September 2018

URGENT Field Safety Notice: RA 2018-1884239

FSCA identification: RA 2018-1884239

Action type: Field Safety Corrective Action: Correction

Affected product:

Product description	Altrix model 8001 units manufactured between October 4, 2016 and June 30, 2017
Model numbers	**UDI**
8001000001	07613327277555
8001000003	07613327277562
8001000008	07613327277630
8001000015	07613327277722
8001000016	07613327277586
8001000017	07613327277609
8001000018	07613327277678
8001000019	07613327277623
8001000023	07613327277777
Serial number(s)	
See Attachment	

The purpose of this letter is to advise you that Stryker Medical is correcting specific serial numbers of Altrix Model 8001 Units.

Product description:

Altrix is a precision temperature management system that supplies water to an individual or multiple thermal transfer devices simultaneously with each of these circuits monitored separately. The system consists of a controller, reusable hose sets, thermal transfer devices (blankets, vests, and leg wraps), patient temperature probes, reusable cable adapter cables, and reusable patient temperature output cables.

Stryker UK
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Reason for Correction:

1. Users may experience alarm fatigue due to frequent alarming relating to patient temperature deviation beyond 0.5°C while in Automatic mode.

2. Users may experience a Remove from Use code 9 (RFU 9) fault condition relating to inadvertent flow alarms.

3. Users may experience code RFU 27 fault condition relating to mechanical interference between the device fan and filter.

Risk to Health:

A Health Hazard Evaluation was completed which identified the potential hazard of interrupted therapy resulting from Remove from Use "RFU" codes. In addition, users may experience alarm fatigue due to patient temperature deviation.

There have been no reports of patient harm to date in relation to these events; however, Stryker has initiated a field action to address these potential hazards.

Actions to be taken by the Customer/User:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Locate the units listed on the attached business reply form and identify the address where they can be serviced

2. Circulate this Field Safety Notice internally to all interested/affected parties.

3. Maintain awareness of this notice internally until all required actions have been completed within your facility.

4. Inform Stryker if any of the subject devices have been distributed to other organisations.
    a) Please provide contact details so that Stryker can inform the recipients appropriately.
    b) If you are a Distributor, note that you are responsible for notifying your affected customers.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.

6. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

7. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

8. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within 07 calendar days from the date of receipt. The target date for completion of this action is 26 October 2018 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
E-mail: nina.goddard@stryker.com

In line with the recommendations of the Meddev Vigilance Guidance Document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,

Nina Goddard
Regulatory Affairs and Quality Assurance

stryker

RA2018-1884239: Affected products

Model	Serial Number
8001000017	201609000500040
8001000017	201609000500041
8001000017	201609000500042
8001000017	201609000500043
8001000017	201701000500049
8001000017	201701000500050
8001000003	201611000100095
8001000003	201611000100094
8001000003	201611000100096
8001000003	201611000100097
8001000003	201611000100126
8001000003	201611000100098
8001000003	201611000100118
8001000003	201611000100119
8001000003	201611000100120
8001000003	201611000100121
8001000003	201611000100122
8001000003	201611000100123
8001000003	201611000100124
8001000003	201611000100125
8001000003	201611000100127
8001000003	201611000100137
8001000003	201611000100138
8001000003	201611000100139
8001000003	201611000100140
8001000003	201611000100141
8001000015	201609000500005
8001000015	201609000500001
8001000015	201609000500002
8001000015	201609000500003
8001000015	201609000500004
8001000015	201609000500006
8001000015	201609000500007
8001000015	201609000500008
8001000015	201609000500009
8001000015	201609000500010
8001000015	201609000500011

Model	Serial Number
8001000015	201609000500012
8001000015	201609000500013
8001000015	201609000500039
8001000015	201609000500050
8001000016	201610000500062
8001000016	201610000500066
8001000016	201610000500067
8001000016	201610000500075
8001000015	201609000500014
8001000015	201611000500053
8001000015	201611000500091
8001000015	201611000500097
8001000015	201611000500098
8001000015	201611000500099
8001000015	201611000500100
8001000015	201611000500062
8001000015	201611000500055
8001000015	201611000500056
8001000015	201611000500057
8001000015	201611000500060
8001000015	201611000500061
8001000015	201611000500093
8001000015	201611000500063
8001000015	201611000500096
8001000016	201610000500072
8001000016	201610000500063
8001000016	201610000500073
8001000016	201610000500074
8001000016	201703000500001
8001000016	201703000500003
8001000016	201703000500004
8001000016	201703000500021
8001000016	201703000500025
8001000016	201703000500027
8001000016	201610000500069
8001000016	201610000500070
8001000016	201610000500076

RA2018-1884239: Acknowledgement Form

FSCA identification: RA2018-1884239

Action Type: Correction

Affected product: Altrix model 8001 units manufactured between October 4, 2016 and June 30, 2017

I acknowledge receipt of the Field Safety Notice for RA2018-1884239 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*			
We have located the following devices:			
Product Description	Product Reference	Serial Number	Qty to correct
We have further distributed subject devices to the following organisations:			
Facility Name			
Facility Address			

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 580300
OR EMAIL TO nina.goddard@stryker.com