

URGENT: FIELD SAFETY NOTICE

Date: 2015-10-01

Ministry of Health, Department of Planning and Organisation of the National Health Service
Directorate General of Medical Devices, pharmaceutical services and safety in healthcare
Via Giorgio Ribotta 5
IT - 00144 Roma

Dear Risk Management,
This is to inform you of a Field Safety Notice involving:

See Appendix I

The T-Piece Circuit is a component used in conjunction with various T-Piece resuscitation devices. Product affected was shipped after 2012-01-18.

This notice has been initiated due to the potential of a silicone mask with a 15 mm male port being able to be forcibly inserted into the protective cap covering the opening of the T-Piece Circuit. Incorrect use of the product in this way will result in complete occlusion of the patient circuit and consequent failure to ventilate the patient.

Immediately notify all personnel subject to using these devices to remove protective cap before connecting a mask (see illustrations below). Further this field safety notice should be read in conjunction with the manufacturer supplied instructions for use.



Incorrect Assembly
(Protective Cap Not Removed)



Correct Assembly
(Protective Cap Removed)

Actions by Mercury Medical are in process to physically eliminate the potential for this erroneous use. Further the instructions for use are being updated to warn users to remove the cap before use.

Your assistance is appreciated and necessary to prevent any undue delay in patient care. Please complete the response card and return to Mercury Medical by mail, fax or email.

Mercury Medical
11300 49th Street North
Clearwater, FL 33762-4807 USA
Phone: 727-573-0088
Fax: 727-573-4966
email: regulatoryaffairs@mercurymed.com

Please contact me if you have any further questions.



Brian L. Morrison
Director, Quality Assurance/Regulatory Affairs
Mercury Medical

*Please Complete This Response Card and Return to Mercury Medical
by mail, fax or email.*

FAX: +1 727-573-4966
email: regulatoryaffairs@mercurymed.com

1. Has your firm received shipments of the product identified under the Field Safety Notice?	Yes ___ No ___
2. Has your firm received notification of the Mercury Medical Field Safety Notice regarding the T-Piece Circuit?	Yes ___ No ___
3. Have you read, understood and communicated the Field Safety Notice to the responsible personnel?	Yes ___ No ___

Date: _____

Name: _____

Reporting Facility (Hospital): _____

Appendix I

Part Number	Description	Lot Number
1050800	Neo-Tee Resuscitator	All
1050801	Neo-Tee Resuscitator	All
1050802	Neo-Tee Resuscitator	All
1050803	Neo-Tee Resuscitator	All
1050804	Neo-Tee Resuscitator	All
1050805	Neo-Tee Resuscitator	All
1050806	Neo-Tee Resuscitator	All
1050807	Neo-Tee Resuscitator	All
1050808	Neo-Tee Resuscitator	All
1050809	Neo-Tee Resuscitator	All
1050810	Neo-Tee Resuscitator	All
1050811	Neo-Tee Resuscitator	All
1050812	Neo-Tee Resuscitator	All
1050813	Neo-Tee Resuscitator	All
1050814	Neo-Tee Resuscitator	All
1050815	Neo-Tee Resuscitator	All
1050816	Neo-Tee Resuscitator	All
1050817	Neo-Tee Resuscitator	All
1050818	Neo-Tee Resuscitator	All
1050819	Neo-Tee Resuscitator	All
1050820	Neo-Tee Resuscitator	All
1050821	Neo-Tee Resuscitator	All
1050822	Neo-Tee Resuscitator	All
1050823	Neo-Tee Resuscitator	All
1050824	Neo-Tee Resuscitator	All
1050825	Neo-Tee Resuscitator	All
1050826	Neo-Tee Resuscitator	All
1050827	Neo-Tee Resuscitator	All
1050828	Neo-Tee Resuscitator	All
1050829	Neo-Tee Resuscitator	All
1050830	Neo-Tee Resuscitator	All
1050900	T-Piece Resuscitator Circuit	All
1050901	T-Piece Resuscitator Circuit	All
1050902	T-Piece Resuscitator Circuit	All
1050903	T-Piece Resuscitator Circuit	All
1050904	T-Piece Resuscitator Circuit	All
1050905	T-Piece Resuscitator Circuit	All
1050914	T-Piece Resuscitator Circuit	All
M1091316VS	T-Piece Neonatal Circuit Kit, Disposable	All
M1091335VS	T-Piece Neonatal Circuit Kit, Disposable	All
M1091365VS	T-Piece Neonatal Circuit Kit, Disposable	All