FSCA Ref: **CAPA62633**

Date: 11/03/2025

Urgent Field Safety Notice (FSN) regarding the recall of Strappal®

Dear customer,

This letter is to inform you about a recall that we are conducting as a precautionary field safety corrective action.

Information on affected devices

Strappal®
(non-elastic strapping tape)
REF 71494-00004-02
LOT 502

Description of the product problem

Strappal® is a non-elastic strapping tape intended for functional taping as treatment and prevention of injuries to muscles, ligaments and joints. There are different versions of Strappal® available, made with different adhesives (with and without natural latex). The article mentioned above has been manufactured with a wrong label, indicating absence of latex while in fact the adhesive of the product contains latex (dry natural rubber).

This imposes the risk that patients with a known allergy to latex use the product and suffer from an allergic reaction. As a precautionary measure we are hereby recalling the products.

The error has been clearly identified and only one single batch is affected.

Type of Action to mitigate the risk

Please check your stock of the affected REF/LOT mentioned above of Strappal®.

Do not use these devices for any medical purpose, but send them back or discard any of the products you hold on stock.

To simplify processing for you, please find attached a response form. Please indicate:

- the number of goods to be taken back,
- the date of when we may collect the goods, and
- the place where we can pick up the items.

Please also use the response form to inform us in case you have already used up all the products from the above-mentioned lots in full.

After having received the response, we will arrange for collection of the affected goods.

BSN medical SAS
1 rue du Millénaire
72320 Vibraye
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www.essity.com

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We apologize for any inconvenience that might be associated with this recall.

Please be assured that the quality of our products and their reliability in daily use are our highest priority.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Contact Person

Our colleague, Jenny DONADI (+39 3426030188) is at your disposal for any questions.

Sincerely,

Essity/BSN medical SAS

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