

Medolla (MO), Italy: April 14<sup>th</sup> 2016

FSCA Number: **FSCA 2016-04-14**  
FSCA Title: **FSCA- Product recall concerning connectors inserted in Trilly Oxygenator**  
Affected Product: **Trilly Oxygenator**

Subject: **FSCA- Product recall concerning connectors inserted in Trilly Oxygenator**

Eurosets S.r.l., sited in Strada Statale 12, n.143 I-41036 Medolla (MO) Italy, legal manufacturer of the **Trilly Oxygenator** devices, intended as oxygenating device for extracorporeal circulation for Infant-Paediatric patients

### NOTIFIES

That on April 13<sup>rd</sup> received the information about one (1) leakage episode in the connector from 3/8" to 1/4".

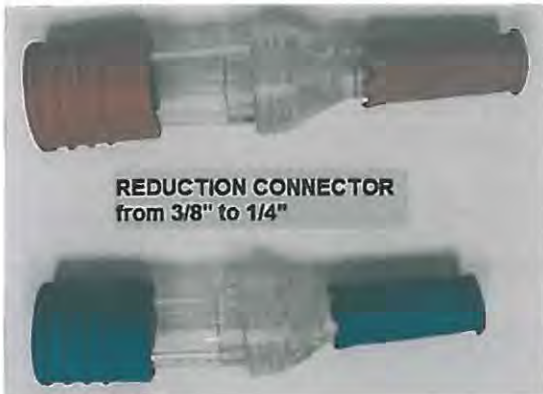
These connectors are inserted in a separate blister, part of the following "Trilly Oxygenator" devices:

**TABLE 1**

CODE	DESCRIPTION	LOT NR
AG5032	TRILLY FULL COATED STERILE	003087201
AG5032	TRILLY FULL COATED STERILE	003126801
AG7626	INFANT PACK W/TRYLLY ONCO D	003158000
EU5032	TRILLY STERILE	003158101
AG5032	TRILLY FULL COATED STERILE	003281301
AG5033	TRILLY A.F.INTEGR.COATED STER.	003300600

The connectors are used in case of infant patients where a 1/4" line is needed.

The leakage event occurred between the connection of the 3/8" PVC tube and 1/4" connector, not properly glued, as shown in the pictures below:



LEAKAGE: the 3/8" PVC tube was not properly glued

**PATIENT RISK**

In a single case claimed, no patient injuries have been reported. However, considering the operative pressure during the standard use of the reduction connector, the components undergoing to pressure, could lead to a disconnection with consequent meaningful blood loss for the patient.

**CORRECTIVE ACTION**

In order to ensure the product performance and safety, we decided to recall all the devices listed in table 1.

**Advices on action to be taken by the user:**

Once received this official notification, the user must:

- 1) Identify and segregate the items listed in table 1, still available at their premises.
- 2) Fill the acknowledgment letter provided in the attachment 1.
- 3) Return all the items to their sales representative, who will replace as soon as possible the received item with new batches.

**Advices on action to be taken by the Eurosets distributor:**

Once received this official notification, the Eurosets distributor must:

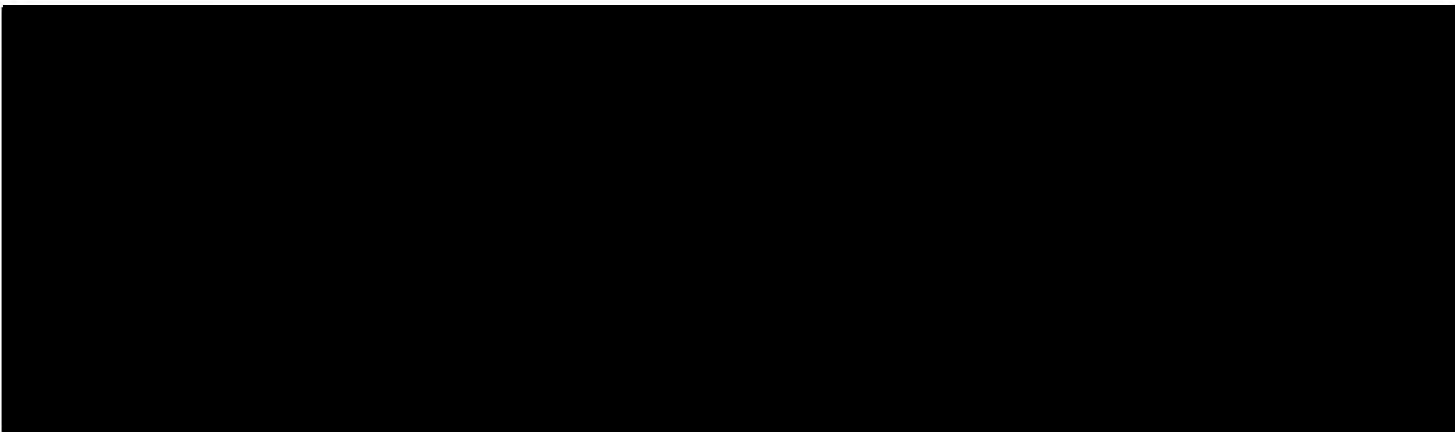
- 1) Through their traceability system, identify all the final users where the devices listed in table 1 have been shipped.
- 2) Identify and segregate the items listed in table 1, still available at their premises.
- 3) Fill the acknowledgment letter provided in the attachment 1.
- 4) Immediately or within maximum 1 working day from receiving, inform their final customers about this recall notification and ensure that the final users will properly understand and conduct the above listed actions (**Advice on action to be taken by the user**).
- 5) Return to Eurosets all the items received by their final customers and still on stock at their warehouse.

As required, we have provided this notification to the necessary Regulatory Agencies of the countries where the devices have been distributed.

Please refer to your local sales agent for any further information you may need or, in alternative, contact directly EUROSETS customer service at +39 0535 660311 ore [info@eurosets.com](mailto:info@eurosets.com)

We apologize for any inconvenience.

Yours sincerely,



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**Subject: Acknowledgment letter**

Please fill in this reply and return to EUROSETS RA/QA Manager at:

Attn. Katia Vescovini

FAX: +39-0535-660379

E-MAIL: [kvescovini@eurosets.com](mailto:kvescovini@eurosets.com)

- We confirm that we have received, read, and understood the FSCA "Product recall concerning connectors inserted in Trilly Oxygenator"
- We declare that we do not have any unit of affected lots at our warehouse
- We declare that we have at our warehouse the following units: (please fill the table below)

CODE	DESCRIPTION	LOT NR	n. pcs. In our stock
AG5032	TRILLY FULL COATED STERILE	003087201	
AG5032	TRILLY FULL COATED STERILE	003126801	
AG7626	INFANT PACK W/TRYLLY ONCO D	003158000	
EU5032	TRILLY STERILE	003158101	
AG5032	TRILLY FULL COATED STERILE	003281301	
AG5033	TRILLY A.F.INTEGR.COATED STER.	003300600	

Name Surname:	
Hospital or Distributor:	
Address:	
Tel. No.:	Email:
Signature	Date