

GIHep Singapore 2010

A New Hemorrhoidal Stapler



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TTS Hospital, Singapore





Disclosure

- Speaker's Honorarium from Covidien

Honorarium noun (pl. honorariums or honoraria) - a payment given for professional services that are rendered nominally without charge

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Stapled versus conventional surgery for hemorrhoids

Jayaraman S, Colquhoun PH.D., Malthaner R

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Summary

Stapled versus conventional surgery for hemorrhoids

Stapled hemorrhoidopexy is associated with a higher risk of hemorrhoid recurrence and prolapse compared to conventional excisional hemorrhoidectomy. While both operations are safe, the traditional excisional techniques were found to be superior to the stapled technique in preventing most clinically important symptoms. If hemorrhoid recurrence and prolapse are considered the most important clinical outcomes, then conventional excisional hemorrhoidectomy remains the "gold standard" treatment for hemorrhoids. However, there may be a sub-set of patients for whom the stapled method is superior; therefore, further study is warranted.

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*Stapled hemorrhoidectomy
higher recurrence and prolapse*

Day Surgery (Private)

Hospitals	Volume ¹	Average Length Of Stay (Days) ²	50th Percentile Bill Size (\$) ³	90th Percentile Bill Size (\$) ⁴
AH	34	1.0	1,055	1,270
CGH	136	1.0	1,126	2,232
NUH	351	1.0	1,508	2,474
SGH	1,301	1.0	2,662	3,445
TTSH	325	1.0	1,288	2,304

Day Surgery (Subsidised)

Hospitals	Volume ¹	Average Length Of Stay (Days) ²	50th Percentile Bill Size (\$) ³	90th Percentile Bill Size (\$) ⁴
AH	203	1.0	408	751
CGH	584	1.0	379	553
NUH	420	1.0	455	727
SGH	108	1.0	479	1,066
TTSH	739	1.0	480	632



SCHEMATIC VIEW

- A) CARTRIDGE SHIPPING CAP
- B) CENTER SHAFT (FULLY EXTENDED)
- C) STAPLE CARTRIDGE
- D) SHELL WITH DEPTH MARKINGS
- E) STAPLER
- F) READY - TO - FIRE INDICATOR
- G) TWIST KNOB
- H) SAFETY
- I) HANDLE
- J) DETACHABLE ANVIL / CENTER ROD ASSEMBLY
- K) PORT
- L) ANOSCOPE
- M) DILATOR



HEM33

- Launched in January 2010
- Sold thousands of units in many major markets worldwide including the US and EU.
- Presently cleared for sale in 19 countries worldwide and receiving additional clearances regularly
- Established relationships with KOLs around the globe, including:
 - v Sang Lee MD, Cornell University, NY, NY
 - v Franco Corno, University of Turin, Italy
 - v F. Sergio Regadas, Federal University of Ceará. Brazil
 - v Mark Mercer-Jones, Spire Washington Hospital, UK



Reasons Not To

- Don't fix what's not broken
- That's the way we do it
- Our experience of 7000 cases since

Reasons To

- Become KOL



Reasons To

- Modify and rename the technique

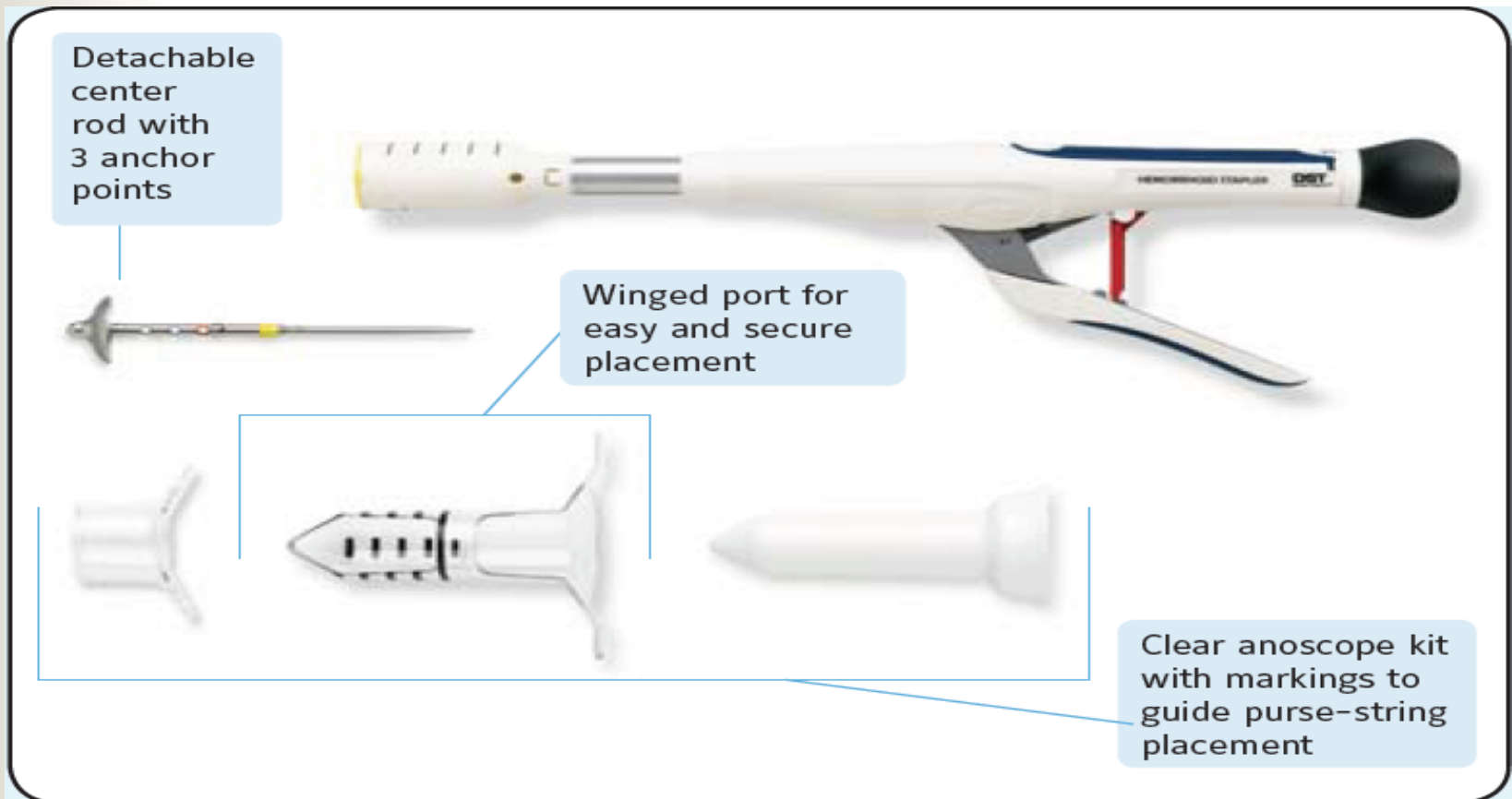


Reasons To

- Room for improvement



Features and Benefits



Features and Benefits

Feature	Benefit	Differentiation
Detachable Anvil	Ease of insertion inside the rectum	One handed placement of anvil provides unparalleled visualization of tissues
Detachable Anvil	Ease of affixing pursestring	Tissues can be visually assessed before resection and affixing the pursestring
Detachable Anvil	Greater visibility of affixed tissues	Tissues are clearly visible before anastomosis—this enables the surgeon to visually assess the tissues before the tissues are clamped in the device
Low Profile Anvil	Minimizes tissue interaction during insertion	Ease of placement proximal to pursestring
Preset pursestring Anchor Points on Center Rod	Eliminates requirement to pass sutures through cartridge shell and eliminates variable finger tensioning	Ease of pursestring anchoring
Preset pursestring Anchor Points on Center Rod	Enables surgeon to vary amount of prolapse captured to individual patient's needs	Surgeon is able to resect the correct amount of prolapse to treat the patient
Extended Reach Center Rod (13.5cm)	Provides easy access and manipulation of captured tissues	Procedure is completed without additional assistance
3.5mm & 4.8mm DST Series™ Technology Staples	Optimal staple formation for a wide range of anastomotic scenarios	3.5mm staples for thin mucosa and submucosa tissues and 4.8mm staples for more extensive tissue resections
Green Firing Indicator	Simplified system for optimal staple formation	Surgeon must decide where to “dial in” staple formation within a range of possibilities
Advanced polymer material molded grips on Instrument and Handle	Ensures optimal gripping throughout procedure	Smooth plastic grip surfaces on other Hemorrhoid Stapler products
Winged Port Design	Enhanced placement of Port	A Circular Port may make positioning difficult
Clear Anoscope Design	Provides new degrees of visibility of the underlying anatomy and existing pursestring	An Opaque competitor Anoscopes does not provide visibility of underlying anatomy
Anoscope Bridge	Provides new levels of access, visibility and working space by suspending prolapsed tissues in the Anoscope	Anoscope without bridge allows tissues to fill working channel
Anoscope Markings	Provides a convenient centimeter guide for circumferential pursestring sutures	Surgeons can use the lines as a guide as they rotate the Anoscope and place a circumferential pursestring.



COVIDIEN

positive results for life

Covidien™ EEA Hemorrhoid
and Prolapse Stapler Set with
DST Series™ Technology

Hemorrhoidopexy

Frank Caliendo, M.D.



Anoscope Kit

Statement/Evaluation	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Comment
Anoscope Kit components nested together effectively	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Port and nested components were easy to insert in the rectum	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Port dilated anal sphincter and stayed in place throughout the procedure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Port was secured to buttocks with stay sutures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Wings of Port fit between the buttocks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Port was sufficiently long to protect the Dentate Line	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Port provided good access to the surgical site	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Statement/Evaluation	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Comment
Anoscope slid easily through the Port	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Transparent Anoscope provided additional visibility of the underlying anatomy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Stapler

Statement/Evaluation	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Comment
Detachable Anvil was smooth and easy to insert proximal to the pursestring suture	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
You were easily able to match the prolapse to an anchor point on the Center Rod	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
You were able to easily attach the pursestring to the center rod	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
You were able to visually assess the tissues captured prior to firing the instrument	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
You were able to digitally assess the tissues captured prior to firing the instrument	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
It was simple to mate the anvil assembly to the stapler?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
The end of the center rod was	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Anastomosis

Statement/Evaluation	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Comment
The staples of the instrument deployed as expected	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
The Stapler provided acceptable hemostasis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
The cut of the instrument was clean and complete	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
The anastomosis was acceptable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
The tissue specimen (donut) was acceptable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Overall

Statement/Evaluation	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Comment
The EEA™ Hemorrhoid and Prolapse Stapler Set is clinically acceptable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
All of the components were compatible with each other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
The anoscope kit and detachable anvil provided superior access to the target tissue prior to capturing it within the						



Conclusions (I)

- There are a number of important advances in the design of the HEM33
- Optimizes visibility and ease of placing the pursestring
- Enhanced consistency in tissue capture
- More extensive tissue resection possible



Conclusions (II)

- Promise, Potential, Performance
- One size fits all, one size fits none
- Automatic vs Manual
- Minor tweaks

Solution in search of problem
Not a breakthrough, but a followthrough