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# Colowrap Fact Sheet

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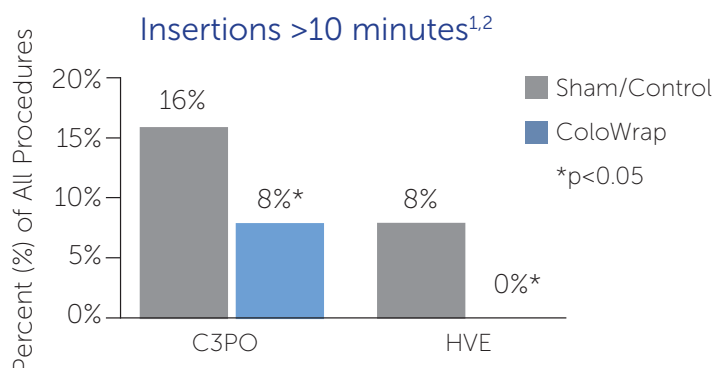


Making colonoscopy safer, more efficient, and more effective.



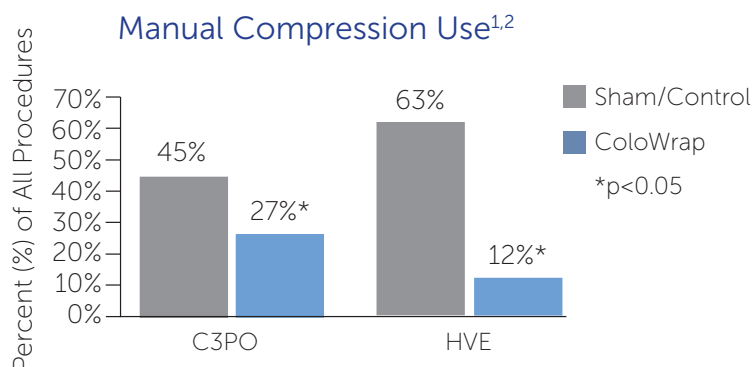
## STAY ON SCHEDULE

50-100% reduction in prolonged insertions<sup>1,2,†</sup>



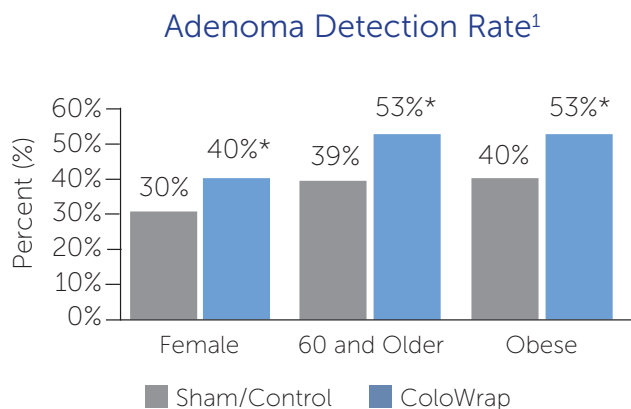
## REDUCE PHYSICAL INTERVENTION

Up to 80% reduction in manual compression and repositioning<sup>1,2,†</sup>



## ENHANCE QUALITY

33%<sup>‡</sup> increase in adenoma detection<sup>1</sup>



ADR = adenoma detection rate. CIT = cecal intubation time. HVE = high volume endoscopist

†When ColoWrap used as directed (per-protocol analysis)

‡Among females, obese patients, and patients 60 and older.

1. Crockett SD. et al, Carolina-ColoWrap® in Colonoscopy Performance and Outcomes Study (C3PO). University of North Carolina, Chapel Hill. March 2015.

2. Spanarkel M, et al. SAGES Conference Annual 2014

ColoWrap is a simple, non-invasive solution that delivers focused, adjustable abdominal compression to reduce looping and improve bowel stability during colonoscopy.



- 1 in 6 endoscopists reduce case volume due to overuse injury
- 1 in 4 endoscopy nurses miss time due to injuries sustained on the job



### ColoWraps Keep You and Your Staff Injury Free

- Reduced looping means less force required to reach cecum
- Need for pressure and patient repositioning dramatically reduced

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For sales inquiries or to request  
a trial please call (888)-815-3376  
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| Product Number | Size              | QTY per Box |
|----------------|-------------------|-------------|
| CWS110         | Small (90cm)      | 10          |
| CWR110         | Regular (100cm)   | 10          |
| CWL110         | Large (120cm)     | 10          |
| CWB105         | Bariatric (130cm) | 5           |



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# Carolina ColoWrap® in Colonoscopy Performance and Outcomes Study: results from a randomized, blinded, sham-controlled clinical trial

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## BACKGROUND

Looping is a common problem during colonoscopy that prolongs procedure time, causes patient discomfort, and increases procedural risk. In addition, looping and bowel instability may hinder adenoma detection during scope withdrawal. ColoWrap® is single-use, non-invasive compression device designed to reduce looping and improve bowel stability.

## METHODOLOGY

Efficacy of the ColoWrap was evaluated in a 350 patient randomized, blinded, sham-controlled clinical trial at the University of North Carolina – Chapel Hill.

## RESULTS

**Cecal Intubation Time (CIT):** Although the mean CIT was similar for the sham and ColoWrap groups, there was a pronounced reduction in insertion time in obese patients (4.7 min vs 6.1 min,  $p=0.03$ ). When the device was used as directed (PPA), use of the ColoWrap reduced CIT across all patients, and cut the frequency of prolonged insertions by 50% (8% vs 16%,  $p=0.05$ ).

**Use of Ancillary Maneuvers:** ColoWrap reduced the use of manual compression and patient repositioning by 40% and 100% ( $p=0.001$  and  $p=0.02$ , respectively) in the PPA.

**Adenoma Detection:** Use of ColoWrap improved ADR in women (40% vs 30%), obese subjects (53% vs 40%), and patients 60 and older (53% vs 39%). In each group, use of the ColoWrap was independently associated with significantly increased odds of adenoma detection and combined adenoma and sessile serrated adenoma detection.

### Odds of Conventional and Sessile Serrated Adenoma Detection with ColoWrap Stratified by Gender, Age, and BMI

|               | Conventional Adenoma<br>(n= 146)<br>OR <sup>a</sup><br>(95% CI) | Sessile Serrated Adenoma (SSA)<br>(n=25)<br>OR <sup>a</sup><br>(95% CI) | Adenoma or Sessile Serrated Adenoma<br>(n=161)<br>OR <sup>a</sup><br>(95% CI) |
|---------------|---|---|---|
| Female        | 2.3 (1.2, 4.5)  | 1.1 (0.4, 3.2)  | 2.0 (1.1, 4.0)  |
| Age >60 years | 2.9 (1.4, 6.1)  | 1.5 (0.5, 4.7)  | 2.9 (1.4, 6.1)  |
| BMI ≥30       | 3.5 (1.0, 12.2)   | n/a <sup>b</sup>  | 5.8 (1.4, 24.7)   |

a OR adjusted for age, gender, bowel prep quality, withdrawal time, and endoscopist experience.

b Too few numbers for stable estimate

## CONCLUSION

ColoWrap reduced cecal intubation time, particularly among obese patients, and significantly reduced the use of ancillary maneuvers when used as directed. In addition, use of the ColoWrap was independently associated with increased adenoma detection in women, obese patients, and patients 60 and older.

ADR = adenoma detection rate. PPR = per protocol analysis.