Chemical indicators are either physical or chemical devices used to monitor one or more of the process parameters of the sterilization cycle. Currently they are divided into 6 classifications. They are as follows:

Class 1: Process indicators are intended for use with individual items, e.g., containers, to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and nonprocessed items. Indicator tapes, indicator labels and load cards are examples of externally visible chemical indicators that are on the outside on the packages.

Class 2: Indicators are intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards. Bowie-Dicks are one type of specific testing most are familiar with. These are used to show the efficacy of air removal and steam penetration.

Class 3: A single variable indicator that is designed to solely show the exposure to one sterilization process at a stated value (SV) of the chosen variable. One example of a single variable is a temperature tube that houses a chemical pellet which melts at a specific temperature.

Class 4: These are considered as multiple variable indicators. They are designed to react with two or more of the critical variables and are intended to indicate exposure to a sterilization cycle at SVs of the chosen variable. Examples of these class 4s would be the paper strips with a color change chemical indicator. These are usually used inside each package.

Class 5: Integrating indicators are designed to react with all critical variables. These can be used as internal chemical indicators in all packs and containers for pack control monitoring. They can also be used as an additional monitoring tool in order to be able to release loads that do not contain implants based on the appropriate Process Challenge Device. These indicators can also be used in implant loads IF a Biological Indicator is run with the class 5 integrator. The load can NOT be released until the BI result is known except in emergencies.

Class 6: These are called emulating Indicators which are cycle verification indicators which are designed to react to all critical variables for specified sterilization cycles. In other words they are considered to be indicative of a complete cycle by showing the presence or absence of specific time and temperature parameters during a cycle. They are currently only available in the US for steam sterilization. Chemical indicators are convenient, are inexpensive, and indicate that the item has been exposed to the sterilization process. In one study, chemical indicators were more likely than
biological indicators to inaccurately indicate sterilization at marginal sterilization times (e.g., 2 minutes).

Keywords: steam indicator class 4, steam indicator class 6, autoclave tape, bowie dick test pack, chemical indicator, class 5 steam integrator ...

Chemical indicators should be used in conjunction with biological indicators, but based on current studies should not replace them because they indicate sterilization at marginal sterilization time and because only a biological indicator consisting of resistant spores can measure the microbial killing power of the sterilization process. Chemical indicators are affixed on the outside of each pack to show that the package has been processed through a sterilization cycle, but these indicators do not prove sterilization has been achieved. Preferably, a chemical indicator also should be placed on the inside of each pack to verify sterilant penetration. Chemical indicators usually are either heat- or chemicalsensitive inks that change color when one or more sterilization parameters (e.g., steam-time, temperature, and/or saturated steam; ETO-time, temperature, relative humidity and/or ETO concentration) are present.

Chemical indicators have been grouped into five classes based on their ability to monitor one or multiple sterilization parameters. If the internal and/or external indicator suggests inadequate processing, the item should not be used. An air-removal test (Bowie-Dick Test) must be performed daily in an empty dynamic-air-removal sterilizer (e.g., prevacuum steam sterilizer) to ensure air removal. The definitions listed above were taken from the ANSI/AAMI/ISO 11140-1:2005 definitions.

Definitions:

Chemical indicator: device for monitoring a sterilization process. The device is designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The “pass” response of a chemical indicator does not prove the item accompanied by the
indicator is necessarily sterile. The Association for the Advancement of Medical Instrumentation has defined five classes of chemical indicators: Class 1 (process indicator); Class 2 (Bowie dick test pack indicator); Class 3 (single-parameter indicator); Class 4 (multi-parameter indicator); and Class 5 (integrating indicator).