

To whom it may concern,

FIELD SAFETY NOTIFICATION (FSN) - EQUASHIELD[®] CSTD (SA-1E)

Product name: EQUASHIELD[®] Closed System Transfer Device, Spike Tubing, Ref. SA-1E.

Lot numbers: 216758A, 218796A, 2214644A, 2214936A, 2215238A, 2215434A,
2315884A, 2317211V, 2317767A.

Reason for FSN: A small number of SA-1E Spike Tubing from specific lot numbers, may be affected by a packaging defect where the packing heat seal has cut the tubing of the device.

Where this defect occurs, the line may be cut, and spillage may occur during use.

If the Spike Tubing Set is to be used with hazardous drugs, the user and/or patient may be exposed to those hazardous drugs. In order to mitigate the risk of exposure to any hazardous substance, prior to using the SA-1E Spike Tubing, the user should visually inspect the tube for any cuts.

FSN Instructions: Customers must:

- Visually inspect the tube for any cuts. This important step will identify any defect prior to use with hazardous drugs.
- If affected stock is identified on visual inspection or during the priming step, the product should not be used and quarantined as well as to notify the manufacturer or your local distributor".

The relevant national competent authorities, Notified body and the EU representative have been advised of this FSN.

Equashield Medical Ltd. request to pass this FSN to all those who need to be aware of it.

Sincerely,

Elian Ben Graff

Regulatory Affairs Manager