The importance of testing the waterproof integrity of flexible medical endoscopes and the relevance to patient cross infection risks.

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Background and Aims: Flexible medical endoscopes are an important and integral part of disease diagnosis and treatment, but are also sources of patient cross infection. The aim of this paper is to raise awareness to the risks of inappropriate leak testing and patient safety impact.

Conclusion: In summary, leak testing is crucial to the success of the reprocessing cycle, in the event that an endoscope with a leak is used for a patient procedure, the risk of cross infection due to patient contamination with this fluid is enormous.

Leak Testing of endoscopes is the most misunderstood and routinely missed step in endoscope reprocessing.

The process of testing the endoscope can be called many different things depending on manufacture and/or facility. Leak test, sheath integrity test, waterproof test and bubble test are all ways that describe the same function. The object of the exercise is threefold:

1 To eliminate the risk of cross infection between patients by contaminated fluid leaks during the procedure.
2 To minimize the level of damage caused to an endoscope by submersion in fluids with a leak in the endoscope.
3 To minimize the cost of repairs caused by submersion in fluids with a leak in the endoscope.

The design of endoscopes incorporates an internal area where all of the components necessary for safe operation are housed. This includes but is not limited to: fiber bundles, wiring harnesses, CCD chips, angulation wires, channel systems, support frameworks and other components. This area is designed to remain dry and is not subjected to contact with detergents, disinfectants or rinse water.

The endoscope is a complex mix of materials and these many parts have to be joined together in a way that is patient safe as well as being watertight and able to be properly cleaned. Endoscopes contain lots of 'O' rings that also can be a source of leaks as well as the relatively soft bending section rubber and thin membranes that cover video switches.

Fluid can enter the inside of the endoscope through leaks in any of the external or internal structure or through damaged 'O' rings. Holes can be miniscule in size and present an extreme challenge to the conventional leak test method.

Larger holes that present as a gross leak are easily identified and the endoscope can be quarantined and removed from patient contact. Smaller leaks are much more difficult to find and potentially pose the greatest risk to patient contamination.

Manual wet leak tests are the most common method of testing, yet are conducted by individuals who may not understand the ramifications of using a leaking endoscope in patient procedures, and may not have been trained on the importance of each of the steps in the process. Leak tests need to be carried out in a sink of clean water. The endoscope needs to be inflated prior to submersion, this will stop the ingress of fluid should there be a leak.

The endoscope channels should be completely filled with water from a 50cc syringe so that all air is expelled from all channels. The external surface of the scope should also be syringed to remove bubbles that may be clinging to the surface of the endoscope. Particular attention should be given to syringing trapped air from under the angulation knobs and other crevices that may trap bubbles.

The endoscope should be observed for as long as possible as more time equals a more accurate test. The bending section should be angulated in each direction to stretch the rubber cover to reveal leaks. The insertion and light-guide tubes should also be manipulated to expose small leaks that remain hidden. Each joint in the body should be slightly stressed to reveal damaged or leaking 'O' rings.

The endoscope should then be observed for any stream (no matter how small) of bubbles emanating from the external surface or from one of the many channel ports on the endoscope. Bubbles from a port indicate an internal leak in one of the channels. The exact location can be ascertained by the port that is leaking air from it. This will indicate the channel that has the leak and whereabouts the leak is in that channel as bubbles will make their way to the closest exit.

Leak tests should not be conducted with detergent in the water as this will mask the small bubbles from a leak. No other manual cleaning activities should be carried out until the leak test is completed.

The time that the endoscope is submerged is crucial to the accuracy of the test, the longer the better. Do not deflate the endoscope until it has been removed from the water.

Do not submerge the endoscope without the waterproof cap(s) fitted. Do not submerge the endoscope with the ETO venting valve fitted as this will cause massive fluid invasion.

If a small leak goes undetected fluid can accumulate inside the endoscope during each procedure and each reprocessing cycle. If the leak is in one of the more common places, such as the bending section rubber, fluid can accumulate in the tip of the endoscope near the source of the leak and potentially leak out during subsequent procedures.

This fluid has not been in contact with disinfectants and may be many procedures old. It may not be detected until enough fluid causes problems with the video system.