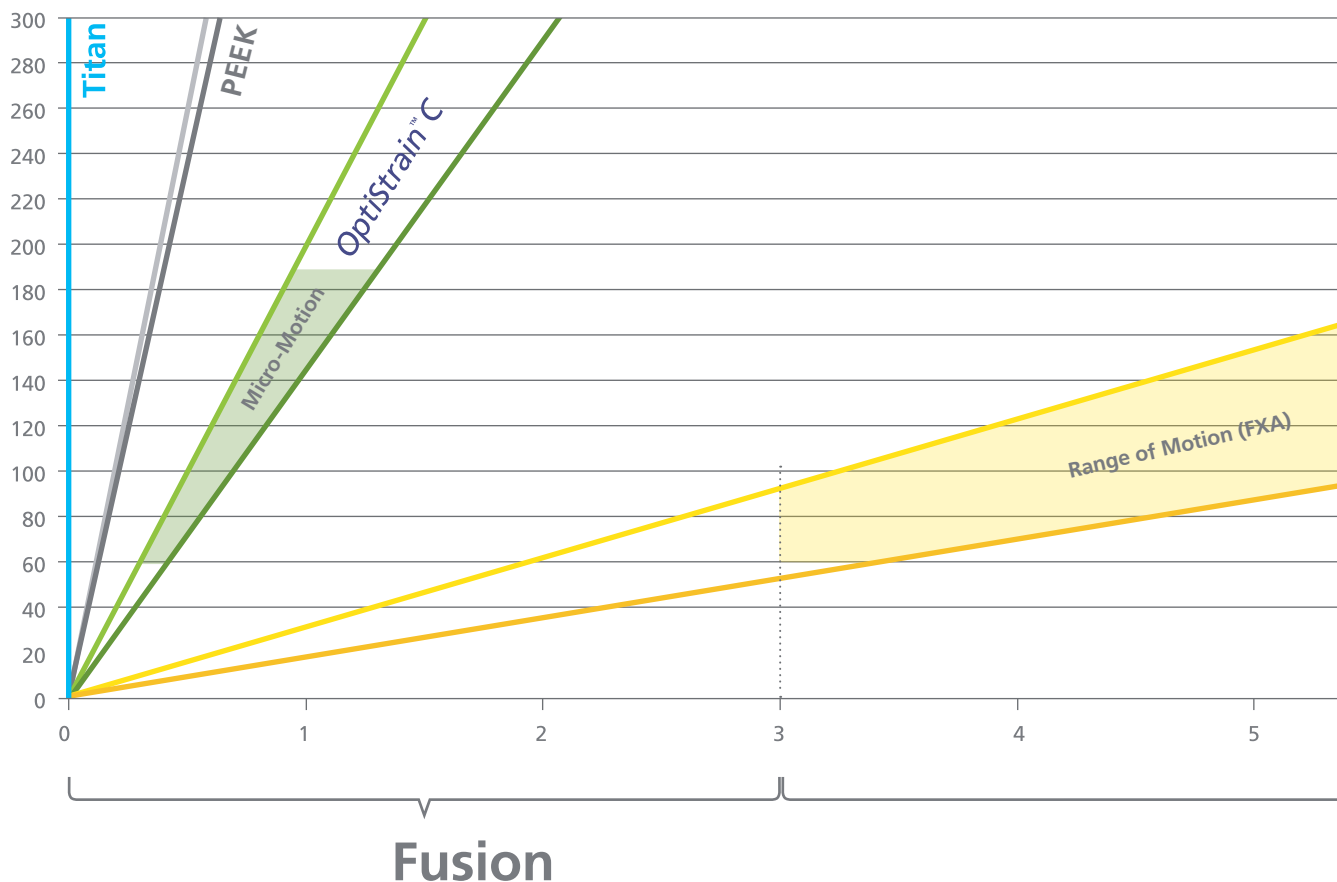
It is indicated for patients with mature skeletons with or without myeloradiculopathy with or without neck pain.

OptiStrain™ C

OPTIMIZED STRAIN

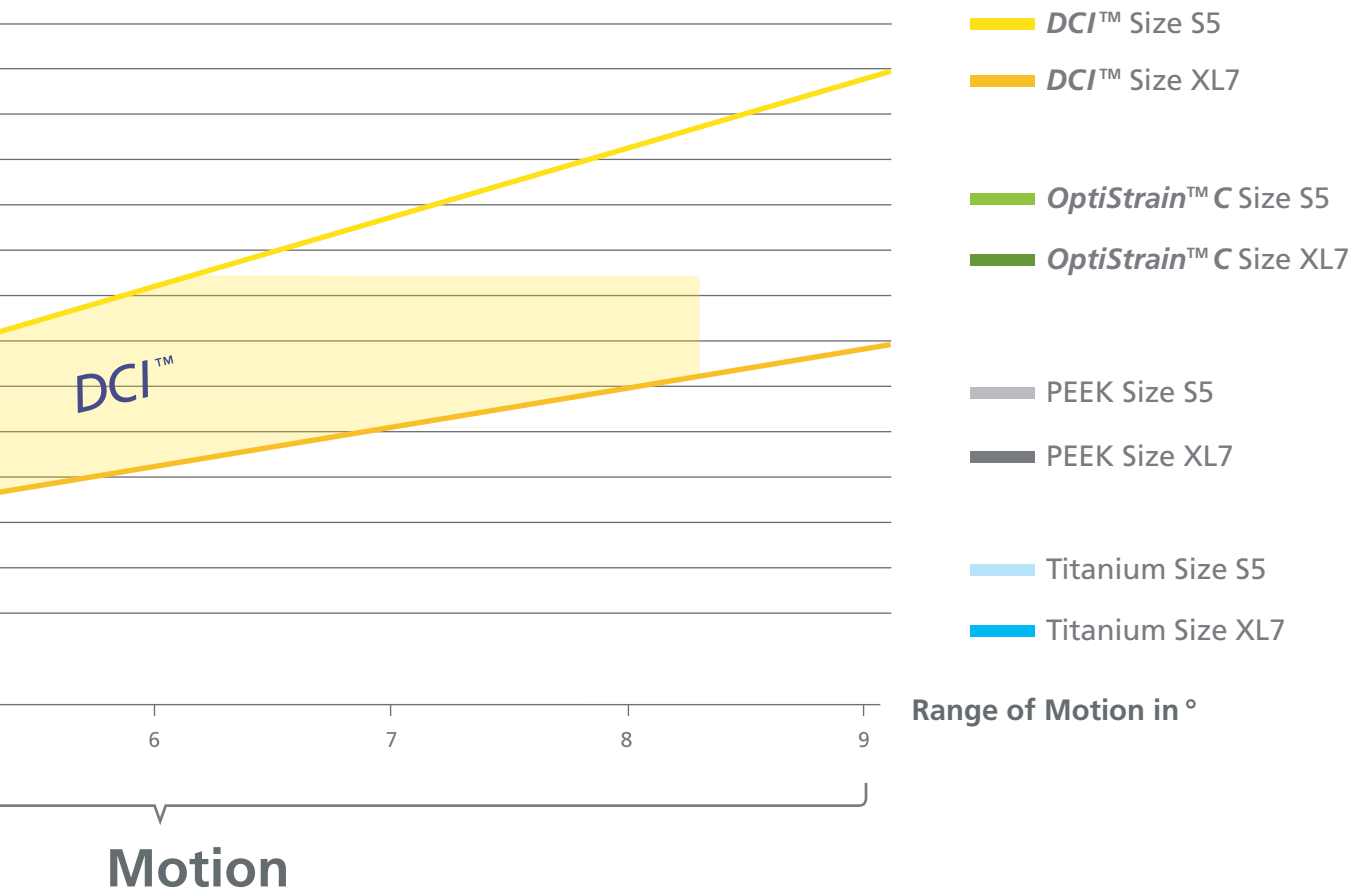
The development of the *OptiStrain™ C* cage was aiming for optimization of the cervical fusion. The osteogenic attributes of titanium have been combined with a load transferring design. The slot of the implant allows for micro-motion to stimulate bone growth and to facilitate solid bony fusion.

Load in N



Summary:

- Because of the stiffness of the material, titanium cages do not allow for any deflection and are very likely to cause stress shielding and subsidence.
- PEEK cages are less stiff than titanium cages, but only allow for a slight deflection under load.
- Only the *OptiStrain™ C* cage allows for an optimized load deflection. Micro-motion supports mechanical load transfer to the bone and the filling material of the cage.



Development of the *OptiStrain™ C* Cage with Micro-Motion

In order to define an optimized load deflection with micro-motion capacity of the *OptiStrain™ C* cage, a functional x-ray analysis (FXA™, Aces GmbH) was performed based on a data set of 57 patients treated with the DCI™ implant.⁽¹⁾ Based on the precisely measured range of motion in flexion and extension, the forces that were applied on the DCI™ implant have been calculated. The *OptiStrain™ C* cage has been designed to allow for micro-motion with maximum of 2 degrees under physiological load. With this, the implant enables cyclic loading of the bone and stimulates bone growth according to the principles of Wolffs' law.

¹ Herdmann, et al. *Eur Spine J* 2012; 21:2329.

SURGICAL TECHNIQUE

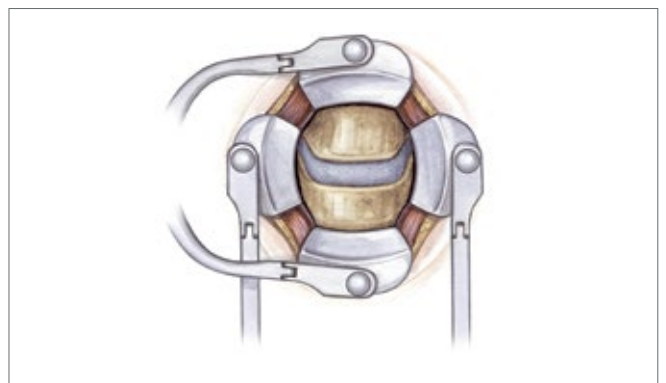
1. Preparation

The patient is placed in supine position with slight hyperextension of the neck supported by a neck roll.



Medial anterior approach to C3-C7 segments is utilized and a standard technique is applied to expose the affected disc level.

The disc space is distracted using the standard distraction technique



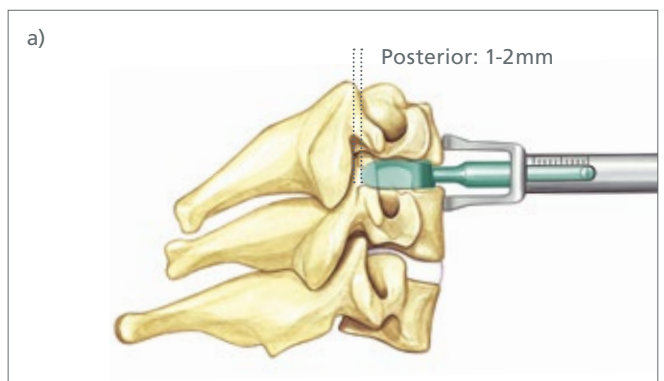
2. Decompression

Microsurgical decompression with complete discectomy is performed relieving all points of neural compression. The discectomy is performed using various rongeurs and curettes. Care must be taken to avoid damaging the vertebral body endplates during preparation of the implant bed. Excessive endplate preparation may compromise the load bearing capacity of the endplates and can lead to a higher risk of subsidence.

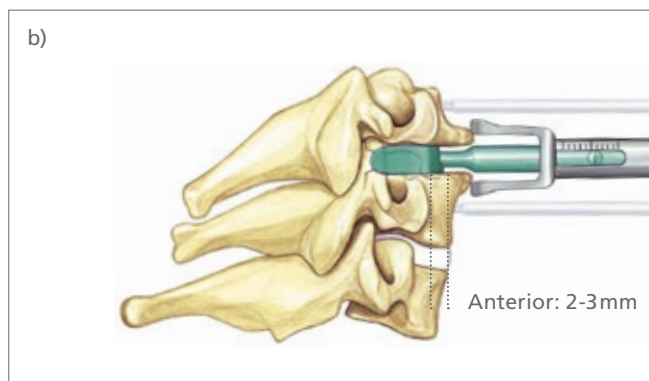


3. Trial Implants

Trial implants are utilized to define the appropriate implant size. The selected trial implant is centered at the midline of the medial-lateral diameter of the vertebral body. Maximum endplate coverage is recommended for optimal stress distribution. Three different heights are available for appropriate height restoration. Note: Segmental distraction should be released when measuring the appropriate implant height. Overdistraction should be avoided and can be controlled fluoroscopically.



By the use of the depth stop, an optimal insertion depth of about 1-2mm inside the posterior (a) and of about 2-3mm inside the anterior border (b) of the original vertebral body contour can be measured. This is verified under radiographic control.



4. Implant Insertion

Filling the cage with autologous bone or bone substitutes is recommended and may aid bone growth. The depth stop of the insertion instrument is adjusted to the depth measured on the trial implant.

The *OptiStrain™ C* cage is carefully introduced along the midline into the disc space under fluoroscopic control.

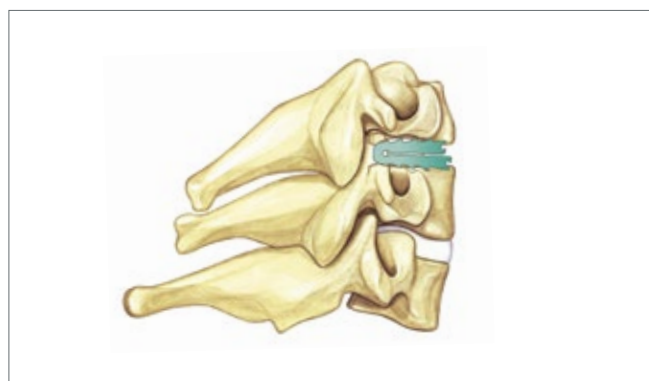
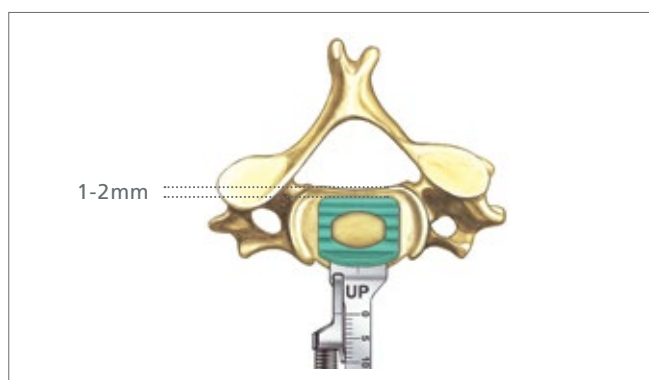
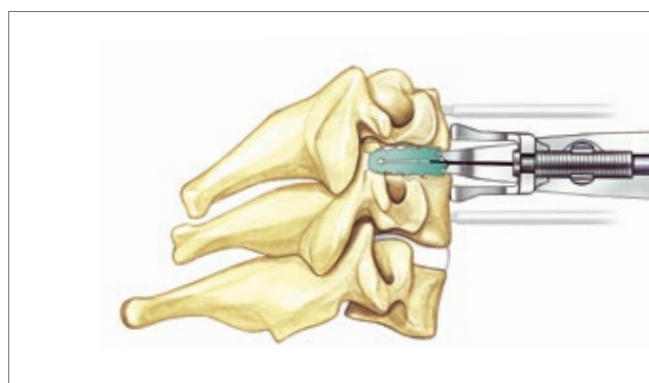
The implant should be positioned far posterior to fit the concavity of the inferior endplate of the superior vertebral body.

Care has to be taken that the posterior edge of the implant has a 1-2mm separation from the dura.

It is important to position the implant 2-3mm inside the anterior border of the original vertebral body contour to provide optimal endplate accommodation and proper teeth engagement for primary stability.

The use of a semi-rigid cervical plate is recommended if indicated.

Final positioning is confirmed fluoroscopically. The wound is closed in the usual manner.



PRODUCT INFORMATION

Sterilization Tray

CAC 00000



Instruments

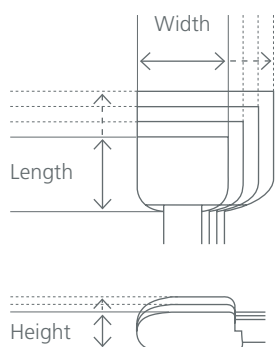


Insertion Instrument CBT20100



Trial Sleeve CBT10001
Turning Knob CBT10002

Trials

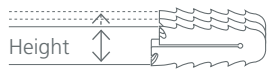
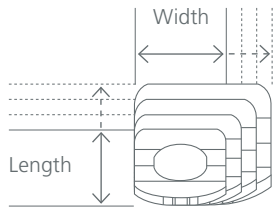


Height	Size M  L: 12 mm W: 14 mm	Size L  L: 14 mm W: 16 mm	Size XL  L: 16 mm W: 18 mm
7 mm	CBT 12147	CBT 14167	CBT 16187
6 mm	CBT 12146	CBT 14166	CBT 16186
5 mm	CBT 12145	CBT 14165	CBT 16185

Hybrid surgeries with *OptiStrain™ C* and *DCI™*

The more segments fused, the higher is the impact on the kinematics in the adjacent segments. Hybrid surgeries performed with rigid and dynamic implants, such as the *DCI™*, can effectively shorten the length of the fusion area. Stress on the adjacent segments can be reduced. The *OptiStrain™ C* cage is implanted with the proven *DCI™* instruments and is an efficient and cost effective option to perform hybrid surgeries with only one set of instruments.

OptiStrain™ C Anterior Cervical Fusion Cage



Height	Size	Size	Size
	M 	L 	XL 
	L: 12 mm W: 14 mm	L: 14 mm W: 16 mm	L: 16 mm W: 18 mm
7 mm	OAI12474	OAI14674	OAI16874
6 mm	OAI12454	OAI14654	OAI16854
5 mm	OAI12434	OAI14634	OAI16834



Material:
Wrought titanium 6-aluminium 4-vanadium alloy
according to ISO 5832-3.

The *OptiStrain™ C* Cage is delivered sterile packed.



PARADIGM SPINE

the movement in spine care

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Product not available in the USA