

## Urgent Field Safety Notice

### Covidien Force TriVerse™ electrosurgical device Recall

February 2020

Medtronic Reference: FA905

Dear Customer / Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of Covidien Force TriVerse™ electrosurgical device.

#### 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 a potentially increased risk for infection. This packaging issue was identified during the manufacturing process; there have been no reported observations of compromised packaging in the field.

This voluntary recall affects only the item codes and lot numbers listed on Attachment A of this notification. These devices were distributed between June 2019 and November 2019.

#### Required Actions:

1. Please immediately quarantine and discontinue use of the affected item codes and lots listed on Attachment A.
2. Please return affected product as indicated below. All unused products from the affected item codes and lots must be returned.
3. If you have distributed Covidien Force TriVerse™ electrosurgical device listed on Attachment A, please promptly forward the information from this letter to those recipients.
4. Complete the Recalled Product Return Form **even if you do not have inventory**.

	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 and to the Medtronic contact provided on the verification form.

Medtronic has notified the Competent Authority of your country of this action.

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

Sincerely,

## Attachment A

### Affected item codes and lots

Item Code	Description	Affected Lot Numbers				
FT3000	Force TriVerse™ Electrosurgical Device 10'	190530412R	191160341R	191650217R	191930107R	192380041R
		190530413R	191160342R	191650218R	191930108R	192450224R
		190600130R	191300316R	191650219R	192000197R	192450225R
		190630011R	191300317R	191720259R	192000198R	192450227R
		190640010R	191370322R	191720261R	192000199R	192520129R
		190880338R	191370323R	191790222R	192000200R	192520130R
		190880339R	191440286R	191790223R	192070038R	192520131R
		190880340R	191440287R	191790224R	192070039R	192600113R
		190880341R	191510192R	191860195R	192070041R	192660097R
		191020334R	191510193R	191860197R	192100007R	192660099R
		191090309R	191580245R	191860198R	192170106R	192660100R
		191090310R	191580246R	191930105R	192170107R	192730131R
		191160340R	191580247R	191930106R	192380040R	192870153R
FT3000DB	Force TriVerse™ Electrosurgical Device 15'	181170378R	192100010R	192240106R	192630089R	192450230R
		181170379R	192170108R	192240107R	192100011R	192660103R
		181170380R	192170109R	192240108R	192660102R	192800040R

### Affected Kit Codes and Lots

Item Code	Description	Affected Lot numbers			
BREASTKIT01	BREASTKIT01 BREAST KIT 1X FT3000&LF1212	0218862144	0218909458	0218938181	0219010001
		0218907363	0218909459	0218940986	0219010002
		0218909452	0218909460	0218953120	0219010003
		0218909453	0218917588	0218953902	0219010004
		0218909454	0218917589	0218954164	0219010005
		0218909455	0218917602	0218962165	0219013846
		0218909456	0218917603	0219009999	0219013847
		0218909457	0218917904	0219010000	0219015316
BREASTKIT02	BOX BREASTKIT02 BREASTKIT FT3000 DISECTO	0218953822	0218908405	0218953514	
LAR28PLN	BOX LAR28PLN ZESTAW DO RESEKCJI 28MM	0218813863	0218782098		
MGBGLOX1	BOX MGBGLOX1 ZESTAW MINIGASTRIC BYPASS	0218836471	0218836472		
SGGLOX1	BOX SGGLOX1 ZESTAW DO BARIATRII	0218836473	0218836474		
HEMICX1	BOX HEMICX1 ZESTAW DO HEMICOLECTOMII	0218836470			
LAPWL	LAPWL ZESTAW VS LAP WLOCLAWEK X1	0218863976			
STOM25PL	BOX STOM25PL ZESTAW DO RESEKCJI ZOLADKA	0218836468			
TGGLOX1	BOX TGGLOX1 DO TOTALNEJ RESEKCJI ZOLADK	0218836475			
TIROIDEKIT	TIROIDEKIT KIT CIRURGIA TIROIDE X1	0218851370			
UROCYSPL	BOX UROCYSPL ZESTAW DO CYSTEKTOMII	0218836469			
VAGHCJ	BOX VAGHCJ ZESTAW DO HIST WAGINALNEJ	0218879245			
VATSZD2	BOX VATSZD2 ZESTAW DO VATS LOBECTOMII	0218836478			
VGYN	BOX VGYN ZESTAW DO HISTEREKTOMII OPEN	0218861244			
VMED	BOX VMED ZESTAW DO VATS SREDNI	0218927160			
VMED3	BOX VMED3 ZESTAW DO VATS SREDNI	0218926415			
ZGVATS1	BOX ZGVATS1 ZESTAWLOBEKTOMII VATS	0218907609			

Attachment B

Identifying Affected Product



## RETURN VERIFICATION FORM

### FA905: Force TriVerse™ electrosurgical device PLEASE COMPLETE THIS FORM IN ITS ENTIRETY

[Please insert date the form was sent]

Customer Contact Details	Medtronic Contact Details
<b>Hospital Name:</b> <b>Covidien/Medtronic Account Number:</b>	<b>To:</b> [please insert name]
<b>Collection Address:</b> <b>Department:</b> Street: City: Postal Code: Contact Person at Point of Collection: Opening Hours:	<b>Address:</b> [please insert Medtronic address]
<b>Telephone:</b>	<b>Telephone:</b> [please insert Medtronic telephone number]
<b>Fax:</b>	<b>Fax:</b> [please insert Medtronic fax number]
<b>E-mail:</b>	<b>E-mail:</b> [please insert contact e-mail address]

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 Cases) 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

**By signing this form, I confirm that I have read and understand the Urgent Field Safety Notice FA905 from Medtronic regarding the Covidien Force TriVerse™ electrosurgical device Issued dated February 2020.**

Customer Name: (Please Print)	Signature:	Date:

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service 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.