

INSTRUCTIONS FOR SURGICAL INSTRUMENTATION

GENERAL INSTRUCTIONS FOR SURGICAL INSTRUMENTATION

Our instruments are manufactured in stainless steel compliant with EN NF 10088-1, 10088-3, NF S94-090.

All devices are supplied NOT STERILE

The instruments must be used by qualified staff.

The instruments must be used in the surgical technique they were conceived for.

Any violation of this instruction would cancel the 5 year guarantee.

If any instrument has to be returned to Oury-Guyé for any reason, it has to be decontaminated before, Oury-Guyé reserves the right to request a decontamination certificate.

STORAGE PRECAUTIONS

For the storage of the instrumentation, the instruments have to be unpacked and stored in a clean and dry place.

The instruments must be stored in a place with no contact or near by corrosive products (containing acid or chlorine)

Unclamp the instruments during the storage

DECONTAMINATION - CLEANING - STERILISATION

Clean the instruments before the first sterilization and after each use.

Decontaminate the instruments following the current protocols.

The instruments are designed to withstand intensive cleaning in sodium hydroxide

OUTLAWED : Any cleaning solution based on acid, abrasive or chlorine.

RULES FOR AN APPROPRIATE USE OF THE INSTRUMENTS

Do not use the instruments just after the sterilization (still hot), there is a risk of irreversible damage/jamming.

Do not store, wash or sterilize the instruments while they're still clamped.

After sterilisation use a suitable lubricant for the mechanical areas of the instruments.(joints, hinges..)

Do not leave instruments with humidity on laser marking. If red or brown stains appears, rub it hard with a soft cloth.

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The following indications are based on NF EN ISO 17664 Vs 2004



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| WARNINGS | Long narrow cannulas and blind holes require a particular attention for cleaning |
| Cycles of sterilisation | The number of sterilisation cycles has little effect on the instrumentation, the end of life of the instruments is generally due the damages occurred by the utilisation. |
| INSTRUCTIONS | |
| Place to use : | Any premises suitable for the practice of medicine and surgery, with appropriate equipment and qualified staff for the implementation and respect of these instructions. |
| Confinement and transport : | No special requirements, it is recommended to treat instruments as soon as it is possible after use. |
| Preparation for cleaning | Always remove any oil trace before cleaning. |
| Automated cleaning | <p>Equipment: washer/disinfector, detergent (enzymatic cleaning solution), tap water (softened water)</p> <p>1 Place instruments in 'opened' position when it is appropriate and allow water to flow through cannulas and blind holes.</p> <p>2 Launch cold softened water prewash cycle (2 min), apply spray detergent, soak in hot softened water (20 sec), enzymatic soak (1 min), rinse twice in softened water (15 sec), wash with detergent in hot water (64 to 66°C, 2 min), then rinse twice with hot softened water (15 sec).</p> <p>3 Check that cannulas, blind holes, etc... are visibly free of any contamination. If necessary, repeat the cycle or process to a manual cleaning.</p> |
| Manual cleaning | <p>Equipment: detergent (enzymatic cleaning solution), brush (do not use metallic brushes or scouring and abrasives pads), tap water that has been purified.</p> <p>Method :</p> <p>1 Rinse the excess waste from instrument (immerse the instrument in detergent for 20 minutes)</p> <p>2 Scrub cannulas and holes with a brush, making sure it reaches down to the bottom of the instrument.</p> <p>3 Rinse with tap water for at least 3 minutes. Make sure that the water flows through cannulas and that blind holes are filled and emptied several times over.</p> <p>4 Place the instruments in an ultrasonic cleaner and run the cleaner for 10 minutes at 45-50 kHz.</p> <p>5 Rinse the instrument in purified water for at least 3 minutes or until any visible waste is eliminated. Rinse holes and other inaccessible areas carefully and thoroughly.</p> <p>6 Dry the instrument with a clean, absorbent and unfluffy cloth.</p> |
| Disinfection : | <p>The disinfection solution (enzymatic cleaning solution) may be used as recommended by the label of the manufacturer.</p> <p>With automatic cleaning, a final rinse with hot water is a possibility, followed by rinsing with purified water (64 to 66°C) for 10 seconds and hot air drying for 7 to 30 min to disinfect.</p> |
| Drying : | Do not exceed 120°C if the drying is a part of a automated cycle. |
| Maintenance : | After cleaning, apply some surgical lubricant on mechanic parts of the instrument to optimise its durability. |
| Checks and tests : | <ul style="list-style-type: none"> - Articulated instruments : Check that joints work easily, without excessive loosening. - Check the locking mechanisms (Hook, clamp, etc...). - All instruments : Check visually any trace of damages or wear. Cutting edges must be continuous and unbroken. - Check long thin instrument (particularly rotating system, to detect any sign of distortion. When the instruments are part of a complex unit, check proper assembly with corresponding components. |
| Packaging : | <p>Single packaging : Instrument can be stored in plastic bags but take care that the bag is large enough to contain the instrument and <u>not</u> <u>hermetically sealed</u>.</p> <p>In instrument sets, the instruments may be placed in a special instrument holder or in ordinary sterilisation trays. Make sure that cutting or sharp edges are protected.</p> |
| Sterilization : | Vacuum autoclaving, 18min at 134°C. <u>WARNING : sterilization of wet instruments can generate stains or marblings on its surface.</u> |
| Storage : | <u>Do not store instruments close to corrosive products (oxygen or acid)</u> |