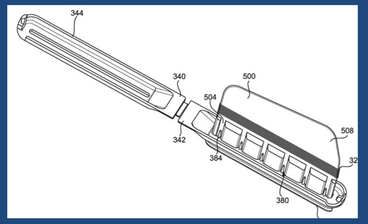


# Endospool:

# Proof of Concept Study

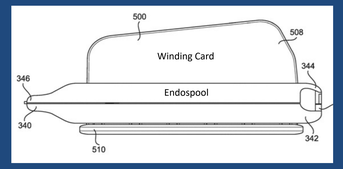
G. Swope Munday, MD, FACS



## Abstract

Endospool is a revolutionary device that will change suture management in all laparoscopic and robotic surgery. This disposable injection device can be loaded with greater than 18" of suture at bedside or pre-packaged with suture by a manufacturer.

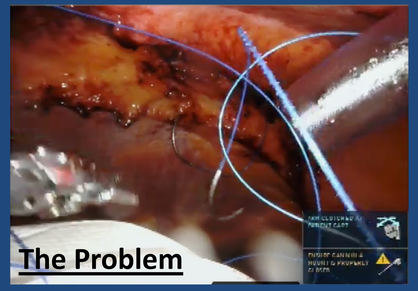
It is designed to attach to a laparoscopic needle driver for suture introduction into the field. Current design can pass through an 8mm trocar. The suture is then able to be accessed by the operating surgeon for use in the case.




This device has patent protection in the US, Canada, Japan, Australia and the EU. Current techniques lead to long operative times, increased surgeon frustration, and pose an array of patient safety concerns.

## Introduction

Poor suture management in the minimally invasive operative field leads to unintentional knotting of the suture material, inadvertent cutting of the suture strand, and/or multiple sutures passed into the operative field which increases risk for lost/retained needles and damage to intra-abdominal contents.

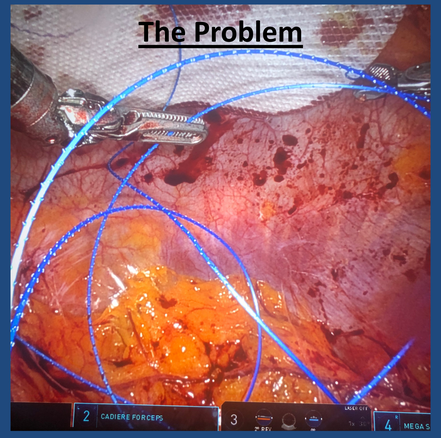



These pitfalls lead to: longer operative times; increased surgeon frustration; increased cost to the healthcare system; and a myriad of patient safety issues.

## Methodology

A dry lab experiment was conducted with ten volunteer test subjects completing a common technical portion of a robotic ventral hernia repair. The participants were timed as they sutured a circular mesh-like material to the simulated anterior abdominal wall. This task was timed both using a bare suture and also using Endospool suture management system. The test subjects had a varying level of surgical skill and operative experience.

This data was analyzed with published console time data from "My Intuitive" App to illustrate the value added from this novel device.



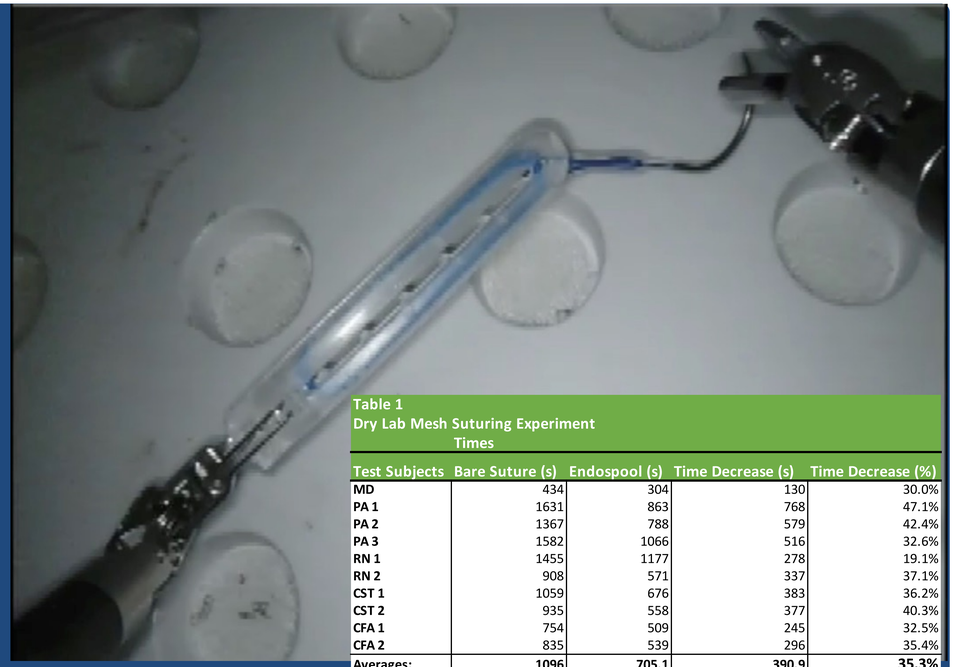



**Table 1**
**Dry Lab Mesh Suturing Experiment**
**Times**

| Test Subjects | Bare Suture (s) | Endospool (s) | Time Decrease (s) | Time Decrease (%) |
|---|---|---|---|---|
| MD | 434 | 304 | 130 | 30.0% |
| PA 1 | 1631 | 863 | 768 | 47.1% |
| PA 2 | 1367 | 788 | 579 | 42.4% |
| PA 3 | 1582 | 1066 | 516 | 32.6% |
| RN 1 | 1455 | 1177 | 278 | 19.1% |
| RN 2 | 908 | 571 | 337 | 37.1% |
| CST 1 | 1059 | 676 | 383 | 36.2% |
| CST 2 | 935 | 558 | 377 | 40.3% |
| CFA 1 | 754 | 509 | 245 | 32.5% |
| CFA 2 | 835 | 539 | 296 | 35.4% |
| **Averages:** | **1096** | **705.1** | **390.9** | **35.3%** |

Table 2
**Endospool Impact on IPOM Ventral, Incisional and Umbilical Hernia**

| | Aggregate AVERAGES Time | | Predicted Time with Endospool | | Time saved with Endospool | |
|---|---|---|---|---|---|---|
| Case Number | US Average (min) | Top 10% (min) | US Average (min) | Top 10% (min) | US Average (min) | Top 10% (min) |
| 1 to 10 | 75.3 | 31.0 | 60.9 | 25.0 | 14.5 | 6.0 |
| 11 to 25 | 68.0 | 30.0 | 54.9 | 24.2 | 13.1 | 5.8 |
| 26 to 50 | 63.3 | 30.7 | 51.2 | 24.8 | 12.2 | 5.9 |
| 51 to 100 | 59.3 | 30.0 | 47.9 | 24.2 | 11.4 | 5.8 |
| 101 and over | 55.7 | 30.3 | 45.0 | 24.5 | 10.7 | 5.8 |

References: 1.Intitive Surgical Website. https://www.intuitive.com/en-us/about-us/company 2.My Intuitive App. Data mined from smart phone accessible application.




## Results

Endospool has reliable and reproducible results in the dry lab decreasing mesh suture times by an average of **35.5%** (see Table 1). The individuals with the the longest bare suture times had the largest percentage decrease in suture time when utilizing Endospool.

This measured decrease in suture time extrapolates to decreased average operative times for robotic IPOM ventral, incisional and umbilical hernias by **19.2%** (see Table 2).

Potential cost savings for these robotic case types is estimate to be up to **$843.83** per case for those near US average and in the first 10 cases. For the most efficient and experienced surgeons (101+ cases and in the top 10% of console times) utilizing Endospool could still produce a **$339.77** cost saving per case (see Table 3).

**Table 3**
**Money Saved with Endospool Utilization**

| Case Number | US Average Surgeon | Top 10% Surgeon |
|---|---|---|
| 1 to 10 | **$843.83** | **$347.24** |
| 11 to 25 | **$761.69** | **$336.04** |
| 26 to 50 | **$709.41** | **$343.51** |
| 51 to 100 | **$664.61** | **$336.04** |
| 101 and over | **$623.54** | **$339.77** |

## Conclusion

Endospool creates a cleaner minimally invasive operative field. It reduces operative times and increases patient safety by providing an efficient method for suture access and utilization. Endospool also allows the robotic learning curve to be shortened for surgeons new to the system. The device provides an efficient method for longer suture utilization which reduces total numbers of needles and assistant passes into the operative field. It will provide a distinct market advantage for a suture or device company in the expanding international robotic and laparoscopic market.

## Patents

This prototype may be covered by one or more of the following patents:
U.S. Patent Nos. 10,660,635; 11,684,357; 11,701,104; 11,937,807
Japanese Patent No. 7192104
Australian Patent No. 2018272115
European Patent No. 22162407.5

This prototype is also subject to the following patent applications:
U.S. Application Nos. 18/305832; 18/588292
Canada Application Nos. 3099384; 3153495
European Application No. 18806708.6
Australian Application No. 2022202088
Japanese Application No. 2022-051483