

BI = Biological Indicators  
CI = Chemical Indicators

Organization	Purpose	Placement		Record Keeping System	Bowie-Dick Type Testing
		External	Internal		
<p><b>AAMI</b> <i>Steam sterilization &amp; sterility assurance in health care facilities,</i> ANSI/AAMI ST46, 2002</p>	<p>Chemical Indicators are sterilization process monitoring devices designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile. The use of CIs is part of an effective quality assurance program; they should be used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process.</p>	<p>Use a Class 1 indicator to distinguish between processed and unprocessed items. Should be affixed to or printed on each package except if the internal chemical indicator is visible.</p>	<p>A Class 3, 4, or 5 indicator should be used within each package in the area least accessible to steam penetration; this might or might not be the center of the pack.  A class 5 integrating indicator may serve as the basis for the release of processed items, excluding implants. These integrating indicators must be used within the appropriate challenge test pack. Using Class 5 integrating indicators for this purpose does not replace the use of BIs.  If the interpretation of the CI suggests inadequate steam processing, the contents of the package should not be used.</p>	<p>Yes (paper or electronic)</p>	<p>A Class 2 CI (Bowie-Dick test) should be carried out each day the sterilizer is used, before the first processed load in an empty chamber.  The Bowie-Dick test should also be carried out during initial installation and after relocation of the sterilizer, sterilizer malfunction, sterilization process failures, and major repairs. Three consecutive cycles should be tested with a Bowie - Dick test in an empty chamber.  The Bowie-Dick test is used to evaluate the efficacy of air removal in dynamic-air-removal steam sterilizers [i.e., 274°F (134°C)].</p>
<p><b>AAMI</b> <i>Flash Sterilization – Steam sterilization of patient care items for immediate use,</i> ANSI/AAMI ST37, 1996</p>	<p>To detect potential sterilization failures that may result from personnel errors or sterilizer malfunction. The "pass" response of a chemical indicator does not prove that the item accompanied by the indicator is sterile.</p>		<p>Should be used in each tray or container.</p>	<p>Yes</p>	<p>Should be carried out each day the sterilizer is used, before the first processed load in an empty chamber.  The Bowie -Dick test should also be carried out during initial installation and after relocation of the sterilizer, sterilizer malfunction, sterilization process failures, and major repairs. Three consecutive cycles should be tested with a Bowie - Dick test in an empty chamber.</p>

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<b>AAMI</b> <i>Steam sterilization and sterility assurance in table-top sterilizers in office-based, ambulatory-care, medical and dental facilities,</i> ANSI/AAMI ST42, 1998	Chemical indicators are physical or chemical devices employed to monitor one or more sterilization process parameters for the purpose of detecting failures in packaging, loading, or sterilizer function. The use of chemical indicators is part of an effective quality assurance program.	Should be attached to or printed on all packages (except for packages that allow visual inspection of an internal indicator).	Should be used within each package, tray, or container, because variations in position or contents may effect steam contact of all surfaces and the time needed to attain the required temperature.	Yes	
<b>AAMI</b> <i>Ethylene oxide sterilization in health care facilities,</i> ANSI/AAMI ST41, 1999	Detect problems associated with incorrect packaging, incorrect loading of the sterilizer, malfunctions of the sterilizer, or incorrect preconditioning.	Should be attached to or printed on all packages except for packages that allow visual inspection of an internal indicator	Should be used within each package in area least accessible to EO penetration; this might or might not be the center of the package.	Yes	
<b>AORN</b> <i>Standards, Recommended Practices &amp; Guidelines,</i> 2004	Although process monitors do not verify sterility, they do indicate procedural errors and equipment malfunctions.  If the interpretation of the external and/or internal process monitors suggests inadequate processing, the item should not be used.  External process indicators differentiate between processed and non processed items.  Internal process monitors show that items have been exposed to one or more conditions of sterilization.	When the process indicator is not visible from the outside of the package, a separate process indicator should be used on the exterior of the package.	Should be used in each package and items being flash sterilized.	Yes	Daily in an empty chamber.

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<b>ASHCSP</b> <i>Recommended Practice for Central Service, Sterilization, Section 6, 2001.</i>	External CIs are used to distinguish processed items from non-processed items.  Internal CIs react to one or more critical sterilization parameters.	<b>Steam:</b> Should be affixed/printed on each package.  <b>EO:</b> Chemical indicators or integrators must be on and/or in each package.  <b>Other Low Temperature Sterilization Processes:</b> Use chemical indicators designed for the process.	<b>Steam:</b> Internal indicators/integrators should be placed inside each package and sterilization container.  <b>EO:</b> Chemical indicators or integrators must be on and/or in each package.  <b>Other Low Temperature Sterilization Processes:</b> Use chemical indicators designed for the process.	Yes	The same time each day and after major equipment repairs.
<b>CDC</b> <i>Guidelines for Handwashing &amp; Hospital Environmental Control, 1985.</i>	Do not reliably document sterility but show item did not bypass a sterilization procedure.	Should be visible on outside of each package.	Might have inside large pack to verify steam penetration.		
<b>JCAHO</b> <i>Comprehensive Accreditation Manual for Hospitals, 2005</i>		As determined by facilities policies and procedures. Policies and procedures should be based on most stringent recommended practices, laws, rules and regulations, and current scientific knowledge.	As determined by facilities policies and procedures. Policies and procedures should be based on most stringent recommended practices, laws, rules and regulations, and current scientific knowledge.	Yes	

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VA Handbook 7176	External indicator denotes package exposed to physical conditions, not evidence of sterility. Internal chemical indicators will not be used as a substitute for BIs.	Must be affixed to each package or item.	Follow manufacturers instructions for use, placement, and interpretation of results.	Yes	Daily