U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Teleflex Medical, MAQUET Servo Humidifier 163 - Cracks in Connector Tubes May Lead to Leak Failures

Recall Class: Class I

Date Recall Initiated: January 12, 2015

Device: MAQUET Servo Humidifier 163

- Manufactured from: September 2012 through September 2013
- Distributed from: June 2013 through November 2014
- Distributed in: Florida, Kansas, Michigan, and West Virginia (100 devices in total)
- Model Number: 01-06-8125-8
- Catalog Number: XKC01-06-8125-8
- Lot Numbers: 201413, 201414, 201415, 201417, 201419, and 201422

See related **Class I Recall notice (/MedicalDevices/Safety/ListofRecalls/ucm435607.htm)**.

Use: The MAQUET Servo Humidifier is a heat and moisture condenser that is placed over a surgically-created opening in the throat (tracheotomy) or a tube inserted into the trachea to warm and moisten gases breathed in by a patient. The primary users of this device are nurses and respiratory therapists.

Recalling Firm:
Teleflex Medical
4024 Stirrup Creek Drive, Suite 720
Durham, North Carolina 27703

Manufacturer:
INMED Manufacturing SDN BHD (A division of Teleflex Medical)
c/o Teleflex
IDA Business & Technology Park
Dublin Road
Athlone Co. Westmeath, Ireland

Reason for Recall: Cracks were found in the connector tubes during the manufacturing process and some devices were distributed before the problem was identified. These cracks may cause oxygen and other gases to leak from the ventilator and prevent the device from delivering sufficient support to the patient. This may potentially cause serious injury or death.

Public Contact: For further information or support concerning this recall, contact your local Maquet representative at **fieldactions@maquet.com (mailto:fieldactions@maquet.com)**.

FDA District: Atlanta District Office

More Information about this Recall:
INMED sent customers an Urgent - Field Safety Notice dated January 12, 2015. The notice identified the product, problem, and action to be taken.

Customers:

- Immediately check inventory.
- Quarantine and discontinue use of the device.
- Return the acknowledgement form sent with the notice back to Maquet within five days of receipt.
- Request a return authorization form from Maquet for the recalled devices.

Additionally, distributors were requested to:

- Immediately stop distributing the recalled device.
- Send the Urgent Field Safety Notice to customers.
- Request customers to complete the acknowledgement form sent with the notice within five days of receipt and return to you.
- Forward the completed acknowledgement forms back to Maquet.

About Class I Recalls:
Class I recalls are the most serious type of recall. They involve situations when it is likely that use of these devices will cause serious health problems or death.

Health care professionals and consumers can report bad reactions or quality problems they had using the device to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX.

More in Medical Device Safety (/MedicalDevices/Safety/default.htm)

- Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)
- 2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)
- 2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)
- 2013 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384618.htm)