Pectus UP surgery kit, the solution for Pectus Excavatum

REV. 07/15

Pectus Up Surgery Kit is a set of surgical implants designed as auxiliaries in the treatment of Pectus Excavatum deformity. The whole system offers surgeons a means to redirect bone structures (sternum, cartilages and ribs) exerting a lifting force on the sternum in order to correct thorax deformity. The device should be removed once the change in shape is evident and indefinite. Plate and components are made of AISI 316L steel, except for the power nut, which is made of AISI 440 steel (possible change to Ti6Al4V grade 5)

INDICATIONS

Correction of Pectus Excavatum and similar deformities of the sternum.

CONTRAINDICATIONS

1. Patients with mental or neurological conditions who refuse or are unable to follow surgeon's instructions.

2. Patients showing sensitivity reactions to metals.

3. Patients with insufficient / poor quality of the bone or fibrous tissue, unfit for remodeling.

4. In case of infection

WARNINGS AND PRECAUTIONS

Pectus Up Surgery Kit gives the surgeon a means of treatment for Pectus Excavatum, a congenital deformity often accompanied by shortness of breath in children. The device is not designed to replace the chest wall structures. Although the device is intended to expand the chest cavity and lessen the characteristics of the deformity, it is not possible to determine in advance the amount of structural change that will be noticed initial or permanently in each individual case. The surgeon must have a thorough knowledge of both the implants and the surgical procedure prior to the performing of the surgery.

It is important to properly choose and place the implant. Preoperative planning to identify the size of the implant and its final position is necessary. Surgeon should avoid bending the device in a closed angle. Neither should xiphoid area be punctured, as this would hinder the sufficient screw-xiphoid grip force to allow the lifting process. Although implant is fixed in place mechanically (threaded to the sternum), it is necessary to proceed carefully to ensure that the central hole of the plate is concentric to the hole made in the sternum and that the plate's ends are correctly supported. If not even a partial reduction of the deformity is achieved, it is possible that the use of a second lifting point or the placement for a dual elevator plate or an alternative method of treatment is required. During surgery and implant placement, it is necessary to thread the screw so it does not protrude too much from the sternum. When considering the removal of the device, the surgeon should consider the risks and benefits of implant removal. In the event that the expected changes are observed, the device should be removed. This procedure must have a period of postoperative monitoring in order to detect recurrence of the deformity. If this were the case, secondary or alternative treatments might be necessary.

Surgical implants should never be used more than once. Even if the implant appears to be intact, it may present imperfections, defects or areas of internal wearing, and consequently may fracture or fail in its performance.

WARNINGS TO PATIENTS

Postoperative care and supervision are important. Metal fixing devices are not able to withstand the same activity levels or load levels that a normal healthy chest wall can tolerate. The implant may loosen or displace when subjected to heavy loads, strenuous activity or traumatic injury. The treating surgeon should warn the patient of the need of limiting their activities accordingly. The limitation of physical activity may be specific to each patient, and they should be warned that neglecting postoperative instructions could lead to the complications listed above. Each patient should also be informed and warned about the possibility of the deformity remaining present in its totality or to some extent even after surgery. In addition, the patient should be warned before surgery about the general risks and of possible adverse effects of the procedure, as listed below.

POSSIBLE SIDE EFFECTS

1. Reactions due to metal sensitivity or allergic reaction to the implant material.

2. Pain, discomfort or abnormal sensations due to the presence of the device.

3. Skin irritation and infection.

4. Displacement or loosening of the implant.

5. Incomplete or inadequate correction of deformity or recurrence of it, before or after removal of the implant.

6. Permanent injuries or death.

STERILIZATION

Product is not sterile when supplied.

Before implantation, steam-sterilize Pectus Up Kit components using properly validated steam sterilization equipment. Individual users must validate the cleaning and autoclaving procedures used in situ, including in situ validation of the recommended minimum cycle parameters described below.

STERILIZER SUBJECT TO PREVIOUS VACUUM (HIGH VACUUM)

Wrapped material

Temperature: 132 ° C

Exposure time: 4 minutes

Drying time: 30 minutes MINIMUM

Medical staff has the ultimate responsibility of ensuring that any packaging method or materials, including reusable rigid container systems, are suitable for their use in the sterilization process and preservation of sterile conditions in medical and health facilities.

Testing should be conducted in the health care facility in order to ensure the essential conditions for sterilization. BV Medical Technologies, S.L. is not aware of the utilization methods, sanitary hygiene procedures and/or microbiological population of each hospital. Therefore, we cannot guarantee the sterility of the product, even if these instructions are followed.

CLEANING

1. After use, place the instruments and various pieces in a container with water, mild soap or a specialized cleaning solution.

2. Rinse with tap water for a minimum of two minutes while brushing with a soft bristle brush to remove visible dirt. Clean the interior lumen with a thin wire to remove any remaining residue.

3. Place instruments in an ultrasonic bath containing enzymatic detergent for five minutes. Scrub instruments again with a soft brush and ream inner lumen to remove any remaining residue.

4. Rinse and flush the instruments for one minute with tap water.

5. Visually examine for any remaining bone fragment or debris, scrub as necessary.

MRIs

Not perform Magnetic Resonance Imaging (MRI) of the patient. Possibility of alteration due to Stainless Steel implant.

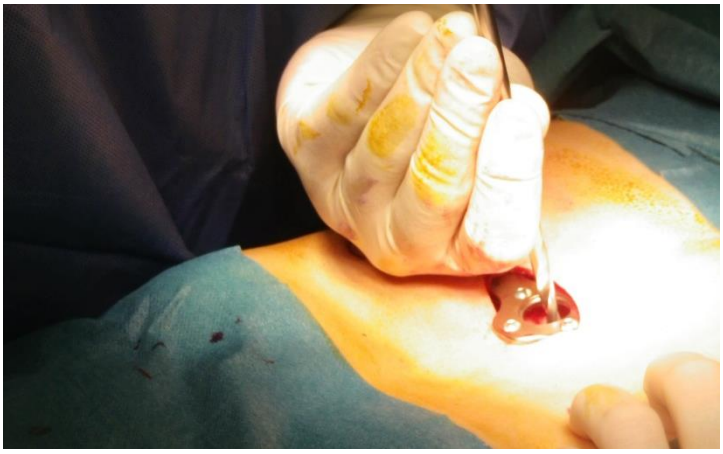
NOTES

1. Operating Surgeons and all personnel involved in handling these products are responsible for acquiring the appropriate knowledge and training within the scope of activities related to the management and usage of this product.

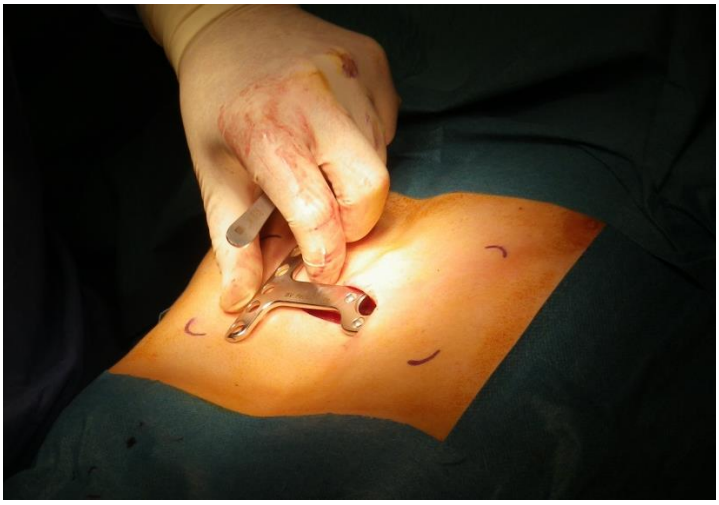
2. Do not remove the implants, surgical instruments or surgical tray from the autoclave until the "drying cycle" is completed.

INSTRUCTIONS FOR USE

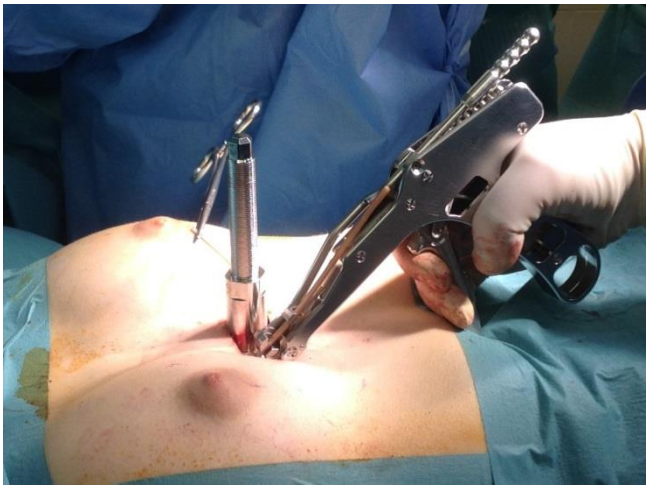
1.- STERNAL DRILLING




2.- PLATE PLACEMENT

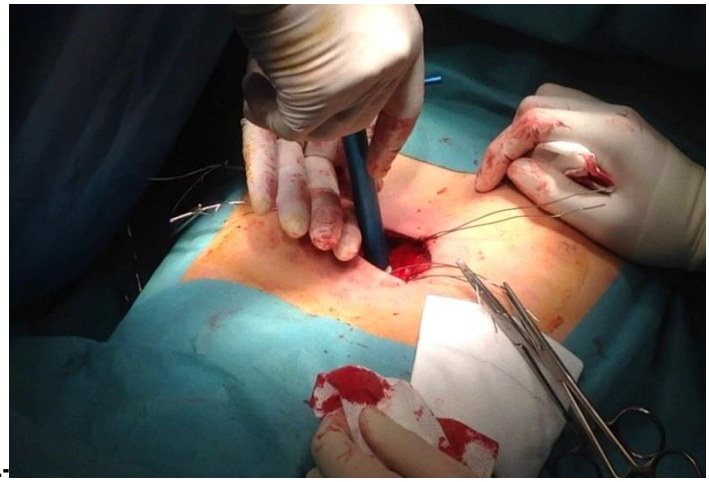



3.- CLAMP AND CLOSING PLACEMENT

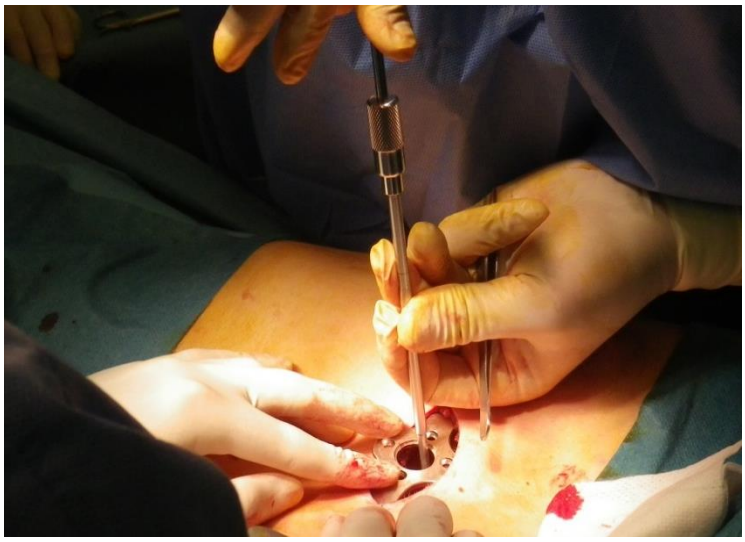



4.- TRACTION SYSTEM INSERTION

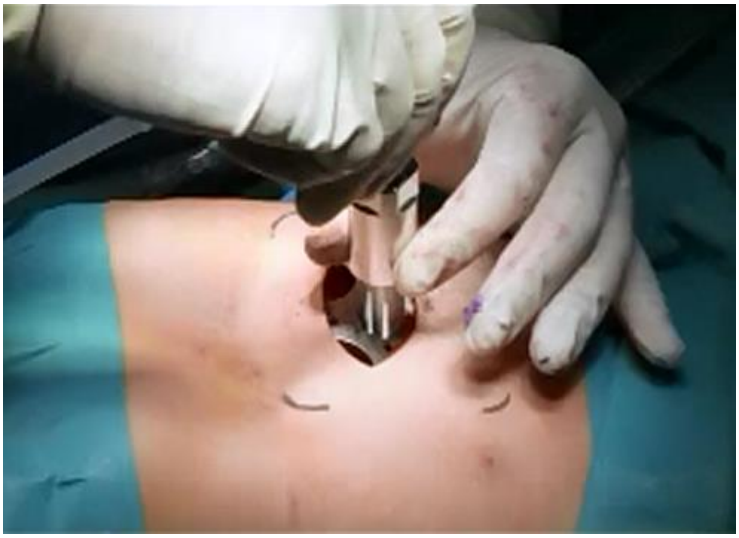
4.A.- ANCHOR INSERTION

.-    

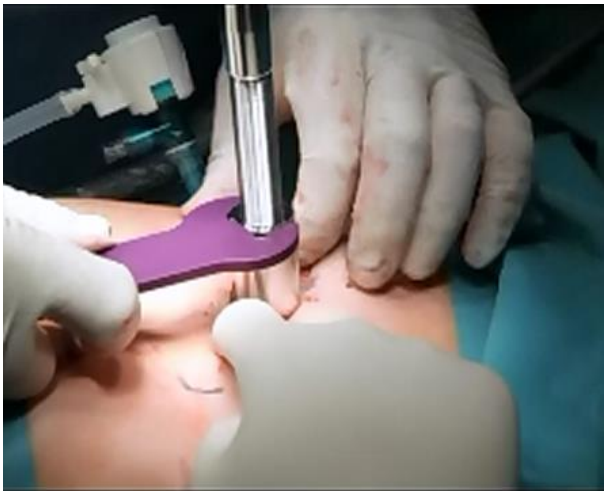
4.B.- DOUBLE-THREADED SCREW INSERTION

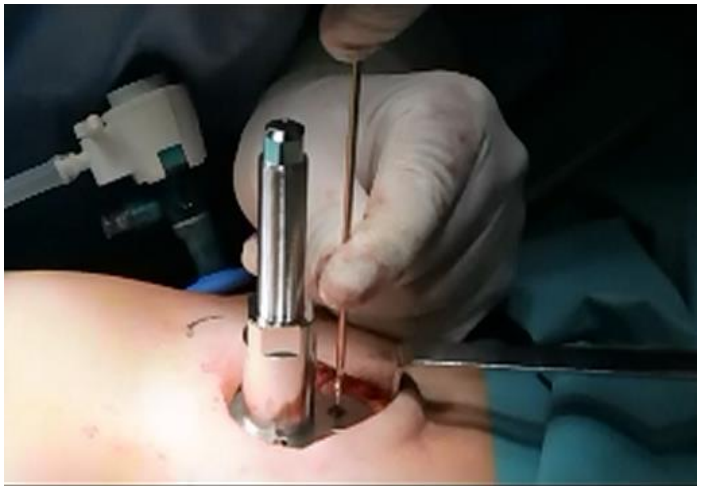
5.- EXTRACTOR SYSTEM CONECTION



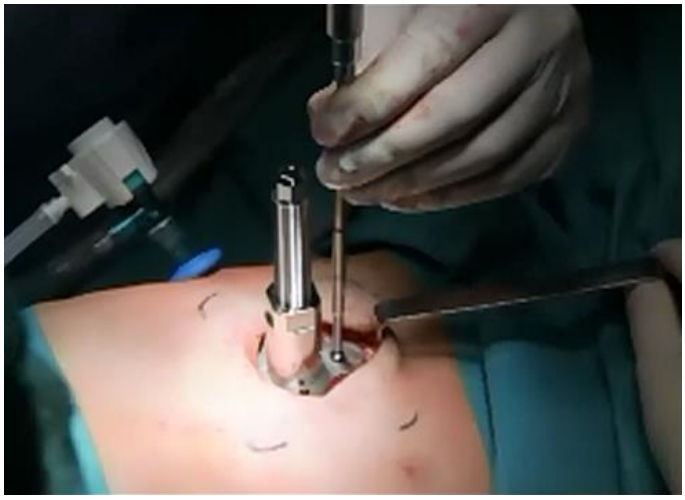
6.- STERNAL ELEVATION



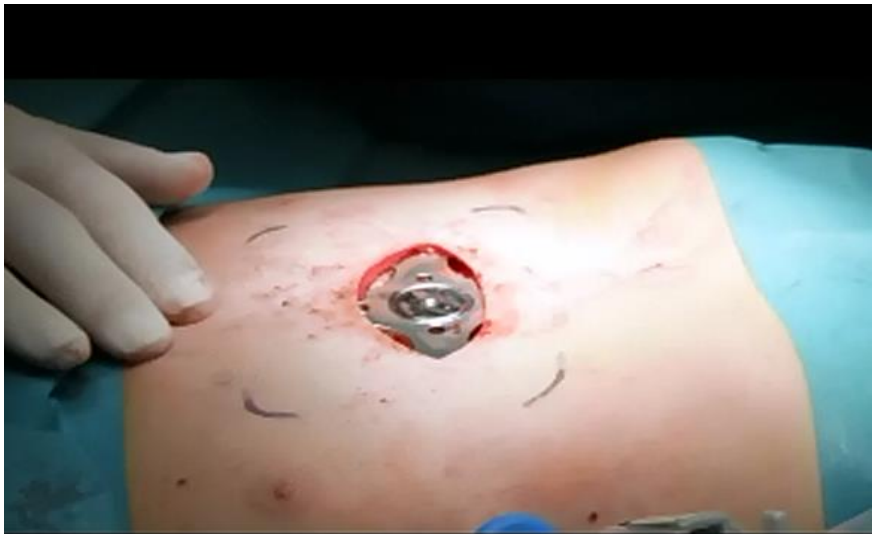
7.- STERNAL DRILLING.



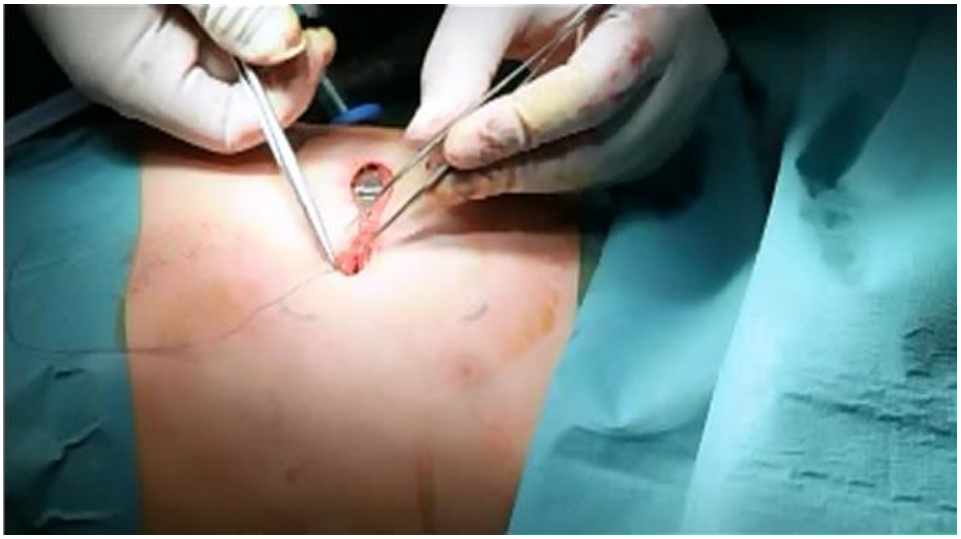

8.- FIXATION OF THE ELEVATED STERNUM.



9.- CAP-SCREW PLACEMENT




10.- CLOSING THE INCISION



A) PROCEDURE WITH ANCHOR SCREW:

The procedural steps of Taulinoplastia's technique, consistent with previous images, are explained below:

1. A horizontal incision is made in the area of maximum depth of pectus excavatum located half of the height of the plate (from 2 to 3 cm). Then a hole is performed by a drill with stop, not exceeding the maximum cm of depth.

2. The surgeon makes a recess which allows the position of the plate.

The plate is placed in this space, with the three holes towards the upper area of the trunk, making the center hole thereof coincides with the hole in the sternum of the patient.

3. Using a rib periosteal elevator, the surgeon *repel* the rib area where the flanges and / or surgical wire that then will wrap the plate by attaching the plate with the ribs.

4.A - Next, the cue system is screwed to the sternum by the hole made in the point 1. First the block (PEEK) is inserted and then the pusher is threaded inside, allowing the expansion of the block and increasing the grip plug-hole.

5. Sternal lift system is installed on the pusher by using a power screw and a nut relevant power.

6. Rotating the threaded power along the screw by using the flat key. It allows that, by supporting it on the plate, a rising sternum occurs while the power screw holds fixed by the pipe wrench.

7. Once the sternum rose to the raised position, making holes by following the central plate holes to accommodate screws.

8. Fastening screws are placed. Flanges and / or surgical wire are tightened creating the fastening system.

9. The lift system and taco system are removed. The surgeon places in the sternum a screw hole / stopper will close the system.

10. The suture of the initial incision is performed.

B) PROCEDURE WITH DOUBLE-THREADED SCREW:

The procedural steps of Taulinoplastia's technique, consistent with previous images, are explained below:

1. A horizontal incision is made in the area of maximum depth of pectus excavatum located half of the height of the plate (from 2 to 3 cm). Then a hole is performed by a drill with stop, not exceeding the maximum cm of depth.

2. The surgeon makes a recess which allows the position of the plate.

The plate is placed in this space, with the three holes towards the upper area of the trunk, making the center hole thereof coincides with the hole in the sternum of the patient.

3. Using a rib periosteal elevator, the surgeon *repel* the rib area where the flanges and / or surgical wire that then will wrap the plate by attaching the plate with the ribs.

4.B.-Then, double threaded pin is inserted into the sternum by the hole made in point 1.

5. Sternal lift system is installed on the pusher by using a power screw and a nut relevant power.

6. Rotating the threaded power along the screw by using the flat key. It allows that, by supporting it on the plate, a rising sternum occurs while the power screw holds fixed by the pipe wrench.

7. Once the sternum rose to the raised position, making holes by following the central plate holes to accommodate screws.

8. Fastening screws are placed. Flanges and / or surgical wire are tightened creating the fastening system.

9. The lift system and taco system are removed. The surgeon places in the sternum a screw hole / stopper will close the system.

10. The suture of the initial incision is performed.

SYMBOLS USED IN LABELING AND INSTRUCTIONS FOR USE

 Manufacturer	 Date of manufacture	 Date of Expiry	 Lote	 Reference	 Non sterile
 Stay out of the sun light	 Stay dry	 Storage temperature limit	 Don't reuse	 Caution: Consult instructions for use	

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