Central Drugs Standard Control Organization

Directorate General of Health Services

Government of India

(Medical Device Division)

Food & Drugs Administration Bhavan,
Kotla Road, New Delhi

File No: 31-1284-MD/2013-DC **Date: 10.12.2013**

MEDICAL DEVICE ALERT

DEVICE

HT Connect Peripheral Guidewire

The detail of the recalled products is tabulated below:

Part No. / Lot No.	Description
1012587	018 HT CONNECT 145 CM
1012588	018 HT CONNECT 195 CM
1012589	018 HT CONNECT 300 CM
1012590	018 HT CONNECT FLEX 145 CM
1012591	018 HT CONNECT FLEX 195 CM
1012592	018 HT CONNECT FLEX 300 CM
1012593	018 HT CONNECT 250 T 145 CM
1012594	018 HT CONNECT 250 T 195 CM
1012595	018 HT CONNECT 250 T 300 CM

BACKGROUND

Hi Torque Connect Peripheral Guidewires indicated to facilitate the placement of percutaneous devices during percutaneous Transluminal Angioplasty in peripheral arteries such as femoral, popliteal and infra- popliteal arteries. This guidewire may also be used with compatible stent devices therapeutics procedures.

It consists of a PTFE coated 0.018" diameter stainless steel core wire one end of which is reduced in diameter in progressive fashions through a contreless griding operation. The profile of this reduced section affords the product a reduced area of stiffness and varied to produced 3 unic levels of supports. Hi Torque Connect Peripheral Guidewire family includes:

- HI Torque Connect
- Hi Torque Connect Flex
- Hi Toque Connect 250T

Abbott vascular issued a notification or 'Field Safety Notice'.

PROBLEM

Voluntary Field action for HT Connect Peripheral Guidewires due to a small number of devices exhibiting partial delamination of the PTFE Coating.

ACTION BY

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

ACTION

- Abbott vascular has ceased distribution of the product while evaluating appropriate corrective and preventive actions.

ADVERSE EFFECTS

There have been no longer terms or irreversible patients effects reported potential risks associated with delamination of the coating include embolism, thrombus, and occlusion in the peripheral vessels.

To date, the frequency of worldwide reported incidents of delemination of the coating is 0.08%.

Patients and Healthcare professionals are advised to report adverse events suspected to be associated with the HT Connect Peripheral Guidewires or other medical device to the Manufacturer and CDSCO.

CONTACTS

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