Field Safety Notice

Product: Flocare® DirectPEG Set and Flocare® Safety+ GT/-Suction
FSN-Type: New
FSN-Identification: 017-22
Action: Information & Precautionary Withdrawal
Date: 01.09.2022

For the attention of users of the Flocare® DirectPEG set for the placement of a percutaneous gastrostomy tube by direct puncture procedure and the percutaneous replacement tube Flocare® Safety+ GT/-Suction.

Product Details

Article Code	Beschreibung
656893	Flocare® DirectPEG Set CH 12
	Lot No.: 22010, 22070
656707	Flocare® DirectPEG Set CH 14
	Lot No.: 21490, 22070, 22110, 22200
673803	Flocare® Safety+ GT CH 12
	Lot No.: 22010, 22070, 22110
673802	Flocare® Safety+ GT CH 14
	Lot No.: 22010, 22110, 22111
673801	Flocare® Safety+ GT /-Suction CH 14
	Lot No.: 22010, 22070, 22110, 22111

Dear users, dear customers,

BS Medical Tech Industry (BS-MTI) is initiating a precautionary, voluntary withdrawal of medical devices for certain lots of the Flocare® DirectPEG Installation Sets and Flocare® Safety+ GT /-Suction Replacement Tubes.

Within the scope of our post-market surveillance, our trend analyses show that in rare cases, detachment of the retention balloon at the gluing point of the tube can occur. In case of excessive pressure, which can be caused, among other things, by over-blocking of the balloon this can occur with the above-mentioned tubes. In such cases secure fixation of the percutaneous tube in the gastric stoma can no longer be guaranteed.

Particularly in the initial phase following the placement of a PEG using the direct puncture method with the Flocare® DirectPEG, this may lead to complications requiring medical intervention (e.g. peritonitis).

The blocking of the balloon as well as the fixation of the tube using the tube indicator with the Flocare® DirectPEG are described in detail in the instructions for use. Despite various preventive and educational measures, we regrettably still see a certain residual risk. We have therefore decided to initiate a withdrawal of the products as a precautionary measure.

We do not see an immediate risk for complications requiring medical treatment with the Flocare® Safety+ GT /-Suction, since the patient's stoma has usually healed, or at least tissue granulation has taken place before this replacment tube is used.

Since both products use the same balloon technology, we decided to include the Flocare® Safety+ GT /-Suction in this corrective measure.

Measures to be taken by users/customers

- Please check your inventory immediately to determine if you have any of the products listed above and ensure that any use is excluded. Our records indicate that you have received at least one product with one or more lot numbers affected by this precautionary withdrawal.

- If you have affected products, please note that considering upcoming product optimizations, we are offering a full credit for all affected Flocare® DirectPEG Installation Sets and Flocare® Safety+ GT/-Suction Replacement Tubes returned from your inventory. Product exchanges cannot be made at this time.

- Please forward this information to all persons in your facility who potentially use the Flocare® DirectPEG Installation Sets and/or Flocare® Safety+ GT/-Suction Replacement Tubes.

- Please complete and sign the enclosed response form to confirm that you have received and acknowledged this notification. Send the completed form by e-mail to medizinprodukte@danone.com or by fax to +49(0) 9131 7782 1269.

- It is not necessary to proactively change Flocare® DirectPEG tubes or Flocare® Safety+ GT/-Suction Replacement tubes which are currently placed in the patient if there are no problems with balloon blockage or with the indicator.

This voluntary measure in the interest of patient safety only affects the products listed on page 1. No other products are affected by this measure.

We apologize for any inconvenience this corrective action may cause you. If you have any questions, please contact your sales representative.

Corrective and preventive measures
The cause of the problem that has occurred will be analyzed in full detail by the manufacturer in the coming weeks. Corresponding corrective measures, still to be defined, will result from this.

Forwarding this message
It is mandatory that this Field Safety Notice is passed on to all persons who should be informed within your facility/organization.
1. Please indicate if you are using Flocare® DirectPEG Installation Sets and/or Flocare® Safety+ GT/Suction Replacement Tubes.
2. Complete the customer response form attached to the Field Safety Notice and return it to us within 14 days of the publication of this Field Safety Notice.

Contact
If you have any questions regarding this Field Safety Notice, please feel free to contact the following person.

Nutricia Milupa GmbH
Am Hauptbahnhof 18
60329 Frankfurt am Main

[redacted]
Head of Medical & Regulatory Affairs Medical Devices DACH
Person Responsible for Regulatory Compliance
E-Mail address: dwayne.troutman@danone.com

Manufacturer information:
BS Medical Tech Industry (BS-MTI)
2, rue de l'Avenir
67470 Niederroedern
Frankreich

I, the undersigned, certify that this Field Safety Notice has been communicated to the appropriate regulatory authorities.

Kind regards

[redacted]
Head of Medical & Regulatory Affairs Medical Devices DACH
Nutricia Milupa GmbH

Field Safety Notice
Corrective Action – Precautionary Withdrawal
FSN-Identification: 017-22
Acknowledgement Form – Flocare® DirectPEG Installation Set & Flocare® Safety+ GT/-Suction Replacement Tube

Please use this confirmation together with the above-mentioned Field Safety Notice. This acknowledgement must be completed, signed by you and returned to Nutricia Milupa within 14 days.

If possible, please use the dispatch by e-mail to medizinprodukte@danone.com or by fax to +49 (0) 9131 7762 1269.

With your signature you confirm receipt of this Field Safety Notice. Furthermore, you acknowledge that you have read it, understood its contents and have passed the information on to all relevant users for their information.

Date / Place	
Customer Reference	<Bezug Serienbrief hinzufügen>
Organisation	<Bezug Serienbrief hinzufügen>
Address	<Bezug Serienbrief hinzufügen> <Bezug Serienbrief hinzufügen>
Telephone Number / E-Mail-Address	
Name (Print)	
Signature	

We do not have any affected products:	
We have affected products:	

If you have affected products, please fill out the following chart:

Article code	Product description	LOT	Amount

Our sales representative will contact you to arrange a pickup.