

SporeCheck™

24 Hour In-Office Test

INSTRUCTIONAL GUIDE



Monitoring Process

Steam sterilizers should be biologically tested at least weekly and with every load that contains an implant.

Processing

STEP 1:

- Identify the biological indicator (BI) vial to be processed by writing the sterilizer number, load number and processing date on the vial label.



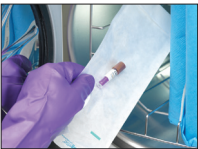
STEP 2:

- Place the test BI vial inside an instrument tray, peel pouch or AAMI challenge pack.
- Also include a steam sterilization integrator in the pack for an added layer of monitoring.



STEP 3:

- Place the test BI vial in the most challenging area in the sterilizer (i.e. the bottom shelf near the door, over the drain of a large sterilizer or in the middle shelf of a smaller sterilizer.)
- Load your sterilizer with instruments as you normally would. Do not overload the sterilizer.
- Process the load according to the sterilizer manufacturer's instructions.



STEP 4:

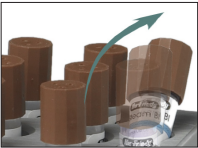
- Retrieve the test BI vial and confirm the chemical indicator on the vial has turned brown.
- Retrieve the steam sterilization integrator and confirm that the color bar has entered the accept window.



Activation and Incubation

STEP 5:

- Activate the processed test BI vial within 8 hours of processing.
- Safety glasses should be worn when handling and crushing processed BI vials.
- Allow the test BI vial to cool 10 minutes before crushing.
- Activate the processed BI vial by gently crushing the inner glass media tube using the built-in vial crusher.
- Gently tap the vial on a hard surface to assist the mixing of the growth media with the spore strip.



STEP 6:

- As a control, an unprocessed BI vial (from the same lot) must be crushed and incubated with the test BI.
- If you are testing more than one sterilizer at a time, only one control vial needs to be used. Controls indicate that the spores were viable at the time of use and the incubator is heating properly.

STEP 7:

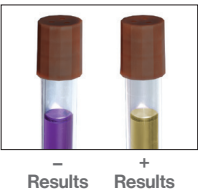
- Place both the processed and control (unprocessed) BI vials into the incubator.
- A green light will illuminate when the incubator is plugged in and functioning.
- Incubate at the preset temperature of 55-60° C for 24 hours checking for spore growth at regular intervals (i.e. 3, 5 and 18 hours).
- Growth of surviving spores has been documented as little as 2.5 hours.



Test Results

STEP 8:

- After incubating 24 hours, remove the test and control BI vials from the incubator.
- The control (unprocessed) BI vial should indicate spore growth by the media changing from purple to yellow (positive result). If the control BI vial does not change color, re-run the test. If the failure repeats, report results immediately to your supervisor.
- Processed test BI results:
 - No color change of the purple media after incubation indicates proper sterilization and a negative result (no spore growth).
 - A color change of the purple media to yellow indicates sterilization failure and a positive result (spore growth).
- Any test BI positive result should be recorded and reported immediately to a supervisor. The sterilizer should be taken out of service until the issue is resolved. Refer to CDC guidelines for further instruction, www.cdc.gov.



Recording Results

STEP 9:

- Record test results in the Sterilizer Record Notebook (IMS-1375).
- Be sure to fill in all information including date, load number, sterilization parameters, etc.
- The record notebook should be retained per sterilization protocol.



Storage and Disposal

- Store BI vials at controlled room temperature and 20-70% relative humidity.
- Do not store near sterilants or other chemicals.
- Protect from light, excessive heat and moisture.
- Do not desiccate.
- Do not refrigerate.
- Do not use beyond stated shelf-life which is indicated on each box.
- Negative (no growth) BI's can be disposed of as normal waste; however, positive BI's (growth) should be autoclaved at 250°F/121°C for at least 30 minutes prior to disposal, this includes all control vials.

For Sterilization Assistance, call **1-800-722-1529**.

PRODUCT ORDERING INFORMATION

IMS-1376	SporeCheck™ Starter Kit Contains: Dry Block Incubator with built-in vial crusher, record notebook and 1 box SporeCheck™ Biological Indicators, 25 count	
IMS-1373	SporeCheck™ Biological Indicator Vials	25 Count
IMS-1373H	SporeCheck™ Biological Indicator Vials	100 Count
IMS-1374	55–60°C Dry Block Incubator	1 Each
IMS-1375	Sterilizer Record Notebook	1 Each
IMS-1377	Replacement Vial Crusher	1 Each
IMS-1241	Steam Sterilization Integrators	100 Count