MHRA Device Safety Information

Reference: MDSI2401 **Issued:** 05 February 2024 **Review Date:** 05 February 2025

Paclitaxel coated devices (PCD) used in the treatment of peripheral arterial disease: update to previous MHRA guidance on use.

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 05 February 2024. The original webpage can be accessed here.

Summary

The MHRA has updated its previous guidance (DSI/2022/003) on the use of paclitaxel coated devices (PCD) in the treatment of peripheral arterial disease (PAD). The MHRA conducted an extensive review of the most recent published literature and sought the advice of the Interim Devices Working Group (IDWG) and invited experts. Following this review, the MHRA has updated its previous advice on PCD to remove restrictions on indication, dose, and repeated exposure.

Where indicated, PCD can be considered a treatment option in patients with critical limb ischaemia (CLI) or intermittent claudication (IC).

Previous MHRA advice relating to the use of the lowest dose PCDs available and to avoid/reduce repeated exposure of paclitaxel coated devices is withdrawn.

Action

1. Direct this notice to all appropriate managers, staff and users.

2. Paclitaxel coated devices (PCD) can be considered (where indicated) as a clinical treatment option for patients experiencing peripheral arterial disease (PAD), including patients with critical limb ischemia (CLI) or intermittent claudication (IC). Previous MHRA advice relating to the use of the lowest dose PCD available and to avoid/reduce repeated exposure of paclitaxel coated devices is withdrawn

3. Routine patient follow-up should continue as per standard of care.

4. Direct any suspected adverse incidents associated with PCD to Scotland's national Incident Reporting & Investigation Centre (IRIC) and to your local incident recording system.

5. When reporting suspected adverse incidents, please include the following information:
   a) details of the device, including manufacturer, model, and batch number
   b) details of problems with the device and when the problems started

6. To assist with the capture of long-term, high quality follow-up outcomes data for possible future evaluation, please ensure details are completed utilising the National Vascular Registry (NVR).

Actions for Patients

7. MHRA has stated the advice it has issued is aimed at the healthcare professionals and teams who are responsible for providing and monitoring medical devices used to treat peripheral arterial disease. MHRA has emphasised that no new safety concerns have been identified for patients and it is advising anyone who has received one of these devices and has concerns should contact their GP or local vascular services / consultant for advice

Equipment details

Description	Information
Manufactured by	Various
Device name:	Paclitaxel coated devices (PCD) used in the treatment of lower limb vascular stenosis / peripheral arterial disease (PAD)
Brand / device name	All makes / models
Affected LOT / serial numbers:	All

Background Information

In January 2019, an independent Expert Advisory Group (EAG) was formed to advise the MHRA on the safety of paclitaxel coated devices (PCD). More specifically, the aim was to review the relationship between PCD and increased mortality, including consideration of the robustness of the statistics of the studies reviewed and provide MHRA with recommendations regarding whether the risk/benefit profile justifies continued use of PCD.

Following additional recommendations received from the EAG, the MHRA last updated its advice on PCD in (DSI/2022/003) in April 2022.

In December 2018, an aggregate level meta-analysis of randomised controlled trials by Katsanos reported an increased risk of death at two- and five-years following use of paclitaxel coated balloons and stents in patients treated for symptomatic femoropopliteal disease1. A further systematic review and study-level meta-analysis by Katsanos in 2020 also reported a reduced amputation free survival at 12 months in patients who received PCD compared to uncoated devices2.

The EAG highlighted limitations of the existing studies, the lack of a mechanism of action to explain the mortality signal and the lack of long-term data which hampered the robustness of the results. The EAG advised that use of PCD should be restricted in patients with mild PAD. In June 2019 the MHRA published both the EAG report and the advice to clinicians through a Medical Device Alert.

In December 2023, new long-term data was published3 which was comprehensively reviewed by the MHRA alongside other existing studies. In January 2024, the MHRA sought the advice of the Interim Devices Working Group (IDWG) on whether the new data supported a revision of the current restrictions on the use of PCD.

The IDWG advised that the new studies did not support a statistically significant increased risk of harm associated with the use of PCD when used to treat patients with PAD irrespective of disease type, severity, or another associated variable. The IDWG advised that the previous advice to use the lowest dose PCD available and avoid/reduce repeated exposure to PCD should be withdrawn.

Stakeholder engagement

The MHRA has consulted with the Interim Devices Working Group (IDWG) and invited external experts as well as with NHS England and representatives from the Scottish and Welsh Governments and Departments of Health Northern Ireland.

Suggested onward distribution (may not include all affected departments)

Clinical Services
Catheterisation Labs
Consultants (specialty)
Day Surgery
Medical Admissions
Nursing
Surgical

Corporate & Support
Device Managers
Risk Management

References and other resources

1. Katsanos, K. and others. Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Journal of the American Heart Association, Volume 7, Issue 24, 2018
2. Katsanos K, and others. Risk of Death and Amputation with Use of Paclitaxel-Coated Balloons in the Infrapopliteal Arteries for Treatment of Critical Limb Ischemia: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. J Vasc Interv Radiol. 2020 Feb;31(2):202-212.
3. Parikh, S. and others. Mortality in randomised controlled trials using paclitaxel-coated devices for femoropopliteal interventional procedures: an updated patient-level meta-analysis, The Lancet, Volume 402, Issue 10415, 2023, Pages 1848-1856, ISSN 0140-6736

Information about IRIC

Incident Reporting & Investigation Centre (IRIC), Facilities Division, NHSScotland Assure 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.

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