

**Notice Information: - Advisory  
16 November 2011**

**Part 1. Product Information**

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

**Part 2. Target Audience**

- a) Target Audience:

**Part 3. Problem/Issue**

- a) Problem/Issue:

**Part 4. Background Information**

- a) Background Information:

**Part 5. Action to be taken**

a) Action to be taken:

Marus has been unsuccessful in their attempts to locate all devices affected by this field safety corrective action (FSCA), as one of the distributors in Ireland, Dacus Dental, has ceased trading. The serial numbers of the devices provided to Dacus Dental are 4714B and 165569B.

The IMB advises that users:

- Identify the affected devices in your facility.
- Ensure the appropriate personnel are made aware of this notice.
- If you (or your facility) have affected devices, follow the recommendations outlined in the attached Field Safety Notice and contact Marus to obtain the self-installation kit.

## Part 6. Enquiries

- a) All enquiries should be made to:

Enquiries to the Manufacturer / European authorised representative should be addressed to:

Ms. Bonnie Dundas

Quality Assurance and Regulatory Affairs Manager

Marus

705 S. Springbrook Rd., Building C

Newberg, OR 97132

U.S.A.

Telephone: +1 503 537 3602

Fax: +1 503 537 3617

E-mail: [bonnie.dundas@marus.com](mailto:bonnie.dundas@marus.com)

Ms. Lorna Sanderson

Medical Device & QA Services Ltd.

76, Stockport Road

Timperley, Cheshire

WA15 7SN

United Kingdom

Telephone: +44 161 870 6751

Fax: +44 161 903 9787

E-mail: [lorna@mdqa.co.uk](mailto:lorna@mdqa.co.uk)

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

the:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: [vigilance@imb.ie](mailto:vigilance@imb.ie)

Website: [www.imb.ie](http://www.imb.ie)

[Please click here to download a PDF copy of this Safety Notice](#)

[Please click here to download the Field Safety Notice](#)