

Right-Sizing Your Cataract Knife Supplies



How to balance quality, cost and the goal of standardization when choosing ophthalmic knives.

Irene Tsikitas | Associate Editor

Four cataract surgeons, each using a different kind of knife. There were diamond and steel, safety and non-safety, reusable and disposable. The Winchester (Va.) Eye Surgery Center stocked them all, despite calls for doctors to standardize.

Jody Looker, RN, CNOR, the clinical director, organized a safety knife trial soon after one of her surgeons stuck himself with a knife that didn't have a guard on it. But the trial ended up like the story of Goldilocks: 1 surgeon said the bevel was shaped too oddly, another said the blade was too sharp and yet another said the knife was just right. The surgeon who'd been stuck was the most vocal critic of all, sending Ms. Looker back to the drawing board yet again. "I'll push to a certain extent, try to get them to standardize on anything," she says. "But the minute they tell me it detracts from patient care, or if it becomes a quality issue, I have to stop."

As Ms. Looker's tale illustrates, managing ophthalmic knife supplies in a facility with multiple cataract surgeons is no easy task and involves a delicate balancing act between satisfying surgeon preferences, complying with safety and infection control regulations, and controlling case costs.

Saving with procedure packs

The Surgery Center of Ophthalmology Consultants in Fort Wayne, Ind., has adopted disposable stainless steel knives that get discarded after every use as the package instructs (see "When Can You Reuse Steel Knives?" on page 40).

The move to single-use knives has "driven our costs up considerably," says Supervisor Jackie Dayton, RN, but the 2-OR, 3-surgeon eye center is in compliance with CMS regulations that require items labeled by the FDA as single-use to be used 1 time for 1 patient. "That's what drove our decision," says Ms. Dayton. Diamond knives, which are not only approved for reprocessing but are supposed to (as the commercials say) live forever, in theory would have eliminated the infection control issue without breaking the bank, since they could be reused over and over again. "We toyed with the idea of using diamond knives," says Ms. Dayton. "They supposedly last forever, but you have to take care of them in such a specific way.... It wasn't the best choice for

▲ TOUGH CHOICE Managing cataract knife supplies in a facility with multiple physicians requires a delicate balancing act between regulatory compliance, cost containment and surgeon preference.

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us.” She calculated that the large initial expense of diamond knives, plus the staff training and expertise needed to ensure they’re properly cared for, would be too much of an investment without assurance that the knives would last long before requiring expensive repairs.

If you’re going with a more expensive option like a single-use steel or silicone blade that you discard as directed, standardization is one way to keep costs

somewhat under control. At Ms. Dayton’s center, standardizing required some time and patience as the youngest of the 3 surgeons convinced his veteran colleagues to switch from the superior approach to the new clear cornea technique for making the first incision. It took a couple years to get the older surgeons to adapt to a new way of doing things, but once they were all on the same page with the clear cornea technique, “it made perfect sense to

When Can You Reuse Steel Knives?

Some steel and silicone ophthalmic knives are specifically labeled as single-use. Others are labeled as limited reuse, meaning you can reprocess and reuse them a certain number of times before discarding. This distinction appears to be causing confusion among eye center administrators torn between the need to comply with infection control regulations and the desire to cut costs by getting the most out of their blades. Nearly one-third of ophthalmology administrators responding to a recent *Outpatient Surgery Magazine* online poll said navigating regulations over the reprocessing, reuse and storage of ophthalmic knives is “very challenging”; another 27.5% said it’s “somewhat challenging.”

“We reuse blades that are meant for one use only,” admits a surgical services director, who says cost is the motivating factor. “We open new blades each day, reuse the blades until the surgeon requests a new one and have done so for the past 15 years without a problem.” When asked what kind of improvements she’d like to see in ophthalmic knives, another administrator expressed a wish for manufacturers to re-label single-use blades as multi-use, “because we all know they can be reused.”

But when CMS surveyors come knocking on your door with an infection control audit sheet in hand, it doesn’t matter if you and your surgeons believe a single-use knife still works just as well after 1, 2 or 3 sterilization cycles, warns Nancy Chobin, RN, AAS, ACSP, CSPDM, sterile processing educator with New Jersey’s Saint Barnabas Health Care System. “They have to go by exactly what the manufacturer puts in writing, not what the sales rep tells them” regarding which devices can be reprocessed and how. “If they’re not in compliance with that, they assume full liability for the safety and reliability of the device.”

Anthony Buccini, CST, surgery coordinator at the Laser & Vision Surgery Center in Manchester, Conn., concurs, noting that sales reps are well aware of facilities’ and surgeons’ desires to reuse devices if possible, and may walk a “fine line” when discussing the parameters for the products they’re selling. “Companies waffle around the issue, and if you’re not really a strong, knowledgeable person, you can easily get bamboozled by

use the same type of knife,” explains Ms. Dayton.

The final step in saving with standardization was getting the knives included in the center’s cataract procedure packs. Fortunately, all 3 surgeons agreed to use a knife manufactured by the same company that puts together the center’s packs. Ms. Dayton calculated that she’d be able to lower the cost from about \$10 per knife to a little more than \$7 per knife by including them in

the packs. “Three dollars doesn’t sound like much, but multiply that by 1,200 cases a year, and it adds up,” she says.

What about reposables?

OR Supervisor Sandra Roegelein, RN, BSN, considers 4 factors to be very important in determining her facility’s ophthalmic knife purchasing decisions: cost, infection control requirements, sharps safety and standardization. With a lot of research, trial-and-error,



▲ ONE AND DONE? Follow a manufacturer’s written instructions for reprocessing steel knives; those labeled single-use must be discarded or sent to an FDA-approved third-party reprocessor.

this,” he says. “The FDA makes it very, very clear that anything that is labeled for single-use only, once you reprocess it . . . at that point the original manufacturer is done with any responsibility, and you as reprocessor assume the role of manufacturer,” says Mr. Buccini.

There are 3 ways to handle single-use ophthalmic knives in compliance with federal regulations:

compliance with federal regulations:

- follow the label’s instructions and discard after every use;
- send used knives to a third-party reprocessing company that has FDA approval to reprocess that particular device; or
- go through the FDA’s rigorous process of becoming an authorized reprocessor of single-use devices so you can sterilize the knives in-house.

Some steel knives are FDA-approved for limited reuse, but even in these circumstances both Ms. Chobin and Mr. Buccini urge caution. “The Joint Commission and CMS are on this 100%,” says Ms. Chobin. “They’re going to ask to see in writing that you have permission to reprocess [the item] and that you’re able to comply” with the specifications for how to do so. Getting everything in writing is key, agrees Mr. Buccini. “The only way around the whole thing is if you can get the manufacturer to give you something clearly in writing, with no ambiguity, that says you can re-sterilize [the knife] X number of times by X method. They have to tell you all the parameters, such as pressure and exposure time. Unless they put that specifically in writing, you’re just asking for trouble.” And Ms. Chobin points out that you should ask for all of this information in writing up front, before you decide to purchase the knife.

— Irene Tsikitas

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Jackie Dayton, RN

▲ PACKAGE DEAL Including single-use knives in their cataract procedure packs saves the Surgery Center of Ophthalmology Consultants in Fort Wayne, Ind., about \$3 per case.

patience and cooperation from the 4 surgeons who do cataracts at the San Antonio (Texas) Eye Center, she was able to find a product that fulfills all 4 criteria. “What we are using is fairly perfect,” she says of the stainless steel, reusable safety knives her surgeons routinely use for their cataract incisions.

At one point, the owner of the center was routinely using diamond knives while the other sur-

geons were using disposables. With the goal of standardization in mind, Ms. Roegelein sought a middle-ground solution: a steel knife that was as sharp and reliable as a diamond but also validated for reprocessing and reuse a significant number of times before its quality began to degrade. Such a knife would satisfy all her surgeons’ competing preferences while also meeting infection control regulations against in-house reprocessing of single-use knives. Finding a product that could fulfill all those criteria was one of the hardest and most crucial aspects of the standardization process.

“Seek out what is the best knife out there on the marketplace, let your surgeons do a trial on it and explain to them the reason you’re trying to standardize,” says Ms. Roegelein. “If they have a vested interest” in the facility, “that makes a big difference. But you have to find a good product to begin with.” After researching the options, Ms. Roegelein found a line of

stainless steel safety knives that wowed her surgeons with their sharpness. “They are really superior to anything we’d used before,” she says. Even better, the manufacturer guarantees that the knives can be reused up to 15 times before the blade quality begins to deteriorate, making them more reliable than diamond knives that need to be carefully handled to retain their sharpness, and more economical than disposable knives that must be tossed after each use. As an added bonus, the reusable knives came with autoclavable safety sheaths to protect the blades and users from injury, a feature the single-use knives they’d been stocking lacked.

Even though the up-front per-knife cost is higher for the new reusable safety knives than it was for the single-use, non-safety knives some of Ms. Roegelein’s surgeons had been using, the per-

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use cost is significantly less. Assuming they last through 15 reprocessing cycles, the new reposables cost \$1.06 per use for the 15-degree knife and \$2.56 per use for the 2.65mm double-bevel slit knife, compared with \$5.16 per use for the single-use 15-degree knives and \$15 per use for the double-bevel slit knives. "Initially [the reposables are] more expensive, but when you divide the price by multiple uses, it brings the cost down, which makes a big difference in a high-volume center," she says. Her surgeons have been satisfied with the quality of the blades even after reprocessing, although Ms. Roegelein notes that there's a little more resistance in pulling the safety sheath back and forth over the blade after a few runs through the steam sterilizer — something her staff has adapted to.

Try, try again

Despite the failure of her center's recent safety knife trial, Ms. Looker isn't giving up on her hopes of standardization. For now, she's letting the 1 surgeon who liked the new knife use it, since it provides him and the staff better protection against sharps injuries. Meanwhile, she'll continue shopping for a guarded knife that all 4 surgeons can work with. "I'd like every one of my knives back there to be a safety knife," says Ms. Looker, but she concedes that in the end, "you have to give the tools to your surgeons that make them comfortable." **OSM**

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