2-IN-1 CERVICAL PLATE-CAGE
FEAT U R E S  A N D  B E N E F I T S

Scient’x has designed a 2-in-1 titanium system combining a plate and a cage. The PCB allows cervical interbody fusion and disc height restoration by an anterior fixation. Its unique stabilization plate prevents any possibility of posterior impaction or anterior ejection of the cage.

Bibliography


The PCB plate-cage is mainly used for the surgical treatment of:

- cervical hard and soft disc herniations
- cervical degenerative pathologies on one or several levels
- instabilities resulting in degenerative disc disease
- corrections of spine statics disturbances

This implant can be implanted from C2 to C7.

The PCB implant is available in different sizes allowing a perfect adaptation to the patient’s anatomical curvature. Its anatomically designed shape fits perfectly the intervertebral space while minimizing stress upon fixation screws. The PCB helps to restore the disc height and maintains correct spine static. This one piece-implant makes the placement easier and thereby reduces operative time.

### Anatomical shape

- Respect the cervical lordosis
- Minimize stress upon fixation screws
- Cage height ensuring the restoration of the intervertebral space

### Immediate stability

- Stabilization plate preventing the pull-out of the cage

### Multi-level implantation

- Asymmetrical shape of the PCB allowing to combine several plate-cages in multi-segment arthrodesis

### 2-in-1 system

- Easy and fast insertion
- Secured fixation of the spinal segment
Surgical protocol / Patient positioning

1. The procedure is performed under general anesthesia with endotracheal intubation. The patient is positioned in supine position on a standard table. The head is placed in a neutral position or rotated in the opposite direction to the approach. Rotation should be approximately 30° to limit stress on the sterno-cleido-mastoid muscle. The shoulders are lowered and fixed with self-adhesive strips in order to release the inferior cervical spine.

2. The skin incision targets the level of the lesion to be treated. It is marked on the skin after locating the lesion with an image intensifier. It may be horizontal, along a skin fold, extended to the opposite side of the median line in the case of bilateral approach, or beyond according to the number of levels to be treated. The platysma muscle is sectioned on the same plane as the skin, then two upper and lower detachments are created to avoid muscle tension. The aponeurotic planes are sectioned with the finger up to the anterior surface of the spine.

3. The muscles along the neck are separated and rugined to thoroughly release the operating area and allow proper retraction using an autostatic distractor.

4. Under scopic control the proper level is located, then the Caspar distractor pins are positioned in the middle of the vertebral bodies over and under-lying the discal space to be treated and parallel to the endplates.

5. Then the anterior vertebral ligament is incised, down to the lateral unco-vertebral articular processes, before distracting the space. Discectomy is then carefully performed, if necessary with the help of a microscope.
2 Discectomy and preparation of the surgical site

The discectomy starts with the rectangular excision of the anterior part of the annulus fibrosus, using a scalpel. The disc material is resected using curettes and rongeurs. It may prove necessary to use a microscope for resecting the posterior disc material. After full discectomy, resecting the posterior osteophytes and the caudal part of the uncus allows foramen release. Depending on the case, the common posterior vertebral ligament may or may not need to be resected. This essential surgical stage gives direct access to the anterior side of the medulla and nerve roots.

3 Preparing the vertebral endplates

The endplate preparation is performed with a curette. This step must be sufficiently thorough in order to extract all discal debris but not so pronounced as not to collapse the cancellous bone, which would lead to secondary graft collapse. Plate positioning is performed after resecting the anterior osteophytes. This step is necessary to obtain a close contact between the plate and the anterior vertebral body surface. The choice of the plate and its correct positioning are essential steps of the osteosynthesis.

4 Placing PCB trials

A set of PCB trials are used to determine the ideal implant size. The trial is secured to the holder and is impacted into the intervertebral space.
5. Holding the PCB

The cage holder is inserted in the slots on each side of the cylindrical opening on the anterior side of the plate. The internal pin of the holder is screwed into the threaded hole of the plate. The small dimensions of the tool allow to preserve visibility of the operative area while ensuring reliable fixation.

6. Positioning the PCB

The PCB implant is inserted by exerting slight pressure on the holder. The convex part of the cage facilitates cage positioning in the interbody space, fully fitting the shape of the intervertebral chamber. The angle of the PCB upper wing can be adjusted (within 3°), to obtain a close match with the anterior wall of the vertebra above. The selected plate-cage will be placed on the centre line of the cervical spine. The holder can be left in place until the screws are secured.

Note: Scient’x offers a pre-shaped block of bone substitute, perfectly matching the PCB shape. This block of biphasic ceramic (hydroxyapatite/tricalcium phosphate) must be placed before positioning the implant, by simply impacting the block into the cage. Being slightly higher than the cage, it provides high compression of the graft and optimum contact with the adjacent vertebral endplates.

7. Inserting the square awl

The square awl is used to prepare screw insertion into the cortical bone. With its short cutting length, it can only provide a pre-drilled hole. The penetration length is limited by its special shape.
8 Inserting the tap

The tap is used to prepare screw rundown. The tap has a fixed stop limiting the penetration length to 14 mm.

9 Fixing the PCB

The selected screws are positioned using a screwdriver. The conical hexagonal end provides security of the screws during placement. The screws are placed one after the other for final tightening to ensure the stiffness of the PCB-vertebrae assembly. The screw length is selected according to the clinical case and to the fixation mode used: unicortical or bicortical.

10 Impacting the graft into the cage

The upper and lower sides of the cage are widely opened to offer an optimum grafting area. The cage can be filled once the implant is positioned. Autologous grafts and/or bone substitute granules are inserted through the circular hole of the anterior side of the PCB. They are carefully impacted using a graft pusher. The amount of impacted graft must be sufficient to allow optimum contact between the graft and adjacent endplates and thus to facilitate fusion as much as possible.
Closing the approach wound

The approach wound is closed after rinsing. The haemostasis is checked and a suction drain is placed on the anterior face of the spine. The platysma muscle must be carefully restored and the skin closed by intradermic stitches with resorbable thread.

Note: The asymmetrical shape of the PCB allows its use in multi-segment arthrodesis.

Post-operative care

The PCB ensures immediate cervical spine stability however, in some cases, according to the physician’s advice, an external collar or brace can be added for the patient’s comfort.

Implant removal before fusion

If the instrumentation needs to be removed, the cervical approach is used down to the instrumented area. The PCB holder inserted in the cylindrical threaded hole of the plate prevents any movement of the implant during removal. The screws are removed using the hexagonal screwdriver. When both screws are removed, the use of a rugine between the cortical layer and the plate will facilitate extraction.
Instructions for use

OBJECTIVE:
The PCB cervical plate/cage implants are intended for surgical cervical treatments.

GENERAL DESCRIPTION:
Thanks to a one-piece design, the PCB cervical plate/cage consists of an intersegmental cage integrated with a plate of fixation by cervical screws. The cage part of the PCB cervical plate/cage have a convex shape on its superior face and is opened on its anterior, inferior and superior parts. The plate part of the PCB cervical plate/cage is bent in the sagittal plan to follow the cervical lordosis, and is drilled to allow fixation to vertebrae. Both superior and inferior plates are curved in the frontal plan (they are diagonally opposite) allowing the implantation of two PCB cervical plate/cage on two adjacent levels. Several sizes are available to allow a better choice for each individual case. The PCB cervical plate/cage is made of surgical implant applications titanium alloy described by ISO standard 5832-3. This material is not compatible with stainless steel or any other metal. The PCB cervical plate/cage must not be used with components from other manufacturers.

INDICATIONS:
The PCB cervical plate/cage are surgical implants for cervical arthrodesis through anterior approach. They are intersegmental spacing cages associated with fixation plates which main objectives are a radicular decompression by axial neutralisation and a design facilitating interbody fusion. Indications for use include: cervical discal hernia, cervical degenerative lesions of one or several vertebrae, instability resulting from degenerative disk diseases, corrections of spinal static disorders.

CONTRAINDICATIONS:
Contraindications of PCB cervical plate/cage include:
- local infection or inflammation
- spinal osteoporosis
- vertebral tumorous affection
- metal allergy or intolerance
- incompatible patient’s age or physical state
- any case not described in the indications

The PCB cervical plate/cage are not designed, intended or sold for uses other than those indicated.

POSSIBLE ADVERSE EFFECTS:
- infection
- instrumentation intolerance
- screw displacement
- damage of the intervertebral disk at above and/or below the level of surgery

Note: Additional surgery may be necessary to correct some of these adverse reactions

Warnings: A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extraneous circumstances may compromise the results.

OPERATING PRECAUTIONS:
The surgeon is to be thoroughly familiar with the PCB cervical plate/cage, the method of application, the instruments and the operating techniques recommended by Scient’x. The correct choice of the size of the PCB cervical plate/cage is very important: this must be done in relation to the patient’s anatomy. The use of a Caspar type distractor is recommended to open the intervertebral space which will receive the implant. Before implantation of the PCB cervical plate/cage, the vertebral end plates must be carefully scraped to avoid vertebral end plate collapse. The cage must be filled with autologous bone, allogenic bone or a bone substitute to facilitate the bone fusion. After implantation, lot numbers and references of all the components of the implanted PCB cervical plate/cage must systematically be recorded in the surgical file of the patient. Surgical implant must never be re-used. An explanted metal implant should never be re-implanted.

PACKAGING:
Packaged delivered sterilized are conditioned in individual sterile packaging. Packaged implants-delivered non-sterile and their instruments are delivered in one or more containers, one (or more) “kits”, except in the case of non-assorted kits for stocks. Each kit must be closed and sealed. The packaging must be intact upon reception. If the stocked kit system is used, complete kit composition must carefully be checked. The proper state of all implants and instruments must be checked prior to any use. Storage conditions must enable implant, accessories and packaging integrity to be maintained. Damaged products must never be used and must be returned to Scient’x.

DECONTAMINATION, CLEANING AND STERILISATION:

For the implants delivered sterile: the implants are sterilised by Gamma radiation at a dose of 25 to 40 kGy. The expiry period is 5 years. The use-by date of sterile components is indicated on the packaging. It is forbidden to re-sterilise implants delivered sterile.

For the implants and instruments delivered non-sterile: all the implants and instruments are delivered non-sterile and must be decontaminated, cleaned and sterilised before and after use. Decontamination reduces the population of micro-organisms and makes the subsequent cleaning easier. Moreover, sterilisation can only be efficient if the material is clean.

Recommended method:

Decontamination: Soak the implants and the instruments in a bactericidal and fungicidal solution such as didecyldimethylammonium chloride diluted to 0.5% (50 ml per 1 litre of warm water) for 20'. Rinse in demineralised water.

Cleaning: Wash the implants and instruments in a LANCER type washing machine with suitable cleaning products, rinse and dry. Any product, such as bleach or formaldehyde, that is likely to damage the metal is prohibited. It is essential to sterilise the kit by steam using the following conditions:

Sterilisation: We recommend sterilising the implants and instruments in an autoclave:

- pre-heating 25' at 110 °C (1 bar)
- vacuum 5 min (0.8 bar under atmospheric pressure)
- heating 5 min at 120 °C (1 bar)
- vacuum 5 min (0.8 bar)
- sterilisation 18 min at 134 °C (2 bar)
- drying 20' return to room temperature

DISPOSAL:
Products must be disposed of in accordance with the precautions used for surgical wastes, in compliance with the standard NFS94-030 or equivalent national or international standards.

PRODUCT COMPLAINTS:
Any Health Care professional (e.g. a surgeon user of the products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, reliability, safety, effectiveness and/or performance of PCB cervical plate/cage should notify Scient’x or the distributor. In the case of incident or risk of incident which might lead to or might have led to the death of a patient or user or to serious deterioration in his state of health, Scient’x or the distributor should be notified as soon as possible by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name, lot number(s), your name and address, the nature of the complaint with all details and notification of whether a written report is requested.

Additional information / Renseignements / Weitere Angaben / Informações complementares

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Cervical plate-cage length 16mm

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Trial implant for plate-cage

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For 11PCB10  21PCB10F*
For 11PCB20  21PCB20F*
For 11PCB30  21PCB30F*
For 11PCB40  21PCB40F*
For 11PCB50  21PCB50F*

Short cervical plate-cage length 14mm

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Trial implant for short plate-cage

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For 11PCB10C  21PCB10CF*
For 11PCB20C  21PCB20CF*
For 11PCB30C  21PCB30CF*
For 11PCB40C  21PCB40CF*

Cervical screw ø 4mm

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Cervical revision screw ø 4.5mm

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Please read carefully the instructions for use bulletin. Devices may be subject to modification. Patented.