

5 January 2012

Name
Title Dept
Hospital
Address 1
Address 2
Address 3
Address 4

Urgent Medical Device Recall

Smith & Nephew Endoscopy Dyonics Power II Control Unit
PRODUCT CODE 72200873
All serial numbers from AAX5001 to AAX8067

Dear Customer,

Smith & Nephew have been notified that the above Control Unit is missing an electromagnetic interference (EMI) gasket. As a precautionary measure, Smith & Nephew will be performing a field corrective action to replace the missing gasket.

There is a small, potential risk that, during a procedure, the DYONICS POWER II Control Unit could radiate emissions and affect other electrical equipment in use. This includes interference with monitors or sensors and inadvertent control parameter changes to other devices in the operating room.

Our records show that this item has been despatched to you recently. A Smith & Nephew representative will be in contact with you to install the capacitive filter. Please complete the declaration on the following page by inserting the number of items held and return the form to FAX 01480 423211

The Medicines and Healthcare Products Regulatory Agency have been informed of this recall.

Yours sincerely,



Tony Horn

Quality & Regulatory Manager

Fax to, Smith & Nephew Endoscopy , on 01480 423211. Please return this declaration by 31 January 2012.

DECLARATION

Smith & Nephew Endoscopy Dyonics Power II Control Unit
PRODUCT CODE 72200873
All serial numbers from AAX5001 to AAX8067

I can confirm that I have the following numbers of affected items in our stock.
(please include a zero in the quantity column, if your stock is nil)

| Product Code | Lot Number | Quantity |
|--------------|--|----------|
| 72200873 | All serial numbers from AAX5001 to AAX8067 | |

Where applicable, these have been segregated awaiting shipping and return instructions from Smith & Nephew Customer Care Department, who have been contacted regarding this matter.

Signed

Print Name

Position

Organisation / Hospital

Date