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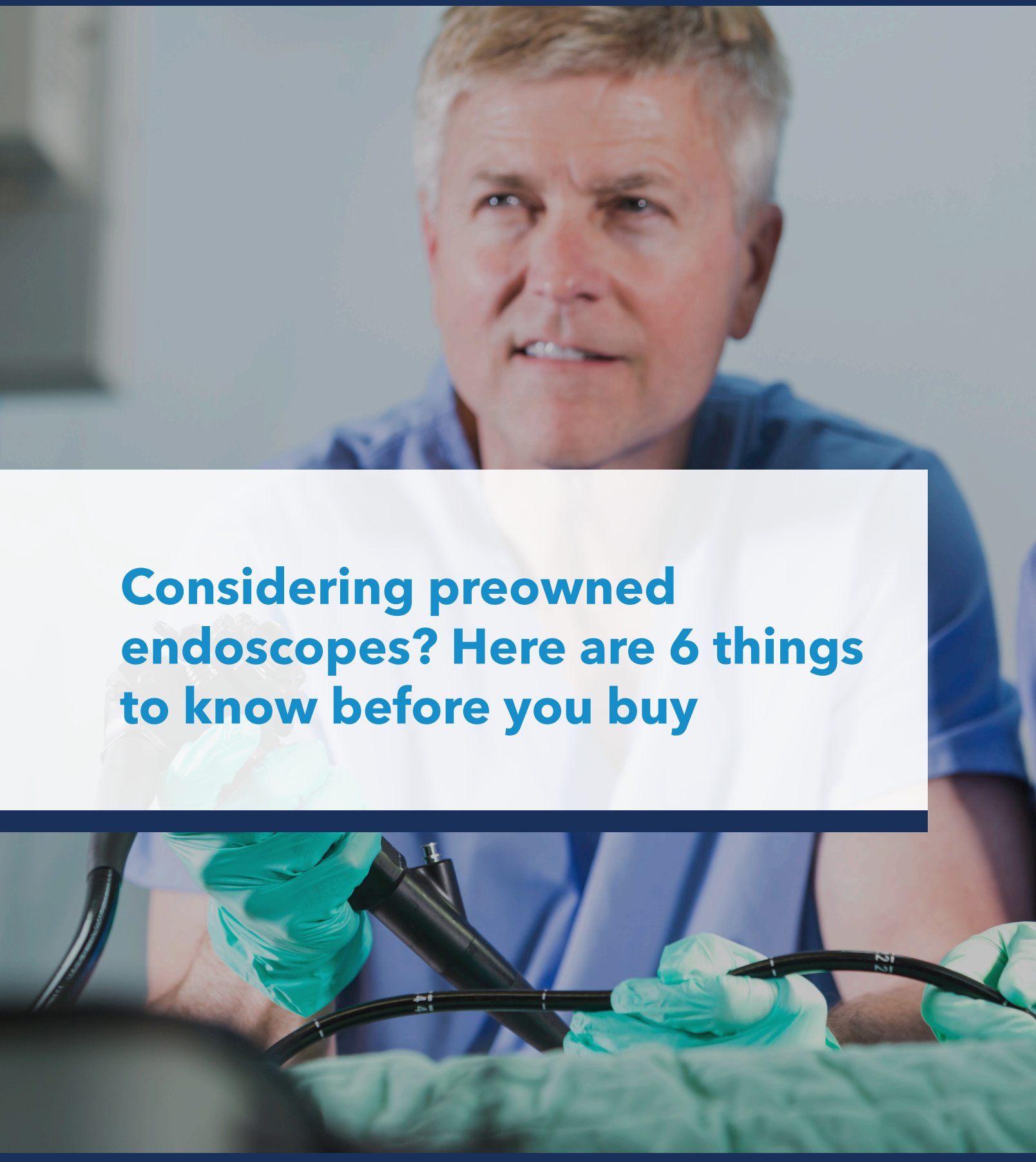

Considering preowned endoscopes? Here are 6 things to know before you buy

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Hospital and ASC administrators facing cost pressures may find relief in their medical device portfolio, where significant savings are possible with refurbished or certified pre-owned endoscopes from an independent service organization (ISO).

Hospitals are caught in the crosshairs of cost, quality and regulatory oversight when it comes to buying and repairing endoscopes. They are often locked in exclusive contracts with original equipment manufacturers, who may warn customers they will sacrifice quality if they choose to buy from third-party companies. To retain a hospital's business, manufacturers may recount horror stories of third parties improperly repairing devices with inappropriate parts, like chewing gum or wood screws.

Due to limited market regulation, not all third party repair shops operate according to the same quality and safety standards. However, many offer safe, cost-effective alternatives or supplements to new devices and in-house maintenance. Armed with the right information, administrators can take the guesswork out of choosing a reputable ISO and use refurbished endoscopes as part of their overall cost containment strategy.

This white paper provides an overview of current challenges associated with buying and maintaining endoscopes, potential workarounds for those challenges and tips for negotiating cost-effective contracts.

Key differences between OEMs and ISOs

Hospital investment in endoscopic devices is increasing as demand for endoscopic procedures grows, driven in large part by an aging senior population requiring greater volumes of more complicated healthcare services. The global endoscopy market is expected to reach $34.8 billion by 2022, up from nearly $25.6 billion in 2017, according to a 2017 report from Research and Markets. Due to the steep costs of new endoscopes, refurbished scopes are a growing segment of this market. By 2020, refurbished endoscopes are expected to account for 25 percent of the gastrointestinal endoscope market, according to iData Research.

Hospitals traditionally sign contracts with OEMs to lease or buy endoscopes, which typically require buyers to service their devices exclusively with the OEMs. Some manufacturers now also offer certified preowned devices, which are certified by the OEM as refurbished to new quality. However, OEMs rarely put certified preowned options on the negotiating table. This has created space in the market for non-OEM competitors to start refurbishing scopes. These third-party companies offer refurbished scopes and repair services at a lower cost than OEMs. They range in size from mom-and-pop shops to national and international ventures.

At face value, third parties offer the lowest cost option. Many providers have found they don't need the latest scope model to achieve quality patient outcomes and can even wait for several generations of scope development before the technology changes enough to justify the cost of buying new. However, using a third party could drive up costs down the line, as few OEMs repair endoscopes that have been modified by outside organizations. Because third parties are typically denied access to OEMs' proprietary design information, they must reverse engineer replacement parts, which can drive up service costs.

Regulatory oversight is another key difference between third parties and OEMs. Third-party repair companies are not subject to the FDA's Quality System Regulations like manufacturers; this caveat has polarized the service and repair space. OEMs contend all third-party repair companies should be subject to FDA regulation to balance the scale and ensure quality and patient safety. However, the third-party servicers say it would create a monopoly for OEMs, slow down processes and ultimately limit patient access to care.

The FDA is considering regulating third-party repair companies. It requested comment in 2016 and held a public workshop — and is required by the FDA Reauthorization Act of 2017 to publish its findings from those activities, accompanied by recommendations on how to ensure patient safety in the third-party device repair space. The report has not yet been published, but Congress is putting pressure on the FDA to produce recommendations and use its legal authority to regulate the industry. Members of Congress called on FDA Commissioner Scott Gottlieb, MD, in February to regulate the industry by requiring all medical device service companies to register with the FDA, report adverse events and establish a quality management system.

Until the FDA offers guidance, healthcare providers bear the responsibility of evaluating third-party repair companies on their own. Fortunately some third-party repair companies — ISOs — are already using quality management systems to distinguish themselves in a crowded market.

How to choose a reputable third-party scope company

Determining the value of a third-party repair company involves evaluating the quality of the parts used to repair the devices, the training of the staff and the processes used to ensure quality and safety. Although horror stories of refurbished scopes gone wrong do exist, these incidents are

extremely rare. According to a study conducted by research nonprofit ECRI Institute, adverse incidents involving refurbished endoscopes accounted for just 0.005 percent of more than 2.1 million records between 2006 and 2015. Rather than rooting out the one bad apple, providers may have greater difficulty choosing between top competitors, particularly when there are no common regulatory standards to measure them against.

Some third-party repair houses are distinguishing themselves from the pack as ISOs with a certification showing they follow the International Organization of Standardization 13485, or ISO 13485. This is an international standard for medical device companies that develop, implement and maintain a quality management system. An ISO 13485 certification indicates a third-party repair company has committed to certain operational standards and follows a planned process for continuous improvement. While ISO 13485 does not govern product standards, it does provide a framework for handling nonconformities, corrective actions and preventive actions. Currently, only a few companies in the industry hold ISO 13485 certification. While the certification is still somewhat unusual, it is a reliable benchmark to compare expertise in capital equipment repair.

Weighing value between new and preowned scopes

However, providers may not always want to buy refurbished scopes — it is important to understand when to buy refurbished and when to invest in new equipment. Few know more about the costs and benefits of preowned scopes than Eric Smith, a manager of clinical engineering and associate technology manager at Johnson City, Tenn.-based Ballad Health. Mr. Smith shared three key considerations for healthcare providers to keep top of mind when deciding between new and preowned scopes.

1. Technological advancement. If healthcare providers want the latest imaging technology, buying new is the way to go. Before investing in new, however, it is important for hospitals to do a side-by-side comparison. Carefully assess just how different a new scope's capabilities are and the effect those capabilities could have on patient outcomes, as compared to existing inventory and the newest available preowned scopes on the market.

2. Upfront investment. If device quality is comparable between new and refurbished scopes, cost becomes the deciding factor. At the end of the day, the skill of the physician will determine the patient outcomes. "The bottom line is the dollar," Mr. Smith says. Mr. Smith said many of their organizations are loyal to one endoscope manufacturer when purchasing new devices due to an enterprisewide effort to standardize all medical equipment through a single purchasing contract. However, the

expense of buying new endoscopes, even with the option to trade in old models, was simply too much. The cost eventually pushed the health system to explore alternatives by partnering with an ISO to repair devices.

ISOs can offer preowned endoscopes for 30 to 50 percent less than OEMs. Although a preowned scope may lose some efficiency due to wear and tear, with a high-quality ISO, it should operate just as well as a new scope. "We use [an ISO] primarily as a repair depot purely because of cost," Mr. Smith says. "The OEM is typically two to five times higher. Other than that, if it's certified preowned and the quality is there, I see no reason not to go with the preowned scope."

3. Long-term maintenance. In the new healthcare economy, hospitals are challenged to derive more value from every dollar spent on endoscopes by maintaining quality and reliability of the device, as well as extending its lifetime with repairs. The estimated cost of maintenance over a medical device's lifetime is 5 to 10 percent of the original device cost, according to the Association for the Advancement of Medical Instrumentation. With the price of new scopes starting at tens of thousands of dollars, device repairs and routine service are important components in the value equation.

It is critical for providers to note cost is more than a face-value dollar amount. The service component and warranty are hugely important when determining the value of using

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preowned scopes. "This is where it gets sticky," says Mr. Smith. "If I have to send a scope back to the OEM that has been worked on by a third-party repair company, and they did not use OEM parts, then [the OEM] will not work on those scopes without replacing those parts."

That means a provider could pay for replacement parts two times over. When they sign the ISO contract, providers need to ensure it includes service and maintenance functions and the device is covered by a warranty. Providers should require their repair vendor to honor the OEM warranty. Keeping in mind the risk of highly specialized issues that require OEM repair, providers need to ensure the value of the entire ISO contract is still worth the price.

Tips and tricks for contract negotiation

Whether buying new or refurbished, Mr. Smith recommends three best practices to negotiate better contracts.

1. **When looking for new endoscopes, buy — don't lease.** Leasing is a popular option for providers seeking the latest endoscopy technology. While the upfront costs of leasing may be lower, the lessee forfeits that value at the end of the agreement whereas buyers keep the asset. Because there is a robust market for preowned endoscopes, buying and reselling scopes becomes a much more lucrative investment than leasing. Plus, leasing keeps providers locked into service contracts with the OEM. This means providers are unable to leverage ISO repair quotes in negotiation because they don't own the equipment.

2. **Third-party repair companies give providers negotiating power — use it.** Health systems or ASCs often buy from one OEM and stay with the brand in subsequent purchases. While this ensures seamless equipment integration, it leaves providers with little power in negotiating OEM contracts. With ISOs in the market, providers can find refurbished, brand-name devices and repairs from experienced personnel, who are often ex-OEM employees. Using an ISO or OEM doesn't have to be an either-or decision. Contracts with both entities are often complementary and beneficial for providers at the negotiating table.

3. **Research, research, research.** When assessing prospective third-parties for repair services, maintenance and preowned endoscopes, research is absolutely critical due to the lack of market regulation. Providers should leave no stone unturned: Check with the automated endoscope reprocessor manufacturer to ensure refurbished scopes can be cleaned properly; work with the third party to understand what models they can service; make sure replacement components meet OEM specifications; and carefully review warranty and service options. Check with colleagues and your extended network about the experiences they have had with third party repair companies and OEMs. Lastly, look for distinguishing factors that may set one third party apart from another, like the ISO 13485 certification, company scale and experience, and any potential partnerships with other major industry players.

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Conclusion

Endoscopy technology is a critical investment for healthcare providers. However, with continuous cost pressure, it is essential providers get as much value as possible out of their contracts with medical device companies. Third-party companies offer a cost-effective alternative to OEM contracts. Although the extremely polarized market may make it seem otherwise, it is possible for OEM and ISO contracts to coexist in an endoscopy portfolio. In fact, if providers can break the OEM chokehold and create a more varied portfolio of partners, they will have more leverage at the negotiating table.

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