Research Summary
Evaluation of Endoscope Sheaths as Viral Barriers

Baker, Karen H. MSN; Chaput, Maria P. BS; Clavet, Clark R. MS; Varney, George W. BS; To, Theresa M. BS; Lytle, C. David PhD

Support for Stryker's Claims

• Stryker's Flexible Cystoscopes featuring Vision Sciences® EndoSheath® Technology are designed to reduce the risk of cross-contamination by providing a sterile, single-use barrier between patient and device.
  
  - “Endoscopes used in ENT practice are contaminated with various types of microorganisms as they pass across the mucosa of the upper airway. If these microorganisms are not removed before subsequent use, there is a risk of disease transmission to other patients. One method of decreasing this risk is the use of a sterile sheath that covers the insertion tube portion of the endoscope.” (p2)

  - “Endoscope sheaths cleared by the FDA as protective barriers (not all sheaths have been allowed this claim) have been demonstrated to be effective barriers to viral passage.” (p6)

• The use of a disposable sheath eliminates the need for high-level disinfection between procedures—resulting in faster equipment turnaround.

  - “The reprocessing step need not be high-level disinfection, but rather meticulous cleaning followed by intermediate-level disinfection.” (p6)

  - “This research supports the conclusion that proper use of an ENT endoscope sheath, meticulous cleaning of the endoscope, followed by an intermediate-level disinfection step, combined with careful aseptic technique, will provide the practitioner with an instrument that can be reprocessed in a timely manner and provide confidence that the endoscope/sheath combination is safe for patient use.” (p7)
Abstract Quotation

OBJECTIVES
Evaluate ENT endoscope sheaths as barriers to virus passage.

STUDY DESIGN
“Defective” sheaths covering an endoscope were challenged with virus to determine how many virus particles could be recovered from the endoscope.

METHODS
Sheaths with small laser-drilled holes (2 to 30 microm) were challenged with high-titer virus suspensions (10⁸ viruses/mL). The inside of the sheath and the endoscope were separately rinsed to recover any virus that penetrated through the hole in the sheath. In an attempt to assess the possible importance of holes in the sheaths, a sequential test was conducted with an initial virus challenge outside a defective sheath (30-micron hole in the sheath), after which the possibly contaminated endoscope was removed and inserted into a second defective sheath (with a 20-micron hole at the same location) to determine whether the contaminating virus would pass outward through the second sheath.

RESULTS
Small volumes of virus-containing fluid penetrated through the hole, e.g., 500 virus particles passed through one of three 30-microm holes. A significant fraction of those virus particles was occasionally found on the endoscope after removal from the sheath. Similar results were obtained with sheaths that had small tears (34-84 microm in length, from punctures with fine wires). Although some virus penetration could occur during the initial challenge contaminating the endoscope, no virus was detected passing outward through the second sheath.

CONCLUSIONS
Use of a sheath combined with intermediate level disinfection should provide a safe instrument for ENT endoscopy.

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