

Important Information for Healthcare Professionals regarding the use of BIOTRONIK VK-99 Cables

December 2008

Dear Sir/Madam

This voluntary letter is to draw your attention to a potential off-label connection between BIOTRONIK VK-99 cables and BIOTRONIK external pacemakers EDP 30/A or EDP 30/S.

Within the scope of BIOTRONIK post market surveillance two cases were observed where due to incorrectly connected VK-99 cables, the atrial and ventricular channel were exchanged. If this substitution remains undetected, insufficient or inadequate stimulation could occur under worst case conditions.

On VK-99 cables and external pacemakers the atrial (A) and ventricular (V) channel are labelled, indicating the right alignment when attaching VK-99 cables to external pacemakers.

According to our records you have been supplied with one or more VK-99 cables. To comply with the labelling and the instructions for use, please consider the following when using the VK-99 cables: -

- Please check if the A/V alignment between the VK-99 cable and the BIOTRONIK external pacemaker is correct according to the labelling.
- Once connected do not disconnect the VK-99 from the external pacemaker. The VK-99 must remain securely connected with the clamps of the external pacemaker.
- As described in the instructions for use, disconnection is only intended to be performed at the patient side of the connection.

Please note that these recommendations are in accordance with the present labelling and the instructions for use and that no VK-99 cable needs to be removed from service.

In accordance with our standard practice, the Competent Authorities have been notified of this issue.

If you have questions regarding this information please contact us on +49 (0) 30 68905-2200 or speak directly with your local BIOTRONIK representative.

Sincerely,



Roman Borkowski
Medical Device Safety Officer
BIOTRONIK GmbH & Co. KG