URGENT – FIELD SAFETY NOTICE

Field Safety Notice N° : FSN-2024-01(ref ANSM R2413146)
Subject : Reduction of the maximum authorised patient weight from 150 kg to 130 kg
Medical devices : Globe-Trotter and Globe-Trotter+ (Crutches)
Products references : W2016 and W2017
Legal manufacturer : Thuasne, 120 rue Marius Aufan, 92300 Levallois-Perret, France
Action type : Product recall

This Field Safety Notice has been approved by the French national competent authority: Agence Nationale de Sécurité du Médicament et des produits de santé - ANSM (*the National Agency for the Safety of Medecines and Health Products*)

Date 14-05-2024

To the attention of the person in charge of vigilance or of the company

Transmission of the notification: this notification must be transmitted to any person who needs to be notified within your organization and/or any organization potentially affected by the device and/or to a third party.
Please keep this notification long enough to ensure the effectiveness of corrective measures.
This action has been reported to the competent health authorities, as required by the regulations in force regarding medical devices, in accordance with European regulations including MEDDEV 2.12-1 Rev 8

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Dear Madam, Dear Sir,

Following tests recently carried out by the CERAH test laboratory, an official accredited body for the evaluation of technical aids according to standard NF EN ISO 11334-1: 2007, we would like to inform you that we have taken the decision, **as a precautionary measure**, to reduce the maximum patient weight authorized for our Globe-Trotter and Globe-Trotter+ crutches from 150 kg to 130 kg and to carry out a product recall for patients weighing more than 130 kg.

Indeed, although **no incidents** have been recorded recently with these crutches, certain test results can sometimes show non-compliance at 150 kg while they remain systematically compliant at 130kg.

W2016021010	**W2016022010**	**W2017021006**
Globe-Trotter	**Globe-Trotter**	**Globe-Trotter+**

Product description :

Globe-trotter and Globe-trotter+ are walking aids for people with reduced mobility. Crutches procure a second point of support behind the arm if compared to classic sticks. Their goal is to provide additional support.

References	Designation	UDI-DI
W2016021010	GLOBE-TROTTER *BLUE* (crutch)	3111790271581
W2016022010	GLOBE-TROTTER *GRAY* (crutch)	3111790271598
W2017021006	GLOBE-TROTTER+ (crutch)	3111797400052

thuasne.com

Siège social / Head & sales Office 118 - 120, rue Marius Aufan - CS 10032 - 92309 Levallois-Perret Cedex - France
Tél. +33 (0)1 41 05 92 92 - Fax +33 (0)1 41 05 89 89 - Fax Export +33 (0)1 41 05 89 50
Établissement industriel / Production Site 27, rue de la Jomayère - CS 33143 - 42031 Saint-Étienne Cedex 2 - France - Tél. +33 (0)4 77 81 10 10 - Fax +33 (0)4 77 81 10 59
Service clientèle / Customer Service France : Tél. 04 77 81 40 42 - Fax 04 77 81 11 99 - Export : Tél. +33 (0)4 77 81 40 01 - Fax +33 (0)4 77 81 67 16

SAS au capital de 1 950 000 euros - 542 091 186 RCS Nanterre - Code APE 1396Z
SIRET Siège Social 542 091 186 00073 - SIRET Etablissement Industriel 542 091 186 00040 - N/Ident. T.V.A./V.A.T. FR 88 542 091 186

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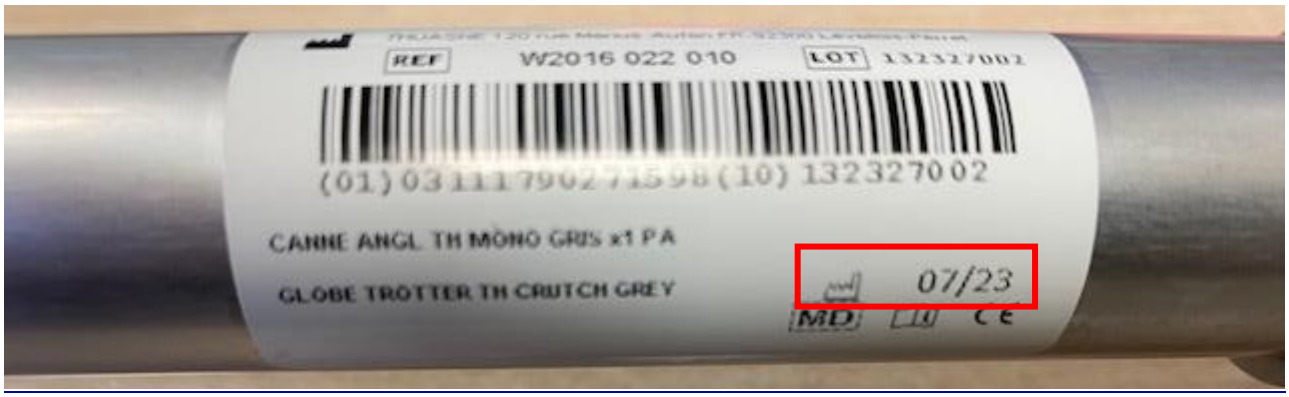
All batches of these 3 references manufactured starting February 2021 are impacted. The manufacturing date is mentioned on the product label (Cf. picture below) next to logo :



Risk for the user :

The identified risk is a risk of **deformation** or even a **breakage** of the product which could lead to a **serious incident** for the patient (Article 2 (65) UE 2017/745 RDM).

Actions and corrective measures to be taken :

Thuasne has decided to reduce the maximum patient weight to 130 kg for the **Globe-Trotter** and **Globe-Trotter+** crutches (W2016 and W2017). This will result in the implementation of the following three actions:

1) **A product recall for people weighing more than 130 kg**.
   Therefore, we **ask you** to inform patients to whom you have already delivered the product by displaying (physically and on your website if applicable) the communication poster attached to this safety notice.
   For patients weighing more than 130 kg, we absolutely ask you to collect the concerned products and bring them back to us following the usual process, mentioning the following reason: "FSN-2024-01".

2) **An intervention on products for patients whose weight is less than 130 kg.**
   If patients weighing less than 130 kg come forward, they can keep their product provided that you can :
   - ⇨ Check the integrity and appearance of the products.
   - ⇨ Add the addendum (which will be sent to you by postal mail) to the instructions for use.
   - ⇨ Add a sticker (which will be sent to you by postal mail) on each product to highlight the change in maximum authorized weight.

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3) **An intervention on products you have in stock.**
   - ⇨ Check the integrity and appearance of the products.
   - ⇨ Add the addendum to the instructions for use.
   - ⇨ Add a sticker to each product to highlight the change in maximum authorized weight.

Furthermore, we also kindly ask you to:

- ⇨ Forward this notification to anyone who needs to be notified within your organization or to a third party.
- ⇨ Complete the acknowledgment form and send it back to the communicated address (vigilance.thuasne@thuasne.fr) within 72 hours.
- ⇨ If you purchased this product from a distributor, please note that the Thuasne® response form is not applicable. If a response form is provided by your distributor or wholesaler, please return it to the supplier in accordance with their instructions.
- ⇨ If you are a wholesaler or distributor/service provider who has supplied these devices to other structures, please inform your customers of this communication, in accordance with your procedures.

If you have any questions about this field safety notice, please contact our advisory service or your usual contact.

Please accept our apologies for any inconvenience caused by this operation. More than ever, we are committed to ensuring patient safety. We remain at your disposal for any questions.

Delphine Hanton
CEO

Caroline Roumestan
Quality & Regulatory Affairs Director

below: Acknowledgment of Receipt Form (1 page)

URGENT – FIELD SAFETY NOTICE

URGENT – SECURITY NOTIFICATION FORM
FSN-2024-01 (ref ANSM R2413146)
ACKNOWLEDGMENT OF RECEIPT

Customer N° :

Medical devices : Globe-Trotter and Globe-Trotter+ (crutches)
Products references : W2016 and W2017
Legal manufacturer : Thuasne, 120 rue Marius Aufan, 92300 Levallois-Perret, France
Action type : Product recall

Please return the completed form within 72 hours to the email address below:

vigilance.thuasne@thuasne.fr

I acknowledge receipt of the information contained in the Field Safety Notice for **Globe-Trotter and Globe-Trotter+ (**crutches).

I have read and understood this safety information and certify it by my signature. All persons to be informed in my establishment have read this document and the immediate measures mentioned have been or are being implemented.

Vigilance contact details :

Name (distributor + contact) : .....

Function : .....

Compagny address or Compagny seal.....

E-mail :.....

Phone number : .....

Date : ..... Signature :