In the current economy, with capital budgets frozen and repair dollars scrutinized, it’s critical to look closely at your repair provider.

IMS encourages managers of surgical equipment inventories to investigate all repair vendors, both manufacturers and independent repair companies, to understand the true cost of instrument repair.

Asking the right questions in your Requests for Proposals can help differentiate between independent repair companies that will provide you technical excellence on par with the manufacturer and those that may compromise your equipment with shortcuts and salvaged components.
The Apple Doesn’t Fall Far From the Tree

Innovation, creativity, and vision are often associated with Apple’s electronic products. Most of us probably own some sort of Apple product, whether it is an iPod, iPad, iPhone, or computer. And now that we have one (or more) of those products, we can’t imagine what life would look like sans Apple technology. Apple pushes the boundary by listening to their customers’ desire and revolutionizing how things are done. For example, the Tampa Bay Buccaneers of the NFL are using Apple iPads instead of thick, heavy playbooks. It allows the players and coaches to review practice and game footage from any location they choose. Apple products are even changing the airline industry. United Airlines is equipping all pilots with an iPad, which will replace the massive paper flight manuals in the cockpit. Pilots will have real-time information at their fingertips at all times. Also, by using the lightweight iPads, planes will be lighter and will save an estimated 326,000 gallons of jet fuel per year!

Apple listens to their customers and provides them with the means to improve the way they do business. So when you send out your well-engineered, expensive equipment for service, you should expect the same from your repair provider. You should expect an innovative, proactive approach that will allow you to be more successful at what you do. You should also expect quality work to be performed and information that will help you make the best decisions. This document will help you separate the good “Apples” from the bad “Apples” when it comes to servicing your equipment. Some companies lead the way, while others follow.
Anatomy of an Endoscope

The rigid scope consists of five major components: objective lens assembly, rod lens/relay system, illumination system (fiber optics), scope body, and eyepiece assembly.

The Objective Lens Assembly

The objective lens assembly contains the negative lens, prism, objective lens, and field lens. The negative lens collects reflected light from the object within a field of view. The prism creates the correct angle of view. The objective lens creates the image, and the field lens corrects for chromatic and spherical aberrations. In most scopes, the objective lens assembly is contained in a metal cartridge at the distal tip of the scope.

The Rod Lens/Relay System

For the user to be able to view the targeted area, the image must be transferred to the ocular assembly. This is done via the rod lens system (relay system). The rod lenses are kept at proper focal length by hollow cylinders called spacers. To reduce reflections inside the rod lens assembly, some spacers have thread-like concentric circles inside them. Most spacers are darkened to further reduce reflections. The retainer ring and springs, centering mechanism, and ocular lens and its holder make up the ocular assembly.

The Illumination System (fiber optics)

The rods lens/relay system is contained inside the inner tube. Between the inner tube and outer tube is a fiber optic bundle that runs the entire length of the instrument. These fibers transfer cold light to illuminate the object under examination.

The Scope Body

The scope body houses the base of the shaft, the light post, the focusing assembly, and other components/valves that allow connection with external accessories.

The Eyepiece Assembly

The eyepiece assembly seals the proximal end of the scope optics and inner components, allowing the scope to be used with a camera or through direct visualization. The ocular lens focuses the image being viewed. The eyepiece window refracts the image and light into an easily viewed image.
Replacing Objective Lens Assemblies To Prevent Deterioration of Performance

Many companies do not use model-specific objective lens assemblies, instead having one generic design for each diameter of scope, which often is not appropriate for the scope it is installed in. When non-model-specific optical components are installed in a rigid endoscope, the result can compromise such parameters as field of view and angle of view, and ultimately degrade image quality for the physician, potentially compromising procedure outcome.

Question: Given that the manufacturer generally does not sell replacement objective lens assemblies on the open market, what is your process for obtaining replacement objective lenses when that component cannot be purchased from the original equipment manufacturer?

Some repair vendors use metal spacers or epoxy, instead of optical gel, to install objective lenses in autoclavable Karl Storz endoscopes. Use of metal spacers will result in reflections, ghost imaging, and internal moisture buildup, all of which degrade image quality and negatively impact a surgeon’s ability to diagnose accurately.

Question: Describe in detail how you install objective lens assemblies into autoclavable Karl Storz® rigid endoscopes.

Maintaining Autoclavable Properties

For a rigid endoscope to be autoclavable, there are three essential elements that allow it to withstand the high heat and pressure of steam sterilization. Listed below are the three major differences, as compared to non-autoclavable endoscopes, that make a rigid scope autoclavable:

1. **Welding of all exposed joints.**
2. The use of heat- and pressure-tolerant adhesives.
3. The use of silver/gold soldering and metalized distal windows to secure the distal window.

If these three essential components and processes are not followed when repairing an autoclavable endoscope, the endoscope will not be able to withstand the harsh autoclave environment and may experience premature failure. In addition, the endoscope may be rendered non-autoclavable through the harsh environment without the facility’s knowledge.

Question: What are your processes to ensure that an autoclavable endoscope remains autoclavable after repair?
Replicating Distal Ends To Prevent Accumulation Of Bioburden

Some models of Karl Storz® and Olympus® rigid scopes are manufactured with a formed distal end (right), which is difficult to replicate. Without the capacity to replicate the rounded tip, repair companies may shear the tip (left), compromising the original design and creating rough edges that can accumulate bioburden.

**Question:** Describe your process for replicating the Karl Storz® and the Olympus® rigid scope distal end design for the following models:

- **Karl Storz®** 7210FA, 7230FA, 28721CWA, 28731CWA, 7210CA, 7230CA, 27005CA, 26046BA, 26046FA, 26006FA

Maintaining Shaft Relationship To Prevent Poor Image Quality

All 0-degree Stryker, Dyonics, Linvatec, Richard Wolf, and ACMI endoscopes (not including operating laparoscopes) have an inner shaft that is concentric (top) to the outer shaft. If an endoscope designed to have a concentric inner and outer shaft is repaired such that the inner shaft is offset (bottom) from the outer shaft, a degraded image quality will result. The resulting image will not be uniformly crisp and clear, may experience diminished illumination, and have compromised centration (image will “wobble”).

**Question:** During the repair process, describe how you maintain the correct inner to outer shaft relationship for all 0 degree Stryker, Dyonics, Linvatec, Richard Wolf, and ACMI endoscopes (not including operating laparoscopes).

Replacing Image Bundles To Prevent Premature Autoclave Failure

Manufacturers use pre-twisted image bundles for the below endoscope models. Third party companies that do not know how to replicate the pre-twisted, stress free image bundles use a regular image bundle, stress-twisting the bundle and gluing the ends, which will result in premature autoclave failure, an inverted image, or no image at all.

**Question:** What kind of image bundles do you install in these semi-rigid ureteroscope models? Describe the image bundles you use and explain why.

- **Karl Storz®** 27001K, 27001L, 27002K, 27002L, 27030KB, 27411K, 27411L, 27430K, 27430L, 27011K, 27011L, 27030AN, 27410SK, 27410SL
- **Stryker®** 502-880-330
- **Olympus®** A37025A, WA02944A, WA02946A, WA29048A, WA29049A
Preventing Condensation

After repair, the endoscope is sealed and humidity from the air inside the endoscope can condensate and result in degraded image quality during operational use. This can happen when the endoscope is transitioned from the “cold” operating room into a warm body because the trapped humidity will condensate on the internal optical assembly. To prevent this, desiccants must be placed into these scopes as the manufacturer designed prior to sealing the instrument. The desiccant must be replaced every time the scope is repaired.

Question: Explain in detail how you properly seal autoclavable Karl Storz, autoclavable Olympus, and Olympus “Endoeye” endoscopes (not including the deflecting tip series), such that any trapped moisture or humidity will not create image quality problems.

Sealing The Eyepiece To Prevent Infection

All Karl Storz® endoscopes, all Olympus® endoscopes, and non-autoclavable Dyonics® arthroscopes have eyepiece windows that are flush with the eyepiece (top photo). In contrast, other endoscopes have recessed windows relative to the eyepiece (bottom photo). In either case, repair should always follow the manufacturer’s original design to correctly seal the endoscope from damage. If a window that should be flush to the eyepiece is not repaired correctly and is mounted recessed, it could result in an infection control problem; cause the eyepiece seal to break down, allowing fluid to enter the endoscope; and cause residue build-up on the eyepiece, which would degrade the image quality.

Question: Describe how you maintain the relationship between the eyepiece window and eyepiece during the repair process for Karl Storz endoscopes, Olympus endoscopes, and Dyonics non-autoclavable arthroscopes.
Questions to Ask Any Repair Company Before You Sign

Transparency
When you send your instruments for repair, you are trusting the vendor with the safety of your patients.
It’s not possible to look inside a repaired instrument, but you can ask to “look inside” the repair process by touring the repair facility and being allowed to talk to technicians working in the lab during your tour.

Engineering
Without a qualified Engineering group, repair facilities are not capable of returning your instruments to the original performance standards.
Engineering is a significant monetary investment in both technology and staffing, but without that expertise, repairs are more likely to include modifications that compromise the original performance standards.

Components
Generic components, used components, and patch jobs can significantly alter your instrument. Each component used in the repair of medical and surgical instruments must be equal in function, material, and dimension to the original.
Repair vendors with in-house machining capabilities can offer customers a more complete service experience.

“Can we tour your lab and talk directly with your technicians and engineers?”

“Do you have a fully functional Engineering Department?”

“How have you validated your repairs with various reprocessing systems?”

“How many engineers do you employ and what is their expertise?”

“What machining equipment do you own?”
Other Important Questions

Repair vendors should welcome potential customers to tour their lab(s) and speak with their staff. A closed-door repair vendor may be a “broker” that outsources your repair to another company, and you should expect to speak to technicians on the floor of the lab.

Question: Provide the name and contact information for the person who schedules your lab and repair facility tours for prospective customers. Include any restrictions on tour groups. Specifically, will a tour group be allowed to interact with your Technicians? Engineers? Tour work spaces while work is proceeding?
Key Concept: Go see their facility.

In order for your instrument to be reprocessed following repair, your repair vendor should have invested in testing, external validation, and be able and willing to explain how their repair processes and materials are validated for use in various reprocessing systems. Failure to validate may result in damage to your instrument if adhesives and other materials are not compatible with the reprocessing systems.

Question: Explain how you have conducted in-house testing of adhesives and materials with common reprocessing methods. Provide us with written assurance of this process on your company letterhead. If you have used an independent laboratory to validate those results, please include the name of the lab with a contact name and number. In addition, if you have purchased any sterilizers for in-house testing, please attach proof of ownership.
Key Concept: Sterility and durability testing?

Reputable repair vendors invest heavily in Technician training and validate competencies. Without a formal process in place to monitor the skill and training of Technicians, as well as formalized work instructions, repair quality will not remain consistent over time.

Question: Attach the specific competency validations and training processes for your repair Technicians and a sample of your formalized work instructions. (You may redact any proprietary specifications).
Key Concept: Work instructions?

Without an on-staff Chief Optical Engineer, repair vendors cannot replicate model-specific endoscope optical components and may substitute generic optics, which will compromise the image.

Question: Attach the curriculum vitae of your Chief Optical Engineer, including years of experience with you and any other employers in the field, as well as degrees and patents held.
Key Concept: Do they have a Chief Optical Engineer?

Without a significant investment in engineering technology and software, repair vendors will not be able to precisely replicate components to meet the manufacturer’s performance standards and may use generic or salvaged components.

Question: Attach a list of all on-site optical and electrical engineering technology, including software.
Key Concept: Engineering software?

Machining capabilities give a repair vendor the ability to perform prevent an instrument or device from being “beyond repair.” Many parts that are created through this process are not readily available on the market, and without the ability to replicate and replace these small parts a customer would have to purchase a new instrument. Machining equipment also allows a repair vendor to manufacture custom parts and instruments, as well as modify existing instruments to meet the customer’s specific needs.

Question: Attach a list of all in-house machining equipment, including tolerances.
Key Concept: Machining equipment?
Reviewing Contracts: An Important Notice

Before You Sign

**Bundling.** In purchasing and financing capital equipment, some contracts bundle repair service with capital purchases so facilities cannot see the cost of the repairs separate from the cost of equipment. These contracts may also require facilities to purchase additional equipment and supplies or to finance purchases a certain way. Generally, the lowest – and most reliable – price is obtained by negotiating repair service and capital purchases separately and excluding “extras.” Bundling also makes it difficult for facilities to accurately compare proposals from different vendors.

*Separate & negotiate.*

**Termination Fees.** Many contracts are vague about termination fees. Sometimes the fees are based on actual consumption during the contract. As a result, it is impossible to know what the fees will be until the contract is terminated. Other contracts impose termination fees even if the termination is for cause. Facilities should not be obligated to pay fees if the contract is terminated due to poor service. Facilities should be able to terminate without penalty if not provided the service agreed upon when the contract was signed.

*No termination fees.*

**Volume Discounts.** Volume discounts make sense – to a certain point. But if the discount covers multiple facilities it is hard to monitor quantities. Also, if a volume purchase discount is not met, many times there will be large fees due at the end of each year of the contract or at the end of the contract term.

*No extra fees.*

**“Free” repairs.** Often, vendors will offer “free” repairs prior to the beginning of a capitated contract. Certain pre-contract inspection repairs, while described as “free,” may be counted toward the facility’s actual consumption. Adding the “free” repairs to the total count can cause the facility to consume more than was contracted for and incur additional fees at the end of the contract term.

*Eat up your capitation?*

**Incomplete Quantities.** Clauses stating that disposable devices (biopsy forceps, snares, etc.) will be included in the contract often lack the actual quantity a facility will be required to purchase. Such information is often included only in the final contract for signature, not the original quote. The quantity that the facility is required to purchase is often significantly higher than the average use. This can result in stockpiling devices in excess of the facility’s needs.

*Know your quantity.*

**Penalty Language**

Before signing, facilities should insist on language within the contract that penalizes the vendor for any hidden fees, overages, or exclusions within the capitated rate. A good contract has a reliable fixed price that is not linked to assorted variables and a reasonable termination clause.

Common penalty language in contracts includes:

*“After the effective date of the agreement, facility shall not be financially responsible for any vendor repair charges in excess of the monthly rate.”*

*“If facility discovers, by audit or otherwise, that vendor has violated any of the contract terms relative to charges which are not fully set out, vendor shall be penalized in the amount of 150% of the excess charge.”*

*“Facility may deduct such penalty from the vendor’s next invoice or bill the vendor directly.”*

*“In the event vendor has violated any of the contract terms relative to charges which are not fully set out, facility may immediately terminate the agreement.”*

In the current economic climate, it’s more important than ever to make certain contracts are transparent to all parties. By understanding the language and tactics employed in service agreements, facilities can be more confident in choosing a vendor that meets their needs.

**A Contract Checklist:**

The contract under consideration should allow your facility to answer “yes” to each of the following.

- Is the contract for repair services only?
- Does the contract include a clearly worded fair termination clause?
- If the contract includes a volume discount, is the volume consistent with the facility’s current usage?
- Does the contract state that “free” repairs are exempt from the total consumption count?
- Does the contract include disposable devices the facility is required to purchase?
- If included, does that number reflect the facility’s current usage?
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