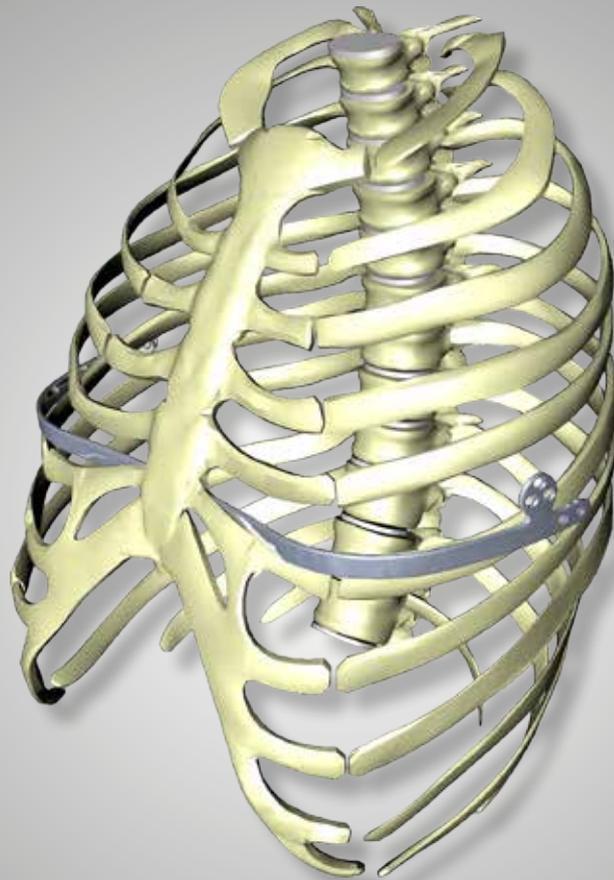


Surgical Technique



# PSI - Pectus Security Implant

## Pectus Excavatum Repair Method





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**Warning**

This description is not sufficient for immediate use of implants and instruments.

An instruction into handling these instruments by a surgeon experienced with them is strongly recommended.

This document provides information about the handling of Hofer implants and instruments.

This operation manual shall be considered as an addition and under no circumstances as a substitute to existing literature about surgical methods within orthopaedics and traumatology.

The content shall be regarded as a recommendation for a standardized procedure of how to apply the products without addressing the issues of any further necessary tasks, additional operative actions and possible extensions of the surgical technique.

The actual selection of the most suitable implant and its implantation method has to happen exclusively by the surgeon based on his education and the individual diagnostic findings.

All illustrations printed here have a purely symbolic character to support the description of the surgical technique and can vary.

These operation instructions don't contain any details on the use of the instruments. Corresponding documents are available in the form of

- Instruction manual for instruments: intra and post-operative handling
- Instruction manual for implants (enclosed to each implant)

Please note that it is the surgeon's function to identify and characterize the respective injury and its subsequent treatment.



For a safe handling and for the various surgical techniques Hofer-medical is pleased to offer detailed training.



**Please contact our 24/7 service hotline:**

Tel.: +43 (0)3382 53388

Mail: [office@hofer-medical.com](mailto:office@hofer-medical.com)

The funnel chest is the most common abnormality of the chest wall that is identifiable already relatively early in the first years of life.

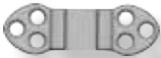
In recent years, the spectrum of surgical techniques for correction of funnel chest, as for example the standard procedure of cartilage resection of Ravitch - Welsh – Rehbein, was extended by a minimally invasive method, which first described Nuss in 1998. Without cartilage resection, this minimally invasive procedure with an implantation of an individually shaped bar provides an alternative with comparably good cosmetic results.

The therapeutic management includes operational correction, the physical therapy with a targeted training of shoulder, back, chest and abdominal muscles. An important indication for surgery is next to a progression of the diagnostic findings, the existence of cardiac and respiratory problems and mental impairment.

## PSI - Pectus Security Implant



PSI-bar with integrated one-side stabilizer wing



PSI-inter costal protection plate, compatible to PSI-bar

### Indications

- Pain in the funnel chest area
- Psychological stress
- Arrhythmias, valve insufficiencies
- Exercise impairment
- Haller Index > 3.2

### Contra Indications

- Child in preschool age
- Some types of post-operative recurrence with extensive rib calcifications
- Wide spread acne across body

### Position of Patient and Approaches

Patient Positioning:

- Standard

Approach:

- Standard, according to NUSS-Technique

### Plate Specific Details

- Low Profile Design due to single-piece implant with already integrated stabilizer wing
- Simplified handling: Intra-operative assembling of a stabilizer basically not necessary anymore
- Exact anatomic shaping of the implant along its total length, including its ends, and of the stabilizer wings, if necessary
- Specially rounded edges for reducing damage to the intercostal soft tissue
- Implantation of several implants at the adjoint intercostal areas without material contact possible
- Optional: Additional plate as support for an improved protection of the intercostal space soft tissue



Severe **acne**, spread to broad parts of the body, should be treated dermatologically before surgery. The patients have to be prepared that they will receive **pain-relieving medicaments** during the first post-operative week. During this phase, in which the thorax is forced into "normal shape" there will be periods of pain, which require treatment. After one week these periods of pain decrease significantly so that after approximately 10 days nearly all patients don't - or only occasionally - need analgesics anymore. In this connection infiltrations are helpful too. According to experience pain is heavier in elderly patients (stiffer thorax). The surgery is performed with **perioperative anti-biotic prophylaxis**. For general anaesthesia a **double-lumen intubation** proves to be advantageous. In this way each lung can be ventilated separately. Besides conventional intravenous analgesic perfusion, elimination of pain can also be achieved by means of an epidural block. The epidural catheter remains in place post-operatively for further pain management. **A duration of the surgery between 45 minutes and 1.5 hours has to be expected.** Blood loss requiring transfusions is not likely. In **elderly patients** it may be necessary to use **two implants** for complete elevation of the sternum and shaping of the thorax.

#### 4.1.1 - The principle of minimally invasive correction

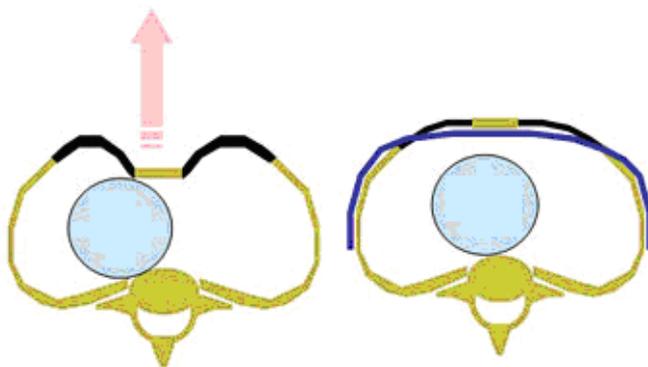


Fig. 1: Minimally invasive correction of a funnel chest

#### 4.1.2 - Position of Patient

Position the patient in **suspine position** with arms elevated laterally to 90°. Approach to the lateral chest wall has to be guaranteed without problems (positioning of the implant and the possibility of lateral thoracoscopy). Determine the **deepest point of the funnel**. So the plane is specified, in which the implant (supporting plate) has to be positioned.



Fig. 2: Determination of deepest point of funnel

#### 4.2.1 - Adjustment of Bending Template

Measuring the distance between the points of intersection of the determined plane (deepest point of the funnel) with the medioaxillary lines (line drawn from the axilla laterally on the body). Then the **bending template** made of soft metal **is adjusted** exactly. The template bent in c-form serves as model for intra-operative adjustment (individual shaping) of the implant.



Fig. 3: Adjustment of the bending template of adequate length with the ends reaching from one medioaxillary line to the other: The implant is chosen 1-2 cm shorter compared to the adjusted template.

#### 4.2.2 - Determination of Implant Length and Skin Incision

Determination of the length of the implant bar. The required **implant has to be chosen 1-2 cm shorter than the distance measured** (i.e. the next smaller available size is implanted), as the measurement represents the outer diameter of the chest.

The implant lies **subcutaneously** below the fat tissue of the skin (ev. submuscular; especially the ends are positioned below the edge of the large back muscle) up to this position, where it - coming through the intercostal space - lies behind the sternum and then reaches the subcutaneous layers of tissue through the contralateral intercostal space again. The **intercostal perforation sites** (sites of implant insertion) should be situated **within the edge of the funnel**.

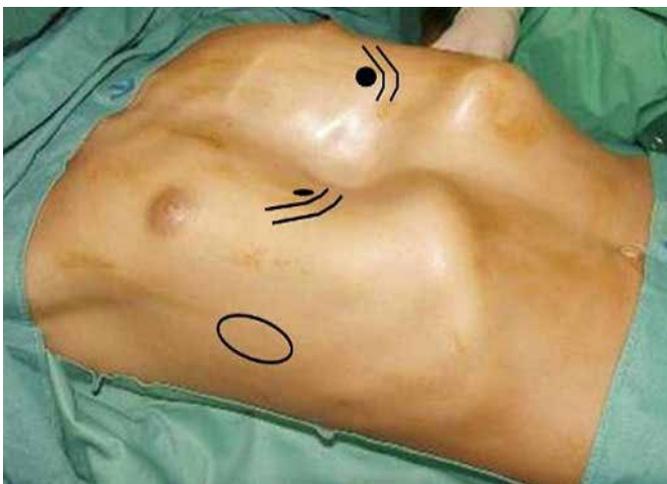


Fig. 4: Lateral incision site (skin incisions) is marked with oval circle. The black points indicate the positions, where the implant should come through the intercostal space.

#### 4.3.1 - Shaping of Implant

Then preparation, i.e. the individual **shaping of the bar in c-form** with a special table top bending device. In the middle part the implant should show a flat curve. The new **PS-Implant with integrated stabilizer** can be exactly adjusted to the form of the thorax. This means that also the stabilizer wing can be curved.



Fig. 5: PS-Implant in various sizes

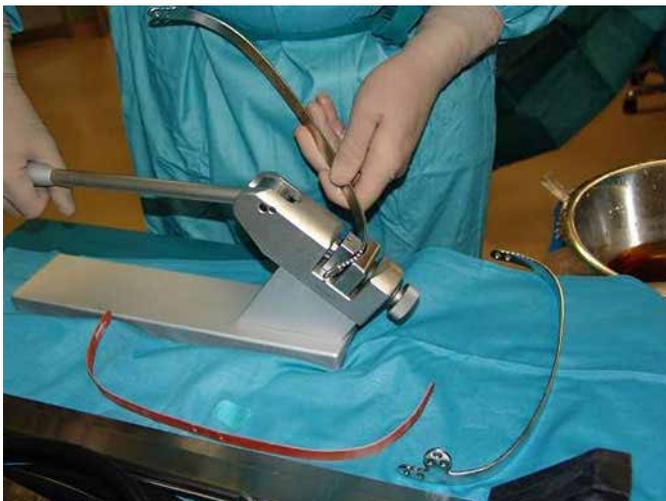


Fig. 6: Individual shaping of implant with special table top bending device



Fig. 7: The PS-implant already curved and prepared for implantation with integrated one-side stabilizer (red circle)

In the previous implant generation the stabilizers were attached to the ends of the implant. So it wasn't allowed to curve the outer ends in an area of approx. 3 cm, so that the lateral stabilizer plates could be pushed up easily onto the bar.



Fig. 8: The previous (alternate) generation of the C-shaped implant and the corresponding stabilizer plates

#### 4.3.2 - Skin Incisions and Lateral Thoracoscopy

On both sides in the area of the medioaxillary lines approx. **2-3 cm long diagonal** (or horizontal) **skin incisions** are performed (intersections of the determined plane through the deepest point of the funnel with the medioaxillary lines). Next the **subcutaneous mobilization** including the preparation of a stabilizer plate bed (mostly coming from the right side) followed by the **preparation of a tunnel** below the skin originating from both incisions reaching slightly above the edge of the funnel, exactly to this point, where the intercostal space shall be perforated.

From the lateral incision (mostly right) already a **lateral thoracoscopy** can be performed (5mm, 0° oder 30° visual appearance), which enables an inspection of the chest cavity and the mediastinal organs (heart and large blood vessels) (Vasa mammarica interna; later: control preparation with special preparation instrument). The overview is obtained either by retracting ventilation of the right lung (in case of double-lumen intubation) or by filling the pneumothorax space with CO<sub>2</sub> gas (pressure: 4-8mmHg).



Fig. 9: Lateral thoracoscopy (Inspection of the lung surface and chest cavity)

Especially in patients with severe funnel chest, it may be advantageous to perform an **additional 2-3 cm long** vertical, medial, **epigastric skin incision** below the processus xyphoideus (end of sternum) in the area of the linea alba (tight tissue between the muscles of the abdominal wall) and to mobilize bluntly (e.g. digitally) the pericardium retrosternally from the epigastrium. By this (not always necessary) approach the preparation in front of the heart mediastinum becomes safer and from this position a clear **mediastino-pleuroscopy** can be performed too. "Instruments are only moved under optimal conditions" is the name of the game.

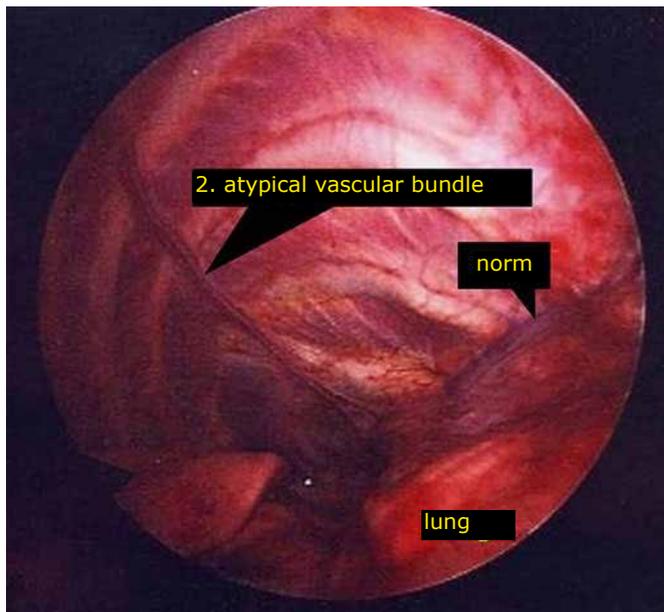


Fig. 10: Vascular bundles

By means of **thoracoscopy** originating from the epigastric skin incision there is an anatomic variant with **two vascular bundles of the thoracic wall** (vasa mammarica interna). In lateral thoracoscopy alone the second vascular bundle would not have been seen. In this case the additional approach from the middle has been an advantage and avoided possible bleeding complications!

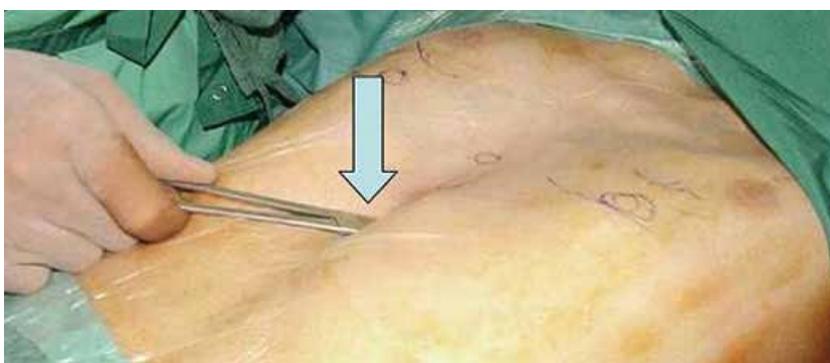


Fig. 11: Epigastric incision

The **epigastric incision** (slightly below the end of the sternum) represents a high safety factor. It enables the pericardium to part from the front chest wall and therefore practically eliminates the danger of heart perforation during preparation of an implant bed. Additionally, this incision enables the **sectioning of tough tissue**, which pulls the sternum inwards (recurrence prophylaxis).

#### 4.3.3 - Preparation of Implant Bed

Actual preparation of the implant bed is performed with a **sword-shaped preparation instrument**. The shaping of this instrument is important and has been further developed within the last few years. The short preparation instrument (less frequently needed) is designated for younger, smaller patients, the long preparation instrument for elderly, larger patients. Guidance of the preparation instrument is performed thoracoscopically and can be controlled digitally from the epigastric incision. The preparation instrument **is slowly moved forward**, first in the subcutaneous (ev. submuscular) area, then medial of the edge of the funnel through the intercostal space selected before, exactly behind the sternum to the contralateral side. The tip of the instrument should in case of retrosternal preparation point to the front thoracic wall and be led in close proximity to the sternum. It is essential not to hurt neither the vasa mammarica interna nor the pericardium during this preparation. The pleura normally is opened on both sides. The instrument is now pushed through the opposite intercostal space (determined position, medially to the edge of the funnel) into the subcutaneous area. Hereby the lateral skin incision is translocated to the front for a short time so that the tip of the instrument can be taken hold of and elevated.



Fig. 12: The ideal way of preparation: this means that the points of passage through the intercostal space have to be chosen within the edge of the funnel.

It is important to find the **exact position within the intercostal space** (within the edge of the funnel). For a deeper funnel this step of surgery often is difficult. It can be helpful, if the sternum is hold by means of a special jig in elevated position during preparation – with already elevated funnel.

The contralateral skin incision in the medioaxillary line is - as already mentioned - translocated to ventral (e.g.: using a round tissue retractor) so that the sword tip of preparation instrument reaches the surface of the body. Here the tip of the preparation instrument can be taken hold of with a retractor and elevated. Lever and abrupt shaking movements of the preparation instrument have to be avoided to save the intercostal muscles (stripping). After this preparatory step additionally **funneling is already compensated** by the inserted instrument. Strong **guiding belts surrounded by a silicon tube** (protection of intercostal muscles; one belt only would have a "sawing effect") are fixed to the tip of the preparation instrument and then pulled through the prepared tunnel (implant bed) towards the opposite side to the surface of the body.



Fig. 13: Guiding belt pulled through (4mm Mersilene®-Belt reinforced with tube) with already attached implant

#### 4.3.4 - Insertion of Implant

The **Pectus Security Implant shaped in C-form** is (mostly) pulled in from the right side of the patient below the sternum, whereby both ends point forwards.

#### 4.4.1 - Implant Rotation and correction of funnel

Then the especially developed **rotation instruments (implant turner)** are attached, the **implant is turned by 180°** and brought in its final position. There has to be an optimal lateral fit. Now the sternum is in elevated position and the funnel has been corrected. In rare cases, in case of an especially stiff - kinked sternum a **partly notching of the sternum** in the upper circumference of the funnel - in the medians - has to be set to straighten the sternum for easier correction of the funnel. By this measure also the pressure to the implant and therefore to the tissue on which the implant is lying is reduced.



Fig. 14: Bar with implant turners



Fig. 15: Bar with implant turner intra-operatively

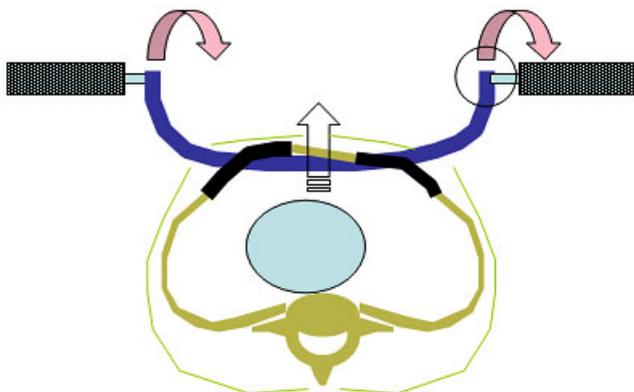


Fig. 16: Principle of double-sided implant rotation: By special implant turners the ends of the implant can be positioned guided and tissue conservingly at the lateral thorax.

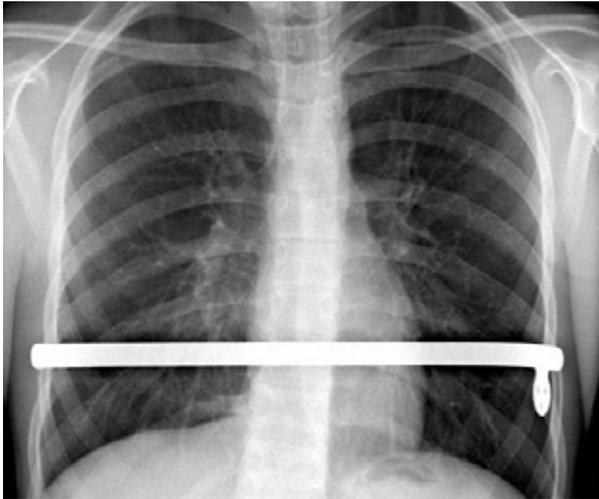


Fig. 17: Excellent position of PS-Implant with integrated one-side stabilizer



Fig 18: Lateral x-ray with PS – Implant

The **one-side stabilizer wing** also has the advantage – contrary to stabilizers on both sides - that in case of a long wearing time no “feeling of tightness”, caused by the implant, occurs. This effect also occurred, if in the previous implant generation not the usual two (original NUSS technique) but only one stabilizer had been used. The occasionally observed sliding of the stabilizer led to the situation that - to be on the safe side - rather two stabilizer plates were pushed to the ends of the implant or, if only one stabilizer was used, it was “wired” to avoid sliding. Unfortunately wires broke from time to time. These observations and experiences were essential for the development of the single-piece PS – Implant with integrated stabilizer wing on one side only.

Occasionally in elderly patients - or in case of a very stiff thorax - the necessity for **implantation of a second bar** may occur, which is placed one to two intercostal spaces above or below the bar already in place. **Double implants** also have the advantage that the pressure of the implant on the lateral thorax is reduced by half.

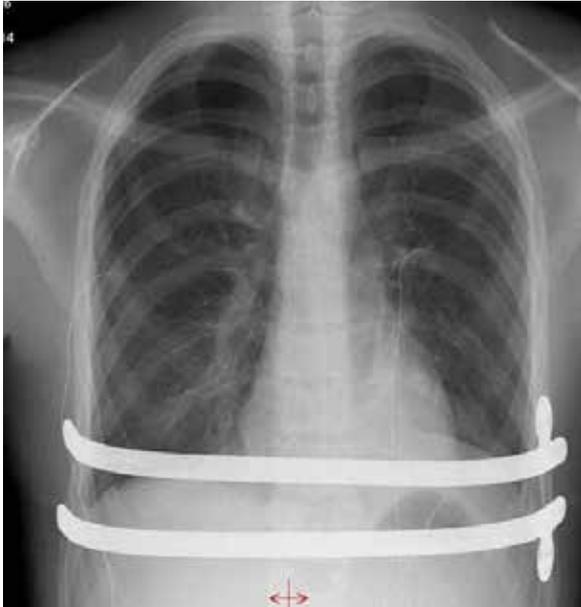


Fig. 19: In elderly patients the implantation of 2 implants is recommendable. Shaping of the PS-Implants avoids the possible metal-metal contact, which could occasionally be observed in the previous implant generation.

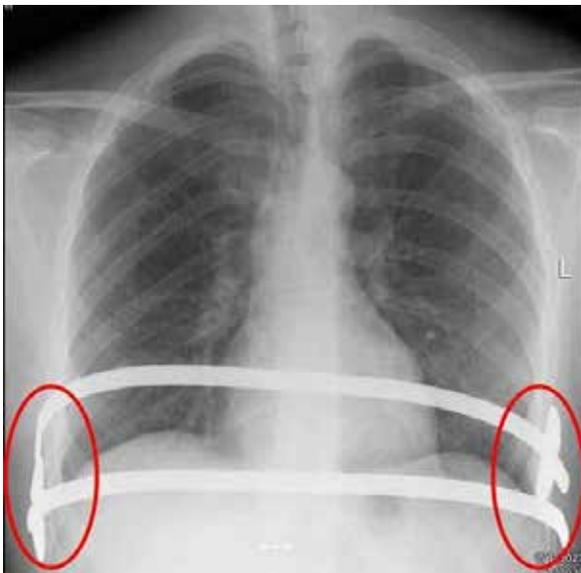


Fig 20: Metal-metal contact in previous implant generation

The **ends of the implant** are positioned below the edge region of the **musculus latissimus dorsi** (large lateral back muscle), quasi in a sort of a "box". Placement below the muscle is an essential preventive measure against movement of the implant (rare but most common complication).

In case of a **large kink of the sternum**, operatively a "notch" has to be created so that the sternum can be straightened more easily (so called partial sternum osteotomy).

A **median drainage** (Bülau-drainage Nr.: 16-24) normally is sufficient, as both pleural cavities communicate via the anterior mediastinum.



Fig 21: So called Bülau-drainage in case of more complex funnel chest correction, with sternum having to be notched too

#### 4.5.1 - Wound Closure and Post-Operative X-Ray

At the end of surgery the chest cavities are evacuated by means of a short term increase of ventilation pressure, i.e. excess air drained from the sternum. The skin incisions are closed in typical way with sutures or clamps.



Fig 22: Patient with corrected funnel chest

Post-operative x-ray of thorax. The x-ray shows the exact position of the pectus bar implant and should be performed subsequent to surgery.

#### 4.5.2 - Post-operative Treatment

The patient should start with breathing exercises as early as possible. Bülow-drainages should be removed as early as possible. The implant should stay implanted for 2-3 years.



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