

## Innovative Technology Facilitates Efficient Colonoscopic Procedures: No Scope Disinfection, power assisted scope advancement – The ColonoSight®: Preliminary Data.

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The new FDA cleared ColonoSight®, operates with uniquely designed disposable components eliminating the need for device disinfection. The ColonoSight®'s disposable sheath and internal channels form a barrier between the scope, the colon and the medical staff thus offering quick instrument and patient turnover and greater cost effectiveness. The number of instruments needed is drastically reduced and scope damage as a result of exposure to harsh disinfection procedures and chemicals, is greatly lessened.

The operability and safety of the ColonoSight® was extensively tested in animals and subsequently in preliminary studies in humans performed in Israel, Italy and the U.S. Screening (and volunteer) colonoscopies were performed in 84 patients, with a cecal intubation success rate of 88%. Therapeutic interventions, including biopsy, polypectomy, APC, were performed without difficulty.

Further animal studies examined barrier qualities of the sleeve. Culture swabs from the physician's gloves, the scope and the animal colon were obtained. Colon cultures grew *E.coli*, *Enterobacter*, *Enterococcus*, and *Proteus mirabilis*, none of these appeared in the cultures obtained from the physician gloves and scope.

Instrument turnover time and intervals between colonoscopies were measured in nine colonoscopies on humans. Device assembly/disassembly times were measured as well as patient prep time on the gurney before the procedure.

Eight (8) men and one (1) woman were examined. The mean patient age was 63 years. The mean downtime between procedures using one scope in one procedure room was 11.2minutes. This downtime included disposable disassembly/assembly and patient prep on the gurney (sedation etc.)

### **Summary:**

The ColonoSight® performed in preliminary clinical trials as well as the current scopes but has the significant advantage of unique disposable parts which eliminate the need to perform disinfection, create a clean environment in the endoscopy room so the staff need not handle instruments soiled with stool and reduce the number of

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scopes and participating healthcare personnel necessary. These advantages lead to lowered scope downtime between patients, may result in greater protection from cross contamination and lead to significant cost savings