



IST Guidance- Terminal IUSS FLASH

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Terminal vs. Immediate Use Steam Sterilization (IUSS) vs. FLASH

Industry Definitions:

Terminal Sterilization

Multi Society Position Paper, 2011 (Page 1, Paragraph 1)

...“terminal sterilization” cycles, where instruments are sterilized within containers, wrappers, or primary packaging designed to maintain the instruments’ sterility and allow the devices to be stored for later use.

AAMI ST79 (ANSI/AAMI ST79 2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, 2.133, page 15)

Process whereby product is sterilized within its sterile barrier system.

AORN (AORN Guidelines for Perioperative Practice, 2017, Guideline for Sterilization, page 890)

A process by which the product is sterilized within a sterile barrier that permits storage for use at a later time.

CMS (CMS Ref: S&C: 14-44 Hospital/CAH/ASC, page 2)

Surgical instruments must ordinarily be sterilized using terminal sterilization cycles within rigid sterilization containers, wrappers, or primary packaging designed to maintain the instruments’ sterility and which allow the devices to be stored for later use (“terminal sterilization”).

Immediate Use Steam Sterilization

Multi Society Position Paper, 2011 (Page 1, Paragraph 3)

Immediate use is broadly defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another.”

AAMI ST79 (ANSI/AAMI ST79 2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, 2.61, page 11)

Immediate-use steam sterilization (IUSS): Process designed for the cleaning, steam sterilization, and delivery of patient care items for immediate use. Previously known as flash sterilization.

Flash Sterilization

Multi Society Position Paper, 2011 (Page 1, Paragraph 1)

Flash sterilization has traditionally been used to describe steam sterilization cycles where unwrapped medical instruments are subjected to an abbreviated steam exposure time and then used promptly after cycle completion without being stored.

Multi Society Position Paper, 2011 (Page 1, Paragraph 1)

The term “flash” arose out of the abbreviated time of exposure of the unwrapped device.

Multi Society Position Paper, 2011 (Page 1, Paragraph 2)

... “flash sterilization” is an antiquated term that does not fully describe the various steam sterilization cycles now used to process items not intended to be stored for later use.

CDC (CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008, page 1)

Flash steam sterilization was originally defined by Underwood and Perkins as sterilization of an unwrapped object at 132oC for 3 minutes at 27-28 lbs. of pressure in a gravity displacement sterilizer 843

TJC (The Joint Commission’s Position on Steam Sterilization, July, 2009, page 1)

Flash sterilization is the most common term used to describe certain types of steam sterilization that do not utilize a full cycle (also known as a terminal cycle). Originally, flash sterilization meant sterilizing unwrapped instruments using steam for 3 minutes, at 270°F at 27 to 28 pounds of pressure.

Shelf Life

AAMI ST79 (ANSI/AAMI ST79 2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, 2.114, page 14)

Shelf life When the term is used with respect to a sterilized medical device, the period of time during which the item is considered safe to use.

AORN (AORN Guidelines for Perioperative Practice, 2017, Guidelines for Selection and Use of Packaging Systems for Sterilization, Recommendations III. D., page 854)

The Shelf Life of a packaged sterile item should be considered event-related. [1. Strong Evidence] The sterility of an item does not change with the passage of time, but may be affected by particular events (e.g., amount of handling) or environmental conditions (e.g., humidity).

AORN (AORN Guidelines for Perioperative Practice, 2017, Guidelines for Selection and Use of Packaging Systems for Sterilization, Glossary, page 861)

Shelf life: When this term is used in conjunction with a sterile device, shelf life is considered to be the length of time a device is safe to use.