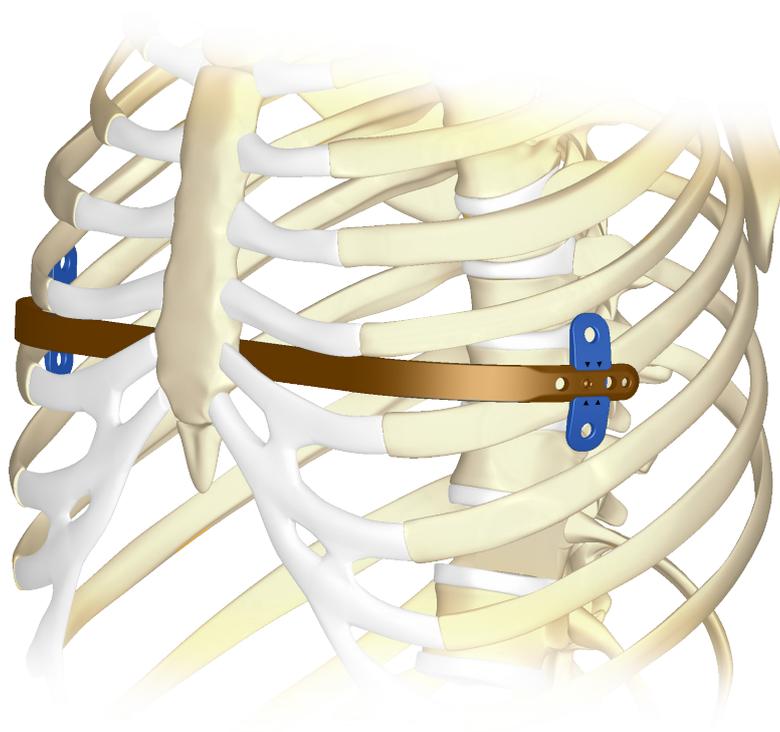


CHM[®]

STERNO-COSTAL PLATE

- *IMPLANTS*
- *INSTRUMENT SET 40.5841.000*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTION



Caution - pay attention to a special procedure.



Perform the activity under X-Ray control.



Information about the next stages of a procedure.



Proceed to the next stage.



Return to the specified stage and repeat the activity.

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*The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu*

I. INTRODUCTION	5
I.1. BACKGROUND INFORMATION	5
I.2. INDICATIONS	5
I.3. CONTRAINDICATIONS	5
I.4. WARNINGS AND PRECAUTIONS	5
II. IMPLANTS	6
III. INSTRUMENT SET	8
IV. SURGICAL TECHNIQUE	9
IV.1. PATIENT POSITION	9
IV.2. SURGICAL APPROACH	9
IV.3. IMPLANT'S SELECTION	9
IV.4. PLATE SHAPING	10
IV.5. TUNNEL PERFORMANCE FOR SEATING OF THE PLATE	10
IV.6. INITIAL CORRECTION OF DEFORMATION	11
IV.7. IMPLANT'S INSERTION	11
IV.8. INITIAL EVALUATION OF CORRECTION	12
IV.9. CROSSWISE PLATE ATTACHMENT	13
IV.10. IMPLANT REMOVAL	13

I. INTRODUCTION

I.1. BACKGROUND INFORMATION

Sterno-Costal Plate is used in the treatment of the funnel chest deformity, so-called pectus excavatum, with use of dr Nuss method (*minimally invasive repair of pectus excavatum – MIRPE*). The method involves insertion of the plate under sternum in order to achieve deformity correction. The procedure is minimally invasive and is associated with reduced operating time and minimal blood loss.

It enables for:

- gaining excellent cosmetic results,
- proper growth of lungs and heart,
- improvement of chest elasticity,
- remarkable breathing improvement.

The average time needed for patient's return to normal activity fluctuates within one month.

I.2. INDICATIONS

Sterno-costal plate is used for treatment of chest deformities, especially the funnel chest (*lat. Pectus Excavatum*). The method of treatment using sterno-costal plate is designed especially for growing children (*when the ribs and costal cartilage are neither too malleable nor too rigid*). Optimal recommended age for reconstruction ranges from 12 to 16 years.

I.3. CONTRAINDICATIONS

Do not use the sterno-costal plate in case of:

- patients with mental illness or neurological disease,
- insufficient bone and fibrous tissue strength,
- infection.

The above list is not exhaustive.

For further information on:



- adverse effects,
- warnings,
- sterilization,
- pre- and post-operative recommendations,

please refer to the Instruction for Use (IFU) for sterno-costal plate, enclosed to the implant package unit.

I.4. WARNINGS AND PRECAUTIONS

The surgeon should avoid bending in sharp curves, reverse bending, and bending the implant at a hole. As a result of inappropriate shaping, size selection, wrong stabilization and fixation and patient's non-compliance with physician recommendations regarding principles of behavior during postoperative period, displacement or rotation of the implant may occur. It may lead in consequence to damage of tissue or organs adjacent to the implant.

During the implantation procedure, extreme caution should be taken to avoid contact of the implant or instruments with heart and lungs, because it may lead in consequences to permanent damage of these organs or in extreme case - death of the patient. After achieving the stable correction of deformity, implant has to be removed. After implant removal patient should be followed by postoperative monitoring to check for reoccurrence of the deformity.

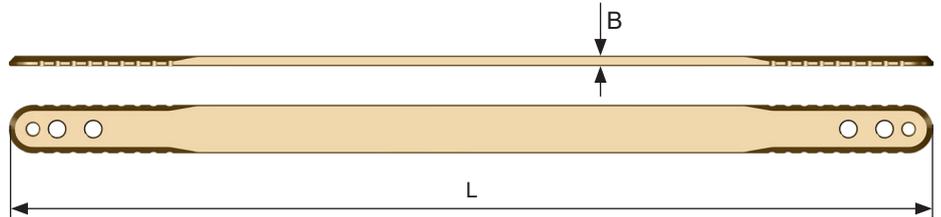


This surgical technique is intended as a guide only. The selection of surgical technique adequate for specific patient remains surgeon's responsibility.
The implantation shall be carried out by the surgeon familiar with adequate rules and operating techniques, and shall acquire practical skills of using ChM instrument set for ChM sterno-costal plate.

II. IMPLANTS

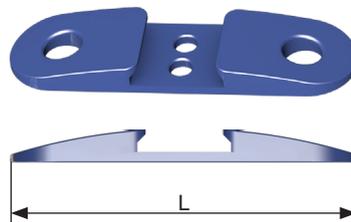
Sterno-costal plate

L [mm]	Titanium	
180	3.6116.180	3.6124.180
205	3.6116.205	3.6124.205
230	3.6116.230	3.6124.230
255	3.6116.255	3.6124.255
280	3.6116.280	3.6124.280
305	3.6116.305	3.6124.305
330	3.6116.330	3.6124.330
355	3.6116.355	3.6124.355
380	3.6116.380	3.6124.380
405	3.6116.405	3.6124.405
430	3.6116.430	3.6124.430



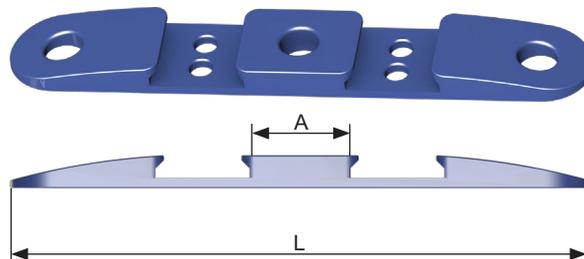
Crosswise plate

L [mm]	Titanium
45	3.6118.045
50	3.6118.050
55	3.6118.055



Dual crosswise plate

L [mm]	A [mm]	Titanium
60	15	3.6119.015
65	20	3.6119.020
70	25	3.6119.025
75	30	3.6119.030
80	35	3.6119.035



The Crosswise plates [3.6118.xxx], [3.6119.xxx] are intended for use with Plate blocker [3.6117.000] only.

Plate-blocker

Titanium
3.6117.000

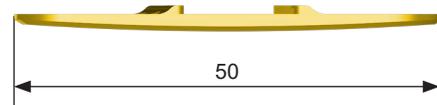
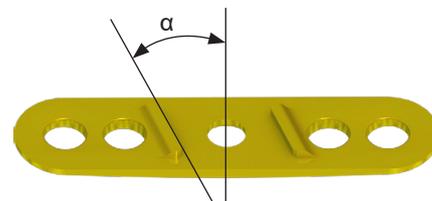
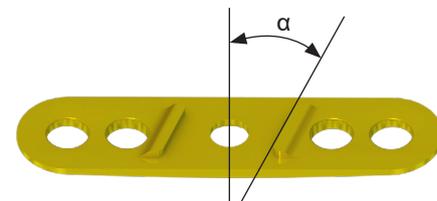
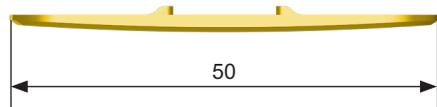


Palette for implants - Sterno-costal plates 40.5843.000



Crosswise plate 0°

Titanium	
3.6114.000	



Crosswise plate

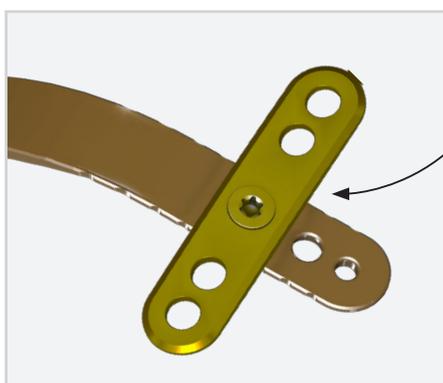
Titanium		
α	left	right
10°	3.6113.010	3.6112.010
20°	3.6113.020	3.6112.020



The Crosswise plates [3.6112.xxx], [3.6113.xxx], [3.6114.xxx] are intended for use with Plate-blocker [3.6115.000] only.

Plate-blocker

Titanium	
3.6115.000	



Palette for implants - Sterno-costal plates 40.5843.500



III. INSTRUMENT SET

40.5841.000

No	Name	Catalogue no.	Pcs
1	 Preparer L=510mm	40.5846.510	1
2	 Bender for plates	40.5848.000	1
3	 Persuader	40.5847.000	1
4	 Persuader	40.5847.100	1
5	 Screwdriver T15	40.5845.000	1
6	Plate trial L=180mm	40.5844.180	1
7	Plate trial L=205mm	40.5844.205	1
8	Plate trial L=230mm	40.5844.230	1
9	Plate trial L=255mm	40.5844.255	1
10	Plate trial L=280mm	40.5844.280	1
11	 Plate trial L=305mm	40.5844.305	1
12	Plate trial L=330mm	40.5844.330	1
13	Plate trial L=355mm	40.5844.355	1
14	Plate trial L=380mm	40.5844.380	1
15	Plate trial L=405mm	40.5844.405	1
16	Plate trial L=430mm	40.5844.430	1
17	Stand	40.5842.000	1
18	 Container solid bottom 1/1 595x275x86mm	12.0750.100	1
19	Lid perforated alu. 1/1 595x275x15mm Grey	12.0750.200	1

IV. SURGICAL TECHNIQUE

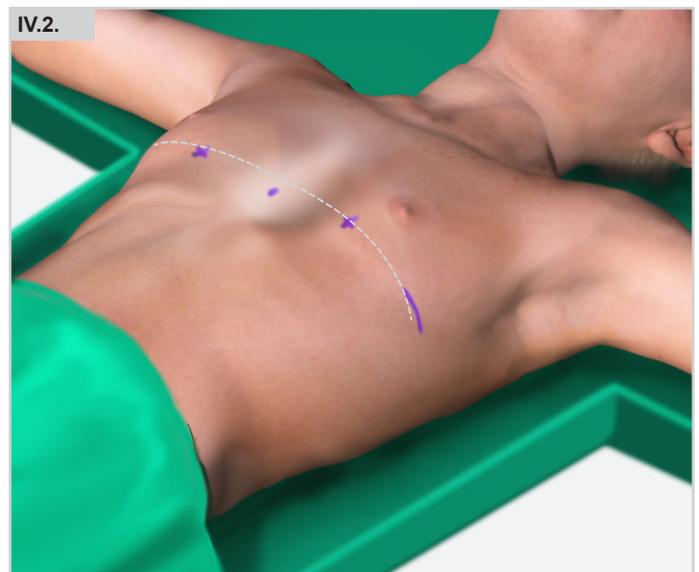
IV.1. PATIENT POSITION

The patient is placed on his back with both arms abducted at the shoulders (*up to angle of 90°*), and the forearms bent to a right angle which allows easy access to the lateral chest wall. Correct positioning of the arms prevent neurological complications.



IV.2. SURGICAL APPROACH

Mark the deepest portion of the chest using a sterile marker (*if the deepest portion of the chest is below the sternum, mark the deepest point on the sternum*). Determine the intercostal space (*on the both side of the chest*) located in line with the point set on sternum (*or passing close to that point*). The entry point (*transverse lateral incision*) is performed on the extension of the drawn line, between anterior axillary line and midaxillary line.



IV.3. IMPLANT'S SELECTION

Because of the numerous types of chest deformation, the selection of the implant (*length*) should be preceded by a proper measurements. The shape and length of the plate is determined by shape of deformation. The appropriate length selection allows to gain suitable plate stability. The measurements has to be taken before the surgery and confirmed during the procedure. A helpful tool during implant selection process be the Plate trial [40.5844.xxx].



NOTE:

The length of required Sterno-costal plate must be smaller than the measured distance because the trial measures the external dimension of the chest and the implant traverses interiorly



IV.4. PLATE SHAPING

Plate shaping has to be made with use of the bender [40.5848.000], suitable for the shape of chest deformity and implant insertion site.



In the case when use of sliding crosswise plates is planned [3.6118] or [3.6119] (*blue color coded*), during shaping of the sterno-costal plate its chamfered ends have to be directed to the outside (IV.4a).

However, in case when use of crosswise plates applied on top surface of the sterno-costal plate is planned [3.6112], [3.6113] or [3.6114] (*gold color coded*), the chamfered ends of the sterno-costal plate have to be directed to the inside when shaping is completed (IV.4b).

NOTE: As a result of acting forces deriving from the sternum and from the pressure present in the chest, the increase of the curvature in the middle of plate might be necessary in order to level the initial deformation of the plate caused by above mentioned forces.

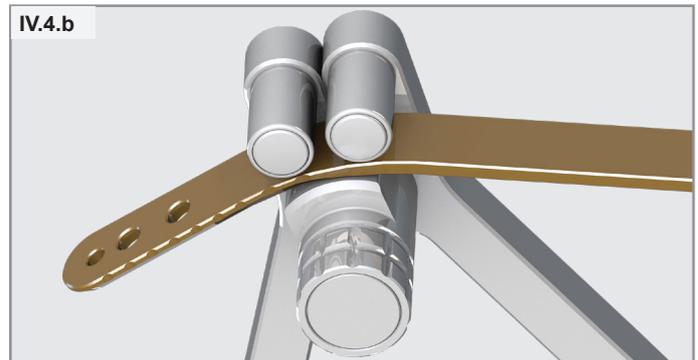
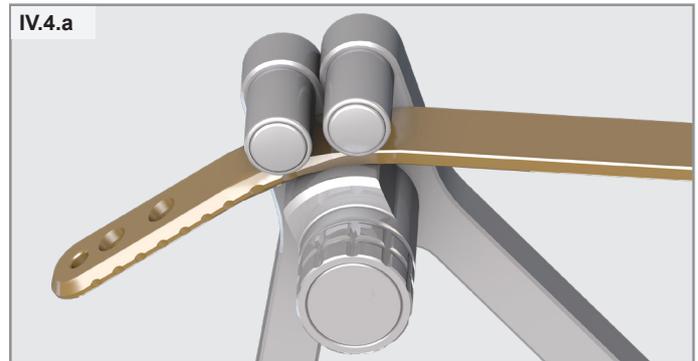
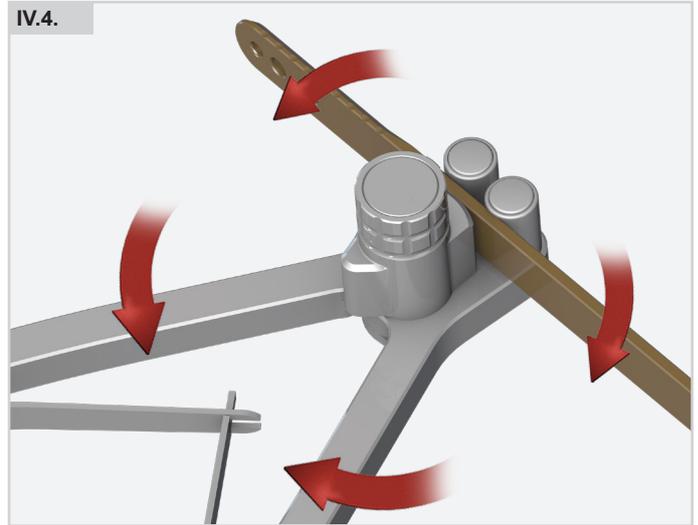
Contouring of Sterno-Costal Plate should only be done with proper equipment.

The operating surgeon should avoid:



- reverse bending of the implant when contouring; reverse bending causes surface defects and internal stresses which may significantly decrease the fatigue life and may result in potential fracture of the implant;
- sharp bending of the implant (bending of a short segment and/or with a small bending radius);
- bending of the implant at a hole.

Do not excessive bend the ends of the plate in portions of the crosswise plates seating and the locking holes. Excessive bending may lead to deformation of the locking thread and/or may cause difficulties with proper seating of the crosswise plates.

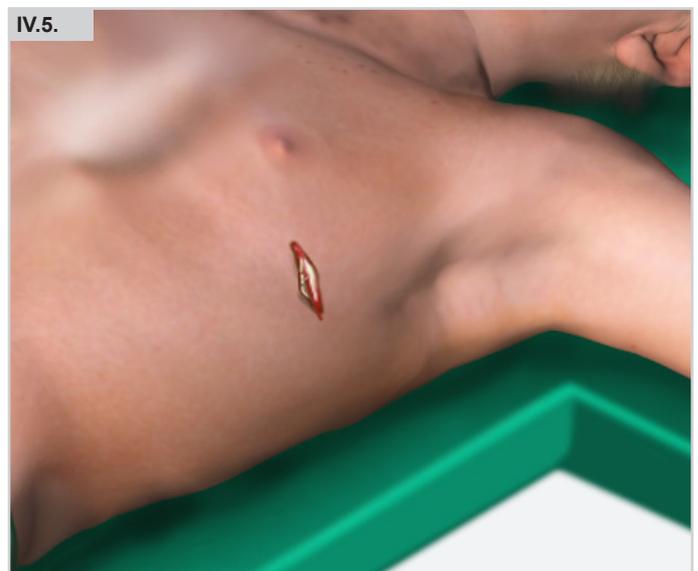


IV.5. TUNNEL PERFORMANCE FOR SEATING OF THE PLATE



During the chest surgery, extreme caution should be taken. Contact of the implant or instruments with heart and lungs may lead in consequences to permanent damage of these organs or in extreme case - death of the patient. Therefore, to increase safety and facilitate the procedure of plate insertion it is needed to use the thoracoscope to visualize the chest organs.

Make the 2,5 cm incisions at both sides of the chest along indicated incision lines.

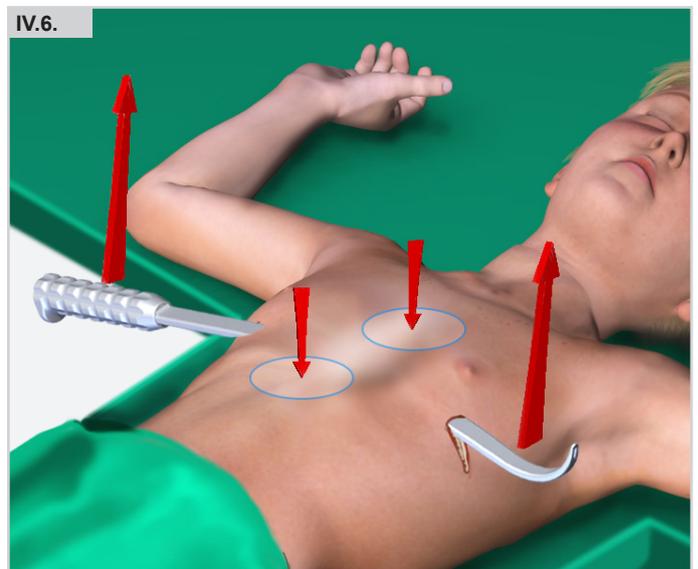


Choose the preparer size to fit the patient's chest. Insert the preparer [40.5846.xxx] to the made incision from the right side of the chest. With gentle movements, push the preparer across mediastinum just below the sternum (*the tip of the preparer should stay in continuous contact with the sternum*), making the tunnel for the implant placement. At the final stage, the tip of the preparer has to be advanced through the opposite incision in the intercostal space.



IV.6. INITIAL CORRECTION OF DEFORMATION

Make the initial deformity correction by lifting both ends of the preparer and pressing above and below the sternum in order to stretch of connective tissues. The initial correction facilitates in the next stage of procedure the rotation of the plate and increase the stability of its seating.



IV.7. IMPLANT'S INSERTION

Fix the umbilical tape to the end of the preparer, and then withdraw the preparer, dragging the end of the tape to the other side of the chest.



Fix the plate to the end of the tape (at the right side of the chest). Gently pull the plate through the tunnel made earlier (the convexity of the plate should be faced posteriorly).



When the plate is in position, by means of persuader [40.5847.000] turn the plate 180° (directing the incurved ends downwards), causing elevation of the sternum and correction of deformity. In order to facilitate the plate rotation, the second Persuader may be used [40.5847.100].



IV.8. INITIAL EVALUATION OF CORRECTION

Initial evaluation of correction is aimed to define what kind of plate stabilization will be required to its stable fixing – the usage of one or two crosswise plates decreasing the probability of plate rotation.



it is recommended to use one crosswise plate. The usage of the second crosswise plate can be determined by patient's age, physical activity, building muscle and it depends on surgeon decision.

In case of achieving insufficient correction (elderly patients, patients with deeper deformity), it may be necessary to place the second sterno-costal plate. Additional plate is placed above or below the seating place of the first plate.

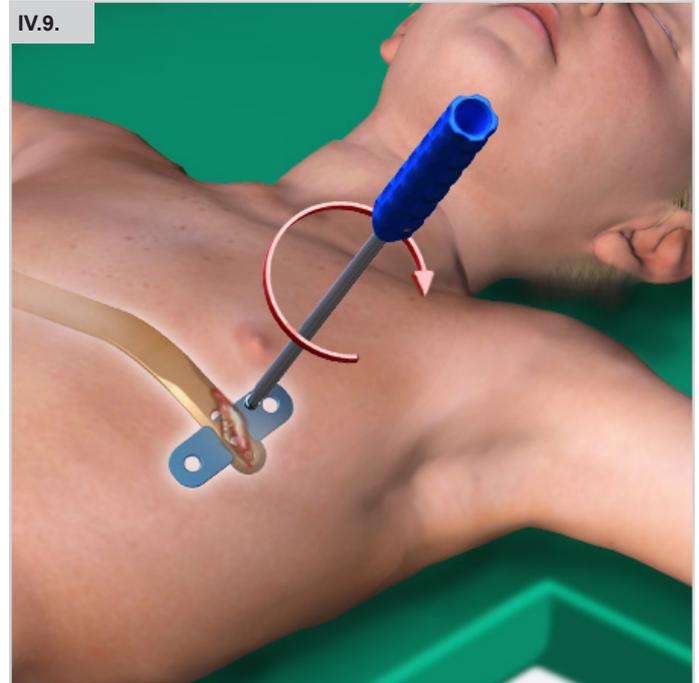
IV.9. CROSSWISE PLATE ATTACHMENT

Fit the crosswise plate on the chosen end of the sterno-costal plate and then determine its position (*the most common is 1-2cm from the end of the sterno-costal plate*). In order to fix the gold color coded crosswise plate, the plate blocker [3.6115.000] shall be used, whereas to fix the blue color coded crosswise plates, one shall use the plate blocker [3.6117.000]. The blockers are screwed in with use of T15 screwdriver [40.5845.000].

It is also possible (*optionally*) to fix position of the sliding crosswise plate (*blue color coded*) on the sterno-costal plate by means of multiple strong figure-8 sutures.

Then, by means of strong sutures, fix the implants to the chest wall muscles, using the holes in the sterno-costal plate and crosswise plate.

Before the wound closure, place the patient in Trendelenburg position, inflate the lungs with air and give positive end-expiratory pressure (*PEEP*) to prevent pleural air trapping. Cover the implants with surrounding soft tissue and skin and then close the wound with an absorbing suture and a dressing.



A chest radiograph should be obtained postoperatively due to possibility of pneumothorax occurrence and to confirm the proper position of the implant.

IV.10. IMPLANT REMOVAL

The procedure of the plate removal is performed with total anesthesia in ambulatory conditions. During the procedure, patient is placed in supine position with arms abducted. In order to remove the plate, incisions are made in the same locations as during the implantation, allowing access to the plate, crosswise plates and sutures. The plate is withdrawn (*after earlier suture removal*) pulling the one end through the incision and turning the patient in the opposite direction. After the implant removal, the wound is closed by means of absorbable sutures. Postoperative chest radiograph is recommended.

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