Object: FIELD SAFETY NOTICE

Field Safety Notice for Medical Devices for Customer and/or Users

Commercial name of the product involved	→ EURIK180V INSERTION KIT-VENOUS → EURIK180VL INSERTION KIT-VENOUS LARGE → EURIK80A INSERTION KIT-ARTERIAL
Lot involved	*all lots in table 2*
Ref. FSN number	FSN 02/2023
Ref. FSCA number	FSCA 02/2023
FSN title	*Dilator 16 Fr with fissuring*
Products involved	*all codes in table 2*
Detail of products involved	*all products in table 2*
Type of action FSCA	Communication from the Manufacturer concerning the use of the device
Type of action FSN	Communication to Customers and/or Users sent by the Manufacturer in connection with FSCA 02/2023

Table 1

Eurosets S.r.l., sited in Strada Statale 12, n. 143, 41036 Medolla (MO) Italy, Legal Manufacturer of the following medical devices:

- **EURIK180V INSERTION KIT-VENOUS**
- **EURIK180VL INSERTION KIT-VENOUS LARGE**
- **EURIK80A INSERTION KIT-ARTERIAL**

intended as accessories for artero-venous devices used to aid in peripheral vascular insertion.
The KIT is indicated for patients undergoing a catheter/cannula vascular insertion through Seldinger technique, during CPB and ECLS procedures.

NOTIFY

that following a (1) single case that occurred on the field, where no consequences were reported for the patient (0), in the 16 Fr diameter dilator a fissuring may occur during use and insertion on the guide wire as shown in (fig. 2), which is evident on the conical end of the dilator tip itself not visible to the naked eye before insertion.

Eurosets S.r.l.
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41036, Medolla (MO)
Italy

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Fax +39 0535 51248
info@eurosets.com
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Codice fiscale e Partita IVA 02005430364
Capitale sociale € 2.072.110,00 i.v.
C.C.I.A.A. MO n. 258632
Reg. Soc. Trib. MO n. 33834

COMPLIANT DEVICE	NON-COMPLIANT DEVICE
	
Fig. 1	**Fig. 2**

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DETAILS OF DEVICES INVOLVED

The lots involved are:

CODE KIT	DESCRIPTION KIT	LOT NR
EURIK180V	INSERTION KIT-VENOUS	8298400
		8692201
		8830701
		8917701
		9105001
		9350702
EURIK180VL	INSERTION KIT-VENOUS LARGE	8298500
		8692301
		8830801
		8917801
		9350502
		9351002
EURIK80A	INSERTION KIT-ARTERIAL	8636801
		8692101
		8830601
		8917601
		9034601
		9350602
		9350802
		9515402

Table 2

Eurosets S.r.l.
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RISK FOR THE PATIENT

The dilator used in combination with the guide wire is intended to facilitate insertion of the cannula.

The fissuring described above could occur during insertion into the vessel and the forcing of the guide wire onto the tip of the dilator.

This event could affect the success of the procedure and/or damage the patient's vessel.

ACTIONS TO BE TAKEN BY THE HEALTHCARE FACILITY

In order to ensure the safe use of the device, Eurosets strongly recommends that operators:

→ **Do not use the 16 Fr diameter dilator.**

→ **All other dilator sizes included in the KIT are compliant and safe for use on the patient.**

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CORRECTIVE ACTION

Eurosets has already identified the cause of the problem.

The corrective actions to be taken within your production process have been defined and implemented, ensuring that the next production runs of the 16 Fr diameter dilator - within the kits - will be compliant and safe for patient use.

Should it become necessary to use the 16 Fr dilator included in the KITs, please contact Your own Eurosets Area Manager for the timing and how to restore.

In order to ensure adequate supply of compliant KITs, we kindly ask you to fill in, sign and return to Eurosets (complaint@eurosets.com) ANNEX 2 with an indication of the parts not yet used and/or to be restored.

ACTIONS TO BE TAKEN BY THE USER

Upon receipt of the official notification, the User shall:

1. Identify the devices listed in *table 2*, that are still available at their premises
2. Fill in the acknowledgement letter of this notice in ANNEX 1 and send it to Eurosets (**complaint@eurosets.com**) duly completed and signed.
3. Notify all healthcare professionals of FSN 02/2023.

ACTIONS TO BE TAKNE BY THE EUROSETS DISTRIBUTOR

Upon receipt the official notification, the Eurosets distributor shall:

1. Through its traceability system, identify all end users to whom the devices listed in *table 2*
2. Immediately or within a **maximum 2 working days** after recepit, inform its end Users of the FSN 02/2023 and ensure that the end users have correctly understood the actions to be performed listed above ("**ACTIONS TO BE TAKEN BY THE HEALTHCARE FACILITY"**).
3. Fill in the acknowledgement letter of this notice in ANNEX 1 and send it to Eurosets (**complaint@eurosets.com**) duly completed and signed.

EUROSETS
EVERY LIFE MATTERS

TRANSMISSION OF THIS FIELD SAFETY NOTICE

1) 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.
2) Please transfer this notice to other Organizations on which this action has an impact.
3) 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 MDR 2017/745, we have provided this notification to the Competent Authorities for the European countries where the devices have been distributed.

CONTACT REFERENCE PERSON

Please for any further information you may need contact directly EUROSETS Customer Service at +39 0535 660311 or send a mail to: **complaint@eurosets.com**

We apologize for any inconvenience.

Yours sincerely,

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

Marco Mantovani
R&D Technical Director
EUROSETS S.r.l.

Stefano Capellini
Global Marketing Director
EUROSETS S.r.l.

Medolla, 21 Dicembre 2023

ANNEX 1

Object: Aknowledgment letter

Commercial name of the product involved	→ EURIK180V INSERTION KIT-VENOUS → EURIK180VL INSERTION KIT-VENOUS LARGE → EURIK80A INSERTION KIT-ARTERIAL
Lot involved	*all lots in table 2*
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Please fill in this reply and return to EUROSETS RA/QA Manager at:
Att. Katia Vescovini e-mail: **complaint@eurosets.com**

☐ We confirm that we have received, read and understood FSN 02/2023 referring to the codes and lots listed in Table 2

☐ We declare that we have informed all health care professionals to follow the instructions of Eurosets given in the **ACTIONS TO BE TAKEN BY THE HEALTHCARE FACILITY** section of this FSN.

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

EUROSETS
EVERY LIFE MATTERS

ANNEX 2

Restore request

Name and Surname	
Hospital or Distributor	
Address	
Tel. No.	
E-mail	

By completing and returning this form I confirm that I have taken the appropriate steps:

☐ Do not require restore as I will not use the 16 Fr dilator
☐ the devices are no longer in stock and have already been used
☐ we are in possession of the following defective units ready for return

CODE	LOT	NUMBER OF UNITS READY FOR RETURN

Signature	
Date	

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