

Medolla (MO), Italy: August 2nd 2019

Field Safety Notice

Important communication to customer and/or users

Commercial name of the Affected Product:	Convenience Kit of Trilly Oxygenator
Ref. to FSN Number:	FSN 01-2019
Ref. to FSCA Number:	FSCA 01-2019
FSN Title:	Connectors accessories included into Convenience Kit Trilly Oxygenator not correctly and safely assembled
Affected Products:	TRILLY PEDIATRIC
Affected Product detail:	EU6582 Convenience KIT Trilly in following devices: TRILLY PEDIATRIC
Type of action FSCA	Advice given by Manufacturer regarding the use of the device – Instruction for use integration
Type of action FSN	Communication to customer and/or users sent out by a Manufacturer in relation to a FSCA 01/2019.

Subject: **FSN- Field Safety Notice concerning connector accessories inserted in Trilly Oxygenator Convenience Kit**

Description of the problem:

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 the 2 additional connectors accessories (*indicated in Figure 1*) allowing that to add luer port on the reservoir, could be defective as not correctly assembled/glued with risk of disconnection with might cause of blood leakage.

These connectors accessories are inserted in a separate blister, part of the “Trilly Oxygenator” devices and their usage is optional and left to the choice of the perfusionists.

The oxygenators and all other accessories present in the convenience kit are conforming and safe for use even without use of the involved connectors reported in Figure 1.

This is a preventive action related only to the specific connectors described in Figure 1 in order to prevent any incident or adverse event.

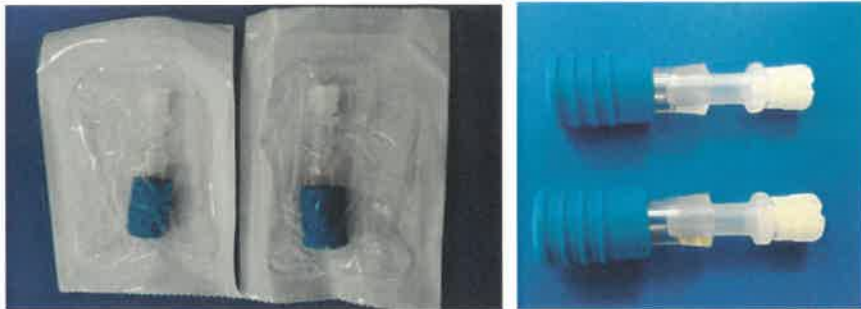


Figure 1

Eurosets recommends not to use the two connectors reported in the Figure 1.

The two connectors subject to this notice are packaged within the convenience kit pouch, together with other components as described in figure 2:

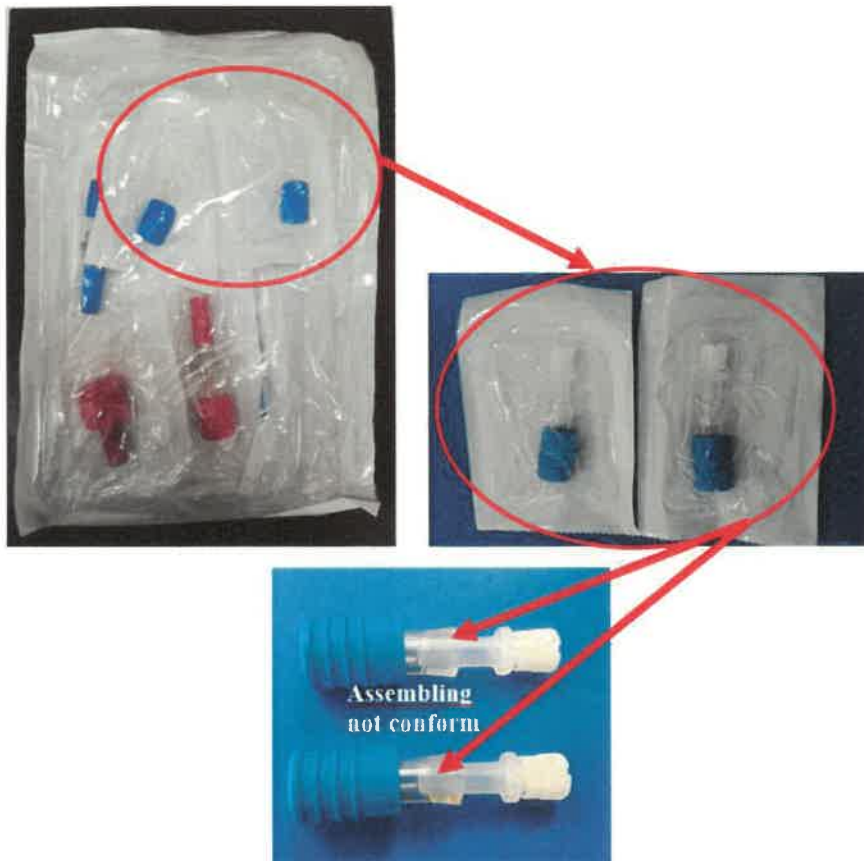


Figure 2

Details on affected devices

Product codes involved are:

TABLE 1

CODE	DESCRIPTION	LOT NR
EU5057	CONVENIENCE KIT TRILLY STERILE	5608200
EU5057	CONVENIENCE KIT TRILLY STERILE	5654900
AG5232	TRILLY PED.AF FULL COATED STE	4969300
AG5032	TRILLY FULL COATED STERILE	5017403
AG5061	TRILLY HT FULL COATED STE	5078802
AG5032	TRILLY FULL COATED STERILE	5078403
AG5232	TRILLY PED.AF FULL COATED STE	5262200
EU5057	CONVENIENCE KIT TRILLY STERILE	5499800
AG5032	TRILLY FULL COATED STERILE	4903703
AG5033	TRILLY A.F.INTEGR.COATED STER.	4903802
AG5232	TRILLY PED.AF FULL COATED STE	4969300

Patient risk

Considering the application of this connectors, even in case they are not correctly and safely assembled/glued, the low pressure applied does not lead to harmful patient conditions.

Nevertheless, for safety reasons, Eurosets asks the operators not to use the connectors.

Corrective action

In order to ensure the product performance and safety, EUROSETS decided to issue a Field Safety Notice as Instructions for use integration for only the batch number involved in the FSCA asking the operators not to use the two connectors of convenience Kit of Trilly Oxygenator.

Advices on action to be taken by the user:

Once received this official notification, the user must:

- 1) Identify the items listed in table 1, if still available at their warehouse.
- 2) Fill the acknowledgment letter provided in the attachment 1
- 3) Inform all the healthcare operators not to use the connectors involved in FSN 01-2019.

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) Immediately or within 5 working day from receiving, inform their final customers about this FSN 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).
- 3) Fill the acknowledgment letter provided in the attachment 1 and send it to Eurosets signed.

Transmission of this Field safety notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

As required by MDD 93/42/CEE and by MEDDEV 2.12-1, we have provided this notification to the Competent Authorities for the European countries where the devices have been distributed.

Contact reference person:

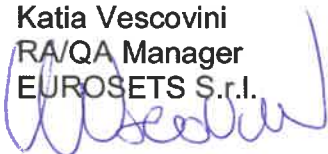
Please refer to your local sales agent for any further information you may need or, in alternative, contact directly EUROSETS customer service at +39 0535 660311 or send a mail to: kvescovini@eurosets.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

We apologize for any inconvenience.

Yours sincerely,

Katia Vescovini
RA/QA Manager
EUROSETS S.r.l.



EUROSETS SRL
Strada Statale 12 n° 143
41036 - MEDOLLA (MO) - ITALY
Tel. 0535 660311 - Fax 0535 51248
Cod. Fisc. e P. IVA 02005430364

Subject: Acknowledgment letter

Commercial name of the Affected Product:	Convenience Kit of Trilly Oxygenator
Ref. to FSN Number:	FSN 01-2019
Ref. to FSCA Number:	FSCA 01-2019
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Please fill in this reply and return to EUROSETS RA/QA Manager at:

Attn. Katia Vescovini e-mail: kvescovini@eurosets.com or pms@eurosets.com

- We confirm that we have received, read, and understood the FSN 01-2019 concerning connectors inserted in Convenience Kit of Trilly Oxygenator of the codes and Batch numbers listed in Table 1.
- We declare that we have informed all the healthcare operators not to use the component as per FSN 01-2019 concerning Convenience Kit Trilly Oxygenator of the lot listed in table 1.

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