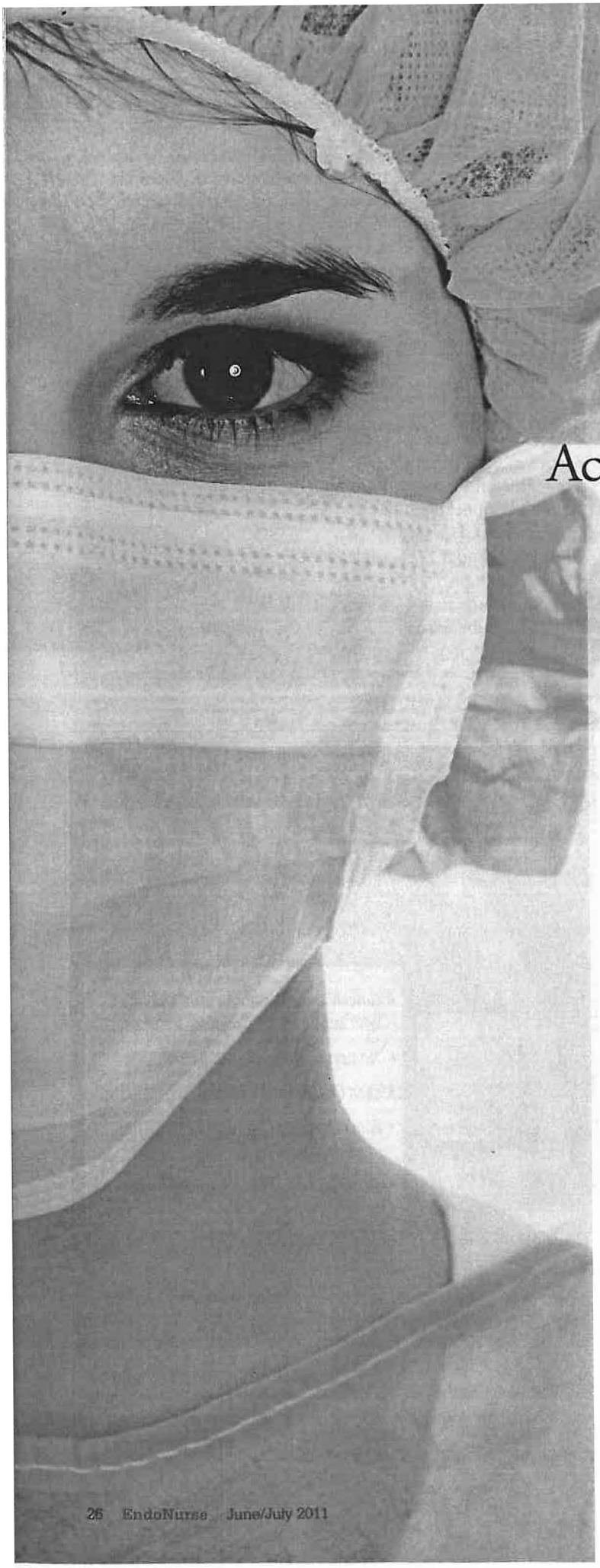


By David Sylvain, John Gibbins, and Maureen T. Niemeier

Exposure to Peracetic Acid-Based Sterilant During Endoscope Reprocessing

The National Institute for Occupational Safety and Health (NIOSH), in the Centers for Disease Control and Prevention (CDC), conducts research and makes recommendations for the prevention of work-related injury and illness. The NIOSH health hazard evaluation (HHE) program is available for employees, employers, or union representatives to ask our comprehensive team of experts for an investigation of their health and safety concerns by requesting an HHE. Our team contacts the requestor and discusses the problems and how to solve them.

This may result in sending the requestor information, referring them to a more appropriate agency, or making a site visit (which may include environmental sampling and medical testing). If we make a site visit, the result is a report of our investigation that includes recommendations specific to any problems found, as well as general guidance for following good occupational health practices. For more information on the NIOSH HHE program, see "Resources and Links."

Endoscope Sterilization HHE

We received a request for an HHE from employees at a general hospital in New York. The request stated that the ventilation in the "STERIS room" in which five employees cleaned and sterilized endoscopes with Klenzyme® Enzymatic Cleaner and STERIS™ 20 Sterilant Concentrate was possibly inadequate.

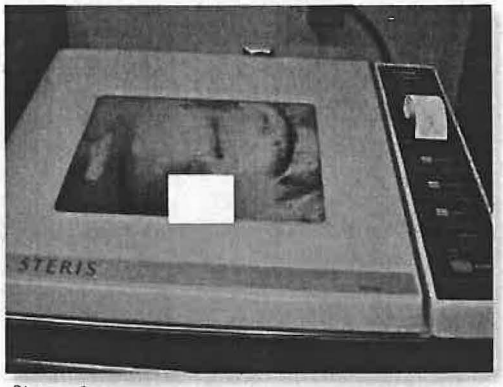
The employees reported they were experiencing headache, shortness of breath, eye irritation, and diminished sense of smell. We conducted a site visit that included an opening conference, a walk-through of the STERIS endoscope sterilization room, air sampling for peracetic and acetic acids, measuring temperature and humidity, observing airflow patterns in the room using smoke tubes, and confidential interviews with several employees.

We asked the employees about possible work-related symptoms, safety and health training, use of personal protective equipment (PPE), chemical exposure incidents, and indoor environmental quality.

Lastly, we searched U.S. Food and Drug Administration (FDA) Adverse Event Reporting System (AERS) data files for reports of sterilant spills, employee exposures, and injuries involving the STERIS SYSTEM 1® (SS1) Processing System at all hospitals for 1996 through 2008. We searched the data files to identify potential occupational safety and health hazards during endoscope reprocessing at this hospital.

The SS1 Processing System had been used at the hospital for approximately 10 years prior to our site visit (picture 1). The STERIS endoscope sterilization room is one of several STERIS rooms at the hospital. Although referred to as a single room, it is divided into two smaller rooms (the "dirty side" and the "clean side"), which are separated by a floor-to-ceiling wall with a sliding window.

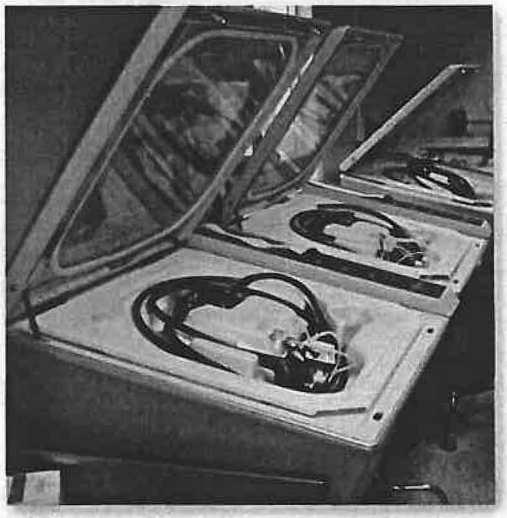
There were six SS1 processors in the clean side at the time of our visit (picture 2). It also contained a GUS® Model G17HS endoscope immersion unit, which contains about one-half gallon of Cidex® ortho-Phthalaldehyde (OPA) Solution (picture 2). The GUS unit is not frequently used for endoscope disinfection; however, Cidex OPA is present in the unit at all times. The STERIS room has a canopy hood over four of the SS1 processors, ceiling diffusers and returns for general ventilation, and was reportedly supplied with 100 percent outside air.



Picture 1

When an endoscopic procedure is completed, the endoscope is brought to the dirty-side of the STERIS room and manually cleaned with Klenzyme enzymatic cleaner. A clean-side technician installs the appropriate channel connectors to the endoscope and places it in a processing tray in one of the SS1 processors, along with a sealed container of STERIS 20 Sterilant Concentrate.

The technician closes the processor lid and starts the 30-minute, microprocessor-controlled sterilization cycle. When the cycle is finished, the technician removes the endoscope and flushes it with isopropyl alcohol. Forced air is used to remove the alcohol from the inside of the endoscope. This procedure is followed for each endoscope that is returned for cleaning and sterilization, and more than one processor may be operating at the same time. The only PPE we observed being worn in the clean side during our site visit was latex gloves, which do not provide adequate chemical protection.


Picture 2

While Klenzyme Concentrate Plus Enzymatic Cleaner and Cidex OPA Solution were not the focus of our investigation, the hazards associated with these products should be noted. Klenzyme can irritate the skin and eyes, and contains enzymes which are known to cause respiratory sensitization (the potential for airway sensitivity symptoms such as cough, wheezing, chest tightness, and breathlessness). OPA is an eye, skin, and respiratory irritant that may also cause sensitization (development of allergic symptoms upon repeated exposure).

We collected full-shift personal breathing zone air samples for each of three technicians in the STERIS room along with two area air samples in the clean side, and one area air sample in the dirty side. None of the air samples contained detectable concentrations of acetic acid.

Although the samples could not be analyzed for peracetic acid because of analytical difficulties, the acetic acid results and our observations indicated very little (if any) exposure to airborne peracetic acid during our site visit. The smoke tubes we used to visualize airflow in the STERIS room indicated that the heating, ventilation, and air conditioning system was not providing sufficient airflow for odor control and worker comfort.

We interviewed four of the five employees who worked in the STERIS endoscope sterilization room. They reported periodic headaches and burning eyes, and stated that these symptoms were more noticeable when SS1 processors malfunctioned and leaked. Gloves, sleeves, and aprons were available for the employees to wear, but some of the employees said they did not wear all available PPE because the room was too warm, especially in the summer.

Employees reported leaving the doors between both sides of the STERIS room and the corridor open to improve ventilation, but were instructed to keep them closed due to odor complaints from patients and nursing staff. Two employees reported experiencing prior chemical burns while using STERIS 20 Sterilant Concentrate, and several reported they had not received formal chemical hazard communication training for working in the STERIS room.

Our review of FDA adverse-event reports for all hospitals during a 13-year period starting in 1996, indicated that exposure to peracetic acid sterilant is unlikely to occur when SS1 processors are maintained and operated according to the manufacturer's recommendations, and when technicians follow the manufacturer's operating instructions.

Our review identified 63 instances of processor malfunction and/or improper handling and disposal of STERIS 20 Sterilant Concentrate that resulted in reports of chemical burns, or eye and respiratory tract irritation. The most common type of injury was a chemical burn of the skin, which varied from what appeared to be minor burns, to several reports of second-degree burns, and at least one report of a third-degree burn.

Several instances of eye contact that reportedly resulted in burns and pain were identified. Respiratory exposures to concentrated peracetic acid sterilant resulted in reports of shortness of breath; nasal irritation and scabbing of nasal passages; and rare events, including lung hypertension and pneumonia, and an asthmatic-like reaction in a hospital receptionist.

Recommendations

The following is an overview of our recommendations for reducing potential exposures to peracetic acid sterilant during endoscope reprocessing. Many of our recommendations may be applicable to your facility. A detailed list of recommendations can be found in the NIOSH health hazard evaluation report at http://www.cdc.gov/niosh/hhe/reports/pdfs/2006-0298-3090.pdf.

What Hospital Managers Can Do

- Require use of appropriate PPE to prevent contact with concentrated peracetic acid, as well as other cleaning chemicals and contaminated equipment.
- Provide formal chemical hazard communication training for endoscope sterilization room employees.

• Notify the FDA MedWatch program if an employee experiences an adverse event when using the SS1 processing system (see "Resources and Links"), and encourage employees to report adverse events to management.

• Train employees in standard operating procedures for spills, leaks, and processor malfunctions.

• Conduct new employee and annual refresher in-service training.

• Make sure processors are inspected periodically for worn parts that can cause leaks.

• Notify STERIS Corporation of leaks and equipment problems.

• Increase ventilation in the endoscope sterilization room for odor control and employee comfort.

What Endoscope Sterilization Room Employees Can Do

• Wear tight-fitting, splash-resistant goggles and acid-resistant gloves, sleeves, and apron when handling sealed STERIS containers ("cups") during normal operations.

• Wear a face shield over eye protection, along with routine PPE, when handling or disposing of a cup that is not completely empty.

• Follow the manufacturer's instructions for handling STERIS cups and operating processors.

• Tell management about problems with processors or STERIS cups, or if you notice worn processor seals or other parts.

• Report adverse events to management and to the FDA MedWatch program (see "Resources and Links").

• Follow standard operating procedures for processor problems, leaks, and sterilant spills.

• Participate in training when provided.

Updated Information (post-NIOSH evaluation)

On April 20, 2010, STERIS Corporation announced an agreement with FDA on the terms of a consent decree regarding the STERIS SS1 Processing System. Under the terms of this agreement, STERIS will provide support (consumables, parts, and service) for the SS1 system through August 02, 2011.

In April 2010, STERIS received FDA approval for STERIS SYSTEM 1E™, which will replace the SS1 Processing System. We reviewed the material safety data sheet for S40™ Sterilant Concentrate, which will be used in the STERIS SYSTEM 1E, as well as technical information concerning STERIS SYSTEM 1E design and operation, and feel our recommendations remain valid to protect worker safety and health when operating this new system.

David Sylvain, MS, CIH, is a NIOSH employee; John Gibbins, DVM, MPH1, is a NIOSH employee, and Maureen T. Niemeier, BBA2, is a freelance technical writer.

Resources and Links

NIOSH HHE program information: www.cdc.gov/niosh/hhe/HHEprogram.html

US FDA MedWatch program for adverse event reports: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/default.htm.

STERIS material safety data sheets for STERIS 20™ Sterilant Concentrate (MSDS No. 612038) and S40™ Sterilant Concentrate (MSDS No. 4000), http://www.steris.com/healthcare/support/msds/search.cfm?app=Sterilant

STERIS Corporation announces agreement with FDA [2010]. http://www.steris.com/media/PDF/news/product/2010/20APR2010%20-%20AGREEMENT%20RELEASE%20-%20FINAL.pdf.

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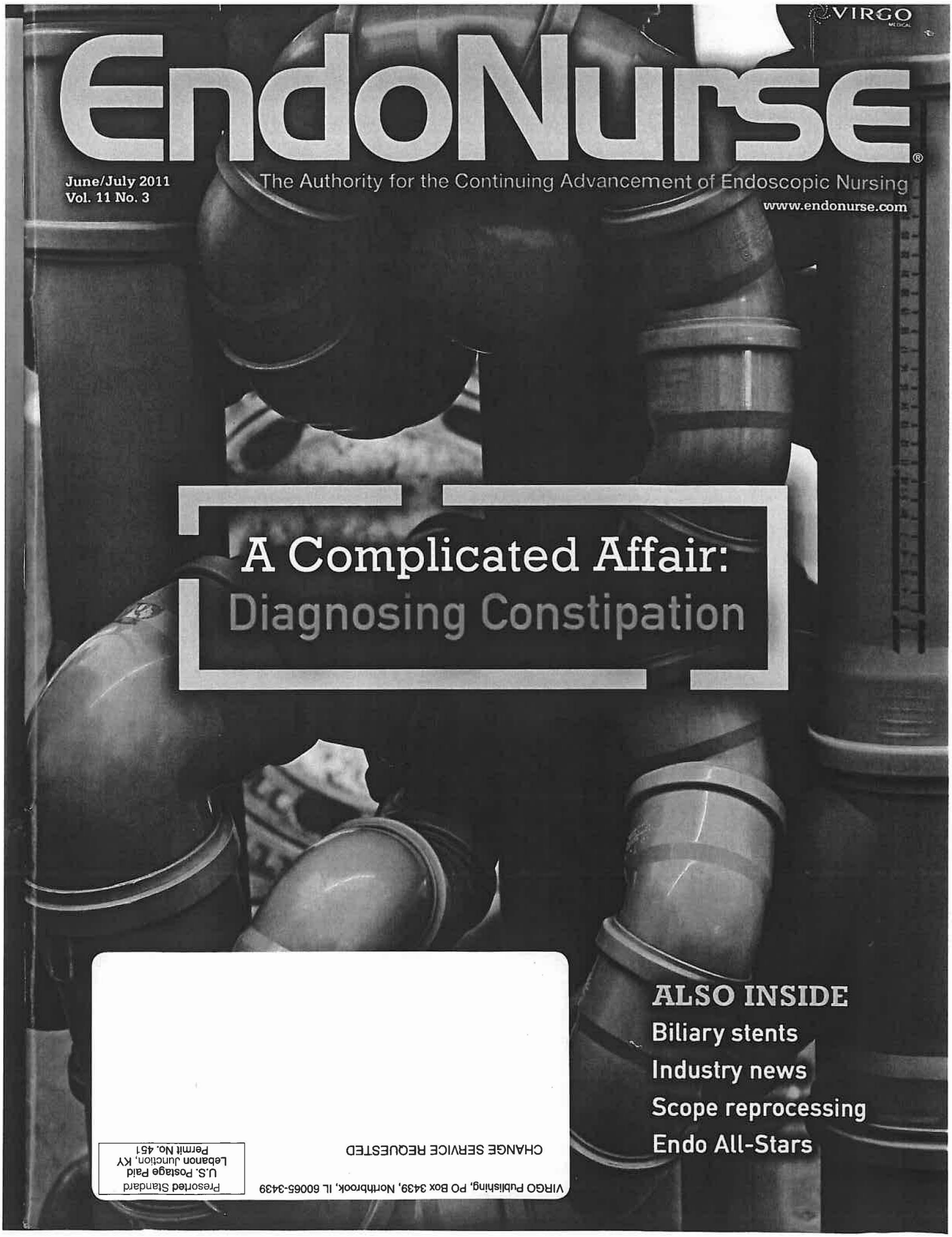

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