Commercial "Single-Use" Device (SUD) Reprocessing/Remanufacturing

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

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Ede

Topics To Be Covered

- Introduction to AMDR
- Overview of commercial SUD reprocessing (remanufacturing)
- European regulations
- Safety, savings, and sustainability

Introduction to AMDR

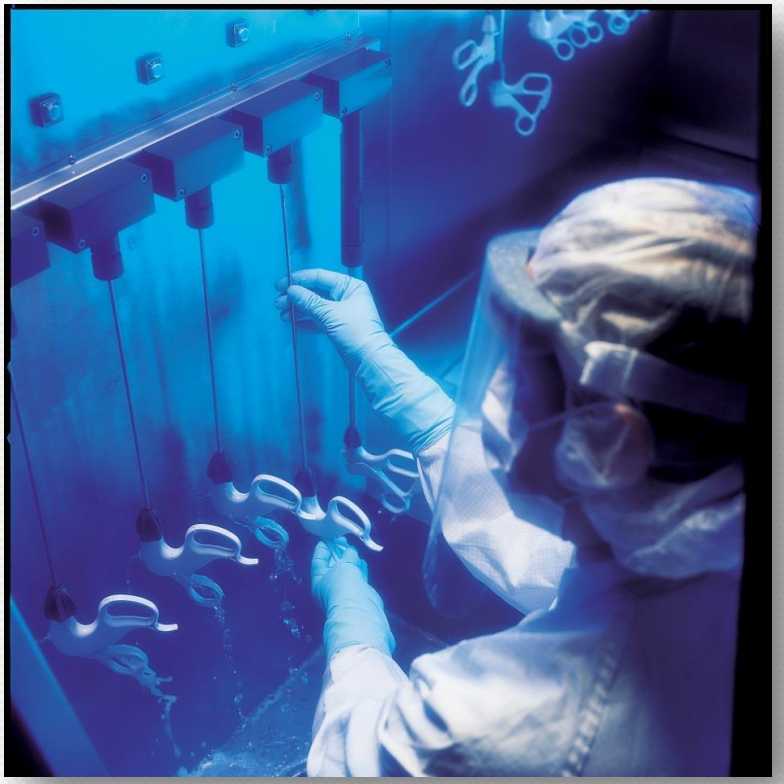
- International, non-profit, trade association formed in 1997 representing the legal, regulatory and other trade interests of commercial SUD reprocessors and remanufacturers

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

- Members reprocess for a majority of U.S. hospitals and German academic medical centers plus over 1,000 European hospitals

Commercial Reprocessing Industry Since 2000

- Regulated as device manu-facturers since 2000 in U.S.
- Regulated and accepted under quality standards and validated procedures in Germany based on device risk as set by KRINKO since 2002
- Nearly $500 million industry today
- Serve every major hospital system in the U.S. and all the “honor roll hospitals”
- Serve 95% of German University medical centers



AMDR Member-Companies

- **Hygia Health Services**
  - Birmingham, Alabama
  - Focus on Non-Invasive Devices
- **Innovative Health**
  - Scottsdale, Arizona
  - Targeted, high-impact cardiology focus
- **Medline ReNewal**
  - Redmond, Oregon
  - Part of Medline Industries, largest privately held manufacturer and distributor of healthcare supplies in U.S
- **Stryker Sustainability Solutions, Inc.**
  - Tempe and Phoenix, AZ and Lakeland, FL
  - Division of Stryker Corporation since December 2009
- **Vanguard**
  - Berlin-Germany
  - European market leader

The "Single Use" Label and How OEMs Discourage Reprocessing

- Chosen by the manufacturer
- Not a regulatory requirement (in Canada, Europe or U.S.)
- Labels switched from "reusable" to "single-use" approximately two decades ago without structural changes for many devices
- Some devices sold as "reusable" in one country and "single-use" in another
- Some OEMs included "cleaning instructions" with SUDs
- Some OEMs had/have reprocessing programs

The "Single Use" Label

"The decision to label a device as single-use or reusable rests with the manufacturer. … Thus, a device may be labeled as single-use because …the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable."[1]

1 GAO, Report to the Committee on Oversight and Government Reform, House of Representatives; *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk* (January 2008), at 1 (emphasis added).

Emergence of Commercial Reprocessing

- Historically, most reprocessing was conducted in-house at the hospital
- The third-party reprocessing industry emerged in the U.S. and Germany approximately two decades ago in response to the growing cost of healthcare, including “single-use” devices and because third-parties can reprocess more effectively
- Globally, in-hospital reuse of SUDs is common

Safety Principles

- All commercially reprocessed devices meet cleaning/biocompatibility, performance and sterility specifications and requirements
- Complies with medical device manufacturer standards
- AMDR safety principles, include, among others:
  - 100% device testing and inspection
  - 100% device traceability
  - Commitment to reprocess only those devices that can safely be reprocessed

Commonly Reprocessed Devices

Commonly Reprocessed Devices

- **Arthroscopic/Orthopedic**
  - External fixation devices
  - Surgical saw blades, bits and burrs
- **Cardiovascular**
  - Sequential Compression Devices/Tourniquet cuffs
  - Pulse oximeter sensors
  - Femoral compression devices
  - Ultrasonic and electrophysiological diagnostic catheters
- **Non-Invasive Devices**
  - ECG leads
  - Air transfer mattresses
  - Blood pressure cuffs
  - Fall alarms
  - Pulse OX and cerebral and somatic sensors
- **Laparoscopic Surgery**
  - Trocars
  - Harmonic scalpels
  - Lap instruments: babcocks, dissectors, scissors/shears, graspers

Commonly Reprocessed Devices & Cost Savings

U.S. Dollars:

Ultrasound cardiac catheter:
- Cost new $2500 (each)
- Cost reprocessed $1250
- Savings $1250

EP diagnostic catheter:
- Cost new $400-600 (each)
- Cost reprocessed $200-300
- Savings $200-300

Harmonic scalpel:
- Cost new $250-500 (each)
- Cost reprocessed $125-250
- Savings $125-250

Euros:

Cardiac ablation catheter:
- Cost new 900-1500€ (each)
- Cost reprocessed 400-750€
- Savings 500-750€

EP diagnostic catheter:
- Cost new 300-500€ (each)
- Cost reprocessed 140-250€
- Savings 160-250€

Harmonic scalpel:
- Cost new 350-450€ (each)
- Cost reprocessed 180-220€
- Savings 170-230€

Reprocessing Procedure Overview

Reprocessing Procedure

Initial receipt and sort:

- All orders are ticketed to assure order content integrity
- Remove rejects, heavily soiled items, and unapproved products

Reprocessing Procedure

Cleaning:

- Array of automated cleaning equipment augments manual processes
- Customized/proprietary device disassembly and cleaning equipment used
- All protocols are device-specific

Reprocessing Procedure

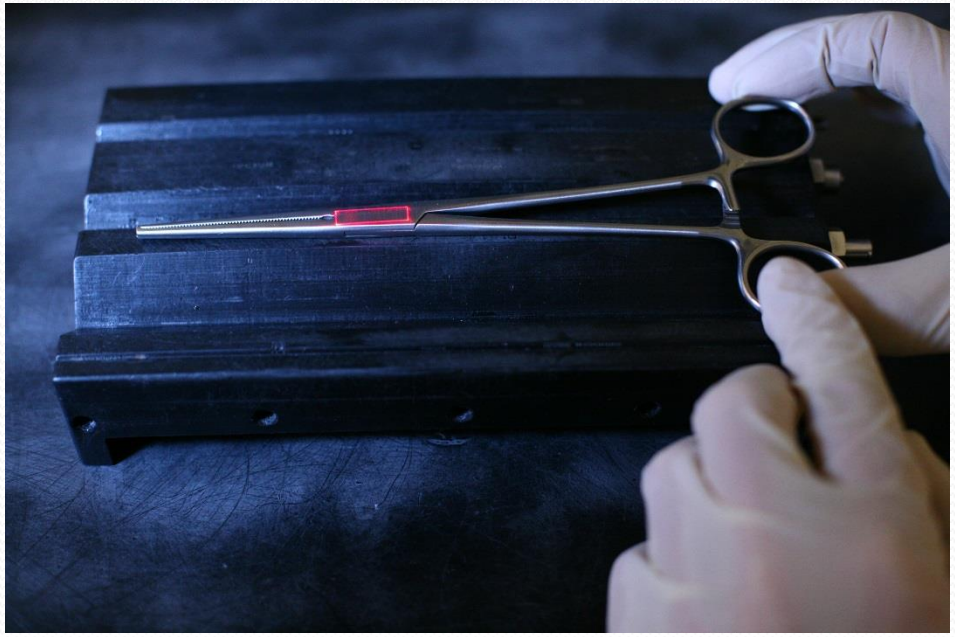
Cleaning continued:

- Ultrasonics
- Vacuum desiccation
- Hydraulic flushing
- Motorized scrubbing

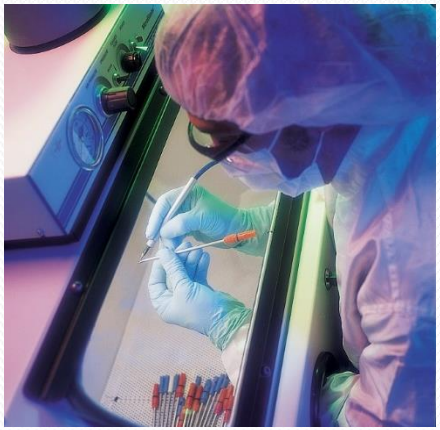
Reprocessing Procedure

Data entry and cycle marking:

- Each device is identified and coded with a distinct mark
- Number of reprocessing cycles indicated

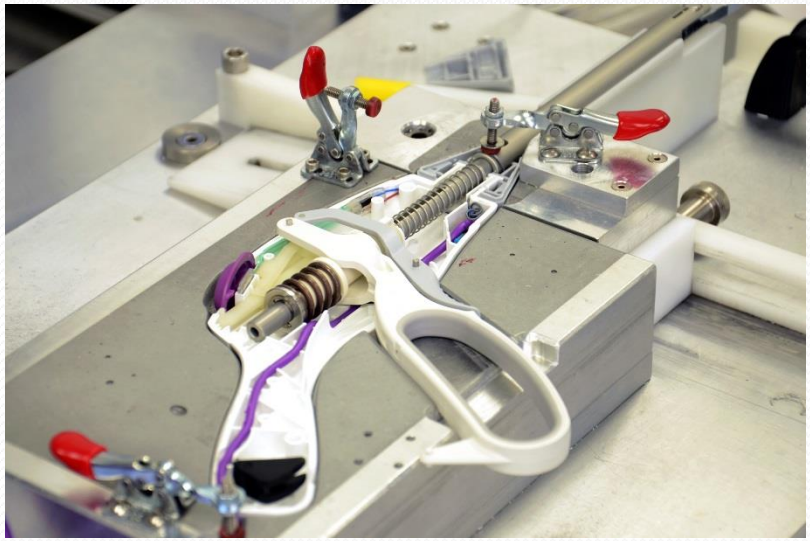


Reprocessing Procedure

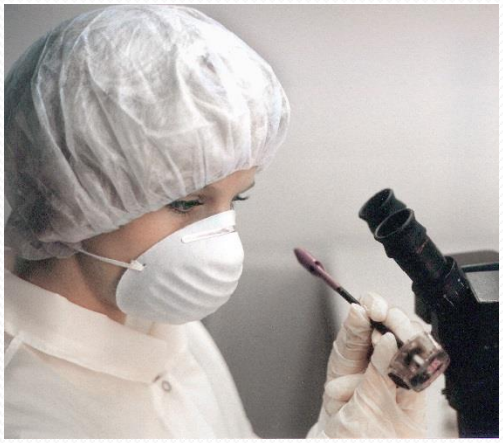


Refurbishment/Restoring:

- Computer-controlled Sharpening and honing of shavers/blades
- Blades sharpened
- Replace components, i.e., sheathing



Reprocessing Procedure



100 % device testing/inspection:

- Confirms that devices:
  - Meeting cleaning requirements
  - Are free of defects
  - Conform to specifications
- Inspectors are trained and audited for each device
- OEMs test only a sampling of new devices, but every reprocessed medical device is safety and quality tested

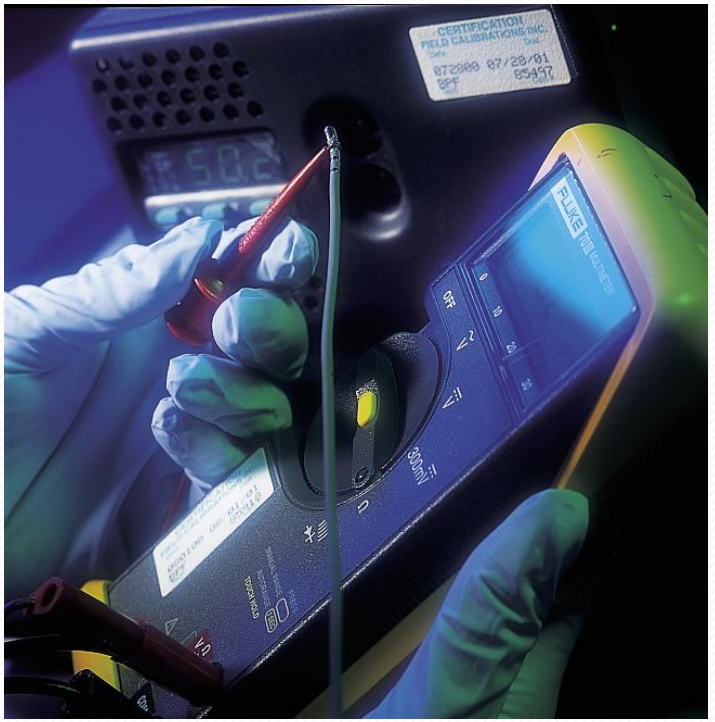
Reprocessing Procedure

Mechanical Tests:

- Sharpness
- Spring actuation
- Pressure test of seals

Electrical:

- Sensor fluctuation
- Insulation
- Image
- Diagnostics



Reprocessing Procedure

Sterilization:

- Ethlene Oxide Gas (EtO)
- SAL of 10^{-6}
- AAMI/ANSI/ISO 11135
- EO Residuals ISO 10993-7/TIR 19

European Regulations

Current European Landscape

- Historically, no SUD reprocessing policy has existed at the European Union level
- Member States regulate on an individual basis
- SUD reprocessing likely occurring in hospitals across all Member States, regardless of national policy
- Regulated, third-party industry exists in Germany

Other Member States' Regulations

- Germany: Legal and regulated
- UK: in-house reprocessing discouraged, CE marked re-manufacturing allowed
- France: illegal
- Portugal: has strict guidelines which allow
- Most other Member States: no position
- Note: AMDR has evidence that the reuse of SUDs is common in Europe, even in countries where the practice is banned and/or discouraged

European Regulations… Council/Parliament Version

- 17.1 – Where permitted by national law
- 17.2 SUD reprocessing is manufacturing
- 17.3 – MS may decide NOT to apply certain rules to reprocessing (for hospital and closed loop reprocessing) and outlines lengthy requirements
- 17.4- Reprocessing by service provider allowed
- 17.5 – Common specifications to be developed
- 17.6 – Only devices put on EU market
- 17.7 – Only safe reprocessing
- 17.8 – Reprocessor must label with their name

What does this mean?

- Unfortunately, not the harmonized approach AMDR had sought
- "Opt in" undermines the "single market"
- Stricter requirements for SUD reprocessors = higher regulatory burden than OEM devices
- MS "service" model:
  - Likely applicable only to Germany which has existing requirements
  - MDR requirements still exceed what hospitals can likely meet: Notified Body certification, reverse engineering, quality system, plus forthcoming common specifications, etc.
  - AMDR discourages other MS from allowing in-hospital, lesser regulated reprocessing

Dutch Policy

- Current: Not allowed, exceptions
- Future: hospital reprocessing or third party?
- Considerations: fairness to patients, healthcare providers, competitors (OEM and reprocessors)
- AMDR urges one standard – CE marking for reprocessed/remanufactured SUDS (same as OEM)

UK Policy

- Prohibits SUD reprocessing
- 2016 Guidance allows SUD remanufacturing
- Remanufactured SUDs must obtain CE mark
- Consistent with EU MDR - so “opting in”

Safety

Regulated Reprocessing is Safe

- In-house (hospital) reprocessing has effectively been stopped in the US and Germany
- Nearly all SUD reprocessing conducted by regulated, third-party firms
- Very few adverse event reports
- 20+ years of clinical history
- Decades of peer-reviewed literature and clinical experience
- Support of major clinical

"we found no reason to question FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs."

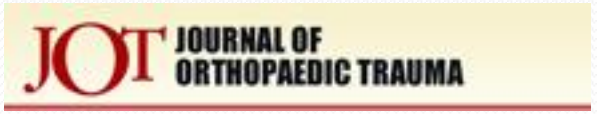
2008 US GAO Report, at 21-22.

"In January, after reviewing eight years of FDA data, the Government Accountability Office weighed in with a report concluding there is no evidence that reprocessed single-use devices create an elevated health risk for patients." –

THE WALL STREET JOURNAL

March 19, 2008, "Hospitals Reuse Medical Devices to Lower Costs."

Scientific Literature



Hospital & Clinical Community Support

Top Hospitals

AMDR members serve all of the "**Honor roll**" **hospitals** recognized by *U.S. News & World Report*

- **Barnes-Jewish Hospital/Washington University**, St. Louis
- **Brigham and Women's Hospital, Boston**
- **Cedars-Sinai Medical Center**, Los Angeles
- **Cleveland Clinic**, Cleveland
- **Duke University Hospital**, Durham
- **Hospitals of the University of Pennsylvania - Penn Presbyterian**, Philadelphia
- **Houston Methodist Hospital**, Houston
- **Johns Hopkins Hospital**, Baltimore
- **Massachusetts General Hospital**, Boston
- **Mayo Clinic**, Rochester
- **Mount Sinai Hospital**, New York
- **Northwestern Memorial Hospital**, Chicago
- **NYU Langone Medical Center**, New York
- **New York-Presbyterian University Hospital of Columbia and Cornell**, New York
- **Stanford Health Care,** Stanford
- **UCLA Medical Center**, Los Angeles
- **UCSF Medical Center**, San Francisco
- **University of Colorado Hospital,** Aurora
- **University of Michigan Hospitals and Health Centers,** Ann Arbor
- **UPMC Presbyterian,** Pittsburgh

Financial

Economic Benefits

Reprocessing Provides a Multi-Fold Benefit to Hospitals:

- **Cost:** Immediate savings using the same brands physicians have always used
  - 50% cost savings, on average, for every reprocessed device utilized
  - Covers all third-party reprocessor costs: R&D, equipment and materials, staff, etc.
  - **Typical U.S. hospital could save around USD $0.5-2 million** per year

Economic Benefits

- **Disposal Cost Reduction:** Immediate reduction in red bag waste and associated disposal costs
- **Competition:** Hospitals that reprocess see reduced OEM pricing for new equipment and downward price pressure on other products
- **Moral high road:** Reprocessing allows hospitals to responsibly bend the cost curve, thereby extending their ability to do more with limited resources
  - Fiscally responsible
  - Environmentally sustainable

Sustainable Hospitals Help Bend the Cost Curve

"The savings achievable through sustainable interventions could exceed $5.4 billion over five years and $15 billion over 10 years."

-- Research from Commonwealth Fund, with support from Health Care Without Harm and Robert Wood Johnson Foundation

- Hospitals' cost savings by contracting with an FDA-regulated medical device reprocessor:
  - Over five years was about $57 per procedure. If adopted nationwide, cost savings would be $540 million annually, or $2.7 billion over five years."
    - Does not require any up-front hospital capital investment to get started
    - Same standard of care
    - Extend the life and value of the medical devices *already own*.

UK Research

- Department of Health research on remanufactured SUD opportunity for NHS
  - £30 mm savings per annum across NHS
  - £8.8mm from Class II and II
  - £10.8mm with class I devices
  - £1.7mm from OEM deflation
  - £9.4mm with use of spent SUDs from other CE countries
  - < £1mm avoided waste disposal costs

Environmental

Environmental Benefits

- Reprocessed SUDs are the single most impactful sustainability initiative currently undertaken by US hospitals
- American Nursing Association, Association of periOperative Registered Nurses, Practice Greenhealth and Health Care Without Harm have all recognized or endorsed reprocessing as a way to reduce waste
- Titanium, gold, platinum, steel and valuable plastics recovered/recycled instead of disposed
- Identified as a Smarter Purchasing initiative of the Healthier Hospitals

Hospital Waste Reduction

- On average, **hospitals can reduce annual medical waste by 50,000 pounds.** This is the equivalent weight of more than 5 elephants.

- Titanium, gold, platinum, steel and valuable plastics can be recovered/ recycled instead of thrown away.

Summary

- Regulated SUD remanufacturing:
  - Promotes patient safety/public health
  - Reduces healthcare costs
  - Promotes competition
  - Protects the environment
  - Levels regulatory playing field
- SUD remanufacturing is coming
- AMDR expects most of Europe will opt IN to the CE marking paradigm

Thank You

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Extra Content Slides

Legal: U.S. FDA Regulation

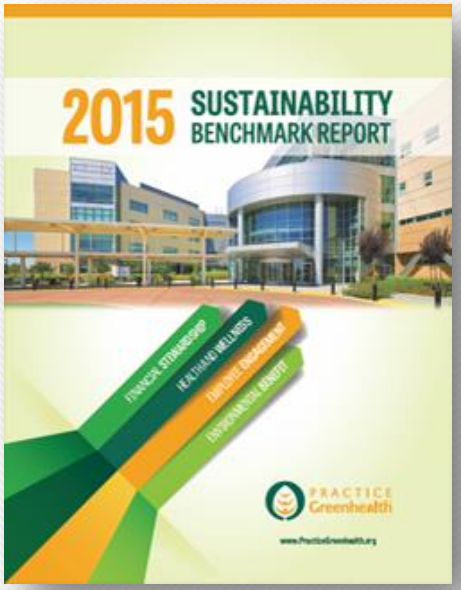
- In U.S., SUD reprocessing is legal and regulated
- All SUD reprocessing is regulated by the U.S. Food & Drug Administration (FDA)
- Reprocessors treated as manufacturers, and regulated and responsible as manufacturers
- Reprocessors must meet all manufacturer requirements, *plus* additional data and labeling requirements
- Reprocessors submit data to FDA that "exceed[s] the requirements for original manufacturers (OEMs)"

-- Dr. Daniel Schultz, Director, Center for Devices and Radiological Health, Food and Drug Administration, September 26, 2006, before Congress.

Now….European Regulations…

- Article 12a of the last Medical Device Directive recast (2007), the Parliament and Council explicitly instructed the Commission to develop a report by September 2010 on the "reprocessing of medical devices in the Community"
- Proposal for SUD reprocessing included in European Commission 26/09/12 draft Regulation
- European Parliament amended that proposal in 09/10/13
- European Council adopted its position 09/
- "Trialogue" agreement struck May 25
- Final ratification expected Q1/2017

Practice Greenhealth Sustainability Benchmark Report



- Activities reported by the 220 winners of Greenhealth Partner for Change, Greenhealth Emerald and Top 25 Awards in PGH's 2015 Environmental Excellence Awards Program
- 85 % of facilities implemented reprocessing collection programs and 80% purchase back
- SUD reprocessing in the OR resulted in aggregate cost-savings of $22,121,321
- SUD reprocessing (non-OR) resulted in aggregate cost-savings of another $13,347,783
- 873 tons of devices were collected for another $337,643 in savings from waste disposal costs

R&D/Design Control

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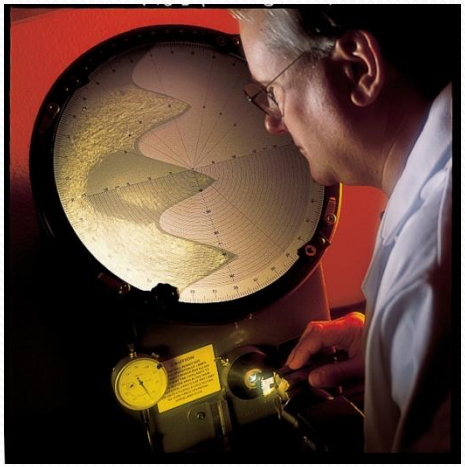
Concerns

- **Use of Re-Engineering to Prove Substantial Equivalence**
- **l Use of Re-Engineering to Provide Materials Data**
- **l Specification of Reprocessing Design Requirements**
- **l Description of Re-manufacturing Process instead of Manufacturing Process**
- **l Re-Manufacturing Process Validation, Including Additional Functional Testing**
- **l Stated Number and Evidence Regarding Maximum Number of Cycle Times**
- **l Native Device Testing**
- **l Description of Cleaning Process**
- **l Cleaning Process Validation**
- **l Augmented Risk Assessment to Account for Re-manufacturing Risks**
- **l Replacement Parts / Components Description and Material**
- **l Modifications to Labeling and Tracking Procedures**
- **l Assessment of OEM Design Changes**

Developing a Reuse Procedure

Premarket research:

- Reverse engineering
- Destructive testing
- Biocompatibility
- Cleaning and process validation
- Endotoxin analysis
- Function testing parameters



Design Inputs: Validating a Device for Reuse

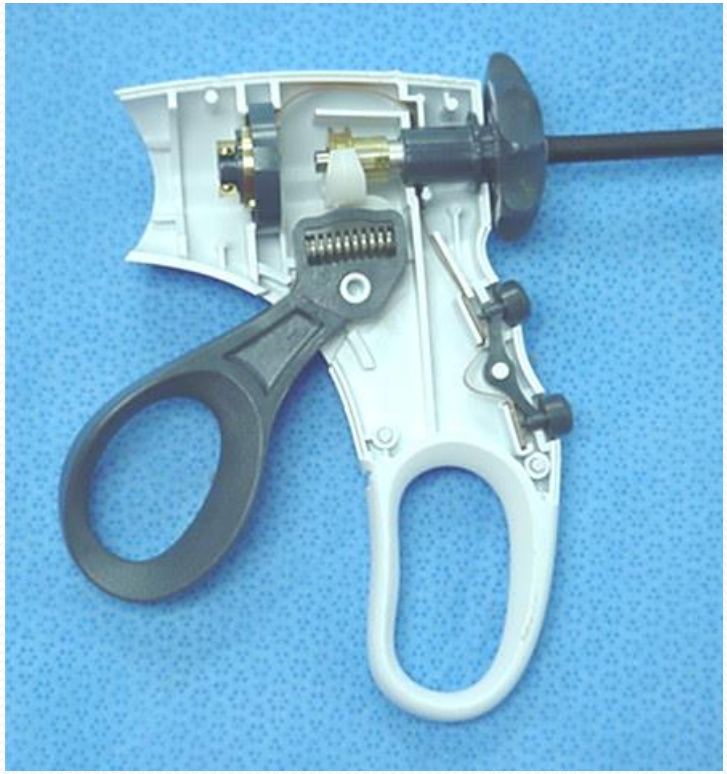
- Is the device similar to others currently reprocessed
  - Evaluate materials of construction
  - Research sterilization methods
  - Evaluate packaging concerns
  - Identify performance characteristics
  - Identify packaging configuration

Validating Devices for Reuse

- Native Soil Characterization
  - Test clinically used devices for existing soil levels prior to cleaning.
  - Establish baseline soiling parameters.
  - Develop soiling (inoculation) procedure unique to each device.
  - Evaluation of “native” devices and assessment of qualitative (visual) and quantitative (extractions for protein, Hb, bioburden, etc.) contamination.

Design Control: Analyzing Functional Performance

- Performance:
  - Reverse Engineering - The process of analyzing a medical device to identify its critical components and their interrelationships in order to better understand function and establish performance specifications
  - OEM Benchmarking – Defining and establishing functional substantial equivalence.
    - Establish pass/fail criteria
    - Mechanical and electrical properties
    - Penetration, Grasping, Cutting Forces



Design Control: Building Device Profile

- Disassembly / Reassembly Methodology
  - Customized fixtures for device disassembly and reassembly, where applicable
- Drawings
  - Product geometry / Surface area calculations
  - Testing fixtures
  - Replacement parts
- Goals:
  - Establish tolerance/dimensions
  - Fixture integration
  - Internal components

Design Control: Process Development

- Cleaning Process Development
  - Chemical identification
  - Process parameters (dwell time, temperature, chemical concentration)
  - Customized cleaning fixtures
- In-line Visual Inspection
  - Cleaning efficacy
  - Proper assembly
  - Structural integrity

Design Control: Process Development

- Performance
  - In-line Function Testing
    - Development of most appropriate in-line functional testing to produce safe and effective product.
      - Electrical Testing
      - Insulation Testing
      - Dye Penetration Testing (Ultrasonic Scalpels)
      - Cannula-Seal Leak Testing (Trocars)

- Packaging & Labeling
  - Development of most appropriate packaging to produce safe and effective product to the customer.
  - Development of labeling that is substantially equivalent to OEM labeling.

Design Control: Verify Biocompatibility

- Identify any biologic hazards the device has as a result of reprocessing.
- Biocompatibility testing follows the recommendations made in ANSI/AAMI/ISO 10993-1.
  - Categorization by nature of body contact and surface contact type
    - Non-contact device
    - Surface-contacting devices
    - External communicating devices
  - Categorization by duration of contact
    - Limited exposure: use likely ≤ 24h
    - Prolonged exposure: use likely > 24h, < 30 days
- Most common evaluation tests based on device types
  - Cytotoxicity
  - Sensitization
  - Irritation
- Devices are prepared under “worst-case” processing parameters (elevated temperatures, chemical concentration, exposure time); sterilized

Design Transfer: Validations

- Validation of Processes
  - Cleaning, Performance (Functionality), Packaging
- Evaluation of Worst-Case Processing Parameters
- Reference:
  - Guideline on General Principles of Process Validation, May 1987 – U.S. Food and Drug Administration, Center for Drug Evaluation and Research

Design Transfer: Sterilization Evaluations

- Ethylene Oxide Residual Evaluation
  - Ensure materials of construction (after reprocessing) are able to properly aerate gas under normal aeration times (ISO 10993-7)
  - Samples are prepared at nominal (routine) conditions
  - Sent to external laboratory (on dry ice)
- Comparative Resistance
  - Purpose: Demonstrate that the test device does not pose a greater sterilization challenge than the PCD used in the validation of the sterilization process.
  - Identify most challenging locations for sterilization for inoculation.
  - Exposed to EO sterilization parameters (with PCD used in validation) to identify which device is more difficult to sterilize
- Annual Sterilization Validations

Design Transfer: Cleaning Validations

- Product Inoculation
  - Simulated clinical use
  - Incubation of product (72 hrs. at 60° C)
- Annual Re-Validation of Cleaning Process
- Visible Contamination
  - Criteria must be established using visual aids
- Quantitative Cleaning Endpoints
  - Hemoglobin, Protein, Bioburden, Pyrogen, etc.

Design Transfer: Cleaning Validations

- Quantifiable Levels verified by product extractions (Laboratory Services)
- Equipment Qualification must be performed as pre-requisite
- Recommendations Found in References:
  - AAMI TIR No. 12 – 1994, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers
  - AAMI / ANSI ST35:1996, Safe handling and biological decontamination of medical devices in health care facilities and in non-clinical settings
  - AAMI TIR 30, A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices

Design Transfer: Performance Validations

- Worst-case Processing Conditions
  - Cleaning process parameters, clinical use, product inoculation, incubation, distribution simulation, thermal cycling (lowest to highest temperature extremes)
- Subsequent Device Testing
  - Function Testing using acceptance criteria derived from OEM benchmark testing.
- Equipment Qualification must be completed on equipment used as prerequisite

Design Transfer: Packaging & Stability Validations

- Worst-case Processing Conditions
  - Distribution Simulation
  - Thermal Cycling
  - Ageing (Accelerated & Real-Time)
- Pouch
  - Tensile Strength Testing
  - Dye Penetration Testing
- Subsequent Performance Verification of device functionality

U.S. Regulatory Controls

- Premarket Approval and Clearance Requirements
- Facility Registration & Listing
- Medical Device Reporting of Adverse Events
- Medical Device Tracking
- Medical Device Corrections and Removals
- Labeling Requirements
- Quality System Regulation (similar to ISO 13485)

German Regulation

- Reprocessing of SUDs is lawful
- Regulated and accepted under quality standards and validated procedures based on device risk as set by the *Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute* (KRINKO)
- No differentiation between “single use” and “reusable” devices
- Result: higher assurance for patient safety, limited number of controlled reprocessors, enormous cost-savings and waste reduction

Regulated Reprocessing is Safe

In **2011 the German Federal Government answered to a parliamentary inquiry** on the reprocessing of single-use medical devices and patient´s safety. The **Government responded** to this inquiry by stating that in **their assessment the legal provisions regulating the reprocessing of both single-use and multiple-use medical devices in Germany is adequate**. The level of patient safety concerning reprocessed medical devices is high. The *quality problems reported on by the press concerned the in house reprocessing of multiple-use medical devices by hospitals*.

http://dipbt.bundestag.de/dip21/btd/17/061/1706174.pdf

Bundesministerium für Gesundheit

Canadian Regulation

Feb. 5, 2015 Health Canada Notice following Bill C-17 (Patient Safety Legislation):

- Health Canada has authority under existing *Food and Drugs Act and Medical Devices Regulations* to regulate commercially reprocessed SUMDs
- Requirements, same as OEM, include licensing, quality system management, labelling, investigating and handling complaints, maintaining distribution records, conducting recalls, reporting incidents and informing Health Canada of any changes to license application
- By September 1, 2016 commercial reprocessors must apply for licenses and phase out non-compliant devices

Japan

- No current ban or regulation
- In-house reprocessing known to take place
- Ministry of Health, Labour and Welfare (MHLW) has formed study group. Have visited U.S. and German reprocessors and regulators
- Draft policy expected, possibly this year

Economic Benefits

Supply Chain
STRATEGIES & SOLUTIONS

Fresh Start Helps NYC Health + Hospitals Multiply its Reprocessing Savings

Reprocessing Program Benefits from CQO-Mindful Staff Education

BECKER'S ASC REVIEW

Dispelling the myth of single use device reprocessing: How this ASC saved $59k & diverted 4.7k lbs of waste

Reprocessing Market

- Global market size forecasts suggest positive increases in demand over time
- Current market growth rates reflect a strong upward trend in the global reprocessing segment

MKT Report Name	Source	Published	Geography	MKT Size (US $)	MKT Growth Rate
Medical Device Reprocessing Accelerating, 10% Penetrated	Caris & Company	2009	Global	$250 - $300M	22 – 25%
Reprocessed Medical Device Market: Global Industry Analysis, Size, Share, Growth, Trends and Forecast	Transparency Market Research	2014	Global	$782M	19%
Medical Device Cleaning & Recycling in the US	IBIS World	2012	US only	$373M	19%
US Markets for Reprocessed Devices 2013	Millenium Research Group	2014	US only	$262M	9%

Regulated Reprocessing is Safe

- In-house (hospital) reprocessing has effectively been stopped in the US and Germany
- Nearly all SUD reprocessing conducted by regulated, third-party firms
- 20+ years of clinical history
- Decades of peer-reviewed literature and clinical experience
- Very few adverse event reports

Future Challenges

- OEM contracting practices including bundling and minimum purchase requirements – minimize reprocessing savings and sustainability benefits
  - Educate
  - Pause and Review
  - Evaluate
  - Seek Support
- Forced obsolescence – sold as “technological upgrades”
  - Pause
  - Weigh the benefit