WOM
A Novanta Company

W.O.M. WORLD OF MEDICINE GmbH | Salzufer 8 | 10587 Berlin

Aesculap AG – part of the B.Braun Group
Am Aesculap-Platz
78532 Tuttlingen
Germany

Berlin, 2023-07-18

Urgent Field Safety Notice (FSN) – MEDICAL DEVICE RECALL

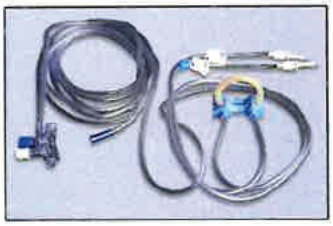
WOM reference no.: 2023-0002

RESPONSE REQUIRED BY JULY 24th, 2023

Dear Sir or Madam,

The purpose of this letter is to inform you that the below mentioned product is subject to a voluntary recall and needs to be returned to the manufacturer.

Product name:	**Tube set with suction/irrigation handle, single use**
Affected REF Numbers:	**PG122SU**
Affected LOTs	**4027697 + 4027700 + 4027302**



Reason for the recall

This recall is being conducted after a complaint was received from our customer Aesculap AG – part of the B. Braun Group which acts in this case as a distributor. The complaint refers to cracks on the pouches (sterile barrier) of a small amount of the product "Tube Set suction/irrigation handle, single use". The root cause is still under investigation and can only be further determined by evaluating a statistically significant quantity of products.

Risk to Health

A crack in the packaging of the tube set results in sterile barrier compromise. This might lead to an increased infection risk during a procedure, above the one already evaluated in the framework of risk assessment activities and may also require medical treatment. To date, there have been no reports of any serious injuries.

Actions to be taken by Aesculap

- Inform individuals within your organization who need to be aware of this recall.
- Check all stock areas and/or operating room storage to determine if any tube sets with lot numbers from Annex 1 are at your facility. If yes, send those back to WOM´s service address.
- Upon receiving the recalled products from the end user, please forward them to the WOM service address promptly.Please complete Distributor Reply Form (Annex 2) and return to Complaints.MIS@novanta.com.

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— Please inform the end user about the recall and the required actions.
— Track the customer reply forms.

— All tube sets recalled in **EMEA** should be sent to the following service address:

W.O.M. WORLD OF MEDICINE GmbH
Attn: Service Point
Alte Poststrasse 11
96337 Ludwigsstadt – Germany

— WOM contact for coordinating the shipment of the requested products to Ludwigsstadt is:

Ms. Miedia Khalid
Miedia.Khalid@novanta.com
Customer Service Account Manager
Phone: +49 30 39981-600

Transmission of this Field Safety Notice:

This notice should be provided as copy to all personnel who need to be made aware of this issue within your organization.

We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter. Please send any questions to Complaints.MIS@novanta.com.

Attachments:

- Annex 1: list of affected LOTs
- Annex 2: distributor reply form

Sincerely,

W.O.M. WORLD OF MEDICINE GmbH

[redacted]

Senior Vice President Global Quality Management
Quality Management Representative

[redacted]

Director of Regulatory Affairs
PRRC Vigilance

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Tube set with suction/irrigation handle, single use — REF: PG122SU

WOM reference no.: 2023-0002

Annex 1 — List of affected LOT numbers

LOT number	Manufacturing date MM/DD/YYYY
4027302	12/02/2022
4027697	11/23/2022
4027700	12/05/2022

Geschäftsführer: Robert Buckley, Florian Denk, Gerald Nastran
Amtsgericht Charlottenburg – HRB 149578 B
USt-IdNr. DE 136593967
WEEE-Reg.-Nr. DE 60787320

W.O.M. WORLD OF MEDICINE GmbH
Sitz der Gesellschaft: Salzufer 8, 10587 Berlin
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Annex 2 – Distributor Reply Form

☐ I confirm receipt of the Field Safety Notice and that I read and understood its content.

☐ I have/will perform the actions as described in the Field Safety Notice has been/ will be brought to the attention of all relevant employees/ users.

☐ I have checked my stock and quarantined inventory and sent it to WOMs Service address

☐ I have identified customers that received or may have received this tube set

☐ I have attached customer list

☐ I have informed the identified customers of this FSN

Institution: _____

Name: _____

Phone/E-mail: _____

Address: _____

City: _____

Country: _____

Date: ____ / ___ / 20____ Signature: _____

It is important that your organization takes the actions detailed in this letter and confirms that you have received this notice for regulatory tracking purposes.

Please e-mail scanned copy to:
Complaints.MIS@novanta.com