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SUD Reprocessing



ASCENT
HEALTHCARE SOLUTIONS

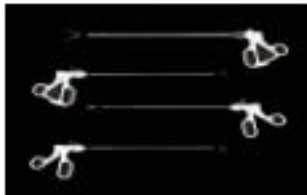
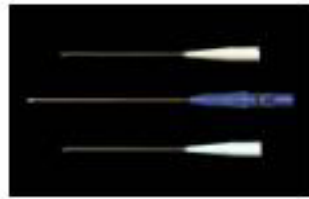
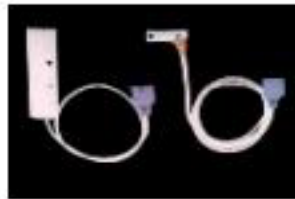
Strategic Supply Cost Management



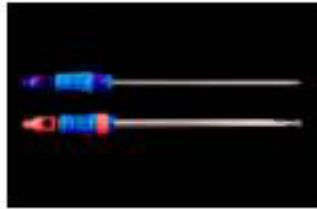
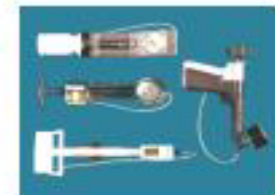
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Reprocessing Devices Labeled as “Single-Use” (SUDs)



\$1B+ Available Annual Supply Savings



Sample 250 Bed & 10 OR Facility



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Reprocessible SUDs

- Few SUDs are suitable for reprocessing (2-5%)

Devices	Unit Savings
EP Catheters	\$50 - \$600+
AcuNav Caths	\$1,600+
OPCAB	\$700+
Lap Devices	\$75+
Ultrasonic Scalpels	\$225+
Pulse Ox	\$5+
External Fixation	\$50 – 500+
DVT Sleeves	\$20+

Reprocessing Defined

- To provide the cleaning, remanufacturing, functional verification, packaging and sterilization of medical devices, specifically labeled and marketed as “single-use” by the original manufacturer.

Single-Use Device (SUD) Labels

- Not all devices labeled as “Single-Use” are limited to one use, but they are “Limited-Use.”
- The label is determined by the manufacturer, not FDA:
 - Perceived limitation of Liability
 - Reduced scrutiny by FDA
 - Increased sales & profits



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Reprocessing is FDA Regulated

- 1999 – General Accounting Office report:
“Little Available Evidence of Harm but Oversight Warranted”
 - Some SUDs can be safely reprocessed, but FDA must regulate the practice
- 2000 – FDA issued a formal restatement of current law;
 - Guidance Doc. initiated “general controls” on all reprocessors
- 2001 – FDA began requiring premarket submissions
- 2002 – Congress passed MDUFMA
 - Implemented reprocessing labeling requirements
 - Authorized FDA to require pre-production validation data
- 2005 – Congress passed MDUFSA
 - Modified device labeling requirements

SUD Quality & Safety

- FDA QSR Compliant
- 72 FDA Cleared 510(k)s
 - 3 add'l pending
 - 10+ add'l filings in '06
- ISO 13485:2003 Certified



Use of Reprocessed SUDs

- FDA Commissioned Survey – 2002
 - Approximately 50% of hospitals reprocess (250+ beds)
 - 84% use 3rd party reprocessor
- 2004 Follow-up Survey
 - 80+% of hospitals use reprocessed devices
- Cost Savings
 - “Reduced supply & waste removal costs”
- Environmental Responsibility
 - “Eliminate thousands of pounds from our landfills”

Professional/Clinical Positions:

- American College of Cardiology
 - “Reprocessing is a safe practice that hospitals and physicians have relied on for more than two decades. A significant body of peer-reviewed literature demonstrates that certain devices labeled as single-use can be safely and effectively reprocessed.”
- Heart Rhythm Society (NASPE)
 - “NASPE adheres to the principle that reuse of electrophysiological catheters is a safe and cost-effective practice provided that they are meticulously cleaned, sterilized, and inspected in accordance with accepted standards of practice as specified by the FDA.”



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Reprocessable SUDs: Scientific Basis

- Clean: Must be safely & effectively cleaned
 - Based on design features
 - Based on materials
- Functional: Must function as intended by maker
 - Evaluation of “normal” use of the device
 - Suitable available tests for functionality
- Sterile: Must withstand sterilization by original means
 - Sterility assurance validated to 1.0×10^{-6}
 - Material characterizations

Do Reprocessed Devices Fail?

- No device is “fail-safe”
 - OEMs have failure acceptance rate
- Do original (new) devices fail
 - Reprocessing cannot “improve” a device
 - Reprocessing can eliminate defective devices
- Liability transferred to reprocessor
 - The reprocessor becomes the manufacturer of record
 - No additional liability over and above original device

Support Environmental Initiatives

“CHAMPION” of H2E Initiative

Waste
Elimination
Requirement by
2010:
50%



Tons
Eliminated
in
2005:
1,012

Reprocessing Can Integrate with Distribution



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Potential Reprocessing Challenges

- **Manufacturer Tactics**
 - Aggressive campaign to surgeons and staff
 - State-level legislative strategy
- **Staff Participation**
 - Value/benefits need to be clear
 - Participation in savings ideal
 - OEM tactics
- **Logistics**
 - Need expert planning and implementation by vendor
 - Ongoing support at senior level required



Reprocessing Advantages: Qualitative

- Assurance of product quality
- Outsourcing to function specialists
- Standardization driver
- Valuable supply-chain data
- Enhanced vendor management
- Unbundling of equipment & consumables

Reprocessing Advantages: Quantitative

- Unit savings from \$5 to over \$1,500 (per device)
- >50% reduction in purchases of original devices
- Facility-wide cost savings of over \$1K+ per bed annually
 - Offsets \$50K in revenue per bed @ 2% margin
- Improved cash flow
- Leverage for lower device acquisition costs

Reprocessing Business Partners



Hospital Corporation of America



> 95% of US News & World Report's "Honor Roll" Hospitals Reprocess



REMEMBER TO
REPROCESS



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