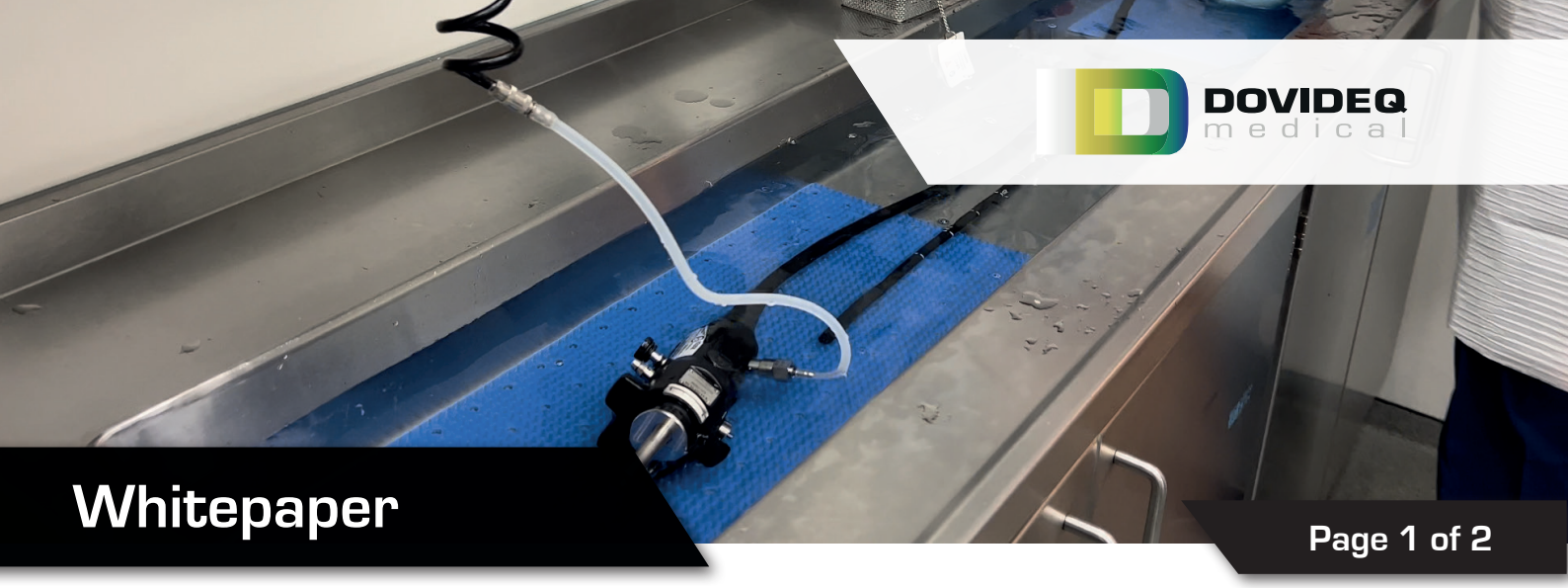


DOVIDEQ medical

Whitepaper

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

Background and aims:

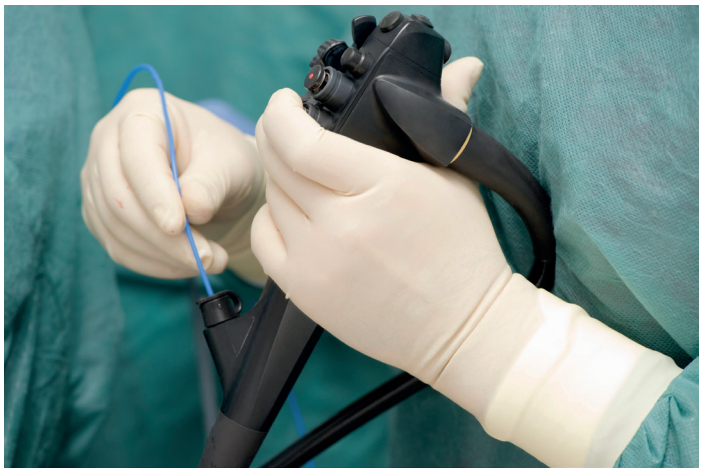
Flexible medical endoscopes are an important and integral part of disease diagnosis and treatment, but are also sources of patient cross infection. The aim of this paper is to raise awareness to the risks of inappropriate leak testing and patient safety impact.

Leak testing is a **vital processing step that detects fluid invasion** in an endoscope. Endoscopes that are inadequately leak tested can pose **a risk for transmission of infection or injury to patients.** Moreover, if not detected, fluid invasion of an endoscope can damage the endoscope and increase repair costs. Leak testing of endoscopes is the most misunderstood and routinely missed step in endoscope reprocessing.

Process

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 used to 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.



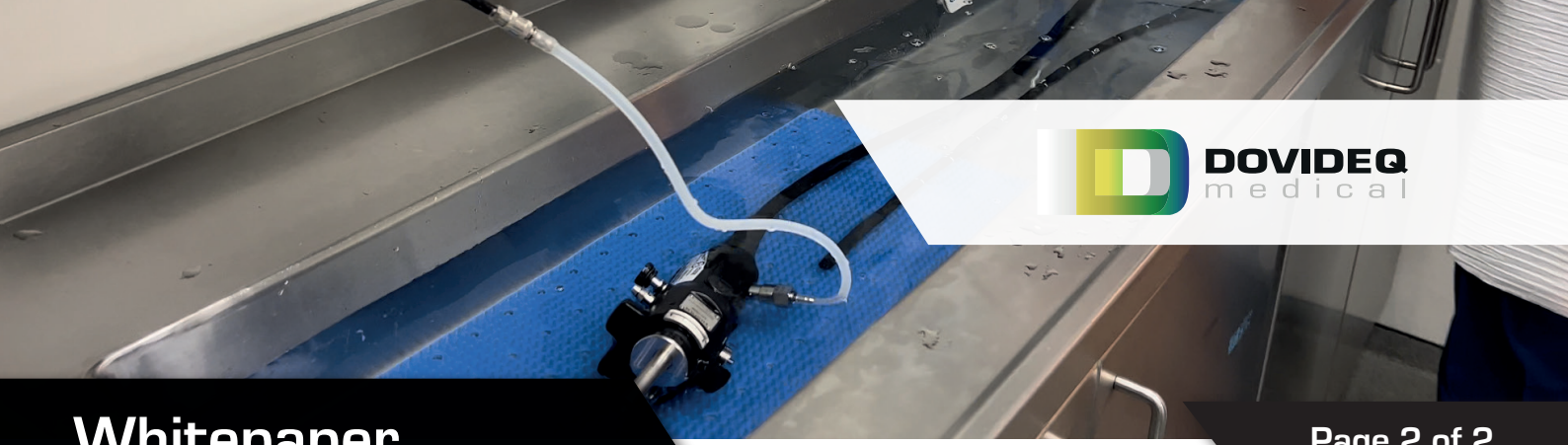
The design of endoscopes incorporates an internal area where all of the components necessary for safe operation are housed. This includes but is not limited to: fiber bundles, wiring harnesses, CCD chips, angulation wires, channel systems, support frameworks and other components. This area is designed 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 watertight and able to be properly cleaned.

Endoscopes contain lots of 'O'-rings as well, that can be a source of leaks. The same goes for 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.

This whitepaper is based on the original scientific paper of Nick G. Bromiley AGTS, CFER, CSPDT, ARIA. Principal Technical Specialist & Trainer, Endoscopes at Medivators Inc.



Whitepaper

Manual test

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. One tester leaves the scope attached to the leak tester for two minutes, the other for only thirty seconds. Longevity is crucial to the accuracy of the test.

One employee detects a leak when the scope goes down from 220mb to 200mb and the other only at 180mb or through the air bubbles in the water bath.

This process is not reproducible and highly dependent on the particular employee and therefore a major risk to patient safety and compliance. After the manual check and pre-cleaning , the scope is placed in the automated disinfector and does not pass the disinfector's leak test. The cause may be a leaking scope, a defective seal or an incorrect connection that causes microleaks that cannot be detected by the human eye.

If such a problem occurs, the disinfection process needs to be interrupted to find and fix the problem, which always costs extra time. The undetected leaks can cause damage to the scope and incur major repair costs.

When 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.

Automated test

An automated electronic leak testing device detects small leaks during pre-cleaning, before they turn into a major repair or a total loss. It also saves a redundant cleaning cycle because of a faulty endoscope and a contaminated cleaning device.

Most importantly, it enables a reliable and reproducible leak testing regardless of brand or type of scope.

Conclusion

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. It is recommended to use an automated system to add a reliable and reproducible test to the reprocessing cycle.

Interested in automated leaktesting?

Many hospitals have already expressed interest in our LeakControl or have these testers in use. The leak tester can be set up to suit each user.

Contact Dovideq today for a quote.

This whitepaper is based on the original scientific paper of Nick G. Bromiley AGTS, CFER, CSPDT, ARIA. Principal Technical Specialist & Trainer, Endoscopes at Medivators Inc.