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FSN Ref: FSN Endoflow CP22
FSCA Ref: FSCA Endoflow CP22

Urgent Field Safety Notice
Endoflow® II – Irrigation and Warming System
"Instruction for use" reinforcement

Dear distributor,
We are proceeding to an action of reinforcement on the Instruction for use **for** the Endoflow device and associated Tubing Set.

DESCRIPTION OF THE AFFECTED DEVICES

Device Description

The ENDOFLOW® II is an irrigation device which can precisely control the intracavity pressure (isostatic pump). It has the characteristic of heat to body temperature the liquid used. This non-invasive method employs single-use, disposable, irrigating and suction sets.
The ENDOFLOW® II must be used exclusively with the ROCAMED Disposable Sets.
The ENDOFLOW® II System is a complete fluid management system permitting, all-in-one, the control of the Irrigation, the temperature of the fluid and the suction. It permits a continuous and non-pulsating liquid flow to inflate and/or clean the surgical field and/or to improve the surgeon's visibility. With the ENDOFLOW® II system, the indicated pressure on the machine is identical to the pressure in the cavity.
The device heats and maintains the fluid bag at 38°C during the entire procedure. The user can disable this function.
In its double chamber version, ENDOFLOW® II offers an aspiration system that can be activated with the touch screen and/or a footswitch.
The ENDOFLOW® II is a reusable, non-sterile and electrically powered device that is available in single or double chamber.

Rocamed SAM

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Rocamed France

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Tel. : 04 94 90 54 00 Fax : 04 94 98 60 55
Adresse postale : BP 719 83030 Toulon Cedex 9

Commercial names	Device Model/Catalogue	Unique Device Identifier(s) (UDI-DI)
Endoflow® II – Irrigation and Warming (Simple chamber)	MEN01	03700512955108
Endoflow® II – Irrigation, Warming and Suction System (Double Chamber)	MEN02	03700512955214

Primary clinical purpose of device(s)
The ENDOFLOW® II is intended to both irrigate and aspirate body cavities and wounds typically during an endoscopic surgical procedure (Urology, Gynecology and General Surgery), usually to facilitate observation. It is intended to remove tissues/fluids/debris through suction, and to irrigate the surgical site with a sterile fluid (e.g., saline).

Software version
2.16d

REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)

If the fluid bag is not connected, or is incorrectly connected to the associated tubing, this leads to accidental injection of air instead of saline, which can result in gas embolism and patient death.

Although the probability of such misuse is very low, this safety action aims to reduce this risk of misuse.

Predicted risk to patient/users
In case of misuse, the risk can be an accidental injection of air that can lead to a gas embolism and patient death.

TYPE OF ACTION TO MITIGATE THE RISK

- Rocamed update the Instruction for use of the entire Endoflow range and associated tubing set, adding this WARNING. Please find attached the updated Instructions for use.

Check to have correctly hit the fluid bag to the associated Rocamed tubing set before closing the Endoflow pressure chamber.

ACTION TO BE TAKEN BY THE CUSTOMER

- The Customer will have to take note of the reinforcement of the Instructions for Use (IFU) sent from Rocamed.
- The Customer receiving this FSN must inform of this FSN all users and persons to whom these DMs are made available.
- The Customer must fill the Field Safety Notice Customer Reply Form and send it back to Rocamed. Please find in Appendix I the template to fill.

Expected time for this action to be completed

Rocamed hopes that all actions with the customer reply will be completed by Q1 2025.

Manufacturer information

Company Name:	ROCAMED France
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List of informed competent authorities:

The ANSM which is the regulatory authority concerning medical devices in France is already aware of the incident.
The relevant competent authorities will be informed of the FSCA and of this FSN.

Once again, we confirm that our primary objective is to ensure the safety of patients and users.

We count on your understanding and full support to ensure the rapid and effective follow-up of our safety action.

We apologize for the inconvenience this situation may cause you and your customers, and we remain at your disposal for any further recommendations or requests.

12/03/2025
TARTAGLIONE Erica
Quality and Regulatory Affairs Director

ANNEX I

Field Safety Notice Customer Reply Form:

Please read Ref.FSN Endoflow CP22 and return this annex I completed and signed as soon as possible or within 5 days of receipt to: et@rocamed.com Check all that apply.	
☐	I confirm that this notice has been read, understood and that all recommended actions have been implemented as required.
☐	I confirm that I have communicated to users the change of the concerned Instructions for Use.

Name of organization:	
Address :	
Postal code:	**Country :**
Phone:	**E-mail address :**
Name, title and signature of the person who completed the document:	