

The Q-Net™ Monthly

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What's News?

This month's newsletter is a double issue that provides guidance to facilities seeking information on disposable and reusable biopsy forceps. Soon this and all of the other newsletters, published from 1995 to the present, will be accessible for downloading from the Internet in PDF format. Happy Memorial Day!

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'Q-Net 99'



Q-Net-99, a bound collection of all of 1999's newsletters, is now available.

What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

Biopsy Forceps

Disposable or Reusable?

Question: "My facility currently uses reusable biopsy forceps. We are thinking of replacing them with disposable biopsy forceps. Can you provide us with any guidance to assist us in our decision?"

Current debate surrounds the safety, performance, and cost-effectiveness of reusable and disposable biopsy forceps.

Background and Answer: Biopsy forceps are the most frequently used accessory in gastrointestinal endoscopy (1). During a procedure, these pliable instruments are passed down the instrument channel of a flexible endoscope and into the patient, where they are routinely used to sample potentially diseased tissues for histological evaluation.

Understanding the complex design and function of biopsy forceps is essential to ensure their safe and effective use. Their outer surface is constructed of a tightly wound, spring-like coil made of stainless steel. A wire, or cable, is threaded through the center of this coil's long and cylindrical shaft.

The distal end of this wire is connected to a hinged set of stainless steel jaws, or cups. These cups are used to grasp and sample tissue. This wire's proximal end is attached to a handle

assembly used by the physician to control the forceps and open and close its cups.

Types of biopsy forceps: Several different types, configurations and cup sizes are available, each designed for a specific endoscopic application. The cups of some biopsy forceps may be small and oval-shaped, while others may be large and rounded. A central spike may be located axially between the cups to facilitate tissue sampling. Both disposable and reusable biopsy forceps are available.

Because of their different applications, biopsy forceps vary significantly in length and diameter. Their length may be as long as 240 cm as required to sample tissue in the colon, or as short as 100 cm if only sampling tissue in the sigmoid. In general, their diameter range from 1.8 cm to 3.4 mm.

Some biopsy forceps may be coated with Teflon® to reduce wear and tear and enhance their maneuverability and advancement through the endoscope's instrument channel. And to facilitate cleaning of their internal shaft, some reusable biopsy forceps are designed with a flushing port.

Disposable or reusable design? Current debate surrounds the safety, performance, and cost-effectiveness of reusable and disposable biopsy forceps. Several studies and an editorial highlighting this debate were published in the March 2000 issue of *Gastrointestinal Endoscopy*.

Facilities researching whether disposable or reusable biopsy forceps may be more advantageous may ask several of the following questions:

è *Do reusable or disposable biopsy forceps perform better? Which type is safer?*

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Which is more cost-effective? After how many uses does a reusable forceps begin to malfunction and have to be repaired? Can reusable forceps be thoroughly cleaned? Why do published guidelines recommend that reusable biopsy forceps only be sterilized using pressurized steam? Is there any brand of disposable forceps that can be reused safely?

Researching the answer to each of these questions may be useful in determining whether disposable or reusable forceps are most suited to satisfying a specific facility's requirements.

With recent technological and design advances, differences between the physical designs of disposable and reusable biopsy forceps are no longer as conspicuous as they once were. While the designs of older plastic disposable forceps were reported to be inferior and prone to mechanical failure(2,3), newer more recent designs, which include stainless steel cups, appear to yield reliable tissue specimens equivalent to those obtained using reusable forceps(3,4).

Indeed, visually discerning one type of biopsy forceps from the other can sometimes be challenging. But while similar in appearance, closer inspection may reveal some significant differences. Whereas the components of reusable forceps are designed using materials that can withstand the rigors of both cleaning and steam sterilization, the handle assembly of most disposable forceps are made of a plastic material readily damaged by heat. And, although both types feature cups made of stainless steel, the cups of disposable forceps are usually less durable and not designed for repeated reuse.

Purchasing considerations: Several factors are likely to influence a health care facility's decision to purchase disposable or reusable biopsy forceps. These factors include: (1) **convenience** (*How easy are they to use and manipulate?*), (2) **performance** (*How well do they perform? Are their tissue specimens adequate for histological interpretation? Can their cups be easily opened and closed? If reusable, how many times can they be reused?*), (3) **safety** (*Are they mechanically sound? If reusable, do they facilitate cleaning?*), and (4) **initial cost** (*Are they cost-effective? What are their associated costs?*). Less important factors might include such intangibles as personal preference and the facility's rapport with a specific company's sales representative.

(A) *Disposables:* In general, disposable biopsy forceps are convenient to use, perform reliably and consistently, and have a lower initial cost(4). Moreover, disposable biopsy forceps (like any disposable item) neither poses a risk of cross-infection nor is associated with the burdens of instrument reprocessing and repair.

But disposable biopsy forceps have their shortcomings. Some reports suggest that they, at least some of their earlier designs, may be more prone than reusable biopsy forceps to the misdiagnosis of deep lesions(5). Also not to be overlooked is their potentially adverse impact on the environment.

(B) *Reusables:* While appealing to some facilities and

their staff, disposable biopsy forceps are not suited to all endoscopy centers. Proponents of reusable biopsy forceps laud their more durable design, which is constructed to withstand repeated reuse and the rigors of cleaning and steam sterilization.

But the initial cost of reusable biopsy forceps is significantly higher than disposable forceps (eg, \$350 vs. \$35, respectively), which can be problematic. Furthermore, unlike disposable forceps, reusable forceps must be cleaned and sterilized after each use (*see Box A and Box C*) and have the potential, if inadequately reprocessed, to transmit disease from one patient to another (*see Box B*). With frequent reuse, not only may the adequacy of their specimens decrease(4), but reusable biopsy forceps may also become damaged, worn and require maintenance and repair(6).

Performing a cost analysis: Crucial to any analysis comparing and contrasting the cost-effectiveness of disposable and reusable biopsy forceps is approximating the number of times the latter type will be reused (before being discarded). Otherwise, the lower initial cost of disposable forceps may be taken out of context. With repeated reuse, reusable forceps are reported to become more cost-effective(1,3,5).

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Box A: "Why steam sterilization?"

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Biopsy forceps routinely enter sterile tissue and therefore are classified as *critical* devices that require sterilization. According to the Centers for Disease Control and Prevention (CDC), the Society of Gastroenterology Nurses and Associates (SGNA), and several other organizations, reusable biopsy forceps (and other critical instruments not damaged by heat) require *steam sterilization*(9,10) - not a low-temperature chemical process - because only pressurized steam can reliably penetrate the forceps's complex spring-like coil and destroy microorganisms that might otherwise be inaccessible(10). Reports of cross-infection linked to biopsy forceps immersed in a liquid chemical sterilant have been reported(11) (*also see this newsletter's November 1997 issue*). But,

✓ *Reports of infection following steam sterilization of biopsy forceps have not been reported*(5).

◆
In the April-May 1999 issue of *The Q-Net Monthly*, the results of a survey were published. Over half of the respondents (81 of 146), in accordance with recommended guidelines, steam sterilized their biopsy forceps. (Thirty-three respondents used a liquid chemical sterilant, and 11 used ethylene oxide gas. Twenty respondents used disposable biopsy forceps; *see Box D*.)

In addition to their initial cost and the number of times they are expected to be reused, the cost analysis for reusable forceps should include: (1) the costs associated with their reprocessing (*see Box C*); (2) the costs associated with repairing them to maintain their high performance and safety; and (3) while difficult to determine and approximate, the potential costs associated with nosocomial infections, in the event that a reusable biopsy forceps were inadequately reprocessed and linked to patient infection.

For disposable biopsy forceps, in addition to their initial cost, the cost analysis should include: (1) the cost to provide adequate space to store them prior to use; and (2) the costs associated with disposing them after use. The purchase and storage of a large number of biopsy forceps (which may be financially beneficial to reduce their initial cost-per-item) and the disposal of infectious medical waste can be significant.

Complicating factors: As with the purchase of most material items, preparing a cost analysis to determine whether a disposable or reusable biopsy forceps is more suited to a specific endoscopy unit may not be straightforward. Whereas one cost analysis may show convincingly that reusable forceps are significantly more cost-effective(1,5,6), another contemporaneous analysis may conclude just as soundly that disposable forceps are more cost-effective(4). Several assumptions that can influence significantly the results must be established and incorporated into the cost analysis.

For example, determining labor costs associated with reprocessing reusable forceps may be difficult to calculate. Also difficult to determine may be the number of times a reusable forceps will be reused before repairing or replacing it. Estimating the costs associated with cross-infection, in the event the forceps were not adequately reprocessed, is also not straightforward. Moreover, the cost of biopsy forceps is

Box B: "Risk of cross-infection?"

□

Published papers have presented impressive photographs displaying what appears to be patient debris contaminating the internal lumen and hinge mechanism of reusable biopsy forceps(4,9). This debris remained despite the forceps having ostensibly been subjected to a recommended cleaning protocol(4). The appearance of any debris remaining in a "ready-for-use" instrument is, at the very least, unsettling and indicates a potential for cross-infection.

Are reusable biopsy forceps associated with a higher risk of cross-infection than disposable biopsy forceps? Reports of infection linked to biopsy forceps have been reported(11), but in each case established reprocessing guidelines were breached. Provided they are cleaned and steam autoclaved after use, reusable forceps are not reported to pose a higher infection risk than disposable forceps(5).

sometimes included in the purchase price of other equipment and therefore may not be obvious. A clear understanding of all of a cost analysis's assumptions and the implications of each are necessary to determine whether the analysis's

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Box C: "How to reprocess biopsy forceps"

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Reusable biopsy forceps require a rigorous cleaning and sterilization process to prevent them from transmitting disease from one patient to another (ie, cross-infection). According to several organizations, steam sterilization of biopsy forceps is essential(9,10) (*see also Box A*).

In addition to steam sterilization, reprocessing of biopsy forceps includes several essential steps:

- (1) After use, promptly **transport** the contaminated forceps to a dedicated reprocessing area. **Soak** them in a fresh detergent solution (eg, an enzymatic detergent). This step is crucial to prevent the drying of organic debris.
- (2) Manually **brush/scrub** the forceps. Then, **rinse** the forceps with clean water. If recommended by its manufacturer, disassemble the forceps for more thorough cleaning, and flush its internal shaft with detergent, if a cleaning port is provided.
- (3) **Ultrasonically clean** the forceps, using an appropriate detergent solution. This step has been shown to effectively remove fine debris. Unless cleaning is complete and successful, the sterilization process is likely to fail. Next, **rinse** the forceps with clean water. (After ultrasonically cleaning the forceps, but before steam sterilization, some facilities may disinfect the forceps[5,7].)
- (4) **Dry** the forceps, using compressed medical-grade air, if available. **Inspect** and reassemble the forceps, if disassembled.
- (5) **Lubricate** the forceps, as recommended before steam sterilization. (Immersing the forceps in a lubricating solution *after* sterilization may recontaminate the forceps and pose an infection risk(12).)
- (6) After wrapping the biopsy forceps, **sterilize** them using a steam autoclave(9,10,12).
- (7) Finally, **transport** the forceps back to the unit for reuse.

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These reprocessing steps for biopsy forceps (and other endoscopic accessories) are intended to supplement, not replace, the reprocessing instructions provided by the instrument's manufacturer, which should be completely read and thoroughly understood. Some endoscopic accessories may require additional or unique reprocessing steps.

conclusions are applicable to a specific endoscopy unit.

Conclusions and summary: In the current managed care environment, reducing the costs associated with endoscopic accessories is essential(13). Performing an analysis to determine which type of biopsy forceps is more cost-effective for a specific facility is therefore recommended.

Analyzing and comparing the costs associated with disposable and reusable biopsy forceps, however, can be a complex and arduous task. Each type is associated with its own unique set of costs. Costs associated with disposable biopsy forceps include its initial cost, and both storage and disposal costs. In addition to its initial cost, costs associated with reusable forceps include reprocessing and repair costs.

Estimating the number of procedures a reusable biopsy forceps performs is essential to evaluating its cost-effectiveness. In general, once a reusable forceps performs a *threshold* number of biopsies, it becomes more cost-effective than a disposable forceps(1,3,5). (This calculation assumes that disposable forceps are *not* being reused.) One study published a few years ago found that reusable biopsy forceps became more cost-effective after as few as 7 reuses(6). The higher the initial cost of the disposable forceps, the lower this threshold number.

Similarly, as the initial cost of disposable biopsy forceps decreases, this threshold number increases. Currently disposable biopsy forceps can be purchased for less than \$40(7). At this price, reusable forceps may have to perform 20 or more biopsies to remain more cost-effective(1,7). Whether the reusable forceps malfunctions and requires repair before this threshold number is reached depends on several factors, including how well it is constructed. Indeed, the cost-effectiveness of reusable forceps is waning in the wake of significant decreases in the initial cost of disposable forceps.

In conclusion, if an endoscopy center is performing few endoscopic biopsies, or is not equipped to both clean and steam sterilize its instruments (and therefore for which outsourcing its reusable biopsy forceps for reprocessing would be required), the convenience of disposable forceps is likely to make them the more appropriate choice(3).

But for a busy endoscopy center that performs many biopsies and is equipped with a reprocessing department, reusable forceps may be more appropriate and cost-effective. Purchasing a reusable biopsy forceps designed and documented to withstand at least 20 procedures without malfunctioning or requiring costly repair may be necessary to ensure and maintain its cost-effectiveness.



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Box D: Trends: Disposable vs. Reusable

In the July-August 1999 issue of this newsletter, the results of a survey were discussed. The results suggest that the use of disposable biopsy forceps may have increased during the past decade(14). Surveys conducted in 1991 indicate that fewer than 2% of responding facilities(15) reported using disposable biopsy forceps, while 14% (20 of 146) of the respondents to this newsletter's survey reported using disposable biopsy forceps. Greater awareness of the physical complexity of reusable biopsy forceps and the formidable challenges their internal designs pose to sterilization in general and cleaning in particular may explain this apparent increase in the popularity of disposable biopsy forceps over the past decade. (Due to a lack of data, the extent to which replacing reusable with disposable biopsy forceps reduces

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Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

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