

Toxic hip alert for 56,000 patients

Daily Telegraph 30th June 2017

By **Laura Donnelly** HEALTH EDITOR
and **Henry Bodkin**

MORE than 50,000 patients with “metal-on-metal” hips are being told they must undergo X-rays and blood tests after watchdogs found they were far more toxic than had been thought.

Every person fitted with the devices is being advised to have checks, in a safety alert issued by the Medicines and Healthcare products Regulatory Agency (MHRA).

Concerns have been raised repeatedly about the devices. Watchdogs previously recommended patients with particular types of implant, or troublesome symptoms, to undergo tests.

The new advice means 56,000 patients – every single person with such implants – is being asked to undergo a series of medical tests to establish whether they are suffering muscle or bone damage, and metal toxicity.

The unprecedented decision could result in thousands of people undergoing surgery to replace the implants.

Watchdogs said the alert had been issued because of growing evidence that muscle damage caused by the implants could become progressively worse, and even irreversible, without patients suffering symptoms.

Surgeons are particularly concerned about the effect on female patients, who will be told to undergo annual checks even if no concerns are detected. It follows a series of investigations by *The Daily Telegraph*, which uncovered widespread problems with the devices, now largely phased out.

Metal-on-metal implants were introduced in this country in the Nineties when they were promoted as offering better mobility than those with a metal ball and plastic socket. They were seen as a better option for younger patients, who were likely to be more active and put more pressure on the joint.

Dr Neil McGuire, MHRA’s clinical director of medical devices, said: “Al-

though the majority of patients with these metal-on-metal devices have well-functioning hips, it is known some may develop soft tissue reactions related to their implant.

“The clinical advice we have received indicates patients will likely have the best outcomes if these problems are detected early, monitored and treated if necessary. If people have any questions about their hip replacement they should speak with their GP or implanting surgeon.”

The previous recalls meant that patients with particular types of devices, and those suffering particular reactions, had been subject to extra checks.

The MHRA was unable to say how many patients this amounted to, but said that as many as half of patients with the devices may already be having some level of monitoring.

The decision was taken after tracking of thousands of cases found the devices are still causing soft tissue reactions, many years after they were implanted.

It means that patients will be asked to undergo a series of checks even if they are suffering from no symptoms.

The decision does not mean that every patient with such hip implants would need to have them removed, the MHRA stressed.

Revision surgery will only be recommended if scans, blood tests or scores used to measure pain suggest the devices are causing unseen harm.

All women who have the implants will need to have annual checks for the rest of their lives, under the guidance. Studies have found that women were particularly likely to need revision surgery.

Men suffering symptoms which could denote muscle damage will undergo annual checks, while those without will have tests at least every three years. The alert states: “MHRA’s clinical
Continued on Page 2

Daily Telegraph
30th June 2017

Thousands face surgery to remove 'toxic' hip implants

Continued from Page 1

orthopaedic experts have... observed that soft tissue necrosis may occur in both asymptomatic and symptomatic patients, and believe early detection of these events should give a better revision outcome should this become necessary."

Registers of patients have found that those who received the implants in the

past decade "continued to show a risk of adverse soft tissue reaction to particulate debris", it states.

In 2013, NHS hospitals were told to stop fitting most metal-on-metal hip replacements after a study found unacceptably high failure rates among 17,000 patients. The guidelines said the NHS should stop using any hip implant with a failure rate higher than five per

cent at five years, ruling out most types of metal-on-metal implants.

In 2010, two hip implants made by the company DePuy were withdrawn from the market after concerns about their safety. These accounted for around 10,000 of the metal-on-metal hips fitted in the UK since 2003.

Moira Mercer, a 64-year-old mother of three from South Wales, had to have

For sale: an EU licence for faulty medical implants

Daily Telegraph reporters go undercover to expose the regulatory loopholes that put British patients at risk



Our exposé of faulty implants in 2012

her metal-on-metal implant removed after doctors detected a pseudotumour "the size of a sausage" in her hip.

She had her left hip replaced in 2009 and began suffering pain five years later. By then she had also had her right hip replaced. The former financial complaints handler was left in such pain she had to quit her job. "I still take pain killers every day," said Mrs Mercer.