



Minimally Invasive Therapies Group  
 60 Middletown Avenue  
 North Haven, CT 06473  
 USA  
[www.medtronic.com](http://www.medtronic.com)

**URGENT FIELD SAFETY NOTICE**  
**Beacon™ EUS delivery system needles**

February X, 2017

**Attention: Risk Management Director and O.R. Materials Management**

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific item codes and production lots of Covidien Beacon™ EUS Delivery System needles. This Field Safety Corrective Action (FSCA) is being conducted following customer reports that the handle of the Beacon™ EUS Delivery System separated during use due to a manufacturing error. Use of a device with a separated handle can increase the potential for user needle sticks. Needles sticks have been associated with transmission of HBV, HCV, and HIV to healthcare personnel. There was one report of a user needle stick associated with this FSCA.

Medtronic is requesting that you quarantine any remaining inventory of the item codes and lot numbers detailed below. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below. If you have distributed the Covidien Beacon™ EUS Delivery System devices affected by this FSCA to other persons or facilities, please promptly forward the information from this letter to those recipients. All affected units must be returned.

This FSCA affects only the item codes listed below.

| Item Code | Product Description                                      | Lot Number                                     |
|-----------|--|--|
| DSC-22-01 | Covidien SharkCore™ Fine Needle Biopsy System (22 GA)    | B000000164, B000000170, B000000173, B000000178 |
| DSN-19-01 | Covidien BNXT™ Fine Needle Aspiration System (19GA).     | B000000176, B000000181                         |
| DSC-25-01 | Covidien SharkCore™ Fine Needle Biopsy System (25 GA)    | B000000174                                     |
| DSL-19-01 | Covidien SharkCore™ LG Fine Needle Biopsy System (19 GA) | B000000166                                     |
| DSN-22-01 | Covidien BNXT™ Fine Needle Aspiration System (22GA)      | B000000167                                     |

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## Required Actions:

1. Please quarantine and discontinue use of the affected item codes and lots listed above.
2. Please return affected product as follows:

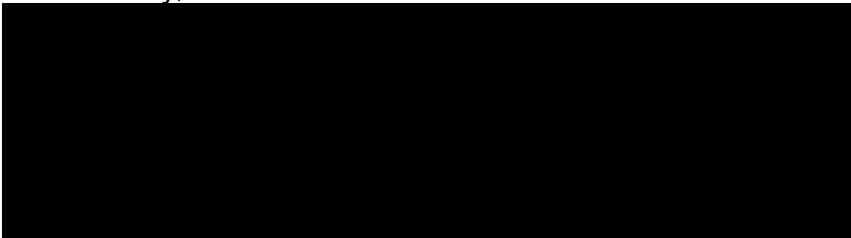
|  | Customer with inventory   | Customer with zero inventory                              | Where to send the completed form   |
|--|---|---|--|
| Purchased <b>directly</b> from Medtronic | Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return. | 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. |

This action is being taken with the knowledge of the [Insert name of local Competent Authority]. We request you report any quality problems experienced with the use of this product to Medtronic:

- Email Medtronic Regulatory Affairs at: [XXXXX@Medtronic.com](mailto:XXXXX@Medtronic.com)

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at (XXX) XXX-XXXX.

Sincerely,



Early Technologies  
Minimally Invasive Therapies Group  
Medtronic

Attachment A

Distinguish affected product by Item Code and Lot Number

### Covidien Ilc BNX™ Fine Needle Aspiration System (19 GA)

QTY - \_\_\_\_\_ EA

CE 0543

Covidien Ilc  
15 Hampshire Street  
Mansfield, MA 02048 USA  
Made in USA

REF DSN-19-01

LOT

STERILE EO

EC REP Covidien Ireland Limited,  
IDA Business & Technology Park,  
Tullamore.

AW1005024-01 Rev E

Item number

Lot number

The diagram shows a label for the Covidien Ilc BNX™ Fine Needle Aspiration System (19 GA). It includes a CE mark with '0543', a factory icon, and the manufacturer's address: Covidien Ilc, 15 Hampshire Street, Mansfield, MA 02048 USA, Made in USA. The label features a 'QTY - \_\_\_\_\_ EA' field, a 'REF' field containing 'DSN-19-01', and a 'LOT' field. Below these are 'STERILE EO' and a biohazard symbol. At the bottom, it says 'EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.' and 'AW1005024-01 Rev E'. Two red boxes with arrows point to the 'REF' and 'LOT' fields, labeled 'Item number' and 'Lot number' respectively.

### Covidien Ilc SharkCore™ LG Biopsy Needle (19 GA)

QTY - \_\_\_\_\_ EA

CE 0543

Covidien Ilc  
15 Hampshire Street  
Mansfield, MA 02048 USA  
Made in USA

REF L-19-05

LOT

STERILE EO

EC REP Covidien Ireland Limited,  
IDA Business & Technology Park,  
Tullamore.

AW1006521-06 Rev A

Item number

Lot number

The diagram shows a label for the Covidien Ilc SharkCore™ LG Biopsy Needle (19 GA). It includes a CE mark with '0543', a factory icon, and the manufacturer's address: Covidien Ilc, 15 Hampshire Street, Mansfield, MA 02048 USA, Made in USA. The label features a 'QTY - \_\_\_\_\_ EA' field, a 'REF' field containing 'L-19-05', and a 'LOT' field. Below these are 'STERILE EO' and a biohazard symbol. At the bottom, it says 'EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.' and 'AW1006521-06 Rev A'. Two red boxes with arrows point to the 'REF' and 'LOT' fields, labeled 'Item number' and 'Lot number' respectively.