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Reference: FSCA-22.191

20<sup>th</sup> September 2022

**FIELD SAFETY NOTICE**

- **DRENOFAST**

**For the attention of:**

All customers that have received at least one of the products with reference numbers 0028470 and 0028480.

0028470	Drenofast base unit low-vacuum 400 ml (min. 330 mmHg)
0028480	Drenofast spare bottle low-vacuum 400 ml (min. 330 mmHg)

**Intended Purpose for DRENOFAST**

Drenofast is a Redon drainage system with built-in vacuum designed to efficiently and continuously evacuate wound exudates post-operatively, with the purpose of facilitating the healing process and avoid complications, stimulating formation of granulation tissue and cell proliferation, reducing bacterial load and enhancing contraction of wound edges.

**Description of the issue**

We have recently been informed by the ANSM (Agence Nationale de Sécurité du Médicament) of an incident that occurred in a hospital when using the Drenofast base unit low-vacuum 400 ml (min. 330 mm Hg) device, due to lack of aspiration of the device. The device aspirated 220cc of exudate, and at that moment lost its vacuum. The patient has shown fever plus left hemiplegia due to the presence of a significant hematoma.

The product functioned correctly according to its technical specifications because the maximum filling capacity of a 400 ml bottle with a 330 mm Hg low-vacuum is approximately half its volume (200-300 mL).

**Risks and actions to be carried out**

Although the instructions for use of the device already mentions the precautions to be taken into account when using the device, i.e. regularly checking the correct functioning of the system, or changing the bottle when the bellows indicates that there is no vacuum left inside, not taking into consideration the contraindications, precautions, and recommendations provided in the instructions for use can seriously damage the patient's health, resulting in hematomas or infections to the patient which may require further surgical intervention, due to device malfunction or lack of drainage once the vacuum has ended.

Always use the drainage system for its intended purpose and follow the defined instructions for use, taking always into account all contraindications, precautions, information, and recommendations provided by the manufacturer.

There are two vacuum levels available for DRENOFAST, 650 mmHg (green bellows) and 330 mmHg (orange bellows), with different filling capacities. Take into account the type of vacuum used when regularly checking the system.

The instructions for use have been updated by adding information on the maximum suction capacity according to the existing vacuum.

Capacidad de llenado botella alto vacío (fuelle verde) / Filling capacity high vacuum bottle (green bellow) / Capacité de remplissage haute aspiration (soufflet vert): min. 200 / 400 / 600 mL según referencia / according to reference / selon référence.

Capacidad de llenado botella bajo vacío de 400 ml. (fuelle naranja) / Filling capacity low vacuum bottle 400 mL (orange bellow) / Capacité de remplissage pour flacons basse pression de 400 ml (soufflet orange): 200 – 300 mL

Pérdida máxima al final de vida útil / Maximum loss at the end of useful life / Perte maximale en fin de vie utile: 20%

The technical sheet has been updated in line with this additional information.

### **Communication of the Field Safety Notice**

Please distribute this notice with the accompanying new Instructions for use to any person within your organization who should be aware of it and to any other organization to which any related products may have been distributed.

The Competent National Authority has been informed of the notification of this “Field Safety Notice”.

You will be provided with the new version of the instructions for use document as soon as it becomes available.

We apologise for any inconvenience this situation may have caused you. If you have any questions about this letter, please contact your usual Iberhospitex S.A. representative.

Yours sincerely,

Montserrat Gambús  
Responsible Technician