

Clever Solutions for Safe Transfer of Environmental Monitoring Materials

Combine convenience with regulatory compliance when manufacturing in critical cleanrooms, RABS or isolators

When aseptically manufacturing and filling pharmaceuticals, you need to introduce materials into the critical area from time to time, particularly consumables and accessories for environmental monitoring. If no validated process is in place to allow an immediate transfer, a new decontamination cycle must be run. This, however, loses you valuable time and money. But now there are clever solutions that make safe equipment transfers time-saving and convenient while keeping you fully compliant.

The **IsoBag® Rapid Transfer Solution** is a unique transportation system that holds ready-to-use ICR Contact or Settle Plates in several single-sleeved packs available for immediate use. It is simply mounted to the rapid transfer port of the isolator.

To support active air monitoring with MAS-100 NT® samplers, we offer **disposable Safe Lids**. These perforated lids can replace the standard aluminum lid, which requires the transfer out of the critical area each day for autoclaving, and back in again when completed.

IsoBag® Rapid Transfer Solution

The IsoBag® Rapid Transfer Solution improves workflows and efficiency by keeping settle plates for air monitoring or contact plates for surface monitoring readily at hand:

- Simply mount to the isolator's alpha port
- Save valuable storage space inside the isolator
- Continue working without interruption for longer periods, even over several days
- Avoid the need to decontaminate primary bags of plates, saving much time
- Mount and remove several times without compromising bag integrity
- Take used plates safely to the incubator in the included gamma-irradiated transportation bags
- Available with a wide variety of ICR and ICRplus Settle or Contact Plates in single-sleeved bags of 10:
 - 8 x 10 settle plates + 20 transportation bags (all single-bagged)
 - 10 x 10 contact plates + 20 transportation bags (all single-bagged)

Regulations and guidances stress the importance of safe material transfers

EU GMP **Annex 1** states that the "transfer of equipment into and out of the cleanrooms and critical zones is one of the greatest potential sources of contamination". It suggests that such transfers be carried out in a unidirectional process and proposes paths for solutions. "Where sterilization upon transfer of the items is not possible, a procedure which achieves the same objective [...] should be validated and implemented [e.g. using an effective transfer disinfection process, rapid transfer systems for isolators [...]]". **Annex 1** also suggests to consider rapid transfer port technology, which the IsoBag® rapid transfer solution uses.



ICR and ICRplus Settle and Contact Plates

Available within the IsoBag® rapid transfer solution as well as separately, our ICR and ICRplus agar plates are designed to meet the demanding requirements for microbial air and surface monitoring in aseptic production environments:

- Available with neutralizers that enable microbial growth in the presence of commonly used disinfectants or β -lactam antibiotics
- Cleanroom-produced and gamma-irradiated to minimize the risk of cross contamination
- VHP-impermeable triple-sleeve packaging (transparent) for safe transfer into Grade A areas
- Data matrix barcode on each plate to support data integrity
- Lockable plates (ICRplus) available for safe transportation
- High 30 mL filling volume (settle plates) for prolonged exposition and incubation
- Room temperature storage
- Long shelf life of up to 12 months, making fewer growth promotion tests necessary



Safe Lid for MAS-100 NT® Air Samplers

The Safe Lid, a disposable, ready-to-use perforated lid made of recyclable ABS for active air monitoring with MAS-100 NT® air samplers, makes workflows more efficient and offers a range of further advantages:

- 24/7 availability, with no time lost on cleaning, autoclaving and associated activities
- Similar physical and biological recovery efficiencies as the standard perforated lid
- Easy to exchange, no twisting needed
- E-beam sterilized and individually double-bagged for safe transfer
- Individual barcodes to support digital workflows and tracking
- Particle generation within ISO 5/Grade A limits
- Compatible with 90 mm Petri dishes, including ICR/ICRplus Settle Plates
- Reproducible results thanks to camera-based checks of all perforations



Find out more about safe transfers and the above products by watching our webinar "Navigating Cleanroom Compliance for Safe Material Transfer".



To place an order or receive technical assistance:

Order/Customer Service: SigmaAldrich.com/order

Technical Service: SigmaAldrich.com/techservice

Safety-related Information: SigmaAldrich.com/safetycenter

SigmaAldrich.com

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

We have built a unique collection of life science brands with unrivalled experience in supporting your scientific advancements.

Millipore® Sigma-Aldrich® Supelco® Milli-Q® SAFC® BioReliance®

© 2025 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved. Merck, the vibrant M, BioReliance, IsoBag, Millipore, Milli-Q, SAFC, Sigma-Aldrich, and Supelco are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.

MK_FL14447EN Ver. 1.0 63663 06/2025

