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EXECUTIVE SUMMARY

- Each year 2.7 million laparotomies, or surgeries requiring large abdominal incisions, are performed in the United States alone. Approximately ten percent of these surgeries result in abdominal compartment syndrome (ACS), an acute increase in abdominal pressure around 20 – 25 mmHg. One-third of ACS cases are fatal.
- ACS can be avoided by gradual closure of the abdominal compartment. However, increasing the amount of time a patient spends with an open abdomen increases the likelihood of other potentially fatal conditions, such as systemic infection. There are several devices out on the market that address the need for gradual, yet as quick as possible, abdominal closure. These include dynamic retention sutures (DRS), the Wittmann patch, and the vacuum assisted wound closure (VAC) system.
- While the VAC system is automated, it does not supply sufficient closure force to quickly resolve large abdominal wounds. The DRS and Wittmann patch systems supply sufficient closure force, but are not automated, and application of the large forces required is performed by attending physicians. These processes do not continually adjust to take up slack from a gradually closing wound. They therefore require frequent input and effort by those attending to the patient.
- Our solution, *CLASP*, attempts to fill this dire need for automated, continuous abdominal wound closure. This device utilizes an electric motor, not human input, to apply pressure in order to gradually close large abdominal wounds. Furthermore, this closing force will continually be monitored. As the wound gradually closes, our device will continuously and automatically take up slack, applying a continuous and steady force to the abdomen. This will reduce costly oversight and effort on behalf of the physicians, as well as more rapidly close wounds, reducing the probability of potentially fatal infection.

PROBLEM AND CLINICAL NEED

Difficulties with Wound Closure

- Infection, bowel desiccation, fistula formation
- Abdominal Compartment Syndrome (ACS) compresses the renal vein causing cardiac, renal and respiratory failures
- 33% of ACS cases result in fatality

Advantages and Limitations of Current Solutions

Dynamic Retention Sutures

- Advantages:** Sufficient Closure Force
- Limitations:** Requires frequent intervention, small area can cause pinching / hinder perfusion, discontinuous force application

Wittmann Patch

- Advantages:** Sufficient Closure Force, large area of wound covered to distribute force
- Limitations:** Requires frequent intervention, force applied by hand, discontinuous force application

Vacuum Assisted Wound Closure (VAC) System

- Advantages:** Automated, reduces edema / swelling, continuous force application
- Limitations:** Insufficient force to close large wounds

MARKET

Overall

- 2.7 million laparotomies per year in the United States alone
- 10% of laparotomies result in abdominal compartment syndrome (ACS)
- One third of ACS cases result in fatality

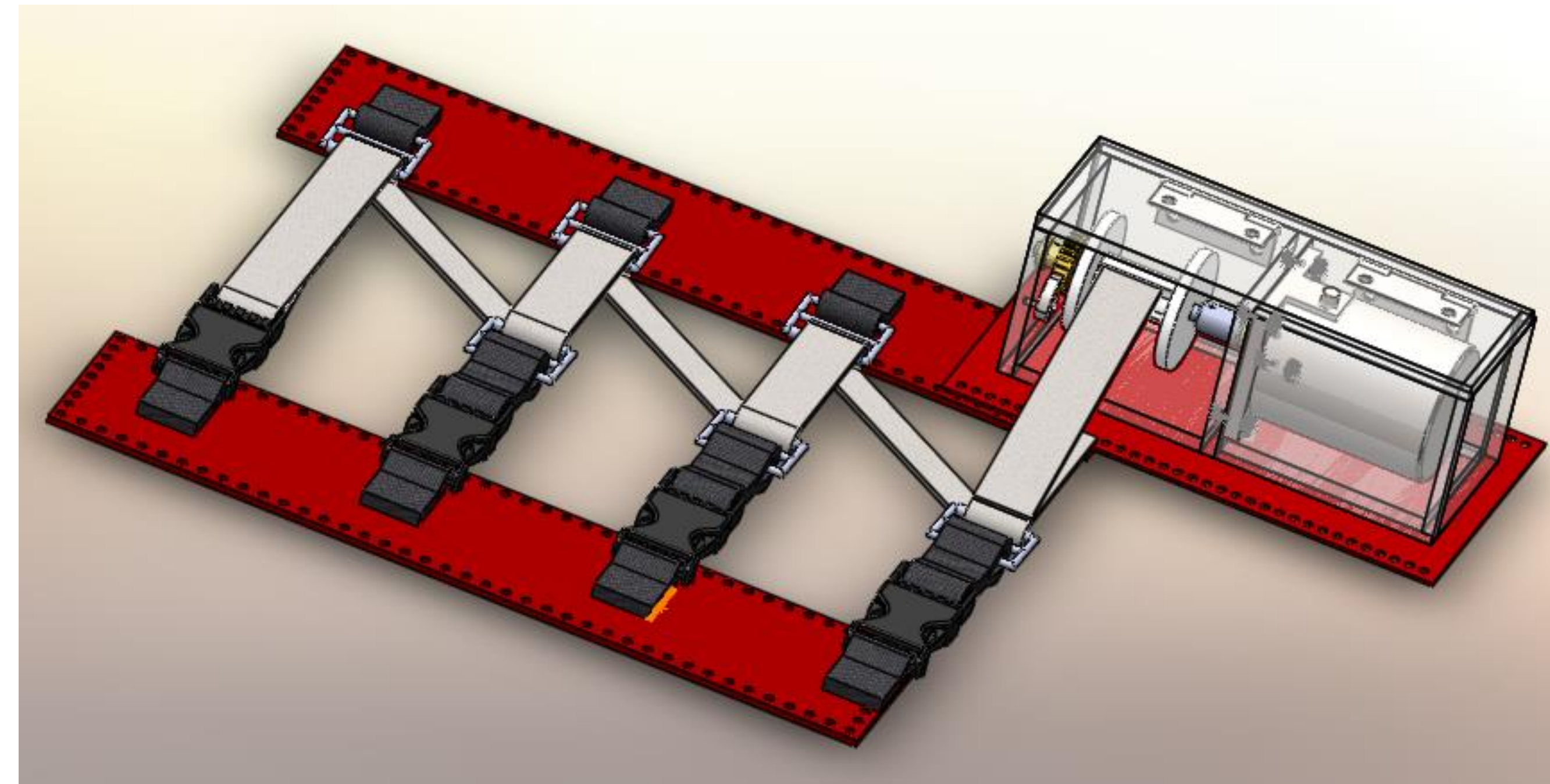
Current Solution Unit Prices

- Wittmann Patch:** ~\$1,600 / unit ⁵
- Dynamic Retention Sutures:** ~\$140 / unit ⁷
- Vacuum Assisted Wound Closure (VAC):** ~\$900 / unit ⁸

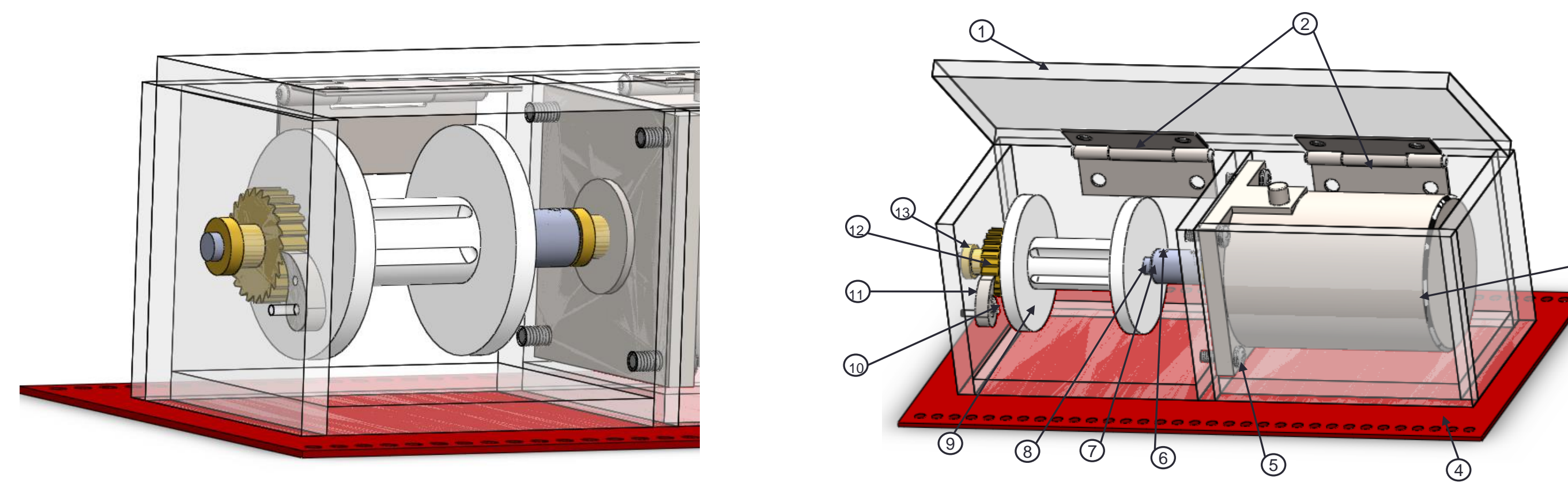
Vacuum Assisted Wound Closure (VAC) Market

- Most rapidly developing wound closure solution; compatible with *CLASP*
- Expected to have 10% compound annual growth rate in the foreseeable future ¹¹
- Worth \$2 billion by 2014 and \$3 billion by 2016 ⁹

DESCRIPTION OF DESIGN



The schematic design of the *CLASP* device is displayed above and functions in a shoelace-like manner. Two suture plates (red) are attached to the skin on either side of the wound and would span the wound vertically. On one side, the low-friction polyester strap (white) is fed through D-rings with rollers (upper side) to further minimize friction. On the other side, side release buckles (lower side) are attached to the suture plate using a nylon strap (black), which also hold D-rings that extend approximately 5cm over the edge of the wound. Once the polyester strap has been laced through the D-rings on both sides, the polyester strap is fed into a ratchet and pawl system, as shown on the left below.



Motor-Box (right) Components	
1	Housing
2	Hinge (2)
3	Motor
4	Suture Mount
5	Machine Screw (4)
6	Set Screw (2)
7	Shaft Coupler
8	Drive Shaft
9	Strap Securement Spool
10	Spring
11	Pawl
12	Shaft Collar (2)
13	Ratchet

The ratchet and pawl system above (left) is maintained by a stainless steel spring (10), responsible for preventing the polyester strap from slipping backwards unless manually released. The metal rod that is connected to the ratchet will be turned gradually by the electric motor above (right) at a constant torque as monitored by the control system.

WHAT IS NOVEL?

Combine Device with VAC System

- Advantages of the VAC System
- Improve upon insufficient force limitation

Automate Closure

- Reduce oversight cost
- Ensure sufficiently low pressure (< 20 mmHg) to avoid ACS through constant torque and monitoring system
- Manual tension override and emergency release to quickly for complete user control

Easy Access to VAC System and Wound Dressing

- No need to disassemble device
- Quickly detach and reattach straps from buckles to avoid infection or bowel extrusion

ESTIMATION OF PRODUCT COSTS

Item	Quantity	Material	Cost per part (\$)
Suture Plates	2	Neoprene	2.61
Rounded Metal Slide	7	Aluminum	0.60
Nylon Strap	1	Flat Nylon Webbing	0.88
Belt Strap	1	Polyester Webbing	2.76
Side Release Buckle	4	Plastic	0.82
Adhesive Velcro	1	Nylon	0.08
Roller Housing	1	ABS	8.36
Metal Rod	1	Aluminum	0.47
Ratchet	1	Brass	5.37
Pawl	1	Carbon Steel	2.54
Spring	1	Stainless Steel	1.39
Cotter Pin	2	Zinc-Plated Aluminum	0.11
Bearing	2	SAE 863	0.46
Motor	1	Steel	100
Controller	1	ABS	100
Total	26		\$222.36

REGULATORY PATHWAY

Classification

- Class III Device
- Sustains human life

Premarket Approval Route

- Fascial Expander
- However, requires scientific review for safety and efficacy in clinical settings

Indications (Wittmann Patch)

- Advanced intra-abdominal pathology
 - Requires reentry
- Only temporary closure attainable
 - ACS or excessive edema
 - Lack of perfusion to abdominal organs
- Not a permanent implant
- No more than five reentries ¹¹

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