Parastomal Hernia Support Harness

This technology offers a simplified hernia belt that is adjustable for comfort and easy use. The hernia belt is composed of a firm panel for abdomen support, dual self-balancing straps to wrap the body, and a panel rotation guided by cables.

What is the Problem?

Over 1 million individuals in the USA are living with gastrointestinal stomas, and prevalence is increasing 3% annually as the national population's mean age increases. Patients who have undergone stoma formation surgery are at risk for parastomal hernias, a dangerous complication, which occurs in 80% of these individuals. Current hernia belt designs have limitations that result in disuse, such as adjustment complexity, donning difficulty, excess motion around the stoma, and discomfort. These issues could lead to decreased mechanical support leading to hernia formation and potentially skin excoriation.

What is the Solution?

The solution is a simplified hernia belt. This design includes a firm panel, which transmits pressure onto the abdomen through a foam medium. Pressure applied around the stoma is controlled using a foam torus, which is a donut-shape material. This localizes the force around the stoma to prevent herniation. The panel is attached to low-elasticity, self-balancing dual straps that wrap around the body to hold the panel in place and securely provide support throughout wear. A simple Velcro closure system makes donning effortless, and a silicone deposition onto the straps makes this belt more secure to wear. Force adjustments are made simple with the use of a cable-driven tightening system. By turning a dial, the force supplied to the hernia-risked region can be adjusted to counteract the forces most likely to create a hernia. Additionally, the cables are guided in a way that prevents panel rotation. Regulatory issues are minimized with this design, which uses materials that are already in medical devices and by designing for extended product life. It is considered a FDA Class I medical device, and would be submitted using the 510(k) exempt pathway based on predicate devices.

What Differentiates it from Solutions Available Today?

Existing hernia belt designs cause discomfort, excess motion around the stoma, and donning and adjustment difficulty. This leads to decreased belt usage and hernia formation. This simplified device provides easy steps for donning and adjusting the device, making it more comfortable and potentially increasing use. The force adjustments, foam system, and cable system allows for solid support of the stoma, which could counteract the forces that lead to

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Category

Device/Other
Selection of Available Technologies

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hernia formation.

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