Minimizing Patient Risk with Single-use Biopsy Valves

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Endoscopy units, as well as the FDA, AAMI, CMS, and the Joint Commission, for many years have been focusing their Infection Control efforts on finding ways to minimize cross-contamination risks and improve patient care. As hospital acquired infections (HAIs) continue to pose a threat to patients and staff, healthcare facilities are taking a deeper look at the infection control risks of using reusable accessories and are considering the benefits of switching to single-use accessories. With an estimated 30 million procedures to be performed this year in endoscopy units[1], this effort will need to be efficient to avoid procedural delays and cost-effective to minimize the impact on hospital budgets.

Healthcare facilities look to professional organizations and device manufacturers for guidance on the best practices to follow to help prevent cross-contamination. The Society of Gastroenterology Nurse & Associates, Inc. (SNGA) has been a leader in establishing evidence-based standards and guidelines in endoscope reprocessing.[2] In 2011, SGNA updated the following position statement on reusable accessories:

"Proper reprocessing of endoscopic accessories and valves is critical to the safe and successful treatment of patients. SGNA supports increased research in the areas of accessory and endoscope design in an effort to manufacture devices that can be easily disassembled, cleaned, high level disinfected, and/or sterilized."[3]

This statement, along with recent reports of inappropriate reprocessing techniques, has focused the attention of healthcare facilities on assessing the overall risks of using reusable accessories and protocols associated with proper reprocessing.

Moving to disposable products is another step in reducing cross-contamination risks. A human element is inherently involved in reprocessing and creates variability in a process that requires strict implementation. Reprocessing protocols and IFUs (Instructions for Use) can be long and confusing to healthcare employees responsible for reprocessing reusable devices. This, coupled with the need to turn equipment over faster, and at times general fatigue, can lead to some reprocessing steps being averted or missed. However, it is critical for the safety of the patient and healthcare staff that each step is followed to ensure proper results. Training is also an integral part of making sure that staff are properly reprocessing endoscopes and endoscope accessories. If any step is skipped or over-looked, it can result in cross-contamination.
One particular GI accessory receiving attention in the GI community is the biopsy valve. Biopsy valves attach to the instrument channel port of an endoscope and are designed to help maintain insufflation in the patient and prevent leakage during device exchange *(See Exhibit A)*. They are a gateway to the body and first point of contact for any endoscopic device being used in the procedure. Additionally, they are designed to "squeegee" any debris from the catheter of the device.[4]

Exhibit A: Endoscope Biopsy Valve

A majority of healthcare facilities are still using reusable biopsy valves provided by the endoscope manufacturer. However, an increasing number of hospitals are starting to convert to single-use biopsy valves due to the risks associated with the improper reprocessing of reusable biopsy valves. Reusable biopsy valves are used multiple times and intended to be reprocessed between each patient. They have a limited shelf life and are typically discarded when they begin to leak, which poses a risk by exposing healthcare staff and patients to infectious biomaterial. It is extremely difficult to visually confirm that reusable biopsy valves have been effectively cleaned, disinfected, and thoroughly dried after each use. This particular challenge leads to an increased risk in cross-contamination between patients.

In 2008, the VA Central Office sent a patient safety alert throughout the VA medical system due to an incident regarding improper reprocessing of semi-disposable (also referred to as reusable) biopsy valves at one of their centers. The alert cited that reusable biopsy valves were not being reprocessed correctly per the manufacturer's instructions; which required that the valves be opened during reprocessing. This resulted in the presence of bioburden inside their reusable biopsy valves. This VA medical center has since switched to using disposable biopsy valves for their flexible endoscopes to minimize the risk of cross-contamination.[5] Additionally, all VA medical centers were asked to consider switching to disposable biopsy valves rather than continuing to use reusable biopsy valves. In response, several other VA medical centers have switched to using disposable biopsy valves to minimize the risk of cross-contamination.

Because of the intricate internal design of the biopsy valve, endoscopic cleaning brushes may be ineffective at reaching all of these interior surfaces. During the cleaning process, the brush used to clean the internal channel can force bio burden into the crevices of the biopsy valve instead of brushing away the infectious material.

The Multi-Society Guidelines for Reprocessing Flexible Gastrointestinal Endoscopes states:

"Use brushes appropriate for the size of the endoscope channels, parts, connectors and orifices (eg, bristles should contact all surfaces) for cleaning. Cleaning items should be disposable or thoroughly cleaned and disinfected/sterilized between uses."[6]

This statement confirms that bristles should contact all surfaces of the inside of a biopsy valve before reuse is safe. The main area of concern continues to be those crevices that can possibly be untouched during the cleaning process.

The cross-section view in *Exhibit B* demonstrates how a standard endoscopic cleaning brush cannot reach all surfaces on the inside of a biopsy valve. The crevices are the area of concern because they can capture tissue and other potentially infectious matter.

Exhibit B: Cross-sectional view of a typical reusable biopsy valve, demonstrating the nooks and crannies that make a reusable valve difficult to clean.

In 2006, a study was conducted by NAMSA Advisory Services to check for lapses in properly reprocessing reusable biopsy valves. This study was randomized and funded by US Endoscopy, a subsidiary of STERIS Corporation (Mentor, OH). The study examined 15 reusable biopsy valves from three different centers in the United States. These reusable biopsy valves had been reprocessed according to each facility's current protocol and were deemed clean and ready for use.

The results of the study were posted in Infection Control Today (June 2007). Over 50% of the reusable valves collected were contaminated and had visual signs of damage and contamination under magnification. This was very alarming news to the GI community. The damage and contamination was not visible to the naked eye so it would be difficult for any healthcare facility to know if the biopsy valve was properly cleaned or not.

The NAMSA Study confirms the risks of using reusable biopsy valves in the endoscopy unit and has prompted many healthcare facilities to shift towards using single-use biopsy valves.

Another risk in using reusable biopsy valves flows from the limitations of tracking and traceability. Healthcare facilities typically have infection control surveillance programs that enable patients to be contacted if there is an infection outbreak. There are a number of ways to accomplish this task. A basic method is to keep a patient log that includes the scope model and serial number.[7] This would apply to tracking endoscopes within the GI unit. However, there is no method to effectively and efficiently track reusable biopsy valves. So traceability becomes an issue with reusable biopsy valves. The use of single use biopsy valves mitigates this risk.

During reprocessing, reusable biopsy valves are removed from the endoscope, manually cleaned with an endoscopic cleaning brush, and then high-level disinfected along with the endoscope. However, once the reusable valves are reprocessed and placed back into storage, they are not identifiable. New reusable biopsy valves are cycled in with older reusable valves so there is no accurate way to know how many times a reusable biopsy valve has been used. Should a cross-contamination issue occur, there would be no way to identify which patients were exposed.

Federal organizations (FDA and CDC) along with professional organizations (ASGE, SGNA, AORN, APIC, the American College of Gastroenterology, and the American Gastroenterology Association) have teamed up in an effort to standardize reprocessing guidelines.[8] Due to this shift of focus on standardizing endoscope reprocessing guidelines, reusable accessories are not getting the much needed attention in conjunction with this effort. Endoscopic reprocessing has become an important topic in the GI community and regulatory agencies due to the complex design of the flexible endoscope. With an increased focus in this area, critical reusable scope accessories can be over-looked leading to an increased risk of cross-contamination.

In 2004, US Endoscopy was the first company to offer a single-use biopsy valve. As the current market leader, US Endoscopy understood the risks associated with reusable biopsy valves and developed a solution for hospitals to implement into their Infection Control process.

Single-use valves provide the best solution for the following reasons:

1) Minimize Cross-Contamination Risks – A new, single-use biopsy valve is used per patient and then discarded after the procedure. This helps to eliminate cross-contamination and traceability concerns specific to biopsy valves.

2) Offer Consistent Performance – A new single-use biopsy valve is used one per procedure which can minimize leakage. On the other hand, reusable biopsy valves may unexpectedly leak at any time due to overuse and damage.

3) Improve unit efficiency – Single-use biopsy valves do not have to be reprocessed which saves additional time for reprocessing room staff.

This paper outlines a number of potential risks associated with reusable biopsy valves and the benefits of switching to single-use biopsy valves. Single-use biopsy valves help eliminate the hidden dangers of reusable biopsy valves and the overall risk of cross-contamination. Healthcare facility endoscopy managers should consider adopting single-use valves as another step in improving Infection Control. Hospitals can be proactive with their Infection Control process and help minimize potential Hospital Acquired Infections by using single-use biopsy valves in their endoscopy units.

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