

## Biological Indicators (BI's) - Load Control 2/03

**3M Health Care**

Steam Sterilization				Quarantine	Recall System	Record Keeping System	Subculture Positive
BI = Biological Indicator CI = Chemical Indicator							
Organization	Test Pact Contents	Placement	Frequency				
<b>AAMI</b> <i>Steam sterilization &amp; sterility assurance in health care facilities,</i> ANSI/AAMI ST46, 2002	16 towels, 16" X 26" folded lengthwise into 1/3's along long dimension, width-wise in the middle, place on top of each other, folds opposite each other, 9 X 9 X 6". One or more BIs between 7th and 8th towel in center. CIs placed adjacent to BIs. Tape with 2 pieces of tape around entire pack to yield a 6" high pack or use a disposable test pack of equivalent performance.	Flat (layer of towels are horizontal), normally in front/bottom, near drain, in a full load for routine testing.	Should be used at least weekly, but preferably daily, each load that contains an implantable.  Biological indicators with enzyme-based early-readout capability may serve as the basis for release of processed items, including loads containing implantable devices. Proper application of these devices requires periodic verification by continuing to incubate for surviving microorganisms to grow out. Periodic verification should be performed at least weekly, preferable every day that the sterilizer is in use.	Implantable devices quarantine until BI results available.	Recall and reprocess materials processed in that sterilizer from the sterilization cycle having the last negative biological indicator to the next cycle showing satisfactory biological indicator challenge results.	Yes (paper or electronic)	Should do
	See test pack above.	Flat (layer of towels are horizontal), normally in front/bottom, near drain, in an empty chamber.	Used for testing sterilizer when sterilizer installed, relocated, after sterilizer malfunction, after sterilization process failures and after major repairs ( 3 consecutive empty cycles).  Ongoing QA testing of representative samples of actual products being sterilized and product testing when major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type of packaging or wrapper used (place BIs and CIs in actual products that represent change).				
		Tests done in a full load.					

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<b>AAMI</b> <i>Steam sterilization &amp; sterility assurance in health care facilities,</i> ANSI/AAMI ST46, 2002 Continued			<p>Indicators fully complying with the requirements for a conventional BI [A biological indicator is a sterilization process monitoring device consisting of a standardized, viable population of microorganism (usually bacterial spores) known to be resistant to the mode of sterilization being monitored. A conventional BI requires incubation for an appropriate length of time to ensure that any surviving microorganisms will grow out.] should be used during initial installation testing, after relocation, after sterilization malfunction, after sterilization process failures, after any major repairs of the sterilizer and for periodic quality assurance testing of representative samples of actual products being sterilized. Early-readout capability should not be relied upon for these critical assessments.</p> <p>Positive Control: Each day a test BI is incubated, at least one BI that is from the same lot and has not been exposed to the sterilant should be incubated as a control.</p>				

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BI = Biological Indicator CI = Chemical Indicator  AAMI <i>Flash Sterilization -- Steam sterilization of patient care items for immediate use,</i> ANSI/AAMI ST37, 1996	Place one of more BIs and a CI in the tray configuration to be tested: a perforated, mesh bottom open surgical tray; a single-wrapped surgical tray; a protective organizing case; or a rigid sterilization container. Locate BIs and CI in most difficult-to-sterilizer portion of tray, case, or container.  See test pack above.  See test pack above.	Bottom shelf, empty sterilizer.  See placement above.  See placement above.	Should be used at least weekly, preferably daily, each load containing implantable devices. Each type of tray configuration (e.g., a perforated, mesh bottom open surgical tray; a single-wrapped surgical tray; a protective organizing case; or a rigid sterilization container) and each type of cycle (e.g., gravity-displacement, prevacuum, steam-flush pressure pulse, flash cycle with single wrapper) in routine use should be tested separately.  Sterilizers tested when installed and after any major repair (test three consecutive cycles with a biological indicator in a test tray).  After a positive biological indicator is obtained the sterilizer should be immediately re-tested.  Quality assurance testing of routinely processed supplies. Place BIs and CIs in the supplies.			Yes	Should Do

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BI = Biological Indicator CI = Chemical Indicator  <b>AORN</b> <i>Standards, Recommended Practices &amp; Guidelines, 2003</i>			<p><i>B. steraothermophilus</i> spore testing should be performed at least weekly and preferably daily.</p> <p>Additional monitoring of several consecutive sterilization cycles after installation, repair, redesign or relocation of sterilizers.</p>	AAMI recommends quarantine of the implantable device until the outcome of the BI result.  If flash an implantable, use immediately after a negative BI readout.	Appropriate action required.	Yes
<b>ASHCSP</b> <i>Recommended Practice for Central Service, Sterilization, Section 6, 2001</i>			<p>Should be used:                      Routinely daily, preferable in each load that contains critical items, e.g., instrument sets, individual surgical instruments, or any item that comes into contact with sterile tissue.</p> <p>After installation testing of sterilizer, after major repairs, or sterilizer relocation.</p> <p>Should be used at least once a day, every load of implantable items, when sterilization process is in question, a departure from normal operation, sterilizer relocation or undergone major repair.</p>		All issued and stored items from the positive biological indicator back to the last negative indicator must be retrieved and reprocessed.	Yes

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<b>CDC</b> <i>Guidelines for Handwashing and Hospital Environmental Control, 1985</i>			Should be used at least once a week and each load if it contains implantable objects.	Implantable objects until biological indicator is negative at 48 hours	Yes, if implantable objects.			
<b>JCAHO-</b> <i>Comprehensive Accreditation Manual for Hospitals, 2000</i>			As determined by facilities policies and procedures. Policies and procedures should be based on most stringent recommended practices, laws and regulations, and current scientific knowledge.					
<b>VA</b> <i>Handbook 7176</i>		Full load	Daily, each load containing an implantable device, after major sterilizer repairs.		Yes	Yes		

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