

Instructions for use, warnings and precautions for MedXpert implants and instruments for the P.E.S Pectus Excavatum System

Filsacines plduteles 1.1.

Information for the user

Please read this information and product insert through carefully. It contains important information for you.

MedXpert implants and instruments may only be used for their intended purpose in the medical specialities by appropriately trained and qualified personnel. The attending physician is responsible for selecting the products for specific applications and for surgical use, as well as for appropriate training and information and adequate experience in the handling of the products.

PART I - APPLICATION

1. INTENDED USE

1. P.E.S sistema, skirta įdubusios kūtines ląstos korekcijoms.

The P.E.S Pectus Excavatum System comprises the following components for treatment of funnel chest (pectus excavatum).

• implants: Pectus Bar, Pectus Bar Stabilizer, Pectus Pectus BarLock™ Pin and Pectus Locking-Screw, Universal (see section 23.1) as well as corresponding

- instruments (see section 23.2) for their application
- storage and organisation containers (see section 23.2)

Indications for the P.E.S Pectus Excavatum System:

- Treatment of symmetrical funnel chest (pectus excavatum)

Using the P.E.S implants, the deformed bone structures of the thorax (chest wall, sternum, etc.) are moved from the inside to the outside, thus correcting the deformity.

Following correction of the deformity the implants must be removed again. According to the current state of knowledge the implants must be removed after 2 years at the earliest and after 4 years at the latest if postoperative progress is devoid of complications.

3. visi sutilai produktai, pagaminti iš med. plieno!

The Pectus Bar, Pectus Bar Stabilizer, Pectus BarLock™ Pin and Pectus Locking-Screw, Universal are made of corrosion-proof stainless steel (1.4441 ASTM F 138).

All the products in the MedXpert P.E.S product line as well as their respective packaging are made of LATEX-FREE material.

1.4441 - t.y. žyva (ant pakuočių etiketės), kad produktas pagamintas iš medicininio plieno.

Technische Dokumentation / Technical Documentation

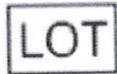
Strasbourg-Thorax-Osteosynthese / PES Pectus Excavatum

*Technini informacija
P.E.S. sistemas*

Basic Information

This paper describes the labels of the MedXpert Products for Instruments riskclass I and Implants IIb. The change of the labels affects the a) MedXpert Logo type and b) the Product Logo Type and c) a Version Number given to all labels. The Label is a part of packaging and even a part of our products.

Explanation of the used logo types:

 Manufacturer	 Reference Number	 Observe instructions for use
 Our Company Logo	 Batch designation	 Non-steril
 Logo for STRATOS Products	 Date of manufacture	<p>R_x only</p> only for professional use
 Logo for STRACOS	<p><i>2.</i></p>  Not for reuse <i>VIENT KARTINIS</i>	<p>CE 0483</p> Conformity as per EC Directive 93/42/EEC
 Logo for PES	 Caution, see accompanying documents	<p>Vers.2020-01</p> Version Number of the label

2.

PAUZYŃSYS sūntonny plėdikėlis pakuoėės etiketė

MedXpert GmbH - Max-Immelmann-Allee 19 - 79427 Eschbach Germany - www.medxpert.de - info@medxpert.de Vers. 2020-11

MEDXPERT

PES



REF 025-07178 LOT 910291 Stück/pcs.: 1 2017-07-24

Material: 1.4441 → med. plėnas

2.
Vienkartinė →



(01)428002958414(10)910291

- DE Pectus Stützplatte, Universal 178 mm
- EN Pectus Bar, Universal 178 mm
- ES Pectus Barra de soporte, Universal, 178 mm
- FR Plaque Pectus, Universal, 178 mm
- IT Barra Pectus, Universal, 178 mm
- NL Pectus steunplaat, Universal, 178 mm
- PT Barras de Pectus, Universal, 178 mm

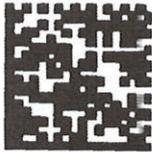
COPY / KOPIE

REF 025-07178 LOT 910291 MEDXPERT REF 025-07178 LOT 910291 MEDXPERT
Pectus Bar, Universal 178 mm Pectus Bar, Universal 178 mm

MedXpert GmbH - Max-Immelmann-Allee 19 - 79427 Eschbach Germany - www.medxpert.de - info@medxpert.de Vers. 2020-0

MEDXPERT

PES



REF 025-08203 LOT 910292 Stück/pcs.: 1 2017-07-24

Material: 1.4441 med. plėnas

2.
Vienkartinė →



R_x only CE 0483

(01)428002958415(10)910292

- DE Pectus Stützplatte, Universal 203 mm
- EN Pectus Bar, Universal 203 mm
- ES Pectus Barra de soporte, Universal, 203 mm
- FR Plaque Pectus, Universal, 203 mm
- IT Barra Pectus, Universal, 203 mm
- NL Pectus steunplaat, Universal, 203 mm
- PT Barras de Pectus, Universal, 203 mm

COPY / KOPIE

REF 025-08203 LOT 910292 MEDXPERT REF 025-08203 LOT 910292 MEDXPERT
Pectus Bar, Universal 203 mm Pectus Bar, Universal 203 mm

MedXpert GmbH - Max-Immelmann-Allee 19 - 79427 Eschbach Germany - www.medxpert.de - info@medxpert.de Vers. 2020-0

MEDXPERT

PES



REF 025-09229 LOT 910111 Stück/pcs.: 1 2017-07-12

Material: 1.4441 → med. pl.

2.
Vienkartinė →



R_x only CE 0483

(01)428002958416(10)910111

- DE Pectus Stützplatte, Universal 229 mm
- EN Pectus Bar, Universal 229 mm
- ES Pectus Barra de soporte, Universal, 229 mm
- FR Plaque Pectus, Universal, 229 mm
- IT Barra Pectus, Universal, 229 mm
- NL Pectus steunplaat, Universal, 229 mm
- PT Barras de Pectus, Universal, 229 mm

COPY / KOPIE

REF 025-09229 LOT 910111 MEDXPERT REF 025-09229 LOT 910111 MEDXPERT
Pectus Bar, Universal 229 mm Pectus Bar, Universal 229 mm

MEDXPERT



REF 024-19483 LOT 912443 Stück/pcs.: 1 2018-07-08

Material: 1.4441

Rx only CE 0483

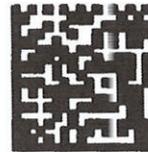
(01)426002958650(10)912443

- DE Pectus Stützplatte, glatte Enden, 483 mm
- EN Pectus Bar, smooth ends, 483 mm
- ES Pectus Barra de soporte, con los extremos lisos 483 mm
- FR Plaque Pectus non-dentelée, 483 mm
- IT Barra Pectus, estremità lisce 483 mm
- NL Pectus staunplaat, gladde uiteinden, 483 mm
- PT Barras de Pectus, extremidades lisas, 483 mm

COPY / KOPIE

REF 024-19483 LOT 912443 MEDXPERT REF 024-19483 LOT 912443 MEDXPERT
Pectus Bar, smooth ends, 483 mm Pectus Bar, smooth ends, 483 mm

MEDXPERT



REF 025-02010 LOT 910108 Stück/pcs.: 1 2017-07-12

Material: 1.4441

→ med. plectus

Rx only CE 0483

(01)426002958427(10)910108

2.
Vierkantweis

- DE Pectus Verschluss-Schraube, Universal
- EN Pectus Locking-Screw, Universal
- ES Pectus tornillo, Universal
- FR Pectus rivet, Universal
- IT Pectus vite, Universal
- NL Pectus schroef, Universal
- PT Parafuso de Pectus, Universal

COPY / KOPIE

REF 025-02010 LOT 910108 MEDXPERT REF 025-02010 LOT 910108 MEDXPERT
Pectus Locking-Screw, Universal Pectus Locking-Screw, Universal

MEDXPERT



REF 025-02020 LOT 907265 Stück/pcs.: 1 2016-03-21

Material: 1.4441

(01)426002958428(10)907265

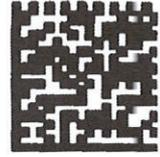
- DE Pectus Stützplatten-Stabilisator, Universal, L, Ø10 mm
- EN Pectus Bar Stabilizer, Universal, L, Ø10 mm
- ES Pectus Estabilizador, Universal, L, Ø10 mm
- FR Pectus Stabilisateur de plaque, Universal, L, Ø10 mm
- IT Pectus Stabilizzatore, Universal, L, Ø10 mm
- NL Pectus steunplaatstabilisator, Universal, L, Ø10 mm
- PT Estabilizador de barras de Pectus, Universal, L, Ø10 mm

COPY / KOPIE

REF 025-02020 LOT 907265 MEDXPERT REF 025-02020 LOT 907265 MEDXPERT
Pectus Bar Stabilizer, Universal, L, Ø10 mm Pectus Bar Stabilizer, Universal, L, Ø10 mm

4.
Page 10

MEDXPERT



REF 025-02027 LOT 910143 Stück/pcs.: 1 2017-07-20
Material: 1.4441

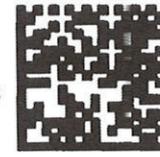
(01)428002958639(10)910143

- DE Pectus Stützplatten-Stabilisator, Universal, L, 2 x Ø4x8 mm
- EN Pectus Bar Stabilizer, Universal, L, 2 x Ø4x8 mm
- ES Pectus Estabilizador, Universal, L, 2 x Ø4x8 mm
- FR Pectus Stabilisateur de plaque, Universal, L, 2 x Ø4x8 mm
- IT Pectus Stabilizzatore, Universal, L, 2 x Ø4x8 mm
- NL Pectus steunplaatstabilisator, Universal, L, 2 x Ø4x8 mm
- PT Estabilizador de barras de Pectus, Universal, L, 2 x Ø4x8 mm

COPY / KOPIE

REF 025-02027 LOT 910143 MEDXPERT REF 025-02027 LOT 910143 MEDXPERT
Pectus Bar Stabilizer, Universal, L, 2 x Ø4x8 mm Pectus Bar Stabilizer, Universal, L, 2 x Ø4x8 mm

MEDXPERT



2. Vientarkitus →

REF 025-02028 LOT 911717 Stück/pcs.: 1 2018-03-15
Material: 1.4441 → *med. plenas*

⊗ ⊠ ⊡ ⊢ R_x only CE 0483

(01)428002958656(10)911717

- DE Pectus Stützplatten-Stabilisator, Universal, R, 2 x Ø4x8 mm
- EN Pectus Bar Stabilizer, Universal, R, 2 x Ø4x8 mm
- ES Pectus Estabilizador, Universal, R, 2 x Ø4x8 mm
- FR Pectus Stabilisateur de plaque, Universal, R, 2 x Ø4x8 mm
- IT Pectus Stabilizzatore, Universal, R, 2 x Ø4x8 mm
- NL Pectus steunplaatstabilisator, Universal, R, 2 x Ø4x8 mm
- PT Estabilizador de barras de Pectus, Universal, R, 2 x Ø4x8 mm

COPY / KOPIE

REF 025-02028 LOT 911717 MEDXPERT REF 025-02028 LOT 911717 MEDXPERT
Pectus Bar Stabilizer, Universal, R, 2 x Ø4x8 mm Pectus Bar Stabilizer, Universal, R, 2 x Ø4x8 mm

MEDXPERT



2. Vientarkitus →

REF 025-02029 LOT 911718 Stück/pcs.: 1 2018-03-15
Material: 1.4441 → *med. plenas*

⊗ ⊠ ⊡ ⊢ R_x only CE 0483

(01)428002958657(10)911718

- DE Pectus Stützplatten-Stabilisator, Universal, L, 2 x Ø4x8 mm
- EN Pectus Bar Stabilizer, Universal, L, 2 x Ø4x8 mm
- ES Pectus Estabilizador, Universal, L, 2 x Ø4x8 mm
- FR Pectus Stabilisateur de plaque, Universal, L, 2 x Ø4x8 mm
- IT Pectus Stabilizzatore, Universal, L, 2 x Ø4x8 mm
- NL Pectus steunplaatstabilisator, Universal, L, 2 x Ø4x8 mm
- PT Estabilizador de barras de Pectus, Universal, L, 2 x Ø4x8 mm

COPY / KOPIE

REF 025-02029 LOT 911718 MEDXPERT REF 025-02029 LOT 911718 MEDXPERT
Pectus Bar Stabilizer, Universal, L, 2 x Ø4x8 mm Pectus Bar Stabilizer, Universal, L, 2 x Ø4x8 mm

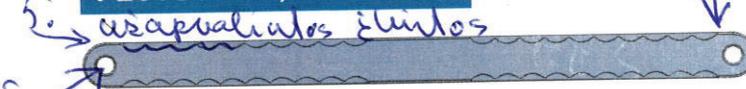
PECTUS BAR, SMOOTH ENDS



- Smooth ends for atraumatic implantation and explantation
- $\varnothing 5$ mm drill holes on both sides for insertion of a thread-through band as well as a Pectus BarLock™ Pin
- Compatible with all Pectus Bar Stabilizers

024-09229	Pectus Bar, smooth ends, 229 mm
024-10254	Pectus Bar, smooth ends, 254 mm
024-11279	Pectus Bar, smooth ends, 279 mm
024-12305	Pectus Bar, smooth ends, 305 mm
024-13330	Pectus Bar, smooth ends, 330 mm
024-14356	Pectus Bar, smooth ends, 356 mm
024-15381	Pectus Bar, smooth ends, 381 mm
024-16406	Pectus Bar, smooth ends, 406 mm
024-17432	Pectus Bar, smooth ends, 432 mm

PECTUS BAR, UNIVERSAL



- Smooth ends for atraumatic implantation and explantation *azapvalinti galaitiesi*
- 5. Rounded recesses placed on both sides for insertion of the Pectus Locking-Screw, Universal, and for secure attachment of the Pectus Bar Stabilizer, Universal
- $\varnothing 5$ mm drill holes on both sides for insertion of a thread-through band as well as a Pectus BarLock™ Pin
- Compatible with all Pectus Bar Stabilizers

025-07178	Pectus Bar, Universal, 178 mm
025-08203	Pectus Bar, Universal, 203 mm
025-09229	Pectus Bar, Universal, 229 mm
025-10254	Pectus Bar, Universal, 254 mm
025-11279	Pectus Bar, Universal, 279 mm
025-12305	Pectus Bar, Universal, 305 mm
025-13330	Pectus Bar, Universal, 330 mm
025-14356	Pectus Bar, Universal, 356 mm
025-15381	Pectus Bar, Universal, 381 mm
025-16406	Pectus Bar, Universal, 406 mm
025-17432	Pectus Bar, Universal, 432 mm
025-18458	Pectus Bar, Universal, 458 mm
025-19483	Pectus Bar, Universal, 458 mm

*5. - ilukos, azapvalintos
 *5. - kiaušynės, kiaušiniui rašyti $\varnothing 5,0$ mm

PECTUS BAR, SERRATED ENDS



- Serrated ends for secure attachment of a Pectus Bar Stabilizer using an aid (wire, suture material, not recommended by MedXpert)
- $\varnothing 5$ mm drill holes on both sides for insertion of a thread-through band as well as a Pectus BarLock™ Pin
- Compatible with all Pectus Bar Stabilizers

022-07178	Pectus Bar, serrated ends, 178 mm
022-08203	Pectus Bar, serrated ends, 203 mm
022-09229	Pectus Bar, serrated ends, 229 mm
022-10254	Pectus Bar, serrated ends, 254 mm
022-11279	Pectus Bar, serrated ends, 279 mm
022-12305	Pectus Bar, serrated ends, 305 mm
022-13330	Pectus Bar, serrated ends, 330 mm
022-14356	Pectus Bar, serrated ends, 356 mm
022-15381	Pectus Bar, serrated ends, 381 mm
022-16406	Pectus Bar, serrated ends, 406 mm
022-17432	Pectus Bar, serrated ends, 432 mm
022-18458	Pectus Bar, serrated ends, 458 mm
022-19483	Pectus Bar, serrated ends, 458 mm

1.2. *Pilusacines ploteiles sablonai*

PECTUS BAR TEMPLATE

DO NOT IMPLANT

- Surgical preparation outside the body for determining a suitable implant
- Pectus Bar Templates may not be implanted

021-07178	Pectus Bar Template, 178 mm
021-08203	Pectus Bar Template, 203 mm
021-09229	Pectus Bar Template, 229 mm
021-10254	Pectus Bar Template, 254 mm
021-11279	Pectus Bar Template, 279 mm
021-12305	Pectus Bar Template, 305 mm
021-13330	Pectus Bar Template, 330 mm
021-14356	Pectus Bar Template, 356 mm
021-15381	Pectus Bar Template, 381 mm
021-16406	Pectus Bar Template, 406 mm
021-17432	Pectus Bar Template, 432 mm

PECTUS BAR STABILIZER

Sliding Pectus Bar Stabilizers onto the Pectus Bar prevents the implanted Pectus Bar from tilting.



022-02010
Pectus Ribas Bar Stabilizer,
Low Profile

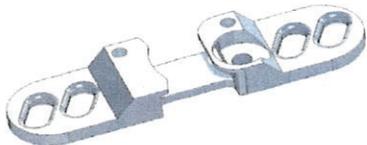


022-01010
Pectus Bar Stabilizer,
Low Profile

PECTUS BAR STABILIZER, UNIVERSAL

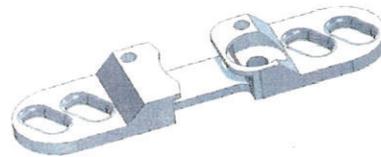
G. Stabilizatorius

Sliding Pectus Bar Stabilizers onto the Pectus Bar prevents the implanted Pectus Bar from tilting.



025-02028
Pectus Bar Stabilizer,
Universal, R, 2 x Ø4x8 mm

Rešiusys



025-02029
Pectus Bar Stabilizer,
Universal, L, 2 x Ø4x8 mm

Kairys

PECTUS LOCKING-SCREW, UNIVERSAL

Using the Pectus Locking-Screw, Universal, the Pectus Bar Stabilizer, Universal can be secured to and locked onto the Pectus Bar, Universal.



025-02010
Pectus Locking-Screw,
Universal

universalus sraigas

PECTUS BARLOCK™ PIN

Pectus BarLock™ Pin for securing the Pectus Bar Stabilizer on the Pectus Bar.



022-01050
Pectus BarLock™ Pin

PECTUS ALLERGY TEST PLATE

Pectus Allergy Test Plate made from implant material (1.4441) for execution of a simple patch test. See separate information that has been included to the product.

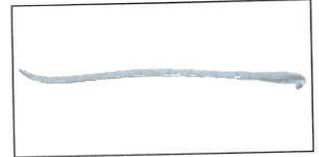


020-00060
Pectus Allergy Test Plate

INSTRUMENTS

Recommended instruments

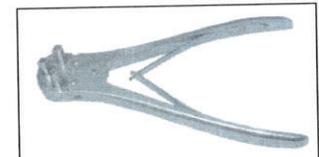
020-00011 Pectus Tunneling Instrument, medium, scaled
Tunneling Instrument for intercostal tunneling under endoscopic control and preparation for implantation.



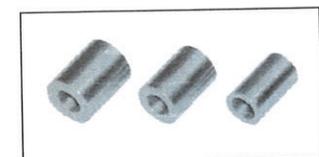
020-00018 Pectus Tunneling Instrument, round, medium, scaled acc. Schwabegger
Tunneling Instrument for intercostal tunneling under endoscopic control and preparation for implantation.



Pectus platitubus laulskykuvar
020-00021 Pectus Bar Bending Forceps, reverse action
For bending the Pectus Bar and final shaping following implantation. Through placement of the Bending Cylinders, the bending radius can be modified and further reduced.



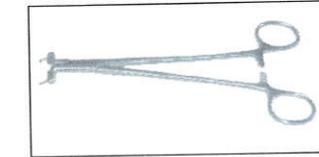
020-00025 Bending Cylinder for Pectus Bars, 9.7 mm supplement to 020-00021
020-00027 Bending Cylinder for Pectus Bars, 11.7 mm supplement to 020-00021
020-00029 Bending Cylinder for Pectus Bars, 13.7 mm supplement to 020-00021
Through placement of the Bending Cylinders onto the Pectus Bar Bending Forceps, reverse action 020-00021, the bending radius can be modified and further reduced.



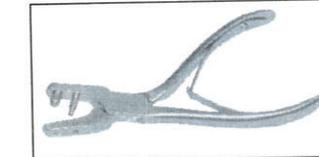
Pectus elevatorius
020-00031 Pectus Im- and Explantation Lever
Pectus Im- and Explantation Lever for rotation of the implants into the final position.



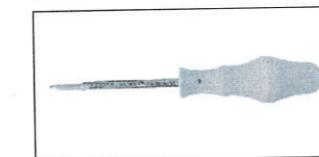
020-00080 Applying forceps for stabilizers
Applying Forceps for securely gripping the Pectus Bar Stabilizer during both implantation and explantation, even where access to the Pectus Bar is narrow.



020-00050 Pectus BarLock™ Forceps
For insertion and secure attachment of the Pectus Barlock™ Pin in order to secure the Pectus Bar Stabilizer against slippage.

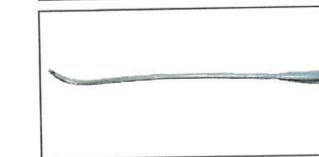
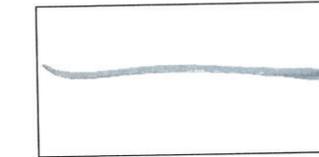


026-00010 Pectus screwdriver
Pectus screwdriver for turning and locking as well as for removal of the Pectus Locking-Screw, Universal (025-02010).

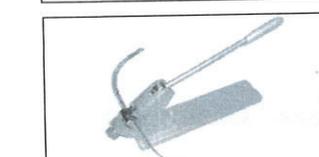


Additional instruments

020-00010 Pectus Tunneling Instrument, short, scaled
020-00012 Pectus Tunneling Instrument, long, scaled
Tunneling Instrument for intercostal tunneling under endoscopic control and preparation for implantation.



020-00019 Pectus Tunneling Instrument, round, long, scaled acc. Schwabegger
Tunneling Instrument for intercostal tunneling under endoscopic control and preparation for implantation.



020-00022 Pectus Bar Table Top Bender
For bending the Pectus Bar according to the shape of the Bar Template.

