

INSTRUCTIONS FOR USE: PR WURTZ TITANIUM PECTUS EXCAVATUM PLATE

1. DESCRIPTION AND ASSEMBLY

The titanium pectus excavatum plate has been CE 1439 approved since June 2009. With respect to customised devices, our company complies with the requirements of Annex VIII of Directives 93/42/EEC and 2007/47/EC and annex XIII of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. Titanium pectus excavatum plates are made in titanium TA6V according to the ISO 5832-3 standard. They are in the form of plates 160 mm to 280 mm in length, and 2 mm thick. They are fixed transversely to the caudal part of the sternum by means of X-shaped absorbable suture (monofil PDS II N°1 or braided Vicryl N°1, Ethicon).

2. MAJOR INDICATIONS

TITANIUM PECTUS EXCAVATUM PLATE: is used during open surgical repair of pectus excavatum (Ravitch-type repair) in patients at the end of the adolescent growth spurt, and with no upper age limit. It can be used in case of heart surgery combined with pectus excavatum repair.

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

These plates are used for stabilize the chest wall after sternochondroplasty in the treatment of pectus excavatum for Male or female, adult or adolescent at the growth end.

The designation and the constituent material of the implant, indicated on the label, specify the recommended use for the implant.

3. CONTRA-INDICATIONS

- Severe chronic infections, local or systemic or any infection that could compromise the function the implant
- Sensitivity and/or allergy to materials. Allergies testing (sensitivity disc) are available to detect any titanium allergies (ref: 36.421.00).
- 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.
- Severe neuromuscular, vascular or mental disorder which 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.
- These plates are not used in children.

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.
- Cardio-pulmonary resuscitation manoeuvres, notably external cardiac massage, can be performed on patients who have undergone Pectus Excavatum surgery and wearing the titanium chest plate. 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:

After surgical treatment of pectus excavatum through the subperichondrial resection of the elongated hypertrophied cartilages (Ravitch-type repair), the straight titanium plate is passed sublaterally after minimal dissection at the level of the sixth paired perichondrial sheaths. The remaining parts of the plate are extrathoracic, inserted by means of a back and forth movement, laterally anterior to the ribs and behind the muscles. Its length must be chosen to ensure placement with both extremities of the plate close to the subcutaneous tissue.

In the case of asymmetrical deformity, the plate can be set slightly obliquely (radiograph). The plate is then firmly secured to the base of the sternum with an X-shaped absorbable suture (monofil PDS II size1 or braided Vicryl size 1, Ethicon) passed at the level of plate notches designed for this purpose (see drawing). Furthermore, the plate acquires a fibrous sheath that contributes to stability. The suture of perichondrial sheaths allows cartilage regeneration with osseous metaplasia in the proper position within 2 months.

The use of this plate does not require any ancillary material.

For more information, see sales documentation and videos on our website <https://medicalex.info/catalogue/thorax> or <http://www.ctsnet.org/article/simplified-open-repair-pectus-deformities>.

It is also advisable to consult the bibliography below:

- Wurtz A et al. Simplified open repair for anterior chest wall deformities. Analysis of results in 205 patients. Orthop Traumatol Surg Res 2012;98:319-26.
- Benhammed L et al. eComment. Substernal metal support after pectus excavatum open repair. Interact Cardiovasc Thorac Surg 2013;17:1058.
- Brian E et al. Substernal Titanium Support After Pectus Open Repair. Ann Thorac Surg 2016;101:832-3.
- Hysi I et al. Cardiac surgery and repair of pectus deformities: When and how? Int J Cardiol. 2015;194:83-6
- Neviere et al. Cardiopulmonary response following surgical repair of pectus excavatum in adult patients. Eur Cardiothorac Surg. 2011 Aug;40(2):e77-82.

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 the 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.
- Never reuse an implant that has already been implanted
- 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.
 - Pay attention to any signs of pain.
 - Consult our company in the 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. ABOLATION OF DEVICE

Concerning implant removal, the plate is maintained for six months as a precautionary measure. Finally, the device is routinely removed, under local anaesthesia through a 1cm-long lateral incision at one extremity, palpable under the skin, during an outpatient procedure. A small punched hole located at the extremity enables easy extraction of the plate by means of a Kocher's forceps.

See the video on our website www.medicalex.info.

8. INTERFERENCE WITH OTHER MEDICAL EXAMINATIONS OR TREATMENTS

- The presence of titanium in the implant generates artefacts in the immediate vicinity of the device. This must be taken into account in relation to medical imaging tests.
- The effects of the magnetic resonance environment have not been determined for these devices. These devices have not been tested for heating or migration in the magnetic resonance environment.

9. HANDLING-STORAGE

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

Follow the required aseptic precautions when extracting the package.

⚠ : 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.

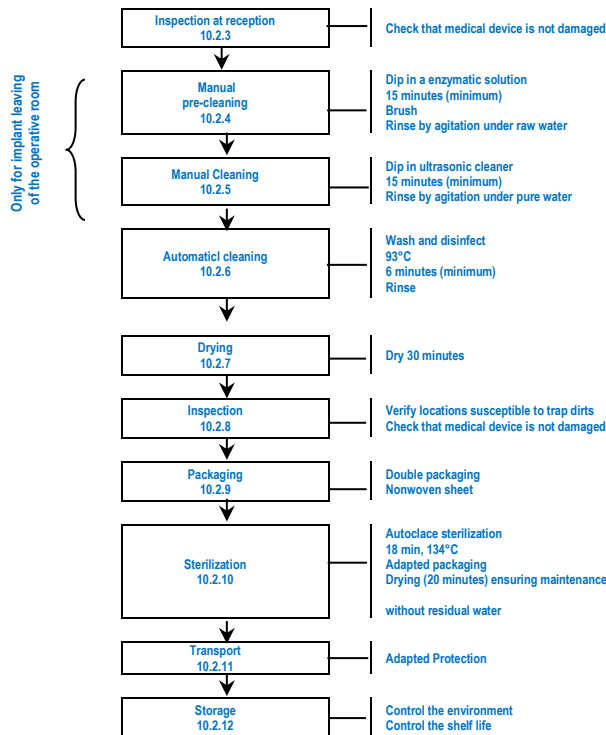
Other methods of treatment not described herein may also be suitable; However, they must be validated by the final user. In case of conflict, national regulations on cleaning and sterilization prevail over Medicalex recommendations.

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 provides 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 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 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

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. 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 split 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

	Catalogue reference		Manufacturer		Consult precautions for use	
	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. Francemed can provide the instructions for use in paper form, at not additional cost, at the latest within 7 calendar days of receiving request.