SAMPLE PROCEDURE
VERIFY® STEAM Integrating Indicator for Internal Pack Monitoring

Product Numbers:

PCC064   VERIFY® STEAM Integrating Indicator 5CM

PCC064B   VERIFY® STEAM Integrating Indicator 5CM

This document contains sample procedures for chemical monitoring of steam sterilization cycles within sterile processing. The procedures contained in this document are only intended to provide a foundation for developing specific policies and procedures for your facility. It is the responsibility of the health care facility to ensure compliance with applicable laws, regulations, standards, and industry-recommended practices. The health care facility should seek expert advice and consultation for guidance with compliance issues. STERIS Corporation makes no representation, express or implied, with respect to this sample procedure's compliance with applicable laws, regulations, standards, and industry-recommended practices. STERIS Corporation shall not be responsible for any loss, injury, damage, or claim arising from use of this document or the sample policies and procedures contained in it.

Title: Internal pack (In-pack) monitoring of steam sterilization processed items using the VERIFY STEAM Integrating Indicator 5CM

Definitions:

Mechanical Monitor: Sterilizer time, temperature, and pressure recording devices.

Chemical Indicators (CI): Systems that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor the attainment of one or more of the variables required for sterilization process (ANSI/AAMI/ISO 11140-1).

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Procedures:

Table 1: Validated Steam Sterilization Cycles

Sterilization Cycle Type	Sterilization Temperature and Time
Gravity	250 °F / 121 °C for 30 minutes
	270 °F / 132 °C for 15 minutes
	275 °F / 135 °C for 10 minutes
Dynamic Air removal (prevacuum and steam-flush pressure-pulse)	270 °F / 132 °C for 4 minutes
	275 °F / 135 °C for 3 minutes
Immediate Use Steam Sterilization	270 °F / 132 °C for 3 and 10 minute Gravity
	270 °F / 132 °C for 4 minute Dynamic Air Removal
	275 °F / 135 °C for 3 and 10 minute Gravity
	275 °F / 135 °C for 3 minute Dynamic Air Removal

For Wrapped Items:

In the Sterile Processing Area:

1. Place an indicator strip(s) inside each tray or package, in the area(s) of greatest challenge to the sterilant but not directly beneath an item of great metal mass.
2. If requested by the Customer/end user, place an additional indicator strip in a highly visible area of the pack or tray.
3. Use process indicator tape to secure wrapped packages. Tape volume should be adequate to secure package but not inhibit sterilization or compromise aseptic presentation.
4. Process the wrapped items in a validated steam sterilization cycle appropriate for the items being sterilized. See Table 1. Follow departmental procedures to release the items sterilized within the cycle.

In the appropriate location at the point-of-use (OR Suite, etc.):

1. Observe external indicator tape for appropriate color change (*insert your color change here*). If tape has changed, aseptically open the wrapped package, remove the indicator(s) and proceed to step 3.
2. If the tape has not reached the appropriate color change (*insert your color change here*), do NOT use the pack. Follow departmental procedures for investigating suspected sterilization failures.
3. Examine the window on the indicator strip.
   a. The strip indicates a "Pass" if the dark has reached the ACCEPT area. The items within the pack may be used.
   b. The strip indicates a "Fail" if the dark bar has not reached the ACCEPT area. The items within the pack may NOT be used. Follow departmental procedures for investigating suspected sterilization failures.

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For Rigid Sterilization Containers:

In the Sterile Processing Area:

1. Place an indicator strip(s) inside each container, in the area(s) of greatest challenge to the sterilant but not directly beneath an item of great metal mass.
2. If requested by the Customer/end user, place an additional indicator strip in a highly visible area of the container.
3. Place an external data card containing a chemical indicator on each rigid sterilization container (if applicable).
4. Close and secure the rigid container with appropriate tamper-evident devices following the container manufacturer's instructions.
5. Process the container in a validated steam sterilization cycle appropriate for the items being sterilized. See Table 1. Follow departmental procedures to release the items sterilized within the cycle.

In the appropriate location at the point-of-use (OR Suite, etc.):

1. Observe the external data card chemical indicator (if applicable) and any chemical indicators that may be present on external disposable locking mechanisms for appropriate color change (*insert your color change here*). If the external data card or locking mechanism chemical indicator(s) has changed appropriately, aseptically open the container, remove the internal chemical indicator(s) and proceed to step 3.
2. If the external data card or locking mechanism chemical indicator(s) has not changed appropriately, (*insert your color change here*), do NOT use the pack. Follow departmental procedures for investigating suspected sterilization failures.
3. Examine the window on the indicator strip.
   a. The strip indicates a "Pass" if the dark bar has reached the ACCEPT area. The items within the pack may be used.
   b. The strip indicates a "Fail" if the dark bar has not reached the ACCEPT area. The items within the pack may NOT be used. Follow departmental procedures for investigating suspected sterilization failures.

For Items Packaged in Peel Pouches:

In the Sterile Processing Area:
1. Place an indicator strip inside each peel pouch package to be sterilized, facing toward the plastic side of the pouch. The process indicator(s) present on the peel pouch does not necessarily represent an internal pack indicator.
2. When double pouching, place the indicator strip inside the inner-most pouch.
3. Place the indicator strip inside the pouch so that it does not impede sterilant penetration.
4. Process the pouch in a validated steam sterilization cycle appropriate for the items being sterilized. See Table 1. Follow departmental procedures to release the items sterilized within the cycle.

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In the appropriate location at the point-of-use (OR Suite, etc.):

1. Observe the process indicator for appropriate color change (*insert your color change here*). If the process indicator has changed appropriately, aseptically open the pouch, remove the indicator and proceed to step 3.
2. If the process indicator has not changed appropriately (*insert your color change here*), do NOT use the pouched item. Follow departmental procedures for investigating suspected sterility failures.
3. Examine the window on the indicator strip.
   a. The strip indicates a "Pass" if the dark bar has reached the ACCEPT area. The items within the pack may be used.
   b. The strip indicates a "Fail" if the dark bar has not reached the ACCEPT area. The items within the pack may NOT be used. Follow departmental procedures for investigating suspected sterilization failures.

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