Medicines & Healthcare products Regulatory Agency

No-React® cardiovascular bioprosthesis implantables: discontinuation of CE marking and manufacture. Remaining stock may continue to be used and any adverse incidents reported nationally (DSI/2023/009)

Product details

Device Name: All No-React® cardiovascular bioprosthesis implantables.

Affected lot numbers/serial numbers: All.

Manufactured by BioIntegral Surgical Inc.

Summary

The MHRA emphasises the importance of national reporting of any suspected adverse incidents associated with the product following CE certification withdrawal and cease of manufacturing.

Background

In mid-2022, BioIntegral Surgical ceased manufacturing; in addition, it voluntarily withdrew their CE certification for all their products for commercial reasons. This action affects BioIntegral's formal contract with their appointed European Notified Body (NB), who are responsible for issuing CE certification and monitoring manufacturer's post-market surveillance activities, including review of adverse incident reports. Furthermore, BioIntegral Surgical no longer has a UK Responsible Person (UKRP). The appointment of a UKRP is a regulatory requirement when placing devices on the GB market to ensure company accountability relating to specific obligations under the relevant medical device regulations.

No-React implantable cardiovascular devices already placed on to the UK market remain legally CE marked and available for sale and use. This includes devices held in stock by UK distributors and those already sold or supplied to UK healthcare settings.

To ensure a robust post-market surveillance framework for remaining products on the UK market, the MHRA emphasises that any suspected adverse incidents associated with their use should be reported to the appropriate national reporting system.

Actions for healthcare professionals

- Products already in use or on the UK market are considered safe.
- Direct any suspected adverse incidents associated with BioIntegral Surgical No-React implants to your national reporting system. This is to ensure effective post-market

surveillance is in place for both previously implanted devices and remaining unused devices on the UK market. Healthcare professionals should report incidents:

    - in England and Wales to the Yellow Card scheme or via the Yellow Card app
    - in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
    - in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

- When reporting suspected adverse incidents, please include the following information, if possible.
    - details of the device, including manufacturer, model, and batch number
    - details of problems with the device and when the problems started

Actions for patients

- The advice in this notice is aimed at the healthcare teams who are responsible for providing and monitoring implantable cardiovascular devices.
- No new safety concern has been identified for patients.
- If you or somebody in your care has received one of these devices and are concerned, please contact your hospital for advice.

Stakeholder engagement

The MHRA has consulted with NHS England and representatives from the Scottish and Welsh Governments and Departments of Health Northern Ireland.

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