An Endoscopic Handling And Reprocessing Solution

1. How was the idea for this product developed? What needs were you looking to meet with this product?

The development of the ProShield took place in several stages, each stage recognizing and addressing a need in the handling, storage, transportation and reprocessing of flexible endoscopes.

While developing an airway cart, John Seitz the cart designer, recognized that sitting a Flexible Bronchoscope down after a procedure, was at best a challenging undertaking. He was puzzled by the thought of: “Where does contamination on the probe go? Additionally, what if it falls off of the top of the cart, being pulled by its floppy shank or light cable? How do we protect the delicate shank from being bent, kinked, or broken?”

Therefore, a single-use sheath was considered, but quickly passed over because storing spare tubes on the airway cart seemed impractical.

Several styles of reusable tubes, carriers and containers were developed and trialed at Yale New Haven Hospital. They provided the desired mechanical protection to the scopes, but proved to be cumbersome and took far too long to clean and prep for the next use. There was always the nagging question: "Was the tube properly cleaned"? Separate clean and dirty tubes were tried, but quickly eliminated from consideration the first time a clean scope was inadvertently put into a dirty tube.

At Yale, the idea to employ a single use tube was re-introduced; 22mm airway tubing was employed. It had its problems--the end was open and wouldn't contain contamination and the tubing was flexible by design, so it didn't offer bending protection.

During a parallel test at Duke University Medical Center, the corrugations of the airway tube caught the tip of a Bronchoscope and caused it to be bent around at 180 degrees completely breaking the scope. That event prompted the almost immediate application of the more expensive but much more effective rigid, clear, smooth bore tube that the ProShield now uses. A molded funnel was added to the entry-end for convenience and speed of inserting a scope.

After successfully using the ProShield to store and handle dirty scopes, it became apparent that the same package would be very helpful for handling clean scopes. The peel-pack envelope pouch was added to ensure the opening stayed clean. The concern of storing the ProShield on carts went away, and now the Scope and ProShield would travel as a pair throughout the entire cycle.

The bottom cap was then sealed against liquids when someone realized that the ProShield made a perfect container. The result eliminated concerns and potential hazards of delayed reprocessing as it was recognized as the perfect solution for immediate bedside soaking of the scopes.

As the ProShield proved to be an effective and safe way of handling and storing endoscopes, users started finding its additional value when transporting scopes to other departments like the ER or the ICU. The latex-free rubber band attachment strap was added to ensure the ProShield and Scope stayed together while the pair safely traveled throughout hospitals.

During the ProShield's introduction at the ASA convention, an interested doctor asked, "How do I know if the scope in the ProShield is either clean or dirty?" thus, the clever two-layer, two color CLEAN/DIRTY label was then added.

Since its initial development, many accessory brackets, stands and cabinets have been added to the product line to enhance the value of the ProShield and further simplify the handling of delicate, expensive flexible endoscopes and TEE Probes.

2. How does this system work?

The main purpose and intended use of the ProShield is to protect the expensive endoscope during transit and aide in cleaning the endoscope. Therefore, soaking of

the scope can now begin at the patient's bedside. To begin the process, or the lifecycle of the ProShield, a scope has to be cleaned and placed into a ProShield. The ProShield itself can be housed in several different capacities, or tailored to the hospitals process. One of the ways it can be housed is by giving the specialist the ability to apply the ProShield to the anesthesia cart, or other general purpose carts, using existing or new hardware. The second way to house the Proshield is either in a cabinet, sold by DeRoyal, or by a c-style bracket that can be mounted on the wall.

After the process is tailored to that specific hospital preference, the clinician would take the clean scope and place it into a new ProShield. Again, the ProShield is necessary to help protect the expensive endoscope and aide in cleaning. The scope can either be rolled into the OR using a cart, with ProShield attached, or simply carried into the room by the clinician or tech. Once the scope is used on a patient the contaminated scope is inserted back into the ProShield. The "Clean" label on the side of the semi-rigid tube would then be removed to indicate the dirty or contaminated flexible scope. After the case is completed the scope would be secured by the ProShield band, and if applicable, the ProShield would serve as a pre-cleaning device and starts the soaking process immediately. This would be of great use for bronchoscopes and ENT scopes so that biomass does not cake in the port of the flexible scope.

We have heard from many clinicians and clinical engineers that complain because of delayed reprocessing. Should the cleaning process be delayed, a crust would form much like that of an oatmeal bowl that has been left in a kitchen sink without being cleaned or soaked immediately. If soaking or delayed reprocessing occurs, a wire brush would need to be inserted through the endoscope port, and this is where a lot of damage occurs with the fiber optics. The surgeon will be the first to know if the fiber optics have been compromised because he/she will see black spots on the screen or in the line of sight. At this step in the process, the clinician would be able to take the ProShield back to the decontamination room to be cleaned. Next, simply remove the scope from the ProShield and place the flexible scope into an endoscope reprocessor. After the scope comes out of the reprocessor, it should go into a clean ProShield where it can be housed for transport from the decontamination room to patient and back, completing the cycle.

The ProShield offers a contamination-free storage holster during the entire procedure. No staff person would need to become a "holder" of a contaminated endoscope. Any necessary reinsertion also becomes a routine and uneventful procedure.

3. What problems does this product address?

Over the years, there have been some highly publicized and very serious issues with endoscopes causing patient illness from cross contamination, the worst being life threatening illnesses, and there needs to be an answer. The ProShield offers a way to effectively identify the scope as clean or dirty by the labeling on outside of the tube. The ProShield also provides clinicians with a clear display of the scopes since each will now be in sight either hanging on wall, in a cabinet, or on stands. This simple but highly effective disposable product gives the staff confidence,

because they are now dealing with a safer system that can help reduce cross contamination instances.

To help put things in perspective, a national publication posted a study about the "Top 10 Health Technology Hazards for 2012." Cross contamination from flexible endoscopes was listed as #4. Additionally, a major national news entity ran a story on the cleaning of reusable instruments and found instances where viruses were spread not only with general instruments, but endoscopes as well.

The concept of the ProShield was a result of listening to the clinical team as well as those in decontamination, clinical engineering or biomed, plus the team leaders responsible for capital expenses and budgeting. Fiber optic scopes range in cost from $20,000 to $80,000, and down time because of repairing broken scopes can be burdensome to any facility. Additionally, the cost to repair the scopes is very high. For example, to send the scope to be reviewed for damage would be an expense of approximately $2,000.

Furthermore, the ProShield will answer many questions and concerns in today's medical setting by helping to reduce the amount of breakage to your fiber optic scopes. This will help free-up time for the tech and will help reduce the additional dollars spent on repairs. More importantly, the facility can now focus on new capital equipment necessary for today's needs rather than repair work.

To give a clearer picture, there are many ways a fiber optic scope can be damaged. For example, it can be shut in the drawer of an anesthesia cart, slammed against a wall in transport, dropped in route to the patient's bedside, and damage can even occur while repossessing or cleaning a contaminated scope. We have also noticed that once the scope has been used at patient bedside, a pillow case or biohazard bag is used to transport back to decontamination. This practice is not ideal because damage can occur to the scope while it is in transit. Additionally, patients and visitors to the hospital do not want to come into contact, or see, the contaminated scope. Therefore, the ProShield gives a safe and more aesthetically pleasing solution to an everyday issue.

The ProShield provides an ergonomic and simple transport system that also allows the device handler to have additional safeguards in place. With the ProShield, the scope is secure when walking to the operating room or specialty suite, the patient bedside after using a bronchoscope, or on the way back to the reprocessing room.

Additional benefits of the ProShield are the ability to offer a contamination-free storage vehicle. Therefore, the surgeon can simply reintroduce the scope during the procedure, and it also provides effortless scope storage during STAT conditions. Thus, there will always be a clean scope nearby with the use of the ProShield. In fact, the ProShield offers a systematic approach that can improve device inventory management as well as handling of clean and contaminated scopes.

4. How can using this product help facilities improve patient safety, infection rates and overall efficiency?

Use of the ProShield by endoscopy and TEE providers has multiple benefits to the facility, the equipment and to the staff. These benefits all translate to improved efficiency, improved patient safety and an improved patient experience. The following sections describe these advantages.

Use of the ProShield:

A. Protects endoscopes from: inadvertent damages; insertion tubes from being pinched in a drawer; falling onto its delicate shank; or its glass fibers being over bent. This minimizes rescheduled cases, reduces the frequency of using lower performing "back-up" devices, or the application of less effective methods when a scope unexpectedly becomes unavailable. A lower repair cost budget due to less damage will ultimately appear as lower procedure costs to patients. Lower costs mean more money in the budget for better care for patients.

B. Protects a clean device while it is on its way from CPD to the procedure room, storage cabinet or to the patient’s bedside. This is especially important when the device must travel a distance, such as to an ICU or ER. Less chance of damage or breakage, and reduced chances of patient contamination are the resulting benefits of transporting a fully protected scope. The possibility of inadvertent splashes causing contamination is eliminated. The patient’s experience is enhanced by the visual comfort of seeing a protected device arrive bedside. Clinicians will not worry or need to ask the difficult question, "How do you know that that scope is clean and has not been splashed with contamination along its way?"

C. Protects the scope and patient mid-procedure by providing a clean, contamination free location for temporary "parking" of the scope if it must be withdrawn and re-inserted into the patient.

D. Allows immediate post-procedure flushing rinsing of endoscopes and their internal ports with water or enzyme soap to remove bio-mass and protein films before they become stubborn and hard to remove. More effective cleaning directly translates into more effective disinfection of scopes, hence reduced chances of cross contamination between patients. Improved cleaning also greatly reduces the frequency of cleaning process damage caused when aggressive means must be employed to remove clogs or dried residues.

E. Allows a dirty scope to remain soaking until the complete reprocessing cycle can begin. There is NO chance for protein films or biomass to harden on or in the scope. When a scope arrives at the reprocessing station, it continues to soak in a ProShield, even if the reprocessing staff and machines are already tied-up with a backlog of devices to reprocess. This soaking reduces the time needed to reprocess a scope, thus saving the facility per cycle costs and reducing the rate of expensive cleaning damage.

F. Provides a safe and secure storage location for clean reprocessed devices, no matter where that is, while they await use on the next case/procedure. Scopes are protected from the errant splash of contamination and are protected from all possible forms of mechanical damage. Having a clean functional scope every time,

for every patient improves case handling efficiency and improves patient safety. Every facility has its own set of unique methods and challenges in the handling and safe reprocessing of flexible endoscopes and TEE Probes. Because of its many-fold benefits and multiple problems solved, use of the ProShield by endoscopy and TEE providers has multiple benefits to patients, care and safety, to the facility and equipment, and to the staff. These benefits all translate to improved efficiency.

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