

Dealing With Manufacturer's Instructions for Use (IFUs)

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The Food and Drug Administration requires that medical device manufacturers provide end-users in healthcare facilities with specific instructions for use (IFU) on how to clean and sterilize their products. This information should be obtained for every device processed at the facility and maintained in a binder. (It is advisable for SPD to have two binders, one for the decontamination area and one for the preparation/packaging/sterilization area.) If a manufacturer fails to provide this information, the healthcare facility should document and report the problem using FDA's MEDWATCH program (<http://www.fda.gov/medwatch/>).

The sophistication of today's medical devices makes it critical that IFUs be obtained and available for all devices being reprocessed, regardless of how long a device has been in use. Many manufacturers regularly update their IFUs; therefore, to ensure the safety of the device, it is essential that SPD technicians have the most current information. The best approach is to obtain the IFU before a device is purchased so that it can be verified that the processing equipment and cycle parameters recommended by the device manufacturer are available at the facility.

If the device is new (has never been used in your facility before), it is important to ensure that you are in-serviced in the cleaning, disinfection, or sterilization of the device according to the IFU. Thereafter, the IFU should be required each time the device is purchased. When the device is received, the IFU should be reviewed and compared to the information on file. If the IFU has been updated, SPD personnel should be in-serviced in the changes and the new IFU dated and placed in the reference binders. If the IFU is the same as what you have on file, no action need be taken.

It is the responsibility of a designated person in SPD to obtain manufacturers' IFUs and to ensure that the most current IFU information is available for use. Manufacturers should be contacted for their IFUs at least every two years; manufacturers of orthopedic and loaner sets (e.g., spinal and total joint sets) should be contacted at least annually. This recommendation is based on the fact that manufacturers constantly update IFUs. It is recommended that a policy and procedure be established for routine review of this information. The IFU should be dated when received to document when the company should be contacted for updates.

At the time of receipt, the IFU should be reviewed to ensure the following:

- ✓ The decontamination recommendations provide for thorough cleaning and defined microbial lethality.

- ✓ The procedures can be performed in the healthcare facility using commonly available chemicals, supplies, and equipment.
- ✓ The procedures can be duplicated by healthcare personnel.
- ✓ The procedures can be easily understood by the user. (For example, diagrams and step-by-step instructions are helpful to personnel.)
- ✓ The procedures are in alignment with the recommendations of professional organizations and with OSHA regulations for minimizing occupational exposure to bloodborne pathogens (21 CFR 1910.1030).
- ✓ The instructions include a method by which users can verify effective decontamination.
- ✓ The instructions for use for the cleaning agent include the dilution/concentration that should be used, the temperature, the water quality (e.g., pH, hardness), and the exposure time (soaking or contact).
- ✓ The type and necessary quality of the water are specified (e.g., distilled water, deionized water, water treated by reverse osmosis, filtered water, hard or softened tap water).
- ✓ The type and quality of cleaning agents and cleaning accessories that should be used are specified.
- ✓ There are instructions for the handling and preparation of the device for cleaning.
- ✓ Instructions are provided for the manual or mechanical method that should be used for cleaning, rinsing, and drying.
- ✓ The time-at-temperature and water pressure parameters for mechanical cleaning equipment are specified.
- ✓ Instructions are provided for any necessary testing of function and cleanliness that should be performed after the decontamination process.
- ✓ Any necessary additives (e.g., lubricants) that should be used in reassembly are specified.
- ✓ The compatibility of packaging with device materials is described.
- ✓ Instructions are provided on the use of packaging materials commercially available to healthcare facilities.
- ✓ The compatibility of the packaging technique with existing packaging practices is described.
- ✓ The compatibility of the wrapped device with the planned sterilization process is described.

Healthcare personnel are responsible for ensuring that the cleaning, packaging, and sterilization methods recommended by the device manufacturer can be duplicated in their environment and that the manufacturer's instructions are followed correctly. Healthcare personnel should follow regular and documented preventive maintenance and calibration procedures for the equipment used in sterilization.

Some healthcare facilities use an on-line service for IFUs. However, what happens when the system is down or when power is lost? Do staff members know how to access the information? If a manual system is used (e.g., placing the IFUs in a binder), how does staff locate the information? Who reviews the IFUs to ensure that they comply with AAMI standards for minimum exposure times and temperatures? How is compliance with IFUs monitored? Noncompliance is not an option.

It is important that sterile processing professionals remember that the device manufacturer's IFU must be followed exactly as written, each and every time the device is processed. Noncompliance with IFUs creates patient safety, standard-of-care, and legal issues for the healthcare facility.

There are two important terms that sterile processing professionals need to understand: validation and user verification. AAMI TIR12 (*Designing, Testing, and Labeling Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers*) defines these terms as follows:

“Validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification. **Validation is performed by MANUFACTURERS, not end users.”**

“User verification: Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met.” (Users are facility personnel who reprocess or use the device.)

The FDA requires medical device manufacturers to validate their product label claims of reusability and to provide complete and comprehensive written instructions for cleaning, disinfection, testing, packaging, sterilization, drying, and aeration (if applicable). Although the device manufacturer is responsible for qualifying the sterilization process for the device, healthcare personnel are responsible for demonstrating that they can replicate that process exactly and consistently.

If the IFUs are not consistent with recommended sterilization protocols (e.g., the specified exposure time is less than the AAMI minimum, the cleaning instructions are insufficient or unclear), the device manufacturer should be contacted to reconcile the discrepancy. The device or set should not be processed until all discrepancies are resolved.

SPD personnel should work proactively with vendors and manufacturers of medical devices to ensure that IFUs are current and to provide training for processing personnel. Training should

- be on-site (preferred),
- be hands-on,
- provide for return demonstration, and
- provide for competency verification.

There should be a comprehensive policy and procedure for Manufacturer’s Instructions for Use so that the OR, SPD and the surgeon are all aware of the need to follow the IFUs at all times. Staff compliance with IFUs should be carefully monitored.

QUIZ: DEALING WITH MANUFACTURER’S INSTRUCTIONS FOR USE (IFUs)

Please click on the link below to take the quiz.

https://www.spdceus.com/ceus/2017/dwmifu_quiz.html

Good Luck!