

# The Q-Net™ Monthly

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## Study of a device recall

Last November, **Olympus America Inc.** recalled 15 bronchoscope models, due to a "potential looseness in the biopsy channel port housing." This design flaw may have been responsible for patient injury.

### One in a series of articles

**Background:** Bronchoscopes are routinely used to sample lung tissue, to evaluate abnormal chest radiographs, and to diagnosis cancer, tuberculosis, pneumonia, and other respiratory diseases. Approximately 500,000 bronchoscopies are performed each year in the United States. Infections linked to contaminated bronchoscopes are rare.<sup>1</sup>

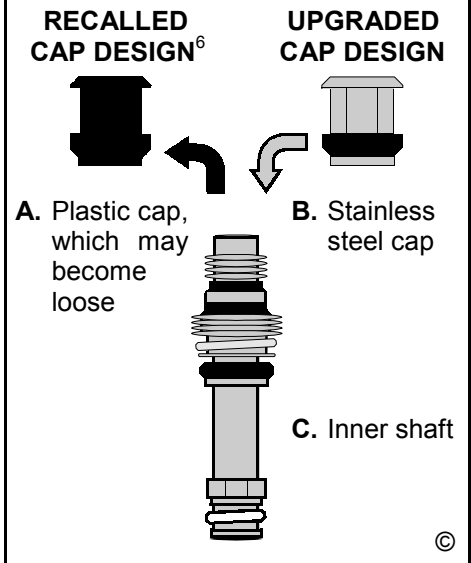
**Skyline Medical Center (SMC):** Last September (2001), Skyline Medical Center ("SMC") in Nashville (TN) noticed that an unusually high number of fluid samples collected from patients who had recently undergone bronchoalveolar lavage (BAL) were contaminated with *Pseudomonas aeruginosa*.<sup>2</sup> During BAL, the physician irrigates the lung's tissues with sterile saline and then

suctions back the lavage fluid for analysis. The bronchoscopes used to collect these contaminated BAL samples were distributed by Olympus America, Inc. (Mellville, NY), a subsidiary of the Olympus Optical Company (Tokyo, Japan). SMC reported its findings to the Tennessee Department of Health (TDH).<sup>2</sup>

Suspecting a possible bacterial outbreak, members of SMC's staff and officials at the TDH and the Centers for Disease Control and Prevention (CDC) investigated this report to determine the source of the contamination. These investigators inspected the bronchoscope and discovered that its biopsy channel port housing (Figure 1), which is supposed to be secure, had become loose.<sup>3</sup> Sections of this loose housing, which were inaccessible to cleaning and disinfection, were sampled and found to be contaminated with the same *P aeruginosa* strain as the patients' contaminated BAL samples.<sup>2,4</sup>

In October (2001), these investigators informed Olympus and the Food and Drug Administration (FDA) that the bronchoscope's loose biopsy channel port housing was the source of the *P aeruginosa*.<sup>5</sup> Although BAL samples taken from the lungs of several patients were positive suggesting infection, only one patient (who recovered) was reportedly infected by the bronchoscope.<sup>2</sup>

**First recall letter:** In response to the  
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**Figure 1. Facsimile of the recalled Olympus bronchoscope's biopsy channel port housing.** As prescribed by Olympus' recall, the plastic cap is removed and replaced with a more secure stainless steel cap. See the main article for more details on Olympus' recall.

The following bronchoscope models were subject to Olympus' recall.<sup>6,9</sup>

**BF-40, BF-P40, BF-1T40, BF-3C40, BF-XP40, BF-XT40, BF-240, BF-P240, BF-1T240, BF-6C240, BF-160, BF-P160, BF-1T160, BF-3C160, and BF-XT160.**

These models were distributed nationwide and to Canada, Mexico, and several other countries between June 5, 1997 and December 10, 2001 (see: [www.fda.gov/cdrh/recalls/recall-032002.html](http://www.fda.gov/cdrh/recalls/recall-032002.html)). Approximately 4700 bronchoscopes in the United States were recalled.

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infection at SMC, Olympus voluntarily recalled 15 bronchoscope models (see model list, p. 7).<sup>6</sup> (A voluntary recall is initiated by the manufacturer and is not at the behest of the FDA.) Olympus determined that these bronchoscope models had a design flaw that could cause a “potential looseness in the biopsy channel port housing” (Figure 1).<sup>6</sup> Olympus mailed a recall letter, dated November 30, 2001, to more than 2000 medical facilities in the US that according to its records had bought a recalled bronchoscope model. In early December (2001), Olympus notified the FDA of the recall.<sup>7,8</sup>

This recall letter instructed the medical facility to inspect its inventory of Olympus bronchoscopes: If the biopsy channel port housing of any of the recalled models was found to be loose, the facility was instructed to remove the bronchoscope from service and return it to Olympus for repair. In addition to requesting a contact name and telephone number, the recall letter asked the facility to complete and return an attached questionnaire acknowledging it had received the letter and understood its instructions.

**Details of Olympus’ design modification:** To address growing concerns of the risk of bacterial contamination, Olympus re-designed the recalled bronchoscope models, replacing the plastic cap (‘A’ in Figure 1, p. 7) that screws onto the biopsy channel port housing’s threaded inner shaft (‘C’ in Figure 1) with a stainless steel cap (‘B’ in Figure 1). (The inner shaft is inserted into the bronchoscope’s body during manufacturing.) Olympus reportedly also used more adhesive and sealant to prevent the new stainless steel cap from loosening during routine use or reprocessing.<sup>9</sup>

**Johns Hopkins Hospital (JHH):** Not every physician or department using one of the defective bronchoscope models was aware of Olympus’ recall. According to officials at Johns Hopkins Hospital (“JHH”) in Baltimore (MD), none of its physicians who perform bronchoscopies received Olympus’ recall letter, because it was mailed to the wrong address.<sup>3,5</sup>

Therefore, unaware of Olympus’ recall and the potential for contamination of the loose biopsy channel port housing, JHH’s physicians continued to perform bronchoscopies. At the end of December (2001), JHH’s physicians noticed that the *P aeruginosa* infection rate for hospitalized patients who had recently undergone BAL was significantly higher than would be expected for this patient group.<sup>10</sup> It is into the

biopsy channel port that a syringe filled with sterile saline is typically inserted to irrigate the patient’s lung tissue during BAL.<sup>11</sup> If this port’s housing were loose and bacteria were to become trapped in it, then bacteria could presumably contaminate the patient during bronchoscopy or the suctioned fluid samples during BAL.

Several weeks later in early February (2002), after conducting an extensive epidemiological investigation into the cause of these bacterial infections, officials at JHH became convinced that the loose biopsy channel port housing of several of its bronchoscopes was the source of the *P aeruginosa*<sup>12</sup>—the same conclusion reported by SMC several months earlier.<sup>2</sup>

JHH’s physicians promptly removed these bronchoscopes from service and notified Olympus of their findings. According to JHH, only then did it learn from Olympus that three of its contaminated bronchoscopes were models subject to the recall issued more than two months earlier.<sup>3,10,13</sup> Officials at JHH called several colleagues to discuss the risk of patient infection associated with the recalled Olympus bronchoscope models. Many of these hospitals were reportedly unaware of the recall.<sup>3,5</sup> At risk of infection are over 400 patients who underwent BAL at JHH between June 1, 2001 and February 4, 2002.<sup>3,5,10</sup> One hundred of these patients reportedly tested positive for *P aeruginosa* and two died.<sup>3,8,10,13</sup>

**Sampling bronchoscopes:** Because the endoscope’s complex design precludes direct sampling of all of its internal surfaces using, for example, a swab, an indirect and imperfect sampling method may be practiced, the most popular of which prescribes flushing a sterile fluid through the biopsy port and collecting the fluid for analysis at the endoscope’s distal tip. When they used this ‘forward-flushing’ sampling method, investigators at JHH detected no bacterial contamination.

But when these investigators instead sampled the bronchoscope by suctioning culture medium in the reverse direction—from the bronchoscope’s distal tip up towards its control head (the ‘reverse-flushing’ sampling method)—bacterial contamination was confirmed.<sup>3,10,14</sup> (See reference #14 for a description of JHH’s sampling procedure.) Several of JHH’s bronchoscopes found to be contaminated with *P aeruginosa* were subject to Olympus’ recall.

**Second recall letter:** As a follow-up to its first recall letter and with input from the FDA, Olympus mailed a second recall letter, dated February 27, 2002, to medical facilities that had not returned either the questionnaire attached to the first recall letter or one of the recalled bronchoscope models.<sup>15</sup> Unlike the first one, Olympus’ second recall letter was clearer and required the return of all recalled bronchoscope models for repair, even if the facility had inspected the biopsy channel port housing and had not found it to be loose.

**Manufacturer’s response:** After conducting its own investigation, the Olympus Optical Company, the manufacturer of

For information on Olympus’ first recall letter, visit:  
[www.olympusamerica.com/files/Bronch\\_press.pdf](http://www.olympusamerica.com/files/Bronch_press.pdf)

A copy of Olympus’ second recall letter can be read at:  
[www.olympusamerica.com/files/bronch\\_recall2.pdf](http://www.olympusamerica.com/files/bronch_recall2.pdf)

The FDA’s posting of the Olympus recall can be read at: [www.fda.gov/cdrh/recalls/recall-032002.html](http://www.fda.gov/cdrh/recalls/recall-032002.html)

the recalled bronchoscopes, disputes the conclusion that a loose biopsy channel port housing was responsible for the reported patient infections at SMC and JHH. According to Olympus, there is insufficient data to draw such a definitive conclusion about any of its bronchoscope models. Nevertheless, because it would be difficult to prove its bronchoscopes were not at fault, Olympus decided to issue a voluntary recall.<sup>6,7,15</sup> Providing its explanation for the outbreaks, Olympus asserts that improper cleaning of the bronchoscopes was probably the cause of the infections at both SMC and JHH.<sup>8</sup>

Olympus acknowledges that it had been notified by SMC and knew in September (2001) that the biopsy channel port housing of some of its bronchoscope models could become loose and trap bacteria.<sup>8</sup> But Olympus did not deem patients at risk of infection, because its own testing indicated that the bacteria could not be transmitted to patients as long as the bronchoscope was properly reprocessed.<sup>8</sup> For its part, Olympus says it “initiated an immediate and vigorous investigation resulting in a prompt recall.”<sup>3,8</sup>

**JHH’s, CDC’s response:** Although Olympus asserts that the patient infections were likely caused by poor cleaning of the bronchoscope, it is worth noting that JHH cleans and disinfects its bronchoscopes using the reprocessing equipment Olympus recommended.<sup>8</sup> In addition, testing by officials of JHH revealed that exposure of a recalled bronchoscope to both cleaning and an ethylene oxide gas sterilization process failed to destroy all of the bacteria in the bronchoscope’s loose housing, reinforcing JHH’s conclusion that the infections were due to a design flaw—not poor cleaning.<sup>8</sup>

Nevertheless, despite being convinced that the bronchoscope’s loose biopsy channel port housing was the source of the *P aeruginosa*, officials at JHH acknowledge that more tests may need to be performed before a causal relationship between the recalled bronchoscopes and the patient infections can be definitely determined.<sup>10</sup> Other factors in addition to (or completely independent of) the bronchoscope’s loose housing may be responsible for or have contributed to the infections. Many of the patients on whom the recalled bronchoscopes were used were ill and suffering from serious diseases.<sup>8,10,13</sup> In truth, *P aeruginosa* infections are not uncommon in this patient group. The potential exists, therefore, that some of the patients who tested positive for *P aeruginosa* may have already been infected prior to their bronchoscopies at JHH.<sup>8,10</sup>

Criticizing Olympus’ recall procedure, officials from JHH and the CDC claim that Olympus’ first recall letter was inadequate, not timely, and lacked a sense of urgency<sup>2,3,5</sup> placing patients at risk.<sup>16</sup> The results of a recent CDC study suggest, in agreement with JHH’s conclusion, that the recalled bronchoscopes’ loose biopsy channel port housing was likely responsible for the *P aeruginosa* infections.<sup>17</sup> JHH and CDC officials also questioned the FDA’s handling of the recall.<sup>3,17</sup> Despite knowing last year of the bronchoscope’s design flaw and the potential risks it could pose, the FDA did not issue an advisory or a warning; nor did it promptly post

Olympus’ recall notice on its website (until March 20, 2002).<sup>18</sup> And, according to officials at JHH, the FDA did not adequately monitor Olympus during the recall process.<sup>3,5</sup> Also questioned is the FDA policy that required Olympus to mail the recall letters only to the medical facilities listed in its files as purchasers of a recalled bronchoscope model, and not to each physician who might be using a recalled model.<sup>3</sup>

**The FDA’s response:** The FDA is investigating whether any of its recall guidelines were ignored or violated by Olympus.<sup>3,16</sup> The FDA is also evaluating its own internal policies for monitoring medical device recalls.<sup>17</sup> On March 20, 2002, Olympus’ recall notice was posted on the FDA’s website.<sup>18</sup> Other recommendations provided by the FDA to prevent patient infection following flexible endoscopy can be read at: [www.fda.gov/cdrh/safety/endoreprocess.pdf](http://www.fda.gov/cdrh/safety/endoreprocess.pdf). The FDA is now working with Olympus to prevent additional infections.<sup>18</sup>

**Has this happened before?** A valid question to ask is whether any of the documented reports of patient infections following bronchoscopy prior to Olympus’ recall were caused by a contaminated loose biopsy channel port housing, although attributed to another factor such as human error. Indeed, some of the recalled bronchoscope models had been in use in the US since 1997. Some experts believe the recalled bronchoscopes may have been responsible for many more reports of patient infection.<sup>13,16</sup> A review of the medical literature and the FDA’s MAUDE lists several reports in the last few years that link one of Olympus’ recalled bronchoscope models to a bacterial outbreak.<sup>1,19</sup> Whether any of these reports attributed to another cause were in fact due to a loose biopsy channel port housing may never be known.

A physician in France recently communicated to this article’s author (LFM) that between March and June of 2001 his hospital noticed that two Olympus BF-P240 bronchoscopes, both of which were subject to Olympus’ subsequent recall, were associated with an unusually high number of BAL samples contaminated with gram-negative bacteria. Five of the hospital’s other bronchoscopes, which were not subject to the subsequent recall and which were reprocessed identically as the two BF-P240 bronchoscopes, were not linked to this potential outbreak. After being reprocessed, the two BF-P240 bronchoscopes were sampled using the reverse-flushing method (see above).<sup>14</sup> The biopsy channel of one of these two bronchoscopes was found to be contaminated with the same strain of gram-negative bacteria as the BAL samples. Removal of these two bronchoscopes from service returned the number of positive BAL samples to normal. The facility’s doctors posited that the bronchoscope was defective and that a section of it inaccessible to the disinfectant was contaminated. In June, 2001, this facility notified Olympus’ French division of its suspicions. This facility did not learn of Olympus’ recall until March, 2002, when it was posted on the Internet.

**Discussion:** The outbreaks at SMC and JHH and Olympus’

recall of over a dozen bronchoscope models underscore the importance of: (a) manufacturers designing reusable medical instruments that facilitate rather than preclude the reprocessing of all of their internal (and external) surfaces; (b) companies being proactive and promptly notifying all users when their devices are recalled; (c) federal oversight and monitoring of medical device companies during the recall process; and (d) surveillance within healthcare facilities to quickly detect and formulate a prompt response to an outbreak.

Further, the investigations into the cause of the *P aeruginosa* outbreaks at SMC and JHH, both of which revealed a flaw in the design of several Olympus bronchoscope models, demonstrate the limitations that the design of flexible endoscopes imposes on microbiologic sampling. Because most of the internal channels of flexible endoscopes cannot be directly sampled microbiologically using, for example, a swab, medical facilities, like JHH, instead typically sample them using an indirect method, such as flushing sterile fluid through the channel and collecting the effluent for culture. But this flushing method can yield misleading results. (Refer to this newsletter's January 2000 issue.) Although a positive culture obtained by sampling an endoscope's channel using a flushing technique<sup>14</sup> likely indicates contamination (i.e., a true-positive), a negative culture does not assure the endoscope is sterile (i.e., a false-negative). Inaccessible microorganisms trapped inside the endoscope may not all be dislodged and recovered for assaying simply by flushing its channels.

As Olympus' recall process demonstrated, the rapid exchange of information between healthcare facilities, medical device companies, and federal agencies is crucial to the prevention of nosocomial infections. As acknowledged by Olympus, the response rate to its first recall letter was poor with fewer than 40% of the recalled bronchoscopes being returned as of early March (2002),<sup>17</sup> the reasons for which are not entirely clear. Also unclear is how many facilities continue to use recalled bronchoscope models. Although several medical facilities in the Maryland, Virginia and Washington D.C. areas received the first recall letter shortly after its mailing, JHH and other facilities in the same geographic region did not know of the recall until February (2002), suggesting an inconsistency in Olympus' recall notification

### ***In the news ...***

Two articles on endoscope reprocessing were recently published in the March 27th (2002) issue of the *Boston Globe*<sup>23</sup> and the April 8th (2002) issue of *USA Today*.<sup>22</sup> Both of these articles, which are recommended reading, discuss several important topics, including the controversy surrounding the reported infection rate following GI endoscopy of one in 1.8 million procedures; the use of disposable sheaths; and the recall of several Olympus bronchoscope models.

Visit SGNA's homepage at: [www.sgna.org/resources/Infection.html](http://www.sgna.org/resources/Infection.html) for a step-by-step set of endoscope reprocessing instructions. Also, review AORN's recommended practices for the use and care of endoscopes at: [www.aorn.org/clinical/endocare.pdf](http://www.aorn.org/clinical/endocare.pdf)

procedure.<sup>20</sup> (According to an Indian newspaper, as of March 7 (2002), most of India's doctors who use Olympus bronchoscopes, the Indian government, and even Olympus' distributor in India were unaware of the recall.<sup>21</sup>)

Soon after JHH began in early March (2002) to contact patients potentially infected during bronchoscopy, Olympus' recall was reported by several news sources, including *The Baltimore Sun* and *The New York Times*. Some of the reports seemed to suggest erroneously that the infections reported at JHH (and other medical facilities) might have been due, not to a flaw in the design of the bronchoscope, but instead to an inherent inadequacy in current endoscope reprocessing practices and guidelines.<sup>22-26</sup> To be clear:

- *When reprocessing staff adhere strictly to published guidelines (assuming the endoscope is not defective), no cases of patient infection following an endoscopic procedure have been reported.*

This study of Olympus' recall of bronchoscopes raises as many questions as lessons it teaches. The next issue of this newsletter will present some of these questions and will provide several recommendations to prevent patient infection following endoscopy. **TO BE CONTINUED NEXT MONTH ...**

#### **References available at:**

<http://www.myendosite.com/refs04502.htm>

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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