SARTURIUS

Touch-Free Transfer of Gelatine Filters: No Forceps Required

Gelatine filter disposables are individually packaged, presterilized and ready-to-use units, each consisting of a gelatine membrane filter (GMF) and a support base. These gelatine filters, used with the MD8 Airscan®, are designed for collecting airborne microbes and viruses in Grade A environments (e.g., at filling lines, depyrogenation tunnels, stopper fills and monitoring isolators during sterility testing).

After sampling with the MD8 Airscan®, the gelatine membrane filters are typically transferred directly onto an agar nutrient plate in a touch-free manner. The gelatine filter being hygroscopic in nature dissolves on the moist surface of the culture media. This facilitates near complete

recovery by allowing microorganisms to be in direct contact with the nutrients. The plates are then incubated at the required temperature, and the colonies are counted.

In special cases, the gelatine filter can be dissolved for evaluations, such as:

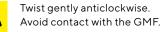
- When inhibitors (e.g., disinfectants or antibiotics) are present in the air being sampled
- When very low colony counts are to be expected for detection via sensitive methods such as PCR
- When the collected microorganisms need to be incubated on several different agar media at the same time of complex data



Instructions for GMF Transfer

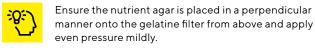
1. Detach the plastic cap of the disposable



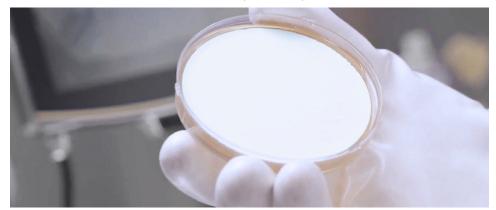


2. Place an inverted 90 mm nutrient media plate onto the GMF





3. Transfer is touch-free and does not require forceps.



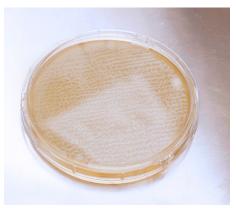
(3)

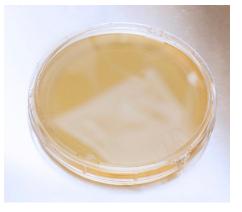
The gelatine filter adheres to the nutrient media within seconds.

Incubate the nutrient media plate at the required temperature.

4. Dissolving of the GMF









Due to its hygroscopic nature, the gelatine filters dissolves onto the surface of the nutrient media plate without any loss of microorganisms. Unlike impaction sampling, which may reduce moisture levels on plates and potentially affect viability, gelatin filters retain moisture from the environment, protecting microbes and viruses via a self-sustaining hydrated shell.

Best Practice Video Guide for Sterility Testing with Sterisart

In the pharmaceutical industry sterility testing is a key compendial final release regulatory requirement and is designed to confirm that sterile products, such as sterile pharmaceuticals and medical devices, do not contain contaminating viable microorganisms, according to EP2.6.1, USP 71, JP 4.06 and ICH Q4B Annex 8. This essential test is part of the strategy to assess if a manufactured batch of a sterile product is suitable for release.

Scan or click the QR code to watch the video, where we guide you through how best to perform your membrane filtration-based sterility testing.

Germany

Sartorius Lab Instruments GmbH & Co. KG
Otto-Brenner-Strasse 20
37079 Göttingen
Phone +49 551 308 0

USA

Sartorius Corporation 3874 Research Park Drive Ann Arbor, MI 48108 Phone +1 734 769 1600