

Safety Notice

Medical Devices

Paclitaxel-coated balloons and Paclitaxel-eluting stents used for peripheral artery disease

Priority 2 – Warning

HPRA Safety Notice: SN2019(13)

Issue Date: 2nd May 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Various manufacturers	V38414

ISSUE

The HPRA would like to raise awareness of the safety signal highlighted in a literature article ([Katsanos et al Dec 2018*](#)) regarding the use of Paclitaxel-coated balloons and Paclitaxel-eluting stents for the treatment of peripheral artery disease. The authors concluded that the risk of death is significantly increased beyond the first year following application of paclitaxel-coated balloons and paclitaxel-eluting stents in the femoropopliteal artery of the leg in patients with intermittent claudication.

Further analysis of associated data is ongoing, however in the meantime, the HPRA advises that users consider the actions and information provided below.

* K Katsanos, S Spiliopoulos, P Kitrou, M Krokidis, D Karnabatidis. (2018). 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*. 7 (24).

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Consider alternative treatment options to Paclitaxel-coated balloons and Paclitaxel-eluting stents until further additional analysis of the safety signal has been performed.
2. Discuss the risks and benefits of all available peripheral artery disease treatment options with your patients.
3. Forward a copy of this safety notice to all relevant personnel within your organisation or to any other organisations these devices have been transferred to.
4. Report any adverse events or suspected adverse events experienced with the use of Paclitaxel-coated balloons and Paclitaxel-eluting stents to the relevant manufacturer and the HPRA.

Vascular surgeons

General surgeons

A&E Consultants

Interventional radiologists

Hospital Managers / CEOs

Risk Managers

Stores / Supplies Staff

Theatre Clinical Nurse Manager

Interventional/catheter laboratory clinical nurse managers

Procurement Managers

BACKGROUND

The HPRA was notified of the referenced article regarding the potential for increased long-term mortality after use of paclitaxel-coated balloons and paclitaxel-eluting stents (collectively "paclitaxel-coated products") to treat peripheral arterial disease (PAD) in the femoropopliteal artery, which was identified in a meta-analysis of randomized trials published in the Journal of the American Heart Association.

Whilst further evaluation is ongoing, the HPRA's preliminary review of this data has identified a signal of increased long-term mortality in study subjects treated with paclitaxel-coated products compared to patients treated with uncoated devices. In line with other authorities' views on this concerning safety signal, the HPRA believes that alternative treatment options should generally be used for most patients until the increased long-term mortality signal is further evaluated for its impact on the overall benefit-risk profile of these devices.

It is recommended that the risks and benefits of all available peripheral arterial disease treatment options be discussed with patients.

The HPRA continues to evaluate the concerns raised in this article, whilst at an international level, there are a number of expert advisory groups assessing this issue in detail. The HPRA may provide an update in due course regarding the outcome of these investigations.

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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E-mail: devicesafety@hpra.ie
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