

Medical Device Quality Alert: Class II Recall of EEATM Auto Suture™ Circular Stapler with DST Series™ Technology 25mm manufactured by Covidien llc 15 Hampshire Street Mansfield, USA

Covidien llc 15 Hampshire Street Mansfield, USA is implementing a voluntary recall of **ALL** batches of EEATM Auto Suture™ Circular Stapler with DST Series™ Technology 25mm.

From: Pharmacy and Poisons Board
Published: 24/06/2022

Recall Reference Number: REC/2022/06

Company name: Hampshire Street Mansfield, USA

Product name: EEATM Auto Suture™ Circular Stapler with DST Series™ Technology 25mm

Medical device: Intraluminal circular stapler

Brief description of the problem

A complaint was received for EEATM Autosuture™ Circular Stapler with DST Series™ Technology (EEAXL2535) reported as “Staples Did Not Deploy”. According to the reporter, during laparoscopic procedure, the circular stapler was able to fire, but the staples did not deploy when attempting to staple a small bowel segment to the gastric pouch. Further, tissue dissection and manipulation were required to recreate tissue and the gastric pouch for anastomosis. The case was completed by using another stapler. The surgical time was extended by at least 2 hours and hospitalization for 1 day.

Action for healthcare professionals

You are advised to immediately quarantine and stop supply/ distribution or use of the impacted batches of the product and return them to your supplier.

Action for patients/caregivers

No action is required for patients as this medical device is used in a healthcare facility setting.

Further Information

You are advised to promptly report any cases of adverse events and suspected substandard and falsified products to the nearest healthcare facility or through the following channels:

- <https://pv.pharmacyboardkenya.org/users/mpublic>
- USSD code at *271#
- Email pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further information please contact the Pharmacy and Poisons Board
by email: pms@ppb.go.ke