

INSTRUCTIONS FOR USE: STAINLESS STEEL PECTUS EXCAVATUM

1. DESCRIPTION AND ASSEMBLY

These products have been CE 1639 approved since May 2007:

With respect to customised devices, our company complies with the requirements of Annex VIII of Directives 93/42/EEC and 2007/47/EC. STAINLESS STEEL PECTUS EXCAVATUM BARS are made in 316L stainless steel bar according to ISO 5832-1. They are in the form of bars of 230 to 410 mm. The thickness of the bar is 3mm. They are fixed using ϕ 1,2 radiopaque cerclage wire (malleable wire in 316L stainless steel) (Ref: 33.360.12).

2. MAJOR INDICATIONS

- CERCLAGE WIRE: for fixation of the bar to ribs.
- STAINLESS STEEL PECTUS EXCAVATUM BAR: is used during repair of pectus excavatum (minimally invasive technique, Nuss type) in young patients 5 to 22 years.

It can be used in case of heart surgery combined with pectus excavatum repair.

The purpose of pectus excavatum repair is mainly cosmetic and let to reduce the psychological suffering of patients. Moreover, the procedure also corrects the functional cardiocirculatory disorders associated with this deformation.

3. CONTRA-INDICATIONS

- Severe chronic infections, local or systemic or any infection that could compromise the function of the implant
- Sensitivity and/or allergy to materials. Allergies testing (sensitivity disc) are available to detect any stainless steel allergies (ref: 36.420.00).
- Destruction or demineralization of bone, prior implantation or all concomitant diseases which may affect the fixation of the implant and/or the success of the intervention.
- Compromised vascularity that would inhibit adequate blood supply to the operative site.
- Inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures of physiological performance.
- Severe neuromuscular, vascular or mental disorder that could create an unacceptable risk of fixation failure or complications in post-operative care.
- Overweight, osteoporosis, other medical or surgical conditions which would preclude the potential benefit of surgery.
- Antecedents of cardiothoracic surgery generators of hazardous parietal adhesions.
- Deep symmetrical shapes with a distance between the spine and the sternum <30mm.
- Important asymmetric shapes with a rotation angle sternal > 30°.

4. ADVERSE EFFECTS AND POSSIBLE COMPLICATIONS

The patient must be warned of the limitations and risks inherent to the placing of the implant. Some complications can require revision surgery.

- Early and late infections, hematomas, allergies, skin necrosis, osteonecrosis or bone resorption, neurological complications (it is advisable to do clinical or electrical monitoring: wake-up test), pain, bone resorption and bone fractures, mechanical complications (unscrewing, rupture of the implant...).
- Cardiovascular disorders, thrombosis.
- The efficiency of cardiac massage has never been evaluated in a stainless steel pectus excavatum bar wearer. However, cardiopulmonary resuscitation manoeuvres can be performed on patients who have undergone Pectus Excavatum surgery. More exertional force may be necessary due to the surgical plate.

Defibrillation for cardiac arrhythmias may be performed. Anterior/posterior paddle placement is necessary to deliver adequate electric charge.

5. GENERAL INSTRUCTIONS FOR USE

- Pre-operative planning:

STANDARD IMPLANTS: The choice of the implant (dimensions) to be used depends on morphology. Please contact us regarding customised implants.

- Surgical technique:

The bar shall be attached under the sternum with ϕ 1,2 strapping wire of stainless steel radiopaque. The flared portion of the bar allows use without stabilizer. It is therefore a less traumatic bar with stabilizer. The design of the bar is low profile.

Implants should be placed with ancillary material provided for this purpose.

They take advantage of the flexibility of the chest in young patients between the ages of 5 and 22. The more the subject is younger and more the cartilage area is important. They're playing on the elasticity of the thorax in growth; the sternum will be repositioned in force in the extension of both hemithorax by lifting it by a retrosternal bar.

For additional information, please consult the videos and documentation available at our website www.medicalex.info.

We suggest to read the bibliography above:

- M. Brunier, J.-L. Jouve, "Correction chirurgicale mini-invasive du pectus excavatum de l'enfant et de l'adolescent : résultats d'une étude bicentrique à propos de 100 cas", Revue de chirurgie orthopédique et traumatologique, 2013.
- P. Kabdjaj, J.-L. Jouve, "Pectus excavatum: contre-indication à la technique de Nuss chez l'enfant et alternative thérapeutique", Revue de chirurgie orthopédique et traumatologique, 2012.
- J.-L. Jouve, "Correction du pectus excavatum de l'enfant et de l'adolescent par la technique de Nuss," Cahiers d'enseignement de la SOFCOT, vol. 99, pp. 385-405, 2010.
- J.-L. Jouve, "Traitement du thorax en entonnoir de l'enfant par voie mini-invasive," e-mémoires de l'Académie Nationale de Chirurgie, vol. 9, no. 1, pp. 09-11, 2010.
- E. Felts, J.-L. Jouve, B. Blondel, F. Launay, F. Lacroix, and G. Bolliani, "Child pectus excavatum: correction by minimally invasive surgery," Orthopaedics traumatology, surgery & research : OTSR, vol. 95, no. 3, pp. 190-5, May 2009.



Warning

- Ensure that the implant corresponds to the indications appearing on the packaging.
- Perform a visual inspection of the implant to detect any possible damage (scratches, pitting, etc.). Avoid any contact with instruments that could alter the surface. In the event of a visible defect, do not use the implant.
- Our company cannot be held liable for any corrective modifications made to implants.
- Improper positioning of implant could result in its failure. Implants should therefore be placed only by a surgeon with the necessary training.
- Do not use implants as test devices.
- Throw implants and waste away when they come into contact with patients in accordance with current regulations.



Do not use if the packaging is damaged



Do not reuse

6. POST-OPERATORY PRECAUTIONS

Advise the patient of precautions to be followed as part of post-operative development:

- Perform radiological follow-up (frequency and protocol determined by surgeon).
 - Proceed with timely and effective treatment of any infection (nearby cutaneous, urinary, bronchopulmonary, dental, etc.), even benign, because of the risk of haematogenous contamination.
 - Be attentive to any signs of pain.
 - Consult our company in case of revision surgery.
- The surgeon is entitled to allow free movement of the patient and to define any limits on patient activity after implantation. However, excessive activity involving the thorax is discouraged.
- The patient must carry with him the card for patients wearing a thoracic device, which is provided with the device.

7. ABLATION OF DEVICE

The surgeon makes the final decision concerning ablation of an implant. Generally, the bar is removed 2 to 3 years after its implantation. The removal of the bar is done using the removing bender which allows renewing a flat shape to the implant to facilitate extraction and allows an easy and a safe removal operation.

8. INTERFERENCE WITH OTHER MEDICAL EXAMINATIONS OR TREATMENTS

The presence of stainless steel in the implant generates artefacts in the immediate vicinity of the device. This must be taken into account in relation to medical imaging tests.

9. HANDLING-STORAGE

The packaging of products delivered sterile is not to be opened until time of use. Store products in their packaging.

Fragile, handle with care.

10. STERILITY

10.1 Products delivered sterile: Sterilized by irradiation

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

10.2 Products delivered non-sterile: Non-sterile

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

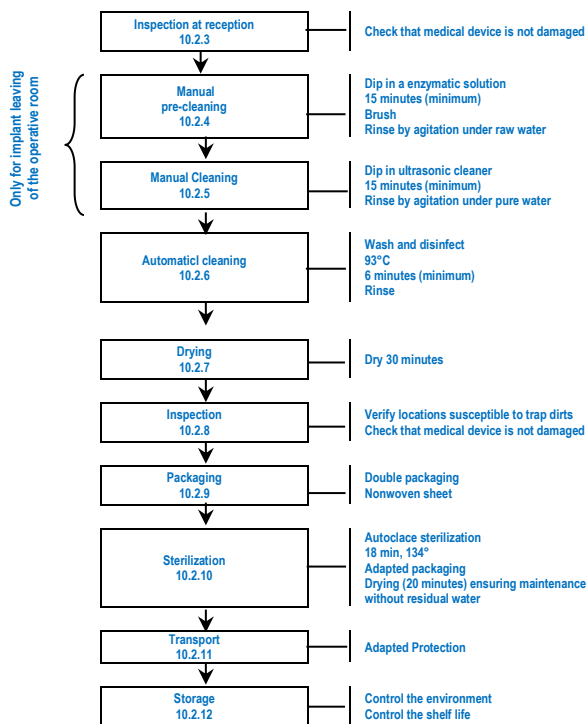
Medicalex has validated the effectiveness of the procedures indicated in this instruction. These processes have been tested 5 consecutive times. Thus, the single use implants can be sterilized a maximum of 5 times. Material, operators, cleaning agents and procedures contribute to the effectiveness of the treatment. The healthcare establishment must ensure that the selected treatment steps 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 Medicalex recommendations.

10.2.1 Warning and precautions

- 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.

10.2.2 Processing instructions for preparing new devices for use

Medicalex recommend an automatic cleaning, using a washer-disinfector compliant to standard EN ISO 1583-1. However, a manual cleaning can be realized in case of leaving of the operative room of an unused implant.



The instruction provided by the detergent's manufacturer about concentration and temperature need to be respected. In case of excess concentration and temperatures, a discoloration or corrosion can be appearing on certain materials. This can be observed too, in case of an insufficient rinsing, after cleaning and/or disinfection. Use only cleaning agents and / or disinfectants specially formulated for cleaning or disinfecting medical devices.

10.2.3 Inspection at reception

Check the entire packaging and labeling before opening it. Remove all products from their packaging. All damaged implants must be removed. All implants must be cleaned, decontaminated and sterilized before use in surgery.

10.2.4 Pre-cleaning

Dip implants in an enzymatic solution (alkaline or neutral pH) formulated to surgical implants (for example, ANIOSYME PLA II, 0.5%), during at least 15 minutes 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 soft bristle brush to clean the implant, paying particular attention to rough areas, recesses and holes. Rinse the device by shaking under the water level (raw water)

Achieve a visual inspection to ensure that all dirt is eliminated, if necessary, repeat the previous step.

10.2.5 Manual cleaning: Ultrasonic cleaners

Dip implants in 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 15 minutes. Rinse abundantly with pure water until there is no trace of detergent solution. If some traces appear, repeat previous step.

10.2.6/7 Automatic cleaning: washer-disinfector

Automatic Cleaning process establish by Medicalex, 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 automatic treatment	6 minutes	93°C	demineralized water
dry	/	30 minutes	Air: 110°C (min)	/
cooling	/	5 minutes	Air: 30°C	/

An alkaline or neutral cleaning product (pH: 6.0-8.5, for example NEODISHER MEDICLEAN at 0.2-1%) must be used.

Follow the manufacturer's instruction about dilution, temperature and duration of soaking. In case of insufficient drying, dry the implant with a blower (medical air).

10.2.8 Inspection

Before sterilization, a visual inspection must be carried out. All parts of the devices must be inspected to verify that all traces of contamination have disappeared. Do not use any damaged implant. Pay particular attention to the recesses of implants likely to maintain dirt.

10.2.9 Packaging

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.

10.2.10 Sterilization

The steam sterilization is the reference sterilization and recommend for Medicalex implants.

Consult sterilization parameters table, recommended and validated by Medicalex:

Method	Steam sterilization according to standard ISO 17665
Cycle	Vapor saturated with spilt elimination forced of the air
Temperature	134°C
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. This cleaning and sterilization process can be done only 5 times.

10.2.11 Transport

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

10.2.12 Storage before using:

After sterilization, implant need to be storage in the sterilization package, in a place dry and exempt from dust. The shelf life depends on the sterile barrier used, the method of storage, environmental conditions and handling. A maximum shelf life before use must be defined for implants sterilized by each healthcare facility.

11. MEANING OF THE SYMBOLS

REF	Catalogue reference	Manufacturer	Consult precautions for use
LOT	Batch number	Date of manufacture	Limit date of use

For additional information, please contact us or your dealer and consult the videos and documentation available at our website www.medicalex.info. Francmed can provide the instructions for use at no additional cost at the latest within 7 calendar days of receiving a request.