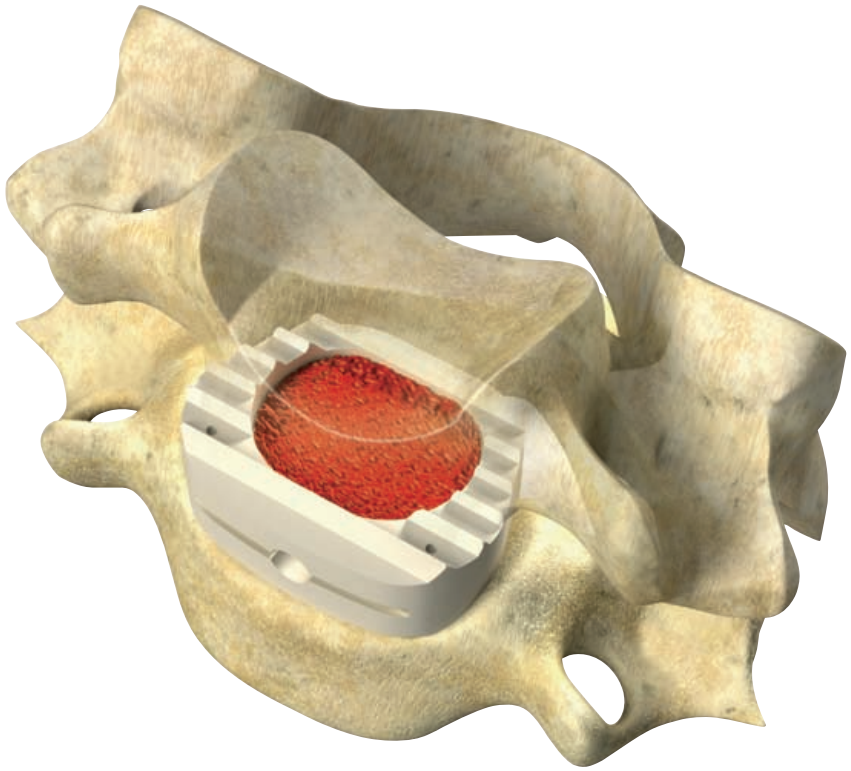
Samarys™

PEEK ANTERIOR ANATOMICAL
CERVICAL CAGE



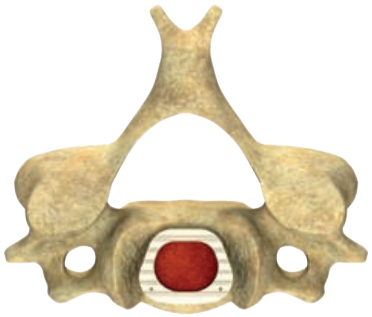
SURGICAL TECHNIQUE GUIDE

Scient'x® Alphatec Spine®
Solutions for the Aging Spine®

Perfect anatomical design for optimum stability

Optimized fusion

Wide open design to optimize graft area and to enhance bone fusion.



Excellent stability

Inferior and superior **teeth** on surface designed to prevent migration.

Original design to maximize contact with the cortical parts of the vertebral endplates for optimum primary stability.

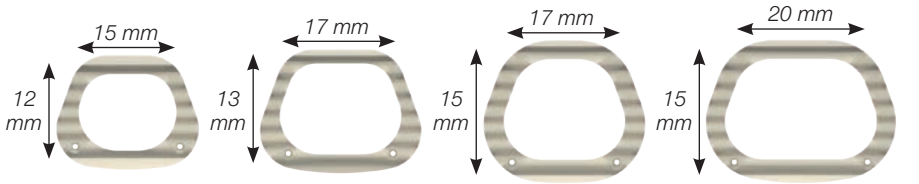
Anatomical shape / Reinforced security

Biconvexity in the frontal and sagittal planes designed to fit to the intersomatic space

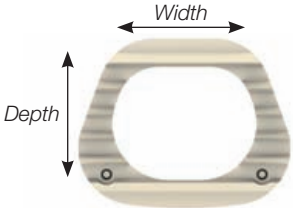
Frontal view

Sagittal view

Various footprints and **heights** designed to adapt to any morphology, restore interbody height and preserve cervical lordosis.



Teeth height: 0.5mm



Large cage to support load distribution and optimal attachment on the cortical bone.

Please refer to the Instructions For Use document enclosed within product packaging prior to use.

Interbody arthrodesis is a secure and efficient technique for the treatment of cervical spine pathologies.
The Samarys™ PEEK anterior anatomical cervical cage fulfills the requirements for this technique.
Its unique design allows for optimum interbody fusion. The anatomical shape and the pure PEEK composition of this implant help to obtain excellent bone fusion. Its broad range of footprints and heights permit to answer the needs of all situations and anatomical variability.

The Samarys™ anterior cervical cage is a surgical implant indicated for cervical arthrodesis via anterior approach, designed to achieve bone fusion from C3 to C7 levels.

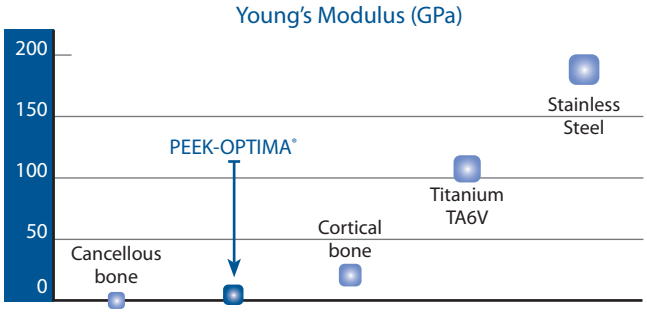
It is an interbody cage whose function is to maintain the discal height and the radicular decompression by interbody distraction. Its design facilitates osteogenesis.

The indications are:

- Stabilization after treatment of a herniated cervical intervertebral disc,
- Osteophytosis compressing the nerve roots and/or spinal cord,
- Degenerative intervertebral instability.

Features and Benefits of PEEK-OPTIMA®

PEEK-OPTIMA® by Invibio is a pure PEEK material designed to meet spine, hip and dental implant requirements.



Safety
- Elasticity designed to prevent subsidence: decreased risk of endplate penetration
- Rupture modulus is lower than metal: decreased risk of bone damage
- Allows for repeated autoclave sterilizations

Medical imaging (X-ray, CT, MRI)
- Radiolucent material to allow fusion follow-up
- Embedded gold markers to facilitate implant placement verification

Biocompatibility
- No carbon fibers: decreased risk of inflammatory reaction
- Long history of implantation (since 1999) and successful use in regulatory approved devices (CE marked and FDA cleared devices)

Enhanced bone fusion
- Load sharing effect
- Optimum load repartition
- Bone growth enhancement due to micromovement

Bibliography:
- Pascal-Mousselard H., Daculsi G., Lazennec JY, Catonné Y, Saillant G., Les cages intervertébrales cervicales: analyse critique de la littérature, Maîtrise Orthopédique n°147 - Oct 2005.
- Pascal-Mousselard h., Anterior Cervical Fusion with PEEK Cages: Clinical Results of a Prospective, Comparative, Multicenter and Randomized Study Comparing Iliac Graft and a Macroporous Biphasic Calcium Phosphate, The Spine Journal, 2006, Volume 6, Issue 5, Pages 136S-136S.

References obtained from congress proceedings:
- Ganem F, Bernard P, Adam Y, Hansen F. Cervical Grafts in Degenerative Disease. Poster session presented at 18th annual meeting Cervical Spine Research Society; 2002 June 13-14; Paris, France.
- Bernard P, Ganem F, Ferreira A. Comparison of a Cervical Fusion Cage with Autologous Bone and with Biphasic Ceramic Bone Substitute. Proceeding 2003 June 19-20; Barcelona, Spain.
- Pascal-Mousselard H, Aguado E, Catonné Y, Rouvillain J.L, Daculsi G., Evaluation of an intervertebral cervical cage filled wth injectable bone substitute. Proceedings of the SpineWeek International Annual Congress. Processing 2004 May 30 - June 5; Porto, Portugal.

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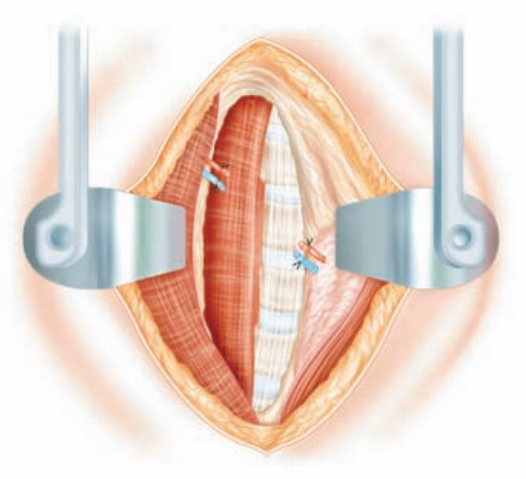
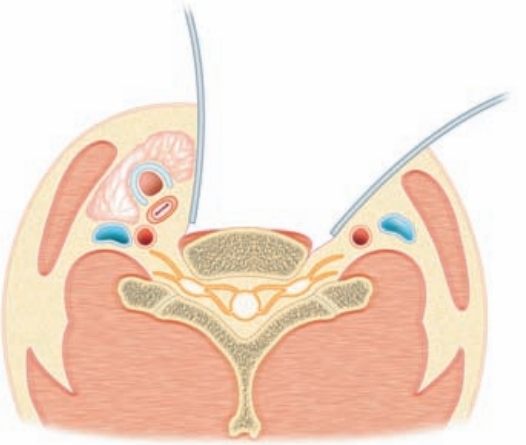
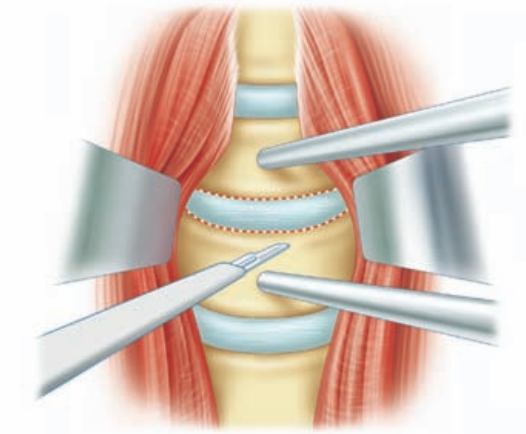






Surgical protocol/patient positioning

The procedure is performed under general anesthesia with endotracheal intubation.
The patient is positioned in the 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.

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 if it is well located. It may also be vertical along the sterno-cleido-mastoid for more than two levels.

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

Under scopic control, the correct level is located.
The use of a Caspar distractor might be useful:
first the cervical distraction pins are positioned using the screwdriver for distraction pin.
They should be inserted in the middle of the vertebral bodies' over- and under-lying the discal space to be treated and parallel to the endplates.
All the threads of the pins should be engaged in the vertebral bodies. After removing the screwdriver, the cervical distractor can be slid onto the distraction pins until it reaches the base of the pins (closest to the vertebral body).
Then the anterior vertebral ligament is incised down to the lateral unco-vertebral articular processes before distracting the space.

Note: In case of further utilization of the trial/cage holder with stopper, in a shallow intervertebral space, do not forget to position the cervical distraction pins as to let enough space for further holder with stopper introduction.

Discectomy and preparation of the surgical site

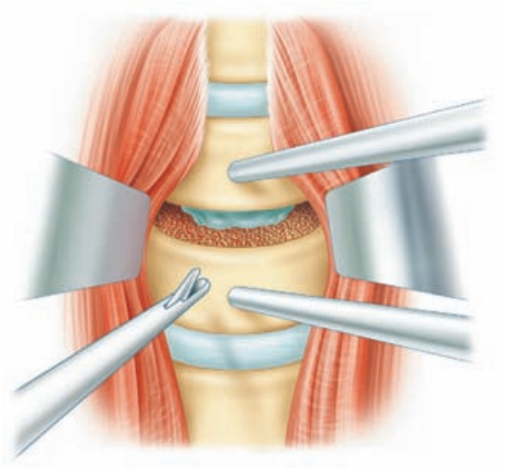
The discectomy starts with the rectangular excision of the anterior part of the annulus fibrosus using a scalpel.

Distraction pin Ø 3.5 mm
21FCD35-xx

Screwdriver for distraction pin
21TRV03

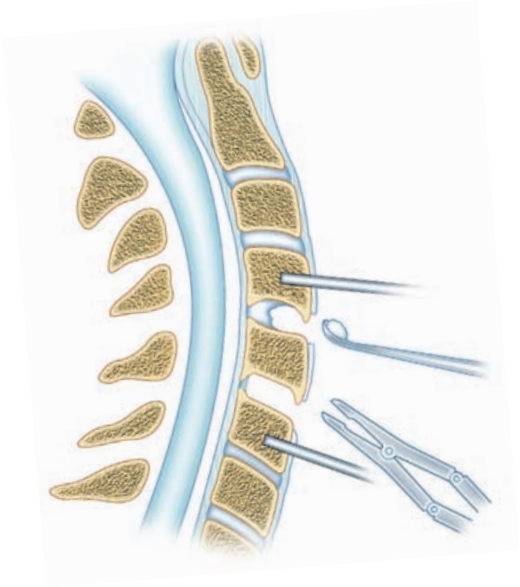
Distractor
21DST02

The disc material is resected using curettes and rongeurs. After full discectomy, resection of the posterior osteophytes and the posterior part of the uncus may provide foramen release. For disc herniations, it may be useful to open the posterior longitudinal ligament to ensure all disc material has been removed. It may prove necessary to use a microscope for resecting the posterior disc material.



Preparing the vertebral endplates

The vertebral plates should be prepared and cleaned carefully with a curette. A damaged surface may cause subsidence of the cage in the vertebral body.
This procedure is essential to ensure optimum contact between the implant and adjacent vertebral endplates and to avoid secondary migration. The removal of the subchondral parts also improves the bone ingrowth through the graft. In order to help you in this disc removal step, a **cervical rasp** (height: 4,5mm) reproducing the shape of the Samarys cage is also included in the Samarys set.



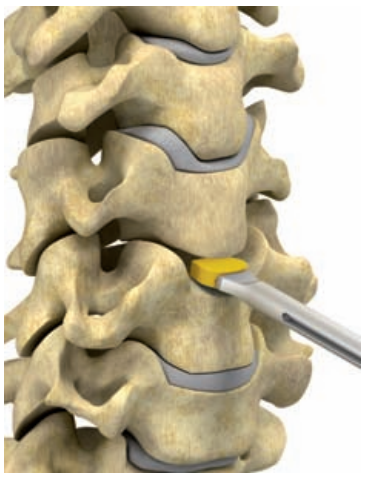
Option: Several cervical rasps are also available upon request in 6 additional heights (ranging from 5 to 10mm). The rasps should be selected according to the intervertebral height and carefully inserted until resistance is felt.

Note: It is important to use these instruments with caution so as not to excessively rasp the endplates and to insert the instrument too posteriorly.

The following steps describe the surgical technique without the distractor.

Insertion of the trial implants

A set of **trial implants** are used to determine the ideal implant size. Trial implants are color coded according to the footprints, facilitating the identification of the corresponding cage. The heights can be checked by the laser-marking. They range from 4.5mm to 10mm.



Trial implant
21CC2A-15-xxF
21CC2AC-17-xxF
21CC2A-17-xxF
21CC2A-20-xxF

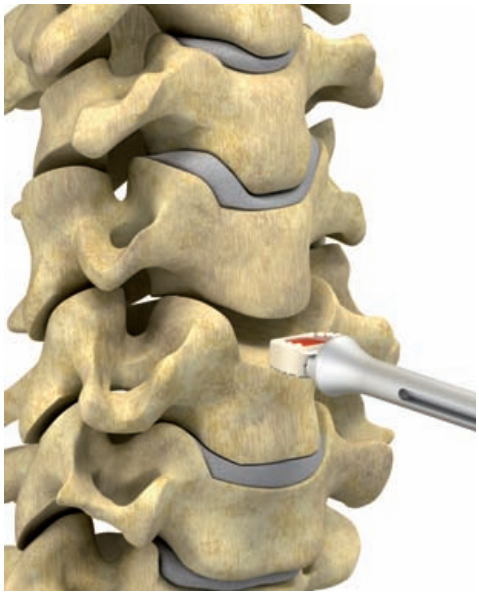
The trial is secured onto the **cage holder** by tightening the inner part of the instrument into the central hole of the trial. A horizontal groove improves the stability during impaction. It is then impacted into the intervertebral space. Having no retaining edges, the trial can be easily removed.

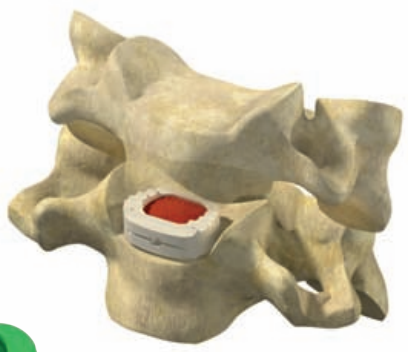
Note: To determine the size of the most suitable cage, it is recommended to first insert the smallest trial implant, and sequentially select the next bigger one till the proper size is achieved. It is recommended to use the biggest implant possible considering patient anatomy. Choice of the adequate size is then left to the surgeon's discretion. The height to be restored can be determined according to the adjacent disc heights or the facet parallelism at the index level.

Note: If caspar distraction is used, it is mandatory to release distraction after insertion of the trial.

Cage holder
21ICC2A01

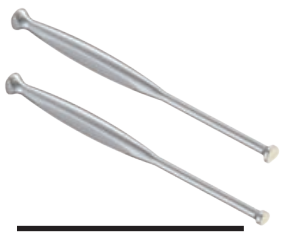
Cervical Rasp
21RAP01-xx





Socket
21SOC02

Cage holder with stopper
21ICC2A03



Graft pusher
21COM03
21COM07

Graft filling

Bone graft material (autologous, bone substitute…) has to be compacted into the implant. To help this compaction, the cage should be positioned on the cage **socket**.

The upper and lower faces of the cage have wide openings to offer optimum graft volume and contact area. A **graft pusher** matching the internal cavity shape of the cage is used to compact the graft (two different graft pushers are available and have to be chosen according to the footprint of the selected cage).

Cage insertion

After filling, the cage is carefully secured onto the **cage holder** or onto the **cage holder with stopper**.
To hold the cage, the inner part of the holder is fixed into the front hole of the cage (same maneuver as for the trial. Be careful to not too excessively tighten the holder onto the cage as to preserve the thread and PEEK cage integrity). Double check the cage orientation (sagittal curvature at the top). To help, the cage also features a triangle marking (Δ) on its lateral face that allows to identify the top of the cage. The holder has small dimensions that prevent visual obstruction of the implant.

The cage should be carefully impacted with the distractor slightly distracted in order to allow for introduction of the cage while preventing the risk to impact it too posteriorly. When using the cage holder with the stopper, the circular stop at the extremity of the instrument prevents the cage from moving too far posteriorly. The anterior edge of the cage stops at 1.5mm from the anterior wall of the vertebrae. Caution: The cages from 8mm have a height superior to that of the stopper; hence the stop is not functional for cages with a height of 8mm and higher. Although the cage holder features a stopper, it is advisable to insert the cage with caution and vigilance. Introducing the cage under C-arm control can be helpful in this respect.

The holder is removed after implanting the cage by releasing its inner part.

Note: The Samarys cervical cage ensures immediate post-operative stability of the spine but, in some cases, internal fixation, cervical plate,... or external collar brace, can be added at the surgeon's discretion.

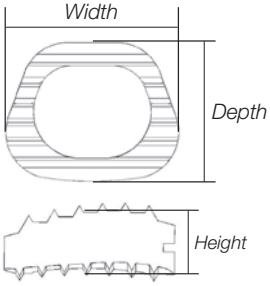
Closing the approach wound

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

Removing the implant (optional)

If the instrumentation must be removed, before fusion, the cervical approach is used, down to the instrumented area. Bone bridges between the implant and the vertebral bodies must be sectioned. The **cage holder** is placed onto the cage to facilitate implant removal.

Implants



Teeth height: 0.5 mm

PEEK Anterior Anatomical Cervical Cage

Height (mm)	Depth 12 mm Width 15 mm	Depth 13 mm Width 17 mm	Depth 15 mm Width 17 mm	Depth 15 mm Width 20 mm
	Ref.	Ref.	Ref.	Ref.
4.5	11CC2A15-45S*	11CC2AC17-45S*	11CC2A17-45S*	11CC2A20-45S*
5	11CC2A15-5S	11CC2AC17-5S	11CC2A17-5S	11CC2A20-5S*
6	11CC2A15-6S	11CC2AC17-6S	11CC2A17-6S	11CC2A20-6S*
7	11CC2A15-7S*	11CC2AC17-7S*	11CC2A17-7S	11CC2A20-7S*
8	11CC2A15-8S*	11CC2AC17-8S*	11CC2A17-8S*	11CC2A20-8S*
9	11CC2A15-9S*	11CC2AC17-9S*	11CC2A17-9S*	11CC2A20-9S*
10	11CC2A15-10S*	11CC2AC17-10S*	11CC2A17-10S*	11CC2A20-10S*

The implants are delivered sterile.

Instruments

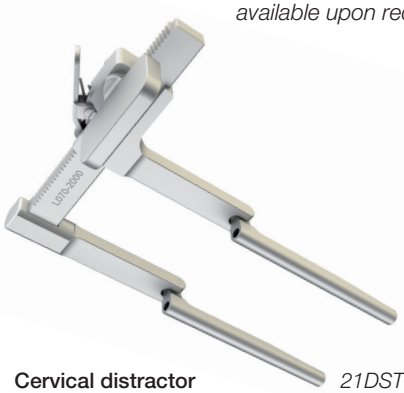
Trial implants for:

	Color code	Ref.
11CC2A15-xx	Gold	21CC2A15-xxF
11CC2AC17-xx	Silver	21CC2AC17-xxF
11CC2A17-xx	Green	21CC2A17-xxF
11CC2A20-xx	Fuschia	21CC2A20-xxF

NOTE: *Trials corresponding to implants size on request, are also available upon request. Delivery time to be confirmed with order.*

Cervical distraction pin Ø 3.5 mm
21FCD35-xx

Length (mm)	Ref.
12	21FCD35-12*
14	21FCD35-14
16	21FCD35-16



Cervical distractor *21DST02*

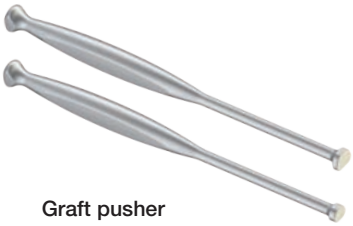
Screwdriver for distraction pin *21TRV03*

21RAP01-5 *21RAP01-8*
21RAP01-6 *21RAP01-9*
21RAP01-7 *21RAP01-10**
21RAP01-45

Cervical Rasp

Cage holder *21ICC2A01*

Cage holder with stopper *21ICC2A03*



Graft pusher *21COM03* *21COM07*

Socket *21SOC02*

*Upon request. Delivery time to be confirmed with order.

Please refer to the Instructions For Use document enclosed within product packaging prior to use.

INSTRUCTIONS

SAMARYS anterior cervical cage

AIMS:

The **SAMARYS anterior cervical cage** is an implant intended for the surgical treatment of the cervical vertebrae.

GENERAL DESCRIPTION:

The **SAMARYS anterior cervical cage** has been designed for stabilisation and arthrodesis between the cervical vertebrae.
The **SAMARYS anterior cervical cage** is convex in shape on its upper face and has openings on the upper and bottom faces.
It comes in several heights to adapt to the variable morphology of the intervertebral spaces.
The **SAMARYS anterior cervical cage** is made of implantable PEEK and includes radiopaque markers made of 99.99% pure gold.
The **SAMARYS anterior cervical cage** must not be used with components coming from other manufacturers.

INDICATIONS:

The **SAMARYS anterior cervical cage** is a surgical implant for cervical arthrodesis by anterior approach, designed to optimize bone fusion from C3 to C7 levels. It is an intersomatic cage whose main function is to maintain the discal height and the radicular decompression by intersomatic distraction. Its design is favouring osteogenesis. The indications are:

- stabilisation after treatment of a herniated cervical intervertebral disc or osteophytosis compressing the nerve roots and/or spinal cord,
- degenerative intervertebral instability.

CONTRA-INDICATIONS:

The contra-indications for the **SAMARYS anterior cervical cage** include:

- local infection or inflammation,
- vertebral osteoporosis,
- malignant vertebral disease,
- allergy or intolerance to PEEK,
- incompatible patient age and physical condition,
- all cases not included in the indications.

The **SAMARYS anterior cervical cage** has not been designed, intended or sold for uses other than those indicated.

POSSIBLE ADVERSE EFFECTS:

- infection,
- pain,
- pseudarthrosis,
- adjacent segment disease,
- post-operative migration of the implant ,
- damage to the vertebrae adjacent to the arthrodesis,
- intolerance to the material.

Note: An additional surgical operation may be needed to correct any adverse event.
Warnings: An entirely satisfactory result is not always obtained at each and every operation. This is particularly true in spinal surgery where many external factors can compromise the results.

OPERATING PRECAUTIONS:

The surgeon must be thoroughly familiar with the **SAMARYS anterior cervical cage**, the method of application, the instruments and the operating technique.
The size of the **SAMARYS anterior cervical cage** must be chosen in relation to the individual clinical case and the desired correction.
It is recommended to use a Caspar type distractor to open the intervertebral space intended for implanting the cage.
Before implanting the **SAMARYS anterior cervical cage**, a careful curetage of vertebral endplates must be conducted to expose healthy tissue but without weakening them to prevent the cage from subsidence.
The **SAMARYS anterior cervical cage** must be filled with autologous or allogenic bone or with a bone substitute to obtain bone fusion.
The correct positioning of the cage with respect to the vertebrae is confirmed by radiographic control during surgery.
After implantation, the **batch number** and the **reference of the implanted SAMARYS anterior cervical cage** must **always** be recorded in the patient's surgical records.
This product is a single use device. Under no circumstances should it be reused. While the device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that the removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for products which have been reused.
Caution: no silicone, formaldehyde or latex based products should be implanted with a SCIENT'X implant.
Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that a regular postoperative follow-up is undertaken to detect early signs of failure of the implants and to consider the action to be taken. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implant. A suitable rehabilitation program must be designed and implemented.

PACKAGING:

The storage conditions must enable implants, the associated instruments and their respective packages integrity to be maintained.
The good condition of the implants and the functionality of the instruments must be checked before use. Do not expose the SAMARYS implants to radiations or extreme temperature. Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases. Damaged products must never be used and must be returned to SCIENT'X. Do not implant the cage if the primary and/or the secondary package of the sterile conditioning are pierced or deteriorated.

DECONTAMINATION, CLEANING AND STERILIZATION:

Products delivered in sachets are not sterile.

For implants delivered sterile: the implants are sterilized by Gamma radiation at doses of 25 to 40 kGy. The expiry date is 5 years. The expiry date of sterile parts is indicated on the packaging.
For implants and instruments not sterile on delivery: all implants and instruments delivered non-sterile must be **decontaminated, cleaned and sterilized** before and after use. Implants and instruments in sachets must be removed from the original packaging for the following operations:

Recommended method:

- **Decontamination**: Plunge the implants and instruments into a bactericidal and fungicidal solution (didecyl ammonium chloride with proteolytic enzymes diluted to 0.5 % (5g for 1 litre of mild water). Deep length: 30 min. Rinse with demineralized water.
- **Cleaning:** Wash the implants and instruments in a LANCER type machine with suitable cleaning products, rinse and dry. Any product that might damage the equipment is forbidden (such as bleach, formol, etc.). Lubricate all hinge and mechanism on instruments with paraffin oil (type Neodisher IP spray).
- **Sterilization**: It is essential to sterilise the kit by steam using the following conditions:
  - pre-heating for 25' at 110° (1 bar)
  - vacuum 5' (0.8 bar under atmospheric pressure)
  - heating 5' at 120° (1 bar)
  - vacuum 5' (0.8 bar)
  - sterilization 18' at 134° (2 bars)
  - drying 20' return to room temperature

COMPLAINTS:

Any complaints, together with the reference and lot number of the incriminated product, must be sent to SCIENT'X.

ADDITIONAL INFORMATION:

For further information, contact the manufacturer:

SCIENT'X
22, rue Jean Bart
78960 Voisins le Bretonneux - FRANCE
tel.: 33 (0)1 39 30 69 30
fax: 33 (0)1 30 43 82 77
e-mail: qualite@scientx.com

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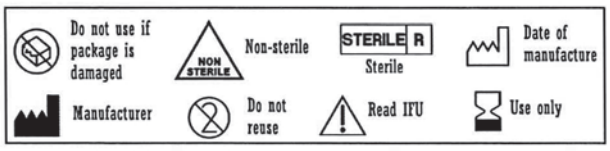
Last revision: 06/2010



Only for information.
Subject to modification without notification.
For updated IFU, please contact your local customer service.

NOTICE D'INSTRUCTIONS

Cage cervicale antérieure SAMARYS

OBJECTIF:

La **cage cervicale antérieure SAMARYS** est un implant destiné aux traitements chirurgicaux du rachis cervical.

DESCRIPTION GENERALE:

La **cage cervicale antérieure SAMARYS** a été conçue pour permettre la stabilisation et l'arthrodèse intersomatique cervicale.
La **cage cervicale antérieure SAMARYS** présente une forme convexe sur sa face supérieure et des ouvertures sur les faces supérieures et inférieures.
Plusieurs hauteurs sont proposées pour s'adapter aux différentes morphologies d'espaces inter-somatiques.
La **cage cervicale antérieure SAMARYS** est fabriquée en PEEK implantable et possède des marqueurs radiologiques en or pur à 99,99%.
La **cage cervicale antérieure SAMARYS** ne doit pas être utilisée avec des composants provenant d'autres fabricants.

INDICATIONS:

La **cage cervicale antérieure SAMARYS** est un implant chirurgical pour l'arthrodèse cervicale par voie antérieure, conçue pour optimiser la fusion osseuse des niveaux C3 à C7. C'est une cage intersomatique dont les principaux objectifs sont de maintenir une hauteur discale et la décompression radiculaire effectuée lors de la chirurgie. Sa conception favorise l'ostéogenèse. Les indications sont:

- stabilisation après traitement de hernie discale cervicale ou d'ostéophytose compressives sur les racines nerveuses et/ou sur la moelle.
- instabilité intervertébrale dégénérative.

CONTRE-INDICATIONS:

Les contre-indications de la **cage cervicale antérieure SAMARYS** comprennent:

- infection ou inflammation locale,
- ostéoporose vertébrale,
- affection vertébrale maligne,
- allergie ou intolérance au PEEK,
- âge et état physique du patient incompatibles,
- tout cas non compris dans les indications.

La **cage cervicale antérieure SAMARYS** n'est pas conçue, destinée ou vendue pour des utilisations autres que celles indiquées.

EFFETS SECONDAIRES POSSIBLES:

- infection,
- douleurs,
- pseudarthrose,
- pathologies des segments adjacents,
- migration post-opératoire de l'implant,
- atteintes des étages vertébraux adjacents à l'arthrodèse,
- intolérance au matériel.

Note: Une intervention chirurgicale supplémentaire peut être nécessaire pour corriger un effet secondaire.
Avertissements: Un résultat entièrement satisfaisant n'est pas systématiquement obtenu à chaque opération chirurgicale. Cela est particulièrement vrai en chirurgie du rachis où de nombreux éléments extérieurs peuvent compromettre les résultats.

PRECAUTIONS OPERATOIRES:

Le chirurgien doit être parfaitement familiarisé avec la **cage cervicale antérieure SAMARYS**, la méthode d'application, les instruments et la technique opératoire.
La taille de la **cage cervicale antérieure SAMARYS** doit être choisie en fonction du cas clinique et de la correction désirée.
Il est recommandé d'utiliser un distracteur de type Caspar pour ouvrir l'espace intervertébral destiné à recevoir la cage.
Avant implantation de la **cage cervicale antérieure SAMARYS**, les plateaux vertébraux doivent être curetés soigneusement et avivés sans être fragilisés pour éviter les risques d'enfoncement de la cage.
La **cage cervicale antérieure SAMARYS** doit être remplie d'os autologue, allogénique ou d'un substitut osseux pour obtenir la fusion osseuse.
Un contrôle radiographique durant la chirurgie permet de constater le bon positionnement de la cage par rapport aux vertèbres.
Après implantation, le **numéro de lot** et la **référence de la cage cervicale antérieure SAMARYS** implantée doivent **systématiquement** être enregistrés dans le dossier chirurgical du patient.
Ce produit est à usage unique. Il ne doit en aucun cas être réutilisé. Bien que le dispositif puisse paraitre en parfait état, il peut présenter de petits défauts ou des contraintes résiduelles résultant d'une utilisation antérieure et pouvant mener à une rupture en fatigue. De plus, veuillez noter que la décontamination des dispositifs réutilisés n'est pas validée et que les dispositifs n'ont pas été conçus en ce sens. La réutilisation d'un tel produit pourrait mener à une contamination croisée et/ou à une dégradation du matériel résultant du procédé de décontamination. Le Fabricant n'accepte aucune responsabilité concernant les produits réutilisés.
Attention : aucun produit à base de silicone, de formaldéhyde ou de latex ne doit être implanté avec un implant SCIENT'X.
Les patients doivent être informés des précautions à prendre dans leur vie quotidienne afin de garantir la durée de vie maximale des implants. Il est recommandé d'effectuer un **contrôle postopératoire** régulier qui permet de mettre en évidence des signes précoces de faillite du matériel et considérer les actions à prendre. La déterioration du dispositif après consolidation osseuse ne peut être considérée comme un dysfonctionnement ou une altération des caractéristiques du matériel. Un programme de rééducation adapté doit être établi et mis en œuvre.

EMBALLAGE:

Les conditions de stockage doivent permettre de maintenir l'intégrité des implants, des ancillaires associés et de leurs emballages respectifs. Le bon état de tous les implants et la fonctionnalité des instruments doit être contrôlé avant toute utilisation. Ne pas exposer les implants SAMARYS à des rayonnements ou à des températures extrêmes. Le non-respect de ces prescriptions peut provoquer une baisse des caractéristiques mécaniques pouvant conduire, dans certains cas, à leur rupture. Les produits endommagés ne doivent pas être utilisés et doivent être retournés à SCIENT'X. Ne pas implanter la cage si le sachet primaire et/ou le sachet secondaire du conditionnement stérile sont percés ou détériorés.

DECONTAMINATION, NETTOYAGE ET STERILISATION:

Les produits livrés en sachets ne sont pas stériles.

Pour les implants livrés stériles : les implants sont stérilisés par rayonnement Gamma à la dose de 25 à 40 kGy. Le délai de péremption est de 5 ans. La date limite d'utilisation des éléments stériles est indiquée sur l'emballage.
Pour les implants et instruments livrés non stériles : tous les implants et instruments livrés non stériles doivent êtres **décontaminés, nettoyés et stérilisés** avant et après utilisation (pour les instruments uniquement). Les implants et les instruments en sachet doivent être sortis de leur emballage d'origine pour les opérations suivantes :

Méthode conseillée :

- **Décontamination** : Plonger les implants et les instruments dans une solution bactéricide et fongicide de type chlorure didécyl ammonium associée à des enzymes protéolytiques, diluée à 0,5 % (5g pour 1 litre d'eau tiède). Durée du trempage: 30 min. Rincer à l'eau déminéralisée.
- **Nettoyage** : Laver les implants et les instruments en machine de type LANCER avec des produits de nettoyage adaptés, rincer, sécher. Tout produit susceptible d'altérer le matériel est à proscrire (eau de javel, formol…). Lubrifier les articulations et mécanismes des instruments à l'aide d'une huile de paraffine type Neodisher IP Spray.
- **Stérilisation** : Nous recommandons le mode de stérilisation en autoclave pour les implants et les instruments :
  - préchauffage 25 min à 110°C (1 bar)
  - vide 5 min (0,8 bar sous pression atmosphérique)
  - chauffage 5' à 120°C (1 bar)
  - vide 5 min (0,8 bar)
  - stérilisation 18 min à 134°C (2 bars)
  - séchage 20 min retour à l'ambiante

RECLAMATIONS:

Toute réclamation, accompagnée de la référence et du numéro de lot du produit incriminé, doit être transmise à la société SCIENT'X.

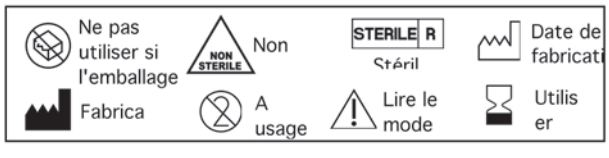
INFORMATIONS COMPLEMENTAIRES:

Pour toute information complémentaire, contactez le fabricant :

SCIENT'X
22, Avenue Jean Bart
78960 Voisins le Bretonneux- France
tél: +33 (0)1 39 30 69 37
fax: +33 (0)1 30 43 86 81
e-mail : qualite@scientx.com

Date de modification : 06/2010

CE 0459 2001



A titre d'information.
Sujet à modification.
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MANUAL DE INSTRUCCIONES
Caja cervical anterior SAMARYS

OBJETIVO:

La **caja cervical anterior SAMARYS** es un implante destinado a los tratamientos quirúrgicos del raquis cervical.

DESCRIPCIÓN GENERAL:

La **caja cervical anterior SAMARYS** ha sido diseñada para permitir la estabilización y la artrodesis intersomática cervical.
La **caja cervical anterior SAMARYS** tiene una forma convexa en su cara superior y unas aberturas en las caras superiores e inferiores.
Se ofrecen varias alturas para adaptarse a las diferentes morfologías de espacios intersomáticos.
La **caja cervical anterior SAMARYS** está fabricada en PEEK implantable y posee indicadores radiológicos de oro puro al 99,99%.
La **caja cervical anterior SAMARYS** no debe utilizarse con componentes que provengan de otros fabricantes.

INDICACIONES:

La **caja cervical anterior SAMARYS** es un implante quirúrgico para la artrodesis cervical por vía anterior, diseñada para optimizar la fusión ósea de los niveles C3 a C7. Es una caja intersomática cuyos objetivos principales son mantener una altura discal y la descompresión radicular efectuada durante la cirugía. Su diseño favorece la osteogénesis. Las indicaciones son:

- estabilización tras el tratamiento de hernia discal cervical o de osteofitosis, compresiva en las raíces nerviosas y/o en la médula.
- inestabilidad intervertebral degenerativa.

CONTRAINDICACIONES:

Las contraindicaciones de la **caja cervical anterior SAMARYS** incluyen:

- infección o inflamación local,
- osteoporosis vertebral,
- afección vertebral maligna,
- alergia o intolerancia al PEEK,
- edad y estado físico del paciente incompatibles,
- cualquier otro caso no incluido en las indicaciones.

La **caja cervical anterior SAMARYS** no ha sido diseñada ni está destinada o vendida para usos diferentes a los indicados..

POSIBLES EFECTOS SECUNDARIOS:

- infección,
- dolores,
- pseudoartrosis,
- patologías de los segmentos adyacentes,
- migración postoperatoria del implante,
- daños en los niveles vertebrales adyacentes a la artrodesis,
- intolerancia al material.

Nota: Una intervención quirúrgica adicional puede resultar necesaria para corregir un efecto secundario.
Advertencias: No se puede conseguir sistemáticamente un resultado totalmente satisfactorio en cada operación quirúrgica. Esto es especialmente cierto en los casos de cirugía del raquis, en los que numerosos elementos externos pueden comprometer los resultados.

PRECAUCIONES OPERATORIAS:

El cirujano debe estar perfectamente familiarizado con la **caja cervical anterior SAMARYS**, el método de aplicación, los instrumentos y la técnica operatoria.
El tamaño de la **caja cervical anterior SAMARYS** debe elegirse en función del caso clínico y de la corrección deseada.
Se recomienda utilizar un distractor tipo Caspar para abrir el espacio intervertebral destinado a recibir la caja.
Antes de la implantación de la **caja cervical anterior SAMARYS**, las placas vertebrales deben ser cuidadosamente raspadas y pulidas sin que se vuelvan frágiles a fin de evitar los riesgos de hundimiento de la caja.
La **caja cervical anterior SAMARYS** debe estar llena de hueso autólogo, alogénico, o de un sustituto óseo para obtener la fusión ósea.
Un control radiográfico durante la cirugía permite comprobar el posicionamiento correcto de la caja respecto a las vértebras.
Tras su implantación, el **número de lote** y la **referencia de la caja cervical anterior SAMARYS** implantada deben **sistemáticamente** ser registrados en el expediente quirúrgico del paciente.
Este producto es de un solo uso. No debe en ningún caso ser reutilizado. Aunque pueda parecer que el dispositivo está en perfecto estado, puede tener pequeños defectos o tensiones residuales debido a un uso anterior y pueden provocar una ruptura por fatiga. Además, sírvase constatar que la descontaminación de los dispositivos reutilizados no está validada y que los dispositivos no han sido diseñados en ese sentido. La reutilización de un producto como este podría provocar una contaminación cruzada y/o una degradación del material como consecuencia del procedimiento de descontaminación. El Fabricante no asumirá ninguna responsabilidad relacionada con los productos reutilizados.
Atención: No se debe implantar con un implante SCIENT'X ningún producto a base de silicona, formaldehído o látex.
Los pacientes deben ser informados de las precauciones que han de tomar en su vida cotidiana para garantizar la máxima vida útil de los implantes. Se recomienda realizar un control **postoperatorio** periódico para poder evidenciar signos precoces de fallo del material. El deterioro del dispositivo tras la consolidación ósea no puede ser considerado como un problema de funcionamiento o alteración de las características del material. Se debe establecer y poner en práctica un programa de reeducación.

EMBALAJE:

Las condiciones de almacenamiento deben permitir mantener la integridad de los implantes, del instrumental asociado y de sus respectivos embalajes. Se debe controlar siempre el buen estado de todos los implantes y la funcionalidad de los instrumentos antes de su utilización. No exponer los implantes SAMARYS a radiaciones ni a temperaturas extremas. El incumplimiento de estas prescripciones puede provocar una caída de los valores de las características mecánicas que, en ciertos casos, puede conducir a su ruptura. Los productos dañados no deben ser utilizados y deben ser devueltos a SCIENT'X. No implantar la caja si la bolsa primaria y/o la bolsa secundaria del embalaje estéril están perforadas o deterioradas.

DESCONTAMINACIÓN, LIMPIEZA Y ESTERILIZACIÓN:

Los productos suministrados en bolsas no son estériles.

Para los implantes suministrados estériles: los implantes han sido esterilizados por radiación Gamma en dosis de 25 a 40 kGy. El plazo de caducidad es de 5 años. La fecha límite de utilización de los elementos estériles viene indicada en el embalaje.
Para los implantes e instrumentos suministrados no estériles: todos los implantes e instrumentos suministrados no estériles deben ser sometidos a **descontaminación, limpieza y esterilización** antes y después de su utilización. Los instrumentos en bolsa deben sacarse de su embalaje original para las siguientes operaciones:

Método aconsejado:

- **Descontaminación:** Sumergir los implantes y los instrumentos dentro de una solución bactericida y fungicida tipo cloruro de didecyldimethylammonium diluida al 0,5% (5mL por 1 litro de agua templada). Duración de la inmersión: 20 min. Enjuagar con agua desmineralizada.
- **Limpieza:** Lavar los implantes y los instrumentos a máquina del tipo LANCER con productos de limpieza adecuados, enjuagar y secar. Se debe excluir cualquier producto susceptible de alterar el material (lejía, formol...). Lubrificar las articulaciones y mecanismos de los instrumentos con la ayuda de un aceite de parafina tipo Neodisher IP Spray.
- **Esterilización:** Recomendamos el modo de esterilización en autoclave para los implantes y los instrumentos :
  - precalentamiento 25' a 110º (1 bar)
  - vacío 5' (0,8 bar bajo presión atmosférica)
  - calentamiento 5' a 120º (1 bar)
  - vacío 5' (0,8 bar)
  - esterilización 18' a 134º (2 bar)
  - secado 20' vuelta a la temperatura ambiente

RECLAMACIONES:

Toda reclamación, acompañada de la referencia y del número de lote del producto incriminado, deberá ser transmitida a la sociedad Scient'x.

INFORMACIÓN COMPLEMENTARIA:

Para cualquier información complementaria, póngase en contacto con:

SCIENT'X
22, Rue Jean Bart
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fax: +33 (0)1 30 43 86 81
e-mail : qualite@scientx.com

Fecha de modificación: 11/2010 CE 0459 2001

Para información soló
Puede ser modificado sin notificación
Para instrucciones de uso actualizados, contactad el atención al cliente local

ISTRUZIONI PER L'USO
Gabbia cervicale anteriore SAMARYS

UTILIZZO

La **gabbia cervicale anteriore SAMARYS** è stata messa a punto per il trattamento chirurgico del rachide cervicale.

DESCRIZIONE GENERALE

La **gabbia cervicale anteriore SAMARYS** è stata sviluppata per permettere la stabilizzazione e l'artrodesi intersomatica cervicale.
La **gabbia cervicale anteriore SAMARYS** ha forma convessa sul lato superiore ed è provvista di ampie aperture sul lato superiore e inferiore.
L'impianto è proposto in varie dimensioni per adattarsi alle diverse morfologie degli spazi intersomatici.
La **gabbia cervicale anteriore SAMARYS** è prodotta in PEEK impiantabile ed è dotata reperi in oro puro al 99,99%.
La **gabbia cervicale anteriore SAMARYS** non deve essere utilizzata con componenti di altri produttori.

INDICAZIONI

La **gabbia cervicale anteriore SAMARYS** è un impianto chirurgico concepito per l'artrodesi cervicale tramite approccio anteriore, sviluppato per l'ottimizzazione della fusione ossea dei livelli da C3 a C7. L'obiettivo principale della gabbia consiste nel mantenere l'altezza discale e la decompressione radicolare ottenuta con l'atto chirurgico. Il design favorisce l'osteogensi. Le indicazioni sono:

- Stabilizzazione dopo intervento di ernia discale cervicale o osteofitosi con compressione a carico delle radici dei nervi e/o del midollo.
- Instabilità vertebrale degenerativa.

CONTROINDICAZIONI

La **gabbia cervicale anteriore SAMARYS** è controindicata nei casi seguenti:

- infiammazione o infezione locale
- osteoporosi vertebrale
- tumore vertebrale
- allergia o intolleranza al PEEK
- incompatibilità del paziente per età o condizioni fisiche
- tutti i casi non previsti nelle indicazioni.

La **gabbia cervicale anteriore SAMARYS** è stata progettata e prevista per i soli utilizzi indicati e non deve essere venduta per utilizzi differenti.

POSSIBILI EFFETTI AVVERSI

- infezione
- dolore
- pseudoartrosi
- patologie dei segmenti adiacenti
- migrazione post-operatoria dell'impianto
- danno ai livelli vertebrali adiacenti l'artrodesi
- intolleranza al materiale

Nota: per la correzione degli effetti avversi potrebbe rendersi necessario un ulteriore intervento chirurgico.
Avvertenza: Non tutti gli interventi chirurgici si concludono necessariamente con un esito totalmente soddisfacente. Ciò vale in particolare per la chirurgia del rachide, i cui risultati possono essere compromessi da numerosi fattori esterni.

PRECAUZIONI CHIRURGICHE

Il chirurgo deve aver maturato una conoscenza approfondita della **gabbia cervicale anteriore SAMARYS**, della metodica di applicazione, dello strumentario e della tecnica chirurgica.
La scelta della dimensione della **gabbia cervicale anteriore SAMARYS** deve essere effettuata in funzione del caso clinico e della correzione desiderata.
Si raccomanda di utilizzare un distrattore di Caspar per l'apertura dello spazio intervertebrale destinato a ricevere la gabbia.
Dopo l'impianto della **gabbia cervicale anteriore SAMARYS**, i piatti vertebrali devono essere accuratamente cruentati senza tuttavia renderli troppo fragili per evitare rischi di cedimento della gabbia stessa.
Per ottenere la fusione ossea occorre riempire la **gabbia cervicale anteriore SAMARYS** con osso autologo, allogenico o con sostituto osseo.
Il controllo radiografico permette di verificare il corretto posizionamento della gabbia in rapporto alle vertebre.
Dopo l'impianto occorre **sempre** registrare **numero di lotto** e **riferimenti** della **gabbia cervicale anteriore SAMARYS** impiantata nella cartella chirurgica del paziente.
Il prodotto è monouso e non deve mai essere riutilizzato. Pur risultando apparentemente in perfetto stato, il prodotto potrebbe presentare piccole difettosità o conseguenze di una sollecitazione residua risultante dall'utilizzo precedente che potrebbero comportare la rottura per fatica. Va inoltre tenuto presente che la decontaminazione dei dispositivi riutilizzati non è una procedura convalidata e che i dispositivi non sono stati progettati a tale scopo. Il riutilizzo del prodotto potrebbe essere causa di contaminazione incrociata, mentre la procedura di decontaminazione potrebbe comportare il degrado del materiale. Il Produttore non è responsabile delle conseguenze del riutilizzo di un prodotto.
Attenzione: non utilizzare prodotti a base di silicone, formaldeide o lattice in combinazione con un impianto SCIENT'X.
I pazienti devono essere informati delle precauzioni da seguire nella vita quotidiana al fine di garantire la massima durata utile degli impianti. Si consiglia di effettuare un **controllo postoperatorio regolare** al fine di evidenziare segni precoci di rottura del materiale, intervenendo di conseguenza. Il deterioramento del dispositivo a consolidamento osseo avvenuto non può essere considerato quale malfunzionamento o alterazione delle caratteristiche del materiale. Deve inoltre essere previsto e seguito un programma di rieducazione adattato al caso di specie.

CONFEZIONE

Le condizioni di stoccaggio devono garantire l'integrità dell'impianto, dello strumentario associato e delle rispettive confezioni.
Le condizioni di tutti gli impianti e del relativo strumentario devono sempre essere verificate prima dell'uso. Evitare di esporre gli impianti SAMARYS a radiazioni o a temperature estreme. Il mancato rispetto di queste prescrizioni può comportare una riduzione delle caratteristiche meccaniche che in determinati casi potrebbe causare la rottura dei componenti. I prodotti eventualmente danneggiati non devono essere utilizzati e vanno restituiti a SCIENT'X. Non procedere all'impianto della gabbia qualora le confezioni interna e/o esterna che garantiscono la sterilità siano perforate o deteriorate.

DECONTAMINAZIONE, PULIZIA E STERILIZZAZIONE

I prodotti consegnati in sacchetti non sono sterili

Impianti consegnati sterili: gli impianti vengono sterilizzati a raggi gamma al dosaggio di 25 – 40 kGy. La scadenza è di cinque anni. La data limite di utilizzo dei componenti sterili è indicata sulla confezione.
Impianti e strumenti consegnati non sterili: tutti gli impianti e gli strumenti consegnati non sterili devono essere **decontaminati, puliti e sterilizzati** prima e dopo l'uso. Gli impianti e gli strumenti avvolti in sacchetti devono essere estratti dal sacchetto d'origine procedendo quindi agli interventi riportati di seguito:

Metodica raccomandata:

- **Decontaminazione:** immergere gli impianti e gli strumenti in soluzione battericida e fungicida, quale ad esempio didecildimetilammonio cloruro con enzimi proteolitici allo 0,5% (5 ml per 1 l di acqua tiepida) per 20 minuti Risciacquare in acqua demineralizzata.
- **Pulizia:** lavare impianti e strumenti in una macchina da lavaggio tipo LANCER con prodotti di pulizia adeguati, quindi risciacquare e asciugare. Non utilizzare prodotti quali varichina o formaldeide che potrebbero danneggiare i materiali. Lubrificare giunti e meccanismi con olio di paraffina tipo Neodisher IP Spray.
- **Sterilizzazione:** si consiglia la sterilizzazione di impianti e strumenti in autoclave:
  - preriscaldamento per 25 minuti a 110°C (1 bar)
  - vuoto per 5 minuti (0,8 bar a pressione atmosferica)
  - riscaldamento per 5 minuti a 120°C (1 bar)
  - vuoto per 5 minuti (0,8 bar)
  - sterilizzazione per 18 minuti a 134°C (2 bar)
  - asciugatura per 20 minuti con ritorno a temperatura ambiente

RECLAMI

Eventuali reclami, accompagnati dai codici e dal lotto del prodotto oggetto del reclamo, devono essere inviati a Scient'x.

INFORMAZIONI ULTERIORI

Per ulteriori informazioni contattare il produttore:

SCIENT'X
22, Rue Jean Bart
78960 Voisins le Bretonneux- France
tél: +33 (0)1 39 30 69 37
fax: +33 (0)1 30 43 86 81
e-mail : qualite@scientx.com

Data di aggiornamento: 06/2010

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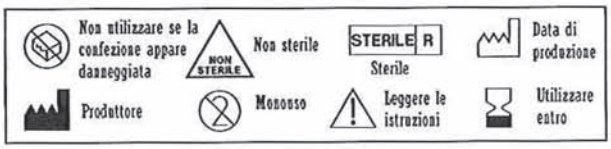

A solo scopo informativo
Soggetto a modifica senza notifica
Per richiedere istruzioni d'uso aggiornate, contattare il Servizio Clienti locale.

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Carlsbad, CA 92008 - U.S.A.
TL +1 460 431 9286
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22, avenue Jean Bart
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Solutions for the Aging Spine®

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