

Change Notice No.	Notification date	Implementation date
CN/17/09	May 10, 2017	June 10, 2017

Subject : Improved Diluent Transfer Needle Assembly of mdi Stericheck: Closed Sterility Test System

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

- SH3*****
- SMP*****
- SPF*****
- SV3*****

Background:

In our efforts to provide the user better products with more convenience, certain changes have been made in the diluent transfer needle assembly of **mdi Stericheck: Closed Sterility Test System** with catalog numbers as mentioned above.

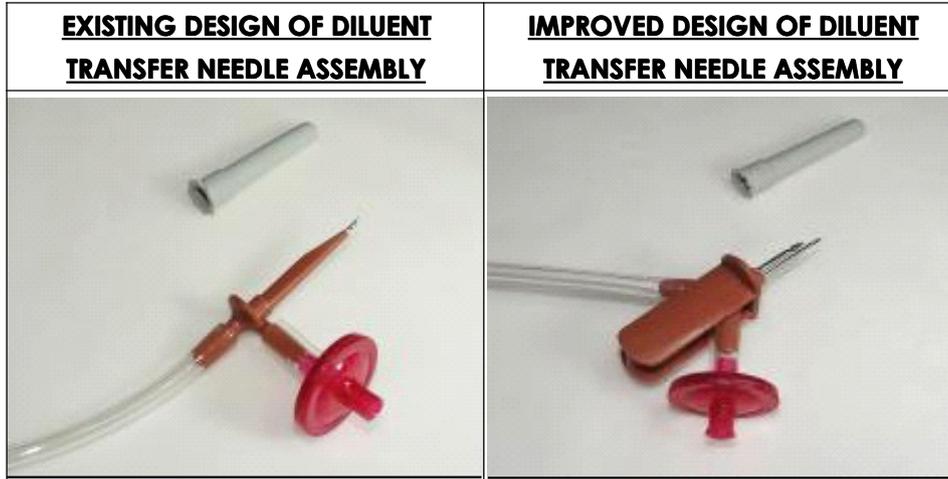
Need for Change:

mdi Stericheck: Closed Sterility Test System with catalog numbers as mentioned above contain two types of needle assemblies/adapters. One is for transfer of drug substances and other is for transfer of diluent. It was observed that when the existing diluent transfer needle assembly is used with small diluent bottles or bottles with small rubber bungs, it is sometimes difficult to pierce the rubber bungs. To address this observation, the design of diluent transfer needle assembly of **mdi Stericheck: Closed Sterility Test System** has been improved for easy piercing of diluent bottles with small rubber bungs. The new design of diluent transfer needle assembly has been verified for critical product performance parameters including transfer of diluent and piercing of the rubber bungs.

How Does It Affect the User:

From a practical point of view this change only improve the piercing of the rubber bung. All other product specifications including materials of construction as well as performance specifications remain unchanged.

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Implementation of Change:

mdi Stericheck: Closed Sterility Test System with catalog numbers as mentioned above, manufactured after the implementation date (**June 10, 2017**) will have the said changes. However, the available stock of **mdi Stericheck:** Closed Sterility Test System (with mentioned catalog numbers) having old diluent transfer needle assembly 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'.



Quality Assurance
Advanced Microdevices Pvt. Ltd.