3M™ Attest™ Steam-Plus Pack 41380

Product Description

The 3M™ Attest™ Steam-Plus Pack 41380 is specifically designed to routinely challenge the steam sterilization process in healthcare facilities. This convenient disposable process challenge device presents a challenge to the sterilization process equivalent to the 16 towel process challenge device (PCD) recommended by AAMI.

Each test pack contains a process indicator on the outside that changes from yellow to brown or darker when steam processed. Each pack contains a 3M™ Attest™ 1262 Biological Indicator (brown cap), a record keeping sheet, and a 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrator. Attest™ biological indicator controls are provided. When steam processed the chemical indicator on the Attest™ vial label changes from rose to brown/black.

Comply™ SteriGage™ Steam Chemical Integrators are Type 5 (Category i5) Integrating Indicators as categorized by ISO 11140-1:2014. The Comply™ SteriGage™ Steam Chemical Integrator consists of a paper wick and a steam temperature sensitive chemical pellet contained in a paper/film/foil laminate. When exposed to steam sterilization conditions, the chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked REJECT or ACCEPT. The extent of migration depends on steam, time, and temperature.

Attest™ 1262 Biological Indicators comply with the requirements of ISO 11138-1:2006 and ISO 11138-3:2006. The Attest™ 1262 Biological Indicator detects the presence of *Geobacillus stearothermophilus* spores by a visual color change reaction. Biochemical activity of the *G. stearothermophilus* organism produces acid by-products that cause the media to change color from purple to yellow. A visual pH color change to yellow indicates a steam sterilization process failure. The final readout of a negative result (media remains purple) is made after 48 hours of incubation.

Indications for Use

Use the Attest™ Steam-Plus Pack 41380 to monitor:

- 121°C (250°F) gravity displacement steam sterilization cycles ≥30 minutes.
- 132°C (270°F) dynamic-air-removal steam sterilization cycles ≥4 minutes.

Contraindications

None.

Warnings

There is a glass ampule inside the plastic vial of the biological indicator. To avoid the risk of serious injury from flying debris due to a ruptured ampule:

- Allow the biological indicator to cool for the recommended time period before crushing.
- Avoid crushing or excessive handling of the biological indicator before cooling which may cause the glass ampule to burst.
- Wear safety glasses and gloves when removing the biological indicator from the sterilizer.
- Wear safety glasses when crushing the biological indicator.
- Handle the biological indicator by the cap when crushing and tapping.
- Do not use your fingers to crush the glass ampule.
- Do not roll the biological indicator between fingers to wet the spore strip.

Precautions

DO NOT use the Attest™ Steam-Plus Pack 41380 to monitor sterilization cycles which it is not designed to challenge:

1. 121°C (250°F) gravity displacement steam sterilization cycles <30 minutes;
2. 132°C (270°F) dynamic-air-removal steam sterilization cycles <4 minutes;
3. 132°C (270°F) gravity displacement steam sterilization cycles;
4. 132°C (270°F) express cycles;
5. Dry heat, chemical vapor, ethylene oxide, or other low temperature sterilization processes.

To ensure the test pack delivers the intended challenge:

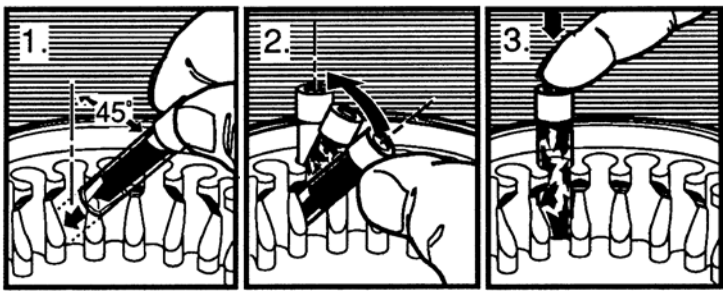
- DO NOT OPEN test pack prior to sterilization;
- DO NOT reuse test pack.

Monitoring Frequency

Follow facility Policies and Procedures which should specify a biological indicator monitoring frequency compliant with professional association recommended practices and/or national guidelines and standards. As a best practice and to provide optimal patient safety, 3M recommends that every steam sterilization load be monitored with an appropriate biological indicator.

Directions for Use

1. Place an Attest™ Steam-Plus Pack flat with the label side up, in a full load in the most challenging area for the sterilant to reach. This is generally on the bottom shelf over the drain. Do not place objects (i.e., another pack) on top of the Attest™ Steam-Plus Pack. This will create too great of a challenge for air removal and steam penetration.
2. Process the load according to established procedures.
3. After the completion of the cycle and while wearing safety glasses and heat resistant gloves, retrieve the Attest™ Steam Plus-Pack.
4. Check to see that the external chemical indicator on the outside of the pack has turned from yellow to brown or darker. Open the test pack and allow heat to dissipate for 5 minutes prior to removing the biological indicator. Then allow the biological indicator to cool outside the test pack for an additional 10 minutes prior to crushing.
5. Check the Comply™ SteriGage™ Chemical Integrator. The dark color should have entered the ACCEPT window. If the dark color has not entered the ACCEPT window, this indicates a REJECT result which means the load was not exposed to sufficient steam sterilization conditions. This load should not be released for use but reprocessed. Record results.
6. Twist the coil off the Attest™ biological indicator.
7. Check the chemical indicator on the label of the processed Attest™ biological indicator. A color change from rose to brown/black confirms that the biological indicator has been exposed to the steam sterilization process. This color change does not indicate that the sterilization process was sufficient to achieve sterility.
8. Identify the processed Attest™ biological indicator by writing the sterilizer, load number, and processing date on the indicator label.
9. For a permanent record, fill out the required information on the record keeping sheet. Record the biological indicator result when it is available.
10. Discard the test pack. Using a test pack more than once will invalidate subsequent test results.
11. While wearing safety glasses, crush and incubate the processed Attest™ biological indicator at 56 ± 2°C (133 ± 3°F).



Attest™ Incubator 120 volt (North American Usage)
Model 116 (14 indicators)

Attest™ Incubator 240 volt (International Usage)
Model 118 (14 indicators)

a. Position indicator in metal block (see Figure 1). Place bottom of the indicator into the incubator's metal heating block so that the indicator is at an angle of approximately 45°.

b. Push the indicator straight back (see Figure 2). This crushes the media ampule and activates the indicator. Be sure that the cap will remain above the metal block when the indicator is pushed back.

c. Push the activated indicator down to seat it in the metal heating block (see Figure 3). Be sure that the cap remains above the metal block when seated in the incubator.

12. Incubate at least one unprocessed Attest™ biological indicator (positive control) in each incubator every day a processed biological indicator is incubated. The positive control indicator should be from the same lot number as the processed biological indicator in the Attest™ incubator.

13. Write a "C" and a date on the label of the positive control indicator. Crush and incubate the control at 56 ± 2°C (133 ± 3°F).

The purpose of the positive control is to ensure:
*correct incubation temperatures are met,
*viability of spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals,
*capability of media to promote rapid growth, and
*proper functioning of Attest™ incubator.

14. Incubate processed and control biological indicators for 48 hours at 56 ± 2°C (133 ± 3°F).

Incubation Times:

Early Detection	12 hours
	18 hours
	24 hours

15. The appearance of a yellow color in the processed biological indicator demonstrates bacterial growth and a sterilization process failure. The load should not be used and a recall should be initiated back to the last negative biological indicator. No color change indicates an acceptable sterilization process. A final negative result is made after 48 hours of incubation. The positive control biological indicator should show a yellow color change within 48 hours for the processed biological indicator results to be valid.

16. Record the processed and control biological indicator results.

Disposal

Dispose of used Attest™ biological indicators according to your healthcare facility's policy. You may wish to steam sterilize any positive biological indicators at 121°C/250°F for at least 30 minutes, or at 132°C/270°F for 10 minutes in a gravity displacement steam sterilizer, or at 132°C/270°F for 4 minutes in a dynamic-air-removal steam sterilizer.

Storage

- Best stored under normal room conditions: 15-30ºC (59-86ºF) and 40-60% relative humidity.
- Store away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/disinfecting agents.
- After use, the Comply™ SteriGage™ Steam Chemical Integrator will not change visually within 6 months when stored at above conditions.

Explanation of Symbols

Caution, see instructions for use

Do not reuse

Use by date

LOT Batch code

Manufacturer

Date of manufacture

STEAM Product is designed for use with steam sterilization cycles.

Made in U.S.A. by

3M Health Care

2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957
3M.com/infectionprevention

Issue Date: 2016-03

34-8718-6262-8