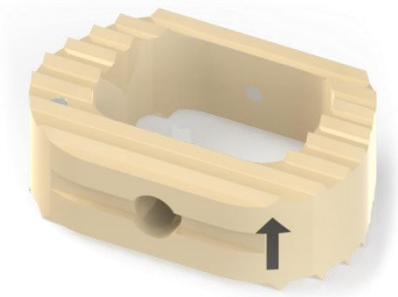
Surgical Technique

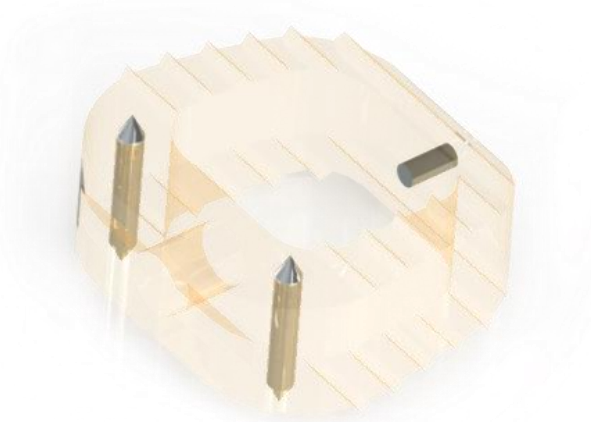
SQUALE™

Anterior Cervical Cage



orthopaedic & spine development

Squale



Mini-Squale

Table of contents

I. PRESENTATION OF THE PRODUCT

a. Implants (Class IIb)

SQUALE cages are intended to be inserted by anterior approach, between two cervical intervertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft or bone substitute material.

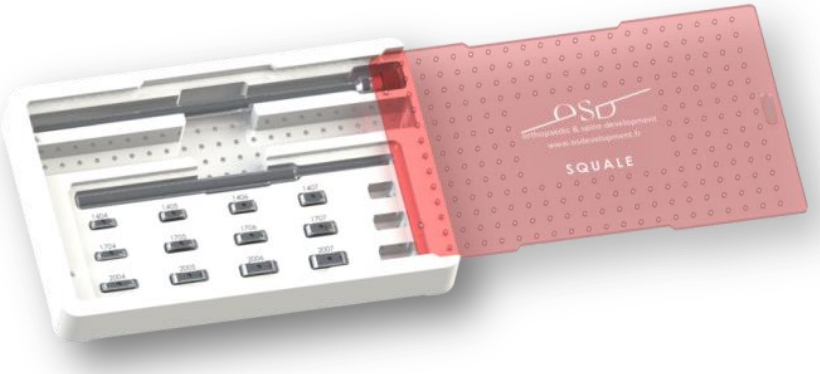
Cages are made in OX-PEKK® (ISO 10993). The markers are made in tantalum Ta (ASTM F560) or Ta and titanium alloy TA6V4 Eli (ISO 5832-3).

Reference	Length x Width (mm)	Height (mm)
SQP-CP-141304S	14 x 13	4
SQP-CP-141305S	14 x 13	5
SQP-CP-141306S	14 x 13	6
SQP-CP-141307S	14 x 13	7
SQA-CP-1704S	17 x 13	4
SQA-CP-1705S	17 x 13	5
SQA-CP-1706S	17 x 13	6
SQA-CP-1707S	17 x 13	7
SQA-CP-1708S	17 x 13	8
SQA-CP-2004S	20 x 15	4
SQA-CP-2005S	20 x 15	5
SQA-CP-2006S	20 x 15	6
SQA-CP-2007S	20 x 15	7

CE 0459

b. Instruments (Class I)

Reference	Description
SQA-2-BO	Instrumentation box
SQA-IM	Trial Implant holder
A-IMS-0001 & A-IMS-0001-02	Impactor/Implant holder
SQA-FA-141304	Trial implant for 14 x 13 x 04 mm
SQA-FA-141305	Trial implant for 14 x 13 x 05 mm
SQA-FA-141306	Trial implant for 14 x 13 x 06 mm
SQA-FA-141307	Trial implant for 14 x 13 x 07 mm
SQA-FA-1704	Trial implant for 17 x 13 x 04 mm
SQA-FA-1705	Trial implant for 17 x 13 x 05 mm
SQA-FA-1706	Trial implant for 17 x 13 x 06 mm
SQA-FA-1707	Trial implant for 17 x 13 x 07 mm
SQA-FA-1708	Trial implant for 17 x 13 x 08 mm
SQA-FA-2004	Trial implant for 20 x 15 x 04 mm
SQA-FA-2005	Trial implant for 20 x 15 x 05 mm
SQA-FA-2006	Trial implant for 20 x 15 x 06 mm
SQA-FA-2007	Trial implant for 20 x 15 x 07 mm



II. RECOMMENDATIONS

Before reading this document, it is important to note that this surgical technique, as well as quoted and recommended sources, cannot and must not be taken as a lecture on Spine Osteosynthesis.

This document shall only be regarded as technical instructions on how to use the implant.

In our concern towards constant improvement of our products, we keep the right to alter this document, as well as the implant, without notice, in order to match them up to the needs of our users.

a. Indications and contraindications

INDICATIONS
1) Degenerative cervical disease 2) Cervical stenosis 3) Discal herniation 4) Spondylosis 5) Traumatic injury
CONTRANDICATIONS
Contraindications brought to the attention of OSD 1) Is contraindicated any patient who may not be able to follow post-operative instructions including some cases of senility and mental illness 2) Acute or chronic, local or systemic infection 3) Allergy, hypersensitivity or intolerance (suspected or known) to one or more materials constituting the device 4) Addiction and/or a tendency to drug abuse, alcohol or tobacco 5) Pathology whose treatment do not requires the placement of such device. 6) Morbid obesity 7) Patient with an immature skeleton 8) Posterior use 9) Sign of local inflammation 10) Pregnancy 11) Neuromuscular disease 12) Tumour, metastasis of cervical spine 13) Age and/or patient's physical condition imcompatible 14) Myelopathy in the instrumented segment 15) Diabetes 16) Major comorbidity

17) Arthritis
18) Arthrosis
19) Osteoporosis
20) Taking steroids over a long period

b. Factors that may compromise the life of the implant

Factors brought to the attention of OSD

1) All cases of poor bone quality which may cause fusion failure, including among other cases of severe osteoporosis, fast joint disease or osteopenia
2) Intense and/or repetitive loads
3) Professional or sportive physical inappropriate activities
4) Tobacco consumption
5) Systemic or metabolic disorders
6) Significant bone deformities

c. Potential adverse events

Potential adverse events brought to the attention of OSD

1) Infection or inflammation
2) Allergic reaction to materials or debris materials
3) Breakage or movement of the implant
4) Degeneration of the adjacent segments
5) Pseudarthrosis
6) Cessation of any potential growth of the operated site
7) Interference with imaging devices
8) Subcutaneous pressure which may cause pain
9) Decrease in bone density
10) Gout
11) Dysphagia
12) Temporary hoarseness
13) Complications linked to the bone graft donor site
14) Dislocation
15) Hematoma
16) Limitation of movement amplitudes
17) Primary or secondary fractures
18) Injuries of skin or other tissues
19) Damage to the nervous system
20) Tearing of the dura
21) Dual leak
22) Loss of neurological functions neuropathy or neurological defective

23) Neuropathy or neurological deficit
24) Cardiovascular disorders
25) Venous thrombosis or pulmonary embolism
26) Problem of hemostasis
27) Hematoma and delayed healing
28) Bleeding
29) Change in mental status
30) Death
31) Swelling of soft tissues
32) Pains
33) Hypo/hypertension
34) Vertebral body collapse

These potential adverse events may sometimes cause a reoperation.

d. Precautions and warnings

SQUALE CAGES ARE SINGLE USE ONLY.
DO NOT RE-USE.

e. Preoperative Precautions

1) Before considering implanting a device, the surgeon must take into account the patient's general condition and the effectiveness or the impossibility of using another operative or non-operative treatment
2) The surgeon must take into account any previous surgery performed on the patient.
3) Any patient with a contraindication should be refused.
4) The patient should be informed of the potential risk of failure and its consequences
5) The patient should also be warned of the risk of non-union related to tobacco.

f. Intraoperative and postoperative precautions

1) The surgeon must warn the patient about the post-operative precautions
2) Clean and decontaminate implants and instruments prior to sterilization
3) Not combine SQUALE devices with devices from another manufacturer that may modify the physical integrity of the device.
4) The surgical technique must be identical to that proposed and described in the SQUALE surgical technique and the surgeon must be familiar with it
5) Choose the correct size and position the implant properly (if the implant cannot be placed correctly, it is recommended to consider other treatment)
6) The surgeon must know the mechanical properties and limits of the devices and the materials used
7) Protection against radiation: the surgeon will take all necessary measures to protect against radiation caused by intraoperative fluoroscopic control of the correct positioning of bone fragments and implants.
8) The implants are only single use.
9) The implants should be associated with appropriate bone substitutes.
10) An external support can be proposed.
11) It is not recommended to do intense physical activities before consolidation
12) Smoking before consolidation is not recommended

g. Packaging

The implants are delivered sterile in individual packaging. Sterile contents except when opened or damaged, in that case, not to use the device and to send it back to ORTHOPAEDIC & SPINE DEVELOPMENT.

Send back implants to ORTHOPAEDIC & SPINE DEVELOPMENT 6 months before the date of lapsing of sterilisation. The instruments are filed in a container.

h. Cleaning

Devices concerned: all non-sterile medical devices.

Process	The person who does the cleaning must wear glove, mask and safety glasses. Use a disposable cloth so as to remove any soil.
Automated cleaning	
	• **Disassembly is absolutely required** • Disassemble the implant holder *A-IMS-0001-02* and the impactor *A-IMS-0001*. • Disassemble the trial implant and the trial implant holder *SQA-IM*. • Immerse all the set instrumentation in cold tap water for 5 minutes at least. • Brush with a soft nylon brush until no residuals of the test soil were visible: • Brush in particular the thread of trial implant holder *SQA-IM*, the thread of the implant holder *A-IMS-0001-02*, the external surface of the instruments and the lid and the tray. • Brush the lumen (narrow hollow cavity) of the impactor *A-IMS-0001* with an appropriate swab. • Rinse all the surfaces (tray, lid, the trial implant) and lumens (Impactor lumens) of the elements, in cold water, 20 minutes at least, at minimum static pressure 4 bars • **Check all the elements,** in particular, the thread and the lumens.
Automated Cleaning (*For example equipment: Miele G 7735 CD (Program:Vario TD)*).	
Description of the cycle cleaning	• 2 minutes pre-cleaning with cold tap water. • Drain. • 5 minutes cleaning with deionized water at 55°C and 0,5% of soft alkalin detergent (*example : NeodisherMediClean - Dr.Weigert*). • Drain. • 3 minutes rinsing and neutralization with deionized water • Drain. • 2 minutes final rinse with deionized water • Drain.
Inspection and Function Testing	• Check instruments and lumen for complete removal of visible soil. • If necessary, repeat cycle cleaning. • After cleaning/disinfection, the disassembled instruments should be reassembled and visually inspected.

i. Sterilization

Devices concerned: all non-sterile medical devices.

Autoclave sterilization (*For example equipment: Selectomat HP MMM*)	
Packaging	• Always put interior and exterior sterilization marks on the box, like physico-chemical indicator to check the efficiency of the sterilization,for each packing before sterilizing. • Place instruments into appropriate configuration within instrument box. • Wrap with protective sterilization pouch.
Sterilization	• The instruments should be sterilized before each surgery by clinics and hospitals according to the legislation in force. • Sterilize the box in a a vapor sterilizer according to the following parameters : o Air elimination o sterilization at 134°C during 5 minutes at maximum 3 bars o Drying during 10 minutes at least. • In France, sterilization must be between 134° and 138°C during 18 minutes at least (according to the instruction DGS/RI3/2011/449 of 1st December 2011). • Do not stack boxes in sterilizer.
Storage	• Store in a clean and dry place.
Addicional information	• Manufacturer and distributor assume no responsibility for the cleaning and re-sterilization of implants, components or re-usable instruments, performed by the hospital. • Re-usable instruments must be cleaned, decontaminated and sterilized before and after use according to the following detailed method and the current legislation (in France, instruction DGS/RI3/2011/449 of 1st December 2011).
Manufacturer contact	ORTHOPAEDIC & SPINE DEVELOPMENT Chemin de Fontanille - BP 11211, 84911 Avignon Cedex 9 - FRANCE Tel : + 33 (0)4 32 74 01 10 / Fax : + 33 (0)4 90 80 02 39 info@osdevelopment.fr / www.osdevelopment.fr

III. SURGICAL TECHNIQUE

a. Exposition

The patient is placed in dorsal decubitus.

b. Discectomy and tray preparation

Put in place the retractor after the lateral detachment of the longus colli muscle.
Incision of the annulus with scalpel, and resection of the disc with the plier until the posterior vertebral ligament. The distraction is made with a distractor. When the radiculomedular decompression gesture is made, we fan the tray with the curette without insult the cortical.

c. Determining the implant size

Screw the trial implant on the impactor (the arrow ↑ indicates the orientation of the trial implants).

Once impacted, check the trial implant's position through the radiography.
Then select the cage corresponding to the trial implant.

d. Preparation of the cage

Screw the implant holder *A-IMS-0001-02* in the impactor *A-IMS-0001*, and place the cage on the impactor. Screw the cage on the impactor with the implant holder until the blocking.

Fill the cage with synthetic bone substitute or osseous graft.

e. Inserting the cage

Before inserting, check the orientation of the cage thanks to the black arrow ↑.
Impact the implant, after having slightly distracted the vertebral bodies, so that a minimal resistance is felt during the impaction.

When the cage is well positioned between the two vertebraes, unscrew the Impactor and remove the Impactor.

Once the implant in place, the distractor is used in compression before being removed.

f. Ablation

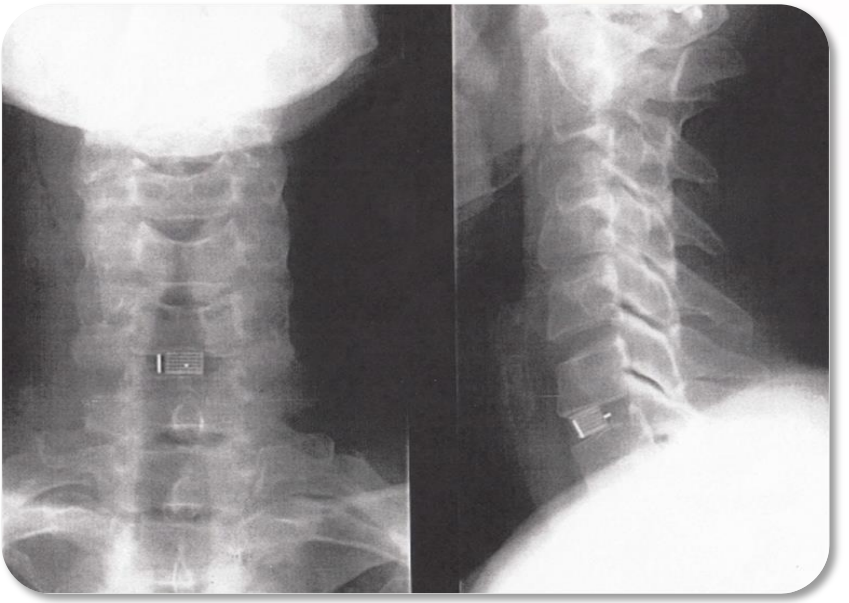
Use the same instruments than for the implantation. Do a distraction if necessary. Screw the implant holder *A-IMS-0001-02* in the thread placed behind the cage. Remove the cage by little jabs.

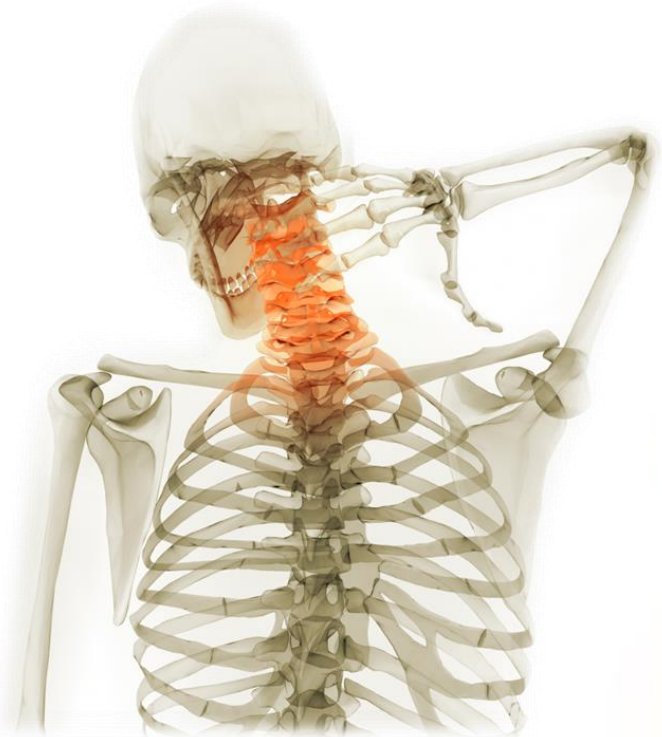
IV. PRECAUTIONS TO TAKE REGARDING THE INSTRUMENTS USE

Re-usable instruments must be cleaned, decontaminated and sterilized before and after use according to the detailed method and the current la legislation (in France instruction DGS/RI3/2011/449 of 1st December 2011 concerning the hazards of Creutzfeldt-Jakob disease).

ORTHOPAEDIC & SPINE DEVELOPMENT recommended a number of cycles of 150 sterilization maximum for its instruments. ORTHOPAEDIC & SPINE DEVELOPMENT instruments must be repaired and should be cleaned, decontaminated, sterilized and before being sent to the address shown on this document. At your return must enclose the traceability sheet.

ORTHOPAEDIC & SPINE DEVELOPMENT (OSD)
Chemin de Fontanille - BP 11211
84911 AVIGNON Cedex 9
Tél : +33 (0)4 32 74 01 10 - Fax +33 (0)4 90 80 02 39
www.osdevelopment.fr





orthopaedic & spine development

ORTHOPAEDIC & SPINE DEVELOPMENT (OSD)
Chemin de Fontanille - BP 11211
84911 Avignon Cedex 9 - FRANCE
Tél : +33 (0)4 32 74 01 10 - Fax +33 (0)4 90 80 02 39
www.osdevelopment.fr