

Seated Trunk Stabilization Device

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 (1 Biomedical Engineering; 2 Chemical Engineering; 3 Material Science; 4 Mechanical Engineering; 5 Design)



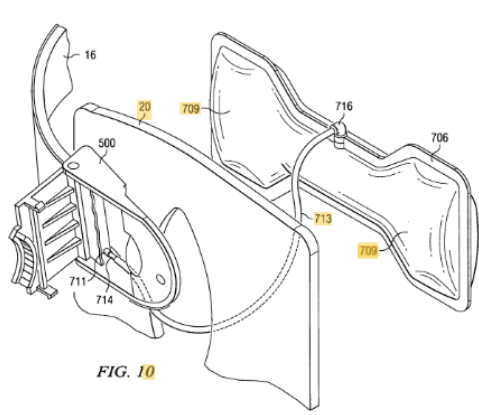
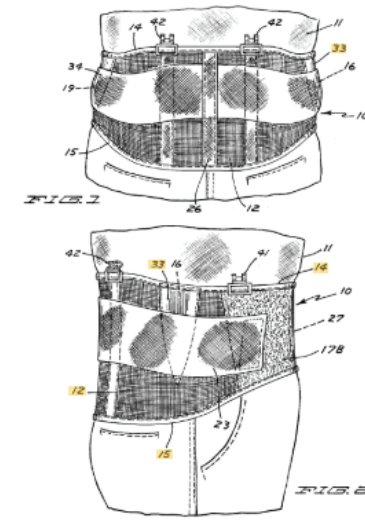
Problem (1,4)

- Hypotonia is characterized by low muscle tone
 - Often diagnosed in childhood but can be present in adulthood
- Symptoms include: poor control of neck, postural issues, & pelvis tipped back
 - 46% had significant impairments
- Common coexisting conditions: Cerebral Palsy, Muscular Dystrophy, & Down Syndrome
 - 6 out of 1000 children in the United States
- Treatment & Management: physical therapy and postural support devices
 - Bulky, expensive equipment with limited adjustability over patient growth
 - Without proper pediatric intervention, hypotonia can present in adolescence and adulthood

Existing Solutions and Patents

Existing Solutions (1,6)

- 1. Benik Vest**
 - Two piece neoprene vest with adjustable velcro straps in the shoulder, waist, and crotch.
 - Difficult to put on, too hot, quickly outgrown
- 2. Thoracic LumboSacral Orthosis**
 - Custom molded rigid or semi-rigid plastic brace to support the entire trunk.
 - Expensive, uncomfortable, quickly outgrown

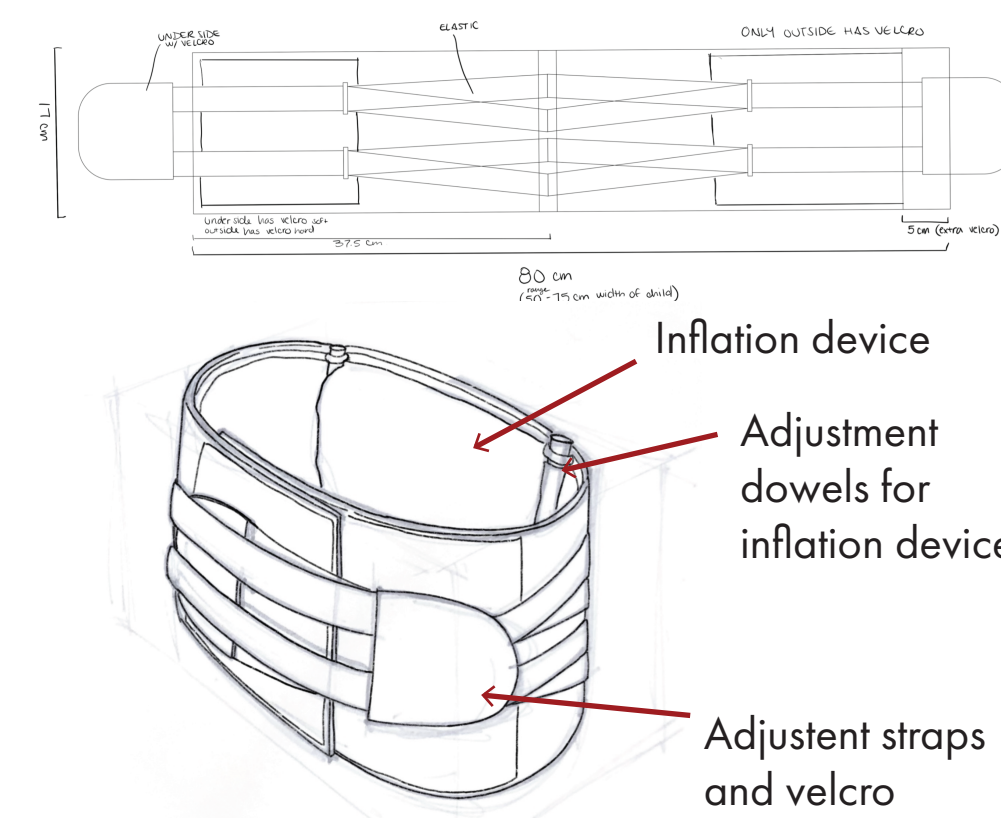


Patents (5,6)

- 1. Private Label Creations Back Belt**
 - Back brace for supporting lumbar region during strenuous athletic activity to prevent muscle damage.
 - Status: Active
- 2. AMEI Technologies Brace with integrated lumbar support system**
 - Brace with inflatable lumbar pad to provide support to the lumbar region and alleviate lower back pain.
 - Status: Expired

Proposed Solution

While the design of our proposed solution is very similar to our prototype, there would ideally be some material changes. Because of the use of the belt is to keep the patient's torso up, the material of the belt would be more rigid to add extra support.



Our Prototype

Inflatable is in the back of belt against the back of doll

Valve that can be connected to the pump

Adjustable straps for the belt



Hypotonic 8 year old doll

Rope (where dowel is inserted) for adjusting inflatable

Main structure of belt (made of canvas material)

Regulation (8)

- **Device:** Orthosis, Limb, For Back Pain. Class II.
- 510(k) submission and notification
 - Introducing a novel concept to the juvenile hypotonia field
- Regulated under Sec. 890.3475 Limb orthosis in the FDA, DHHS regulatory protocol for medical devices

Evaluation

"The efficacy of treating low tone with orthoses is very poorly studied, but it is the standard of care because I feel intuitively that we can help these kids, and because we've seen good clinical results."

-Kathy Martin, PT, DHS

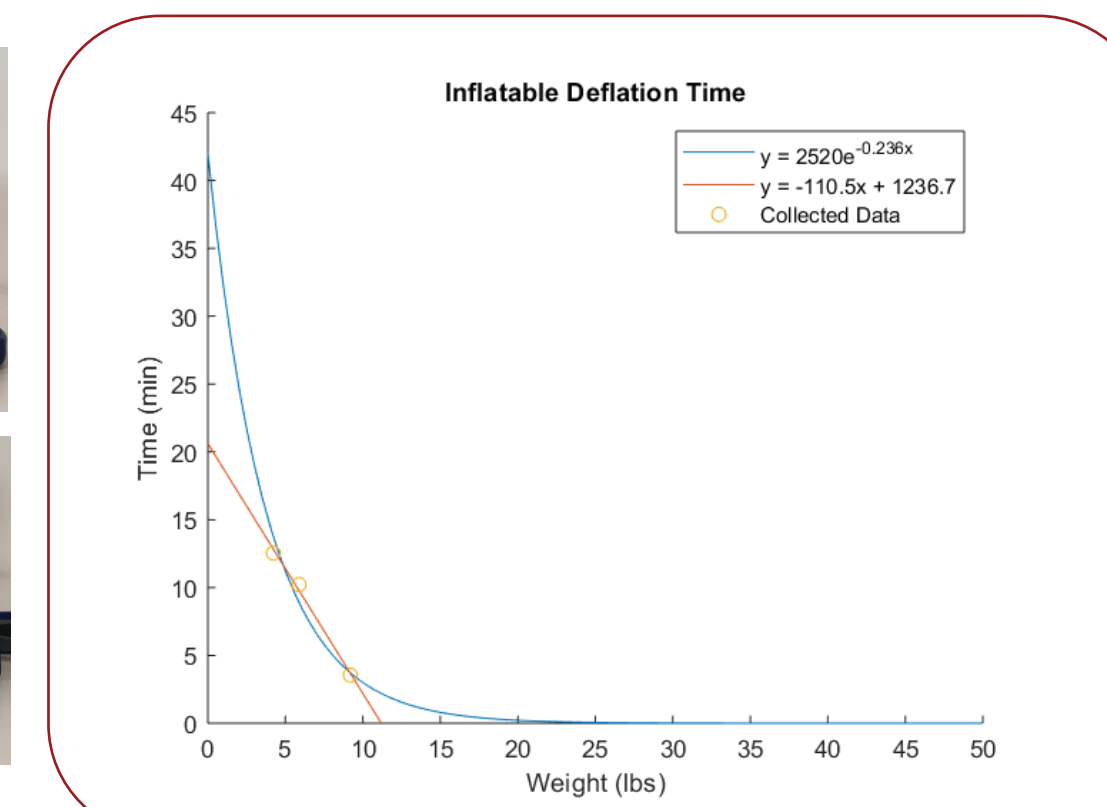
Three metrics will ensure that the device meets functional specifications:

1. Ability to raise a hypotonic child to an upright seated position (60° from femur)
2. Maintenance of upright position over an appropriate amount of time
3. Universal usability

Ran deflation test to find time which the inflatable can exert force under a known weight.



Deflation test fully inflated (top) and deflated (bottom)



Need

Our need is a device that increases stability for pediatric patients with trunk muscular hypotonia in order to ease execution of seated activities of daily living and adjusts throughout the patient's growth. We narrowed this need down into four main goals we hope to achieve with our project. Goals are as followed:

1. Support a wide range in severity of hypotonia
2. Support seated activities of daily living
3. Adjust with growth of the patient between ages of 4-8
4. Fasten device onto patient without help from practitioner/therapist

Reimbursement & Cost (9)

Insurance type	Reimbursement?
Flexible Spending Account (FSA)	No
Health Savings Account (HSA)	No
Health Reimbursement Arrangement (HRA)	No
Limited Care Flexible Spending Account (LCFSA)	No
Dependent Care Flexible Spending Account (DCFSA)	No
Medicare	Yes (at 80% cost)

Material Component	Estimated Cost (per unit)	Estimated Cost (total)
Ripstop fabric for inflatable body	\$1.00/m ²	\$0.21
Belt Fabric	\$1.00/m ²	\$0.27
Velcro	\$0.10/m	\$0.04
Seat belt and elastic material	\$0.01/m	\$0.03
Schrader valve	\$0.22/valve	\$0.22
Plastic Dowels	\$0.10/m	\$0.04
Miscellaneous		\$0.15
Estimated Total:		\$0.96

Acknowledgements

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