HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Rebound HRD/HRD-V

Priority 2 – Warning

HPRA Safety Notice: SN2019(10) **Issue Date: 10th April 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
ARB Medical LLC	V37968

ISSUE

ARB Medical LLC initiated a field safety corrective action (FSCA) in October 2018 in which they recalled all lots of the Rebound HRD/HRD-V product distributed and sold in Europe by DUOMED.

This FSCA / Recall is due to complaints of the fracture of the frame (ring) of the product (which is implanted to repair hernias) and also due to the suspension of ARB Medical's CE Mark Certificate.

In the intervening months, HPRA understand that ARB Medical LLC has dissolved as a result of which, further information on supply has been difficult to obtain. HPRA is therefore issuing this Safety Notice as a precautionary measure, as we do not have oversight of the distribution network for the Irish market.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Ensure that affected product is removed from use.
2. Forward a copy of this Safety Notice and the field safety notice (FSN), to all relevant personnel within your organisation, or to any organisation/persons to which/whom these devices have been transferred.
3. Follow the guidelines issued by the manufacturer, as outlined in the FSN regarding follow up of patients in whom the product has been already implanted.

4. Report any adverse incidents associated with these devices to the HPRA.

TARGET GROUPS	
General Surgeons All surgical wards and theatres Theatre Staff Directors of nursing	Hospital Managers / CEOs Risk Managers Supplies managers Purchasing Managers

BACKGROUND

ARB Medical LLC has initiated this recall due to complaints of the fracture of the frame (ring) of the product (which is implanted to repair hernias) and also due to the suspension of ARB Medical's CE Mark Certificate.

HPRA understands that the company who manufacture these devices has subsequently been dissolved. It has not been confirmed if any of these devices are on the Irish market.

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

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie