

Change Notice No.	Notification date	Implementation date
CN/F/23/003	April 26, 2023	April 28, 2023

Subject : Improved primary packaging for mdj Stericheck (Closed Sterility Test System)

Scope : This change will affect the products with following catalog numbers: (# can be any alphabet or numeral):

- SHFC0902#####
- SHLC0902#####
- SHPC0902#####
- SH1#0902#####
- SH1#0902#####
- SH2#0902#####
- SH3#0902#####
- SLV#0902#####
- SMLC0902#####
- SMP#0902#####
- SPC#0902#####
- SPF#0902#####
- SVCC0902#####
- SV1#0902#####
- SV2#0902#####
- SV3#0902#####
- SV4#0902#####

Background:

In our efforts to continuously improve our products, certain changes have been made in the primary packaging of mdj Stericheck with catalog numbers as mentioned in the scope. This advance change notification is initiated to communicate this updated information to the user.

Need for Change:

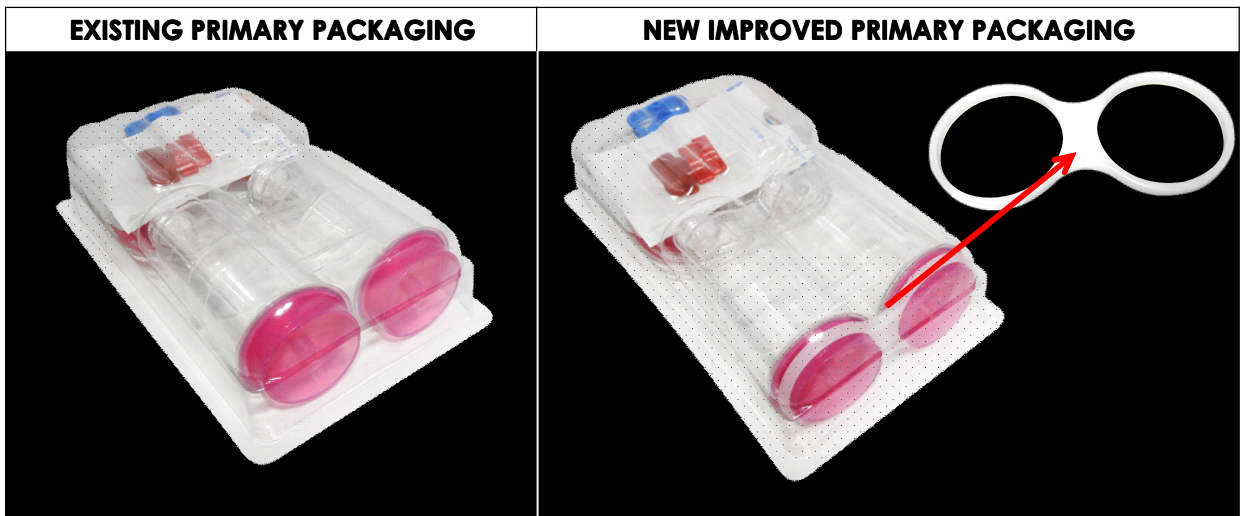
mdj Stericheck canisters (02 nos.) are assembled/packed in a primary blister packaging before sterilization. The canisters can move and collide with each other in the blister pack. After sterilization, 10 blister packs are packed in secondary white E-flute boxes and transported to the customers/users. It was observed that sometimes Stericheck canisters get damaged or become cosmetically defective during transit due to collision between the two canisters packed in a single blister pack. To prevent this damage/cosmetic rejection, the primary packaging (i.e. packing of canisters in blister) of mdj Stericheck has been improved by providing a provision for holding individual canister inside the primary blister pack. This shall be done through introduction of a place holder for placement of individual canisters prior to packaging in blister.

No change has been done in materials of construction of fluid contact surfaces/components or performance parameters or manufacturing process or critical dimensions or traceability.

Change Notice No.	Notification date	Implementation date
CN/F/23/003	April 26, 2023	April 28, 2023

How Does It Affect the User:

This change is related to the primary packaging of **mdi** Stericheck and the primary blister packaging will be improved/strengthened. All product specifications including materials of construction of fluid contact surfaces/components as well as performance specifications shall remain unchanged. The pictures describing the change are shown below.



Implementation of Change:

mdi Stericheck with catalog numbers as mentioned in the scope, released by QA after the implementation date will have the said changes. However, the available stock of **mdi** Stericheck with catalog numbers as mentioned in the scope and without separate compartments for holding individual canister inside the primary blister packaging will be received by you till 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
Advanced Microdevices Pvt. Ltd.