

Reprocessing of Medical Devices: Concerns about Sharps

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Objectives

- Historical perspective on medical device reprocessing
- Review of regulations and guidance from FDA
- Provide perspectives as they relate to the medical waste disposal industry



The Pennsylvania Hospital



The Amphitheatre served as the operating room from 1804 through 1868.
<http://www.uphs.upenn.edu/paharc/tour/tour5.html>

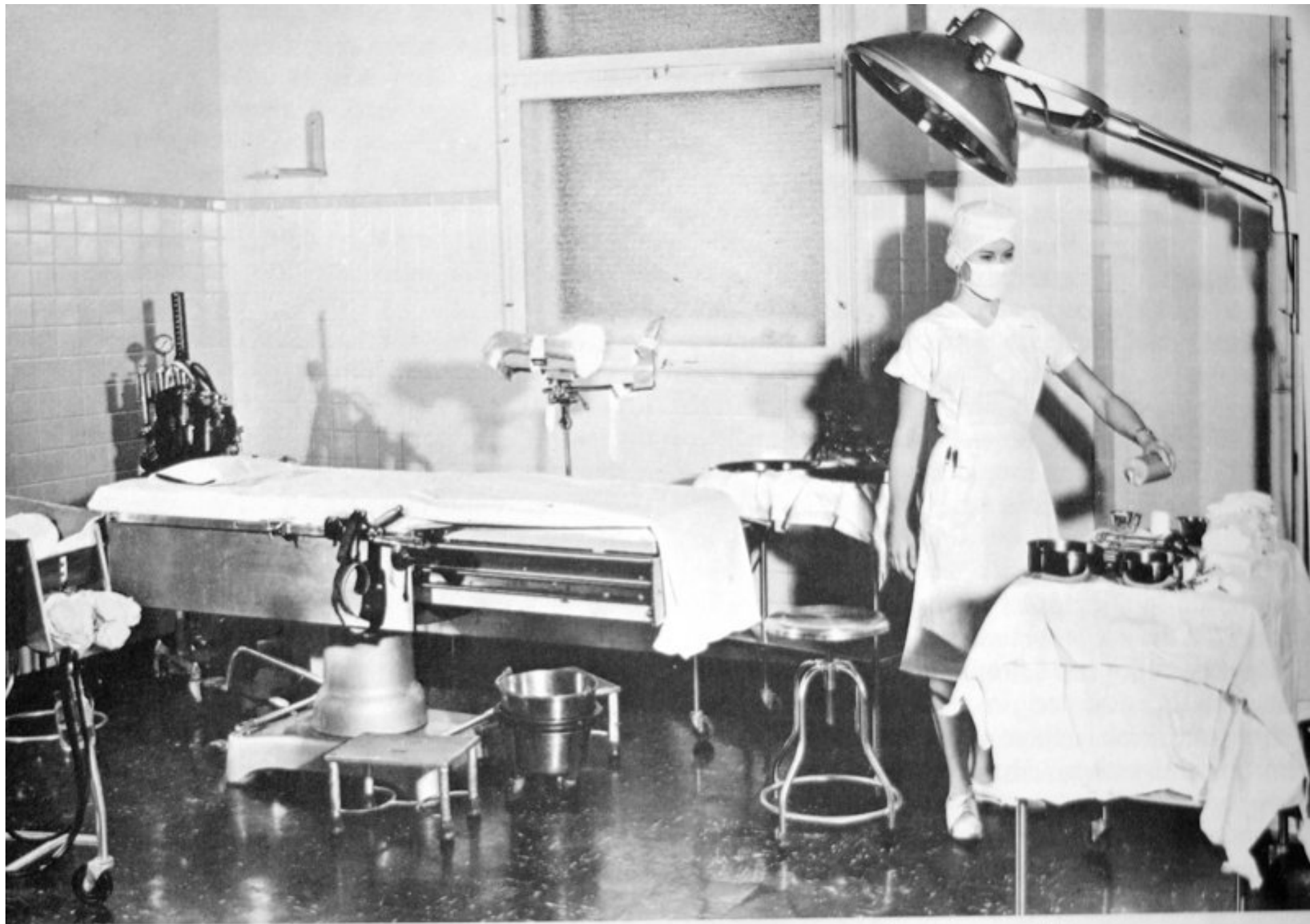


FIG. 13-10. The delivery room. Nurse is preparing instrument table.



Modern Operating Room





17th-century surgical instrument called the *Elevatorium biploidum*.

The instrument was used to raise an indented portion of the skull, as from the wound produced by the low-velocity guns of the day.



Trocar



Biopsy forceps

- **Background and history**

The practice of reprocessing single-use devices (SUDs) for reuse began in hospitals in the late 1970's. Approval of the practice of reusing hemodialyzers in the early 1980s by the US Public Health Service led the way for current activity.

- **An FDA survey of hospitals conducted in February 2002, found that 24 percent of hospitals were using at least one type of reprocessed SUD and the majority of them used "third parties" to reprocess their SUDs. The most commonly reprocessed SUDs and percent of hospitals reprocessing these devices in 2002 were:**
- **Sequential compression device (SCD) sleeves (15.8 percent of hospitals)**
- **Drill bits, saws, blades, or burrs (7.3 percent)**
- **Biopsy forceps, snares (6.2 percent)**
- **Endoscopic/laparoscopic scissors, graspers, dissectors, or clamps (6.1 percent)**
- **Electrophysiology (EP) diagnostic catheters (3.9 percent)**

Reference: <http://www.premierinc.com/quality-safety/tools-services/safety/topics/reuse/>

GAO

Report to the Committee on Oversight
and Government Reform, House of
Representatives

January 2008

REPROCESSED SINGLE-USE MEDICAL DEVICES

FDA Oversight Has
Increased, and
Available Information
Does Not Indicate
That Use Presents an
Elevated Health Risk



Regulation of Reuse of Sharps Containers

Office of Compliance
General Hospital Devices Branch
FDA

Slides courtesy of US FDA – Ms. Diane Goldsberry

The Food and Drug Administration (FDA)

Is a regulatory agency responsible for
the protection of public health

FDA Authorities

- Federal Food, Drug, and Cosmetic Act (FD&C Act) & (Implementing Regulations)
 - Inspection Authority
- Section 704 of the FD&C Act

FDA Authorities

- Federal Food, Drug, and Cosmetic Act (FD&C Act) & (Implementing Regulations)
 - Title 21, Code of Federal Regulations (21 CFR)
 - Part 820 (Quality Systems Regulations)
 - Part 803 (Medical Device Reporting)
 - Part 801 (Labeling)
 - Part 807 & 814 (Premarket Requirements)
 - Part 803 (Medical Device Reporting)

Center for Devices and Radiological Health

Responsible for regulating:

Devices, as defined in §201(h) of the Federal Food, Drug, and Cosmetic Act

Mammography Quality

All Radiological products that emit radiation

Medical Devices

Are classified into 1 of 3 Classes based upon level of regulation necessary to protect the public.

- Class I - General Controls (GC), 510(k)*
- Class II - Special Controls + GC, 510(k)
- Class III – Premarket Approval

*510(k) is a premarket notification clearance procedure, not an approval

Office of Compliance

- Office of Compliance is responsible for:

Regulatory operations

- Establishment Registration
- Device listing
- Import sampling and testing
- Automatic Detention
- Coordination with personnel from district office
- Health Hazard evaluation and recalls

Office of Device Evaluation

- Premarket Notification [510(k)] review and clearance
- Premarket Approval
- Coordinates with Office of Compliance

Office of Surveillance and Biometrics

Responsible for:

- Medical Device Reporting - (301) 594-3060
- Medwatch

Office of Health and Industry Programs

- Division of Small Manufacturers Assistance
(301)443-6597
- Human Factors

Office of Science and Technology

- Scientific testing/support
- Sample Analysis

Winchester Engineering and Analytical

- Sample Analysis

Now, let's examine CDRH's Concerns

Overall - Safety & Effectiveness

- Human Factors
- Labeling
- Quality upon delivery

Interaction with Industry

- Plant Inspections

Compliance with Quality System Regulations
domestic and foreign

- Educational efforts

- ✓ presentations at industry conferences
- ✓ publications and guidance documents
- ✓ satellite broadcasts
- ✓ video programs

Let's Talk About
Sharps
Containers and Reuse

Why Deal with this Issue?

- Same regulatory controls needed as new devices
Reprocessing IS manufacturing
- Public concern
- Protection of Public Health

Sharps Container Inspection Data

Many reprocessors are unaware that
sharps containers are classified
as medical devices

Sharps Container Inspection Data (Continued)

FDA's Findings from Inspection:

- Reprocessors lacked:
 - ✓ Written cleaning procedures
 - ✓ Validation of cleaning procedures
 - ✓ Training program
 - ✓ Specifications for cleaning and decontaminating parameters
 - ✓ Labeling on containers

Schedule of Premarket Submissions by Risk for Reuse Devices

Device Class	Submission Date
Class III	February, 2001
<i>Class II*</i>	<i>August, 2001</i>
Class I	February, 2002

* Sharps Containers are Class II devices

The Regulated Industry Needs to Comply with the Following

- Premarket submissions
- Establishment registration and device listing
- Conform to labeling requirements
- Comply with quality systems regulations

Definition of “Clean”

- FDA does not have a definition for “clean” devices
- Some states have definitions
- OSHA defines “cleaning” and decontamination

Cleaning and Decontamination

- What is the process for decontamination and cleaning?
- Coordinate with hospitals and other medical facilities to assure appropriate criteria are established and expectations met

Who Will Conduct Inspections?

- FDA for Third-Party Reprocessors
- Possibly JCAHO and some state survey agencies for hospital reprocessors
- FDA will also inspect hospital reprocessors to document possible enforcement actions when necessary

Relationship Between FDA Requirements and State Agencies that Regulate Sharps Containers

FDA has met with the following agencies concerning the public health risk associated with the reuse of Sharps containers:

OSHA

EPA

DOT

Key Elements of Quality System Regulation

What is the scope of FDA's authority to ensure that containers are cleaned before being reused?

Management Controls (21 CFR 820.20)

Design Controls (21 CFR 820.30)

Corrective and Preventative Actions

(21CFR 820.100)

Production and Process Controls

(21 CFR 820.70)

Management Controls (21 CFR 820.20)

- Management Reviews
- Quality Policy and Quality Plan
- Quality Audits and Quality System Procedures/Instructions

Design Controls (21 CFR 820.30)

- Design Plan
- Design Inputs and Outputs
- Design Verification and Validation
- Risk Analysis
- Design Revisions and Design History File

Production and Process Controls

(21 CFR 820.70)

- Verification of Processes
- Specifications
 - The new device must be defined with specifications and tolerances
 - Specifications must be verified
- Device History Records
- Validation as Necessary
- Employee Training

Corrective and Preventative Actions (21 CFR 820.100)

- Evaluations of Existing Problems: Corrective Action
- Identification of Potential Problems: Preventative Actions
- Statistical Methods
- Investigation of Failures
- Implementation and Documentation of Actions
- Effectiveness of Actions

Reusable Sharps Containers

Some of FDA's Requirements for Reusable Sharps Containers can be found in the Occupational Safety and Health Act, Section 1910.1030 Bloodborne Pathogens

Suggested Simulated-Use Testing for Reusable Sharps Containers

- Specify a reuse test for the containers
- Determine the worst case scenario
- What is the collection Schedule?

For example, assume 1 pick up per week; therefore, decontamination takes place 52 times per year

- Fill container with representative sharps

Suggested Simulated-Use Testing for Reusable Sharps Containers

- Simulate transport of the container (vibration test)
- Process and decontaminate containers according to normal process
- Visually inspect the container and note the presence of scratches, nicks, dents, cracks, discoloration, etc.

World Wide Web/CDRH homepage:

<http://www.fda.gov/cdrh/reprocessing/>

Studies from the literature

Investigation of Single-Use Versus Reusable
Infectious Waste Containers as Potential
Source of Microbial Contamination

Neely, et al

American Journal of Infection Control

February 2003 Volume 31 Number 1, p.13-17.

Study assessed the bacterial contamination of single use versus reusable medical waste containers

Findings - Reusable containers had a large concentration of microorganisms as compared to single use/cardboard containers

Authors further go on to conclude the use of the cardboard containers contributed to a reduction in nosocomial infections in patients who are compromised.

- Study limitations

Did not control or look at other cleaning issues or variables e.g. Were other areas sampled for bacterial contamination? Were other infection control practice changes also implemented?

Did not consider or stratify patient severity before or after changes in practices

Bacterial and viral contamination of reusable sharps containers in a community hospital setting

Jack C. Runner, MBA, MT(ASCP), SM(AAM)
Sandusky, Ohio

American Journal of Infection Control

October 2007 Volume 35 Number 8, p. 527-
530

Table 2. Bacteria isolated from reprocessed sharps containers

Isolate	Number of containers positive for isolate	Percentage of containers positive for isolate
<i>Bacillus</i> species	24	80%
<i>Acinetobacter lwoffii</i>	2	6.6%
<i>Enterobacter agglomerans</i>	2	6.6%
<i>Acinetobacter baumannii</i>	1	3.3%
<i>Escherichia vulneris</i>	1	3.3%
<i>Staphylococcus epidermidis</i>	1	3.3%
<i>Staphylococcus hominis</i>	1	3.3%

Bacterial and viral contamination of reusable sharps containers in a community hospital setting

Runner, *American Journal of Infection Control* October 2007 Volume 35 Number 8, p. 527-530

Table 3. Viruses isolated from reprocessed sharps containers

Virus	Number of containers positive for virus	Percentage of containers positive for virus
HCV	4	13.3%
HIV	3	10%
HAV	2	6.7%
HBV	2	6.7%

Bacterial and viral contamination of reusable sharps containers in a community hospital setting

Runner, *American Journal of Infection Control* October 2007 Volume 35 Number 8, p. 527-530

- **Study limitations**

- **One swab used to samples interior and exterior of container - difficult to differentiate where actual contamination is located (interior or exterior of the container)**
- **One location**
- **PCR testing does not differentiate live and dead agents; it merely provides DNA evidence that an agent is present. Consequently, in the case in which viability is important and the ability to grow samples in culture becomes important, the choice of sampling and preservation methods is crucial.**

Conclusions

- Standards and guidance exist for the reprocessing of medical devices
- Data is still being collected on the impact of SUDS
- Similar standards and guidance exists for reusable sharps containers
- Limited published data on the efficacy and impact of cleaning that would suggest issues with the existing approach

Thank you!

