PrimeSight™

Clinical Summary

Endoscopy with EndoSheath® Protective Barrier

PrimeSight™ Endoscopy with EndoSheath® Protective Barrier

- 30+ research studies since 1992
- 5 million sold with no reports of cross contamination
- Included in national standards and guidelines for flexible cystoscope reprocessing
- Used in Bronchoscopy, Cystoscopy, Esophagoscopy and Laryngoscopy

About the company:

In 1992, Vision Sciences, Inc. introduced the sterile, single-use EndoSheath protective barrier that could be used with the company's unique endoscopes. After two decades of product developments and enhancements, Vision Sciences merged with Uroplasty, Inc. to form Cogentix Medical.

Cogentix Medical

SAFETY

A microbiological evaluation of level of disinfection for flexible cystoscopes protected by disposable Endosheaths

Jørgensen, P.H., et al. (2013). *BMC Urology, 13*(1), 46.

Study Design:

- Microbiological evaluation of cystoscopes used in 100 cases following the use of the EndoSheath barrier and performing reprocessing per the User's Manual
- Samples were taken after the cystoscopes were cleaned with a detergent cloth, rinsed with tap water, disinfected with 70% ethanol disinfection and then dried
- All EndoSheath units underwent a leak-test for barrier integrity

Outcomes:

- 100% of EndoSheath units passed the leak-test
- 100% of microbiology samples showed a clean flexible cystoscope after the use of the EndoSheath barrier and the Company's recommended cleaning procedure
- The study authors concluded that the Company's reprocessing method featured a low risk of pathogen transmission, high-patient safety and a valid alternative to the recommended high-level disinfection procedure of competitive flexible cystoscopes

Microbiologic assessment of disposable sterile endoscopic sheaths to replace high-level disinfection in reprocessing: a prospective clinical trial with nasopharygoscopes

Alvarado, C. J., et al. (2009). *American Journal of Infection Control, 37*(5), 408-13.

Study Design:

- Prospective clinical trial of 100 cases to assess microbiological safety of nasopharygoscopes after EndoSheath use and reprocessing according to the User's Manual
- Cultures were taken from the control heads and insertion shafts of endoscopes before application of the EndoSheath, immediately post-procedure after removing EndoSheath; and after cleaning and intermediate level disinfection
- 100 used sheaths and 20 unused sheaths were subjected to high-pressure leak testing

Outcomes:

- Bacteria detected pre-procedure on 16 control heads and 6 shafts and immediately post-procedure on 13 heads and 1 shaft
- No bacteria detected on the endoscopes following cleaning, ethanol disinfection, and drying
- No EndoSheath showed loss of barrier integrity on leak testing
- Authors concluded that the use of EndoSheath "can provide a reliably decontaminated, patient-ready instrument, eliminating the need for high-level disinfection of endoscopes."

Urinary tract infection following flexible cystoscopy: a comparison between sterilised cystoscopes and disposable sterile sheaths

McCombie, S.P., et al. (2013). *Journal of Clinical Urology, 6*, 220-4.

Study Design:

- Prospective clinical trial comparing the incidence of urinary tract infections after cystoscopy using a conventional cystoscope and a cystoscope with the EndoSheath protective barrier. 200 patients were assigned 1:1 to the groups
- 2 mid-stream urine samples were taken from patients (pre-cysto and 3 days after)

Outcomes:

» No significant difference in post-procedure UTI in requirement for antibiotics

» Authors concluded that flexible cystoscopy using EndoSheath does not have a higher incidence of UTI and can therefore transform flexible cystoscopy into an outpatient clinic procedure

Evaluation of endoscope sheaths as viral barrier

Baker, K. H., et al. (1999). *The Laryngoscope, 109*(4), 636-9.

Study Design:

» Independent bench study conducted by the FDA to evaluate the effect of virus on "defective" sheaths

» 22 sheaths with small laser-drilled holes (2 to 30 µm) were challenged to high-titer virus suspension (10^8 viruses/mL). The EndoSheath was removed and then the sheath and endoscope were rinsed separately

» The endoscope was inserted into a second "defective" sheath with a hole in identical location to determine if the contaminating virus would pass outward through the second sheath

Outcomes:

» No virus was detected passing outward through the second sheath

» Authors concluded that the "Use of a sheath combined with intermediate level disinfection should provide a safe instrument."

A comparison of two methods for preventing cross-contamination when using flexible fiberoptic endoscopes in an otolaryngology clinic: disposable sterile sheaths vs. immersion in germicidal liquid

Elackattu, A., et al. (2010). *Laryngoscope, 120*(20), 2410-6.

Study Design:

» Prospective controlled trial to assess the efficacy of using a sterile sheath to prevent cross-contamination

» 100 endoscopes assigned 1:1 to sheath or germicidal immersion group

» Swabs taken from multiple sites on 100 endoscopes for cultures to detect the presence of bacteria and/or viruses before and after use in patients

Outcomes:

» Microbial counts on the endoscopes in the groups were similar

» Average time was 89 seconds for EndoSheath method vs. 14 minutes for the immersion method

» Authors concluded EndoSheath was a relatively safe method of avoiding the transmission of infection when using an endoscope successively in multiple patients

Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: clinical and economic burden

Seoane-Vazquez, E., et al. (2006). *Curr Med Res Opin, 22*, 2007-21.

Study Design:

» Review of 64 scientific articles describing 70 outbreaks

» Bronchoscopy accounted for half of all reported outbreaks

» Inadequate decontamination practices were the leading cause of contamination; equipment malfunction became the second leading cause of contamination during the period 1990–2004

» More than 91% of the infections identified could be prevented by health care providers if quality control systems are improved and implemented

» The available economic information concerning exogenous endoscope related events is very limited

Outcomes:

» Proper decontamination practices, the use of protective sheaths, and the improvement of surveillance systems could reduce the clinical and economic burdens associated with exogenous endoscopy-related events

CLINICAL EXPERIENCE

Out-patient flexible cystoscopy using a disposable Slide-On® EndoSheath® system

Kimuli, M., et al. (2007). *Ann R Coll Surg Engl, 89*, 426-30.

Study Design:

» To determine feasibility of out-patient flexible cystoscopy, 27 patients were invited to undergo outpatient cystoscopy using the EndoSheath protective barrier

» Product performance was assessed through physician evaluations and patient questionnaires

Outcomes:

» Authors conclude that "It is possible to perform out-patient flexible cystoscopy safely, economically and efficiently with the aid of a disposable endoscope system."

Evaluation of practice efficiency with a novel sheathed flexible cystoscope: a randomized controlled trial

Krebs, A., et al. (2007). *Urology, 70*, 883-7.

Study Design:

» Prospective, randomized trial evaluating practice efficiency of EndoSheath

» 100 patients assigned 1:1 to conventional cystoscopy or cystoscopy using EndoSheath

» Questionnaires to assess cystoscope setup, handling, optical quality, and patient comfort were completed by the physician, nursing staff, and patients. Reprocessing time was also recorded

Outcomes:

» No statistically significant difference was found between groups for procedure time, optical quality, or patient comfort, either during or after the procedure

» The mean preparation time of the cystoscopes was 10.7 min with EndoSheath (n= 49), 14.7 min with Rapticide (n= 21) and 42.2 with Cidex OPA (n = 27) ($P < 0.01$ for all comparisons)

Cogentix Medical
Cogentix Medical
5420 Feltl Road
Minnetonka, MN 55343
cogentixmedical.com
TEL 866.258.2182
FAX 866.255.4522