



STERILIZATION

STEAMPlus™

Class 5 Steam Integrators

HEALTH INSURANCE
AUTO INSURANCE
LIFE INSURANCE
HOME INSURANCE
LIABILITY INSURANCE
TRAVEL INSURANCE
FLOOD INSURANCE
FIRE INSURANCE
CREDIT INSURANCE



Immediate readout integrators that provide you with your very own Sterility Assurance Policy...

- ▶ For less than 50¢ an integrator, you'll immediately know whether or not your sterilizer is functioning properly
- ▶ Confirms the conditions for sterilization have been met - **Time, Temperature & Steam**
- ▶ Allows you to confidently **release non-implant loads** while awaiting weekly spore test results
- ▶ Detects potential sterilizer failures with a **distinct pass-or-fail result**

The STEAMPlus Sterilization Integrator is an "advanced technology" medical device that provides a simple, accurate method of assuring that proper conditions for sterilization have been met during a sterilizer cycle. For use with all steam processes (gravity, prevacuum and flash), the STEAMPlus has documented performance equivalent to a biological indicator.

How to Use:

1. Place a STEAMPlus Integrator (at least once daily) inside a load (i.e. middle of the load or inside the densest pack). A STEAMPlus Integrator should be used in every load containing an implantable device.
2. Process the load according to the sterilizer manufacturer's instructions.
3. Release the load if the dark bar on the STEAMPlus Integrator has entered the blue SAFE area. If the dark bar has not entered into the blue SAFE area, DO NOT release the load.



STEAMPlus Class 5 Integrators do not replace weekly biological spore testing, as recommended by the CDC, as they do not contain live spores. However, since STEAMPlus Class 5 Integrators parallel biological spore testing so closely, practices using Integrators once daily, or with every load, can confidently release non-implant loads immediately. The more frequently used, the less disruption of potential costly recalls when alerted to biological failures.

Protect patients, staff and practices with STEAMPlus™ Class 5 Steam Integrators

Tested to AAMI ST-60 and ISO 11140-1:2005 standards performance requirements.
Note: The FDA does not recognize Class 3, 4 or 5 indicators as defined in ISO 11140-1:2005.



Ordering Information

Description	Quantity	Ref. #
STEAMPlus™ Class 5 Sterilization Integrator	100/ bag	SSI-100



ENSURE THE EFFICACY OF YOUR INFECTION CONTROL PROCESSES

The use of Class 5 integrators can provide an extra level of assurance when documenting the effectiveness of the sterilization cycle.

Recently, world news highlighted a disturbing story in Oklahoma where thousands of dental patients were allegedly exposed to blood-borne pathogens. Major breaches in instrument processing and failures in sterilization protocol were reported as the causes of the potential cross-contamination. This news story highlights the importance of maintaining infection control protocol in the dental setting. The goal of such processes is to reduce the risk of disease transmission and to provide a safe environment for everyone who works in or visits a dental office.

Role of Class 5 Integrators

Effective sterilization is a key component of infection control protocol, and Class 5 integrators can help oral health professionals ensure the efficacy of the sterilization process. A Class 5 integrator mimics the abilities of a biological indicator at three different times and temperatures without requiring incubation. These integrators can detect certain types of sterilization process failures, such as inappropriate air-steam mixtures and inadequate air removal, which may not be noticed by physical monitors or other types of chemical indicators. Class 5 integrators used daily, or even with every load, may improve patient and clinician safety and reduce the cost and disruption of potential recalls when a biological indicator fails.

The AAMI steam sterilization standard requires the use of biological monitoring to ensure the lethality of the sterilization process. Although Class 5 integrators do not contain spores, their performance is similar to biological spores, providing a margin of safety that spans the entire spectrum of normal steam sterilization temperatures and offering added assurance that, once the dark bar enters the safe area, proper sterilization conditions have been met. Please note that Class 5 integrators do not replace weekly spore testing.

Technical Design

The base of a Class 5 integrator is made of aluminum foil with a temperature and steam-sensitive chemical placed in the cavity embossed in the foil. When subjected to a heated steam environment, the chemical melts and moves sequentially across the visual gauge. Achievement of the critical sterilization variables (i.e., time, temperature, and the presence of steam) is indicated when the dark bar reaches the endpoint as indicated by the "safe" zone on the strip (Figure 1). This means a Class 5 integrator is able to detect failure conditions when the parameters for sterilization have not been met.



Figure 1. Class 5 integrators note whether a sterilization cycle has reached all three required parameters: time, temperature, and the presence of steam. They serve as an additional level of assurance in the sterilization process, and are used as an adjunct to the gold standard of biological monitoring.

Additional Benefits

A significant benefit of the Class 5 integrator is its ability to provide a distinct pass-or-fail result, which provides confidence to safely release the instruments in every sterilization cycle. As biological indicators are often run only weekly (and with implantable devices), and require an incubation period, the Class integrator 5 provides immediate peace of mind when used in every sterilization cycle. However, biological indicators remain the gold standard for ensuring the sterilization process had sufficient lethality to produce the desired sterility assurance level.

While there is no reference to the use of a Class 5 integrator in the CDC guidelines, is it worth skipping this step? The average cost of an integrator strip is less than 50¢, yet it can provide enhanced confidence about the success of the sterilization process. When it comes to sterility assurance, it is always better to be safe than sorry.