

Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	MicroClave™ Clear Connector w/Red Ring
Device Model	011-MC100RR
Lot No.	5726283
Manufacturer	ICU Medical, Inc.
Country of Origin	USA
Reference	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=195578
Reason of Recall	NHRA initiates this FSN due to a manufacturing defect which results in a visible gap between the connector's top and bottom housing. This defect may potentially cause or lead to delayed delivery of infusion solution during setup/infusion, fluid leak, blood loss/exposure to patient blood, air embolism, exposure to allergenic/caustic substances, or fluid path contamination.
Action should be taken	Please stop using the above mentioned medical device and contact the Manufacturer to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh