

Change Notice No.	Notification date	Implementation date
CN/A/24/004	November 22, 2024	November 30, 2024

Subject : Change in design of AseptiFit fittings used as components in Single Use Assemblies.

Scope : This change will affect the AseptiFit fittings with catalog number mentioned in annexure attached.

Background:

In our efforts to improve the product design, a change has been initiated for AseptiFit fittings (Tee, Cross, Reducer, Straight, Elbow and Y connector) used as components in Single Use Assemblies. The fittings shall be strengthened by addition of ring design at the corners. This change will not impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

The existing AseptiFit fittings have been validated for appropriate connection in the assemblies. Sometimes, whiteness was observed in gamma irradiated AseptiFit fittings after application of excessive force on it, which impact the physical appearance of the fittings. However, the functionality of the fittings remains same.

In order to strengthen the AseptiFit fittings, the design of same shall be improved.

No changes have been made/done to the material of construction, performance parameters, manufacturing process, critical dimensions and traceability.

How Does It Affect the User:

This change is related to design of AseptiFit fittings, used as a component in Single Use Assembly. All product specifications including material of construction as well as performance specifications for fittings shall remain unchanged. The pictures describing the change are shown below.

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Existing design of Tee Connector



Proposed Design of Tee Connector



Existing design of Y Connector



Proposed Design of Y Connector

Implementation of Change:

AseptiFit fittings catalogue no. as mentioned in the annexure manufactured after the implementation date, will be with improved design. However, the available stock of AseptiFit fittings with old design will be supplied til the stocks last.

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



**Head - Quality Assurance Single Use Systems
Advanced Microdevices Pvt. Ltd.**

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Annexure

Part No. of affected AseptiFit fittings

Tee Connector	Y Connector	Cross Connectors
FPXA02HHXXXX	FPXA01AAXXXX	FPXA05HHXXXX
FPXA02QQXXXX	FPXA01HHXXXX	---
FPXA02IIXXXX	---	---
FPXA02QBXXXX	---	---
FPXA02QHXXXX	---	---