

Urgent Field Safety Notice

Fast Nut for toilet raiser fixed Hi-LOO and toilet armrest Supporter

2015-04-20

Dear valued customer,

With this Field Safety Notice, Etac provides information on important issues in relation to a Field Correction of Hi-Loo and Supporter. The Field Safety Notice is intended to ensure that all health facilities with influence of fixed Hi-Loo and Supporter users will receive important information on the background and execution of this Field Correction.

Background:

Etac has received information from a few users of malfunctions with the toilet raiser fixed Hi-Loo and toilet armrest Supporter. It is reported that the Fast Nuts fastening the toilet raiser and the toilet armrest to the toilet in some cases are loose. Etac is unaware that loose Fast Nuts would have resulted in any serious injuries. There is however a potential risk for harm and injury if the Fast Nuts loses and the toilet raiser or toilet armrest thus becomes unstable.

Field correction:

To prevent a potential situation of fixed Hi-Loo or Supporter coming loose, Etac is voluntarily issuing this Field Correction of all potentially affected toilet raisers and armrests. Hi-Loo, Supporter and accessories, delivered from Etac from December 12, 2014 until April 17, 2015 are within the scope of this Field correction. The Fast Nuts of the toilet raisers and toilet armrests shall be replaced to ensure a continuous long term safe use.

You will be contacted by an Etac representative to arrange for this replacement of Fast Nuts to be performed.

The activities will start in April 2015 and carried out as soon as possible, at latest September 30, 2015.

There are no reasons for an immediate stop of using fixed Hi-Loo or Supporter. However, as an intermediate precautionary action awaiting the Fast Nuts replacement, user facilities are requested to be observant and inspect the fixed Hi-Loo and Supporter to see if there are visible signs of a Fast Nut coming loose.

Etac apologizes for any inconvenience and asks that this notice is 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. This notice should also be passed to end users concerned by the affected products.

Should you have any concerns or questions in relation to this notice do not hesitate to contact your local Etac sales company or Etac distributor.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Anderstorp 2015-04-20

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Sincerely,

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Quality Manager

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Affected medical devices:

Toilet raiser fixed Hi-Loo and toilet armrest Supporter

Art No	Name	Affected serial No
1316-2	Hi-Loo II part assembled with arm supports 6 cm VG	Higher than 224017
1317-2	Hi-Loo II part assembled with arm supports 10 cm VG	Higher than 224017
1318-2	Hi-Loo II part assembled with arm supports sloping VG	Higher than 224017
3112-2	Supporter II part assembled VG	Higher than 224017
80301106	Hi-Loo fixed, without arm supports, 6 cm	Higher than 59058
80301107	Hi-Loo fixed, without arm supports, 10 cm	Higher than 46887
80301113-2	Supporter II without arm supports	Higher than 224017
80301316-2	Hi-Loo II part assembled with arm supports 6 cm	Higher than 224017
80301317-2	Hi-Loo II part assembled with arm supports 10 cm	Higher than 224017
80301318-2	Hi-Loo II part assembled with arm supports sloping	Higher than 224017
80303018-2	Supporter adjustable	Higher than 76582
80303112-2	Supporter II part assembled	Higher than 224017
80304002	Adjustment kit Hi-Loo/Supporter	Accessory, no serial number
84001122	Assembly nut 10 pcs	Spare part, no serial number
84001125	Screw kit / pair	Spare part, no serial number
84001299	Attachment Hi-Loo II with armrest 6 cm	Spare part, no serial number
84001322	Attachment Hi-Loo II with armrest 10 cm	Spare part, no serial number

The table contains all affected articles. However, not all affected articles are distributed to all markets.

Customer Reply Form

Please complete and return this Reply Form to the contact listed below as confirmation that you have received this notification until May 18, 2015.

Address and email of your Etac Distributor

Please list the quantity of Hi-Loo and Supporter and accessory kits within the affected range which are in your possession.

Art No	Serial No (if known)

We confirm that we have read and understood the information provided in FSN and that we have passed on the information to those who need to be aware where the potentially affected products have been transferred.

Reply recorded by:
(please print name)

Title

Telephone number

E-mail

Return this form with the information completed below as confirmation

Signature / Date: _____

Facility Name and Address: _____
