



# Instruction for Use CERVICAL CAGE WeTOP

## 1 | PURPOSE

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

## 2 | 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 | 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 | 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 | 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 | 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 | 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 | 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 | 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 | 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](mailto:contact2@yellowsteps.net)

To request a Surgical Technique, please send an email to [contact2@yellowsteps.net](mailto:contact2@yellowsteps.net) or visit our website: [www.yellowsteps.net/en/downloads](http://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-sterilized
	Do not use if package damaged or seal broken
	Sterilized by Gamma radiation



### Manufacturer:

**Yellowsteps**

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69150 DECINES – France

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[www.yellowsteps.net](http://www.yellowsteps.net)

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