QUAD
GLOBAL ACCREDITATION AUTHORITY

Why Should an IFU Matter to You?

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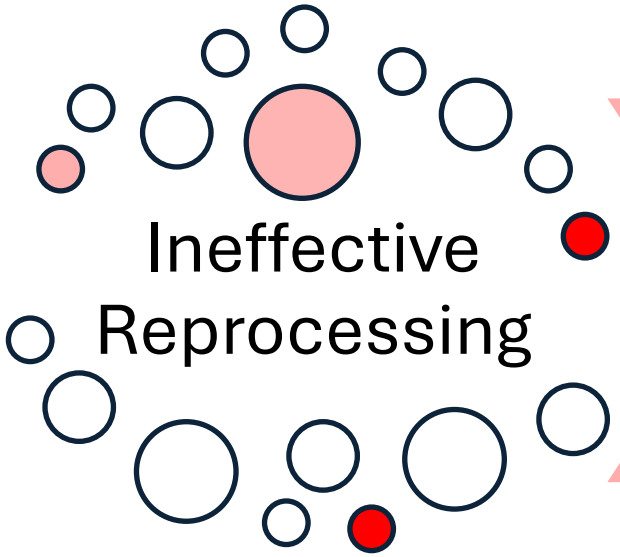
Patients First. *Always.*

Benefits of Effective Medical Device Reprocessing

- Maintains Functionality & Integrity of the Device
- Prevents Transmission of Harmful Pathogens
- Regulatory Compliance

Consequence of Non-Compliance with the Manufacturer's Instructions for Use (IFU)



Risk of Injury or Infection to the Patient

Risk of Legal, Financial, and Regulatory Penalties

WHERE DOES AN IFU FALL WHEN ASSESSING INFECTION CONTROL REQUIREMENTS?

Rules and Regulations

- Federal, State, or Local Requirements or Regulations
- OSHA, FDA, and EPA

CMS Requirements (only applicable facilities)

- Conditions of Participation and/or Conditions for Coverage

Manufacturer's Instructions for Use (IFUs)

- Reprocessing must be consistent with intended use (Spaulding Classification)

Evidence-Based Guidelines (EBGs) and National Standards

- QUAD A accreditation infection prevention standards are based on current Guidelines from the Centers for Disease Control and Prevention (National Standards)
- AORN, APIC, AAMI

Consensus Documents

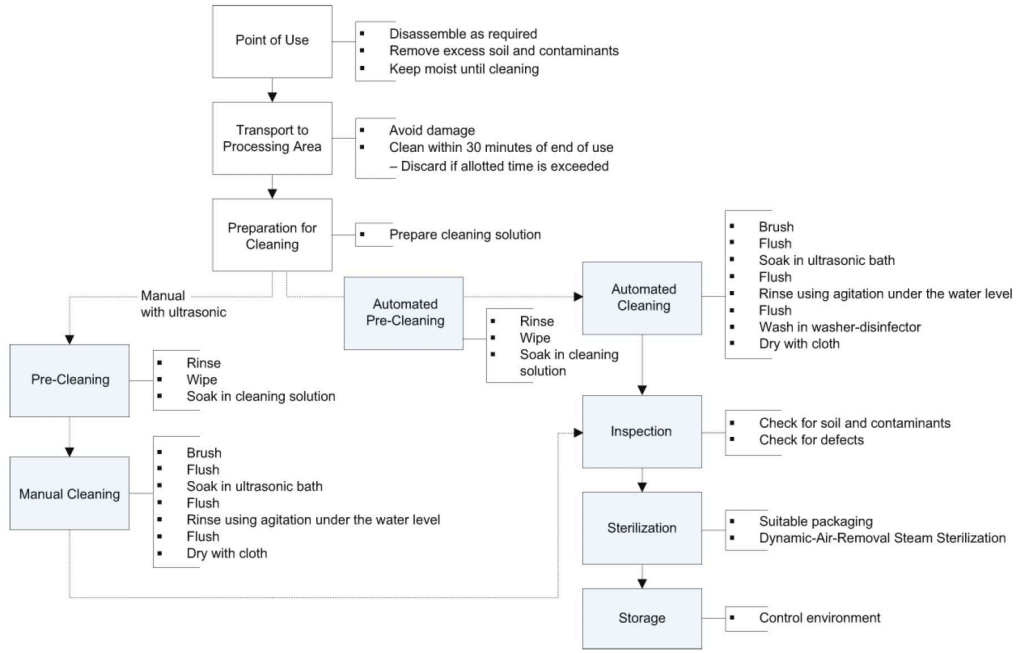
- Consulted when a requirement is not already evident based on the hierarchy
- Professional Organizations and Expert Panels

Organizational Policy & Procedures

FDA Requirements for the Manufacturer's IFU

- Product Identification (name, model, manufacturer info)
- Intended Use & User (purpose, target population, user profile)
- Safety Information (contraindications, warnings, potential adverse events)
- Usage Instructions (step-by-step procedures for set-up, use, maintenance, and when applicable, disposal)

INDICATIONS FOR USE
The MicroAire PAL Manual Wand and Cannulas are indicated for the removal of tissue or fluid from the body during general surgical procedures, including suction lipoplasty, for the purpose of aesthetic body contouring.



FDA Requirements for the Manufacturer's IFU

- Technical Details (sterilization methods when applicable, storage/handling)
- Traceability (unique device identifier, expiration dates, lot/serial #)
- Symbols & Language (concise and simple, logical flow)

6. Maintenance and Inspection

a. Using 10x-15x magnification, inspect the Wand to ensure that all visible soil and contaminants have been removed. Repeat the cleaning process if soil and contaminants are found.

b. Visually inspect for defects and wear.

NOTE: If there is concern that the functionality of the device may be compromised, please contact MicroAire.

7. Packaging

Once cleaned and inspected, wrap the dry Wand individually in a standard FDA cleared medical grade steam sterilization wrap (such as Cardinal Health® Convertors® Bio-Shield® Sterilization Wraps - supplier part #4040). The wrap Must be large enough to contain the instrument without stressing the packaging.

8. Sterilization

Dynamic-Air-Removal Steam Sterilization: full cycle with 4-minute exposure time at 132°C (270°F), 20 minute minimum heated dry time.

PAL Manual Wand Sterilization Instructions

Cycle Type	Dynamic-Air-Removal
Pulses	4
Set Point Temperature	132° C / 270° F
Exposure Time	4 minutes
Dry Time	20 minutes

9. Storage

Sterilized multi-use instruments should be stored in a dry, dust-free location with appropriate environmental controls.

IFU Will Declare Reuse Limitations

- The manufacturer must clearly designate the number of times a device can be reprocessed
  - Single-use (disposable)
  - Limitations (e.g., “may be sterilized an additional 19 times”)
  - Reusable without limitations
- Single-use items will not have cleaning instructions and will include a “DO NOT REUSE” pictogram on the device or the packaging

- Limited-use items require evidence of tracking to ensure limits are not exceeded, as device integrity is no longer guaranteed

Reviewing an IFU Before Making Purchases

- Consider a multi-disciplinary review of the IFU before purchasing
  - No IFU ≠ no purchase
  - Assess need for additional chemicals, supplies, equipment, or staff
  - Weigh costs for reprocessing versus disposable devices
- Look for comprehensive, accurate, and understandable information to ensure safe device operation and reprocessing instructions
  - Instructions are unclear → Contact the Manufacturer
  - Too complex to undertake → Should you reconsider the purchase?

Resolving Issues with the IFU

- Inconsistencies, missing information, or recommended chemical/supply not currently available → Contact Manufacturer
- Devices should not be processed if the manufacturer cannot resolve the discrepancy or provide instructions
- Adopt a strong policy requiring that any device used in the facility be cleared by the FDA for use as a medical device
- If a manufacturer cannot provide an IFU for a device, report this at Medwatch: The FDA Safety Information and Adverse Event Reporting Program

Resolving Issues with the IFU

- Deviating from the IFU is risky business because the manufacturer's IFU states that the end user should use the **validated** methods for reprocessing
- The FDA only allows facilities to verify methods, not validate methods
- When an IFU is not followed, the facility assumes **FULL RESPONSIBILITY** for the safety and efficacy of the device
- Be cautious of any rep approving a deviation from the IFU – ask for this in writing

Process for New Devices and Equipment

- Review the equipment for integrity
- Insert the IFU into the library
- Confirm all requirements in place before first use of device
    - Water type (e.g., distilled, reverse osmosis)
    - Chemicals (e.g., enzymatic detergents, disinfectants)
    - Supplies (e.g., correct type and size brushes, lint-free sponges)
    - Equipment (e.g., ultrasonic, instrument washer, compressed air)
    - Inspection devices (e.g., lighted magnifiers, borescopes)
    - Packaging
- Audit new practices to ensure compliance

Staff Training

- Ensure adequate time to review training material for complex equipment or devices with intricate cleaning protocols (e.g., powered equipment, narrow lumens)
- Schedule training from representatives when possible
- Define how competency is validated (and by whom)

Deficiencies Related to IFU Non-Compliance

- Environmental Cleaning
  - Inadequate disinfectant contact time
  - Storage of chemicals (e.g., labeling, decanting, expiration dates)
- Point-of-Care Lab Equipment
  - Wrong disinfectant used on device (e.g., blood glucose monitors)
- High-Level Disinfection
  - Inadequate manual cleaning (e.g., skipping steps)
  - Leak testing not performed
  - Testing of the minimum effective concentration in disinfecting solutions
  - Temperatures not in range per the IFU
  - Channels not sufficiently dried (e.g., 10 minutes)
  - Scopes touching in storage

Deficiencies Related to IFU Non-Compliance

- Decontamination
  - Delayed processing protocols (e.g., > 30 min)
  - Soaking times, brushes, and flushes
  - Not using the ultrasonic cleaner per the IFU
  - Not inspecting with a lighted magnifier per the IFU
- Packaging
  - Incorrect packaging per the IFU (e.g., implant sizers in peel pouches)
  - Double-pouching (folded, not validated by manufacturer)
  - Self-sealing pouches are not sealed on the seam (leaving gaps)
  - Peel pouch requires time-related sterility versus event-related sterility
  - Inadequate labeling (traceability)

Deficiencies Related to IFU Non-Compliance

- Sterilization
  - Instruments not disassembled or in the closed position
  - Packages not loaded according to the sterilizer's IFU
  - Incongruent device and sterilizer recommended cycle parameters
  - Not using the sterilizer's programmed cycle selections
  - Criteria not met for short-cycle sterilization (SCS)
    - Device, packaging, and sterilizer have IFUs for SCS
    - Containment device is validated for terminal sterilization
    - Verification by the facility if the dry time is shortened
  - IUSS of instruments not in a rigid container validated for IUSS
- IFUs not available, accessible (Standard 4-E-5)

Getting Started -Creating an IFU Library

- Audit all areas of the facility for devices and equipment
- Strategy may include creating a spreadsheet from the master inventory list
  - Name of set, device, or piece of equipment
  - Manufacturer and model number
  - Special chemicals, supplies, or equipment noted in the IFU
- Attain *current* IFUs from:
  - Insert from new purchases
  - Manufacturer's website
  - Search online (can be risky due to outdated versions)
  - An electronic IFU portal

Library Accessibility

- Store all IFUs in a centralized area or a searchable electronic repository
- Only keep current version easily accessible
- Ensure access to all staff in all areas
- Backup plan for electronic access during power loss or internet outage
  - Printed IFUs for complex equipment or critical items
- Does the facility have a process to ensure IFUs are received and reviewed before loaner sets are processed?

Sustaining IFU Compliance

- Visual cues and prompts at the point of use
- Rounding to observe current practices and identify gaps
- Staff engagement for problem-solving at the point of use
- Implement changes
- Continue monitoring until compliance is sustained

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