3M™ Attest™ Biological Indicator Monitoring Starter Kit
An undetected sterilization process failure can put patients, staff, and the financial health of your facility at risk. Additional costs associated with postoperative infections, and other health care liabilities, make the implementation of a sterilization process monitoring program an extremely critical practice for all health care facilities. The 3M Sterilization Assurance Program is a comprehensive and practical approach to sterilization monitoring procedures and methods that you can count on to reduce your risk of an undetected sterilization process failure.

The 3M Sterilization Assurance Program helps you control and monitor sterilization procedures. It provides you with an easy to follow set of guidelines to help ensure safety and product sterility throughout your facility.

The 3M Sterilization Assurance Program consists of five separate, but interrelated steps: Load Control, Pack Control, Equipment Control, Exposure Control and Record Keeping. These five steps monitor every aspect of the sterilization process and help you establish, manage and maintain a consistent protocol for sterilization in your facility.

Health care professionals worldwide have come to trust the complete line of 3M sterilization monitoring products to help them monitor all stages of the sterilization process. 3M sets today’s standard for sterilization process monitoring with dependable, high-performance products, an effective, easy-to-follow program, customer service, and technical support.

3M Health Care Helpline:
1-800-228-3957

Outside the United States, contact the local 3M subsidiary.
Your instruments may have been through the sterilizer—but that doesn’t mean they’re sterile.

Many things can adversely affect the sterilization process. The sterilizer can malfunction. Time or temperature may be incorrect. Air may not be removed. Or steam may not reach the center of the packs. Improper loading or packaging can be problems too.

There are five basic steps in the sterilization process itself: Clean, Prep/Pack, Sterilize, Store and Issue/Use. Sterilization process monitoring impacts just two of these steps, Sterilize and Issue/Use. Monitoring tools help to insure the outcome of “Sterilize” and supply safeguards to the “Issue/Use” step so that no nonsterile medical devices can go beyond this point. The threat of postoperative infections caused by nonsterile medical devices makes sterilization process monitoring extremely important.

3M™ Attest™ Biological Indicators contain *Geobacillus stearothermophilus* spores especially resistant to the steam sterilization process. Following the sterilization cycle, the vial is crushed, providing media that will promote growth of any spores that may not have been killed during the sterilization process. An easily detected color change in the vial indicates that the sterilization process was not successful. It alerts personnel to a problem with the sterilizer or the sterilization process.

Daily monitoring of the steam sterilization process is recommended by organizations such as the Association of Operating Room Nurses and the American Society of Healthcare Central Service Professionals.

The Attest Monitoring Starter Kit makes this process easy. 3M provides everything your staff needs for effective monitoring of the steam sterilization process, including:

- **Load Control**
  - Attest Biological Indicators—The Attest 1262 biological indicator (brown cap) is designed for monitoring steam sterilization processes. Final readout in 48 hours.
  - 3M™ Attest™ 116 Incubator—A compact incubator designed specifically for the needs of smaller health care facilities. The incubator allows quick, on-site monitoring by non-lab personnel.

- **Exposure Control**
  - 3M™ Comply™ Steam Indicator Tape—A tape that closes packages securely and quickly identifies processed from unprocessed items at a glance. Chemical indicator stripes change color when the tape is exposed to steam sterilization.

- **Pack Control**
  - 3M™ Comply™ Chemical Integrators—Internal chemical integrators for determining that the sterilant penetrated inside the pack or tray. Accept or Reject readout—no need for interpretation.

- **Record Keeping**
  - 3M™ Attest™ Log Book—An easy way to accurately keep track of the sterilization process, which is essential to protect your practice.

In addition to this overview of the 3M Sterilization Assurance Program, your kit includes the booklet “The Fundamentals of Sterilization Process Monitoring”, detailing the steps of the sterilization process, and the enclosed wall chart for easy reference.

You now have everything you need to implement a complete sterilization program in your facility!
Identify the Attest biological indicator by noting the sterilizer number, load number and processing date on the label of the vial.

Place the Attest steam biological indicator and the Comply chemical integrator in the center of a suitable test pack or tray which is representative of the load and is the greatest challenge to the steam sterilization process. Close the test pack with Comply Indicator Tape.

NOTE: Do not use 3M steam monitoring products with dry heat, chemical vapor, ethylene oxide or other low temperature sterilization processes.

Place the test pack or tray in a full load in the most difficult area for steam to reach in the sterilizer. Process the load as usual.

After completion of the cycle and while wearing safety glasses and gloves, fully open the sterilizer door for a minimum of 5 minutes prior to removing the Attest biological indicator.

Warning: Crushing or excessive handling of the biological indicator before cooling may cause the glass ampule to burst which may result in personal injury from flying debris. Therefore, the use of safety glasses and gloves when removing biological indicators from the sterilizer is recommended. Safety glasses should also be worn when crushing biological indicators. All safety procedures recommended by your facility should also be followed.

If the biological indicator is not contained in a test pack or any other heat absorbing packaging material, remove the biological indicator from the sterilizer and allow to cool for an additional 10 minutes prior to crushing.

If the biological indicator is contained in a test pack or other heat absorbing packaging material, the test pack or any other heat absorbing packaging material should be removed from the sterilizer and opened up for 5 minutes to dissipate heat 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.

Check the indicator tape on the outside of the test pack for color change to black.

Check the biological indicator label for a change from rose to brown. Check the chemical integrator for an ACCEPT result. An incomplete color change on the biological indicator label or a REJECT result on the chemical integrator may indicate an inadequate sterilization process.

Push the activated indicator down to firmly seat in the metal heating block. Be sure the cap remains above the metal block.

Incubate the biological indicator as soon as possible. For optimal performance, leave the incubator plugged in at all times.

As shown, place the bottom of the biological indicator vial into the incubator’s metal heating block so that the vial is at an angle of approximately 45°.

Push the vial straight back. This crushes the vial and activates the indicator.
Interpretation

1. Examine the biological indicator at regular intervals (8, 12, 24 and 48 hours) for any color change. Appearance of a yellow color (a positive readout) indicates bacterial growth and an inadequate sterilization process. No color change indicates an adequate sterilization process.

2. A final determination of sterility can be made at 48 hours of incubation for 3M Attest 1262 and 1262P biological indicators.

3. Record results in the record keeping log book.

Use of Positive Controls

The use of positive controls is required to ensure correct incubation conditions, viability of spores and capability of the medium to promote growth. A non-sterilized 3M Attest 1262 or 1262P biological indicator from the same lot should be used in each incubator each day biological indicators are used as a positive growth control.

1. Place a non-sterilized Attest biological indicator in the incubator each day you put in an activated sterilized biological indicator.

2. Examine the positive control indicator at regular intervals such as 8, 12, 24 and 48 hours. Appearance of a yellow color is evidence of bacterial growth. A yellow color in the control vial demonstrates correct incubation, viability of spores and capability of the medium to promote rapid growth.

3. Record results in the record keeping log book.

4. Dispose of used indicators in accordance with facility policy. You may wish to sterilize any positive indicators at 250°F (121°C) for at least 15 minutes or at 270°F (132°C) for 10 minutes in a gravity displacement steam sterilizer.
### Ordering Information

**3M™ Attest™ Monitoring Starter Kit**

Contains one roll of Comply 1222-6N Indicator Tape, one box of Attest 1262P Biological Indicators, an Attest 116 Incubator, one bag of Comply 1243B Chemical Integrators, one Attest 1266 Log Book, and wall chart.

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<thead>
<tr>
<th>Cat No.</th>
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<tr>
<td>115</td>
<td>3M Attest Monitoring Kit</td>
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**3M™ Attest™ Biological Indicators**

For use with steam sterilizers—*Geobacillus stearothermophilus*.

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<th>Product Name</th>
<th>Description</th>
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<td>1262P</td>
<td>3M Attest Biological Indicators</td>
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**3M™ Attest™ Incubators**

3M Attest Steam Incubator for use with 1262/1262P Attest biological indicators (56°C).

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<tr>
<td>116</td>
<td>3M Attest Incubator</td>
<td>14 vial capacity</td>
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<tr>
<td>126</td>
<td>3M Attest Incubator</td>
<td>28 vial capacity</td>
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**3M™ Comply™ (SteriGage™) Chemical Integrators**

Internal chemical integrator for steam sterilization.

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<td>3M Comply (SteriGage) Chemical Integrators</td>
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**3M™ Comply™ Steam Indicator Tape**

Individually packaged:

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<tr>
<td>1/2&quot;</td>
<td>1222-ON</td>
<td>1&quot;</td>
</tr>
<tr>
<td>3/4&quot;</td>
<td>1222-6N</td>
<td>2&quot;</td>
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**3M™ Attest™ Record Keeping System**

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<th>Charts/Book</th>
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<tr>
<td>1266</td>
<td>3M Attest Log Book and Charts</td>
<td>For use with steam sterilization</td>
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<tr>
<td>1266S</td>
<td>Replacement Record Charts</td>
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*These Products Contain Dry Natural Rubber.*

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