

Endoscope Repair Decisions Add Up To Fiscal, Frustrating Tug-of-War

OEMs vs. third-party repair companies decision akin to disposables vs. reusables debate.

By Rick Dana Barlow

Hospitals and other healthcare facilities can make some curious decisions about how to cut costs in their organizations. In fact, many still struggle to take seriously enough whether to rely on the original equipment manufacturer (OEM) or a third-party repair company (stationary or mobile) to service expensive endoscopy equipment.

On the surface, the mental debate seems obvious enough even though it's rooted in generalities that may be misleading. For non-warranty repairs, the OEM may charge more than third-party firms or may steer the provider toward spending more for a costly replacement or upgrade. Alternatively, the third-party repair company may charge less than the OEM, but the hospital may question the quality of the work and the replacement parts used.

Basically, it adds up to a lot of confusion about selecting a qualified repair provider – OEM or third party. But doing a little upfront homework can alleviate that confusion.

Although there's nothing inherently wrong with choosing to use a third-party repair service – and many hospitals do it frequently – the problems emerge when hospitals wind up with one of any number of unscrupulous firms out there who may be focused more on short-term revenue gains than long-term revenue generation from referrals and repeat business based on their ability to do the job right. Unfortunately, those unscrupulous companies manage to infect the perceptions of hospitals that may quickly condemn all third-party repair companies based on the actions of one. The trick is to locate those reliable and scrupulous third-party firms that are willing to help the provider protect and maintain their endoscopes and related devices.

Admittedly, Melville, N.Y.-based Olympus America Inc., has seen its share of customers who turn to third-party repair firms to save money only to return to the OEM and end up spending more. Scott Froehlich, senior product manager of service at Olympus, says the most important item to realize is that OEMs must comply with the Food and Drug Administration's Quality System Regulation (21 CFR Part 820). "The establishment of a quality system is a significant undertaking, in comparison, for example, to the establishment of a quality

assurance system," says Froehlich. The requirements include establishing written service procedures, verifying that the company meets those specified requirements, implementing corrective and preventive action if quality problems come up, and subjecting yourself to a complete audit inspection by the FDA, he adds.

Furthermore, OEMs must provide repair devices that meet their own specifications, notes Froehlich. "Third-party repair companies cannot easily verify that a service action meets OEM specifications because they're not in possession of the original manufacturing specifications, nor are third-party repair companies required to validate their service actions," he says.

What Olympus uses to differentiate itself from third-party firms and other competitors is the notion that it restricts access to all of its product specifications and parts. "Unauthorized third-party companies have no link to any upgrades in our repair parts or processes," says Froehlich. "We continue to update our repair parts and procedures, validated by Olympus R&D to maintain superior performance of the endoscope. Unauthorized third-party repair companies cannot offer the incremental improvements to the endoscope that are developed by the original manufacturer as a result of our research and analysis."

Olympus restricts access to original factory parts, tools, test fixtures and specifications used in manufacturing the devices they are repairing. Without these parts or plans, the third party firms may rely on "reclaimed parts or custom parts from third-party manufacturers," he says, and "they may develop alternative ways (unauthorized by the OEM) of repairing devices." He adds that if any third party says they get their endoscope parts from Olympus "be aware that Olympus doesn't sell its proprietary tools and test fixtures, patented lubricants and lenses or certified parts to unauthorized third parties."

As a result, Froehlich warns about third-party repair companies substituting "inferior parts and processes to reduce cost" that may change the overall performance of the Olympus device in the long run. "When parts are substituted by third parties, especially insertion tubes and optical components, the endoscope may not perform as originally designed," he says.

Froehlich dismisses the commonly held belief among providers that third-party repair companies are less expensive than the OEMs, with some qualifiers. “On a case-by-case basis, third parties may be less expensive than OEMs for specific minor repairs, but in reality, the cost over the long term is frequently higher,” he says, particularly for complex repairs that may require frequent follow-up, which translates to higher long-term repair cost and increased downtime. “Third-party repair companies in many cases can only perform minor repairs,” he continues. “This forces the healthcare facility to utilize multiple repair providers. It’s also difficult to compare prices of repairs because the repair descriptions may not accurately describe exactly what the repair [involves].”

Should a third-party repair company service an Olympus endoscope with “non-manufacturer approved parts,” Froehlich notes that Olympus may not be able to repair the device to satisfy FDA requirements. “Unfortunately, the additional cost of undoing the repairs performed by the third party is incorrectly associated with the OEM,” he says. “In many cases, the OEM must perform additional repairs to endoscopes that were previously repaired by a third party because third-party repair companies may patch holes or splice tubing to save costs rather than replace these parts outright with new parts.”

Another compounding problem is that if a third-party repair company uses parts that are not OEM-approved, the OEM may not be able to repair the device to the original manufacturer’s specifications as required by the FDA, according to Froehlich. Non-OEM parts may “compromise the functional characteristics of the device relative to the original product design” and those “materials can shorten the useful life of the device and may compromise patient safety,” he adds. In fact, a complete, and perhaps costly, refurbishment most likely would be necessary.

Without disassembling an endoscope that was serviced by the OEM or a third-party repair company on-site in the operating room and inspecting every component, how can a hospital truly know whether it has received quality service with quality parts?

“It’s important for the hospital to have an educated staff that understands the basics of the endoscope,” says Froehlich. “The hospital has to put a lot of trust in their repair provider because they cannot see what’s inside the scope. As an OEM, Olympus has seen some very disturbing repairs performed on our endoscopes by third-party repair

Figure 1



Figure 1: Third-party spliced channel repair

Figure 2



Figure 2: Olympus replacement channel repair

Figure 3

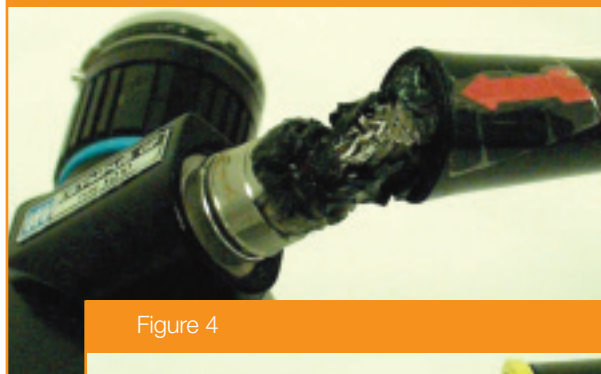


Figure 3: Third-party light guide tube repair patch

Figure 4



Figure 4: Olympus light guide tube replacement repair

Figure 5:
Third-party
repair using boot
extenders



Figure 5

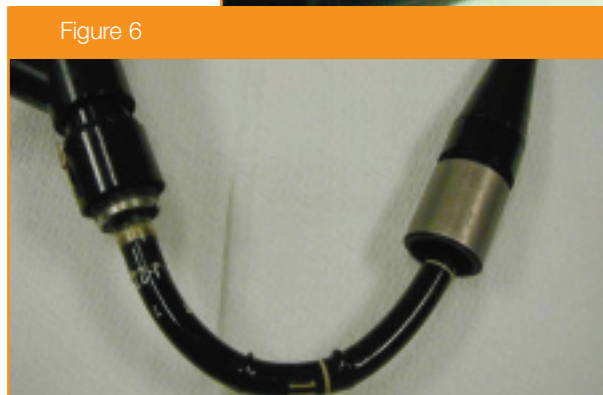


Figure 6

Figure 6: Third-party boot extenders hide buckles



Figure 7

Figure 7: Third-party bending section braided mesh (distal end) band-aid repair

Figure 8: Olympus braided mesh and bending section replacement repair



Figure 8

companies that most people would find shocking.” They include insertion tubes of the wrong length and Teflon tape to cover up frayed wires on the bending section, he adds.

Before a provider can choose between an OEM and a third-party repair company, Froehlich recommends the provider audit the facilities of their choices. That audit should include finding out where they buy parts, what processes they follow, what specifications they are repaired to, how the devices are handled and how they are inspected – all of which are critical elements to the quality of the repair. He encourages providers to assess whether the OEM or repair company offers hospital staff members educational seminars on how to reduce repair costs and monitor and maintain inventory as preventive measures to costly repairs.

One key aspect to repair work that hospitals typically overlook is when the company they choose to handle the repairs of their endoscopes farm out certain steps in the process to brokers. “Hospitals should be very concerned with repair providers who broker or farm out work,” Froehlich says. “Aside from the additional cost incurred by the hospital for multiple companies handling the repair, it doesn’t say much for the ability of the repair providers who cannot perform their own work. In addition, the hospital may be assuming unnecessary risk when non-qualified repair providers perform repairs. Improper repairs could result in patient injury and legal or financial claims against the hospital.”

Ultimately, endoscopes have been around for more than two decades, and with them scope repairs, so why haven’t hospitals and other healthcare facilities learned what to do? “The selection of a repair provider is still such a difficult decision for hospitals because of the capital investment and the high cost of operation that can be consumed with excessive repairs,” says Froehlich. “By nature, endoscopes experience a lot of ‘wear-and-tear’ during daily use. It’s important for the healthcare facility, when selecting a repair provider, to take advantage of any educational opportunities that will help the facility reduce the frequency and cost of repairs.” ♦FM

Editor’s Note: Froehlich encourages customers to visit Olympus America’s National Service Center in San Jose, Calif., as well as any of the company’s 17 regional service centers to view its repair procedures. In addition, Olympus America provides much of its educational programming through Olympus University. For more information, visit www.olympusuniversity.com.

