Advertorial

Third-Party Servicing of Medical Endoscopes

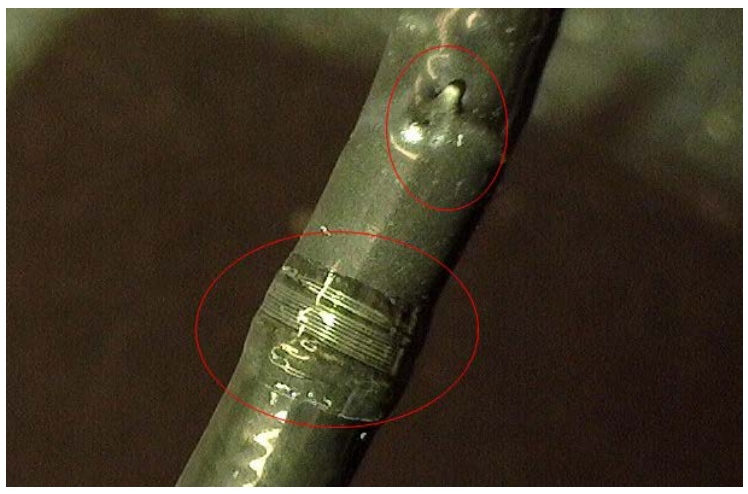
Are you really saving money on third-party repairs? If so, at what risk?

What to know about Third-Party Servicing of Endoscopes[1]
Maintenance and repair of medical endoscopes by third-parties has become the subject of increased attention, including state and federal legislation, FDA requests for comments, a public workshop, and a request by Congress for an FDA report on the subject.

Why is there such a concern?
Manufacturers are required to conduct their service activities, and ensure the qualifications of servicers they contract with, under FDA's Quality System Regulations (QSR) and are subject to FDA inspections. However, independent servicers not contracting with manufacturers are not subject to QSR and are not subject to FDA inspections. Thus, there is a ***risk that servicing is done by inadequately trained personnel or repairs are done with inappropriate replacement parts***.

Is there any oversight over third-party repair facilities?
No. There is no agency that oversees the activities of independent service providers repairing medical devices. Independent servicers do not even need to register with the FDA.

Would additional oversight increase costs to third-party?
Patient safety should be the primary concern with regard to oversight of third-party servicing of medical devices. Requirements to register with the FDA and report data to the FDA are not cost-prohibitive measures and would significantly improve the FDA's ability to ensure appropriate servicing of medical devices and the availability of safe and effective products.



Improper material used, causing holes and tears

Optim's Statement on Third-Party Endoscope Repairs
Optim strongly discourages our customers from using third-party repair facilities to repair the Optim ENTity™ series of endoscopes. Third-party repairs void ***Optim's 2-year Warranty, invalidates material compatibility and cannot be returned to original specifications by a third-party***. These repairs typically lead to a required repair through the original equipment manufacturer, leading to additional repairs and costs.

> *"Our customers have come to depend on Optim endoscopes to be the brightest in the market. This is achieved through our patented process which cannot be replicated by a third party."*
> ***David Guy VP Sales Optim LLC***

How can this affect your Optim ENTity Endoscope?

- Optim restricts access to original factory components, tools, test fixtures and specifications used in manufacturing the endoscopes a third-party is attempting to repair. Without these parts or specifications, third-party repair facilities substitute untested parts which may compromise the overall performance and integrity of the Optim ENTity endoscope.
- The non-original parts and the adhesives used by third-party repair facilities have not been tested for material compatibility in relation to HLD or AER systems. There is no assurance that these scopes repaired by third parties are compliant.
- There is no requirement for third-party facilities to maintain a quality management system, or to track and report adverse events to the FDA.

Optim cares, how we can help.
Repairs of endoscopes can be a frustrating experience but Optim works to make the process simple and timely. A loaner is available for scopes in the repair process, and Optim provides a clear repair report only charging for the time and materials needed to repair the scope.

Optim works with its customers to provide repair pricing competitive with third-party repairs while providing first quality work. Optim's repair returns the endoscope back to the new specifications. Optim adheres to FDA quality management systems.

Optim LLC

ENTity™ Endoscopy Systems | *Powerful Innovation. Proven Performance.*

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1. https://www.advamed.org/sites/default/files/resource/1125_6_2_2016_advamed_comments_on_dkt_no_fda_2016_n_0436_third_party_repair.pdf