STERISIMPLE™

Reprocessing. Simplified.

Biological Indicator and Recall Flowchart

This information is presented to better understand what to do if a Biological Indicator (Spore Test) fails during instrument reprocessing.

Background

Every sterilizer must be challenged with a Biological Indicator (BI, or spore test) each day it is used. This is to ensure that the sterilizer will actually kill microorganisms. processed spore vials require a certain time to incubate before indicating results.

BIs are considered to be the most reliable indicator of sterilization, more important than mechanical indicators (temperature, pressure and time) and chemical indicators (Class I indicators, Class 4 indicators, etc.).

If your daily BI passes, you can assume that your sterilizer is performing as it should and you can release and use the instruments you have sterilized with the sterilizer during the day.

The next day, if your BI fails, you cannot assume that any of the loads sterilized the day before have actually passed. There is a certain chain of events you must follow in this case.

Recall Programs

A recall program occurs when your Recall Policy must be activated. You must have written instructions available.

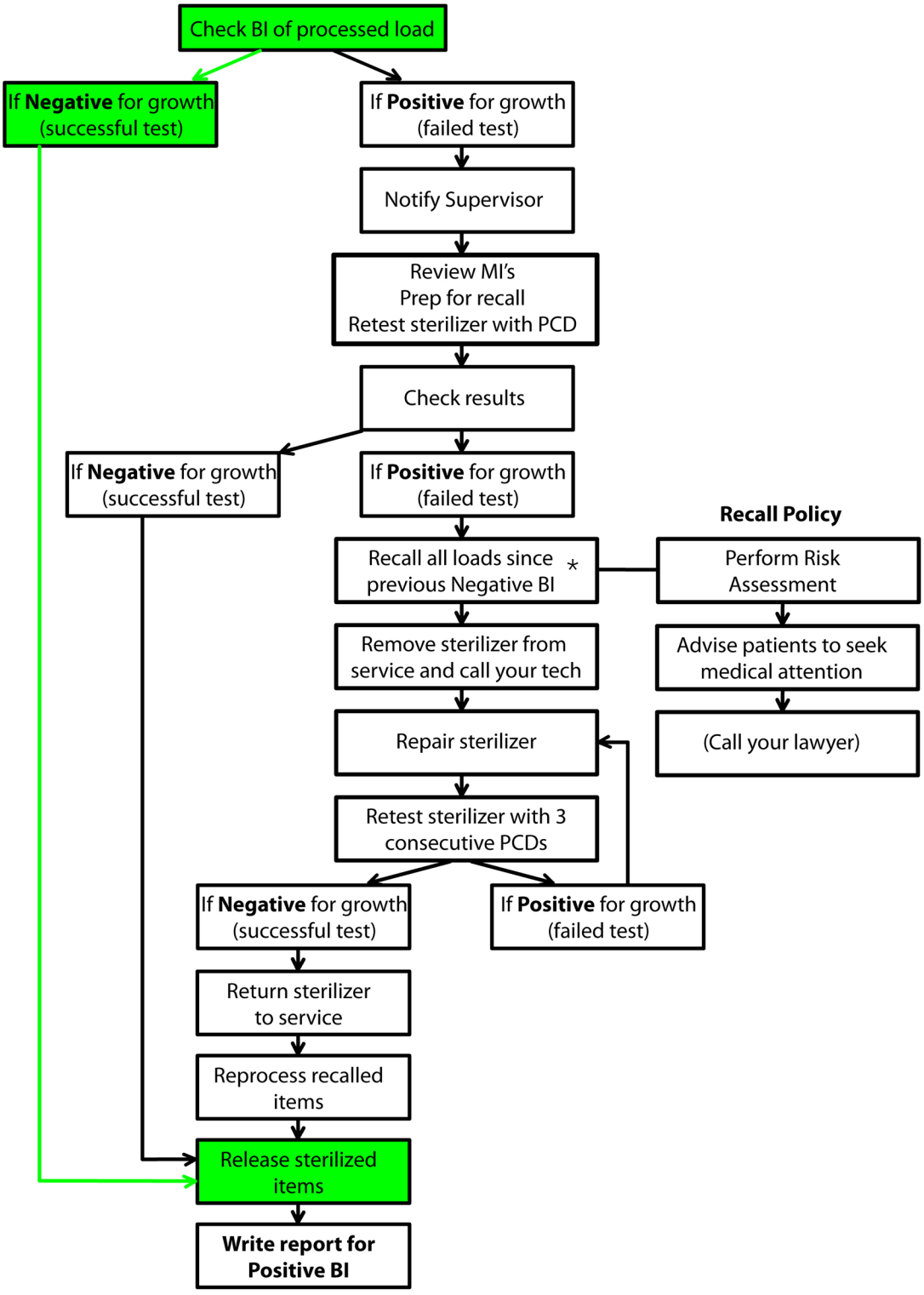
It includes, among other things:

A Risk Assessment: To determine the liklihood that the sterilization failure will impact your patients.
It includes, for example, the geographic prevalence of Hep or HIV in your area,
The percentage of Hep+ and HIV+ patients in your practice,
Consideration of the procedure: did it involve critical areas or not, etc.
Consideration of the instruments used: were they single-piece or hinged or difficult to disassemble, etc.
Evaluation of human error,
Evaluation of whether or not someone has deviated from the normal workflow of reprocessing, etc.

Instrument Recall:
You must be able to identify the instruments in the questionably sterilized loads.
You must be able to identify which specific patients were treated with instruments from the questionably sterilized loads.
You must be able to contact and advise these patients to seek appropriate medical attention, if indicated.
You must be able to identify and collect any of the affected instruments still in storage, for reprocessing.

This means you must assign a patient name and date of use to each instrument used in a particular procedure and be able to track the instruments from sterilization to storage to use.

A “Recall Program” refers to instrument tracking and use, not correction of mechanical difficulties with sterilizers.



The pathway in green indicates the normal course of action, when your daily BI passes.

*STERI*RECALL* was written specifically for automated instrument tracking and recall.

Visit **sterisimple.ca** to learn more.

Reprocessing.
Simplified.