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LEARNING OBJECTIVES

1. *Understand the background and make up of chemical sterilization indicators (CIs)*
2. *Understand the way in which chemical indicators change color during exposure to sterilization processes*
3. *Understand how and under what circumstances chemical indicators are used*

SELF-STUDY SERIES

Chemical Indicators for monitoring sterilization processes

by Brian Kirk

There are many processes used for the sterilization of single use and re-usable medical devices.[1] In industrial settings where large scale sterilization takes place, physical processes such as irradiation with gamma, e-beam or "soft" X-rays and chemical processes employing ethylene oxide gas, are used. Steam sterilization is extensively used in the Pharmaceutical Industry to produce many water based injectable fluids. In the healthcare sector such as hospital sterile processing departments (SPDs), or dental surgeries and general practitioner's offices, steam sterilization is the predominant process used. In hospital SPDs there are some reusable medical devices such as flexible endoscopes, which need to be sterile but cannot withstand the high temperatures and pressures used in steam sterilization. In these cases, low temperature sterilization processes are used employing ethylene oxide or vaporised hydrogen peroxide. Low temperature steam mixed with formaldehyde vapor is also used in some countries, but not in the U.S.

Whichever and wherever a sterilization process is used, it must be validated and routinely monitored to ensure ongoing efficacy.[2] The characteristics that must be monitored within the process are those that kill any microbial contaminants present on the medical device; these are called the process variables.[3] Thus, for example, in steam sterilization, the characteristics of the process which cause microbial kill are the temperature and time of exposure in the presence of moisture.[4] The steam sterilization process takes place in a saturated steam environment in a sealed pressure vessel (called an autoclave), so moisture is present in a more-than-adequate amount. However, the presence of residual air from an inadequate air removal stage during the process or the presence of contaminating gases in the steam supply (called non condensable gases; NCG) can lead to inadequate moisture levels at the surfaces that need to be sterile. This compromises the efficacy of the process.

There are three basic methods for monitoring sterilization processes. One measures the physical characteristics of the process such as temperature or time of exposure (physical indicators). Another consists of a preparation of bacterial spores, presenting a known resistance to the process, but inactivated by an efficacious process (biological indicators). The third method consists of a mixture of reactive chemicals (printed on a substrate) that responds to defined characteristics of the processes so that visible change is observed after suitable exposure (chemical indicators; CIs). It is the purpose of this series of articles to expand further on this latter approach for monitoring sterilization processes.

CIs for monitoring sterilization processes

Historical perspective:

Chemical indicators are, in essence, products which give some visual evidence of exposure to a specific combination of process variables. Thus, in moist heat sterilization they respond to time and temperature in the presence of moisture when autoclaved. Chemical indicators have been used for many years and textbooks from the early part of the 20th century discuss their use.[5,6] One of the earliest was a wax plug enclosed within a sealed glass ampoule, called a Diak tube,[7] designed for monitoring steam sterilization processes and still available today. The wax melts at the sterilization temperature indicating that at least this had been achieved but provides no evidence of time of exposure or presence of moisture. Autoclave tape has been used for many decades.[8] Several studies have been conducted to assess CI performance,[9,10] including one in 1958 by the famous microbiologist, Kelsey, who proposed the attributes of the ideal chemical indicator.

"The ideal chemical indicator should follow a temperature time curve which runs parallel to that of a pathogenic spore bearing organism but offset by a distance which allows a reasonable margin of safety…… The indicator should show an unequivocal color change which is completed

suddenly at the end of the exposure time and it should be stable in storage, cheap and, if possible, sensitive only to moist heat….."

Chemical Indicator formats.

The simplest form of chemical indicator is an ink printed on a substrate. The substrate may be paper or plastic based and used to make an adhesive label which can be fixed onto the outside of surgical instrument sets and sterile packs. The ink might be printed directly onto sterile packaging materials such as paper bags or pouches. The ink might also be applied to adhesive tapes to make indicator tape which can be used to secure instrument sets wrapped in flexible wrapping materials.[8]

There are also special kinds of chemical indicators, called "moving front" CIs.[11] These CIs have a more complex construction. They consist of a pellet of dye which is placed within an indentation on a foil base. A paper wick is then placed in contact with the dye pellet and the whole assembly then sandwiched between a semi permeable membrane and the foil base. An adhesive label is then usually placed over the semi permeable membrane with informational material printed on it. Figure 1, below, shows the construction of a typical moving front chemical indicator.

In recent times a new kind of CI has been introduced in which the indicator ink is printed on a substrate covered with an impervious polymer sheet with gaps cut along its length. Beyond the "accept" line printed on top of the CI, the overlying sheet totally encloses the ink creating a small gap down which the sterilant must penetrate to affect the color change.[12]

Chemical Indicators have also been supplied in other formats in which they are incorporated into some form of test device which is then used in a special test to ensure the sterilizer is functioning correctly, for example the Bowie and Dick test.[13]

Chemical indicator inks.

The inks used for making printed CIs are usually made from chemical substances which react together when exposed to the process variables of a sterilization process. For example, in steam sterilization the presence of moisture enables the reaction to rapidly take place and the time and temperature of exposure enable the reaction to proceed at an appropriate speed so that the color change occurs by the end of the process. The chemical reactions which take place usually give rise to a color change which can then be interpreted by the observer. As an example, two reagents may be included in the ink which give a cream starting color but during the reaction they combine to give a black colored by-product.[13] These inks often contain inorganic chemical reagents. Alternatively, the color change may be due to the two reacting chemicals giving rise to a change which cause an additional reagent included in the ink to change color. For example, the ink may contain a pH indicator which changes color due to the release of an acidic by-product from the reaction between the two principal reagents. These inks often contain organic chemical reagents.[15] A third category of ink is one in which the moisture present in the sterilization process causes the ink to change color. In this instance the chemical reagent is reacting with the moisture in the steam to change from one hydrated state to a second,[16] this giving rise to the color change. Figure 2 shows examples of the reactions which are used. It is important to recognise that CIs are designed for use in specific sterilization processes because the chemical reagents included react to the process variables associated with the sterilization process. Thus, a steam CI should not be used in an ethylene oxide sterilization process and vice versa because the EO indicator will have reagents which are designed to react with the EO present in the process.

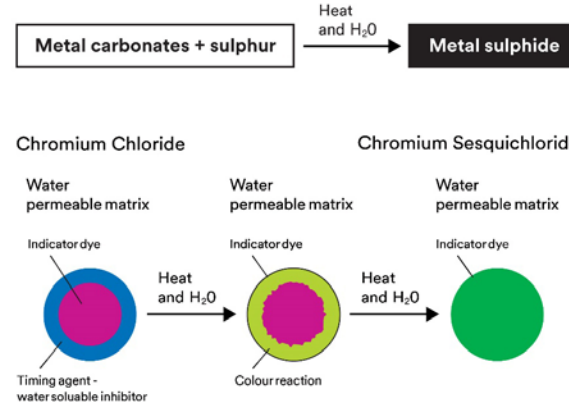

Figure 2:
Some exampls of chemical reactions used in chemical indicators

For moving front chemical indicators, the color change is due to a physical change - rather than a chemical reaction. When exposed to the process variables the dye pellet enclosed within the sandwiched layer of foil base and semipermeable membrane (see figure 1) melts and begins to migrate along the attached wick due to capillary action. The speed of migration is governed by the temperature of exposure and by the presence of moisture passing through the semipermeable membrane.[11, 17]

The nature of the color change.

The nature of the color change depends on the reactions taking place within the ink. For some color change indicators, the change from the starting color to the end color is gradual. Figure 3 shows a plot of the depth of color (optical density) occurring as the time of exposure in a steam sterilization process progresses. It can be seen from the shape of this curve that as the exposure time increases the speed at which the color changes slow down until it reaches a plateau. For other printed inks the color change may be quite rapid at a specific point in the reaction. Thus, the starting color is maintained until a predefined exposure time is reached at which point the color changes to a second color over

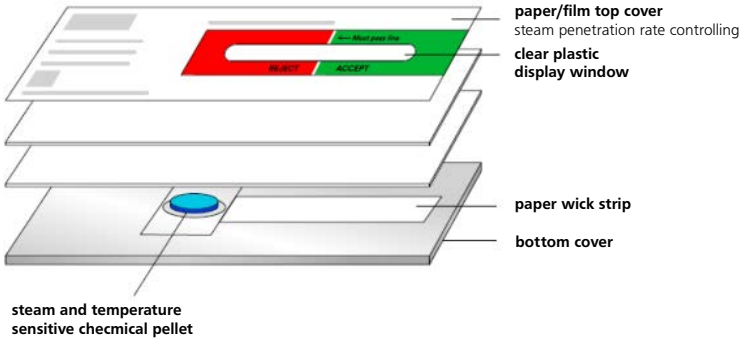

Figure 1:
The construction of a moving-front chemical indicator showing an aluminum platen (bottom), and indicator dye pellet (indicated), a paper wick (indicated), a semipermeable membrane (middle) and a paper label showing graphics (top).

Self-Study Test Answers: 1. B, 2. A, 3. D, 4. C, 5. D, 6. A, 7. D, 8. B, 9. C, 10. A

a period of a few seconds and then stays at that color for the remaining exposure time.[15]

For CIs used in special tests the indicator ink will be designed to react to certain conditions occurring in the sterilization process. As an example, in the Bowie and Dick test, the indicator inks will be designed to change color when exposed to a specified temperature (.g. 134ºC) for a defined period (3.5 minutes) when in the presence of moisture (saturated steam). The sensitivity of the ink towards moist heat conditions is especially important in this test since the concept behind the test is that any residual air within the test device prevents the ingress of moisture and so the ink does not change color.[13]

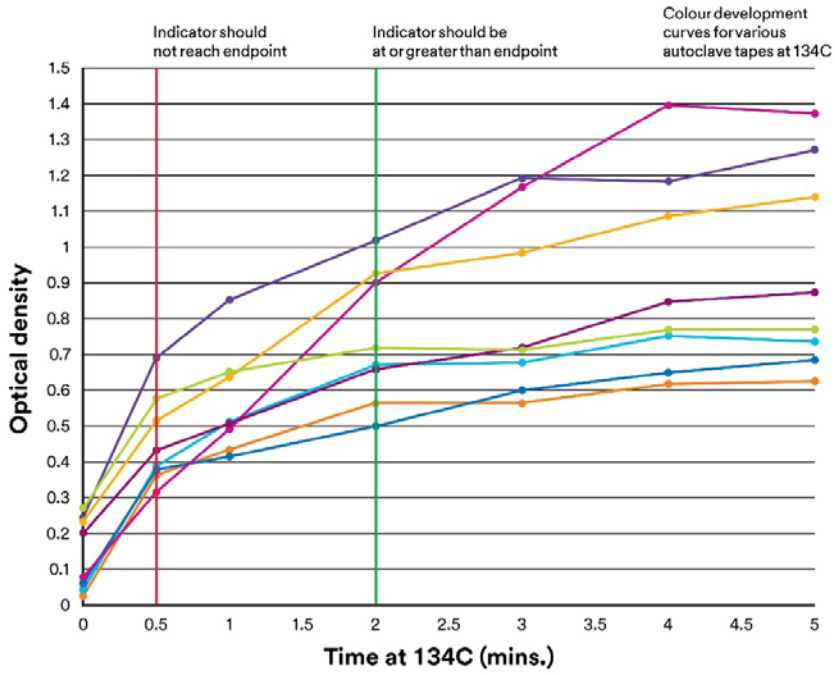

Figure 1:
Graph showing the color change of some chemical indicators printed on commercially available autoclabe types. The vertical lines show the exposure conditions to whicha type 1 process indicator must show a fail result (red line) and pass result (greenline).

The use of chemical indicators.

Chemical indicators are used to monitor various aspects of a sterilization process and can be divided into three categories based on how they are employed:

- External chemical indicators
- Internal chemical indicators
- Special test indicators.

External chemical indicators are placed on the outside of every sterile pack to give a clear indication whether the pack has been exposed to a sterilization process or not. It is important to understand that these types of indicators do not provide any evidence that the pack is sterile, but simply that the pack has been put through a process. The overarching purpose of such indicators is to ensure that instrument packs which have not been processed are not released from the SPD and aid product flow through the SPD. They are also used by the operating room professionals to again ensure that they are using a sterile set which has been processed. Such indicators should have a very clear color change which cannot be misinterpreted.

Internal chemical indicators are placed inside sterile packs during assembly. They are designed to indicate that sterilizing agent has penetrated through the packaging materials and appropriate conditions have been met at the point of placement. It is important to understand that such indicators cannot alone be used to judge if the pack is sterile; other factors must also be considered.[2] Internal pack indicators are primarily interpreted by the OR practitioners, and it is vital that they are appropriately trained in the interpretation of the CIs and have available appropriate reference material such as wall charts and clear instructions. It is vital that the SPD has a good communication channel with the OR management teams so that any changes in the internal indicators used can be communicated to the end user.

Special Test Indicators are used in specific performance tests described in standards and guidance documents to ensure that the sterilizer is performing according to specification. An example of such a CI would be the Bowie and Dick Test, which employs a chemical indicator placed within a stack of textile material (13). When used daily within the sterilizer, the test is designed to assess the capability of the process to remove air and enable steam penetration. The test is described in many standards and guidance documents[2, 4] and involves placement of a chemical indicator A4 sheet placed in the centre of a stack of towels. There are many alternative commercially produced test packs available which have equivalent performance but are more consistent and convenient in use.

Conclusions

Along with Physical measurements and Biological Indicators, Chemical Indicators are one of the three basic types of technology which can be used to routinely monitor the efficacy of sterilization processes used in industry and the hospital SPD. They can be used to identify unprocessed from processed surgical instrument sets when adhered to the outside of packs thereby avoiding non sterilized packs being sent to the OR department. They can be used to indicate that sterilizing agent has penetrated through the sterile barrier system packaging and stated exposure conditions have been met thereby avoiding inadequately or incorrectly processed loads being used.

Chemical Indicators are therefore an extremely useful and practical tool for ensuring SPD processes are functioning correctly. HPN

This article is part of a three-article series. Part two will be in our December issue.

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Chemical Indicators for monitoring sterilization processes

Circle the one correct answer:

1. **Radiation sterilization is used extensively in hospitals for sterilizing surgical instruments**
   A. True
   B. False

2. **Steam Sterilization is used to sterilize many intravenous infusion fluids.**
   A. True
   B. False

3. **Select the basic method for monitoring sterilization processes:**
   A. Chemical Indicators
   B. Biological Indicators
   C. Physical Indicators
   D. All of the above.

4. **Chemical Indicators were first used in...**
   A. The 1600's
   B. The 1700's
   C. The 1900's
   D. The 2000's

5. **What is a characteristic of a moving front CI?**
   A. A dye pellet
   B. A foil base
   C. A semi permeable membrane
   D. All of the above

6. **Some chemical indicators rely on physical changes to cause the color change.**
   A. True
   B. False

7. **There are three basic uses of CI's. Indicate the correct ones.**
   A. External CIs
   B. Internal CIs
   C. Special test CIs
   D. All of the above.

8. **Internal CIs are designed to show that the pack is sterile.**
   A. True
   B. False

9. **The Bowie and Dick test is used to test a sterilizer:**
   A. Hourly
   B. Every Shift
   C. Daily
   D. Weekly

10. **Commercially produced Bowie and Dick Test packs must have equivalent performance to a standard stack of towels with a CI sheet.**
    A. True
    B. False

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