

Poor awareness: FDA chief suggests roping in NGOs to educate patients about implants

Sumitra Deb Roy | TNN

Mumbai: Three years after Johnson & Johnson recalled its all metal hip implant globally, less than 10% of the 4,500 Indian patients have approached the company's redressal agency till date. The Indian response, among other things, highlights how most patients continue to know little about implantation procedures or its implications.

Food and Drug Administration commissioner Mahesh Zagade suggested that NGOs should step in to educate patients. "We also need specialized courts and compensation laws in the country to tackle these emerging issues better."

In the J&J controversy, the doctors had informed the 280 patients about the failure of the metal-on-metal articular surface replacement (ASR), and not the other way round. Even before the implant was recalled, researchers had started talking about the unusually high revision surgery rates. But, a few doctors continued using it with no protests from patients. Time has come, say experts,

KNOW YOUR RIGHTS



WHAT YOU SHOULD ASK

➤ All details of the implant, including why the selected one is more beneficial than others, such as there must be benefit-risk profile before using metal-on-polyethylene, ceramic-on-polyethylene and ceramic-on-ceramic in hip surgeries

➤ Pay attention to conditions that may contraindicate a type of implant

➤ Find out risk factors that may predispose a device to excess wear and high failure possibility

➤ Do independent research about make, price, longevity of implant & discuss with surgeon



J&J faulty implants: \$2.5b payout in US, Indians left in lurch

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Mumbai: Pharmaceutical giant Johnson & Johnson recently agreed to pay \$2.5 billion over 10 years to settle lawsuits filed by patients who had used the company's hip implants with its faulty hip implants. The settlement, one of the largest in pharmaceutical history, is

HIPS DON'T LIE

In 2010, the major Johnson & Johnson globally recalled its faulty hip implants which caused metal poisoning. ➤ Has agreed to pay \$2.5 billion as compensation to around 9,000 US citizens who had used the company. ➤ In India, around 4,500

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PRECAUTIONS TO TAKE AFTER AN IMPLANT

➤ Understand and practise exercises advised by physiotherapist before leaving hospital

➤ Get information on how to walk, climb stairs, sleep, about exposure to water among others

➤ Side-effects of medicine, such as nausea, drowsiness and itchiness, should be

reported if found unusual

➤ Take blood/urine test to check if implant is causing unusual reactions. Norms suggest if metal ion levels in the body are more than 7 parts/billion, blood tests should be repeated every three months

➤ Watch out for blood clots, sudden pain, swelling, infection, low blood count, sudden limping, dislocation

side them."

Certain surgeons, however, follow a protocol of their own. "We usually make it a point to show patients a model of the implant and explain about the positives and negatives," said Dr Pradeep Bhonsale, head of orthopaedic department, KEM Hospital.

Most Indian patients, say surgeons, are contended with the implant being an imported one. "They cannot be bothered about its make, longevity, quality or other issues. As long as it is manufactured by a foreign company, they are satisfied," said Dr Arvind Goregaonkar, head of Sion Hospital's orthopaedic department. "We cannot blame the uneducated patients for blindly relying on doctors. But there is a problem with internet being the sole source of information for the educated lot."

Cosmetic surgeon Dr Mohan Thomas said the need of the hour is to have stringent regulatory bodies that can carry out sampling and other preventive steps. "Onus lies on doctors as well as government agencies to protect the interest of patients."

to ask if patients should blindly trust the decision of their doctors.

A banker, who had opted for the ASR implant for his mother, said that he was never given any choice between implants. "I was told this

was the best implant in the market. I had known the surgeon for over five years, so I did not even consider taking a second opinion," he said. He admitted that he never did his own research about the implant, its beneficial or

adverse effects.

A senior doctor from one of the city public hospitals said, "It is ironical, but people do more research before buying a mobile phone or television set than for an implant that will remain in-