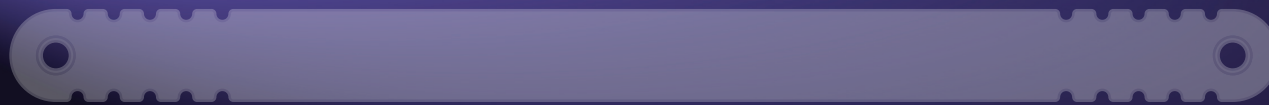


# Pectus Bar

# Pectus Excavatum Correction



**BIOMET**<sup>®</sup>  
MICROFIXATION  
Anticipate. Innovate.<sup>™</sup>

# An Innovative Technique for the Correction of Pectus Excavatum

Anticipation and innovation. These two qualities have made Biomet Microfixation an industry leader. Founded by Walter Lorenz more than thirty years ago, Biomet Microfixation offers instrumentation, plating systems and related products for a wide range of surgical procedures. Using the Nuss Technique, along with the Pectus Bar, surgery to correct Pectus Excavatum is accomplished in less time and with more ease than with other techniques.

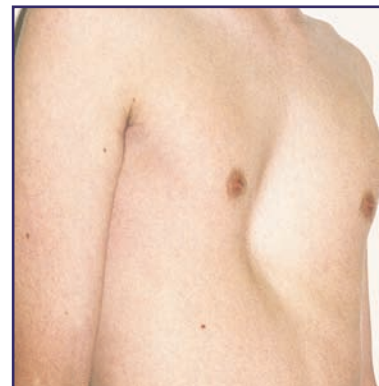
Dr. Donald Nuss, in cooperation with Biomet Microfixation, has developed a minimally invasive surgical procedure and Pectus Bar implant to remodel the chest wall over a 2 to 3 year period. The Nuss Technique, also known as the "Minimally Invasive Repair of Pectus Excavatum" (MIRPE), uses principles of minimal-access surgery and thoracoscopy combined with the proper placement of a Pectus Bar to achieve correction of Pectus Excavatum.

Pectus Excavatum is a chest disorder occurring in approximately one of every 1,000 children. This congenital deformity is characterized by a concave, "funnel" shaped chest. The inward facing sternum can apply pressure to the vital organs of the chest resulting in restricted organ growth and shortness of breath. Mildly present at birth, Pectus Excavatum usually becomes more serious throughout childhood, often magnifying considerably during the teenage years.

## Pectus System Features

- ▶ The Pectus Bar's rounded ends and blunt edges help minimize tissue destruction during implant insertion.
- ▶ The Pectus Bar comes in a variety of lengths ranging from 7 inches (17.8 cm) to 17 inches (43.2 cm) to accommodate most Pectus Excavatum correction procedures.
- ▶ All instruments in the Pectus System are designed to increase simplicity during the Nuss Procedure.
- ▶ The Pectus System Container comes in two sizes and conveniently houses the entire range of Pectus implants and instruments.
- ▶ Specialized titanium bars and stabilizers available for patients with nickel allergies.\*
- ▶ Pectus-size bars available for the following:
  - Special sized bars
  - Pre-bent bars developed in accordance with patients' CT scans\*

\*Titanium and pre-bent bars for pediatric indications only



Severe case of Pectus Excavatum. Pre-operative photo.



2 year Postoperative photo at 1 month after bar removal.

## Benefits

**Minimally Invasive Operation** - Use of the MIRPE technique requires neither cartilage incision nor resection for correction of pectus excavatum. There is no need to make an incision in the anterior chest wall, raise pectoralis muscle flaps, resect rib cartilages, nor perform sternal osteotomy.

**Reduces Operating Time** - The procedure requires approximately 40 minutes, as opposed to the 4 to 6 hours required of a chest reconstruction.

**Minimal Blood Loss** - Blood loss is generally 10 to 30cc, compared to the 300cc lost with the other products and techniques.<sup>1</sup>

**Return to Regular Activity** - The average time for a patient to resume daily activities, once treated with the Pectus Bar, is one month.\*

\*Return time varies depending on each patient. Always consult your physician before resuming any activity.

**Chest Correction** - Using the Pectus Bar the patient can experience ease of breathing, normal chest expansion and elasticity, and proper lung and heart growth.

**Excellent Long-Term Cosmetic Result** - "A 10 Year Study of a Minimally Invasive Technique for the Correction of Pectus Excavatum", indicated excellent long-term results. The Journal of Pediatric Surgery, 1998; 33(4). Donald Nuss, M.B., Ch.B.; Robert E. Kelly, Jr., M.D.; Daniel P. Croitoru, M.D.; Michael E. Katz, M.D.

## Indications and Patient Selection

Patients with pectus excavatum are considered for surgical reconstruction between the ages of 4 and 18 years when the ribs and costal cartilage are neither too malleable nor too rigid. The ideal age is between 8 and 13 years, prior to the adolescent growth period.

A complete physical exam and full medical history are completed for all patients to place them into either asymptomatic or symptomatic classifications based on the following criteria:

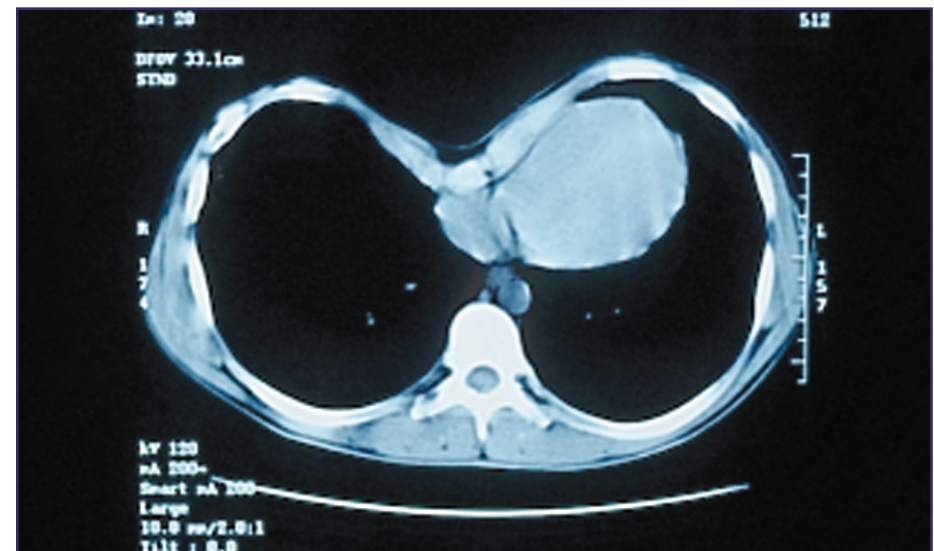
- ▶ History of progressive worsening of the pectus excavatum.
- ▶ History of the symptoms related but not limited to exercise intolerance, chest pain, and shortness of breath.
- ▶ Clinical evaluation showing severe pectus with the demonstration of cardiac displacement and pulmonary compromise.

Asymptomatic patients are given an exercise program to correct their posture and are reevaluated every six months to follow their progress. Patients will be moved into the symptomatic group as indicated by their symptoms and lack of progress.

Symptomatic patients are sent for a CT scan, pulmonary-function studies and cardiology examinations. Surgery is supported by the results of the objective criteria obtained from these exams. The criteria includes a CT index (Haller index) of 3.2 or greater, atelectasis, abnormal pulmonary function, cardiac compression, mitral valve prolapse, heart murmurs and A-V conduction delay. These patients may have other abnormalities, such as Marfan's syndrome, Ehlers-Danlos or Poland's syndrome.

Prior to the day of surgery, the patient's chest is measured to determine the length of the Pectus Bar. Proper measurement is performed utilizing a measuring tape or a Pectus Bar Template over the deepest portion of the pectus from the right midaxillary to the left midaxillary line. The length of the Pectus Bar required is 1 to 2 cm less than the measured distance because the tape measures the external diameter of the chest and the Pectus Bar traverses the internal diameter.

1. Nuss D, Kelly RE, Croitoru D, Katz M., **A 10 Year Study of a Minimally Invasive Technique for the Correction of Pectus Excavatum**. The Journal of Pediatric Surgery, 1998; Vol 33 April, 1998; pp 545-552



Heart compression and displacement

# Operative Technique



**1.** A course of antibiotics is started at the time of surgery to prevent infection and reduce the development of pneumonia. The procedure is performed under general endotracheal anesthesia with muscle relaxation and an epidural block for both operative and postoperative pain control.

**2.** During the procedure, the patient is positioned with both arms abducted at the shoulders to allow access to the lateral chest-wall. Padding under the arms and proper positioning of the arms will help prevent neurologic injury.

Patient positioned with both arms abducted

**3.** The patient is draped, and the chest is marked for surgery with a sterile marking pen. The deepest portion of the pectus is marked. If the deepest point of the pectus is inferior to the sternum, then mark the lower end of the sternum. Using this point, establish a horizontal plane across the pectus region by marking the intercostal spaces at the top of the pectus ridge on both sides. Extend the horizontal plane to the lateral chest wall and mark between the anterior and midaxillary lines for transverse lateral incisions.

Patient is draped and marked for surgery



**4.** The preoperative chest measurement is reconfirmed, and a Pectus Bar is selected for bending into the desired chest-wall curvature. The Pectus Bar Template can be used to visualize the shape necessary to correct the deformity. Special care should be taken in choosing the correct Pectus Bar length to maximize bar stability.

Confirming preoperative measurements using a Pectus Bar Template

**5.** Using the Pectus Bender, shape the selected Pectus Bar from the center outward making small gradual bends. Position the cam on the bender at position "0" (minimum radius) then move the cam to position "1," and finally to position "2" (maximum radius). It may be necessary to exaggerate the curvature slightly to allow for the anterior chest-wall pressure and downward force of the sternum. To insure proper union between bar and stabilizer, avoid bending the lateral ends of the Pectus Bar. The selected bar is shaped for each patient. Incisions being made at the predetermined marks

The selected bar is shaped for each patient





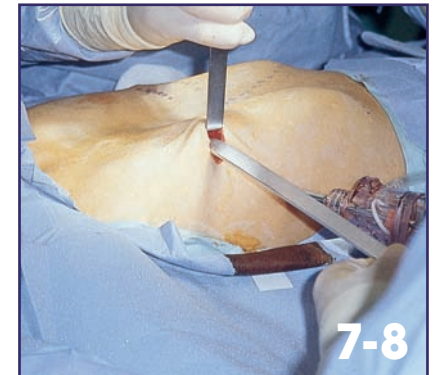
**6.** Bilateral 2.5 cm transverse, thoracic incisions are made at the marks previously drawn in line with the deepest point of the depression in each lateral chest wall between the anterior and midaxillary lines. A skin tunnel is raised anteriorly from both incisions to the top of the pectus ridge at the previously selected intercostal space. The Pectus Bar enters the chest slightly medial to the top of the pectus ridge.

Incisions being made at the predetermined marks

**7.** A 5mm, 0° or 30° thoracoscope is used during the procedure to visualize the chest organs. Insert the scope on the patient's right side, one to two intercostal spaces below the space which has been chosen for the Pectus Bar. The scope can be used bilaterally using the incision made on the patient's left, or a new stab incision can be made one to two intercostal spaces below the space which has been chosen. The chest is insufflated with CO<sub>2</sub> for adequate visualization.

**8.** Enter the chest from the patient's right with the proper Pectus Introducer in order to dissect a tunnel for the implant. The small introducer is for younger, smaller patients, ages 4-12. The long introducer is for older, larger patients, ages 13-18. Advancing the Pectus Bar Introducer to dissect a tunnel for the pectus bar.

Advancing the Pectus Bar Introducer to dissect a tunnel for the pectus bar



**9.** The Pectus Introducer is slowly advanced across the mediastinum immediately under the sternum and is gently pushed through the intercostal space on the opposite side. The tip should face anteriorly and stay in contact with the sternum. Advance the device far enough through the opposite incision to allow for elevating the sternum and attaching of the umbilical tape.

Introducer is advanced through the chest and the opposite incision

**10.** Elevate the sternum by lifting the advanced introducer from both sides of the patient. Apply pressure above and below the sternum to obtain the desired curvature of the sternum. Repeat several times in order to stretch the connective tissues and correct the deformity prior to inserting the bar. Correcting the pectus excavatum by elevating the sternum with the introducer greatly facilitates initial bar rotation and improves bar stability.

Pressure is applied to the sternum to stretch the connective tissues



# Operative Technique

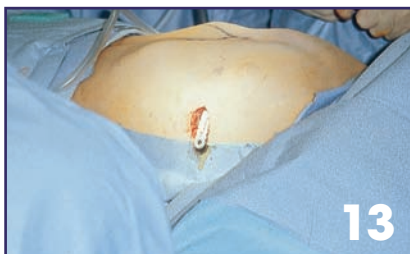


**11.** Two strands of umbilical tape are tied through the hole in the end of the introducer and then pulled through the tunnel by withdrawing the introducer from the patient's right side. One strand is used as a backup, while the other strand of umbilical tape is then attached to the bar and used to guide it through the tunnel.

Umbilical tape used to guide the bar

**12.** The curved Pectus Bar is pulled under the body of the sternum from the patient's right side with the convexity facing posteriorly. When the bar is in position, it is flipped with the Pectus Flipper causing the sternum and anterior chest wall to rise into the desired position.

Guiding the convex bar through the chest with the convexity facing posteriorly



**13. STABILITY OF THE BAR MUST BE DETERMINED AT THIS TIME.** Such assessment will dictate the need for bar stabilization and for placement of a second bar behind the sternum. Typically, patients require one bar. Older, larger and more active patients or patients with a more severe deformity may require an additional bar to achieve proper correction and stability. If needed, a second bar is placed one or two intercostal spaces superiorly or inferiorly to the first bar.

Pectus correction and implant stability are evaluated

**14.** A subcutaneous pocket is made posteriorly at each incision where the lateral end of the bar will be fitted with a Pectus Bar Stabilizer. One stabilizer is recommended for every bar implanted to limit rotation of the bar. Recommended patient ages for use of the stabilizers are:

- ▶ Patients 4 - 13 years - use one stabilizer per bar implanted
- ▶ Patients 14 - 18 years - use one stabilizer per bar implanted, however one may choose to use two per bar depending on the patient's pectus, muscular development, activity level (ie: sports), and the stability of the bar.

Trial fitting a stabilizer (01-3801) to the implant





**15.** An Elongated Stabilizer is chosen and fitted with the channel facing anteriorly and 1 to 2 cm of the lateral end of the bar exposed through the stabilizer. The stabilizer is then secured to the bar and sutured to the muscle after being properly fitted. The bar and stabilizer(s) should not be too anterior or posterior on the patient as this can lead to pain and tissue erosion.

- ▶ Elongated Stabilizer - Suitable for all patients in the recommended age range.

Trial fitting a stabilizer (01-3801) to the implant

**16.** The bar and stabilizer are secured to each other and to the chest wall with multiple sutures to anchor the bar and stabilizer to the chest wall and bury the bar and stabilizer with tissue. The size and types of suture presently used are as follows:

- ▶ Secure the stabilizer to the bar with a "figure-8 suture" around the junction of both devices with No. 3 cardiac wire or size "O" non-absorbable suture.
- ▶ Secure the holes in the bar and stabilizer to the chest wall muscles with size "O" absorbable or non-absorbable suture attached to a UR 6 (right-angle) needle.
- ▶ Secure muscle over the bar with "mattress sutures" using size "O" fast or slow absorbable suture attached to a large needle.
- ▶ Close the wound with a small-size, fast-absorbing suture and a dressing.



Cardiac wire is used to "figure 8" suture both the bar and the stabilizer



**17.** Prior to closing the incisions, place patient in Trendelenburg's position, inflate lungs and apply positive end expiratory pressure (PEEP) of 4 to 6 cm H<sub>2</sub>O to prevent pleural air trapping.

Suture to the chest wall muscles to anchor the device

**18.** A chest radiograph should be obtained postoperatively to check for pneumothorax. The radiograph is excellent in showing final bar placement and may be obtained in the operating room or surgery-recovery area, as required.

Patient is ready for recovery



# Postoperative Patient Care

Patients are kept well sedated for the first 1 to 3 days for postoperative pain management and to prevent bar displacement. Medications and therapies depend on the patient's response to pain and may include the use of an epidural catheter, intravenous morphine for breakthrough pain, patient-controlled analgesia and oral analgesia.

Postoperative patient handling by the hospital staff is important for avoiding bar displacement. Patients are discharged from the hospital when they are able to walk unassisted.

## Recommended Postoperative Protocol

### Day 1 Post-Op

- ▶ Out of Bed (OOB) to a chair with assistance OOB ambulation, as tolerated with assistance medical immobilization by nursing staff, as required eggcrate mattress (as indicated)
- ▶ NO chest or waist bending
- ▶ NO twisting
- ▶ NO LOG ROLLING
- ▶ Deep breathing and incentive spirometry every hour while awake

### Day 2 Post-Op

- ▶ OOB to a chair with assistance
- ▶ OOB ambulation, as tolerated with assistance supine with hip flexion
- ▶ NO chest or waist bending
- ▶ NO twisting
- ▶ NO LOG ROLLING
- ▶ Deep breathing and incentive spirometry every hour while awake

### Day 3 Post-Op through Discharge Day

- ▶ OOB ambulation with minimal assistance supine with hip flexion
- ▶ NO chest or waist bending
- ▶ NO twisting
- ▶ NO LOG ROLLING
- ▶ Deep breathing and incentive spirometry every hour while awake

Once discharged, the patient should maintain good posture and limit activity for the first month, with regular activity permitted after 4 to 6 weeks. The following guidelines have been developed to assist the patient's return to regular activity and reduce the risk of bar displacement:

- ▶ Walking should be done frequently

- ▶ Deep-breathing exercises performed twice a day, every morning and evening
- ▶ Patient can bathe and/or shower after five (5) days
- ▶ No waist bending, twisting or log rolling for first four (4) weeks at home
- ▶ Patient should keep a straight back with no slouching for the first month
- ▶ No heavy lifting for the two (2) months following surgery
- ▶ No sports for the first three (3) months following surgery

The implant remains in the patient for a minimum of two years. Should the patient require emergency medical attention during this period, the following recommendations will apply:

- ▶ MedicAlert® identification is recommended
- ▶ MRI of the chest or upper abdomen can be performed\*
- ▶ Cardiac defibrillation, if necessary, is performed with anterior/posterior paddle placement to deliver electrical charge to the heart

The patient should visit the doctor at regular intervals for evaluation of the chest wall. The implant is removed when the chest wall is deemed strong enough to support the sternum. Generally, the bar will remain implanted for a minimum of 2 years, and up to a maximum of 3 years.

## Bar Removal

1. Surgery for removal of the support bar(s) and stabilizer(s) is performed under general anesthesia as an outpatient procedure. The patient is in the supine position with the arms abducted. Incisions are made in the same locations as during the implantation.
2. The incision will allow access to the lateral tip of the support bar for removal of all stabilizers and any remaining sutures. The support bar is removed by pulling the bar through one incision while rolling the patient to the opposite side.
3. The incisions are closed with absorbable sutures, and a postoperative chest radiograph is recommended.

### \*MRI Information

Ref: Woods TO. Standards for medical devices in MRI: present and future. J. Magn Reson Imaging. 2007; 26:1186-9

The Pectus Support Bar System is MR-conditional according to the terminology specified in the ASTM International, Designation:F2503-05. Non-clinical testing demonstration that the Pectus Support Bar System Bar is MR Conditional. A patient with this implant can be scanned safely immediately after placement under following conditions: Static magnetic field of 3-Tesla or less and a maximum spatial gradient magnetic field of 720-Gauss/cm



## Pectus Bar Implant

Size in Inches	Size in cm	Part #	Template Part #
7	17.8	01-3707	01-3807
7.5	18.1	01-3707-05	01-3807-05
8	20.3	01-3708	01-3808
8.5	21.6	01-3708-05	01-3808-05
9	22.9	01-3709	01-3809
9.5	24.1	01-3709-05	01-3809-05
10	25.4	01-3710	01-3810
10.5	26.7	01-3710-05	01-3810-05
11	27.9	01-3711	01-3811
11.5	29.5	01-3711-05	01-3811-05
12	30.5	01-3712	01-3812
12.5	31.8	01-3712-05	01-3812-05
13	33.0	01-3713	01-3813
13.5	34.3	01-3713-05	01-3813-05
14	35.6	01-3714	01-3814
14.5	36.8	01-3714-05	01-3814-05
15	38.1	01-3715	01-3815
15.5	39.4	01-3715-05	01-3815-05
16	40.6	01-3716	01-3816
16.5	41.9	01-3716-05	01-3816-05
17	43.2	01-3717	01-3817

\*Patient specific size bars are available; please contact customer service.  
**Note:** Templates are not implantable and should be used for surgical planning only.



Pectus Bar Implant  
(See chart for details)



Standard Container  
01-3920

X-Long Container  
01-3925



Elongated Pectus Stabilizer  
01-3801



Pectus Removal Benders, Pair  
01-3911



Pectus Bender  
01-3905



Pectus Bender X-Long  
01-3907



Pectus Flipper  
01-3900



Pectus Table Top Bender  
01-3906



Pectus Introducer

Small (18.8")  
01-3909

Large (20")  
01-3908

X-large (22.4")  
01-3908X

# Warnings and Precautions for Pectus Support Bar System

## Description

The Biomet Microfixation Pectus Support Bar and stabilizers are surgical implants intended to aid treatment of a Pectus Excavatum deformity. The Pectus Support Bar provides the surgeon with a means to reposition bony structures (sternum, breastbone) by applying internal force outwardly eliminating the funnel shape deformity. The device should be removed when remodeling is evident. The Pectus Support Bar and stabilizers are made from Stainless Steel, ASTM F 138.

## Indications

Pectus Excavatum and other sternal deformities.

## Contraindications

1. Patients with mental or neurological conditions who are unwilling or incapable of following instructions.
2. Patients presenting metal sensitivity reactions.
3. Patients with insufficient quantity or quality of bone or fibrous tissue to allow remodeling.
4. Infection

## Warnings and Precautions

The Pectus Support Bar provides the surgeon with a means of treating Pectus Excavatum, funnel chest, a congenital deformity often accompanied by shortness of breath in children. The device is not intended to replace chest wall structures. While the device is intended to expand the chest wall cavity eliminating the features of the deformity, the degree of initial reshaping and permanent remodeling for each case cannot be predetermined. The surgeon is to be thoroughly familiar with the implants and the surgical procedure prior to surgery. The correct selection and placement of the implant is important. Preoperative planning to determine the most appropriate size and final position of the implant is required. The surgeon should avoid sharp bends,

reverse bends, or bending the device at a hole. The implant can become dislodged, shift, or flip as a result of improper device selection, improper stabilization, not suturing the device(s), or patient activity too soon after surgery.

Even though the implant is mechanically fixed (sutured) in position, care is to be taken to assure that the device is rigidly in apposition to the area of the deformity, as demonstrated by total or partial elimination of the visible deformity. If the deformity is not partially eliminated, a secondary Pectus Support Bar may be required or an alternative method of treatment is to be considered. During the course of the surgical procedure, and during implantation, extreme care is to be taken to avoid contact with the heart and lungs with either the implant or instruments, as contact to these organs can cause death or permanent injury to the patient. When considering removal, the surgeon should weigh the risks versus benefits when deciding when to remove the implant. Where evidence of adequate remodeling is present, removal should be performed. Implant removal is to be followed by postoperative monitoring to check for reoccurrence of the deformity. Where reoccurrence is encountered, a secondary treatment or alternative treatment may be necessary. Surgical implants should never be reused. Even though the implant may appear undamaged, it may have imperfections, defects, or internal stress patterns which may lead to breakage or inadequate performance.

## Patient Warnings

Postoperative care and monitoring is important. Metallic fixation devices cannot withstand activity levels and loads equal to those placed on a normal healthy chest wall. The implant can loosen, migrate, bend, or break as a result of weight bearing, load bearing, strenuous activity, or traumatic injury. The patient is to be warned by the operating surgeon to limit activities accordingly. Limitation of physical activities may be unique to each patient and the

patient should be warned that noncompliance with Postoperative instructions could lead to complications described above. The patient must be made aware and warned that the deformity or some degree of deformity may be present even after treatment. In addition, the patient is to be warned of general surgical risks and possible adverse effects as listed, prior to surgery.

## Possible Adverse Effects

1. Metal sensitivity reactions or allergic reaction to the implant material.
2. Pain, discomfort, or abnormal sensation due to the presence of the device.
3. Surgical trauma; permanent or temporary nerve damage, permanent or temporary damage to heart, lungs, and other organs, body structures or tissues.
4. Skin irritation, infection, and pneumothorax.
5. Fracture, breakage, migration, or loosening of the implant.
6. Inadequate or incomplete remodeling of the deformity or return of deformity, prior to or after removal of implant.
7. Permanent injury or death.

## Sterility

Steam sterilize the Pectus Support Bar prior to implantation using steam sterilization equipment which has been properly validated. Following is a recommended minimum cycle for steam sterilization that has been validated by Biomet Microfixation under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of recommended minimum cycle parameters described below.

Pre-vacuumed Steam Sterilization (Hi-VAC) Wrapped:  
Temperature: 270° Fahrenheit (132° Celsius)  
Time: Four (4) minutes  
Drying Time: Thirty (30) minutes MINIMUM

Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Since Biomet Microfixation is not familiar with individual hospital handling methods, cleaning methods and bioburden, Biomet Microfixation ca not assume responsibility for sterility even though the guideline is followed.

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

**Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities with which they are involved in the handling and use of this product.**

## Pectus Bar Technique Taken from:

1. Nuss D, Kelly RE, Croitoru D, Katz M. "A 10-Year Review of a Minimally Invasive Technique for the Correction of Pectus Excavatum." Journal of Pediatric Surgery, Vol 33, No 4 (April), 1998; pp 545-552.

"The Nuss Procedure" video, Children's Hospital of the King's Daughters and Eastern Virginia Medical School, 1998.

Please refer to the product insert for full explanation of warnings and considerations. Strength testing conducted at Biomet Microfixation, Jacksonville, FL.

Physicians Address:

Donald Nuss, M.B., Ch.B., F.A.C.S., (C), F.A.A.P.  
601 Children's Lane, Suite 5B  
Norfolk, VA 23507

## MRI Information

The Pectus Bar Implant, Part #01-3717 is MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the Pectus Bar Implant, Part#01-3717 is MR-Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:

### Magnetic Field Interactions

Static magnetic field of 3-Tesla or less-Maximum spatial gradient magnetic field of 720-Gauss/cm or less.

### MRI-Related Heating

In non-clinical testing, the Pectus Bar Implant, Part #01-3717 produced the following temperature rises during MRI performed for 15-min in 1.5-Tesla (1.5-Tesla/64MHz, Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR2002B DHHS) and 3-Tesla (3-Tesla/128-MHz, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR systems, as follows:

Highest Temperature Change	MRI Condition
+2.5°C	1.5-T/64-MHz
+3.7°C	3-T/128-MHz

Therefore, the MRI-related heating experiments for the Pectus Bar Implant, Part#01-3717 at 1.5-Tesla and 3-Tesla using a transmit/receive RF body coil at MR system reported whole body averaged SARs of 2.4-W/kg (i.e., associated with a calorimetry value of 2.0-W/kg) and 2.5-W/kg (i.e., associated with a calorimetry value of 2.2-W/kg), respectively, indicated that the greatest amount of heating that occurred in

association with these specific conditions was equal to or less than 2.5° C at 1.5-Tesla and 3.7° C at 3-Tesla.

### Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Pectus Bar Implant, Part #01-3717. The artifact size information is, as follows:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	34,454-mm <sup>2</sup>	20,670-mm <sup>2</sup>	54,785-mm <sup>2</sup>	17,877-mm <sup>2</sup>
Imaging Plane	Parallel	Perpendicular	Parallel	Perpendicular

Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

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**BIOMET®**  
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For more information on Pectus Bar, please contact us at:

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This brochure is presented to demonstrate the surgical technique, patient selection and post-op protocol utilized by Dr. Donald Nuss. As the manufacturer of this device, Biomet Microfixation does not practice medicine and does not recommend this product or surgical technique for use on a specific patient. The surgeon who performs any implant procedure must determine the appropriate device and surgical procedure for each individual patient. Devices shown in this brochure may not be cleared or licensed for use or sale in your individual country. Please contact your local distributor for information regarding availability of this product. Information contained in this brochure is intended for surgeon or distributor information only and is not intended for patient distribution. All surgeries carry risks. For additional information on these risks, please see appropriate package insert, or visit our web site at [www.biometmicrofixation.com](http://www.biometmicrofixation.com) or call 1-800-874-7711.