

## [Insert Account Name & Address]

October 30, 2013

via Federal Express

# URGENT - MEDICAL DEVICE RECALL (Removal) IMMEDIATE ACTION REQUIRED

## MAQUET VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System "HEMOPRO 1" Catalog Number: VH-3000

Distribution Dates: May 24, 2013 to October 1, 2013

### **AFFECTED LOT NUMBERS:**

25081686, 25081595, 25081460, 25081204, 25080939, 25080744, 25080418, 25080351 25080264, 25079982, 25079913, 25079724, 25079449, 25079363, 25079086, 25078931 25078713, 25078463, 25078291, 25078104, 25077927, 25077643, 25077563, 25077126 25076989, 25076372, 25076371, 25076133

#### Dear Risk Manager,

This letter is to inform you that MAQUET is initiating a voluntary product removal involving multiple lots of its VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System, "HEMOPRO 1". The HEMOPRO VH-3000, "HEMOPRO 1", is activated by a toggle switch on the harvester tool handle. MAQUET has received an increase in the number of complaints for "self-activated/remains activated/overheats" for the HEMOPRO VH-3000, "HEMOPRO 1".

The HEMOPRO VH-3000, "HEMOPRO 1", should deactivate in the "off" position; however, MAQUET has received an increase in the number of complaints where the tool remains activated/heated while in the "off" position. The above units have been identified as having an increased risk of remaining activated in the "off" position.

The tool remaining activated/heated while in the "off" position could cause burns to the patient or user. A burn or flame may occur if the activated device comes in contact with the patient or flammable material.



A review of our records indicates that you have purchased product from specific lots of MAQUET VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System "HEMOPRO 1" (catalog number VH-3000) affected by this recall.

Please examine your inventory immediately to determine if you have any of the affected VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System (HEMOPRO 1) VH-3000 with the lot number(s), as specified above. The VH-3000 catalog number and lot number are located on the package label. Please remove the affected VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System and place in a secure location.

NOTE: <u>VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System</u> <u>"HEMOPRO 1" lot numbers not listed are not affected by this recall and should not be removed</u>. HEMOPRO 2 is not affected by this recall.

Your MAQUET Cardiovascular Sales Representative will contact you shortly to assist with the completion of the enclosed Acknowledgement Form ("Fax Back Form), the return of any affected VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System "HEMOPRO 1" product and arrange for necessary replacement.

We apologize for any inconvenience this may cause. If you have any questions, please contact your local MAQUET Cardiovascular Sales Representative or MAQUET Customer Service at 1-888-880-2874, Monday through Friday, between the hours of 6:00 a.m. and 5:00 p.m. PST.

Thank you for your cooperation and immediate assistance.

Sincerely

Karen LeFevere
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