
Urgent Field Safety Notice**Parking brake for wheelchairs****Field Correction****2018-08-29**

Dear valued customer,

With this Field Safety Notice, Etac provides information in relation to a Field Safety Corrective Action of *parking brake for wheelchairs*. The Field Safety Notice is intended to ensure that users and health facilities with influence of *parking brake for wheelchair* will receive important information on the background and execution of this Field Correction.

Affected medical devices:

Parking brake for wheelchairs. For article No's and distribution: see page two of this document.

Background:

Etac has received information from a few users of malfunctions with the *Parking brake for wheelchairs*. It is reported that the product in a few cases show reduced brake force. This is assessed to be caused by durability variation in the brake components, which may over time lead to that the function may decrease.

There is a potential risk for harm and injury if the *Parking brake for wheelchairs* have a reduced brake effect when a user by himself/herself is moving from or to the wheelchair.

Field correction:

To prevent a potential situation of *Parking brake for wheelchairs* with reduced brake effect, Etac is voluntarily issuing this Field Correction of all potentially affected *Parking brakes for wheelchairs* by offering replacement spare parts for exchange at any convenient opportunity, i.e. reconditioning or planned service and replace any affected products in stock.

There is no reason for an interruption of using *Parking brake for wheelchairs*, however as an intermediate precautionary action, you are requested to be observant of any visible sign of *Parking brakes for wheelchairs* with decreased brake effect. For correct parking brake adjustment, please see relevant wheelchair manual.

All articles in the table on page two are within the scope of this field correction.

Etac regrets any inconvenience that this field correction may cause, and request user facilities 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.

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 2018-08-29

Sincerely,



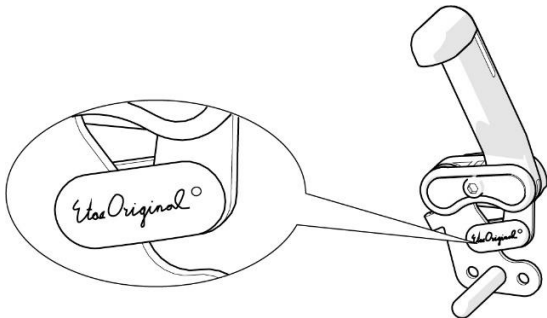
Etac Supply Center AB
Box 203
SE-33424, Anderstorp, Sweden

Affected devices and distribution

Art no	Device name	Distribution
27528-1/-2	Brake Cross angled handle R / L	<p>All deliveries shipped from Anderstorp, Sweden, from August 2017 to May 2018, assembled to wheelchairs and as spare parts.</p> <p>Affected serial No's:</p> <p>Assembled on wheelchair Cross from 37A54363 to 37A71465</p> <p>Assembled on wheelchair Twingo from 39A2606 to 39A2894</p>
27532-1/-2	Brake handle Cross mod 3 R / L	
83113	Brake Cross base model R	
83114	Brake Cross base model L	
27530-1/-2	Brake Cross extended handle R / L	

Art No that ends -1 means Right hand, art No that ends -2 means Left hand.

Picture 1: **Older** brakes with the logotype "Etac Original" as shown below are not affected by this FSN.



Picture 2: **Later** brakes with white marking as shown below are not affected by this FSN

