

Central Drugs Standard Control Organization

Directorate General of Health Services

Ministry of Health and Family Welfare

Government of India

(Medical Devices and Diagnostics Division)

Food & Drugs Administration Bhavan,

Kotla Road, New Delhi.

File No: 31-113-MD/2006-DC (Re. Reg. 03)

Date: 02 JUN 2017

MEDICAL DEVICE ALERT

DEVICE

The details of product are tabulated as below:

S. No.	Product Brand Name	Model No.	Lot Number
1.	Beacon® Tip Torcon NB® Advantage Catheter	HNBR5.0 HNBR6.0	All lots
2.	Beacon® Tip Royal Flush® Plus High-Flow Catheter	HNR5.0	All lots
3.	<ul style="list-style-type: none">Beacon® Tip Centimeter Sizing Catheters,Beacon® Tip White Vessel Sizing Catheters,Beacon® Tip Vessel Sizing Catheters.	NR5.0	All lots
4.	Shuttle® Select Slip-Cath	SCBR5.5-/-SHTL	All lots
5.	Slip-Cath® Beacon® Tip Catheter	SCBR5.0,SCBR5.5,SCBR6.5	All lots
6.	Haskal Transjugular Intrahepatic Portal Access Set	HTPS	All lots
7.	Liver Access and Biopsy Needle Set	LABS-100, LABS-200	All lots
8.	Neff D'Agostino Percutaneous Access Set	NPAS-100	All lots
9.	Aprima™ Access Nonvascular Introducer Set	NPAS-/-SST, NSSW-/-SST	All lots

BACKGROUND

The above mentioned products were approved by this office vide Registration Certificate no MD-113 dated 09.06.2016 and Import License no MD113-1128 dated 14.06.2016 valid upto 30.04.2019.

These products Registration Certificate and Import License were renewed based on the documents submitted by the Indian agent/manufacturer.

The Indian agent M/s Cook India Medical Devices Private Ltd., has informed this office that the manufacturer has initiated a voluntary recall for all products having Beacon® Tip technology.

PROBLEM

There is an increase in reports of Polymer degradation of the catheter tip, resulting in tip fracture and/or separation.

ACTION BY

- Medical Directors/Healthcare professionals
- Distributors and the Users

- Staff involved in the management of patients.

ADVERSE EFFECTS

Patients and Healthcare professionals are advised to report adverse events suspected to be associated with the use of above mentioned products to the manufacturer, Importer and CDSCO.

CONTACTS

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