

Change Notice No.	Notification date	Implementation date
CN/A/25/004	March 10, 2025	April 10, 2025

Subject :Minimization of EPE (Expanded Polyethylene) used as protective packaging in the packing of mdi Single Use Assemblies/Systems.

Scope :This change will affect the packaging of gamma sterilized mdi Single Use Assemblies/Systems, part number is mentioned below (where # can be any numeral or alphabet):

- **A#####3##**

Background:

Currently, EPE (Expanded Polyethylene) is wrapped around the single use assemblies to provide cushioning and to prevent damage due to sharp edges of the components such as locking ties, oetiker clamps, pinch clamps etc. The wrapped assemblies are further primary packed in packaging pouch followed by secondary packaging.

Need for Change:

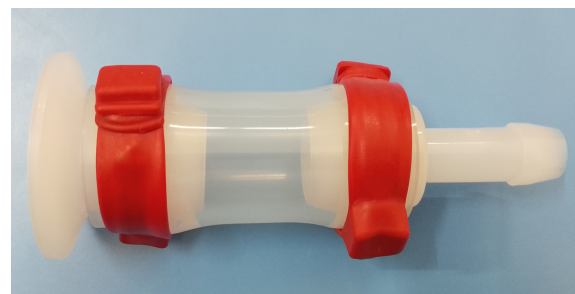
The EPE used in packaging of single use assemblies is opaque in nature and it is difficult to inspect the components during final inspection of packed assemblies. To facilitate the visual inspection and to improve the transparency of packed single use assemblies/systems, the usage of protective packaging i.e. EPE shall be minimized.

In order to do so, the followings changes are proposed:

- Use of EPE as a complete over wrap shall be discontinued to facilitate the final visual inspection of packed assemblies.
- In order to prevent any damage to primary packaging pouch, sharp edges of components such as locking ties, oetiker clamps and pinch clamp shall be covered with red caps and tie guards/oetiker guards (as shown in pictures below).



Pinch Clamp with red cap



Connection covered with oetiker and tie guard

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- The large components such as capsule filters, threaded clamps etc. shall be covered with EPE.
- To prevent the sticking of assembly with the packaging pouch (in absence of EPE wrap), the same shall be wrapped in transparent film prior to primary packaging.

How Does It Affect the User:

From a user point of view, the minimization of EPE shall provide better visibility of packed single use assemblies/systems. All product specifications including material of construction as well as other performance specifications shall remain unchanged.

Implementation of change

mdi gamma sterilizable Single Use Assemblies manufacture after the implementation date will have the said changes in product.

In case you have any queries, please feel free to contact our Technical Support Team at 'info@mdimembrane.com'.



**Head - Quality Assurance (Single Use System)
Advanced Microdevices Pvt. Ltd.**