Central Drugs Standard Control Organization

Directorate General of Health Services
Government of India
(Medical Device Division)
Food & Drugs Administration Bhavan,
Kotla Road, New Delhi

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MEDICAL DEVICE ALERT

DEVICE

"ECHELON Endoscopic Linear Cutter Reloads Black (ECR60T)"

BACKGROUND

The Echelon FAMILIES OF Endoscopic Linear Cutters (articulating and straight) are sterile, single patient use instruments that simultaneously cut and staple tissues. These are six stagerred rows of staples, three on either side of the cut line. The ECHELON 60 have a staple line that is approximately 60mm long and a cut line that is approximately 57mm long. The shaft can rotate freely in both the directions and an articulation mechanism on articulating instruments enables bending the distal portion of the shaft to facilitate lateral access of the operative site. The Instruments are shipped without a reload and must be loaded prior to use. The instrument lock-out feature is designed to prevent a used reload from being refired.

PROBLEM

Recall of "ECHELON Endoscopic Linear Cutter Reloads Black (ECR60T)" due to the potential for incomplete Staple Line Formation from reload damage during firing sequence which may result in insufficient tissue apposition that could require surgical intervention to help achieve and maintain anastomotic integrity.

Product Code	Affected Lot
ECR60T	J4AY8Z
	J4CC1F
	J4CJ78
	J4CM9X
	K4C94W
	K4C94W
	K4CC0L
	K4CF5D

ACTION BY

- Medical directors/ Healthcare Professionals
- Distributors and Users.
- Staff involved in the management of patients

ACTION

- Examination of the inventory to determine if you have affected/recalled product in hand.
- Return all affected lots to the manufacturer.
- Inform all Health Authorities about this recall
- Inform all of the appropriate staff at the facility
- The inventory of the recalled product at the warehouse will be destroyed and the destruction certificate will be submitted to the manufacturer.

ADVERSE EFFECTS

Insufficent tisssue apposition that could require surgical intervention to ensure anastomotic integrity. Most occurrences result in the prolonged operative time, malformed staples or an incomplete staple line. The clinical outcome from these staple line issues can result in intra-operative bleeding or anastomic breakdown with peritonitis.

In India 3 complaints were reported for the affected lots.. Globally the manufacturer has received 51 customer complaints identified architectural design differences in the internal components of the ECRT60T reload. In 2013, there were 5 adverse events attributed to ECR60T issue which resulted in the escalation to field action.

CONTACTS

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