By Tonya Resutek and Mary Ann Drosnock, MS, CIC, CFER

Tighter budgets can mean new adjustments in a variety of areas, such as stocking the break room with bargain brand coffee and powdered NDC a.k.a. “non-dairy creamer” (seriously, what is that stuff?). It can also mean that your existing patient-care equipment, such as your endoscopes and electronics, have to work harder with less down time, similar to the staff that operates them!

So how can your capital dollars stretch further?

One way is to consider certified pre-owned (CPO) endoscopes and electronics. Most original equipment manufacturers (OEMs) offer a “CPO” program, and it’s a great way to relieve some of the stress on your current scope line-up or add additional full suites to help handle the load.

However, there are a number of factors to consider before dipping your toe in the pre-owned pool. It is important to consider the quality of the parts and the expertise that went into the item you’re thinking about purchasing, as well as its validation for your current reprocessor, and the warranty and support that you are promised after the sale.

So here’s question No. 1: is the selling company an FDA-regulated OEM or an independent service organization (ISO)?

Sure, they both might sell the same model of scope, but this is a question that can lead to many other questions and a heap of additional homework for you. As stated by the American Society for Gastrointestinal Endoscopy (ASGE), “OEMs must comply with the FDA’s Quality System Regulations (QSR) [which] requires any repairs [or refurbishments by the OEM] to return the instrument to the manufacturer’s original specifications… ISOs are not regulated by the FDA [and are only responsible for returning the refurbished item to] a reasonable approximation of the manufacturer’s specifications.”

Often times the refurbishments made on pre-owned equipment are internal and not visible to the purchaser’s eye, so a great deal of trust and reliance is placed upon the reputation of the seller.

“ISOs are not required to comply with the QSR, nor are they subject to routine inspection and audit [by the FDA],” according to ASGE, so without FDA audit, the need for extensive due diligence is placed upon the buyer.

It is important to thoroughly question your pre-owned equipment seller if you choose to forgo a purchase from the OEM, because the FDA will not have done this leg-work for you. Your careful investigation will ensure that you are purchasing a product that performs exactly as you would expect a new product of the same type to perform straight from the manufacturer.

When administrator Gigi Lang, RN, BSN, at Centennial Surgery Center, in Frisco, Texas, was looking to add additional scopes to her facility’s current line-up to help handle a growing patient load, she considered her options. Ultimately she selected additional CPO scopes from an OEM that she trusted and that had outfitted her center in the past. Service and support for her reprocessing and clinical teams, along with a sound warranty, were important factors for Lang.

“While there were multiple seller options for pre-owned equipment, Lang chose “[the OEM] because they stand by their products, and we knew what we were getting, which was the customer service and support we expected.”

Lang added, “You get what you pay for.” The OEM who installed the majority of equipment in her suites was able to immediately bring these CPO scopes into the fold, and incorporate them into her existing support plans without interruption. Lang was also able to count on an outstanding warranty and a single after-sales support system which included her OEM’s sales representative, customer support team, technical support team, endoscopy support specialists and clinical specialists, without interruption.

“We have been really satisfied,” Lang said.

In addition to ensuring that you have
all the support needed after the sale, it’s also imperative that the pre-owned scope you purchased is validated for your automated endoscope reprocessor (AER).

When purchasing a CPO item from an OEM, the refurbishments completed will bring the endoscope back to its original like-new specifications. As a result, OEM products are already validated by the majority of AER manufacturers. However, as evidenced in certain position statements, AER manufacturers are skittish about guaranteeing the results of their reproprocessors when used with scopes refurbished by ISOs.

One company states that it “cannot assume responsibility for inappropriate or incomplete disinfection due to the incorrect repair of the endoscope by a third-party repair facility.” Another company’s position statement outlines that “third-party companies have no way of validating their repair process to original OEM specifications, [and] products utilized by the third-party repair companies may not meet the materials compatibility or sterilization parameters ... resulting in damage to the scopes in question.”

If you purchase your pre-owned item from someone other than the OEM, you will need to perform your own investigation to determine if your scope is validated for effective reprocessing by your reprocessor manufacturer. This results in additional legwork for you before you can feel comfortable that your purchase will integrate with your current reproprocessing systems.

A great amount of due diligence will be required before making a purchase from a company other than the OEM, to avoid future hiccups and headaches. The onus to ensure you are getting exactly what you expect will be solely upon you, as the FDA does not regulate ISOs in the same way they do with OEMs.

Life is full of compromises … we’ve all “enjoyed” our share of non-dairy creamer. But don’t compromise on the level of performance for your endoscopy equipment. Ask the tough questions of your pre-owned equipment seller: Are you validated by my reprocessor? Are you going to support me to the level to which I’ve become accustomed? Can I expect my equipment to perform exactly the same as “brand new”? The answers to these questions will help you to make an educated decision about purchasing pre-owned equipment that benefits your facility over the long term.

Mary Ann Drosnock, MS, CIC, CFER, is manager of infection control at Olympus, and Tonya Resutek is a product manager at Olympus.

Reference
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