Surgical Technique

Cervical Cages

WeTOP

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Surgical Technique

STEP 1:

Patient positioning and incision

The patient is placed in a dorsal decubitus position with the head slightly extended in order to provide a clear view to the site operated.

The skin incision targets the level of the lesion to be treated. Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine.

STEP 2:

Distract segment

Distract the segment with the distractor placed in the vertebral bodies.

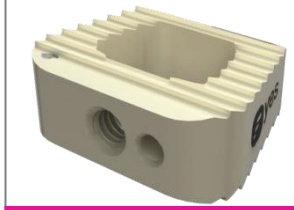
Implants used

- **Anatomical cervical cage**

Ref: WTIAXXXX-X

- **Lordotic cervical cage**

Ref: WTIDXXXX-X



Instruments used

- **CASPAR**

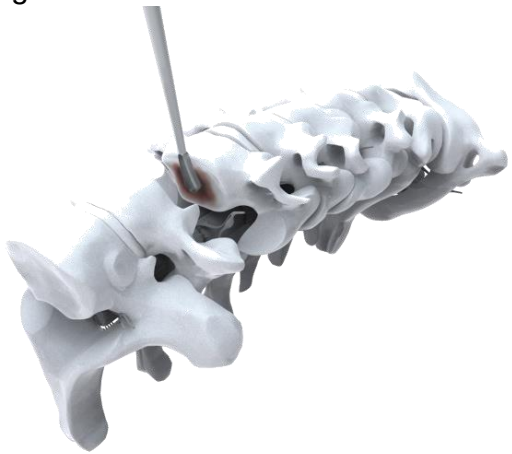
Ref: WTACASP70

Surgical Technique

STEP 3:

Preparation of the vertebral endplates

Remove the cartilaginous layers from the surface of the adjacent vertebral end plates and rasp the end plate in order to accelerate the osteointegration. Use the spoon or window curette to complete this operation. Be careful in rasping the bone and not to weak the end plates.



STEP 4:

Determine the implant size.
Please select a trial implant that best match the prepare end plates and load it on the trial instrument.
Please make sure to respect the Cranial/Caudal orientation and insert it in the intervertebral space.

Use the image intensifier to check the correct position of the trial implant which should fit tightly and accurately between the end plates.

WARNING: Selection of the trial spacer (anatomic or lordotic) depends on the height, width and depth of the intervertebral space, the preparation technique, and patient anatomy.
The surgeon must be aware that the trial cages sizes are identical to the final cage to be selected, in shape, heights, width and depth in order to optimize the positioning of the implant.
All trial cages are laser marked with width, length and height (mm) which correspond to final cages.

Instrumentation

- **Curette cuillère**

Ref: WTACU10

- **Curette fenêtre**

Ref: WTAOC20

- **Trial Holder**

Ref: WTATH10

- **Trial Holder with Stopper**

Ref: AWTTHS

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STEP 5:

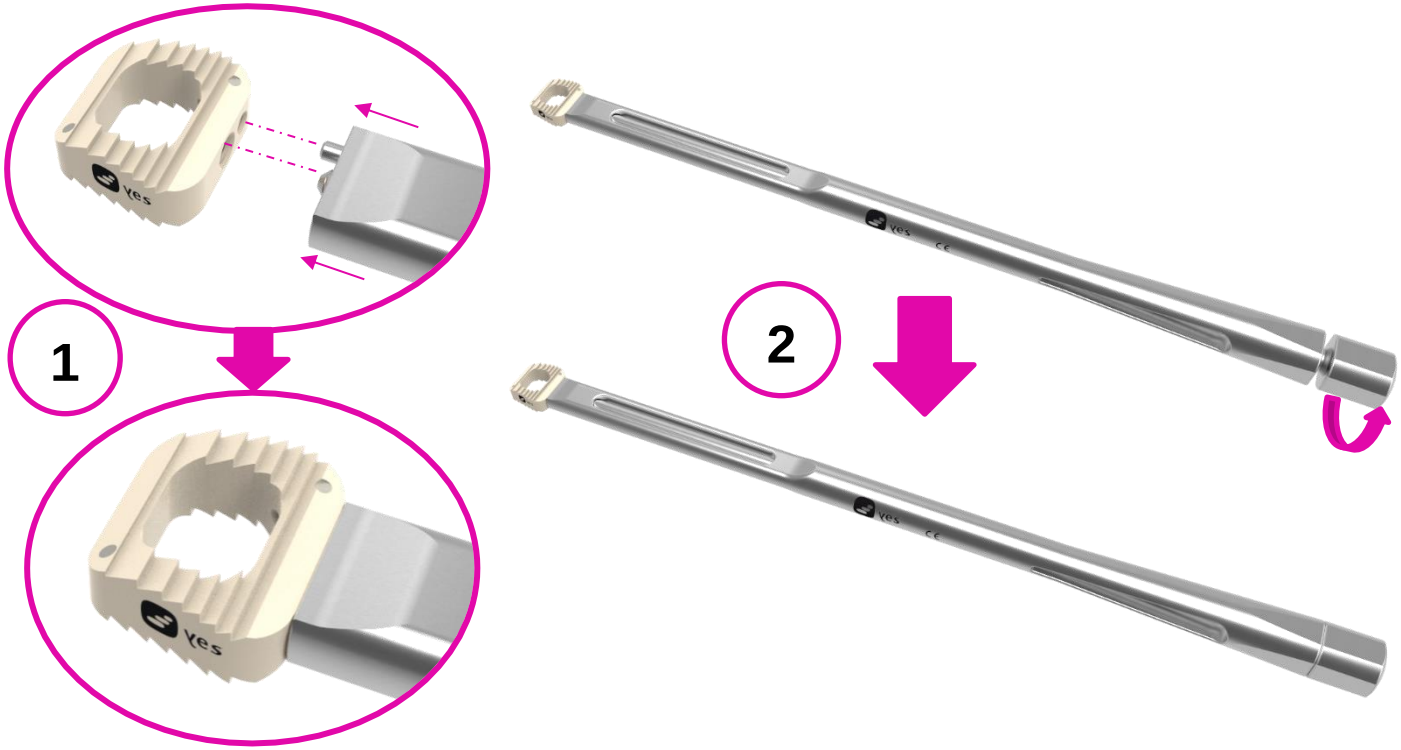
Bone graft filling

Position the final cage on to the bone filler and fill bone substitute or cancellous bone. Use the bone filler to compact the bone into the cage area.

STEP 6:

Connect cage to holder

Connect the selected implant cage to the holder (1) and tight the instrument (2). Once the implant is block onto the instrument in the cranial position, it can be inserted in the intervertebral space.



Instrumentation

▪ **Bone Filler**
Ref: WTABF60

▪ **Graft pusher**
Ref: WTAGP80

▪ **Implant Holder**
Ref: WTAIH40

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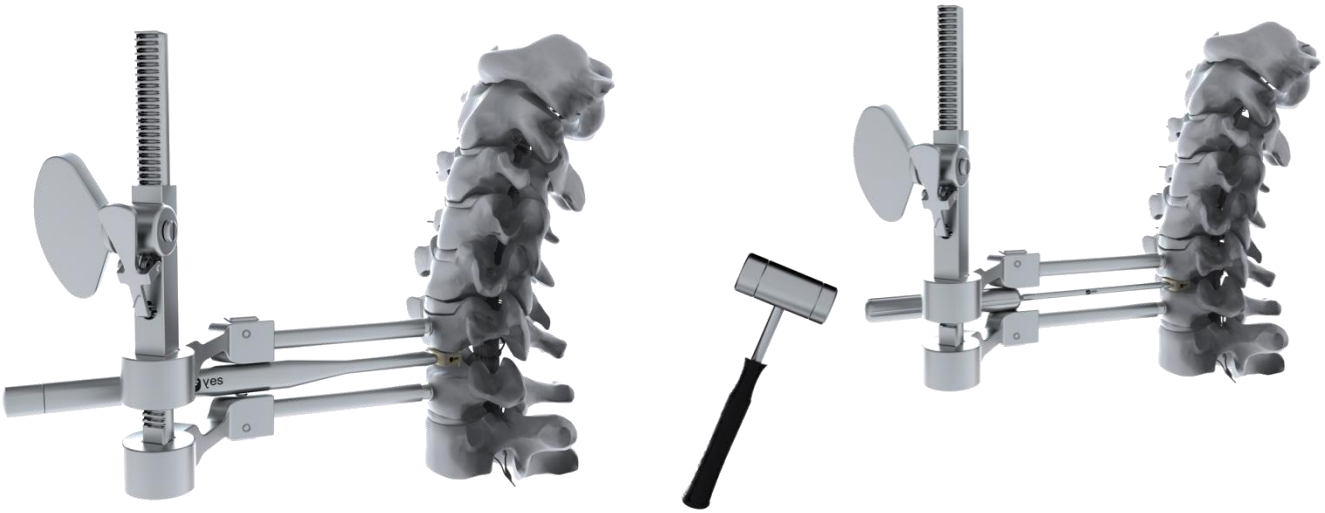
STEP 7:

Insertion of the cage.



Final impaction can be performed gently with the final impactor.
Once the distractor is released, check the correct stability of the cage.

The optimal position of the cage is centered within the periphery of the vertebral end plates and the cage should be placed 2 mm behind the anterior edge.

Then, all instruments are removed and the closing and suturing can be performed.

Instrumentation

▪ **Final Impactor**
Ref: WTAFIM50

Instruction for Use
CERVICAL CAGE WeTOP

1 I PURPOSE
The WeTOP anterior cervical cage is an implant intended for the surgical treatment of the cervical vertebrae.

2 I GENERAL DESCRIPTION
The WeTOP anterior cervical cage has been designed for stabilization and arthrodesis of the cervical vertebrae. The WeTOP anterior cervical cage is a surgical implant for cervical arthrodesis by anterior approach and designed to optimize bone fusion from C3 to C7 levels. It is recommended to use the implant in combination with an Anterior cervical plate.

The WeTOP anterior cervical cage is convex or lordotic in shape on its upper face and has openings on the upper and bottom faces to facilitate bone contact and guarantee its stability between vertebrae.
It comes in several widths, heights and lengths in order to accommodate varying anatomical conditions.
The WeTOP anterior cervical cage is made of implantable PEEK ASTM F2026 and includes radiopaque markers made of Tantalum according ASTM F560-13 in order to identify the implant on X-rays for post-operative clinical follow up.

The WeTOP anterior cervical cage has been developed to be used with simple instruments to reduce surgical time. Instruments from other manufacturers shall not be used for implant of the WETOP implant.

3 I INDICATIONS
The indications for the implant are:
- stabilization after treatment of a herniated cervical intervertebral
- disc or osteophytosis compressing the nerve roots and/or spinal cord
- degenerative intervertebral instability
- Disc herniation
- Spondylolisthesis
- Myelopathy

4 I CONTRA-INDICATIONS
The contra-indications for the WeTOP anterior cervical cage include:
- local infection or inflammation,
- vertebral osteoporosis,
- Fractures
- malignant vertebral disease,
- allergy or intolerance to PEEK and tantalum (nickel),
- incompatible patient age and physical condition,
- Pregnancy women
- Tumor

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

5 I STORAGE CONDITION
The implants must be kept in clean and dry storage conditions away from humidity, UV Do not implant the cage if the primary and/or the secondary package of the sterile conditioning are pierced or deteriorated.

The good condition of the implants and the functionality of the instruments must be checked before use. Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.

6 I DECONTAMINATION AND CLEANING
The implants are delivered sterile (Gamma sterilization) and intended for single use and damaged products must never be used and must be returned to Yellowsteps.**(DO NOT IMPLANT IF PACKAGE DAMAGED OR SEAL BROKEN)**
At no point implant can be used or reused if package damaged or seal broken because sterility would not be guaranteed.

Instruments to be used with cage WeTOP and delivered non-sterile must be decontaminated and sterilized before use in accordance with No.DGS/SC/DHOS/E2/2001/138 du 14 Mars 2001. The instruments must be cleaned with adapted products, rinsed and dried.

Only stainless-steel instruments, silicone or POM can be treated in sodium solution of 1M of NaOH for 60 minutes at 20°C. None of those instruments can be cleaned with Chlorine solutions.

7 I STERILIZATION /RESTERILIZATION

Implants are delivered sterile: the implants are sterilized by Gamma radiation at doses of 25 to 40 kGy. The expiry date is 5 years.
At no point implants can be re-sterilized by whatever mean. The re-sterilization is not recommended because it could alter the mechanical properties of the implant and increase risk for the patient.

Instruments must be sterilized by steam autoclaving procedure in containers and in compliance with ISO1765-1 (134°-18 min).

8 I OPERATING PRECAUTIONS
Pre-operative
The surgeon must be thoroughly familiar with the WeTOP anterior cervical cage, the method of application, the instruments and the operating technique. All implants and instruments must be available before starting surgery. Please check that enough sizes by implants are available. At no point instruments or implants from other manufacturers can be used in combination with instruments and implants dedicated to the implant and manufactured by Yellowsteps

Per operative
The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Make sure that implants are properly positioned as describe in the surgical technique.

Post-surgery
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. A suitable rehabilitation program must be designed and implemented.

9 I POSSIBLE ADVERSE EFFECTS
- infection,
- pain,
- pseudarthrosis,
- adjacent segment disease,
- post-operative migration of the implant prior bone consolidation,
- damage to the vertebrae adjacent to the arthrodesis,
- intolerance to the raw material.
- dysphagia

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.

10 I INFORMATION AND COMPLAINTS
Any complaints, together with the reference and lot number of the incriminated product, must be sent to the distributor or directly to **Yellowsteps, 161 Avenue Franklin Roosevelt, 69150 Decines France or at** contact2@yellowsteps.net
To request a Surgical Technique, please send an email to contact2@yellowsteps.net **or visit our website:** www.yellowsteps.net/en/downloads

	**Use By**
	**Caution, consult accompanying documents**
	**Consult operating instructions**
	**Keep dry**
	**Keep away from sunlight**
	**Do not re-use**
	**Do not Re-sterelized**
	**Do not use if package damaged or seal broken**
	**Sterilized by Gamma radiation**

Manufacturer:
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Surgical Technique

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