



CardioFocus, Inc.
500 Nickerson Road
Suite 500-200
Marlborough, MA 01752

URGENT FIELD SAFETY NOTICE

CardioFocus Endoscopic Ablation System (EAS) – HeartLight
FSCA-2012-001
Recall of Catheter Lot #'s 7957, 7975, 8006, 8011

March 9, 2012

Dear Dr. NN:

We are writing to inform you of an important safety notice – a Field Safety Corrective Action (FSCA) or recall of CardioFocus Endoscopic Ablation System (EAS) – HeartLight Catheters Lots 7957, 7975, 8006 and 8011. Our records indicated you received one or more catheters from the affected catheter lots. Attached is a sample of the outer catheter box label with the lot number circled.

Due to manufacturing variability, some catheters in the affected lots may have endoscope stops with weaker than desired bond strengths. If the endoscope stop dislodges (comes loose) during clinical use of the catheter, it is possible that the endoscope could put a hole in the EAS balloon. This could result in patient injury such as a cardiac perforation or embolization. We have had two clinical incident reports of balloon pin-hole caused by the endoscope stop malfunction. Neither incident resulted in any patient injury.

We request you immediately quarantine any of the affected catheters and arrange for them to be returned to CardioFocus. If you determine you have none of the affected catheters at your institution, please email this information to me immediately.

This notice should be passed on to all those who need to be aware within your organization or any other department where the potentially affected devices have been transferred.

The primary contact for this FSCA is Burke T. Barrett of CardioFocus. His direct dial phone number in the U.S. is (508) 658-7226, his cell phone is (██████████) and e-mail address is bbarrett@cardiofocus.com. The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

Sincerely,

██████████
Vice President, Regulatory & Clinical Affairs



500 Nickerson Road
Suite 500-200
Marlborough, MA 01752 USA
Phone: (508) 658-7200
Fax: (508) 480-0600



18-2531-N250(EU) EASAC Catheter/Generator

Size: 25 mm Style: **Blunt Bell, 90A**

Catheter Serial Number: **7957-01**

Generator Serial Number: **12 - 7987 - 0315**

09/12

09/11

EC	REP	EMERGO Europe Molenstraat 15, 2513 BH, The Hague	The Netherlands PH:31.70.345.8570 F: 31.70.346.7299
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06-2728 Rev C ECN 1732



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18-2531-N250(EU) EASAC Catheter/Generator

Size: 25 mm Style: **Blunt Bell, 90A**

Catheter Serial Number: **7975-01**

Generator Serial Number: **12 - 2941 - 0355**

10/12

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EC	REP	EMERGO Europe Molenstraat 15, 2513 BH, The Hague	The Netherlands PH:31.70.345.8570 F: 31.70.346.7299
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18-2531-N250(EU) EASAC Catheter/Generator

Size: 25 mm Style: **Blunt Bell, 90A**

Catheter Serial Number: **8006-01**

Generator Serial Number: **12 - 1053 - 9353**

12/12

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EC	REP	EMERGO Europe Molenstraat 15, 2513 BH, The Hague	The Netherlands PH:31.70.345.8570 F: 31.70.346.7299
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18-2531-N250(EU) EASAC Catheter/Generator

Size: 25 mm Style: **Blunt Bell, 90A**

Catheter Serial Number: **8011-01**

Generator Serial Number: **12-8590-5968**

12/12

12/11

EC	REP	EMERGO Europe Molenstraat 15, 2513 BH, The Hague	The Netherlands PH:31.70.345.8570 F: 31.70.346.7299
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