

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: 31-128-MD/2006-DC(Re-Reg.02)

Date: 11.12.2013

MEDICAL DEVICE ALERT

DEVICE

"Cancellous Bone Screws (A component of the Hip System)"

BACKGROUND

The Cancellous Bone Screws are used during primary and revision hip arthroplasty to assist in fixating the acetabular implant to the bone.

PROBLEM

There has been a voluntary recall of the 2 lots of the Bone Cancellous Bone Screw because the length of the screw in the package does not match the length described on the Package Label.

ACTION BY

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

ACTION

- Cease Further Distribution or use of the affected product immediately
- Communication to all the Surgeons, Health professionals, Distributors where these products have been transferred.

ADVERSE EFFECTS

If the screw is too Long: The adverse events reported are Pain, Soft Tissue Irritation, Inflammation, Damage to surrounding structure. Minor injury to the patient during surgery which may result in hematoma, causing increased pain during recovery.

If the screw is too short: The adverse events reported are Loosening, i.e. weakening or separation of the prosthesis connection to the bone, Poor Joint Mechanics, compromised range of motion or stability of joint.

CONTACTS

- 1. M/s. Depuy Orthopaedics Inc, 700 Orthopaedic Drive, Warsaw, Indiana 46581-0988, USA having factory premises at M/s. Depuy Orthopaedics Inc., 325, Paramount Drive, Raynham, Massachusetts 02767, USA**
Tel: 001 574 371 4984
Fax: 001 574 371 4987
E-mail: cswanso2@its.jnj.com
- 2. M/s. Depuy Medical Private Limited., Shed No. A1/50, Paiki Room No. 1to 9, 100 Shed Area, Degam Road, G.I.D.C, Vapi, Taluka: Pardi, District Valsad-396195**
Tel: 0124-4781700
Fax: 0124-4285855
E-mail: ksaini@its.jnj.com
- 3. Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhavan, ITO, Kotla Road, New Delhi -110002**
Tel: 91-11-23236975 / 23236971
Fax: 91-11-23236973
E-mail: dci@nb.nic.in