



# The Brace Check Cureous Minds

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### Pectus Carinatum – The Problem

Pectus carinatum is a condition in which the breastbone protrudes outwards. The condition affects 1 in 1000 people and is most common in adolescent males. The current treatment involves an uncomfortable corrective brace that is worn 23 hours a day and is often worn at an incorrect tightness leading to longer treatment times and frustration.

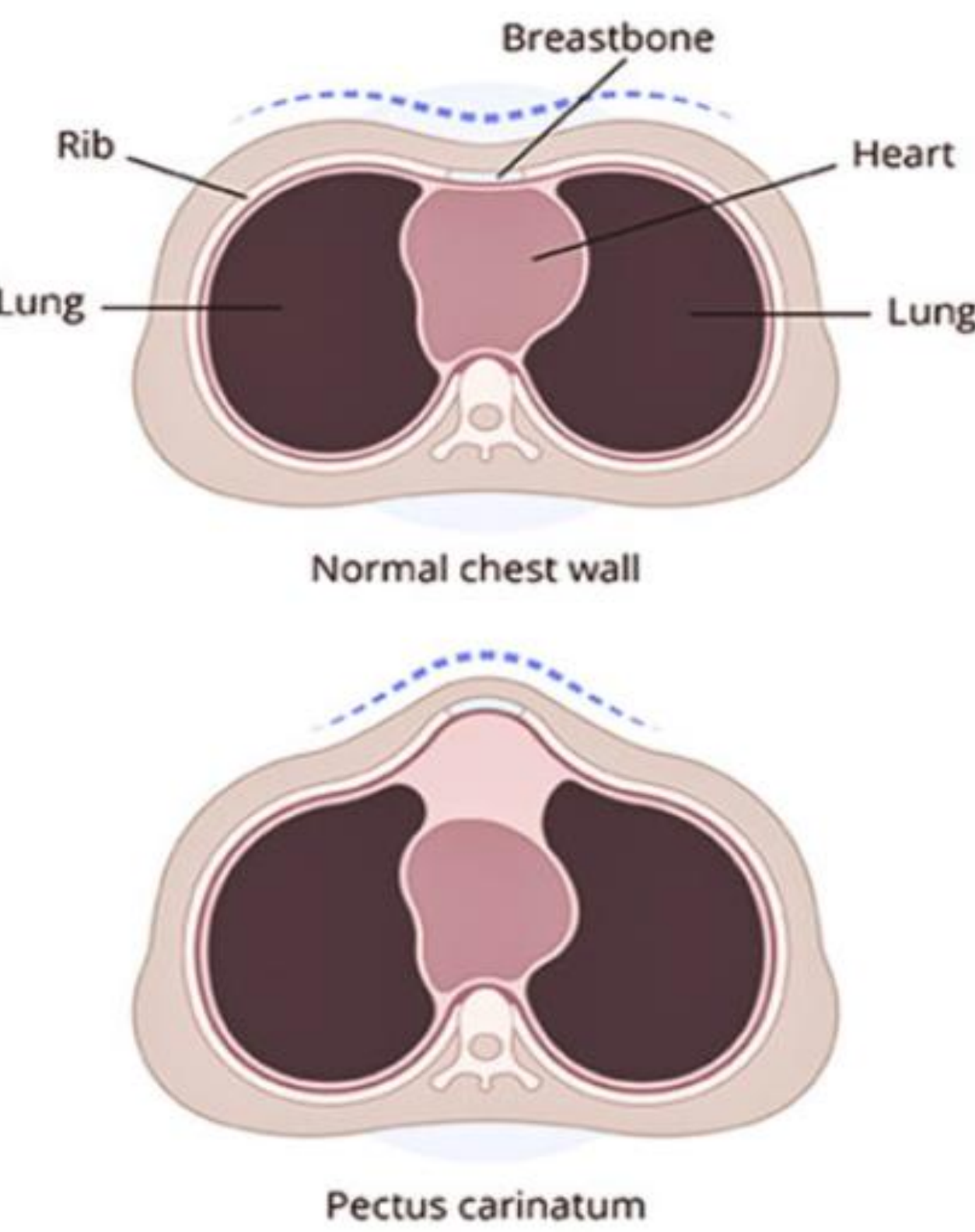


Figure 1. A transverse view of the pectus carinatum condition. The breastbone protrudes outwards in patients with pectus carinatum.

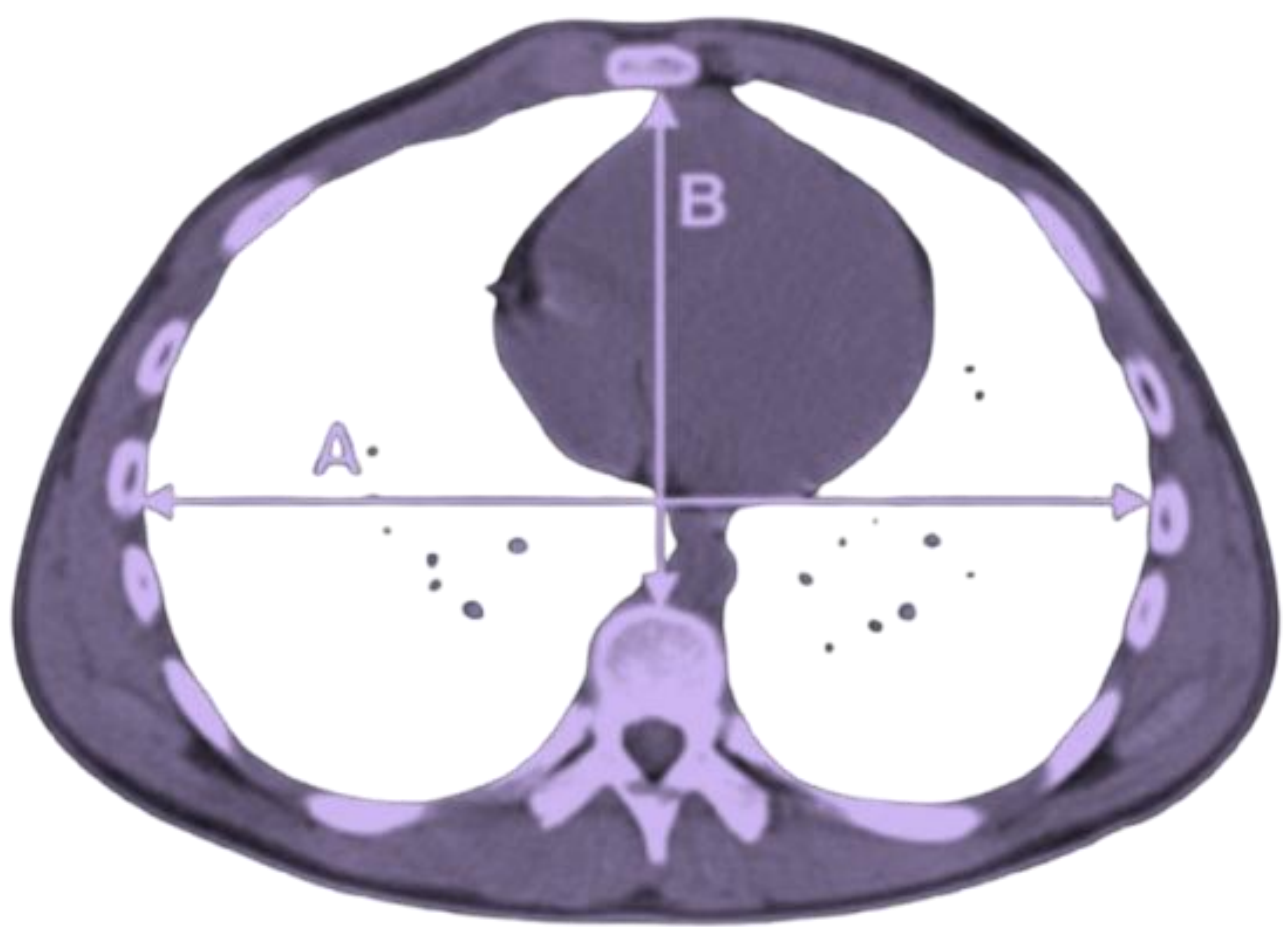


Figure 2. The Haller Index is a value calculated by dividing the chest width (side-to-side diameter) by the front-to-back diameter. This value is used to diagnose and characterize pectus carinatum

### Existing Solutions



	Tightenability	Size	Comfort	Consistency
Existing solution	✓	✗	✗	✗
The Brace Check	✓	✓	✓	✓

### Regulatory Considerations

Current corrective braces are Class I medical devices and not covered by insurance as they are not considered "medically necessary". In order to maintain the current availability and price point of treatment, we decided to pursue a mechanical solution with no electronics so as not to upgrade this to a Class II medical device.

### Need Statement

A way to increase the Haller Index by 0.2 in adolescent patients with pectus carinatum by optimizing corrective orthotic brace tightness.

### Our Solution

We are developing a brace that contains a front pad with an inflatable bladder—similar to a blood pressure cuff—that allows for direct pressure measurement and adjustment using a standard gauge and detachable hand pump, enabling both clinical calibration and at-home maintenance of proper brace tightness.



Figure 3. Frontal view of The Brace Check. The inflatable bladder shown is applying pressure to the chest



Figure 6. Rear view of The Brace Check. A hard surface makes up the back pad of the brace which provides additional support for the brace.



Figure 4. Side view of The Brace Check. One of the two BOA strap tightening mechanisms depicted along with the quick release mechanism.



Figure 5. Side view of The Brace Check. BOA strap on the other side of the brace depicted.



Figure 7. Pressure gauge used to determine appropriate brace tightness.



Figure 8. Pressure bulb used to inflate the brace to the appropriate tightness.

### Instructions for Use: Just Three Simple Steps



1. Clasp on brace and tighten to comfortable fit with BOA straps



2. Inflate bladder using the bulb



3. Check pressure with gauge and adjust pressure to match prescribed pressure.

### Verification and Validation Testing

#### Maintaining pressure under a load

After 1 hour of constant external applied pressure of 5 lbs., the brace maintained a constant pressure of 96 mmHg without deflating.

#### Wearing time

	Time (s)
Existing solution	19.58
The Brace Check	4.38

#### Pressure consistency between designs

A force sensitive resistor, when inserted between the chest and the front pad reads a similar value for both brace designs when worn at the same tightness.

Validation testing will include a clinical trial to determine the change in Haller index over a prescribed period of time with both brace designs being compared.

### Steps Moving Forward

Fabrication  
Quotes

Refine the  
Design

Validation  
Testing

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