



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 BI vial inside an instrument tray, peel pouch or AAMI challenge pack.



STEP 3:

- Place the 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 BI vial and confirm the chemical indicator on the vial has turned brown.



ACTIVATION AND INCUBATION

STEP 5:

- Activate the processed BI within 8 hours of processing.
- Safety glasses should be worn when handling and crushing processed BI vials.
- Allow the 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.
- 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 BI vials from the incubator.
- The Control (unprocessed) vial should indicate spore growth by the media changing from purple to yellow (positive result). If the control vial does not change color, re-run the test.
- Processed BI results:
 - No color change in the purple media after processing indicates proper sterilization and a negative result (no growth).
 - Positive results are indicated by media changing from purple to yellow (spore growth).
- Any 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.



- Results + Results

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-Hu-Friedy**.

To reorder Sporecheck BI Vials, use part-code IMS-1373 or IMS-1373H.