INSTRUCTIONS FOR USE: CRANIAL HALO, GARDNER-WELLS TRACTOR, BRACES

1. DESCRIPTION

Cranial halo: It is composed of an halo hoop fixed to the skull with 4 or 5 pins. In particular case of a very young child, the surgeon could use 8 pins. It can be combined with traction cradles or a thoracic contention device.

Gardner-Wells tractor: It is made of a traction arc pinned to the skull with two pins.

External braces: They have a certain number of standards parts: pins, some joints, some ball-and-socket hafts, some union and sliding rods. The mobility of the rods inside the ball-and-socket joint enables adaptation of the brace to most anatomical situations.

The cranial halo and Gardner tractor are indicated in the context of spinal pathologies which are traumatic, infectious or degenerative but also to correct spinal curvatures.

For the Pins and the wires Do not reuse.

Other elements are reusable. The constituent material is indicated on the label.

CE labelling since 1998 :

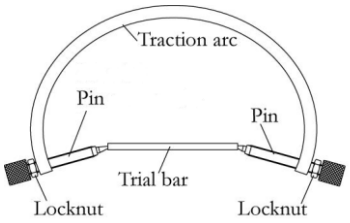
*Non implantable components: CE * Pins and wires : CE 0120

For custom-made products, our company conforms to the requirements of the additional clause VIII of the Directive 93/42/CEE.

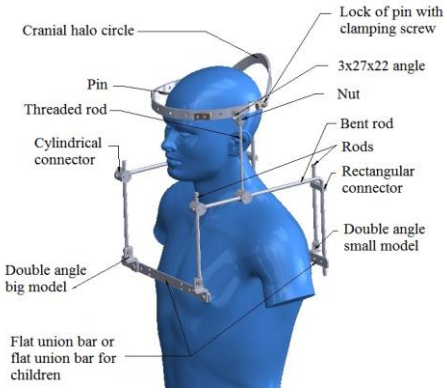
2. ASSEMBLY

Do not assemble elements of devices from diverse origins. Use only components produced by our company. If not, we can not be held responsible. Titanium pieces are not compatible with the stainless steel pieces and conversely.

Gardner-Wells tractor's assembling drawing :



Example of a cranial halo assembling :



3. MAIN INDICATIONS

Halo and Tractor: Spinal fractures and luxations, fusions, spinal deformations, scolioses, tumors, rheumatoid arthritis.

Braces: Fractures, loss of bone substance, arthrodeses, osteotomies, persistent calluses, pseudoarthroses, elongations, osseous malformations, resumption of previous interventions.

4. COUNTER-INDICATIONS

Genito-urinary pathology, occipito-atlantoidienne luxation, osseous mineral deficiency which could affect the device fixing, disease of the skin, sensitivity to the material.

Severe neurological, vascular or muscular deficiencies, which affect the concerned extremity.

5. SIDE-EFFECTS AND POSSIBLE COMPLICATIONS

The patient should be informed of the limits and danger inherent in the placing of the devices mentioned above. Some complications may lead to a change in the pins, wires, or to ablation of the device.

- Pains, rigidity,
- Neurological problems,
- Cutaneous problems (scabs, necroses, post-operative scars), allergies, internal or external infections,
- Bone lysis, pseudarthroses, slowed consolidation, persistent calluses,
- Mechanical complications : material ruptures, dismantling,
- Thrombosis, cardio-vascular disorders,
- Deformation of the skull, penetration of the pins at the internal table, vertebral subluxations, intracranial hypertension, desarthrodeses.

6. INSTRUCTIONS FOR GENERAL USE

- Operative planning: The choice of the device to implant must be made according to the morphology and pathology of the patient.

- Operative technique:The device must be set with the ancillary material provided for this.

See "rachis" section of our website www.medicalex.info

The hair and the pins have to be cleaned with an anti-septic aerosol. The penetration point of the pins is marked on the vertical axis of the external auditory canal, at the temporal crest. At each penetration point, local anesthesia is injected. After a few moments, the tractor is applied with or withoutskin incision. Then, the tractor is moved back and forth to stabilize the pins in the skull.

: Attention

- Check that the product corresponds to the indications on the packaging.
- Follow required asepsis directions when removing from packaging.
- Proceed with a visual exam of the pins and wires in order to detect potential deteriorations. In case of visible defects (i.e.: bent pin points or wires), implants must not be used.
- In case of corrective actions on devices, our company can not be held responsible.
- Do not apply the pins on fragile parts of the skull.
- The device must be set by a surgeon who has acquired the necessary training.
- Do not ever re-use pins or wires which have been already used.

7. POSTOPERATIVE PRECAUTIONS

- Perform a radiological surveillance whose periodicity and protocol will be defined by the surgeon.
- Perform a neurological surveillance. (eyes mobility, swallowing, lingual movements)
- Perform a local surveillance at the penetration points of the pins and/or of the wires, in particular by a daily dinsinfection.
- Check regularly that the pins are well-tightened,
- Perform an orthopaedic surveillance, especially for rigid fixations,
- In cases of halo-casts, when the patient is lying down, the halo must not lean on the bed.
- It's up to the surgeon to define the patient's activity.

8. ABLATION OF THE MATERIAL

It's up to the surgeon to make the final decision in regards to the ablation of the device.

9. INTERFERENCES WITH OTHER EXAMS OR MEDICAL TREATMENTS

The presence of stainless steel generates artefacts around the material. Take it in consideration during medical imaging exams.

10. HANDLING-STORAGE

Some products have sharp components that could injure the handler.

: Fragile, handle with care.

10. STERILITY

All the material is sold not sterile, with the exception of the pins which can be be sold sterile or not sterile.

11.1 Products delivered sterile:

Re-sterilization of products delivered sterile by our compagny may cause risks of infection and/or cross-contamination.

11.2 Products delivered non-steri : Non-sterile

This chapter is intended to provide the instructions for the treatment of non-sterile implants. All Francemed's implants received non-sterile, must imperatively, be decontaminated, cleaned and sterilized before use by the healthcare establishment, in accordance with current regulations.

Francemed has validated the effectiveness of the procedures indicated in this instruction. Material, operators, cleaning agents and procedures contribute to the effectiveness of the treatment. The healthcare establishment must ensure that the selected treatment step are safe and effective.

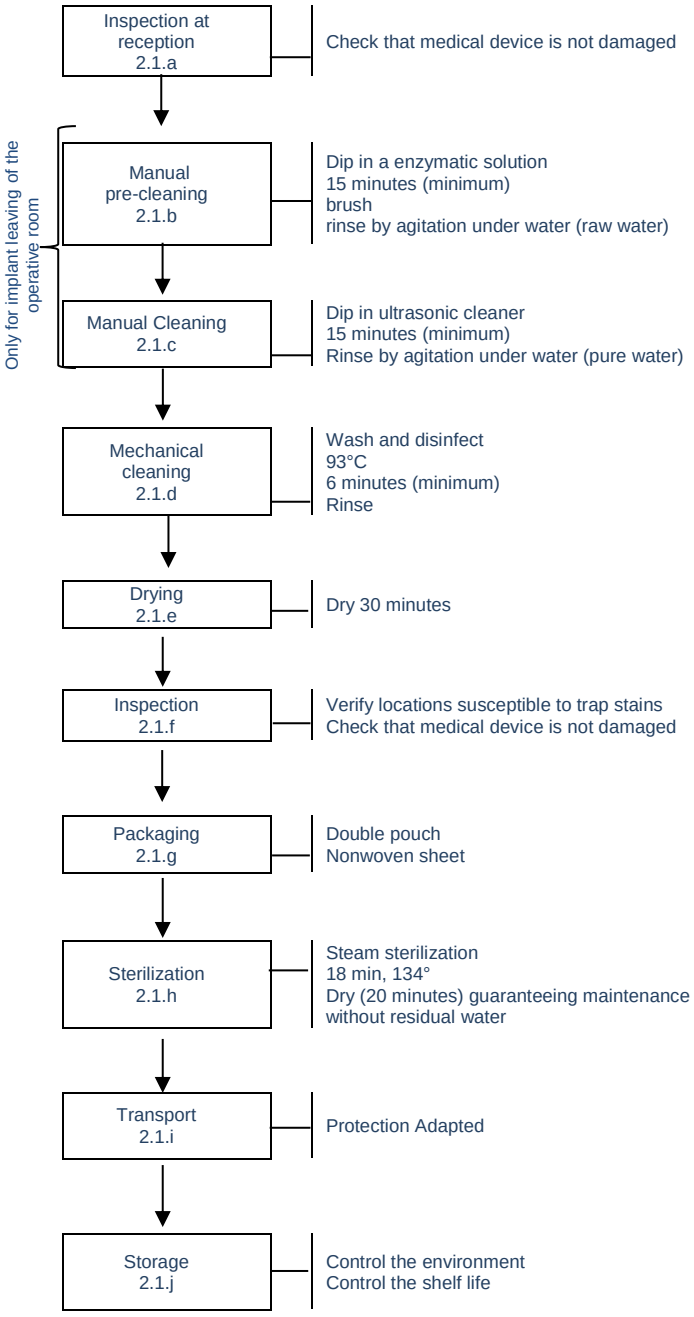
Other methods of treatment not described herein may also be suitable; However, they must be validated by the final user. In case of conflict, national regulations on cleaning and sterilization prevail over Francemed recommendations.

11.2.1. Advertising and precaution

Single use devices must not be reused. Mechanical, physical or chemical characteristics of certain devices may be altered if they are repeatedly cleaned and sterilized, thereby compromising the integrity of the structure and / or material of the device and, hence, the safety, performance and / or compliance with current standards. All implants are for single use.

10.2.1. Processing instructions for preparing new devices for use

Francemed recommend a mechanical cleaning, using a washer-disinfector compliant to standard EN ISO 15883-1. However, a manual cleaning can be realized in case of leaving of the operative room of an unused implant.



Use only specific detergent designed for cleaning or disinfection of medical devices.
The instruction provides by the detergent's manufacturer about concentration and temperature need to be respected. In case of excess concentration and temperatures, a discoloration or a corrosion can be appears on certain devices. This can be observed too, in case of an insufficient rinsing, after cleaning and/or disinfection.
Use only specific product, formulated for cleaning or disinfection of medical devices.

10.2.2. Inspection at reception
Control the totality of the packaging and the labelling before opening. All device damaged must be eliminated. Remove the device from packaging. All implants need to be cleaned, disinfected and sterilized before surgery.

10.2.3. Pre-cleaning
Dip implants in an enzymatic solution (alkaline or neutral pH) formulated to surgical implants (for example, ANIOSYME PLA II- 0,5%), during 15minutes at room temperature. Follow the detergent's manufacturer recommendations about dilution, temperatures and duration of soaking. Check that all surfaces of the implant are in contact with the solution and there is not air in the corners or drilling of the implant.
Use a brush with soft-haired to clean implant by insisting on the rough zones, the corners and the drillings.
Rinse the device by agitation under water (raw water).
Achieve a visual inspection to ensure that all soil are eliminated, if necessary, repeat the previous step.

10.2.4. Manual cleaning : Ultrasonic cleaners
Prepare an ultrasonic bath with a cleaning solution (raw water + detergent without aldehyde; alkaline or neutral pH, for example NEODISHER MEDICLEAN between 0.5% and 2%) formulated for surgical implants. Respect detergent's manufacturer's instructions about concentration, temperatures and duration of soaking. Dip implants in the bath and activate it for at least 15minutes. Rinse abundantly with pure water until there is no trace of detergent solution. In case of, some traces appears, repeat previous step.

10.2.5./7. Mechanical cleaning :
washer-disinfector (according to standard ISO 15883) and drying
Mechanical Cleaning process establish by Francemed, is mentioned in following table:

Step	Product type	Time by step	Temperature	Water
Pre-cleaning	water	2 minutes	Room temperature	Raw water
cleaning	Alkaline detergent with surfactant	3 minutes	55°C	Raw water
Rinsing	water	2 minutes	Room temperature	demineralized water
thermic disinfection	Liquid of rinsing for the mechanical treatment	6 minutes	93°C	demineralized water
dry	/	30 minutes	Air : 110°C (min)	/
cooling	/	5 minutes	Air : 30°C	/

Use an alkaline or neutral product (pH : 6.0-8.5, for example NEODISHER MEDICLEAN at 0.2-1%).
Follow the manufacturer's instruction about dilution, temperature and duration of soaking.
In case of inssufisant drying, dry the implant with a blower (medical air).

11.2.8. Inspection
Before sterilization, a visual inspection need to be realized. All part of the device need to be inspected to verify that all soil's traces are cleaned. Do not use damaged implants.
Be careful with implants' corners capable to keep soils.

11.2.9. Packaging (according to standard ISO 17665-1, 17775 and 11607-1)
It is essential to correctly dry the implant before package it for sterilization and storage. If an implant is wet when packaged, it is possible that after sterilization, it still wet and consequently, compromise the sterilization.
Put the implant in an adequate autoclave sheath or bag to the sterilization method use. Follow the loading instructions of the implant, provide by the sterilizer's manufacturer.

11.2.10 Sterilization
The steam sterilization is the reference sterilization and recommend for Francemed implants.
Consult sterilization parameters table, recommended and validated by Francemed:

Method	Steam sterilization according to standard ISO 17665
Cycle	Vapor saturated with split elimination forced of the air
Temperature	134°
Exposure time	18 minutes (minimum)
Drying time	20 minutes (minimum)

Multiple sterilizations at steam sterilization had minimal effects on devices if it is not use. However, devices need to be inspected systematically. All devices which present corrosion, scratches, notches, residues, fragments or a change of color must be eliminated.

11.2.11 Transport
To prevent damage of the device during the transport, the use of a locker, tray, or rigid containers is encouraged.

11.2.12 Storage before using:
After sterilization, implant need to be storage in sterilization package, in a place dry and exempt from dust. The shelf time depend to sterile barrier use, storage method, environmental and manipulation condition and manipulation. A maximum shelf life before use should be defined for sterilized implants by each health care facility.

12. MEANING OF THE SYMBOLS

REF	Catalog reference		Manufacturer		Consult precautions for use
LOT	Batch's number		Date of manufacture		Limit date for use

For additional information, please contact us or your dealer or consult the videos and documentation available at our website www.medicalex.info