

Amersfoort, September 8, 2015

The 37Company
Beeldschermweg 6F
3821 AH Amersfoort
The Netherlands

Voluntary Field Safety Notice

Affected product: Fluidio® Trauma Set (671500)
FSCA-identifer: VO610919
Type of action: Voluntary Field Safety Notice
Date: September 8, 2015
Attention: Risk / Safety Managers, Clinicians, Nursing, Emergency
Departments, Operating Rooms, Anaesthesia Departments,
Distributors and other users of these disposable sets.
Details on affected sets: Fluidio® Trauma Set
LOT numbers 70150505 and 70150621
Shipped in July and August 2015

Dear Business Partner,

The 37Company is conducting a voluntary recall for a limited number (1410 pieces) of Fluidio® Trauma Sets (article number 671500). This voluntary recall is being conducted with the knowledge of the relevant Regulatory Agencies.

Description of the problem:

The Fluidio® Trauma Set has been composed with an inappropriate roller clamp for its intended use. When using pressure chambers at a set pressure of > 100 mmHg, in combination with the set, the roller clamp could alter its occlusivity resulting in an uncontrolled administration of perfusates to the patient, leading to a potential risk of fluid overload.

This Field Safety Notice only applies to Fluidio® Trauma Sets with LOT number 70150505 and 70150621.

While The 37Company has not received any reports of patient injury, and not all sets will experience this issue, The 37Company is proactively recalling all sets from the affected batches.

Advice on action to be taken by the distributor:

The 37Company is requiring its distributors to return all unused sets:

1. Immediately stop distributing and quarantine all inventory of affected sets;
2. Perform a count of affected product currently in inventory;
3. Inform the concerned hospitals using the letter attached;
4. Complete and return the attached Product Response Form by email to our Quality Department at quality@the37company.com

Transmission of this Urgent Field Safety Notice

This Field Safety Notice needs to be passed on to all personnel who need to be aware within your organisation or to any organisation where the potentially affected sets have been transferred.

Please transfer this notice to concerned hospitals on which these actions have an impact. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of this Field Safety Notice.

If you should have any questions regarding this information, please contact The 37Company, K. van Hassel by email vanhassel.kees@the37company.com or by phone +31 33 450 7250.

The 37Company is committed to providing quality products and services to its customers. We apologize for the inconvenience this situation may have caused.

Yours sincerely,

Kees van Hassel
Director Regulatory Affairs & Quality Assurance
The 37Company

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