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

"LPS Lower Extremity Dovetail Intercalary Component"

BACKGROUND

The LPS Lower Extremity Dovetail Intercalary component is intended for use in the replacement of the mid-shaft portion of the femur, proximal distal and or total femur and proximal tibia especially in cases that require extensive resection (e.g tumors, trauma and infections etc.,)

Bench testing stimulating loads under normal walking conditions demonstrated that patients over approx.. 200lbs. are at higher risk and that increasing weight may pose increasing risk. However, common activities such as stair ascent and descent and rising from chairs may exert forces higher than those under normal walking conditions.

PROBLEM

LPS is a limb Preservation System, One of its component of the i.e Lower Extremity Dovetail Intercalary Component has the potential for the fracture of the female component when exposed to certain physiological loads. This recall is only applied or this component and not the whole knee System.

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 for use in primary surgeries.
- Communication of surgeons with patients who received these implants regarding the risk of the implant fracture
- Surgeons review each patient's case to determine the best treatment options, considering patient weight, activity level and/or any other potential contributing factors.
- Inform all the Healthcare professional/surgeon
- Inform all patients implanted with LPS Lower Extremity Dovetail Intercalary Component

ADVERSE EFFECTS

The possible Clinical Implication related to the issue, which could occur if the product should fracture include Poor mechanics and loss of function, Pain, Dislocation i.e the separation of the male component from the female component, adverse tissue reaction, damage to bone in areas that are important for revision surgery. The clinical Implication may potentially require revision surgery. The possible risks associated with revision surgery include Infection, Additional Scaring, Neural and vascular damage, Additional pain to the the patient.

CONTACTS

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