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# PECTUS EXCAVATUM IS TREATABLE

**Pectus Bar Caregiver  
& Patient Education**





# Pectus Excavatum is not preventable, but it is treatable.

While some live a normal, active lifestyle with Pectus Excavatum (sunken chest), the treatment of more severe cases includes surgery. Searching for options when it comes to sunken chest can be overwhelming. Thankfully, there is a minimally invasive surgery called the Nuss Procedure.

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## Appointment Log

Please be certain to take this log book to all appointments.

Date and time of \_\_\_\_\_

Name of healthcare professional \_\_\_\_\_

Notes for this appointment \_\_\_\_\_

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A photograph of a male coach in a white polo shirt and dark shorts sitting on the grass, talking to a group of five young male soccer players. The players are also wearing white jerseys and dark shorts, some with numbers like '2' and '7'. They are on a grassy field with a soccer goal in the background. A semi-transparent blue box is overlaid on the right side of the image, containing the title and text.

# Partnership for innovative care.

Zimmer Biomet has developed the Pectus Support Bar, in collaboration with Dr. Donald Nuss, for patients seeking a less invasive treatment option. As a result of these efforts, this less invasive procedure combined with use of the Pectus Support Bar implant has become a widely accepted method for surgeons treating pediatric patients with pectus excavatum.<sup>1</sup>

## What is pectus excavatum?

Pectus excavatum is a congenital chest deformity caused by abnormal growth of the cartilage that holds the ribs to the breastbone (sternum). The breastbone is pushed inward creating a condition in the chest sometimes referred to as “funnel chest” or “sunken chest.” The condition seems as though the lower half of the breastbone has been scooped out, therefore leaving a dent.<sup>1</sup>

Pectus excavatum is typically present at birth and can become more severe as a child gets older, especially during growth spurts in adolescent years, though that is not always the case.<sup>2</sup> Severe cases of pectus excavatum may interfere with the function of the heart and lungs, but also may play a part in a child’s self-esteem.<sup>3</sup>

## How common is pectus excavatum and what causes it?

Pectus excavatum occurs in approximately 1 out of every 300 to 400 births, making it one of the most common chest wall deformities. Males are three times more likely to have the condition than females.<sup>4</sup>

The causes of pectus excavatum are not well understood; However, researchers believe that there may be a hereditary link, as well as an association with certain cartilage disorders, such as Marfan Syndrome.<sup>5</sup>

**1 OUT OF EVERY 300-400**

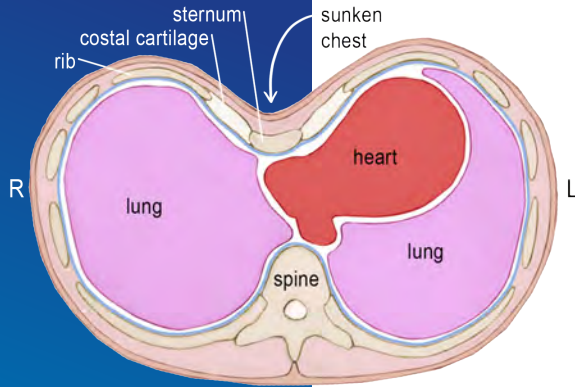
Chest with  
Pectus Deformity



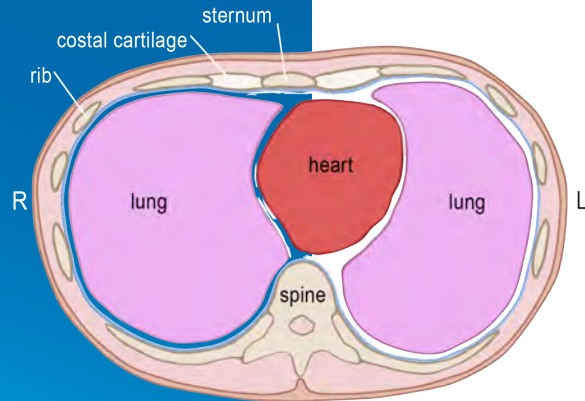
Normal Chest



## Pectus Excavatum Chest



## Normal Chest



## What are the common physical symptoms of pectus excavatum?<sup>6</sup>

While the depression in the chest is noticeable, sometimes pectus excavatum does not cause any symptoms. However, symptoms can occur when the condition applies pressure to the heart and lungs. You should consult a healthcare provider if any of the following symptoms are experienced:

- ◆ Chest pain
- ◆ Constant fatigue
- ◆ Shortness of breath
- ◆ Rapid heartbeat

Various psychological effects should not be overlooked and should be treated with the same care as are the physical symptoms.<sup>7</sup>

- ◆ Depression
- ◆ Feelings of embarrassment
- ◆ Social anxiety
- ◆ Frustration and anger







A photograph of four young men in athletic wear (dark blue, yellow, blue, and teal) in starting blocks on a red running track. They are all smiling and looking towards the camera. The background shows a line of trees and a clear blue sky with some clouds. A semi-transparent blue banner is overlaid on the bottom half of the image, containing the text 'Who is a surgical candidate?' in white. The text is followed by a superscript '8,9'.

Who is a surgical candidate?<sup>8,9</sup>





## Who is considered a surgical candidate?<sup>8,9</sup>

Pectus excavatum is not preventable, but it is treatable. Patients should seek treatment if they are having physical symptoms and/or psychological symptoms from their pectus condition.

Patients are considered candidates for corrective surgery with the following criteria:

- ◆ If regular heart and lung functions or quality-of-life is negatively impacted
- ◆ How severe the deformity is as measured by the Haller index
- ◆ If psychological impact of the deformity leads to significant self-esteem issues, such as clinical depression

Results with the Pectus Support Bar will vary due to health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Only a medical professional can determine the treatment appropriate for your specific condition. Appropriate post-operative activities will differ from patient to patient.

Talk to your surgeon about whether the minimally invasive Nuss procedure and the Pectus Support Bar is right for you and the associated risks, therewith, including but not limited to the risks of allergic reaction, pain or discomfort, infection, fracture, breakage, movement or loosening of the bar, inadequate or incomplete remodeling of the deformity or permanent injury or death.<sup>10</sup> For a complete list of risks associated with Zimmer Biomet's Pectus Support Bar, see Patient Risk Information.

# Know your options

## Overview<sup>11,12</sup>

Surgical treatment of pectus excavatum is intended to reduce pressure on vital organs and create a more normal chest shape by repositioning the chest including the ribs, sternum or “breastbone,” and the cartilage that connects the ribs to the breastbone.

Until the widespread adoption of the minimally-invasive Nuss Procedure during the 1990s, an “open” surgery that is commonly referred to as the

Ravitch Procedure was the most common surgical option for repairing pectus excavatum. Both surgeries are performed while the patient is asleep under general anesthesia but vary in the way that the chest anatomy is repositioned.



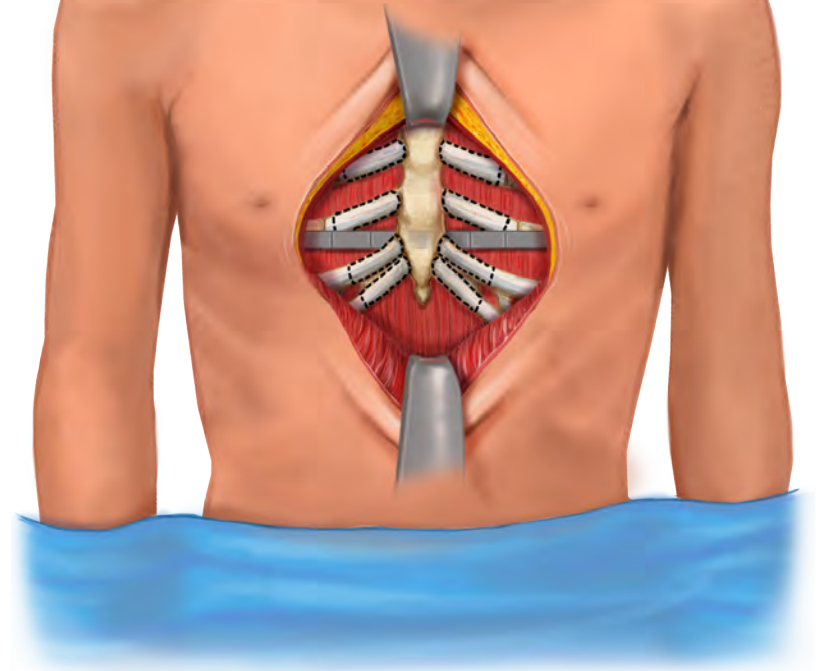


## Ravitch Procedure<sup>11,13</sup>

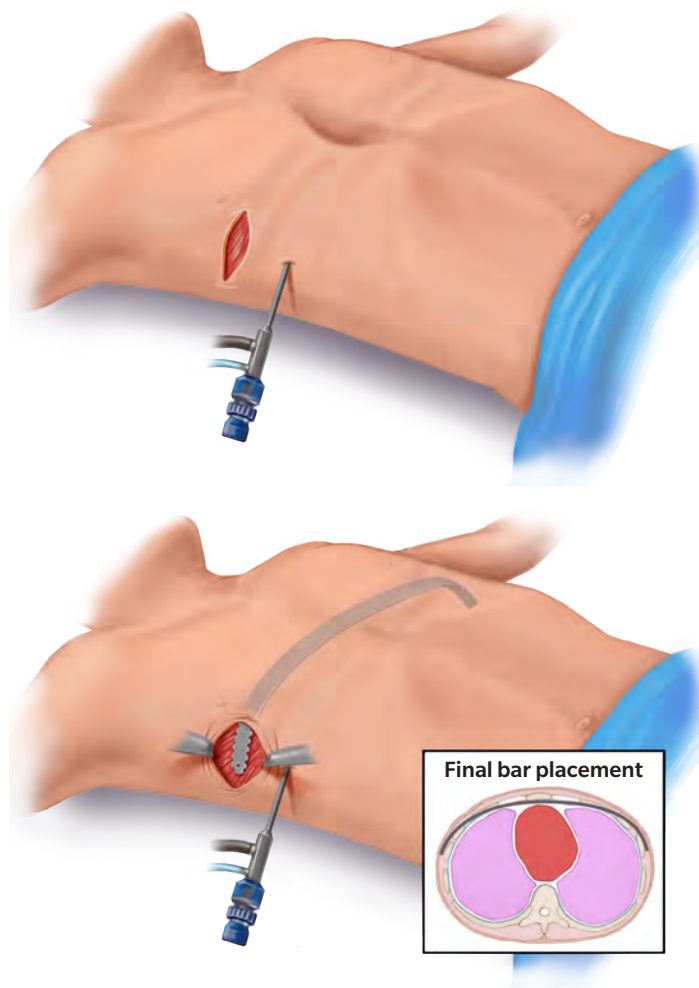
This surgery corrects the shape of the chest by making a long cut, or incision, below the breast line across the chest. After the surgeon raises the chest muscles off the breastbone and ribs, he or she removes the abnormal cartilage, moves the breastbone into a normal position and places a short steel bar behind the breastbone to keep it in place. Following the 4 to 6 hour surgery, the cartilage will regrow and reconnect the breastbone to the ribs.

A Ravitch Procedure generally follows these steps:

- ◆ An incision is made across the front of the patient's chest.
- ◆ Deformed cartilage is removed (resected) and the lining that covers the ribs and cartilage is left in place to help the cartilage grow back correctly.
- ◆ A cut (osteotomy) is made in the breastbone so it can be raised to a flat position. The surgeon may use a metal bar or strut to support the sternum in this position as it heals.
- ◆ To help drain fluids out of the body, a tube is sometimes placed at the area of the repair.
- ◆ The incision is closed at the end of the surgery.
- ◆ After approximately 6 to 12 months, the metal support struts (if used), are removed through a small incision.



**Dotted lines represent removed cartilage**



## Nuss Procedure<sup>11,14</sup>

This 1 to 2 hour surgery corrects the shape of the chest by using a curved metal bar that is placed under the breastbone. With the help of a small camera, the surgeon will create a pathway across the chest under the breastbone and insert a Pectus Support Bar. The bar is shaped to fit the patient and lifts the chest into a normal shape. As the bar pushes the breastbone forward, it bends the cartilage that holds the breastbone to the ribs, promoting that cartilage to heal in a new, normal shape.

A Nuss Procedure generally follows these steps:

- ◆ Two small incisions (usually 2 inches in length) are made to provide access under the sternum. Exact position of the incisions can vary depending on whether the patient is male or female.
- ◆ A video camera used for surgery (called a thoracoscope) is inserted through a third small incision on one side below the others.
- ◆ While using the camera to see inside the chest, a curved introducer instrument is used to create a pathway across the chest below the sternum.
- ◆ A metal bar shaped to fit the patient, called a Pectus Support Bar, is placed in the pathway under the sternum and then rotated to lift the chest and correct the deformity.
- ◆ The video camera is removed and all incisions are closed at the end of the surgery.
- ◆ After approximately 2 to 3 years, the Pectus Support Bar is removed through a small incision on the patient's side.







A photograph of three young people running outdoors on a sunny day. In the foreground, a young woman with long brown hair is running towards the camera, smiling. To her left, a young man with dark hair is running, also smiling. To her right, a young man with short dark hair is running, smiling. They are all wearing athletic clothing. The background is a blurred green landscape with trees and a clear blue sky.

# Knowing your risks.

From cosmetic concerns to pressure on internal organs, like the heart and lungs, it's important to explore the right option for you.

Carefully reviewing the available options for pectus surgery will allow you to make an informed decision as to what procedure would be appropriate to correct the deformity. Each individual is unique and results and timelines will vary from case to case. Always consult your doctor for medical advice and before starting any activities.



## What are the risks associated with surgical repair of pectus excavatum?<sup>10</sup>

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To help minimize risk, it is important to follow the post-operative care instructions provided by your surgeon and attend regular follow-up appointments. The physical restrictions prescribed by your surgeon are intended to help prevent complications as metallic fixation devices cannot withstand activity levels and loads equal to those placed on a normal healthy chest wall.

While uncommon, complications can occur during and after surgery. Complications include, but are not limited to:

- ◆ Metal sensitivity reaction or allergic reaction to the implant (Pectus Support Bar) material (metal).
- ◆ Pain, discomfort, or abnormal sensation due to the presence of the device.
- ◆ Surgical trauma; permanent or temporary nerve damage, permanent or temporary damage to heart, lungs, and other organs, body structures or tissues.
- ◆ Skin irritation, infection, and pneumothorax (air leaking in the space between the lung and chest wall, which may cause the lung to collapse).
- ◆ Fracture, breakage, migration, or loosening of the implant.

- ◆ Inadequate or incomplete remodeling of the deformity or return of deformity, prior to or after removal of implant.
- ◆ Permanent injury or death.

You are not a candidate for treatment with the Pectus Support Bar if you have any of the following:

- ◆ Active infection
- ◆ Certain metal allergy or sensitivity
- ◆ Insufficient quantity or quality of bone or tissue to allow chest wall remodeling
- ◆ Mental condition preventing compliance with post-operative care instructions

For a complete list of risks associated with Zimmer Biomet's Pectus Support Bar see patient risk information at [www.PectusBar.com](http://www.PectusBar.com).

# Benefits of the Nuss procedure

## Surgical Procedure Benefits

When comparing the Nuss Procedure to older “open” surgical options, there are several benefits of the procedure’s less invasive method.

The primary benefits include a shorter operating time, less blood loss, and smaller, less visible incisions.<sup>1</sup> Some clinical data also suggests that because no cartilage or pieces of rib are being removed during the procedure, the patient’s chest and rib cage will be able to grow and repair itself in a natural manner.<sup>15</sup> The combined effect of these benefits means that a patient’s body is subjected to less trauma compared to other open surgery options. The Nuss Procedure is a widely-accepted effective method for treating pectus excavatum.<sup>15</sup>

## Lung Function Matters

Research focusing on the Nuss Procedure indicates that post-operative patients, who have had the bar removed, show significant improvement in lung capacity as tested by “Forced Expiratory Volume in 1 Second” or FEV1. This data suggests that these patients have similar or equivalent lung function to healthy individuals with no history of pectus excavatum.<sup>16,17,18,19,20</sup> This demonstrates that a patient’s lungs may be able to transfer more air and function more efficiently following treatment with the Nuss Procedure and removal of the Pectus Support Bar.<sup>21</sup>

## Heart Function Matters<sup>17,19</sup>

Healthcare professionals use function tests to evaluate how well (or poorly) certain organs are working within the body. The results of function tests are always compared to a “reference range” which is a range of values that would be observed in healthy people of similar age, sex, race, etc. to the patient. Heart function is evaluated in this way.

Data shows that surgical correction of Pectus Excavatum can improve specific heart function values. This means that:

1. The values may be within the reference range when they were not before surgery or
2. The values are closer to the reference range than before surgery.

Specific tests to measure heart function:

- ✓ Improved “Maximum Cardiac Index” which is a measure of how well the heart performs compared to the size of the patient
- ✓ Improved “Stroke Index” which is a measure how efficiently a patient’s heart pumps blood
- ✓ Increased “Oxygen Pulse” which is a measure of the amount of oxygen delivered to the bloodstream during each heartbeat while the patient is resting

All of the above measurements contribute to improved heart and lung function. Benefits of improved cardiopulmonary function might include more stamina during exercise, not tiring as quickly, and the ability to participate in sports for a longer period of time than was possible before the corrective procedure.<sup>22</sup>

## Recurrence Rate Matters

When considering a corrective surgery, many patients are concerned that their deformity will reoccur. Published data evaluating the success rate of the Nuss Procedure, indicates that recurrence is reported in less than 2% of cases.<sup>23,24,25,26,27,28,29</sup> A high probability of successful deformity correction and a low chance of recurrence is a significant benefit of the Nuss Procedure.



Aside from the potential physical benefits of the Nuss Procedure, many surgeons assert that humanistic or quality-of-life measures such as “satisfaction with appearance” and “increased confidence after surgery” should also be considered when evaluating the success of the surgery. Some of the more common aspects of humanistic outcomes include:

- ✓ Confidence towards change of appearance after surgery
- ✓ Better body feeling after surgery
- ✓ Better self-acceptance after surgery
- ✓ General satisfaction
- ✓ General interest in sports
- ✓ Higher self-confidence after surgery
- ✓ Being more sociable after surgery

The response data in clinical research shows that patient satisfaction after surgery is high and approximately 82% of parents believe their child to be “satisfied” or “very satisfied” with the results. These results indicate that the likelihood of a patient being satisfied with the results of the Nuss Procedure, barring complications, is high.<sup>31,32</sup>





## Immediately After Surgery

Following surgery, patients are transferred to the Post Anesthesia Care Unit (PACU) for observation. It is here that the patient will wake from the anesthesia used during surgery. The PACU is staffed by specially trained medical professionals who monitor the condition of patients immediately following surgery. Patients are typically transferred to regular rooms within a few hours.



## Length of Hospital Stay

The typical hospital stay for most patients is 3 to 5 days. During that time, hospital staff will work to effectively manage post-operative pain, provide physical therapy, such as deep-breathing exercises, and provide instructions on recovery.

# Get back to living after the Nuss Procedure.

36,37,38,39





## 1 to 4 Weeks After Surgery

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During the first four weeks after surgery, patients will have multiple follow-up appointments with their surgeon to monitor recovery.

Patients will receive information on specific physical limitations prior to returning home from the hospital. It's important to follow the activity guidelines provided by the surgeon or hospital staff. Specific instructions may vary on a case-by-case basis but patients should plan on taking it easy for the first four weeks after surgery. As pain lessens during this time, it is important to continue following the guidelines provided by the surgeon. Adhering to the guidelines will help your recovery.



## 4 to 6 Weeks After Surgery

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Patients are typically cleared to return to normal daily activities within a four to six week timeframe but should continue to follow all doctor recommendations on activity and movement restrictions.<sup>14,33</sup>

Once a patient is four to six weeks post-op, surgeons may advise that patients should do the following:

- ✓ Frequent walking
- ✓ Deep-breathing exercises performed twice a day, every morning and evening
- ✓ No waist bending, twisting, or log rolling
- ✓ Keep a straight back with no slouching



## 6 to 12 Weeks After Surgery

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Once you are six to twelve weeks into your recovery, you may be able to return to unrestricted activity and may begin playing certain non-contact sports. Contact sports are never recommended; however, non-contact activities like heavy lifting may be allowed after 2 months. Surgeons may advise that patients can get back on the field, court, or in the pool after 3 months.<sup>34</sup> However, activity levels and cardiopulmonary function will vary and patients may not notice a difference in these functions.



## 12 Weeks After Surgery

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After 12 weeks surgeons may advise that patients are cleared to resume all normal activities.

Published clinical research suggests that your cardiopulmonary function during exercise may improve after your surgery.<sup>17</sup>

It is always important to follow specific instructions from your physician, but most patients are not forced to sacrifice participating in regular daily activities at this time point.



## Bar Removal

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The Pectus Support Bar should be removed once your surgeon determines that your treatment is complete. Bar removal usually takes place 2 to 3 years after your original surgery and typically does not require an overnight hospital stay.<sup>33</sup> One or both of the original incisions are used to gain access to and remove the bar.<sup>35</sup>



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The information herein is of a general nature and does not represent or constitute medical advice or recommendations and is for general education purposes only. The information includes descriptions of a medical device that a surgeon may choose for the repair of Pectus Excavatum.

Zimmer Biomet manufactures medical devices, including the Pectus Support Bar and stabilizers that may be used by your surgeon to repair the pectus deformity. We do not practice medicine. All questions regarding your medical condition must be directed to your doctor(s).

Results with the Pectus Support Bar will vary due to health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Only a medical professional can determine the treatment appropriate for your specific condition. Appropriate post-operative activities will differ from patient to patient. Talk to your surgeon about whether the minimally invasive Nuss procedure and the Pectus Support Bar is right for you and the associated risks, therewith, including but not limited to the risks of allergic reaction, pain or discomfort, infection, fracture, breakage, movement or loosening of the bar, inadequate or incomplete remodeling of the deformity or permanent injury or death. For a complete list of risks associated with Zimmer Biomet's Pectus Support Bar, see [www.PectusBar.com](http://www.PectusBar.com) risk page.

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