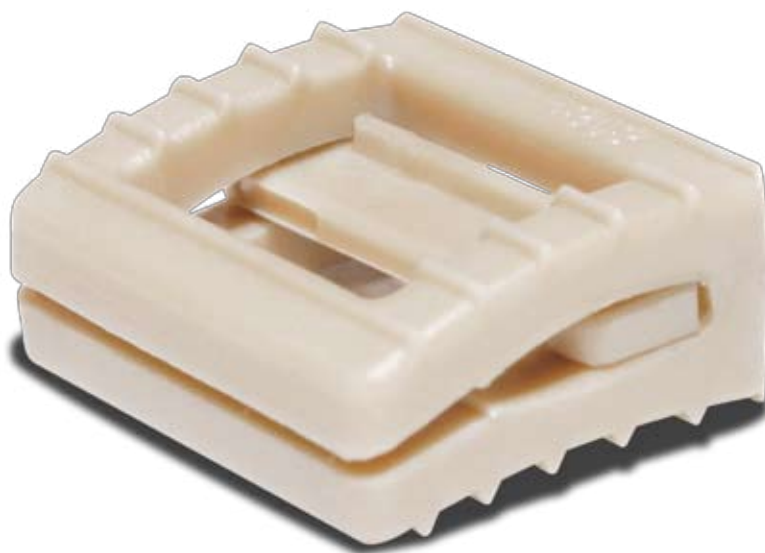


SmArtCage-C: The expandable cervical cage that simplifies spinal surgery



Surgical Technique

Anterior Cervical Interbody Fusion



Foreword

Warning/Disclaimer

This document is not a course on the cervical athrodesis surgical technique. It contains SmArtCage-C instructions for use during the cervical fusion procedure. Perfect knowledge and good surgical experience of the anterior cervical de-compression & fusion technique is mandatory.

Product Packaging

Important: The implant is distributed as both a Sterile ('ST' suffix) and Non-Sterile product ('NS' suffix). The Non-Sterile implant must be sterilized in steam autoclave prior to use (the steam sterilization temperature must not exceed 134°C).

Improvements

SmArtSpine strives to produce quality products with quality documentation. Please forward any comment or questions to your distributor or directly to us at the contact information listed on the last page.

Indications for Cervical Arthrodesis:

All cervical disc diseases for which anterior cervical discectomy and fusion are indicated:

- Ruptured and herniated discs,
- Degenerative disc diseases and instabilities,
- Pseudoarthrodesis or failed spondylodesis,

Note: For multi segmental fusion, additional stabilization with a cervical plate and screws is recommended.

Contraindications

- Any local, acute or chronic infection,
- Severe osteoporosis,
- Spinal tumors,
- Spinal fracture,
- Drug and/or alcohol addiction and/or abuse,



Patient Preparation

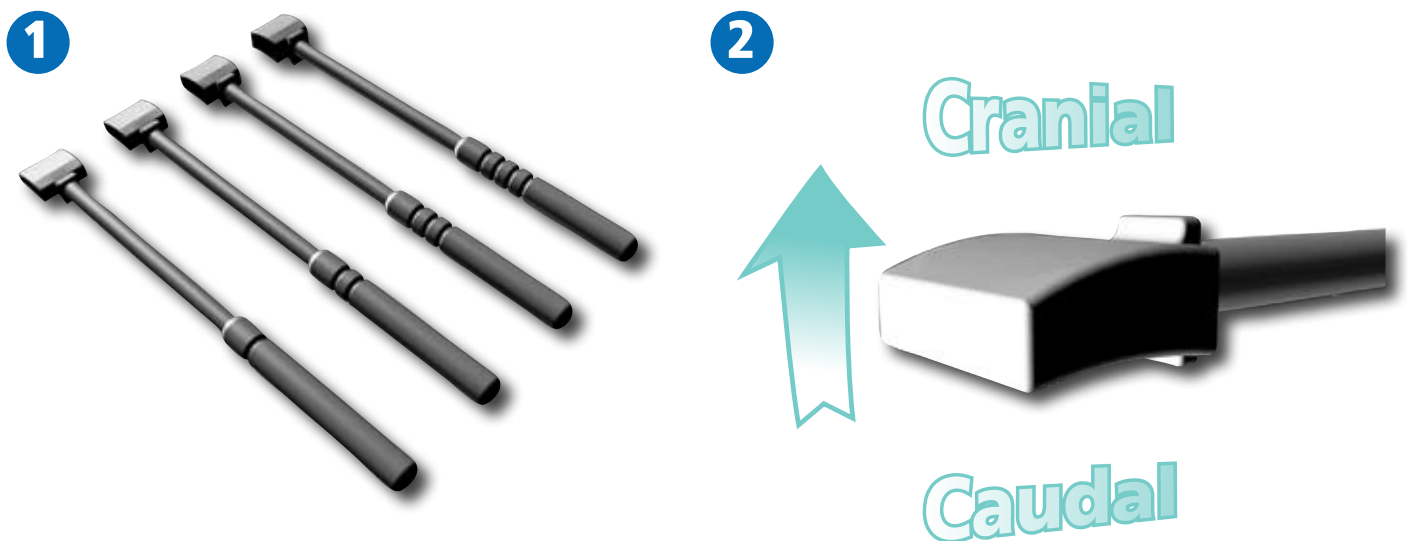
- The patient is placed in a supine position with the head slightly in extension. The posterior cervical spine is supported to maintain a physiological cervical lordosis,
- The level targeted for surgery is localized by an image intensifier. A skin incision centered on that level is performed,
- The anterior side of the cervical spine is exposed. Discectomy and decompression are then performed according to standard surgical procedures. A cervical distractor can be used to open the disc space,
- The endplates are carefully refreshed, using a curette or a high speed drill, removing only the cartilage.

Sizing the Implant

The applicable instrument references are (Figure 1):

- SASC-02210 – Template Size T5 (single ring on handle),
- SASC-02220 – Template Size T6 (two rings on handles),
- SASC-02230 – Template Size T7 (three rings on handle),
- SASC-02240 – Template Size T8 (four rings on handle),
- Starting from the smallest to the largest size, templates are successively inserted in the disc space with the convex shape of the template in a cranial situation (Figure 2) until the depth limiter comes in contact with the anterior part of the vertebral body,
- The correct size is selected when the template provides a good stability after the vertebral distractor release and when restoration of the desired height is achieved. A fluoroscopy control can be done to confirm the size.

Note: the templates represent the unexpanded cage without anchoring ridges. Therefore, do not seek high retention (especially in the posterior part) during the sizing process.



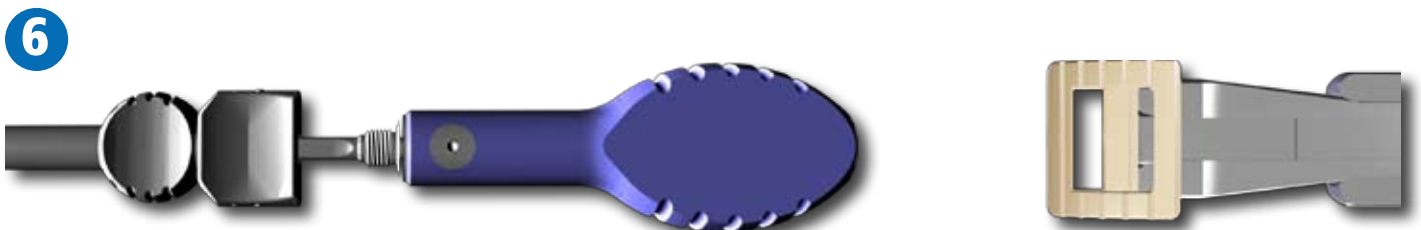
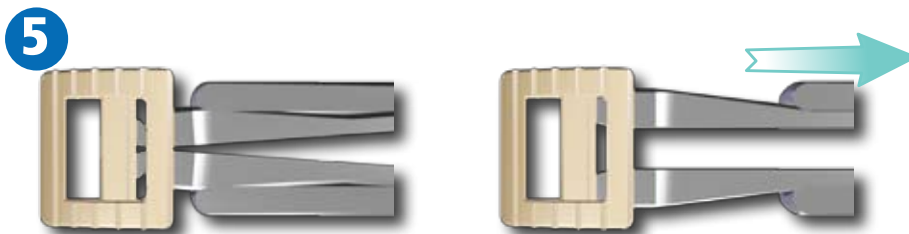
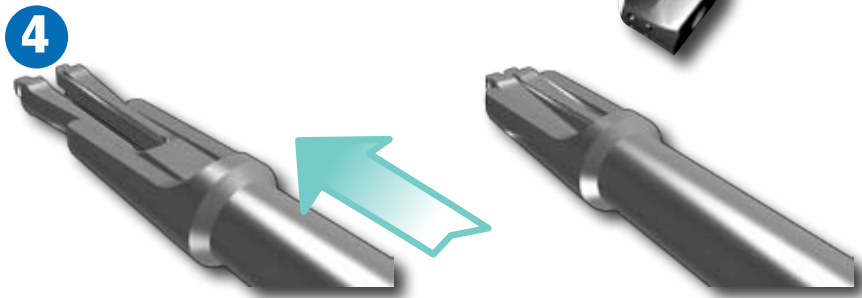
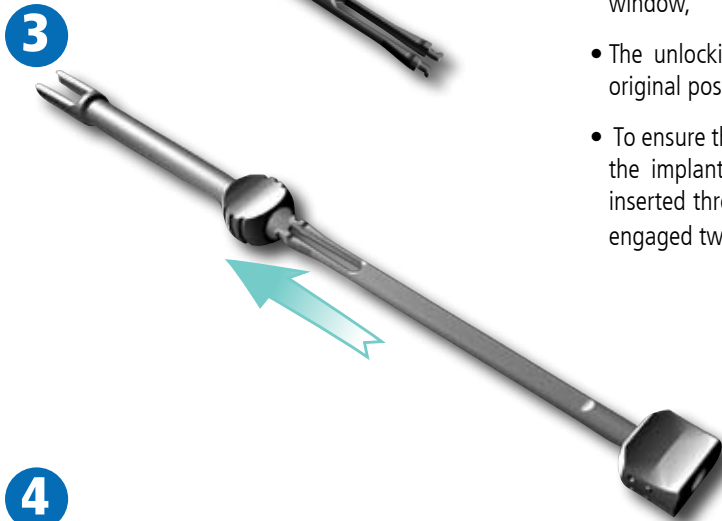


Cage Holder Assembly

Connecting the implant with the holder

The cage holder is initially assembled from 2 separate instruments:

- SASC-02110 – Locking wrench (Figure 1),
- SASC-02120 – Unlocking wrench (Figure 2),
- The locking wrench (SASC-02110) is inserted in the unlocking wrench (SASC-02120) through its widest opening (Figure 3) until it exits the opposite opening,
- The locking wrench (SASC-02120) features two prongs on the lateral side of its branches, designed to mate with the implant anterior window,
- Positioning the implant on the locking wrench (SASC-02110) requires introducing the retaining tabs through the implant anterior window. This operation is eased by pushing (forward) the unlocking wrench (SASC-02120) on the locking wrench (SASC-02110) until the tip narrows sufficiently to penetrate the implant anterior window,
- The unlocking wrench (SASC-02120) can then be retracted (backwards) to its original position to allow the prongs to revert to their original shape (Figure 5),
- To ensure that the tips of the unlocking wrench remain spaced apart and maintain the implant in a locked position, the expansion screw driver (SASC-02130) is inserted through the threaded opening of the locking wrench (SASC-02110), and engaged two turns to maintain the prongs spread (Figure 6).



Implant Insertion & Expansion



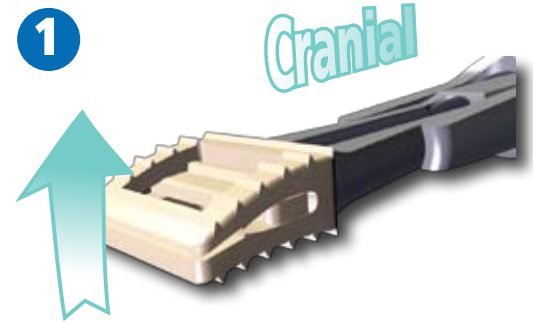
Positioning the cage in the disc space

Note: the convex surface must be positioned cranially to match the endplate profile (Figure 1).

- The cage holder can be impacted to facilitate implant progression in the disc space until the ideal position is reached. A mallet can be used to give a gentle impaction on the bottom of the cage holder,

Caution: inserting the cage too deeply can damage the spinal cord.

- The ideal position is 1 mm beyond the anterior wall of the adjacent vertebral bodies (Figure 2). In the case of anterior osteophytes special care must be exerted to ensure that the implant is effectively positioned 1 mm beyond the original wall of the vertebral body if the osteophytes are not removed,
- Ensure depth adequacy via a lateral fluoroscopy - in addition to visual control.

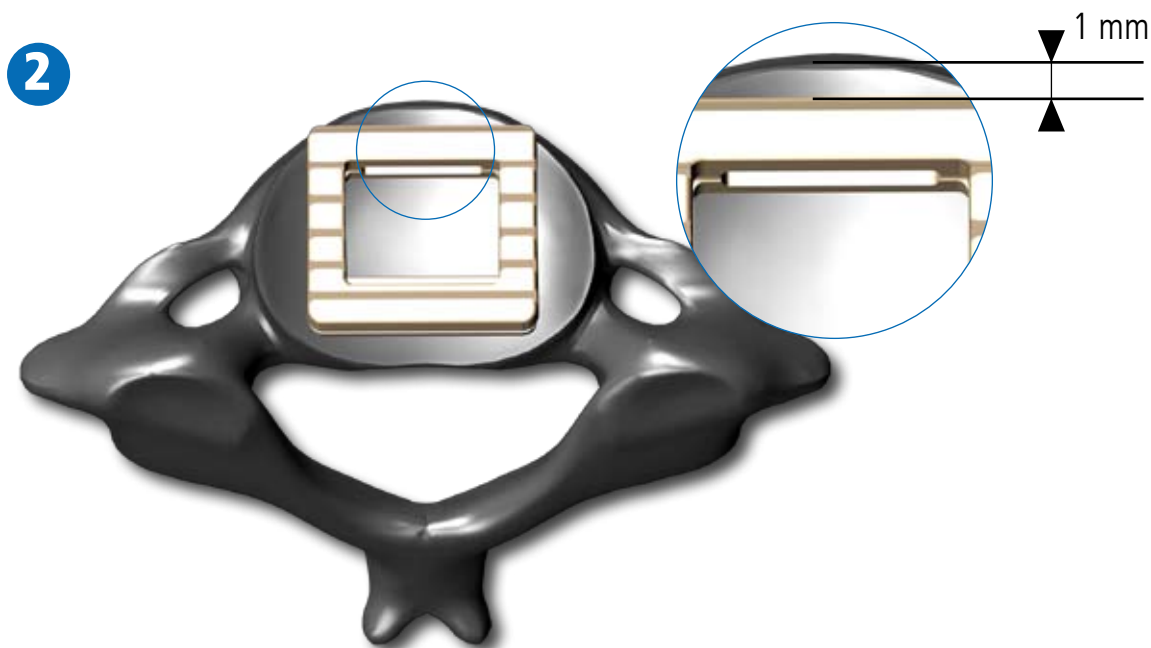


Implant Expansion

- If a vertebral distractor has been used for discectomy, it should be released at this time.
- Expansion of the implant is achieved by screwing the expansion screwdriver (SASC-02130) clockwise until further rotation is no longer possible.

Note: It is not unusual to hear a light mechanical noise during expansion. This noise emanates from the sliding of the expansion core inside the implant body during expansion.

Multilevel fusion: Please insert cages one level at a time and perform full expansion only at the end so as to limit compression on adjacent operated levels (which is induced by subsequent insertions).





Implant Release, Removal

Implant Release

- The expansion screwdriver (SASC-02130) is fully unscrewed (counterclockwise) and removed,
- The unlocking wrench (SASC-02120) grip on the implant is released by pushing the unlocking wrench (SASC-02120) forward on the locking wrench (SASC-02110), until the locking wrench (SASC-02110) can be disconnected from the implant.

Caution: The implant may not be uncoupled from the cage holder without removing the expansion screw driver first. Attempting to uncouple the implant from the cage holder with the expansion screw driver inserted will create permanent damages that will disable part or all of the functionality.

Final Tasks

- A final imaging control can be done to ensure that a full expansion took place,
- The implant chamber is completely filled with bone graft material through its anterior window,
- The addition of a cervical plate is decided by the clinician, depending on the primary stability of the implant and/or the number of levels fused,
- Closure is done according to standard practices.

Implant removal

If once in position it becomes necessary to remove the implant, please proceed as follows:

- If necessary completely clear the anterior window from any bone material,
- If present, remove the expansion screw driver completely (SASC-02130) from the unlocking wrench (SASC-02120),
- Push the unlocking wrench forward (SASC-02120) on the locking wrench (SASC-02110) in its farthest position without fully removing it,
- Insert the two prongs inside the implant anterior window,
- Retract the unlocking wrench backwards (SASC-02120), so as to restore the spacing of the prongs, hence firmly grabbing the implant,
- Insert and screw the expansion screw driver fully (SASC-02130), in order to secure the implant on the instrument,
- Extract the implant by pulling in an unidirectional pull motion - consider using a vertebral distractor to assist in the process,
- Caution: an extracted implant may not be reused, as the expansion is irreversible. Bone graft material may however be reused.

Sterilization instructions

Important: Permanent damages to the instrument may result if sterilization is performed on a fully assembled instrument. Please disassemble the cage holder completely before sterilizing in a steam autoclave.



SmArtCage-C Instrumentation: Ergonomics & Simplicity

SmArtCage-C Technical Specifications:

Available References, sterile version:

- SASC-1150-ST: Size T5 (5 mm height),
- SASC-1160-ST: Size T6 (6 mm height),
- SASC-1170-ST: Size T7 (7 mm height),
- SASC-1180-ST: Size T8 (8 mm height),

Available References, non-sterile version:

- SASC-1105-NS: Size T5 (5 mm height),
- SASC-1106-NS: Size T6 (6 mm height),
- SASC-1107-NS: Size T7 (7 mm height),
- SASC-1108-NS: Size T8 (8 mm height),

Material:

PEEK Optima® with Baryum Sulfate Additive.

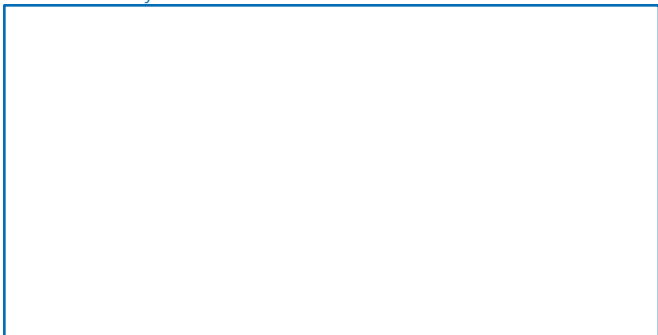
SmArtCage-C Instrument Set References:

Instruments are listed according to their most common usage order.

SASC-02000	Instrumentation Container
SASC-02110	Locking wrench
SASC-02120	Unlocking wrench
SASC-02130	Expansion screw driver
SASC-02210	Template T5
SASC-02220	Template T6
SASC-02230	Template T7
SASC-02240	Template T8



Distributed by:



SmArtSpine

SmArtSpine SAS
186 Bd Pasteur
Centre d'Activité Pasteur
F-13730 Saint Victoret
France

Phone: +33 4 42 34 63 89
Fax: +33 4 88 71 44 30

info@smartspine.fr
www.smartspine.fr