

URGENT FIELD SAFETY NOTICE: RA2018-1965478

STRYKER SUSTAINABILITY SOLUTIONS: REPROCESSED 2515 NAV ECO VARIABLE EP CATHETERS

ATTN: Risk Manager, Operating Room Director, Materials Manager

December XX, 2018

FSCA identification: Product recall RA2018-1965478

Action type: Field Safety Corrective Action

Product description: Reprocessed 2515 NAV eco Variable Electrophysiology (EP) Catheters

Catalogue Numbers: D134301

GTIN: 00885825011680

Specific D134301 devices are affected. Affected devices may be identified through one of the following methods:

- Serial Number – A list of affected Serial Numbers can be found in Attachment 1.
- Expiration Date – Devices with expiration dates on or after 9/14/2020 are affected. Attachment 2 outlines the expiration date location on the device label.

Please note: Attachment 1 includes all affected Serial Numbers in scope of the recall. Attachment 1 is not specific to facility.

PRODUCT DESCRIPTION

The Reprocessed 2515 NAV eco Variable Electrophysiology (EP) Catheters are specially designed for electrophysiological mapping of the atria of the heart when used with the CARTO® 3 EP navigation System and a reference device.

INDICATIONS FOR USE

The Reprocessed 2515 NAV eco Variable Electrophysiology (EP) Catheters are indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. They are designed to obtain electrograms in the atrial regions of the heart. The Reprocessed 2515 NAV eco Variable EP Catheters provide location information when used with compatible CARTO® EP Navigation Systems version 2.3 or higher.

Reason for the recall

Stryker's Sustainability Solutions division has received an increase in reports indicating that an EEPROM chip error code may occur when Reprocessed 2515 NAV eco Variable Electrophysiology (EP) Catheters are used with CARTO® EP Navigation Systems. There have been no injuries reported as a result of this event.

Risk to health

There are no associated adverse health consequences. A device with the EEPROM failure is unusable with the CARTO® EP Navigation Systems.

Actions Needed

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

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.
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 **XXX** calendar days from the date of receipt.

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: _____ **Position:** _____ **email:** _____

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 Sincerely,

ACKNOWLEDGEMENT FIELD SAFETY NOTICE: RA2018-1965478

STRYKER SUSTAINABILITY SOLUTIONS: REPROCESSED 2515 NAV ECO VARIABLE EP CATHETERS

FSCA identification: Product recall RA2018-1965478

Action type: Field Safety Corrective Action

Product description: Reprocessed 2515 NAV eco Variable Electrophysiology (EP) Catheters

Catalogue Numbers: D134301

GTIN: 00885825011680

I acknowledge receipt of the Field Safety Notice for RA2018-1965478 and can confirm that:

We have not located any of these devices in our inventory: <i>(please delete if not applicable)</i>			
We have located the following devices:			
Product Description	Product Reference	Serial Number	Qty to return
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 X

FIELD SAFETY NOTICE: RA2018-1965478 Appendix A:

Please Note: Attachment 1 includes all affected Serial Numbers in scope of the recall. Attachment 1 is not specific to your facility or distribution site.

Catalog Number D134301

Affected Serial Numbers:

2674940	2724318	2761521	2794036	2879309	2918829
2677298	2724320	2763683	2794073	2879312	2920167
2677324	2726887	2767521	2794191	2887266	2925629
2677325	2727015	2767528	2804281	2887691	2925630
2677326	2727016	2767537	2843017	2889131	2925632
2677327	2732728	2777174	2843547	2892701	2925633
2677328	2736609	2777175	2862775	2893277	2930750
2677331	2742516	2777185	2862776	2896226	2930753
2677398	2742579	2777186	2869100	2896229	2941324
2677399	2742580	2777187	2871151	2898832	2970121
2683282	2746664	2786407	2873812	2898836	2970300
2692529	2746673	2786426	2873898	2898840	2970301
2692536	2751680	2786502	2873899	2898845	2970302
2719705	2755589	2786506	2873924	2898846	2986705
2719707	2755641	2786537	2873935	2906003	2993057
2724210	2755694	2786538	2875420	2906077	3002383
2724283	2761520	2786568	2876114	2917968	3002384
					3007144

FIELD SAFETY NOTICE: RA2018-1965478 Appendix B:

Affected Expiration Dates:

Affected devices may also be identified by the Expiration Date. Devices with **expiration dates on or after 9/14/2020** are in scope of the recall. Attachment 2 provides the expiration date location on the device label.

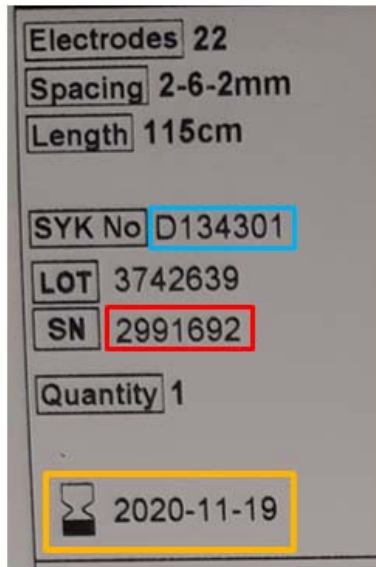


Figure 1: Label on top of box. Device identifiers which may be used to identify affected product include catalog number (outlined in blue), serial number (red) and expiration date (yellow).



Figure 2: Labels on top edge of box. Device serial number is outlined in red and catalog number is outlined in blue.