Implementing a Successful Reprocessing Program at an Ortho Spine Center

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Key Market Statistics

Reprocessing Market (National)

• $2+ Billion Dollar Annual Savings Opportunity
• $400 Million Dollars in Annual Savings
• 15% Annual Growth in Reprocessing
• 16 U.S. News & World Report Top Twenty Hospitals Reprocess
• 3,000 Hospitals Reprocessing Today
• 1,000 are only “Donating” or “Recycling”
• 1,500 ASCs Reprocessing Today
• 70 Million Reprocessed Devices Used Nationally
• 10 Million Pounds of Waste Reduced Nationally

• Opportunity: $15 - $25k Savings per Operating Room
Background

• Skyrocketing health care costs
• Complaints about infections/injuries/deaths to patients due to reuse of single use devices processed in HCFs
• Instances of health care workers forced to reprocess or lose their jobs
• 1999 Congress became involved due to family member who died from HCF reused device.
Background

• The idea of reusing a medical device is not a new one.
• Years ago, reuse was rampant.
• Medical devices were made from durable materials like glass, rubber and metal.
• When reprocessed (i.e. probes and surgical instruments) involved little more than hand wiping, dipping and soaking in a disinfectant and/or sterilization.
Background

• Market demand and new material developed into SUD industry
• The practice of reprocessing SUDs expanded when an increasing number of hospitals decided that reuse was a cost-saving measure and when the amount of medical waste generated by disposable devices became noticeable (e.g. cardiac catheters).
Between August 1996 and December 1999, FDA’s Medical Device Reporting (MDR) system documented 245 adverse events associated with the reuse of SUDs.

- 7 deaths
- 72 injuries
- 147 malfunctions
- And 19 “other” incidents, as reported by manufacturers.
Background

• The reports listed 70 different types of products, but FDA could not discern a pattern of failures with reused SUDs that differs from those observed with their initial use.
Background

- Resulted in Congress granting FDA over $1m to investigate reuse issue
- Local meetings held throughout US
- Most HCFs denied reuse
- No one tracking injuries/deaths – did not want to report them
- Resulted in August 2000 Enforcement Priorities for Reuse of Single Use Devices
Background

- Under regulation, any hospital or company that reprocessors SUDs must register with the FDA and comply with GMPs
- Many HCFs still look at reuse as a lower standard of care for patients
- Not Convinced it is safe and efficacious
The Facts

- MDR industry in existence for over 20 years
- Over 30 million devices have been re-processed
- As a new industry under continual scrutiny of federal, stat and local organizations
- Many articles about MDR but most written by OEMs; are one-sided
The Facts

• All HCFs must examine cost savings initiatives that can
  • Maintain quality patient outcomes
  • Save the facility money
• Medical Device Reprocessing is on solution
• Usual cost is ½ of the cost of a new device
The Facts

- Need to understand the science behind the process
  - Facts, not fiction
- What is MDR?
  - Identify specific, durable, single use items that fit well-defined criteria
  - Re-processing of the items to the substantial equivalent of an OEM is the charge of the MDR
The Facts

• Unless the device is “re-manufactured” to the specifications of the OEM the device cannot be re-processed
  • HCFA has agreed that a re-processed device can be charged to the patient the same amount as a new device
• A reputable MDR will select specific devices to reprocess
The Facts

• Devices selected should be based upon
  • Materials used in manufacturing
  • Function
  • Ability to clean device
  • Ability to sterilize
  • Economic benefit to the HCF
Commonly Reprocessed Devices

- Surgical Saw Blade
- Surgical Drill
- Surgical Stapler
- Laparoscopy Scissors
- Orthodontic (metal) Braces
- Electrosurgical Electrodes and Pencils
- Surgical Gown
- Endotracheal Tube
- Balloon Angioplasty Catheter
- Biopsy Forceps
- Umbilical Scissors
- Gas Mask
- Ophthalmic Knife
- Irrigating Syringe
Steps in the MDR Process

- Cleaning
- Inspection (100%)
- Testing (100%)
- Packaging
- Sterilization
FDA Regulations

- The August 2000 FDA regulations requires that both third party MDRs and hospitals would be subject to the same requirements as the OEM.
- June 26, 2003, MD User Fee and Modernization Act (MDUFMA) established requirements that hold the reprocessing manufacturer to more stringent requirement than the OEM.
FDA Classifications

- Based on device’s ability to function correctly; safety of device and potential to cause infection
- Class III – highest risk
- Class II – moderate risk
- Class I – low risk
- Classification constantly changing
Requirements

MDRs are already in compliance with the following
• Registration and listing
• Medical device reporting
• Medical device tracking
• Medical Device corrections and removal
• Quality systems regulations
• Device labeling
FDA

• FDA state that reprocessed medical devices are to be viewed no differently from the OEMs
FACT or FICTION?

- Manufacturers label some medical devices “single use” because these devices are unsafe for more than one use…
FICTION
FDA

• FDA has no labeling requirements regarding number of times a device can be used
• “Single use only” term was developed by OEMs on products deemed disposable
• Objection to reprocessing is not on the part of the FDA but of the OEMs
  • Cheaper and faster approval process for OEM
• Original Equipment Manufacturers (OEMs) recognize that many of the devices that they have labeled “single use” can appropriately be reprocessed and used again.

• Over the last couple of decades, OEMs have changed the labels on some devices from “reusable” to “single use” without substantially changing anything about the devices.
FACT

• The General Accounting Office (GAO) and the Association of Orthopedic Surgeons have criticized OEM misuse of the “single use” label.
Joint Commission

• JC not opposed to re-processed devices
• Does require specific policies and procedures for this practice
• Policies must exist whether the HCF chooses a third party MDR or if the facility performs its own re-processing of SUDs
Informed Consent

- Informed consent does not apply to re-processed SUDs
- Relates to a physician sufficiently informing a patient of all procedural risks or treatment risks
- Physicians do not inform patients about products used
- Instruments and medical supplies also based upon physician/facility preferences
JC and FDA

- JC defers to the FDA on issues of regulation and MDR
- FDA does not require informed consent
- FDA views re-processed devices as equivalent to the OEMs product
  - Therefore, no additional risk to the patient and no ethical obligation to require informed consent
Joint Commission

• JC has shown that accreditation will not be adversely affected if a hospital reuses SUDs that are re-manufactured according to regulations.
Competencies for MDR

- Two most critical core competencies are cleaning and testing
- Bioburden – amount of microbial contamination on a specific item
- Protocols developed for every specific item with proprietary methodologies and detergents developed for each device
- Proper cleaning impacts on sterilization
Competencies for MDR

- MDR must identify composition of device, its use, function and then methods to reduce the bioburden to a minimum level
- Steps involved in cleaning can include
  - Manual cleaning/rinsing
  - Soaking in enzymatic detergent
  - Sonication/cavitation/pasteurization
  - Mechanical cleaning, drying, visual inspection
Testing

• MDR must develop functional testing for all devices re-processed
• MDR assures that re-processing does not substantially alter the material components, measurements or electrical readings (if applicable)
• Every item must meet stringent criteria for functional performance.
Testing

- Rejection rate per products and manufacturer are compiled and included in reports
- As opposed to OEMs production standards, every re-processed medical device is 100% inspected and tested for functional performance.
Packaging

• Re-processed medical devices are packaged consistent with the OEMs packaging

• Labeling of package includes
  • OEMs name
  • Description of device
  • Catalog #
  • MDR’s name
Monitoring and Recall Procedures

- Each re-processed device is marked with a unique identifying number.
- Provides a history of each device including:
  - All steps throughout the re-processing process
  - Collection site (HCF)
  - Job control #
  - # of time the item has been re-processed
Recalls and Monitoring

- Numbering system facilitates monitoring durability per product and manufacturer
- Recall procedures are similar to OEMs
  - Hospital notified
  - Product removed
  - Product examined and required to proceed through the QA process
Collection of Devices

- FDA approved collection container used
- Collects and contains invasive medical products
- Strategic locations of containers maximizes compliance and savings
- Causes minimal interruption to existing work flow processes.
Medical Device Reporting

• In a congressional hearing (Feb. 2000) estimated that 464 out of 3,000,000 reported adverse events could have been attributed to reuse of a SUD
  • David Feigal, CDRH

• Therefore 99.8% of reported adverse events may have occurred with OEM devices (new)
FACT or FICTION

Remanufactured medical devices fail more often than original devices, leading to more patient harm....
FICTION
FDA

- FDA analysis of adverse events related to SUDs shows that there is no “causative link between a reprocessed SUD and reported patient injury or death.”
FDA

• Hospital participants in FDA focus groups (MedSun) said that there were actually fewer performance problems with reprocessed devices than with new devices. GAO found that after review of available information, there is no indication that use of SUDs presents a greater risk to patients than use of new devices.
FACT

• Third party re-processors in the US are the only segment of the device industry actually reducing the costs associated with health care, while reducing medical waste and still providing the highest quality of medical care possible.

• The GAO report validates reprocessing as a critical tool for modern health care cost containment.
Regulation of MDR

- The FDA rigorously regulates the reprocessing industry. MDUFMA (The Medical Device User Fee and Modernization Act – 2002) subjected reprocessors to more stringent regulation than OEM’s.
- MDUFSA (The Medical Device User Fee Stabilization Act – 2005) created stipulations related to the clear labeling of all devices.
FACT

• The science of re-manufacturing SUDS indicates this practice is:
  • Safe
  • Effective
  • Cost Effective

• The main reason we have difficulty with this change in protocols is:
  • Sacred Cows
  • OEM interference
What You Need to Know

- Recognize the savings for your facility
- Investigate various MDR companies
  - Not all alike
  - Visit their facilities
  - See what their philosophy is (do they re-process everything or are they selective?)
  - Are their employees certified?
Getting Started

• While selecting a company; establish a Re-processing Committee
  • Suggest you call it a Re-Manufacturing Committee

• Get representation from
  • OR, Materials Management, Infection Control, SPD, Risk Management, QIP, other departments deemed necessary.
Why Sustainability?

• Limited renewable resource
• Need to protect the air, water and land
• Landfills overloaded with garbage including medical waste – seeps into ground water
• No on though of single use devices and their impact on the environment.
Lessons Learned

- Develop an intensive educational program for surgeons and staff
- Educate, educate, educate, early and often
- Use in-house personnel to augment MDR company
- Give factual information
Is there increased liability with Remanufactured Devices?

• No – the Food and Drug Administration applies the same standard of liability as for a new device. The remanufacturing company is the manufacturer and bears full responsibility for the safety and efficacy of the device as any OEM (Original Equipment Manufacturer).
Reprocessing is not in the Best Interest of Our Patients

- Of the top 200 hospitals in the US 69% are reprocessing using the Association of Medical Device Re-processors (AMDR) members.
Honor Roll Facilities

- John Hopkins Hospital
- Mayo Clinic
- UCLA Med Center
- Massachusetts General Hospital
- Cleveland Clinical
- Duke University Medical Center
- University of California, San Francisco
- Barnes-Jewish Hospital
- University of Michigan
- University of Washington-Seattle
- New York Presbyterian
- Brigham & Women’s
- Hospital University of Pennsylvania
- University of Chicago Hospital
- Stanford University Hospital
- University of Pittsburgh Medical Center
- Vanderbilt University
Only the OEM can Safely Reprocess a Device

• NO! Whomever is reprocessing the device must ensure that the device will be the substantive equivalent of a new device.
• The device re-processor must show documentation to the FDA that their reprocessing process will provide a safe and effective product. OEMs do not have to do this!
The Physician is Liable if a Reused Product Fails

- NO! – the OEM (or re-processor who becomes the OEM) bears full responsibility and liability for the safety and efficacy of the device.
- There is no distinction because the devices are equivalent
- There are no standard of care issues.
Testimonial

American College of Cardiology:

“When it comes to treating patients, our number one concern is patient safety. The reprocessed medical devices used in diagnosing and treating cardiac patients are in fact safe and effective.”
Testimonial

• American Academy of Orthopedic Surgeons

“It is in the best financial interest of the manufacturer to label every device for single use in order to sell more units of devices. Interestingly, even devices that have an electric motor are labeled for single use. The AAOS does not believe that any rationale exists to the labeling of such devices as “single use”.”
Testimonial - GAO

“The safety of reprocessing some types of devices has been established by well-developed clinical studies. Studies have shown both that reprocessing procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of reprocessed (single use) devices.”
Testimonial - ANA

The 2010 House of Delegates of the American Nurses Association adopted a resolution related to the safe and effective use of SUD’s in Healthcare...
It was resolved that:

• There is significant cost savings associated with the use of reprocessed devices
• There exists a significant body of research literature from peer reviewed journals supporting the safe use of SUD’s
• It is estimated that tens of thousands of tons of medical waste can be diverted from landfills using SUD’s
FACT

- Hospitals (next to the food industry) create more waste than any other industry.
- Sustainability in the healthcare environment, it is key to focus on the Operating Room.
- The OR is the center of Today’s hospitals.
Sustainability

- It is estimated that the OR generates over 42% of hospital revenue.
- The OR spends more than 50% of its budget on supply costs.
- The OR also generates between 20 and 30% of a hospital’s total waste volume.
- Sustainability initiatives are the future.
Therefore

- Most sustainability programs begin in the OR
- However, all departments can benefit
  - Cath Lab, Radiology, ER,
  - Common devices:
  - Opened, not used, pulse oximeters, outdated product (some)
Lessons Learned

- You cannot under educate
- Emphasize the safety
- We thought we educated enough then found the OEMs undermined the entire process
- Substantially reduced our potential savings (3.5 m for 9 hospitals to .5 m over one-year-2003)
Lessons Learned

- Get any resistors to visit the MDR facility early on
- Have Committee in place before any decisions are made
- Work will get out quickly so you need to work fast
- Don’t take a “try it” approach; may give a signal that the process is not safe.
Lessons Learned

• Require the MDR provide continual education
• Take advantage of the MDR’s resources to go into the OR and work with the surgeons and nurses
• Have numerous location for device pick-ups
• Some MDRs require you do pre-cleaning…why????
• Make sure the containers shipped meet DOT regulations.
Lessons Learned

- Have HCF notify MDR if they receive recall notice from OEM
- If MDR has a recall, have a system in place for immediate notification (email blast)
- Establish monthly meeting to discuss objectives, savings, issues, etc.
- Keep minutes
Important

- Document quality issues; save product and packaging if possible
- Save MDR QA report
- Keep updated record of all devices your MDR has reported to the FDA as being re-processed
- Ask for copy of their most recent GMP inspection by the FDA
Lessons Learned

• RHS has been reprocessing since 2008
• Still have physician and staff resistance
• Difficult to undo the damage from sales reps who are unhappy that they will lose business
• Be proactive not reactive!
SHOW ME THE MONEY
SHOW ME THE BENEFITS!
Conclusions

• The FDA has regulated re-use of single use devices
• Need to “get over” the bad impressions of this practice from the days when we re-processed devices
• A visit to a MDR facility will convince you how far the science has come
• Not all MDR companies are the same – do your homework.
Conclusions

• You can significantly impact on the financial savings to your facility by embracing this process
• In today’s healthcare environment, we need to explore all savings opportunities
• The time has come to change…
The End

QUESTIONS?