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

"ONYX Liquid Embolic System"

BACKGROUND

The Onyx Liquid Embolic System (Onyx HD-500) is indicated for the Embolization of lesions in the peripheral and neurovasculatur, including arteriovenous malformations and hypervascular tumors.

Onyx is a non-adhesive liquid embolic agent comprised of Ethylene Vinyl Alcohol copolymer dissolved in DMSO and suspended micronized tantalum powder to provide contrast for visualisation under fluoroscopy. It is used to block blood flow in abnormally formed blood vessels in the brain, also known as brain arteriovenous malformations or brain AVMs, before their surgical remova.l Onyx is delivered by slow controlled injection through a micro catheter into the aneurysm under fluoroscopic control.

Onyx has been linked to catheter entrapment. Catheter breakage could also result in migration of the Onyx plug or catheter fragment to other parts of the body.

PROBLEM

Recall of "ONYX Liquid Embolic System" due to catheter Entrapment, which could lead to breakage haemorrhage and possibly death.

ACTION BY

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

ACTION

- Safety Communication to Inform physicians and patients about the risk of catheter entrapment associated with the use of Onyx.
- Specific Changes in the Information of Use to include additional safety information

ADVERSE EFFECTS

Catheter Entrapment happens when the catheter becomes stuck in the implanted Onyx material. The most serious complication includes hemorrhage and death. Other Complication include migration of the Onyx plug or catheter fragment to the other parts of the body. Patients with catheter entrapment may need to make antithrombic drugs to prevent blood clots around the catheter, and may need to undergo one or more imaging procedures to locate a piece of the catheter and Onyx plug, increasing their exposure to radiation.
Five Deaths were reported globally associated with catheter entrapment from 2005 to 2012. One death was reported from July 2012 to Februrary 2013 and 89 complaints reported in 2013 globally.

Till Date 1503 units of "Onyx" has been imported in India of which 84 units are held by distributos and sub distributors and 52 units are held in the hospital.

Patients and Healthcare professionals are advised to report adverse events suspected to be associated with the Onyx Liquid Ebolic System or other medical device to the Manufacturer and CDSCO.

CONTACTS

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