

August 15, 2011

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Medical Device Bureau  
Ministry of Health Malaysia  
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## **URGENT VOLUNTARY PRODUCT RECALL**

### **ENDOPATH® ETS Compact Flex 45mm Articulating Linear Cutter**

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Dear Sirs:

This letter is to inform you that Ethicon Endo-Surgery has initiated a global voluntary recall for specific production lots of ENDOPATH® ETS Compact Flex 45mm (240mm shaft length) articulating linear cutters.

**The recall involves the following product codes with lot numbers identified as per listed in Attachment A:**

- **CTS45** - ENDOPATH® ETS Compact-Flex 45 Articulating Endoscopic Linear Cutter (240mm)
- **CTS45NK** - ENDOPATH® ETS Compact-Flex 45 No Knife Articulating Endoscopic Linear Cutter (240mm)
- **SCW45** - ENDOPATH® ETS Compact-Flex 45 Articulating Linear Cutter for open procedures
  - 45mm Staple Line 2.5mm Staple Leg Length (Vascular/Thin)
- **SCG45** - ENDOPATH® ETS Compact-Flex 45 Articulating Linear Cutter for open procedures
  - 45mm Staple Line 4.1mm Staple Leg Length (Thick)
- **6CB45** - ENDOPATH® ETS Compact-Flex 45 Articulating Linear Cutter for open procedures
  - 45mm Staple Line 3.5mm Staple Leg Length (Standard) 6 row
- **SCB45** - ENDOPATH® ETS Compact-Flex 45 Articulating Linear Cutter for open procedures
  - 45mm Staple Line 3.5mm Staple Leg Length (Standard)

### **Summary**

As a precautionary measure, Ethicon Endo-Surgery initiated a voluntary global recall for specific production lots of ENDOPATH® ETS Compact Flex 45mm articulating linear cutters because the possibility exists that damage to the blister pack may have compromised the sterility of the device.

The voluntary recall is being conducted with the full knowledge of the U.S. Food and Drug Administration (FDA).

**Actions**

We have identified 2 affected lots (total of 9 units) imported and sold into Malaysia listed below. We have no affected products in our inventory.

Material Product Code	Lot numbers	Expiry Dates
SCG45	G4R72N	Dec-14
SCW45	G4RX1E	Mar-15

**Communication of this Field Action**

All our customers will be notified to return all recalled product to our distributor. Credit Notes will be provided for all returned materials. The product codes and lot numbers are printed on container boxes.

If you require additional information regarding this matter, please contact the Johnson & Johnson Regulatory Affairs Manager on +603 7962682.

Kind Regards



**Ong Yean Ting**  
Johnson & Johnson Sdn Bhd, Medical Division  
Regulatory Affairs Manager

## Attachment A

CTS45 Packaging Lot Number	Expiration Date
F4PD36	Jul-2014
F4PD9U	Jul-2014
F4PG0X	Aug-2014
F4PG42	Aug-2014
F4PG92	Aug-2014
F4PH1N	Aug-2014
F4PH4N	Aug-2014
F4PJ4U	Aug-2014
F4PK4W	Aug-2014
F4PM4R	Sep-2014
F4PM61	Sep-2014
F4PN2E	Sep-2014
F4PN8Z	Sep-2014
F4PP1A	Sep-2014
F4PP9F	Sep-2014
F4PR1V	Sep-2014
F4PU0Y	Sep-2014
F4PU6Y	Sep-2014
F4PV1E	Oct-2014
F4PW2Z	Oct-2014
F4PX14	Oct-2014
F4PX5J	Oct-2014
F4PX81	Oct-2014
F4PY36	Oct-2014
F4PY9W	Oct-2014
F4PZ7L	Oct-2014
F4PZ9H	Oct-2014
F4R11D	Nov-2014
F4R14L	Nov-2014
F4R172	Nov-2014

CTS45 Packaging Lot Number	Expiration Date
F4R213	Nov-2014
F4R299	Nov-2014
F4R31F	Nov-2014
F4R435	Nov-2014
F4R45U	Nov-2014
G4R54T	Dec-2014
G4R81J	Dec-2014
G4R823	Dec-2014
G4R971	Dec-2014
G4R97A	Dec-2014
G4R99A	Dec-2014
G4RD0H	Jan-2015
G4RD6P	Jan-2015
G4RE6K	Jan-2015
G4RG45	Jan-2015
G4RG7C	Jan-2015
G4RH07	Jan-2015
G4RH1E	Jan-2015
G4RL49	Feb-2015
G4RM0M	Feb-2015
G4RN6U	Feb-2015
G4RN81	Feb-2015
G4RP03	Feb-2015
G4RP4M	Feb-2015
G4RP8C	Feb-2015
G4RR9N	Feb-2015
G4RT2F	Feb-2015
G4RT7H	Feb-2015
G4RU9U	Mar-2015
G4RV45	Mar-2015

CTS45 Packaging Lot Number	Expiration Date
G4RV6G	Mar-2015
G4RV95	Mar-2015
G4RW0J	Mar-2015
G4RX6X	Mar-2015
G4RY1G	Mar-2015
G4RY2D	Mar-2015
G4RY4N	Mar-2015
G4RZ1U	Mar-2015
G4T04U	Apr-2015
G4T099	Apr-2015
G4T12L	Apr-2015
G4T159	Apr-2015
G4T39L	Apr-2015
G4T43Y	Apr-2015
G4T48N	Apr-2015
G4T553	Apr-2015
G4T59H	Apr-2015
G4T86K	May-2015
G4T92W	May-2015
G4T96N	May-2015
G4TA3E	May-2015
G4TC5W	May-2015
G4TC82	May-2015
G4TE91	Jun-2015
G4TG0U	Jun-2015
G4TK3C	Jun-2015
G4TK5X	Jun-2015
G4TL66	Jul-2015
G4TL6N	Jul-2015
G4TM1L	Jul-2015

## Attachment A

CTS45 Packaging Lot Number	Expiration Date
G4TN19	Jul-2015
G4TN5F	Jul-2015
G4TP0Y	Jul-2015
G4TP51	Jul-2015
G4TP88	Jul-2015
G4TR5K	Jul-2015
G4TR9T	Jul-2015
G4TT8Z	Jul-2015
G4TU1G	Aug-2015
G4TU1J	Aug-2015
G4TV44	Aug-2015
G4TX08	Aug-2015
G4TX3H	Aug-2015
G4TZ93	Aug-2015
G4U020	Aug-2015
G4U10D	Sep-2015
G4U13F	Sep-2015
G4U19A	Sep-2015
G4U22Z	Sep-2015
G4U28H	Sep-2015
G4U51C	Sep-2015
G4U62P	Sep-2015
G4U62V	Sep-2015
G4U83X	Oct-2015
G4U91N	Oct-2015
G4U94C	Oct-2015
G4UA7G	Oct-2015
G4UC07	Oct-2015
G4UC4D	Oct-2015
G4UC88	Oct-2015

CTS45 Packaging Lot Number	Expiration Date
G4UD43	Oct-2015
G4UD5C	Oct-2015
G4UG3F	Nov-2015
G4UG3J	Nov-2015
G4UG82	Nov-2015
G4UH9L	Nov-2015
H4315X	Dec-2015
H4317R	Dec-2015
H4320H	Dec-2015
H43303	Dec-2015
H43369	Dec-2015
H43409	Dec-2015
H43436	Dec-2015
H4351F	Dec-2015
H43914	Jan-2016
H43966	Jan-2016
H43985	Jan-2016
H43A2A	Jan-2016
H43A4W	Jan-2016
H43C68	Jan-2016
H43E38	Feb-2016
H43F4A	Feb-2016
H43F6N	Feb-2016
H43H3M	Feb-2016
H43H64	Feb-2016
H43H8J	Feb-2016
H43J4N	Feb-2016
H43M40	Mar-2016
H43N4D	Mar-2016
H43N5P	Mar-2016

CTS45 Packaging Lot Number	Expiration Date
H43P11	Mar-2016
H43R8Y	Apr-2016
H43T5E	Apr-2016
H43U8W	Apr-2016
H43V5H	Apr-2016
H43W06	Apr-2016
H43W6C	Apr-2016
H4402J	May-2016
H4404X	May-2016
H44303	May-2016
H44369	Jun-2016
H44604	Jun-2016
<b>H4465K</b>	Jun-2016

## Attachment A

CTS45NK Packaging Lot Number	Expiration Date
G4TZ37	Aug-2015
G4UC08	Oct-2015
H43A10	Jan-2016
H43W25	Apr-2016

6CB45 Packaging Lot Number	Expiration Date
F4PE3Z	Aug-2014
F4PH99	Aug-2014
F4PR04	Sep-2014
F4PX54	Oct-2014
F4R204	Nov-2014
G4R554	Dec-2014
G4RD0F	Jan-2015
G4RF4W	Jan-2015
G4RJ23	Jan-2015
G4RJ4D	Jan-2015
G4RM6R	Feb-2015
G4RR8N	Feb-2015
G4RT26	Feb-2015
G4RV11	Mar-2015
G4RW1U	Mar-2015
G4TJ4J	Jun-2015
G4TN2N	Jul-2015
G4TV1Z	Aug-2015
G4UA7F	Oct-2015
G4UC4C	Oct-2015
H4345P	Dec-2015
H43L03	Mar-2016

SCB45 Packaging Lot Number	Expiration Date
F4PE3E	Aug-2014
F4PL2N	Aug-2014
F4PL31	Sep-2014
F4PU2W	Sep-2014
F4PV36	Oct-2014

## Attachment A

SCG45 Packaging Lot Number	Expiration Date
F4PL3M	Sep-2014
F4PU2X	Sep-2014
F4PX78	Oct-2014
G4R72N	Dec-2014
G4RC02	Dec-2014
G4RJ3X	Jan-2015
G4RL3U	Feb-2015
G4RW9M	Mar-2015
G4TC56	May-2015
G4TR5C	Jul-2015
G4UD5R	Oct-2015
H43753	Jan-2016
H43E0M	Feb-2016
H43L83	Mar-2016

SCW45 Packaging Lot Number	Expiration Date
F4PD3H	Jul-2014
F4PE5V	Aug-2014
F4PF5T	Aug-2014
F4PL3P	Sep-2014
F4PM1H	Sep-2014
F4PU40	Sep-2014
F4PV44	Oct-2014
F4PW81	Oct-2014
F4R15T	Nov-2014
F4R27D	Nov-2014
F4R352	Nov-2014
G4R69T	Dec-2014
G4R809	Dec-2014
G4RC03	Dec-2014
G4RF2X	Jan-2015
G4RJ4K	Jan-2015
G4RL44	Feb-2015
G4RM75	Feb-2015
G4RP7N	Feb-2015
G4RU54	Mar-2015
G4RX1E	Mar-2015
G4RX62	Mar-2015
G4T14R	Apr-2015
G4T63F	Apr-2015
G4TA7E	May-2015
G4TF2K	Jun-2015
G4TM93	Jul-2015
G4TX42	Aug-2015
G4U04J	Sep-2015
G4U164	Sep-2015

SCW45 Packaging Lot Number	Expiration Date
G4U74G	Oct-2015
G4UA6K	Oct-2015
H4305X	Dec-2015
H4324F	Dec-2015
H4329P	Dec-2015
H43755	Jan-2016
H43C2U	Jan-2016
H43H0K	Feb-2016
H43M8E	Mar-2016
H43R6T	Apr-2016
H4406Z	May-2016