

STERILIZATION OF MEDICAL DEVICES

In the last weeks, we received some reports regarding the umpteenth fake news on the nasopharyngeal swabs used for COVID-19 testing. According to an error-filled YouTube video, these swabs could have a carcinogenic effect due to their sterilization process with ethylene oxide or irradiation. Let's shed some light on the topic.

What is a swab?

Swabs are devices intended to collect biological samples from the human body, for subsequent analysis. Copan Swabs are sterile and ready to use.

What does Sterile mean?

Sterile means “free of viable microorganisms”. Microorganisms such as bacteria and viruses are present on all people's skin and mucosa, surfaces, soil, and water and are responsible for many diseases and infections. In the late 19th century, Louis Pasteur discovered that removing bacteria from medical equipment eliminates the risk of infection. It was at this point that sterilization of medical devices was conceived².

Why Sterile?

Sample collection is performed touching the skin or mucosa with the swab – through body orifices or wounds – for a few seconds.

The swab sterility guarantees that no contaminants are transferred from the swab to the patient, ensuring both patient safety and the quality of the diagnostic results.

How do I know if a Copan swab is sterile?

Sterile swabs are identifiable by the presence of standardized and internationally recognized symbols² printed on their label, such as:



These two symbols indicate that the swab has been sterilized using, respectively, Irradiation (R) or ethylene oxide (EO).

The sterilization modality — R or EO — is determined by material compatibility, process availability and location, and legacy regulatory approval².

Are R irradiated Copan swabs safe for use?

Yes, irradiated swabs are safe for use.

The irradiation process is performed exclusively in plants specifically authorized and certified to sterilize medical devices. Irradiation can be performed with electron-beam rays or gamma rays. Electron beams are generated by an electrical source. On the other hand, Gamma rays photons are generated at a distance from a naturally decaying Co₆₀ (Cobalt) source. Under controlled conditions, both these technologies are widely used to sterilize several types of medical devices.

Depending on the process type, the swab, protected in its final packaging, is exposed to the irradiation source for a time ranging between a few minutes to a few hours. In both cases, the energy used to irradiate the product is much lower than the energy that would be needed to induce radioactivity in the materials.

The irradiation process is tightly regulated by international standards⁴. Medical devices sterilized by irradiation are subjected to rigorous process validation and product controls before being placed on the market, to ensure they are safe to use.

Are EO-treated Copan swabs safe for use?

Yes, EO- treated swabs are safe for use.

EO is the most widely used gaseous sterilization agent globally and has been around for nearly 90 years.

The manufacturer must follow several regulatory requirements for the EO sterilization process, supervised by the Competent Authority². The EO sterilization process is conducted exclusively in plants specifically authorized and certified to sterilize medical devices. The sterilization process includes several steps: preconditioning and humidification, gas introduction, exposure, evacuation, and air washes. Afterward, air washes and product aeration are set to reduce gas residuals on the device further.

The EO sterilization process is tightly regulated by international standards⁴ and controlled to ensure negligible residues are left on the product after its exposure to the gas. Medical devices sterilized by EO are subjected to rigorous controls before being placed on the market to ensure they are safe to use⁶.

Are there limitations to the use of Copan swabs in young people or for multiple sampling?

No, there are no limitations for use in specific age individuals or in case of multiple sampling.

Sterile swabs are safe for use, and they have been tested according to the most restrictive international standards to guarantee that their biocompatibility. Copan Sterile swabs are safe for use and have been widely used for nearly 40 years.

**Any question? Contact our customer service department
customercare365@copangroup.com**

References

1. *ISO 11139:2018(en) Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*
2. (2017, August 31). *A Comparison of Gamma, E-beam, X-ray and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products*. Retrieved March 13, 2019, from <http://iiaglobal.com/wp-content/uploads/2018/01/White-Paper-Comparison-Gamma-Eb-Xray-and-EO-for-Sterilisation.pdf>
3. *ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
4. *ISO 11137-1:2006 Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices- Amd1:2013-Amd 2:2018*
5. *ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

6. ISO 10993-7:2008/AMD 1:2019 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants

7. ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process