<ev3 Letterhead>

Urgent Field Safety Notice

Product: ev3 SilverHawk Cutter Driver

Model Number FG 02550

<Date>

Dear Cath Lab Manager / Risk Manager:

This letter is to inform you that ev3 Inc. is conducting a voluntary recall of specific lots of the **SilverHawk® Cutter Drivers (Model Number FG 02550).**

Issue Summary
This voluntary action is being taken because ev3 has observed damage to the packaging of a small number of Cutter Drivers (Model Number FG 02550).

The SilverHawk Peripheral Atherectomy System consists of two major components which are packaged separately, but used together during atherectomy procedures. The two components are the atherectomy catheter and the Cutter Driver. The atherectomy catheter packaging is not affected by the recall.

The Cutter Driver does not come into direct contact with the patient.

Affected Product
An investigation has determined that less than 2% of the pouches of the Cutter Driver lots identified below may have been damaged during the manufacturing process. This damage to the packaging may compromise the sterile barrier of the Cutter Driver.

The affected product model number is FG 02550.

The affected product lot numbers include the following:

7341279	**7366716**	**7373759**	**7381976**	**7408387**	**7426555**
7470350	**7481467**	**7497872**	**7505507**	**7516513**	**7526519**
7534809	**7534812**	**7536344**	**7555071**	**7574961**	**7584246**
7696072					

Required Action
Our records indicate that you received one or more Cutter Drivers that are subject to this voluntary recall. The affected lot or lots delivered to your facility are listed on the attached Field Action Reconciliation Form. **Please take immediate action to locate and remove from use the specified Cutter Driver(s).** Your ev3 representative will assist you in arranging for the return of all unused **Cutter Drivers** of the specified lots to ev3. Replacement will be provided for any unused devices that your hospital may have purchased.

Thank you for your cooperation. We sincerely apologize for any inconvenience this may cause. If you have any questions regarding the issue, please contact your local ev3 Responsible or the European Customer Service at: + 31 4 33 65 9229.

Sincerely,

<ev3 Letterhead>

FIELD SAFETY NOTICE / DEVICE RECALL
Field Action Reconciliation Form

Product Name: Cutter Driver
Reference: FG 02550
Affected Lot Numbers: See Below

Please complete the Field Action Reconciliation Form following the steps listed below:

1. Verify listed device status (used or available for return).
2. **If all devices were used**, indicate the quantity used in the "Quantity Used" column below, check the box below indicating no devices remain at the site and complete this form, **including the signature of the site representative**.
3. **If device is unused**, immediately segregate the device to prevent its use. Contact your local ev3 responsible or the European Customer Service at + 31 4 33 65 9229 to obtain an RGA number and record it in the box below. Indicate the quantity to be returned in the "Quantity Returned" column below, complete this form, **including the signature of the site representative.**
4. Verify the "Quantity Used" and "Quantity Returned" matches the total "Quantity Sent" indicated below.
5. After completion, sign below and make a copy of this form for the site records.
6. Fax the completed form to your local representative or to Leon Peeters, ev3 International, Inc. at +31-433.646.395
7. Return device(s) and the original form to **ev**3 with the returned product to the following address:
<*Local ev3 address or European Distribution Center Address*>

RGA# ☐
Site: _____
Address: _____

Our records show that the following device(s) were sent to the site:

Model Number	Lot Number	Qty Sent	Qty Used	Qty Returned
FG 02550				
FG 02550				
FG 02550				
FG 02550				
TOTAL				

☐ Check here to verify no devices remain at the site.

Site Representative: _____ Date: _____
(Signature)

_____
(Printed Name)

Phone Number: _____