TECHNOLOGY STATUS EVALUATION REPORT

Endoscope Repair by Original Equipment Manufacturers and Independent Service Organizations

JANUARY 2003

INTRODUCTION

In order to promote the appropriate use of new or emerging technologies, the ASGE Technology Committee has developed a series of status evaluation papers. This process presents relevant information about these technologies to practicing physicians for the education and care of their patients. In many cases, data from randomized controlled trials are lacking and only observational clinical studies are available. Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, societal, and economic aspects of the technologies.

BACKGROUND

As the clinical applications of GI endoscopy have evolved, so too have the industries that support it. Endoscope repair and refurbishment is of considerable importance to GI endoscopists, endoscopy unit/center managers, institutional finance officers, the patient-public, and governmental and industry regulatory agencies. Satisfactory repairs are important to ensure patient safety and the effective function of the endoscope. The timeliness and quality of repairs may impact the frequency and complexity of subsequent repairs and the usable life of the endoscope.

The GI endoscope market is dominated by three Original Equipment Manufacturers (OEMs) (Olympus America Inc., Melville, N.Y.; Pentax Precision Instrument Corp., Orangeburg N.Y.; and Fujinon Inc., Wayne, N.J.). All OEMs provide repair services for their instruments. For many years, OEMs were the sole source of endoscope repair and refurbishment. With the growth of GI endoscopy, Independent Service Organizations (ISOs), also known as Third-Party Repair companies, have proliferated during the past decade. This Status Evaluation Report examines aspects of GI endoscope repair by OEMs and ISOs.

TECHNICAL CONSIDERATIONS

Regulatory issues

The Food and Drug Administration (FDA) classifies all devices intended for human use into 1 of 3 categories assigned according to the extent of control necessary to ensure the safety and effectiveness of each device. Endoscopes are categorized as Class II. Devices in Class II are those for which general controls are insufficient to provide reasonable assuredness of safety and effectiveness and for which sufficient information exists to establish special controls to provide this assurance. As such, an endoscope cannot be released for sale until an application (510[k]) has been submitted by the OEM and reviewed and cleared by the FDA. A 510(k) application includes both clinical and nonclinical data on the safety and efficacy of the endoscope.

Unless otherwise specified, OEMs consider themselves to be the only authorized entity to perform repair and refurbishment of their endoscopes. OEMs use proprietary parts, adhesives, lubricants, specifications, and repair manuals. OEMs must comply with the FDA's Quality System Regulations (QSR). These regulatory requirements extend to repairs performed by OEMs and require repairs to return the instrument to the manufacturer's original specifications. These regulations extend to all replacement parts, tools, jigs, adhesives, lubricants, and test fixtures; training and monitoring of repair personnel; the repair environment; documentation process; and continuing quality improvement. The repair and refurbishment process is subject to regu-

Table 1. Common minor and major (based loosely on cost) endoscope repairs listed in general order of frequency

Minor	Major
Bending section cover repair	Fluid invasion repair
Angulation adjustment	Video control/switch repair
Distal tip cover replacement	Biopsy/suction channel repair
Angulation control knob repair	Insertion tube repair
Nozzle replacement	Air/water assemblies repair
Electrical connector replacement/repair	CCD imaging unit replacement
Light guide connector repair	Overhaul
Air/water O-ring replacement	Elevator repairs
Air/water cylinder replacement	Light guide lens unit repair/replacement
Air/water valve replacement	Universal cord replacement

Sources: Olympus America, Inc. (Melville, N.Y.) and Precision Endoscopy of America, Inc. (Hunt Valley, Md.).

lar FDA audits and must comply with Medical Device Reporting (MDR) requirements. Meeting these requirements consumes considerable financial and personnel resources.

ISOs are independent entities that provide repair services for GI endoscopes. ISOs may be diversified, repairing several different brands of GI endoscopes, as well as other endoscopic and surgical instruments. The FDA considers ISOs as "refurbishers" or "reconditioners." As such, ISOs are not regulated by the FDA if they only service and repair medical instruments to a reasonable approximation of the manufacturer's specifications. Further, the FDA feels that voluntary *registration* of ISOs with the FDA is inappropriate in that it promotes a misrepresentation of FDA-regulated status. ISOs are not required to comply with QSR nor are they subject to routine inspection and audit. However, the FDA may audit any ISO if there is legal reason to do so.

Many ISOs voluntarily have systems in place that conform to QSR standards. Industry accrediting agency certification, such as International Standards Organization 9002/European Standard (EN) 45002 (specific to medical devices), may be considered barometers of internal quality control. The distinction between the designations "certified" and "compliant" should be emphasized. Certification status indicates the establishment of Quality Systems in conformance with standards set by an independent third party and subject to periodic review and inspection. The designation "compliant" is self-appointed and does not imply review by a third-party.

There is concern that inadequate repairs performed by third-party vendors may reflect negatively on the original manufacturer and that such repairs (1) present risk of liability for the facility/provider if the device should fail to perform to the user's expectation; (2) create concerns about regulatory issues associated with the FDA requirements imposed on OEMs but not ISOs; and (3) present legal issues such as trademark infringement when a refurbished device retains the name and trade dress of the OEM. However, the FDA does not consider the provision of repair services alone to constitute re-manufacturing. Similarly, the practice of endoscope repair and re-sale (re-marketing) by ISOs does not fall under FDA regulation. However, re-marketing enterprises are subject to re-labeling regulations that require written characterization as such on the instrument (though this is not commonly done).

Materials and labor

OEMs use proprietary parts, adhesives, and technical manuals in repair and refurbishment of their endoscopes. Pentax and Fujinon have established service partner relationships with specific ISOs and have certified/authorized them to perform repairs on their endoscopes. Pentax and Fujinon provide their authorized ISO service partners with access to proprietary parts, adhesives, training, and repair manuals. Olympus has no established relationships with ISOs involved in endoscope repair in the United States. As such, all ISOs performing repairs on Olympus endoscopes, and nonauthorized ISOs performing repairs on Pentax and Fujinon endoscopes, do not have direct approved access to the OEM materials, training, and/or repair manuals.

Unaligned ISOs obtain replacement parts from independent vendors. Typically these parts are developed through reverse engineering. Ideally these parts and adhesives are approved for medical use and compatible with liquid, steam, and chemical vapor sterilization processes. One OEM alleges that repairs performed by unauthorized ISOs with unauthorized parts and adhesives may have unpredictable effects on endoscope performance, cleaning, and disinfection, and on patient safety. They cite examples of material incompatibilities and suboptimal repairs, obscure to the user, which have resulted in compromised endoscope function and contributed to the need for more extensive repair. It is acknowledged that OEMs

themselves are not invulnerable to design and material flaws that might impact patient safety.

INDICATIONS

Minor repairs require a minimum amount of endoscope disassembly, parts, and labor and include replacement of the bending section cover, distal tip cover, light-guide connector, and tip angulation adjustment. *Major* repairs involve the replacement of one or more of the major components of the endoscope such as replacement of the insertion tube, replacement of the biopsy/suction channel, and replacement of the air/water assembly (Table 1).

The performance of minor and major repairs is indicated when use results in compromise of endoscope function and/or when further use would result in more extensive damage to the instrument. Timely recognition and execution of minor and major repairs may reduce the need for more extensive repairs and refurbishment. *Refurbishment-level* repairs, also known as complete *overhaul*, typically require the replacement of all critical components and all patient contact components of the endoscope with new ones. Examples of when refurbishment is required include damage to the optical charge-coupled device (CCD), light guide fiber damage, and fluid invasion.

EFFICACY

Endoscope repair and refurbishment performed by OEMs and OEM-certified ISOs are under regulatory scrutiny to return the instrument to the original instrument manufacturers specifications. There are insufficient data to indicate that non-OEM–certified ISOs do or do not meet this same expectation.

EASE OF USE

When an endoscope is determined to be in need of repair, a variety of communication and delivery arrangements (e.g., personal courier, express mail) are needed. These are vendor- and contract-dependent. Additional features may include remote or on-site loaner replacements.

SAFETY

A MEDLINE/PubMed search (September 27, 2002, terms: endoscope refurbishment, endoscope repairs) identified no journal publications linking injury, infection, or adverse events in patients undergoing GI endoscopic procedures to suboptimal endoscope repair. A review of the FDA Manufacturer And User-Facility Device Experience (MAUDE) database identified no adverse events directly related to suboptimal endoscope repair.

OEMs are required by the FDA to report post-market adverse events related to instrument repairs, whereas ISOs are not. The FDA's Office of Compliance has indicated that the agency has not received sufficient documentation of adverse outcomes attributed to third party vendor repairs to warrant their active oversight. In that the MAUDE database is a voluntary reporting system and that adverse outcomes attributable to suboptimal endoscope repair may go unrecognized, the potential for underreporting of pertinent events is possible. The impact of suboptimal endoscope repairs on compromised endoscope function is difficult to quantify and has not been established.

FINANCIAL CONSIDERATIONS

The complexity of the repair is typically reflected in cost. Negotiated financial arrangements between repair organizations and consumers (i.e., health systems, hospitals, ambulatory endoscopy centers, and office-based endoscopy settings) are variable and include fee-for-service, cost-per-procedure, and capitated service contracts. Many consumers have contracted with third-party service partners that oversee instrument and equipment maintenance and repair. Such contractual relationships may limit flexibility in the choice of endoscope repair services. Charges may vary considerably among service organizations and consumers. ISOs compete on cost and convenience.

COMPARISONS OF AVAILABLE RESOURCES

There is no literature comparing endoscope repair by OEMs, OEM-certified ISOs, and/or independent ISOs.

SUMMARY

There are limited options for repair and refurbishment of gastrointestinal endoscopes. There is variability in regulatory oversight between OEMs and ISOs. There is considerable variability in third-party certification among ISOs. Access to proprietary original manufacturer parts, materials, training, and technical manuals are advantages to OEMs and authorized ISOs. The potential for suboptimal repair(s) to impact negatively on endoscope function and durability is recognized. Compromise to patient safety remains undocumented.

In addition to quality, cost and convenience are considered when selecting an endoscope repair vendor. Endoscopists and endoscopy unit managers should be aware of the differences in regulatory oversight, certification, and parts and materials sources when considering endoscope repair options. They should also acknowledge the potential for suboptimal endoscope repair to affect endoscope performance, durability, overall costs, and patient safety. Incidents that impact patient safety attributed to suboptimal repair should prompt MDR submission to the FDA's Office of Surveillance and Biometrics.

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