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LEARNING OBJECTIVES

1. *Identify the differences in IFU based upon a medical device's FDA classification*
2. *List the components necessary to meet FDA requirements for medical device IFU*
3. *Describe two IFU challenges that exist today*

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SELF-STUDY SERIES

Making sense of your medical device IFU

by Heide Ames and Delores O'Connell

The instructions for use (IFU) that are delivered with every new medical device by the manufacturer are intended to enable safe use of the item. They are a mandatory component for the sale and use of the device because of the product's impact on patient safety. Although IFU have been a longstanding source of confusion and contention for many sterile processing departments, great strides have been made in recent years to standardize content, expand reprocessing instructions and provide actionable processing steps. Sterile processing departments often focus on the reprocessing instructions for the reusable medical devices they clean and sterilize every day, but for many of the systems, sterilization chemistries and tests they use are also medical devices with IFU. Since patient safety is the ultimate focus of all the work done in the department, it is critical for sterile processing personnel to understand and include all medical device IFU appropriately when developing their processes and procedures.

Three types of IFU

IFU provide critical information on the application and preparation of a medical device for use. In the United States, the Food and Drug Administration (FDA) regulates all medical devices, including those used in sterile processing departments. Before it can be sold in the U.S., a medical device may need to be reviewed by the FDA to determine if it is safe and effective. The extent of review depends upon the class of medical device.

1. PMA IFU

The most stringent review occurs for Class 3 medical devices, which include any medical device that sustains or supports life, is implanted within the patient, or poses a high risk of harm to the patient should it be ineffective. Examples include pacemakers, implanted prosthetics, orthopedic screws and defibrillators.

Class 3 medical devices undergo the Premarket Approval (PMA) process. A PMA is the most thorough review process, requiring extensive testing and often, clinical trials. As part of the process, the IFU is reviewed and approved by the FDA. Approval indicates that FDA supports the IFU as sufficient for the safe use of the medical device.

2. Reviewed IFU

This type of IFU is supplied with Class 2 medical devices, which present a moderate risk of harm since they are often similar to another device already being used in healthcare facilities (a predicate device). Class 2 medical devices include such items as infusion pumps, some surgical instrumentation, and biological indicators. Some Class 2 medical devices are items used in the sterile processing department to process other medical devices.

Most Class 2 medical devices undergo the 510(k) review process. This process requires submission of testing to demonstrate that the new medical device is similar to, and as safe as a medical device currently being sold in the U.S. For example, consider a company that has developed a cranial drill for a specific procedure. When the manufacturer applies to the FDA for clearance to market the new cranial drill using the 510(k) process, they predicate their new cranial drill on the safety of other cranial drills currently on the market.

Class 2 510(k) testing is typically limited to a performance comparison, and clinical trials are not usually required. The FDA confirms that all required sections have been completed and that the device is substantially equivalent to comparable products. However, for the Class 2 review process, the FDA does not approve the IFU; it only reviews them. In the past, the FDA review focused on the intended use, indications for use, warning and precautions sections. Other sections of the IFU were not a focus in the review process, but going forward, FDA has stated that it expects manufacturers to provide reprocessing validation information for the IFU, including all cleaning and microbiocidal processes dictated by the instructions for certain reusable devices.

3. Manufacturer controlled IFU

This third type of IFU applies to Class 1 medical devices, which include items such as elastic bandages and exam gloves. Devices in this category are deemed to present minimal risk to the patient and are exempted from FDA review. They have the least regulatory oversight. Manufacturers are expected to perform appropriate testing and develop IFU based on the most current recommendations, but the FDA does not review the supporting testing or the IFU. It is up to the manufacturer to ensure that appropriate measures have been taken.

Regardless of the amount of oversight provided by the FDA, all medical device IFU have specific information that must be provided. These are detailed in the FDA document "Labeling: Regulatory Requirements for Medical Devices."

FDA-required IFU content

IFU arrive at medical and dental facilities in several forms. They can be an operator's manual, a separate instruction leaflet or a user guide. They may be a single document or may have additional documents such as wall charts and reference guides. Regardless of the format, the FDA requires specific information to be provided. This includes the *name and place of business,* the *intended use, warnings and precaution statements,* and the *directions for use*.

The *name and place of business* provides valuable information beyond the obvious. The term "manufactured by" indicates that the vendor owns the design and the manufacturing process. This type of vendor has ultimate control over the medical device for they have the design, research, testing and the know-how used to make the medical device.

An IFU stating "manufactured for" indicates the design is owned by the vendor but they do not make the device. Manufacturing is performed by a third party.

An IFU stating "distributed by" indicates that the vendor neither owns the design nor the manufacturing know-how. These are often referred to as "private-labeled" distributor devices. This vendor relies on the design owner to ensure the quality and compliance of the medical device.

The IFU must also identify the *intended use*, a broad, general description of the purpose of the device. "Monitoring steam sterilizers" and "For visualization and diagnostic/therapeutic access to the adult lower gastrointestinal tract" are examples of intended use statements.

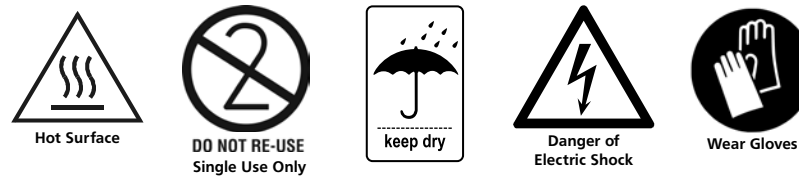
The intended use can also include or be replaced by an *indications for use* section, which provides specific information that clarifies and limits the intended use. In the following example, the first sentence represents the intended use. The following paragraph details the indications for use.

> *The [redacted] cover and [redacted] pad are intended as a microbial barrier between the patient and medical imaging electronics.*
>
> *The [redacted] cover and [redacted] pad are used, without the need for ultrasound coupling gel, in adult and pediatric patients, for diagnostic ultrasound imaging, in sterile and non-sterile fields, that currently use an ultrasound coupling gel or fluid alone or in combination with a protective transducer cover, including ultrasound guided venous access, ultrasound imaging over surgical wounds, during transcutaneous biopsy; for intraoperative, endocavity, or transcutaneous imaging procedures; or to enhance acoustic coupling to difficult geometries.*

Every IFU must identify all necessary *warnings and precautions* when using or preparing the device for use. Warnings and precautions identify harm or potential harm that can arise with the patient, user or preparer. A typical precaution warns of conditions that might cause harm. "Protect the device from heat" is an example where heat may damage the device making it inoperable. A warning is a known harm that will occur. "Hot: Handle with thermal protective gloves" is a warning to protect sterile processing technicians from burns that can occur by handling hot items from a steam sterilizer.

Warnings and precautions can also be expressed as symbols. It is critical that users understand every symbol, so a key will be included in the IFU if symbols are used. Note that similar looking symbols can have very different meanings.

Examples of Warning and Precaution Symbols:



The FDA requires *directions for use* that are adequate to assure safe use and safe preparation of the device for use. Although this has been a requirement since 1989, manufacturers' interpretations of what "preparation of a device for use" means have been highly variable. Manufacturers' IFU have posed challenges for users, such as leaving out steps to effectively clean the device or requiring processes that are not available in the U.S. To address these challenges, a new guidance document was issued in 2015 and updated in 2017. "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" defined what is needed to ensure that adequate directions for use, including thorough processing instructions, were defined and usable by U.S. healthcare facilities.

This document states, among other requirements, that manufacturers must design reusable medical devices with cleaning in mind. The cleaning process included in the IFU must be validated. Proper microbiocidal treatments, as defined by the Spaulding Classification, must also be identified (see **Table 1**). This guidance also requires manufacturers to verify that the instructions are clear and achievable by healthcare personnel with responsibility for the task at hand. In other words, vendors must demonstrate that sterile processing technicians can effectively clean and perform the appropri-

TABLE 1: Spaulding classifications and appropriate reprocessing processes.

Device Classification	Example	Microbicidal Process
Non-Critical		Low- or Intermediate-Level Disinfection
Semi-Critical		High-Level Disinfection or Sterilization
Critical		Sterilization

Self-Study Test Answers: 1. C, 2. D, 3. A, 4. A, 5. C, 6. B, 7. D, 8. A, 9. C, 10. C

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ate microbiocidal treatment using the IFU provided with the device.

Challenges still exist

The current FDA guidance has significantly helped sterile processing professionals as newer devices have entered the market. However, it has not solved all the challenges. The guidance is not retrospective, and older original 510 (k) clearances do not expire, so old devices that were cleared before implementation of this newer guidance document are not required to resubmit. Older devices may reference cleaning processes that are no longer available or sterilization processes that are not available to U.S. healthcare facilities.

The good news is, there may be ways to address these problems. Healthcare facilities with older devices may be able to get updated IFU or reprocessing instructions from the original device manufacturers, and old devices may meet the design and compatibility requirements for newer alternative processes. For example, devices requiring an extended steam sterilization cycle may be compatible with a standard vaporized hydrogen peroxide sterilization cycle.

However, old device IFU are not the only challenge. The *intended use or indications for use* of older 510(k) clearances and PMAs may be too general. Medical devices are typically grouped into categories. When a new category is first introduced, the intended use and indications for use tend to be broad and generalized. As the device becomes popular and new medical devices are cleared for similar uses, the indications for use for the newer devices become more specific. This gives the false impression that the older devices are more versatile than the newer devices.

Here's an example of how this can happen. In 1993, the first vaporized hydrogen peroxide gas plasma sterilizer was cleared for sale in the U.S., along with several monitoring accessories that were also considered to be Class 2 medical devices. These included items such as sterilization pouches, indicator tape and biological indicators. The indications for use of these accessories did not list specific sterilization cycles or sterilizer models; they simply stated, "vaporized hydrogen peroxide sterilization." Later, as new vaporized hydrogen peroxide sterilizers were cleared by the FDA, the monitoring accessories, cleared with the newer sterilizers, listed specific sterilization cycles and sterilizer models. The general intended use labeling of the older accessories cleared with the first units gave the impression that they could be used in all hydrogen peroxide sterilizers, which was not the case.

This can also be a problem even if indications for use have some specificity. In 1995, the first enzyme-based early-readout biological indicators were cleared. By 2012, the FDA had learned that healthcare facilities were using non-standard steam sterilization cycles and published new guidance around the clearance of non-standard steam sterilization cycles. In this guidance, references to non-standard sterilization cycles and the use of temperature and exposure time ranges were eliminated in favor of specific time and temperature conditions. This was reflected in the exposure time specificity change of the enzyme-based early-readout biological indicator cleared in 2012. **Table 2** illustrates the indications for use differences over time.

The increased specificity of newer clearances and approvals in product categories is a natural evolution. Healthcare facilities must be aware of this progression and ask critical questions when dealing with older product clearances and approvals. It can be helpful to include your supply chain professionals in conversations about the important role of IFU when selecting products and contracting for medical device and equipment purchases.

All IFU are important

Every day, sterile processing professionals use FDA-classified medical devices (washer-disinfectors, sterilizers, HLD systems, biological indicators, process monitoring devices) to reprocess other FDA-classified reusable medical devices. In a department with a mix of older and newer technologies, SPD managers who understand the bigger IFU picture can help ensure that their departments continue to appropriately select and safely use their medical devices. **HPN**

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Table 2: Example of increased intended use specificity

July 1995 Clearance First Enzyme-Based Early Readout-Biological Indicator	October 2012 Clearance After several enzyme-based early-readout products have been introduced
Indications for use: Use the [redacted] RRBI to monitor: 1. 250°F (121°C) gravity steam sterilization cycles 2. 270°F (132°C) vacuum-assisted steam sterilization cycles	Indications for Use: Use the [redacted] Biological Indicator [redacted] in conjunction with the [redacted] Auto-reader [redacted] to qualify or monitor dynamic-air-removal (prevacuum) steam sterilization cycles of 4 minutes at 270°F (1 32°C) and 3 minutes at 275°F (135°C). The [redacted] Biological Indicator [redacted] provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.

CONTINUING EDUCATION TEST • MARCH 2020

Making sense of your medical device IFU

Circle the one correct answer:

1. **Which medical device classification requires approval of the instructions for use (IFU) by the Food and Drug Administration (FDA)?**
   A. Class 1
   B. Class 2
   C. Class 3
   D. Class 4

2. **Which is true of Class 1 medical devices?**
   A. Class 1 medical device IFU are reviewed by the FDA
   B. Class 1 medical devices require sterilization
   C. Class 1 medical devices include pacemakers and implantable devices
   D. Class 1 medical devices have the least amount of FDA oversight

3. **What is the difference in FDA oversight between a Class 3 and Class 2 medical device?**
   A. Class 3 devices require premarket approval whereas most Class 2 devices require 510(k) clearance
   B. Class 3 device IFU are not reviewed by the FDA but Class 2 device IFU are approved
   C. Class 3 devices have the most stringent FDA process whereas Class 2 have the easiest FDA process
   D. Class 3 devices never require clinical trials whereas Class 2 devices always require clinical trials

4. **"Manufactured for" indicates that the vendor _____.**
   A. Owns the medical device design and has a third party make the medical device
   B. Makes the product but does not own the medical device design
   C. Owns the medical device design and makes the product
   D. Does not own the medical device design nor make the product

5. **Which statement included in the IFU indicates the vendor with the most control of the medical device?**
   A. Distributed by
   B. Manufactured for
   C. Manufactured by

6. **What does the intended use provide?**
   A. Gives specific information for safe use of the medical device
   B. Provides a general description of the medical device's use
   C. Gives detailed cleaning instructions
   D. Identifies the microbiocidal process to use

7. **Why is an indication for use included with an intended use?**
   A. The intended use needs to be expanded to include other uses
   B. The device is the first in an FDA device category
   C. The device has additional warning or precautions
   D. The intended use must be clarified or limited

8. **A warning is provided when a known harm will occur.**
   A. True
   B. False

9. **Why are older device IFU challenging?**
   A. Older device IFU have very limited indications for use
   B. Older device IFU often list multiple sterilization processes
   C. Older device IFU can be missing cleaning steps or reference processes not available in the U.S.
   D. Older device IFU must be updated by the device manufacturer before they can be used

10. **The intended use or indications for use of older 510(k) clearances and PMAs may be too:**
    A. Specific
    B. Detailed
    C. General
    D. None of the above

CONTINUING EDUCATION TEST SCORING

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