Pectus Bar Correct System

Product Catalog

Digitally signed by Grabazei Alexandru
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BIOTECH

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VB-003-PROSP-PC

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02

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CE 1011

"Movement is Life"

Biotech Pectus Bar Correct System

Pectus Excavatum is the most common deformity of the chest (1:1000).

The mobility of the chest by breathing is often obstructed, just like the cardiac action, which can also be partially restricted sometimes.
Additionally, by almost 25% of the patients the spine is deformed, the back and shoulder muscles are incorrectly developed resulting in most of the cases in not proper posture.

Initially the new

Minimally Invasive Repair of Pectus Excavatum - shortly "MIRPE"-

was only applicable for children from the age of 5, however during the past few years there were also some cases for patients until the age of 40. These were not really appreciated by the conservative methods.
The significantly reduced OP time - from 5-7 hours to 1 hour - just like the small 2 cm incisions and the positive cosmetic solution resulted in a very fast break-through in Children-, Thorax- and Plastic-Surgery departments world-wide.

The excellent long-term results of hundreds of patients stand for themselves (supported by relevant studies since 1988).
Minimal blood loss, just like the economic advantage of the significantly reduced hospital-stay - normally approximately 5-7 days - are also not neglectable.

Product description

Pectus bar manufactured of stainless steel for medical use in different sizes - from 20,5 cm to 45,5 centimetres - with rounded ends, blunt edges, 12 notches on each end and 1 perforation.
Elongated Pectus Stabilizers manufactured of special implant-stainless steel for medical use.

Implants

113-7080-0000	Pectus Implant	20,5 cm
113-7090-0000	Pectus Implant	23,0 cm
113-7100-0000	Pectus Implant	25,5 cm
113-7110-0000	Pectus Implant	28,0 cm
113-7120-0000	Pectus Implant	30,5 cm
113-7130-0000	Pectus Implant	33,0 cm
113-7140-0000	Pectus Implant	35,5 cm
113-7150-0000	Pectus Implant	38,0 cm
113-7160-0000	Pectus Implant	40,5 cm
113-7170-0000	Pectus Implant	43,0 cm
113-7180-0000	Pectus Implant	45,5 cm

113-8010-0000 Pectus stabilizer

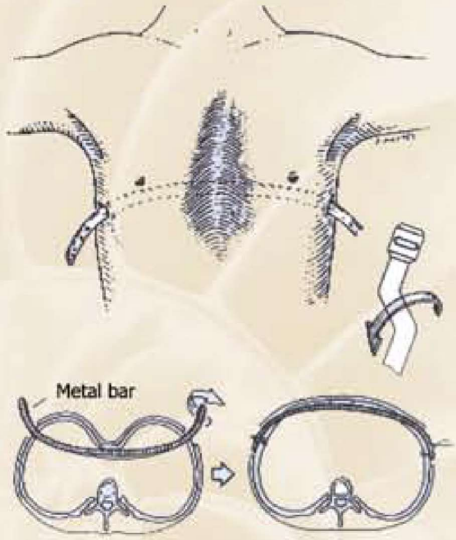
113-8030-0000 Pectus screwed stabilizer

113-8040-0000 Pectus Screw

Operative steps

If possible meet the requirements for single lung ventilation. The first step is the measurement from the medioaxillary to the medioaxillary line at the level of the deepest part of the funnel for determination of the bar length (1-2 cm less of the measured distance). A pectus bar template can be used to visualize the shape necessary to correct the deformity. In patients with a rigid thorax or in older patients two bars may be necessary.

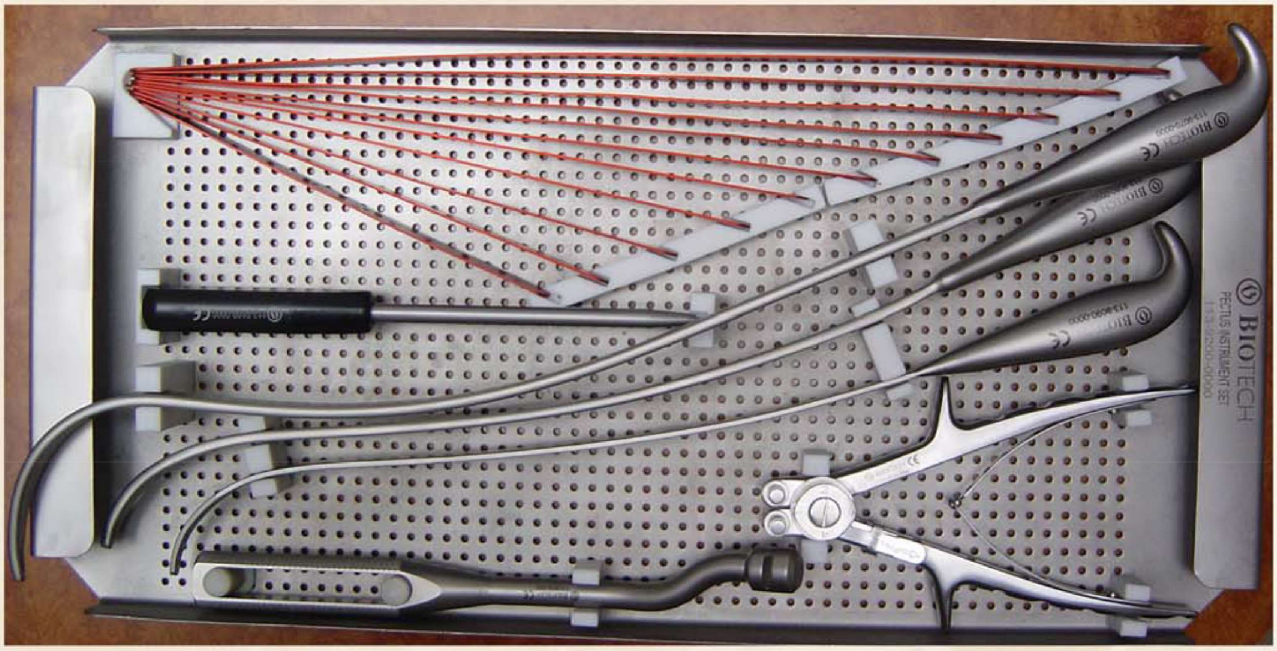
- Preoperative administration of antibiotics for infection prevention.
- Two short incisions (3 cm) in the medioaxillary line and subcutaneous mobilization (ultra scission, avoid squeezing the tissue) in that area. For safety reasons a third median incision below the processus xyphoideus that divides the linea alba is sometimes performed. From that incision a retrosternal mobilization and mediastionscopy is performed. Thoracoscopy (e.g.: 5 mm port) is performed mainly from the right lateral incision.
- For optimal bar placement the intercostal space should be perforated slightly medial to the top of the pectus ridge (within the edge of the funnel) using a special "sword like" instrument. Caution: lesion of the arteria thoracica interna; lesion of the lungs or the pericardial sack or the heart. Visualization using the thoracoscopy is necessary. Visualization of the left intercostal perforation may be difficult because of the heart. Via the additional median subxiphoidal incision and anterior mediastinal mobilization (pericardium, pleura, fibrous adhesions) the tip of the preparation instrument may be guided by the surgeons finger tip.
- A strong tape is fixed to the tip of the preparation instrument on one side and the end of the C – shaped bar on the other.
- The connection between the bar and the tape is covered with a thoracic tube to achieve atraumatic intercostal passage. The preparation instrument is pulled back and the bar is positioned behind the sternum with both ends looking to the front.
- Afterwards the bar is twisted (180°) and fixed with not resorbable sutures to the lateral thoracic muscles (musculus serratus) using the special stabilizer plates. The stabilizer plates should be fixed to the bar using wire sutures to prevent dislocation, or screws in case of using stabilizers with screws. Some surgeons prefer the fixation with sutures going around the rib.
- Lateral chest tubes are used for drainage. If an additional median incision was performed, a single chest tube may be placed in the anterior mediastinum draining both opened pleural spaces.



Postoperative steps

- Antibiotics for about 5 days.
- Analgetics are especially necessary in the first postoperative week (piritramid 0, 1mg/kg BW/h or the pain-pump). The patient should start with breathing exercises as soon as possible.
- The patient should have a pectus – pass port with him (including a small thoraxic X-ray picture).
- The patient should maintain good posture and limit activity (especially with the arms) for the first postoperative month. Deep – breathing exercises should be performed twice a day. The patient should avoid heavy lifting for two months following surgery and no contact sports for the first three months following surgery.
- In situations of resuscitation: Cardiac defibrillation (if necessary) is performed with an anterior/posterior paddle placement.
- Surgical removal of the bar(s) under general anaesthesia is recommended after a period of 2 to 3 years.

PECTUS INSTRUMENT SET 113-9200-0000



Instruments

113-9000-0000	Pectus Flipper	
113-9050-0000	Pectus Bender	
113-9090-0000	Pectus Introducer size small	48,0 cm
113-9080-0000	Pectus Introducer size medium	51,0 cm
113-9070-0000	Pectus Introducer size large	53,0 cm
725-0005-0002	Screwdriver 2,5 mm	

Templates

113-8070-0000	Pectus Template	18,0 cm
113-8080-0000	Pectus Template	20,5 cm
113-8090-0000	Pectus Template	23,0 cm
113-8100-0000	Pectus Template	25,5 cm
113-8110-0000	Pectus Template	28,0 cm
113-8120-0000	Pectus Template	30,5 cm
113-8130-0000	Pectus Template	33,0 cm
113-8140-0000	Pectus Template	35,5 cm
113-8150-0000	Pectus Template	38,0 cm
113-8160-0000	Pectus Template	40,5 cm
113-8170-0000	Pectus Template	43,0 cm
113-8180-0000	Pectus Template	45,5 cm

Responsibility for proper selection of patients, for adequate education of the surgical team, for sufficient training and experience in the choice and application of implants as well as the time of implant removal rests with the surgeon attendance.

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EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-776-200-1509

The **Directorate of Device Testing and Clinical Engineering (EMKI)**

certifies that the manufacturer:

Biotech GmbH
Hagenauer Str. 17-19
65203 Wiesbaden
Germany

for the products / product category:

Sterile and non-sterile orthopaedic implant systems

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-066-2007**

This certificate is valid together with EC Design-Examination Certificates according to Directive 93/42/EEC on Medical Devices, Annex II (4) **No. 5-777-204-1509** and **No. 5-778-204-1509**.

This certificate is valid until **2021-09-08** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 5 First issued: 2015-09-09

Budapest, 2018-05-16

Head of EMKI

EMKI 2007

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering
H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33
E-mail: cert@emki.hu, Web: www.emki.hu
H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

ATTACHMENT TO EC CERTIFICATE

Additional information for Certificate No. 5-776-200-1509

The certificate is valid for the following manufacturing sites / facilities:

Biotech GmbH
Hagenauer Str. 17-19
65203 Wiesbaden, Germany

Biotech GmbH Magyarországi Fióktelepe
Petőfi Sándor utca 43-47
2049 Diósd, Hungary

The certificate is valid for the following products:

Sterile and non-sterile orthopaedic implant systems	***Class***
Biotech Sterile Knee Endoprosthesis Systems	III
Instruments and Trial Tray for Biotech Sterile Knee Endoprosthesis Systems	IIa
Biotech Sterile Hip Endoprosthesis Systems	III
Instruments and Trial Tray for Biotech Sterile Hip Endoprosthesis Systems	IIa
Biotech Traumatological Implant Systems for Osteosynthesis	IIb
Biotech Pectus Bar Correct System	IIb
Biotech Spinal Implant System	IIb

The detailed product list is kept by EMKI under No. 42-066-2007.

Issue: 5 Date: 2018-05-16 First issued: 2015-09-09

Head of EMKI

EMKI

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QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-492-135-1809

The **Directorate of Device Testing and Clinical Engineering (EMKI)**

as a Certification Body with ID No. NAH-4-0096/2016
accredited by the National Accreditation Authority for management system certification

certifies that the quality management system applied by

BIOTECH GmbH
Hagenauer Str. 17-19, 65203 Wiesbaden
Germany
and
Magyarországi Fióktelepe
Petőfi Sándor utca 43-47, 2049 Diósd
Hungary

meets the requirements of standard

EN ISO 13485:2016

in the field:

Design, development, manufacture and distribution of non active surgical implant systems;
Design, development, manufacture and distribution of surgical instrument systems

Registry number of the related audit report: **43-066-2007**

This certificate is valid until **2021-09-08** supposed that the results of the regular yearly surveillance audits are satisfactory.

Budapest, 2018-09-09

Head of EMKI

EMKI 2092

The authenticity and validity of the certificate are verifiable at EMKI.

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