



TITLE:
TEMPORARY CARDIAC PACING LEADS: QSTIM™
(SUPPLIED BY BIOSENSE WEBSTER AND
MANUFACTURED BY VASCOMED)

MANUFACTURER/SUPPLIER
VascoMed (Supplied by Biosense Webster)

PROBLEM
Difficulty in imaging the body of QStim™ temporary cardiac pacing leads when using low dose X-ray settings.

DISTRIBUTED BY NIAIC TO:
Chief Executive of each HSS Board, Trust and Agency.
NIAIC Liaison Officers.

For onward distribution as appropriate to:
This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

Liaison Officers	Independent Health Care Providers
Risk Managers	Operating Theatre Staff
Health & Safety Officers/Advisors	Coronary Care
Clinical Governance Leads	Intensive Care
Medical Directors	Cardiologists
Nurse Directors	Cardiac Surgeons
	Catheter Laboratory Managers
	Radiographers

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

- ACTION**
- Be aware that it may be difficult to image QStim™ temporary cardiac pacing leads under low dose X-ray settings.
 - If visibility under X-ray is reduced, the position of the leads may be determined by observing the metal distal tip.
 - Ensure that the level of visibility of pacing leads under X-ray is appropriate for the clinical procedures being undertaken. Where doubt exists, consider exploratory testing to determine suitability.

BACKGROUND
NIAIC has been informed that the Medical Devices Agency (MDA) has become aware of three incidents where imaging problems were experienced during the imaging of QStim™ temporary pacing leads where low dose X-ray settings were used. The leads are supplied by Biosense Webster and manufactured by VascoMed. In one incident, the patient suffered heart block due to difficulties in visualising the body of the lead during insertion. In another incident, patient and staff exposure to X-rays was prolonged in attempting to locate the lead tip.



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NOTICE

The reduced visibility under X-ray in the above incidents was associated with a change in the physical structure of the leads supplied. Leads containing a radio-opaque braided metal component were substituted for leads incorporating only a radio-opaque additive within the lead insulation (i.e. 20% barium sulphate (BaSO₄) resulting in reduced radio-opacity). On 2 August 2002 VascoMed and Biosense Webster advised customers about visibility problems when QStim™ leads containing 20% barium sulphate were viewed under low dose X-ray settings (see attached advisory letter-marked appendix 1).

VascoMed and Biosense Webster intend to supply QStim™ leads with a barium sulphate content increased to 30%. Product codes will remain the same as for those included in the advisory notice of 2 August 2002 but labelling of the modified QStim™ lead will indicate "For radio-opacity: 30% BaSO₄".

Since X-ray equipment and settings may vary between hospitals, the visibility of leads that do not contain a braided metal component may require local evaluation, especially where reduced patient exposure to X-rays is practised.

ENQUIRIES

Enquires to the manufacturer should be addressed to:

Mr Stuart Jameson
Business Unit Director
Biosense Webster
Johnson & Johnson Medical Ltd
Coronation Road
South Ascot
Berkshire
SL5 9EY

Tel: 07768 741149 (Mobile)

Fax: 013 44 87 11 79

Enquires to the NIAIC should quote the reference number SN(NI) 2003/04 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates,
Estate Policy Directorate,
Stoney Road,
Dundonald,
Belfast BT16 1US
Tel: 02890 523714,
Fax: 02890 523900,
Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2003/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Aisíneacht Feidhmeannach don Roinn Sláinte. Serbhísí Sóisialta agus Sábháilteacht Phoiblí*

August 2, 2002

TEMPORARY PERVENOUS PACING LEADS

Re: Radio-opacity of temporary pacemaker lead products (QStim™) distributed by BIOSENSE WESTER (CORDIS).

Dear,

In March 2002 Biosense Webster launched a new line of Temporary Pervenous Pacing Leads. These products are a replacement for our previous existing line of Temporary Pervenous Pacing Leads.

Please note that you may be more familiar with this range of products as being supplied by us in the past under the name of CORDIS. The manufacturer of the newly supplied lead is VascoMed.

Based on previous experiences, changes were implemented to improve product performance:

- 2 sterile adapters are included with each pacing lead
- A Peel away sheath for each pacing lead is also supplied

Please note that the catheter body of this new pacing lead is less radio-opaque when compared to our former Cordis lead. The visibility of the catheter body can be significantly less when imaging systems with default low dose settings are used, as these settings contribute to reduced visibility overall. Please refer to the users manual of the fluoroscopic X-ray systems to check which fluoro characteristics are being used.

When using low-dose systems, physicians are advised to follow the catheter tip during the insertion procedure, which will be visible. Attempting to visualize the reduced radio-opacity lead body only, may lead to an increase in procedure time. Clinicians are advised to ensure that the reduced radio-opacity leads are suitable for the procedures they plan to undertake, including their visualization in the imaging systems available.

The difference in radio-opacity between the new pacing lead and our former Cordis lead is due to differences in design. The former Cordis lead contained a stainless steel core wire, whereas the new pacing lead contains barium sulphate (BaSO₄), which makes this lead less opaque at the current concentration.

With this letter we would like to draw your attention to this difference when using the new products. We have advised the Medical Devices Agency (MDA) of this issue.

We are preparing a packaging insert to reflect the above.

We would like to apologize for the inconvenience this might cause and remain at your full disposal should you have any question

Best regards,

For the Manufacturer; VascoMed

Mr Jörg Reinhardt
President
VascoMed Institut für Kathetertechnologie
Germany



For the Distributor

Mr Stuart Jameson
Business Unit Director
Biosense Webster (UK)



* Please find attached the product codes affected by this change.

Former Biosense Webster Product code	Product description	New Biosense Webster Product Code
370-113	4F Curve: Multi Purpose Spacing: 10mm Length: 100cm	PL4M010P
370-132	4F Curve: Multi Purpose Spacing: 10mm Length: 100cm	PL4M010P
370-135	4F Curve: Multi Purpose Spacing: 4mm Length: 100cm	PL4M004P
370-230	5F Curve: Multi Purpose Spacing: 10mm Length: 100cm	PL5M010P
370-420	5F Curve: J-Atrial Spacing: 10mm Length: 100cm	PL5J010P
370-330	6F Curve: Multi Purpose Spacing: 10mm Length: 100cm	PL6M010P
371-114	6F Curve: Multi Purpose Spacing: 10mm Length: 100cm Extra Torque	PL6M010PE