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
Food & Drugs Administration Bhawan,
Kotla Road, New Delhi.

F.No.29/Misc/03/2021-DC (355) **Date: 14th 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
Tel +91-124-4709800
Fax +91-124-4206850

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)**	☑Product Recall
		☐ Other Corrective actions
2.	**Type of Report**	☑ Notification
		☐ Preliminary Report
		☐ 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**	rs.indiaregulatory@medtronic.com
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 ☐ Yes ☐ No
		Is the device marketed globally ☐ Yes ☐ No
		If yes provide details:
In India		
1.	**Device Regulatory Status**	Is the device registered in India ☑ Yes ☐ No
		Is the device marketed in India ☑ Yes ☐ No
		If yes provide details : IMP/MD/2018/000215
2.	**Manufacturer(s) and Contact Details**	Legal Manufacturing Site : M/s Covidien IIc, 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**	**Manufactured in India**
		Period : NA
		Imported into India- 2625
		Period : Jun 2017 to Feb 2022
		Supplied in India- 2408
		Period : Jun 2017 to May 2022
		Expected Shipment to India- NA
		Expected Date of Arrival: NA
2.	**Number of affected units supplied to each consignee**	Please refer attachment#1 FA1245
3.	**FSCA Strategy gk**	• A voluntary FCA will be implemented to communicate the issue to all consignees who have received affected product according to Medtronic records. • Consignees will be asked to confirm receipt of FCA notification. • Consignees, including Medtronic field representatives, will be asked to return all unused affected sold product within their possession. • Reconciliation of returned product will be managed per Product Hold Order
4.	**Did the FSCA arise due to an adverse event ?**	☒ Yes ☐ No
5.	**If yes, what is the category of adverse event ?**	☐ Serious Public Health Threat
		☐ Death
		☒ Serious Injury
		☐ Non-Serious Injury
6.	**Did this adverse event occur in India ?**	☒ Yes ☐ No
		If Yes then adverse event Ref. No. & Summary : N/A
7.	**Evaluation of risk associated with affected device (Health Hazard Evaluation Report)**	**Risk Summary and Acceptability** 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).

8.	**Give reason & detail for FSCA (if other than the adverse event)**	Not Applicable

Affected Device Details (e.g. device identifiers, lot/batch No.) listed in the FSCA Communication		
For Other than India		
1.	**Has the FSCA communication been sent to all consignees ?**	Yes
2.	**Date of commencement of FSCA by product owner (dd/mm/yyy)**	13-May-22
3.	**Date of commencement of FSCA (if applicable)**	13-May-22 to 30-May-22
4.	**Countries to which FSCA has been reported (if any)**	Information Awaited
5.	**Proposed date of completion of FSCA (if applicable)**	21-Jul-2023
6.	**Summary of root cause analysis**	CAPA2022-018332 was issued to investigate the root cause of the issue
7.	**Summary of Corrective and Preventive Action (CAPA)**	CAPA2022-018332 was issued to investigate the root cause of the issue
For India		
1.	**Affected device details**	Please refer attachment#1 FA1245
2.	**Has the FSCA communication been sent to all consignees ?**	☒ Yes, Date Sent : (dd/mm/yyy) ☐ No (dd/mm/yyy) Expected Date to be sent : 25-May-2022
3.	**Date of commencement of FSCA by product owner (dd/mm/yyy)**	13- May-2022
4.	**Date of commencement of FSCA in India (if applicable)**	25-May-2022
5.	**Countries to which FSCA has been reported (if any)**	Information Awaited
6.	**Proposed date of completion of FSCA (if applicable)**	21-Jul-2023

7.	**Summary of root cause analysis**	CAPA2022-018332 was issued to investigate the root cause of the issue
8.	**Summary of Corrective and Preventive Action (CAPA)**	CAPA2022-018332 was issued to investigate the root cause of the issue.
Change Notification (if applicable)		
1.	**Type of change (software change, design change, labelling)**	No change in software, design or labelling
2.	**For software change, have any feature not related to FSCA incorporates**	☐ Yes ☑ 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.

Signature : .....

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

Date of Notification : .....