

3M™ Attest™ Steam Chemical Integrator Test Pack 41360



Product Description

3M™ Attest™ Steam Chemical Integrator Test Pack 41360 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 the Association for the Advancement of Medical Instrumentation (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™ Steam Chemical Integrator and a record keeping sheet. The 3M™ Attest™ Steam Chemical Integrator consists of a paper wick and a steam and 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. 3M™ Attest™ Steam Chemical Integrators are Type 5 (Category 5) Integrating Indicators as categorized by ISO 11140-1:2014.

This Product Is Not Made with Lead.

Indications for Use

Use the 3M™ Attest™ Steam Chemical Integrator Test Pack 41360 to monitor:

- 121°C (250°F) gravity displacement steam sterilization cycles at 30 minutes
- 132°C (270°F) dynamic-air-removal steam sterilization cycles at 4 minutes
- 135°C (275°F) dynamic-air-removal steam sterilization cycles at 3 minutes

Contraindications

None

Precautions

1. DO NOT use the 3M™ Attest™ Steam Chemical Integrator Test Pack 41360 to monitor sterilization cycles which it is not designed to challenge:
 - 121°C (250°F) gravity displacement steam sterilization cycles <30 minutes
 - 132°C (270°F) dynamic-air-removal steam sterilization cycles <4 minutes
 - 135°C (275°F) dynamic-air-removal steam sterilization cycles <3 minutes
 - 132°C (270°F) gravity displacement steam sterilization cycles.
 - 135°C (275°F) gravity displacement steam sterilization cycles
 - 132°C (270°F) express cycles
 - Dry heat, chemical vapor, ethylene oxide, or other low temperature sterilization processes
2. To ensure the test pack delivers the intended challenge:
 - DO NOT OPEN test pack prior to sterilization;
 - DO NOT reuse test pack.

Monitoring Frequency

The Association for the Advancement of Medical Instrumentation (AAMI) recommends that an Integrating Indicator process challenge device may be used to release non-implant loads.

Directions for Use

1. Place a 3M™ Attest™ Steam Chemical Integrator Test Pack 41360 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 3M™ Attest™ Steam Chemical Integrator Test Pack 41360. 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, retrieve the test pack. Check to see that the external chemical indicator on the outside of the pack has turned from yellow to brown or darker.
4. After cooling, open the pack and remove the 3M™ Attest™ Steam Chemical Integrator.
5. Check the 3M™ Attest™ Steam Chemical Integrator. A dark color in the green ACCEPT window of the chemical integrator confirms that the inside of the pack has been exposed to sufficient steam sterilization conditions. If the dark color has not entered the green ACCEPT window, a red REJECT result is indicated. This indicates the inside of the pack was not exposed to sufficient steam sterilization conditions and the load should not be released for use. Record integrator result.
6. If utilized, fill out the required information on the record-keeping sheet.
7. Discard the test pack. Using a test pack more than once will invalidate subsequent test results.

Storage/ Shelf Life/Disposal

- Best stored under normal room conditions: 59-86°F (15-30°C), 40-60% relative humidity.
- Store 3M™ Attest™ Steam Chemical Integrator Test Packs 41360 away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/ disinfecting agents.
- After use, the 3M™ Attest™ Steam Chemical Integrator will not change visually within 6 months when stored at above conditions.
- There are no special disposal requirements for the 3M™ Attest™ Steam Chemical Integrator Test Packs 41360. Dispose of 3M™ Attest™ Steam Chemical Integrator Test Packs 41360 according to your healthcare facility's policy.

For further information, please contact your local 3M representative or contact us at 3M.com and select your country.

Explanation of Symbols

Symbol Title	Symbol	Description and Reference
Manufacturer		Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. Source: ISO 15223, 5.1.1
Date of Manufacture		Indicates the date when the medical device was manufactured. Source: ISO 15223, 5.1.3
Use-by date		Indicates the date after which the medical device is not to be used. Source: ISO 15223, 5.1.4
Batch code		Indicates the manufacturer's batch code so that the batch or lot can be identified. ISO 15223, 5.1.5
Catalogue number		Indicates the manufacturer's catalogue number so that the medical device can be identified. ISO 15223, 5.1.6
Do not re-use		Indicates a medical device that is intended for one use or for use on a single patient during a single procedure. Source: ISO 15223, 5.4.2
Caution		Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. Source: ISO 15223, 5.4.4
Steam indicator		Indicates product is designed for use with steam sterilization processes. Source: ISO 11140-1, 5.6

For more information, see HCBRegulatory.3M.com

Made in USA with Globally Sourced Materials

3M Company

2510 Convoy Ave.
St. Paul, MN 55144 USA
1-800-228-3957 (USA only)
3M.com

3M and Attest are trademarks of 3M.
Used under license in Canada.
© 2019, 3M. All rights reserved.

3M et Attest sont des marques de commerce de 3M, utilisées sous licence au Canada.
© 2019, 3M. Tous droits réservés.

Issue Date: 2019-09, rev. 7
34-8724-5860-8