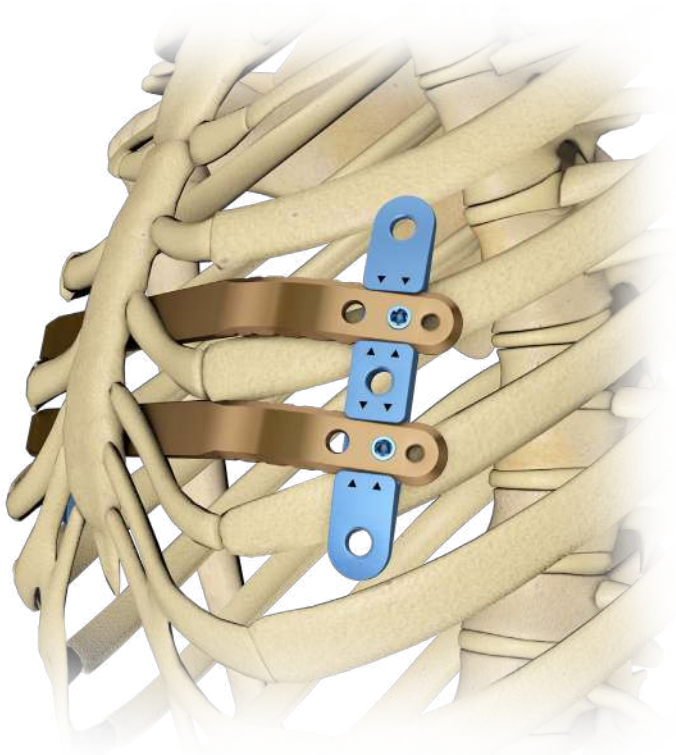
ST/42B

ChM®

STERNO-COSTAL PLATE

- *IMPLANTS*
- *INSTRUMENT SET 15.0911.101*
- *SURGICAL TECHNIQUE*



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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.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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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

1. INTRODUCTION

1.1. 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 a patient to return to normal activity is about one month.

1.2. 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.

1.3. 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 Instructions for Use (*IFU*) for sterno-costal plate, enclosed to the implant package unit.

1.4. 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 to damage of tissue or organs adjacent to the implant.

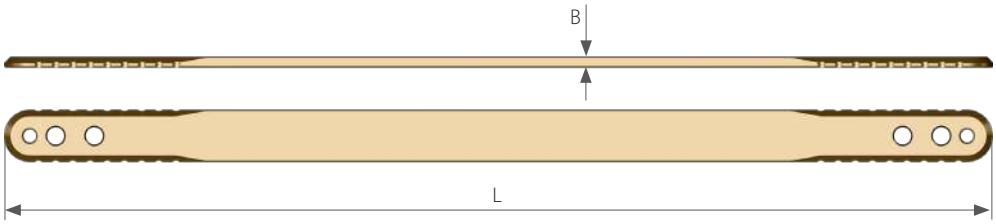
During the implantation procedure, extreme caution should be taken to avoid contact of the implant or instruments with heart and lungs, because it may lead to permanent damage of these organs or in extreme case - death of the patient. After achieving the stable correction of deformity, implant has to 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 a surgeon's responsibility.
The implantation shall be carried out by the surgeon familiar with adequate rules and operating techniques, and who has acquired practical skills of using instrument set for ChM sterno-costal plate.

2. IMPLANTS

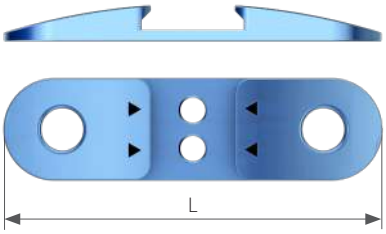
Sterno-costal plate

L [mm]	Titanium	
	B=2.5 [mm]	B=3.0 [mm]
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

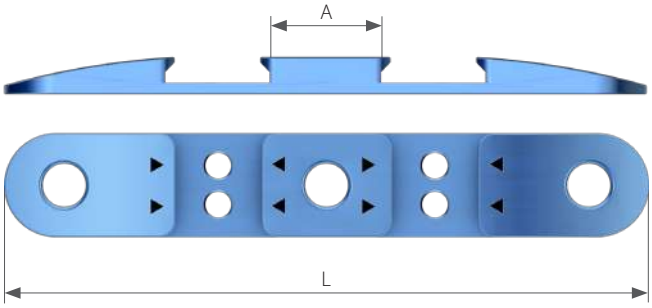


Plate-blocker

Titanium
3.6117.000

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

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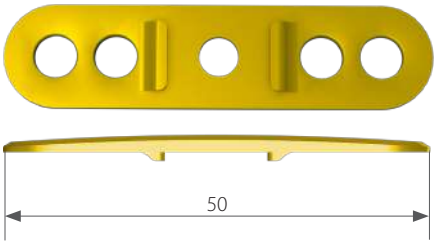
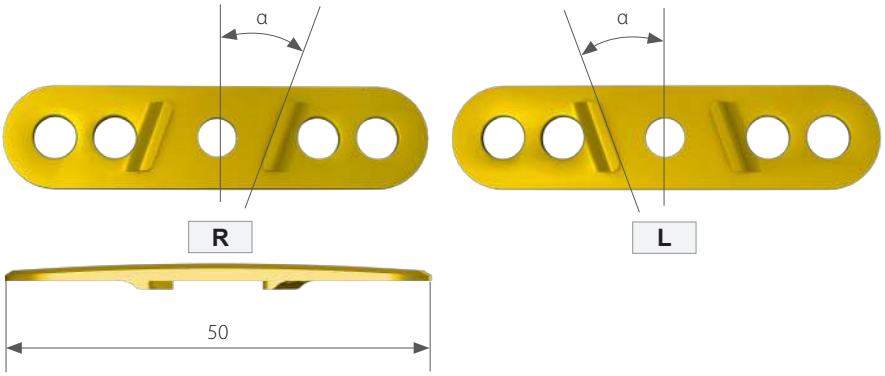
Crosswise plate 0°

Titanium
3.6114.000



Crosswise plate

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



Dual crosswise plate

L [mm]	A [mm]	Titanium
60	15	3.6120.015
65	20	3.6120.020
70	25	3.6120.025
75	30	3.6120.030
80	35	3.6120.035

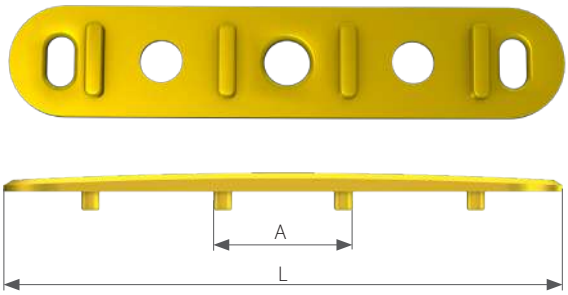


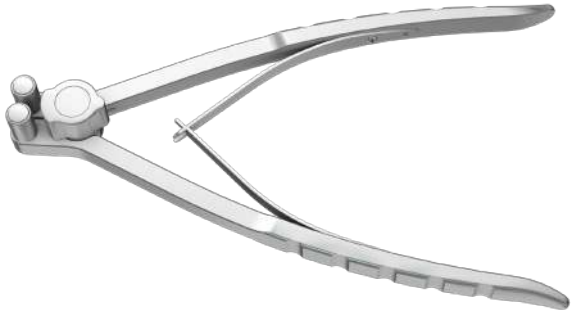
Plate-blocker

Titanium
3.6115.000

Crosswise plates [3.6112.xxx], [3.6113.xxx], [3.6114.xxx], [3.6120.xxx] are intended for use with plate-blocker [3.6115.000] only.

3. INSTRUMENT SET

3.1. INSTRUMENT SET FOR STERNO-COSTAL PLATES [15.0911.101]

15.0911.101	Name	Pcs	Catalogue no.
	Raspatory L=510mm	1	40.6142.510
	Bender for plates	1	40.5848.000
	Persuader	1	40.6143.000
	Persuader	1	40.6144.000
	Torque handle 2Nm	1	40.6657.000
	Screwdriver tip T15	1	40.5677.000
	Plate trial L=180mm	1	40.5844.180
	Plate trial L=205mm	1	40.5844.205
	Plate trial L=230mm	1	40.5844.230
	Plate trial L=255mm	1	40.5844.255
	Plate trial L=280mm	1	40.5844.280
	Plate trial L=305mm	1	40.5844.305
	Plate trial L=330mm	1	40.5844.330
	Plate trial L=355mm	1	40.5844.355
	Plate trial L=380mm	1	40.5844.380
	Plate trial L=405mm	1	40.5844.405
	Plate trial L=430mm	1	40.5844.430
	Container lid 9x4	1	14.0911.102
	Container 9x4H	1	14.0911.101

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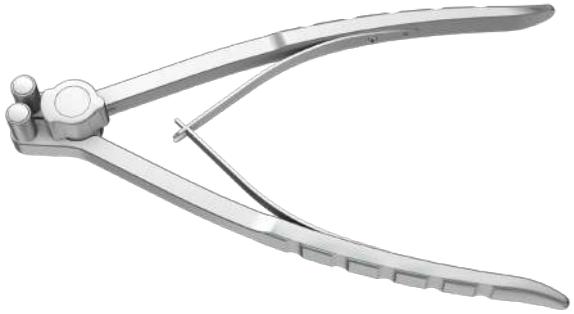
3.2. SET - STERNO-COSTAL PLATES [**15.0911.001**]

15.0911.001	Name	Pcs	Catalogue no.
	Raspatory L=510mm	1	40.6142.510
	Bender for plates	1	40.5848.000
	Persuader	1	40.6143.000
	Persuader	1	40.6144.000
	Torque handle 2Nm	1	40.6657.000
	Screwdriver tip T15	1	40.5677.000
	Plate trial L=180mm	1	40.5844.180
	Plate trial L=205mm	1	40.5844.205
	Plate trial L=230mm	1	40.5844.230
	Plate trial L=255mm	1	40.5844.255
	Plate trial L=280mm	1	40.5844.280
	Plate trial L=305mm	1	40.5844.305
	Plate trial L=330mm	1	40.5844.330
	Plate trial L=355mm	1	40.5844.355
	Plate trial L=380mm	1	40.5844.380
	Plate trial L=405mm	1	40.5844.405
	Plate trial L=430mm	1	40.5844.430
	Container lid 9x4	1	14.0911.102
	Tray for implants - Sterno-costal plates	1	14.0911.601
	Container 9x4H	1	14.0911.101

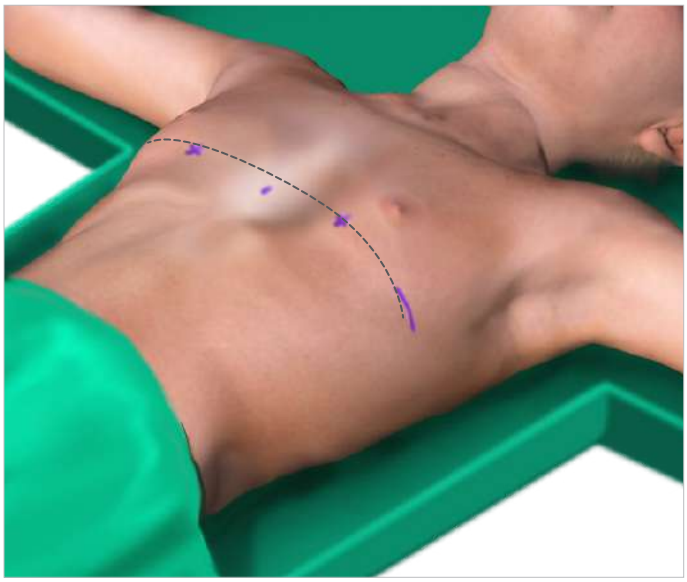
4. SURGICAL TECHNIQUE

4.1. PATIENT POSITIONING

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

4.2. 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 spaces (*on the both side of the chest*) located in line with the point set on the 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.



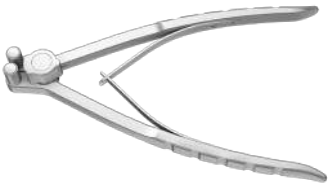
4.3. IMPLANTS SELECTION

40.5844.xxx

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

NOTE:
The length of required sterno-costal plate must be smaller than the measured distance because the plate trial measures the external dimension of the chest and the implant is inserted inside.

4.4. PLATE SHAPING



40.5848.000

Plate shaping has to be performed with use of the bender **[40.5848.000]**, according to the shape of chest deformity and implant insertion site.

In the case the 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 outside (*IV.4a*). However, in the case the 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 inside when shaping is completed (*IV.4b*).

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 excessively bend the ends of the plate in places the crosswise plates are attached and at 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.4.a

IV.4.b

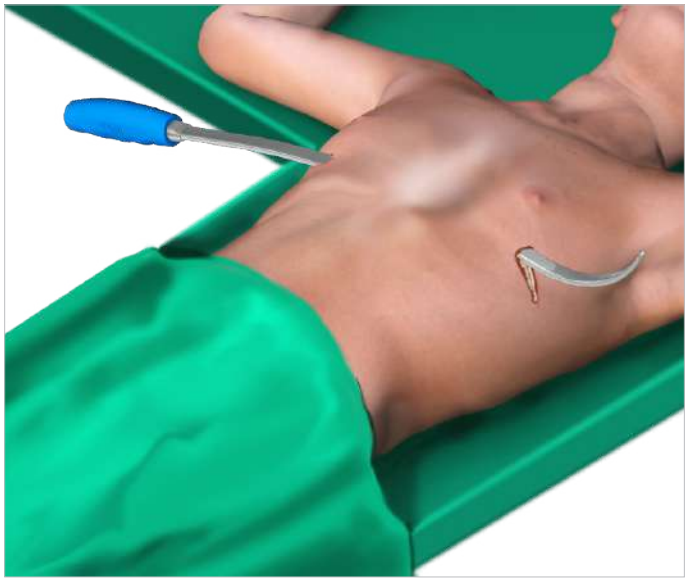
4.5. TUNNEL PERFORMANCE FOR PLATE INSERTION

During the chest surgery, extreme caution should be taken. Contact of the implant or instruments with heart and lungs may lead 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 required 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.

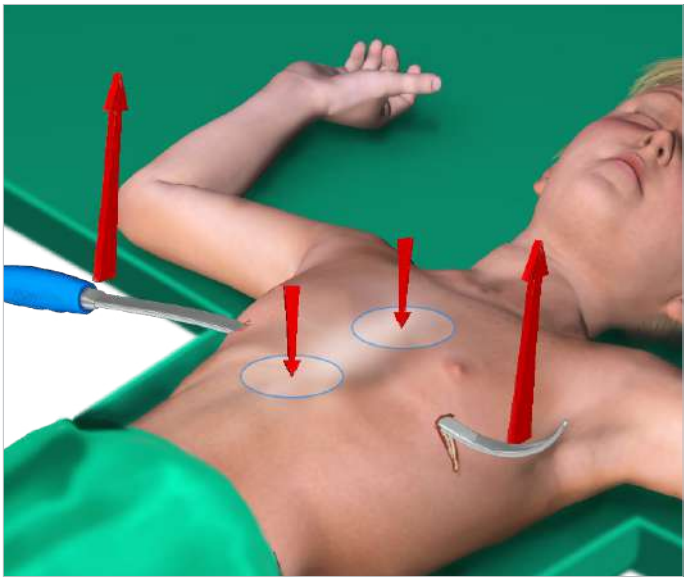

40.6142.510

Insert the raspatory **[40.6142.510]** to the incision from the right side of the chest. With gentle movements, push the raspatory across mediastinum just below the sternum (*the tip of the raspatory should stay in continuous contact with the sternum*), making the tunnel for the implant placement. At the final stage, the tip of the raspatory has to be advanced through the opposite incision in the intercostal space.



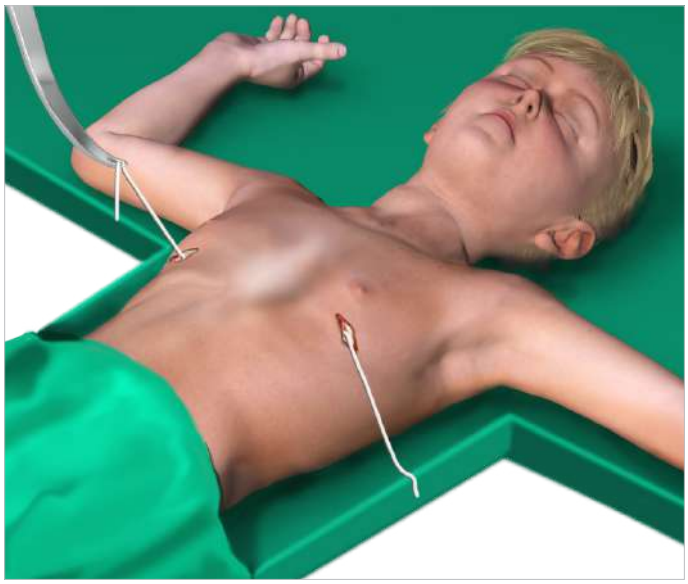
4.6. INITIAL CORRECTION OF DEFORMATION

Perform the initial deformity correction by lifting both ends of the raspatory **[40.6142.510]** and pressing above and below the sternum in order to stretch the connective tissues. The initial correction facilitates in the next stage of procedure the rotation of the plate and increases the stability of its positioning.

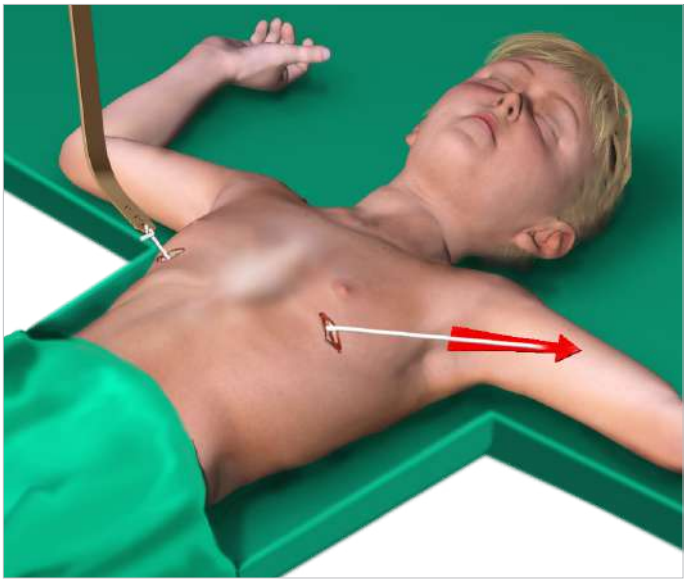


4.7. IMPLANT INSERTION

Attach the umbilical tape to the end of the raspatory **[40.6142.510]**, and then withdraw the instrument, dragging the end of the tape to the other side of the chest.



Attach the plate to the end of the tape (*at the right side of the chest*). Gently pull the plate through the already prepared tunnel (*the convexity of the plate should be faced down*).




40.6143.000


40.6144.000

When the plate is in position, use the persuader **[40.6143]** turn the plate by 180° (*directing the curved ends downwards*), causing elevation of the sternum and correction of deformity. In order to facilitate the plate rotation, the other persuader may be used **[40.6144]**.

4.8. INITIAL EVALUATION OF CORRECTION

Initial evaluation of correction is aimed at defining what kind of plate stabilization will be required for its stable fixation – the use of one or two crosswise plates decreasing the probability of plate rotation.

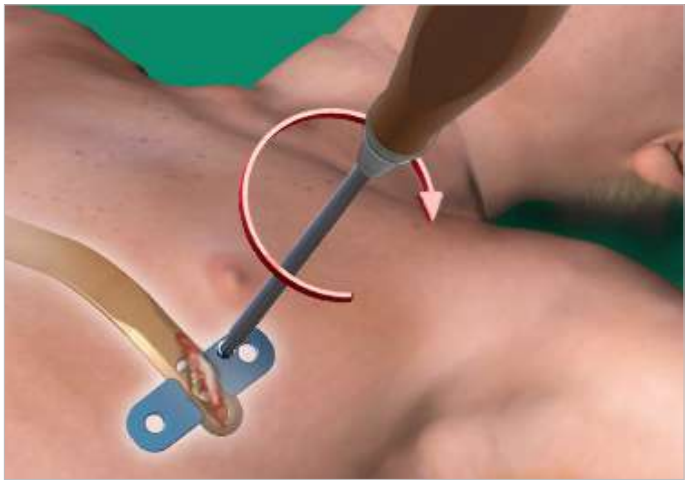
it is recommended to use one crosswise plate. The usage of the second crosswise plate can be determined by patient's age, physical activity, musculature and depends on a surgeon's decision.

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 first plate.

4.9. CROSSWISE PLATE ATTACHMENT


40.6657.000


40.5677.000



Attach the crosswise plate on the chosen end of the sterno-costal plate and then stabilize its position using a plate-blocker.

For crosswise plates **[3.6118]**, **[3.6119]**, use plate-blocker **[3.6117.000]**, whereas for crosswise plates **[3.6113]**, **[3.6114]**, **[3.6120]** - plate-blocker **[3.6115.000]**. The colors of plate-blockers (*blue and gold*) correspond to the colors of the crosswise plates.

Then, use strong sutures to attach the implants to the chest wall muscles, using the holes in the sterno-costal plate and crosswise plate.

Before 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 taken postoperatively for pneumothorax occurrence and to confirm the proper position of the implant.

4.10. IMPLANT REMOVAL

The procedure of the plate removal is performed with total anesthesia in ambulatory conditions. During the procedure, patient is placed supine 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 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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