

## Central Drugs Standard Control Organization

Directorate General of Health Services

Ministry of Health and Family Welfare

Government of India

(Medical Devices and Diagnostics Division)

Email: [ddcimd-cdsco@nic.in](mailto:ddcimd-cdsco@nic.in)

Food & Drugs Administration Bhawan,

Kotla Road, New Delhi.

F.No.29/Misc/03/2021-DC (355)

Date: 14<sup>th</sup> June 2022

### MEDICAL DEVICE ALERT

#### DEVICE

**EEA Auto Suture Circular Stapler/ Loading unit with DST Series Technology  
(Staple)**

#### BACKGROUND

The DST Series™ EEA™ stapler is used throughout the alimentary tract for the creation of end-to end, end-to side, and side-to-side anastomoses in both open and laparoscopic surgeries.

Distributed 25mm EEA Auto suture Circular Staplers with DST Series Technology, with model numbers EEA25, EEAXL25, EEA2535, and EEAXL2535, have the potential for the staple guide to not be securely attached to the instrument. This issue is related only to the 25mm EEA Auto suture Circular Staplers with DST Series Technology. No other Medtronic products or other sizes of EEA Auto suture Circular Staplers with DST Series Technology are affected by this issue.

#### Reason for Recall

- A staple guide not attached to the instrument could cause the component to disengage and if disengaged, could allow the device to transect tissue without forming staples. This could result in delay of treatment, extended hospital stays, unspecified tissue injury, unintended radiation exposure, unexpected medical intervention, foreign body in patient, failure to anastomose, and hemorrhage.

#### Who May Be Affected

- Patients going for surgical procedures with the DST series EEA stapler used throughout the alimentary tract for the creation of end to end, end-to side, and side-to-side anastomoses in both open and laparoscopic surgeries.

**Important Note:** CDSCO have not received any complaints from the market on this issue.

## **FURTHER DETAILS & CONTACTS**

M/s India Medtronic Pvt. Ltd, Gurugram, Haryana had issued a Field Safety Notice which is attached herewith this alert.

**M/s India Medtronic Pvt. Ltd.**

4th Floor, Tower A & B SAS Tower

Medanta The Medicity Complex

Sector 38, Gurugram 122001

Haryana, India

[www.medtronic.co.in](http://www.medtronic.co.in)

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## FIELD SAFETY CORRECTIVE ACTION NOTIFICATION (FSCA) FORM

1. Before filling this form, the reporter collects and collates the prescribed information in the form.
2. This form will serve as the reporting tool in lieu with the Medical Devices Rules, 2017.  
Fourth Schedule  
[See rule 20(2), 21(2), 34(2), 63(1) and 64(1)] Part II (ii) (b) and Appendix II for intimating, notifying CDSCO for any Field Safety Corrective Action (FSCA) in relation to medical device product recall and other corrective action.
3. A scanned signed copy of PDF version of this form is to be sent to CDSCO via email to dci.nic.in
4. Additional information that may be pertinent for the completion of this form can be provided as an attachment.
5. All the field safety notices will be published on the CDSCO website and the reporter holds the full responsibility for the information contained in the Field Safety Notification and reporter must indemnify CDSCO for all losses, claims, demands, liabilities, causes of action, expenses of any kind arising from CDSCO's publication of the FSN.

Primary Information		
1.	Type of Field Safety Corrective Action (FSCA)	<input checked="" type="checkbox"/> Product Recall
		<input type="checkbox"/> Other Corrective actions
2.	Type of Report	<input checked="" type="checkbox"/> Notification
		<input type="checkbox"/> Preliminary Report
		<input type="checkbox"/> Final Report
3.	Date of Report (dd/mm/yy)	10-May-2022
4.	Reference Number (auto generated by system)	
Particulars of Reporters		
1.	Contact Person Name	Latika Vats
2.	Job Title	Director-Regulatory Affairs and Quality Assurance
3.	Telephone Numbers	+917227907498
4.	Email Address	<a href="mailto:rs.indiaregulatory@medtronic.com">rs.indiaregulatory@medtronic.com</a>
5.	Office Address	Medtronic India Medtronic Pvt Ltd, 4t Floor, Tower A & B, SAS Tower, Medanta The Medicity complex Sector 38, Gurugram 122001, Haryana India
6.	Local Contact Details (if reporter not based in India)	Same as above

Device General Information		
1.	Device Name	EEA Auto Suture Circular Stapler/ Loading unit with DST Series Technology (Staple)
2.	Accessories / Associated Devices Affected	NA
3.	Device Intended Use	The DST Series™ EEA™ stapler is used throughout the alimentary tract for the creation of end-to end, end-to side, and side-to-side anastomoses in both open and laparoscopic surgeries.
Regulatory Details		
Other than India		
1.	Device Regulatory Status	Is the device registered globally <input type="checkbox"/> Yes <input type="checkbox"/> No
		Is the device marketed globally <input type="checkbox"/> Yes <input type="checkbox"/> No
		If yes provide details:
In India		
1.	Device Regulatory Status	Is the device registered in India <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
		Is the device marketed in India <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
		If yes provide details : IMP/MD/2018/000215
2.	Manufacturer(s) and Contact Details	Legal Manufacturing Site : M/s Covidien llc, 15 Hampshire Street, Mansfield, MA 02048, Country: United States Telephone No.: 303-305-2841 FAX: 303-305- 2212 E-Mail : Michael.Aymami@covidien.com
3.	Product License Holder / Local Authorized Representative Name & Address	Actual Manufacturing Site : M/s Covidien, Building 911-67, Sabanetas Industrial Park, Ponce, Puerto Rico 00731, Country: United States Telephone No.: 787-259-6505 FAX: 787- 259-1485 E-Mail : carlos.rodriguez@medtronic.com
4.	Importer(s) / Distributor(s) and Contact Details	M/s India Medtronic Private Limited, Plot No 609 Survey/Shed-188 (part) Chamunda Compound,Kasheli Village, Dist Thane, Bhiwandi 421301 Maharashtra , Thane, Maharashtra (India) - 421301 Telephone No.: 22330747001 FAX: 22330747001
Impacted Device Information		
1.	Model Number	Please refer attachment#1 FA1245
2.	Catalogue Number	Not applicable
3.	Serial Number	Not Applicable
4.	Affected Lot / Batch Number	Please refer attachment#1 FA1245
5.	UDI Number	NA
6.	Accessories / Associated Devices Affected	NA

Device Related to FSCA Information		
1.	Number of affected Unit	<b>Manufactured in India</b>
		Period : NA
		<b>Imported into India- 2625</b>
		Period : Jun 2017 to Feb 2022
		<b>Supplied in India- 2408</b>
		Period : Jun 2017 to May 2022
		<b>Expected Shipment to India- NA</b>
		Expected Date of Arrival: NA
2.	Number of affected units supplied to each consignee	Please refer attachment#1 FA1245
3.	FSCA Strategy gk	<ul style="list-style-type: none"> <li>• A voluntary FCA will be implemented to communicate the issue to all consignees who have received affected product according to Medtronic records.</li> <li>• Consignees will be asked to confirm receipt of FCA notification.</li> <li>• Consignees, including Medtronic field representatives, will be asked to return all unused affected sold product within their possession.</li> <li>• Reconciliation of returned product will be managed per Product Hold Order</li> </ul>
4.	Did the FSCA arise due to an adverse event ?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.	If yes, what is the category of adverse event ?	<input type="checkbox"/> Serious Public Health Threat
		<input type="checkbox"/> Death
		<input checked="" type="checkbox"/> Serious Injury
		<input type="checkbox"/> Non-Serious Injury
6.	Did this adverse event occur in India ?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
		If Yes then adverse event Ref. No. & Summary : N/A
7.	Evaluation of risk associated with affected device (Health Hazard Evaluation Report)	<b>Risk Summary and Acceptability</b> The overall risk falls into Zone 1 and Zone 2 for the potential harms of failure to anastomose, unspecified tissue injury, hemorrhage/bleeding, delay to treatment/therapy, unexpected medical intervention, foreign body in patient, and unintended radiation exposure. The highest potential of harm is a severity of 4. The scoring of this IIA reflects the full risk of harm (severity of 4).

<b>8.</b>	<b>Give reason &amp; detail for FSCA (if other than the adverse event)</b>	Not Applicable
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## Affected Device Details (e.g. device identifiers, lot/batch No.) listed in the FSCA Communication

### For Other than India

<b>1.</b>	<b>Has the FSCA communication been sent to all consignees ?</b>	Yes
<b>2.</b>	<b>Date of commencement of FSCA by product owner (dd/mm/yyyy)</b>	13-May-22
<b>3.</b>	<b>Date of commencement of FSCA (if applicable)</b>	13-May-22 to 30-May-22
<b>4.</b>	<b>Countries to which FSCA has been reported (if any)</b>	Information Awaited
<b>5.</b>	<b>Proposed date of completion of FSCA (if applicable)</b>	21-Jul-2023
<b>6.</b>	<b>Summary of root cause analysis</b>	CAPA2022-018332 was issued to investigate the root cause of the issue
<b>7.</b>	<b>Summary of Corrective and Preventive Action (CAPA)</b>	CAPA2022-018332 was issued to investigate the root cause of the issue

### For India

<b>1.</b>	<b>Affected device details</b>	Please refer attachment#1 FA1245
<b>2.</b>	<b>Has the FSCA communication been sent to all consignees ?</b>	<input checked="" type="checkbox"/> Yes, Date Sent : (dd/mm/yyyy) <span style="margin-left: 200px;"><input type="checkbox"/> No (dd/mm/yyyy)</span> Expected Date to be sent : 25-May-2022
<b>3.</b>	<b>Date of commencement of FSCA by product owner (dd/mm/yyyy)</b>	13- May-2022
<b>4.</b>	<b>Date of commencement of FSCA in India (if applicable)</b>	25-May-2022
<b>5.</b>	<b>Countries to which FSCA has been reported (if any)</b>	Information Awaited
<b>6.</b>	<b>Proposed date of completion of FSCA (if applicable)</b>	21-Jul-2023


7.	<b>Summary of root cause analysis</b>	CAPA2022-018332 was issued to investigate the root cause of the issue
8.	<b>Summary of Corrective and Preventive Action (CAPA)</b>	CAPA2022-018332 was issued to investigate the root cause of the issue.

**Change Notification (if applicable)**

1.	<b>Type of change (software change, design change, labelling)</b>	No change in software, design or labelling
2.	<b>For software change, have any feature not related to FSCA incorporates</b>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes then provide details :

**Other Information**

I attested that the information submitted is true and accurate and that I am authorized to submit this form in behalf of company.



Digitally signed by Latika Vats  
 DN: cn=Latika Vats, o=India  
 Medtronic Pvt. Ltd.,  
 ou=Regulatory Affairs/ Quality  
 Assurance,  
 email=latika.vats@medtronic.com,  
 c=IN  
 Date: 2022.05.25 18:17:55 +05'30'

**Signature** : .....

**Name of reporting person** : Latika Vats (Director-Regulatory Affairs and Quality Assurance)

**Date of Notification** : .....