



## Urgent Field Safety Notice

### LigaSure™ Exact Dissector Nano Coated 20.6mm-21cm

Item Code LF2019, specific lot numbers

#### Recall

March 2018

Medtronic reference: FA809

Dear Health Care Professional, Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling 4 specific lot numbers of the **LigaSure™ Exact Dissector Nano Coated 20.6mm-21cm, model number LF2019.**

#### Issue Description:

This voluntary recall is being conducted due to the potential for the sterile packaging to be compromised. The use of products with this condition may result in an increased risk for infection. There have been no reports of infection associated with this issue. This voluntary recall affects only the item code and lot numbers listed below:

Item Code	Item Description	Affected Lots
LF2019	LigaSure™ Exact Dissector	72550127X
LF2019	LigaSure™ Exact Dissector	72770140X
LF2019	LigaSure™ Exact Dissector	72770141X
LF2019	LigaSure™ Exact Dissector	73000048X

Medtronic records indicate potentially affected products were shipped to your facility between November 2017 and February 2018. We request that you quarantine and return any unused affected products you may have in your inventory. Unused products from the affected lots should be returned as described in Appendix A.

#### Customer Actions:

1. Please quarantine and discontinue use of the affected products
2. Please return affected product as indicated below.
3. Complete the Verification Form even if you do not have inventory.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred. Please maintain a copy of this notice in your records.

The Competent Authority of your country has been notified of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,



## Appendix A: Return Instructions

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly from <b>Medtronic</b>	<p>Please complete the attached Returns Verification Form in its entirety.</p> <p>Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.</p>	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a <b>distributor</b>	Complete <b>all</b> fields on the form and contact your distributor directly to arrange for return of product	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor & to the Medtronic contact provided on the verification form.

**VERIFICATION FORM**  
**LigaSure™ Exact Dissector Nano Coated 20.6mm-21cm**  
**PLEASE COMPLETE THIS FORM IN ITS ENTIRETY**

Customer Contact Details	Medtronic Contact Details
<b>Hospital Name:</b> <b>Covidien/Medtronic Account Number:</b>	<b>To:</b>
<b>Collection Address:</b> <b>Department:</b> Street: City: Postal Code: Contact Person at Point of Collection: Opening Hours:	<b>Address:</b>
<b>Telephone:</b>	<b>Telephone:</b>
<b>Fax:</b>	<b>Fax:</b>
<b>E-mail:</b>	<b>E-mail:</b>

Please list the quantity of affected product at your facility, if you have **no** inventory, please tick the box below.

No Inventory (Please check):

Item Code	Invoice or Despatch Note (if available)	Lot number	Quantity (Eaches or Boxes) Please specify

**Please complete this form and return it to Medtronic even if you have no affected inventory**

Information for the courier:

Number of parcels to collect: \_\_\_\_\_

Weight:  < 45kg  > 45kg

# Medtronic

**By signing this form I confirm that I have read and understand the Urgent Field Safety Notice from Medtronic regarding the LigaSure™ Exact Dissector Nano Coated 20.6mm-21cm**

<b><u>Customer Name: (Please Print)</u></b>	<b><u>Signature:</u></b>	<b><u>Date:</u></b>

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Care will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.