MHRA Device Safety Information

Reference: MDSI2309 **Issued:** 04 Sept 2023 **Review Date:** 04 Sept 2023

BioIntegral Surgical Inc. No-React® cardiovascular bioprosthesis implantables: discontinuation of CE marking and manufacture

Summary

BioIntegral Surgical ceased manufacturing in 2022 and withdrew the CE certification for all its products. MHRA advise that No-React® implantable cardiovascular devices already placed on to the UK market may continue to be sold and used. However, there is no manufacturer post-market surveillance and MHRA therefore emphasise the need to use national incident reporting systems.

Action for healthcare professionals

1. Products already in use or on the UK market are considered safe.

2. 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:

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

3. When reporting suspected adverse incidents, please include the following information, if possible.

    a. details of the device, including manufacturer, model, and batch number
    b. details of problems with the device and when the problems started

Equipment details

Device Name:	All No-React® cardiovascular bioprosthesis implantables.
Lot / serial numbers:	All.
Manufactured by:	BioIntegral Surgical Inc.

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.

Suggested onward distribution

Cardiology	Device Managers	Risk Management
Cardio-Thoracic Surgery	Operating Departments	Supplies / Procurement

Stakeholder engagement

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

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

Report an incident: Information on how to report an adverse incident

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/