

Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

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EO Sterilisation & Packaging - Medistri

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The design of the product's packaging should be developed during the early-stages of a medical device's creation-phase.

Outside of the validation and regulatory criteria's that both the medical device and its packaging must meet - the primary intention of the packaging is to keep a sterile barrier until the final medical device is in usage. This means the safe delivery of the product from the manufacturing phase to final use with its patient.

It is critical when evaluating packaging materials that the risks from sterilisation methods are assessed. Different types of sterilisation methods impact materials and products in different ways.

All sterilisation packaging systems must undergo multiple testing to demonstrate the material to withstand the sterilisation parameters maintains sterility post processing and also allows for the sterilant to penetrate and achieve the required sterility assurance level (SAL)

When a medical device's packaging is not considered a priority early-on, the manufacturer may be faced later-on by a number of problematic and costly challenges.

Most importantly, it may lead to delays during the Sterilisation Validation stage

All adjustments to the medical devices's packaging should be made early-on. And in order to increase cost-efficiency and reduce bottlenecks - there are a number of considerations that need to be taken into account. With considerations for the cycle vacuum, packaging must be able to intake and outtake gas, therefore a breathable material must be used. Porous materials are required for processing in EO.

Packaging engineers should have a solid understanding of the cycle parameters before embarking. Factors include temperatures, dwell times, pressure and (maybe most critically) the rates of change for these key parameters.

- 1 - The Packaging's Physical Quality, Strength & Reliability
- 2 - The Development & Manufacturing Costs of the Packaging
- 3 - The Packaging's User-Experience
- 4 - Regulatory Challenges of Future Markets
- 5 - The Package Ease-of-Sterilisation

Medistri's team has gathered more than a decade of experience working with the world's most innovative healthcare companies and helping them scale globally. Working early on with Medistri's Sterilisation Team during the product development process will help prevent potential costly failures.

🔗 To learn more about our Ethylene Oxide Contract Sterilisation Services, visit our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri team

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