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## Auditing Repair Quality

*Inferior endoscope repairs can compromise device safety.*

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# Auditing Repair Quality

## Inferior endoscope repairs can compromise device safety.

*Olympus endoscopes are complex medical devices that provide the healthcare community with invaluable diagnostic and therapeutic capabilities.<sup>1</sup> Properly maintaining and repairing these delicate instruments is essential to ensure their ongoing reliability and precision performance. This publication is designed to provide customers with objective data to help them evaluate the quality of their current repair service.*

### The True Cost of Quality

Every repair can have a long-term impact on the integrity of the instrument and its useable life. Therefore, the true cost of a repair can only be fairly evaluated by analyzing the overall costs required to maintain and service a piece of equipment throughout its lifetime. In doing so, it becomes apparent that while there may be a cost premium associated with superior quality repair processes, the cost for inferior quality repair work can grow exponentially over time.

### Not all Repairs are Equal

Cosmetically, an Olympus endoscope may look like the original product after service is performed by a non-Olympus (third-party) repair vendor.<sup>2</sup> However, there can be many problems inside the scope that are indiscernible until the instrument is disassembled. These repairs can compromise the performance characteristics of the scope and shorten its useful life.

### Only One Authorized Service Provider

Customers select Olympus products because of their superior design and performance. Using Olympus-authorized maintenance and repair service ensures those quality characteristics endure throughout the life of the equipment. Olympus differentiates itself from all other repair providers in six key areas:

### 1 Factory-Trained Technicians

A recent survey conducted by Olympus at the Association of Healthcare Resources Material Manager's Conference (AHRMM) in July 2001, revealed that 30% of the respondents erroneously believed that more than one company is manufacturer-authorized to restore Olympus endoscopes to original factory specifications.<sup>3</sup> The fact is, Olympus-authorized service technicians are the only manufacturer-sanctioned repair providers in the United States.<sup>4</sup> Only they receive extensive and ongoing training and regular updates to ensure Olympus endoscopes are repaired to original specifications following the most current manufacturer's guidelines. They are able to perform the newest cost-saving repairs the moment they are released by Olympus Research and Development (R&D).

### 2 Proprietary Equipment

Every tool, machine and test fixture used during an Olympus repair is specifically designed for each assembly and repair process to ensure optimal scope performance. Only Olympus-authorized service technicians have access to this proprietary equipment along with the most up-to-date guidelines, bulletins and technical manuals.

### 3 Manufacturer's Materials and Parts

All materials used in the Olympus repair process are factory-approved and tested through Olympus R&D to ensure that critical tolerances and functional performance are maintained after every repair. No patches, band-aids or boot extenders are used. Olympus-authorized service technicians replace damaged parts with approved manufacturer's components to return the instrument to its original factory specifications.

### 4 Exclusive Repair Protocols

Beginning with a thorough and consistent quality estimate, each and every Olympus endoscope repair follows the same comprehensive inspection and repair process to ensure the highest quality and reliability — no shortcuts, no guesswork. All repair processes have been factory tested and approved. Olympus continues to introduce many new and exclusive repair processes validated by Olympus R&D which are designed to maintain the superior performance of the endoscope, reduce the cost of repairs and achieve maximum product durability.

### 5 FDA QSR Compliance

The same AHRMM survey also revealed that 71% of the respondents erroneously believed that all repair vendors (Original Equipment Manufacturers [OEMs] and third-party vendors) must comply with the Food and Drug Administration's (FDA) Quality System Regulation (QSR).<sup>5</sup> The fact is, third-party vendors are not regulated by the FDA. Olympus, on the other hand, is regulated by the FDA; as an OEM, it must comply with the FDA's QSR. Olympus-authorized service technicians utilize original manufacturer's parts and factory repair processes that restore products to original specifications of form, fit and function that are consistent with the FDA's QSR requirements. This ensures the protection of both the patient and user/facility.

## Case Studies in Compromised Quality

The following case studies illustrate the most egregious examples of damaged equipment sent to Olympus by customers after third-party repairs were performed.

### ⑥ Comprehensive Medical Device History Records

Consistent with the FDA's regulations, Olympus maintains a Medical Device History Record for every Olympus endoscope. The scope's entire history with Olympus becomes part of this record — from product sale through every maintenance and repair procedure performed by Olympus.

*At Olympus, keeping pace with cutting-edge technology and techniques in the field of endoscopy is a critical part of its ongoing efforts to develop cost-saving repairs with no compromise in quality. Olympus is committed to protecting its customers' investment by maintaining the superior quality of Olympus equipment at every stage of its lifecycle.*

### Case Study I Channel Splicing

**Fig. 1: Third-party spliced channel repair**



#### Third-Party Compromises

The third-party repair illustrated in Fig. 1 compromised the performance characteristics of this endoscope in several ways:

##### ① Forceps Operation

A spliced channel changes the performance characteristics of the endoscope and provides an opportunity for forceps or other instruments to “catch” or “snag” within the channel, possibly forcing the physician to abort the procedure.

##### ② Cross-Contamination

The splice creates an additional crevice or area where bacteria can develop, introducing the risk of cross-contamination.

##### ③ Material Compatibility

Splicing with unknown, potentially untested material may affect the compatibility and functionality aspects of the channel.

##### ④ Scope Rigidity

Spliced channels can kink, jeopardizing the flexibility of the scope. Non-Olympus replacement channels can also add rigidity to the insertion tube which hinders the maneuverability of the endoscope.

##### ⑤ Fluid Aspiration

Due to the spliced channel, the endoscope may have limited ability to aspirate fluids, which presents a potentially serious patient hazard.

**Fig. 2: Olympus replacement channel repair**



#### Olympus-Authorized Repair

The Olympus-authorized repair shown in Fig. 2 requires the damaged channel to be replaced with a new Olympus channel. When a certified Olympus repair is performed, the bending section covering is removed from the distal tip. The distal tip and the body control unit are opened to expose the channel. The entire channel is then carefully removed and a new channel is installed while maintaining the proper arrangement of the endoscope's internal elements. The distal tip and the body control unit are reassembled and a new bending section covering is installed. Once reassembled, a suction capacity test is performed to ensure the endoscope meets original factory specifications and the endoscope is leak tested to ensure watertight integrity.

##### ⑥ Fluid Invasion

Spliced channels increase the risk of fluid invasion. Fluid invasion may affect the video image, causing the user to be unable to clearly visualize the patient anatomy. Additionally, electro-surgical integrity may be compromised as a result of excessive moisture. This, in turn, may cause the electrical switches to malfunction.

## Case Study II Light Guide Tube Patching With Silicone Sealant

Fig. 3: Third-party light guide tube repair patch



### Third-Party Compromises

The third-party repair shown in Fig. 3 used silicone sealant to cover up a cut or puncture on the light guide tube. This unauthorized repair process compromises the endoscope in several ways:

#### ① Fluid Invasion

Patching can lead to fluid invasion during reprocessing causing damage to the internal components of the endoscope.

#### ② Bending Section Movement

Prolonged exposure to moisture from fluid invasion may restrict bending section movement and reduce image quality.

#### ③ Corrosion

Fluid invasion may also cause internal components to corrode, which can lead to impaired switch operation and product inoperability.

Fig. 4: Olympus light guide tube replacement repair



### Olympus-Authorized Repair

The Olympus-authorized repair as shown in Fig. 4 requires the damaged part to be replaced with a new Olympus light guide tube. When a certified Olympus repair is performed, the light guide connector is disassembled and the light guide tube is removed.

A new light guide tube is installed and the light guide connector is reassembled. (In the case of an EVIS product, the light guide connector is assembled with new contact pins.) After reassembly, the endoscope is leak tested to ensure watertight integrity.

## Case Study III Boot Extenders

Fig. 5: Third-party repair using boot extenders



### Third-Party Compromises

The third-party repair shown in Fig. 5 uses boot extenders to mask insertion tube damage. Boot extenders are not an Olympus-authorized repair process. Their use can compromise both the integrity of the endoscope and patient safety as follows:

Fig. 6: Third-party boot extenders hide buckles



#### ① Buckle Masking

Several third-party vendors use boot extenders to mask insertion tube damage such as buckles below the boot as demonstrated in Fig. 6. Boot extenders hide problems that could be fixed more economically at an earlier stage. Left unattended, these problems can lead to more serious damage and escalating repair expense.

#### ② Insertion Tube Strength

Due to stress in the area of the buckle, it will become a weak point on the insertion tube. The insertion tube may collapse and damage the delicate elements inside.

**Fig. 7: Olympus insertion tube replacement repair**



### Olympus-Authorized Repair

The Olympus-authorized repair, as demonstrated in Fig. 7, requires the damaged part to be replaced with a new Olympus insertion tube. When a certified Olympus repair is performed, the endoscope is disassembled and inspected. The insertion tube is carefully removed and replaced with a new one. This repair also includes the replacement of the bending section, the bending section covering and the four angulation wires. If they meet Olympus quality specifications, original internal components are reused along with the original endoscope exterior, including control body, grip and the light guide connector. The light guide connector is assembled with new contact pins. A full panel of precision testing is conducted on the endoscope including leak testing to ensure watertight integrity.

### ③ Insertion Tube Length

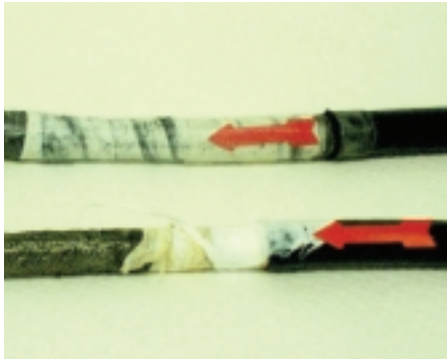
The working length of the insertion tube is clinically reduced by using boot extenders. The reduction in the tube length changes the performance characteristics of the endoscope.

### ④ Endoscope Weight

Boot extenders add additional weight to the endoscope making it noncompliant with the original factory specifications. The additional weight can impact the ergonomic design of the scope and contribute to physician fatigue.

## Case Study IV Bending Section Braid Covered by Teflon Tape

**Fig. 8: Third-party bending section braided mesh (distal end) band-aid repair**



### Third-Party Compromises

The third-party repair shown in Fig. 8 uses Teflon tape (plumbers tape) to cover multiple broken strands from the bending section mesh. This inferior repair compromises device safety and the integrity of the original instrument in several ways:

#### ① Bending Section Covering

Teflon tape may allow wires to pop through the bending section covering, causing further damage to the scope.

#### ② Patient Perforation

Broken mesh strands that pop through the bending section covering can present a perforation hazard to the patient during a procedure.

#### ③ Electrical Isolation

Broken mesh strands may also compromise the electrical isolation at the bending section, putting electrical safety of the patient and the user at risk.

#### ④ Fluid Invasion

Damage to the bending section covering may jeopardize the watertight seal, leading to fluid invasion.

#### ⑤ Image Quality

If fluid invasion occurs, the user may not be able to visualize patient anatomy and the procedure may need to be aborted.

**Fig. 9: Olympus braided mesh and bending section replacement repair**



### Olympus-Authorized Repair

The Olympus-authorized repair, as demonstrated in Fig. 9, requires the replacement of the braided mesh and bending section with a new Olympus bending section covering and braided mesh. When a certified Olympus repair is performed, the bending section covering (formerly called bending rubber) is removed and the distal tip is disassembled. The braided mesh is removed and a new braided mesh is carefully installed. The distal tip is reassembled and a new bending section covering is installed to conform to original specifications. The endoscope is leak tested to ensure watertight integrity.

#### ⑥ Bending Section Movement

Exposure to moisture may restrict movement in the bending section and reduce the ability to angulate the endoscope properly. Additionally, the Teflon tape used by third parties may increase angulation stiffness (and size) in the bending section and cause additional stress on the angulation cable system. This can potentially result in breakage of the angulation cables.

# 90-Day Study Shows Third-Party Repairs Decrease Quality, Increase Cost Over Time

In Fall 2000, Olympus conducted a 90-day study of all incoming scopes received at the National Service Center. The purpose of the study was twofold:

- 1) to determine the type and quality of repairs being performed by third-party vendors, and
- 2) to compare the incidence of Olympus refurbishment-level repair work between two separate study groups.

The first group (Group A) included all incoming scopes that exhibited evidence of handling by third-party repair firms (e.g., non-Olympus parts/repair protocols/processes). The second group (Group B) included all incoming scopes that received maintenance and repair work exclusively through Olympus under a service agreement contract.

## Type and Quality of Repairs Performed by Third-Party Vendors

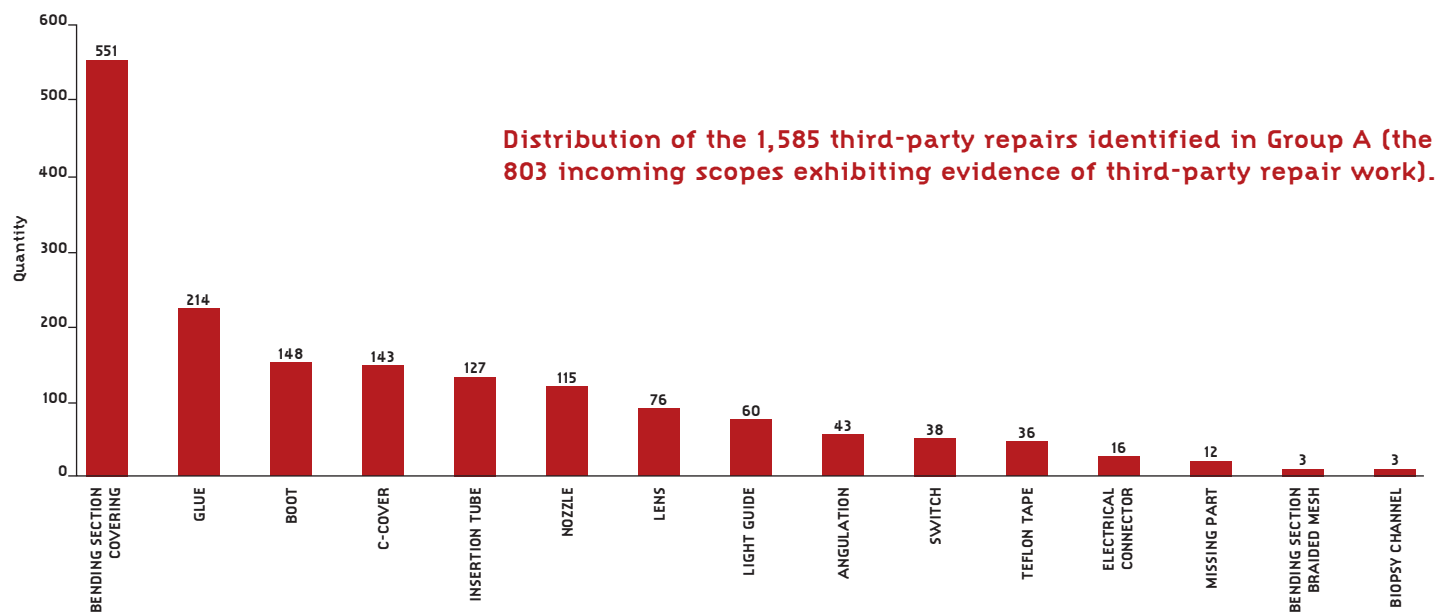
During the 90-day study, Olympus received 803 endoscopes which exhibited evidence of third-party repair work (Group A). On these scopes, Olympus identified 1,585 non-Olympus repairs, shown in Graph 1 by third-party repair type.

## Findings: Third-Party Repairs Decrease Quality

The 90-day study revealed that a large number of third-party repairs involved work performed on the insertion tube (see Graph 1), which includes many patient-contacting components. These third-party repairs utilized non-Olympus parts and repair processes. Since these repairs did not restore Olympus endoscopes to factory specifications, they introduced the following concerns:

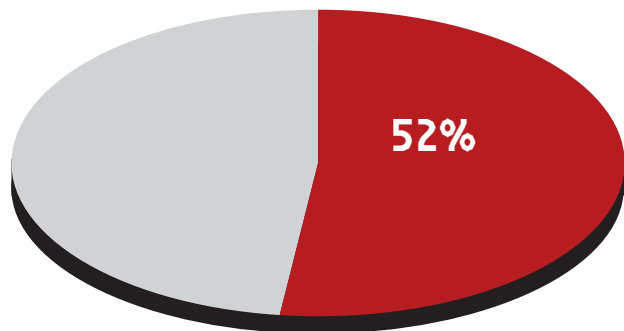
- Incorporation of non-Olympus materials and parts into an Olympus endoscope presented functional and biocompatibility concerns. This may reduce the useful life of the scope and accelerate the need for refurbishment.
- These scopes showed deviations in their physical properties relative to the original product design, which changed the performance characteristics of the scope. For example, the non-Olympus bending section covering material used by a third-party could adversely impact angulation (see data on page 9).

**Graph 1**  
**Type of Third-Party Repairs**



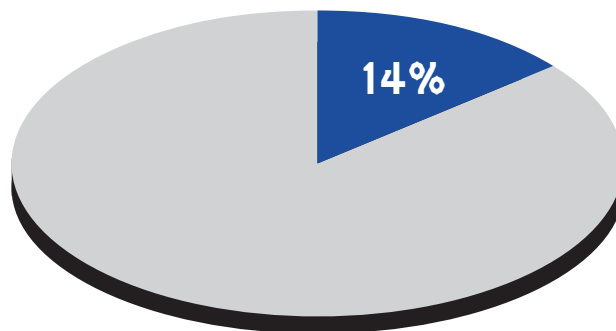
**Graph 2**  
**Percentage of Incoming Scopes Requiring Olympus Refurbishment-Level Repairs**

**Group A Refurbishments**



**52% of incoming scopes exhibiting evidence of third-party repairs (Group A) required refurbishment.**

**Group B Refurbishments**



**14% of incoming scopes repaired exclusively through Olympus under contract (Group B) required refurbishment.**

**Incidence of Refurbishment Repair Work Between Two Study Groups**

The second purpose of the 90-day study was to determine if there were differences in the repair requirements of Group A versus Group B. Olympus repair levels were determined by the service required to return each scope to its original factory specifications of form, fit and function. A refurbishment-level repair is the most costly and requires the entire unit to be fully disassembled and inspected with all critical parts replaced.

**Findings: Third-Party Repairs Increase Cost Over Time**

The data in Graph 2 shows a significant difference in the incidence of refurbishment-level repairs between the two study groups. Of the scopes in Group A (scopes exhibiting evidence of third-party repairs), 52% required refurbishment-level repairs to restore them to factory specifications as compared to just 14% in Group B (scopes repaired exclusively through Olympus under contract). The study findings suggest that scopes repaired by third-party vendors often require refurbishment-level repairs at a much higher rate than scopes repaired exclusively through Olympus.

The study results are not surprising, given the compatibility concerns associated with non-Olympus parts and materials utilized by third parties. It is not uncommon for endoscopes repaired by third-party vendors to exhibit fluid invasion. It is uncertain how well third-party component parts and materials hold up to the harsh reprocessing environments used in many hospitals. The useful life of the scope may be compromised due to the premature failure of components that have not been fully tested and validated as part of the original product design.

**Study Conclusions**

*Based on the findings from the 90-day study, two conclusions are evident:*

- 1) third-party repair work decreases the quality of an Olympus endoscope by using non-Olympus parts, processes and materials, which change the scope's performance characteristics, and*
- 2) third-party repair work may actually increase the cost of repairs over the lifetime of an Olympus scope by requiring more frequent refurbishment-level repairs or by shortening the useful life of the instrument.*

# Key Differentiators: Olympus Versus Third-Party Vendors

Following are a few key differentiators that distinguish repairs performed by Olympus-authorized service technicians from those performed by third-party vendors.

## 1 Flame Welding Delivers Superior Performance Over Soldering

A properly functioning angulation system within an endoscope is crucial for a doctor to successfully navigate through the human body. During the manufacturing process, Olympus follows exacting design parameters to ensure patient safety and product reliability. In the angulation sub-assembly system shown in Fig. 10, the Olympus braided mesh and four angulation wires are flame welded to achieve maximum tensile (pull-test) strength along with integrity of deflection.

The bending section of an endoscope is comprised of many special ring components that are connected to the angulation cables. The end of the angulation cable is attached to the end of the bending section. When the cable is pulled, the special ring components will move (bend) to achieve angulation. During the manufacturing of new endoscopes, a flame-welding process performed at temperatures as high as 760°C ensures a sound, highly durable welded joint.

**Fig. 10: Olympus angulation sub-assembly**



### Olympus Flame Welding Achieves Highest Performance

Olympus flame welding is a high-quality welding process that utilizes special proprietary material and equipment. Because of the high temperatures associated with this process, it is impossible to employ flame welding after a scope has been assembled — the intense heat would damage many of the endoscope’s internal components, including the sensitive video chip (CCD) unit and

fiber optic bundle. For this reason, when repairing angulation cables, Olympus replaces the broken cable with a completely new, flame-welded sub-assembly with four new angulation cables. This replacement cable assembly is capable of reaching tensile strengths as high as 25 kgf (see Table 1) without compromising the integrity of the welded joint.

### Third-Party Soldering Doesn’t Pass the Pull Test

Olympus does not sell the proprietary material and equipment used in the Olympus flame-welding process to third-party vendors. Instead, many third-party vendors employ a soldered-joint process to repair damaged sub-assemblies. This process uses tin-lead soldering material with soldering temperatures of approximately 250°C. This type of soldered joint repair is only capable of reaching tensile strengths of 10 kgf (see Table 1). The reduction in tensile strength does not meet original manufacturing specifications and compromises the durability of the cable system making it more likely to detach from the soldered area. If detachment were to occur, it would be impossible to perform proper angulation and could pose a risk to the patient.

**Table 1  
Tensile Strength of Flame-Welding Versus Soldering**

Process	Olympus Flame-Welded Joint	Third-Party Soldered Joint
Melting temperature °C	620-760°C	230-270°C
Material	BAg1 (silver alloy)	Sn-Pb (tin-lead alloy)
Tensile strength in kgf (kilograms of force)	25 kgf	10 kgf
Durability	High	Low

## 2 Physical Properties of Bending Section Coverings— There is a Difference

The bending section covering is an integral part of the entire insertion tube assembly. It must be flexible yet durable without placing additional strain on other key components, which may hinder angulation performance.

The elasticity of the bending section covering material is determined by its stiffness. That is, the greater its stiffness, the lower the elasticity of the bending section covering under a given load. Consequently, stiffness is an important element in the overall design of the endoscope relative to mechanical loads and forces that are applied. Specific requirements for elasticity must be met to ensure that all performance characteristics associated with proper angulation are achieved. Moreover, the physical properties of the bending section covering must also provide maximum strength and durability.

**Fig. 11: Olympus-certified bending section covering compared to third party**



## Olympus Bending Section Coverings Conform to Original Factory Specifications

Every Olympus scope model has a unique bending section covering specifically designed for the performance characteristics of that scope. The bending section coverings used by Olympus during the repair process are original manufacturer's parts that restore the equipment to factory specifications, maintaining the scope's working length, diameter and angulation capabilities.

## Third-Party Bending Section Coverings Force Equipment to Work Harder

While a generic or "universal" third-party bending section covering may at first appear to be thicker and provide additional strength, it actually places more stress on the entire bending section, forcing the scope and angulation system to work harder. Angulation cables become stretched, requiring more frequent angulation adjustments and, in some cases, causing premature breakage of the cable. As a result of the additional stress placed on the bending section, performance characteristics of the endoscope are also compromised and the ability to achieve maximum angulation may be limited (see Table 2).

## 3 Proper Angulation Settings are Key to Procedural Success

Considering the hundreds of moving parts that make up an angulation system assembly, torque specifications have a significant influence in the operation of knob tension, angulation, and the free and engage features of an endoscope. Maintaining the original manufacturer's torque specifications is critical to ensuring the ongoing reliability and functionality of the product.

## Olympus Uses Precision Instruments for Angulation Adjustments

During the Olympus repair process, angulation settings on Olympus endoscopes are performed using proprietary test fixtures to maximize angulation responsiveness and minimize knob play. The positions of angulation stoppers used during the angulation setting are determined by precision measurement equipment. This process ensures maximum performance from the instrument and conformance to original Olympus product specifications.

## Third-Party Adjustments do not Conform to Factory Specifications

Olympus does not sell its proprietary tension test fixtures to third-party vendors. These tension test fixtures are necessary to restore an Olympus endoscope to its original factory specifications. Slight discrepancies in torque can negatively impact the performance characteristics of the endoscope.

**Table 2  
Differences in Bending Section Covering Load Requirements**

Bending Section Covering (Sheath)	Characteristics	Olympus Part	Third-Party Part	Impact of Third-Party Part
Large diameter (large-body endoscopes)	Length of sheath: Average load required to stretch 1":	4" 2.53 lbs	4" 3.54 lbs	Increases load requirement by 40%
Small diameter (small-body endoscopes)	Length of sheath: Average load required to stretch 1":	4" 1.57 lbs	4" 3.85 lbs	Increases load requirement by 144%

# Conclusions

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*Olympus endoscopes are renowned for their exceptional quality. A third-party repair vendor can quickly compromise that quality by using non-Olympus parts, tools, materials, test fixtures and protocols in the repair process. These third-party repair processes may not only jeopardize device safety and performance, they can also impact the useful life of the equipment and the overall cost to maintain it.*

*Conversely, every endoscope repaired by an Olympus-authorized service technician is assembled, tested and thoroughly inspected to ensure it is restored to the high standards established by the manufacturer. Using Olympus-authorized service exclusively for all Olympus endoscope repairs ensures that the scope's superior performance characteristics are maintained throughout the equipment's lifetime. Olympus-authorized service is also the best strategy for reducing overall endoscopy repair costs over time.*

**For questions or comments regarding this publication, please contact Mike Jensen at 408-935-5170 or Hilda Barrs-Mosenthine at 408-935-5020.**

## About The Author

### Mike Jensen

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Over the past 12 years, Mike Jensen has worked in a variety of quality assurance capacities in both the telecommunications and aerospace industries and has coordinated the establishment of quality systems in accordance with FDA (QSR), Mil-Q-9858 and ISO9000 requirements. Mr. Jensen began his tenure with Olympus America as an associate quality

assurance engineer in April of 1994. Today, as the manager of quality assurance, he is responsible for all aspects of quality and compliance relating to service and repair performed at the National Service Center in San Jose, California. Mr. Jensen holds a Bachelor's of Science degree in Quality Assurance and Industrial Technology with a minor in

Business from San Jose State University. He is a member of the American Society for Quality (ASQ), Association for the Advancement of Medical Instrumentation (AAMI) and the Regulatory Affairs Professional Society (RAPS).

# Auditing Repair Quality Using the Olympus Standard

*Make comparisons, not compromises. If your facility elects to use third-party vendors, make sure to use this check sheet to compare their services against those provided by Olympus.*

Third Party	Olympus	The Olympus Standard for Quality
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Factory-trained technicians with ongoing instruction on new/upgraded products and repair protocols
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Turnkey repair services, from minor repairs to full-scale refurbishments
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Quality assurance manager with QSR compliance oversight
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Proprietary tools and test fixtures along with current manufacturer guidelines, bulletins and technical manuals
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Automated angulation test equipment and OEM torque wrench specifications
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Exacting equipment calibrations, closely monitored and documented
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Factory-approved, biocompatibility-tested materials and processes; no patches, band-aids or boot extenders
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Original manufacturer's components to replace damaged and worn parts
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Latex-free replacement parts and repair processes
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Exclusive factory-tested repair protocols, validated to meet original manufacturing specifications
<input type="checkbox"/>	<input checked="" type="checkbox"/>	New cost-saving repair processes, tested and validated by Olympus R&D
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Documented Olympus repair processes for Medical Device traceability from date of sale, tracked by factory number
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Repairs performed following FDA Quality System Regulations
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Comprehensive tracking system to monitor and correct return rates under warranty
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Preventive repairs at no additional charge
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Loaner program for Olympus customers
<input type="checkbox"/>	<input checked="" type="checkbox"/>	On-site loaner back-up for service agreement customers
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Flexible service agreements to meet customer requirements and budgets
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Olympus University endoscopy courses/seminars for CME, contact hour and CEU credits as well as biomedical certification and training programs
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Nurse Consulting services
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Site visits and on-site technical assistance
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Product in-service training sessions
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Repair reduction assistance/advice and preventive audit programs
<input type="checkbox"/>	<input checked="" type="checkbox"/>	24/7 phone support for service agreement customers

## Footnotes

<sup>1</sup> Medical devices vary widely in their simplicity or complexity and their degree of risk or benefit. All do not require the same degree of regulation. As a result, section 513 of the Food, Drug and Cosmetic (FD&C) Act requires the Food and Drug Administration (FDA) to classify all devices intended for human use into one of the three categories, assigned according to the extent of control necessary to ensure the safety and effectiveness of each device. Endoscopes are categorized by the FDA as Class II. Class II includes devices represented to be for use in supporting or sustaining human life. Devices in the Class II category are those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness, and for which sufficient information exists to establish special controls to provide this assurance.

<sup>2</sup> Third-party repair firms/vendors (third parties) are independent service organizations not affiliated with Olympus America Inc.

<sup>3</sup> For a copy of the survey conducted by Olympus at the Association of Healthcare Resources Material Manager's Conference (AHRMM) in July 2001, please contact Hilda Barrs-Mosenthine at 408-935-5020.

<sup>4</sup> Olympus-authorized service technicians include Olympus service technicians and Olympus-certified biomedical/clinical technicians and engineers.

<sup>5</sup> Food and Drug Administration (FDA) Quality System Regulation (QSR) 21, CFR Part 820. The FDA regulates the commercial distribution of medical devices under the authority of the Food, Drug and Cosmetic (FD&C) Act. For example, manufacturers in the U.S. commercially distributing or marketing medical devices must register with the FDA, obtain FDA clearance to market their devices, list their devices, manufacture their devices under an FDA-mandated quality assurance system, properly label their devices, etc., in order to meet the regulatory requirements in the FD&C Act.

## References

Regulatory Requirements for Medical Devices—Fifth Edition. U.S. Department of Health and Human Services. Public Health Service Food and Drug Administration (p 1-1)

Medical Device Quality Systems Manual. Reprinted from HHS Publication FDA 97-4179 by Canon Communications LLC, Santa Monica, CA (p 1-1, 16-1)

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## THE Q INSIDE THE O<sup>SM</sup>

Our mission has always been clear.  
To focus on life. To give life hope.  
To improve the lives of millions  
of people who have diagnostic or  
treatment procedures performed with the  
products and services we provide. It is a  
commitment that is visible in the  
pioneering, solution-oriented products  
and services we create and at the heart  
of the close collaborations we foster  
with health care professionals.  
And it means that we never  
compromise on quality.  
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