HAEMONETICS®
THE Blood Management Company

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April 29, 2011

FIELD NOTIFICATION
CL101099-US (AC)

URGENT - FIELD RECALL:
OrthoPAT® ORTHOPEDIC PERIOPERATIVE AUTOTRANSFUSION DEVICES

This letter is to advise you that Haemonetics is conducting a recall of the OrthoPAT® autotransfusion device. This recall covers two (2) models of the OrthoPAT device

1. The original OrthoPAT model **is not equipped** with a spill collection drainage system. This model will be removed from the market. Actions required: Please follow the enclosed directions to (1) confirm your possession of any units of this model and (2) arrange for their return to Stericycle.

2. The current OrthoPAT model **is equipped** with a spill collection drainage system. This model will remain in the market. Enclosed with this letter are instructions for deployment of the spill collection drainage system, revised operations manual on CD and Quick Reference Guide Addendum. You should keep these instructions and other training materials handy to ensure continuing appropriate use of the spill collection drainage system. A Haemonetics representative will deliver additional copies of the revised Operations Manual, Quick Reference Guide Addendum and training video that also include these instructions. Action required: Please complete the enclosed Customer Confirmation sheet, indicating the serial number of all OrthoPAT devices in your possession and return via fax to Stericycle at 866-792-5450.

Further use of devices not equipped with a spill collection drainage system should cease immediately. This recall is being conducted to address the possibility of fluid intrusion into the OrthoPAT device. Fluid intrusion may occur when excessive volumes of fluid enter the interior of the device during the cleaning process or in connection with a disk-related blood spill or leak. Fluid intrusion poses an electrical hazard as well as a bio-hazard risk that cannot be mitigated by the user.

You will need to verify which OrthoPAT model(s) are located in your facility to determine their proper disposition. **To determine whether your OrthoPAT device is equipped with the spill collection drainage system, please refer to the illustrations on the following page.**

TOP VIEW OF ORTHOPAT DEVICE

To determine whether your OrthoPAT device is equipped with a spill collection drain port:

1. **Open the cover.**
2. **Remove the metal containment ring located on the top deck.**
3. **Observe the spill collection area to see if it has a spill collection drain port.**
4. **The drain port appears in the <u>right photo</u> below as a <u>small black hole</u> in the outer ring.**

<u>WITHOUT</u> spill collection drain port
PLEASE RETURN

<u>WITH</u> spill collection drain port
DO NOT RETURN

OrthoPAT devices WITHOUT spill collection drain port should be returned to Stericycle.

OrthoPAT devices can also be identified by their unique serial numbers, which are located on the rear panel of the device as shown in the illustration below. Devices with serial numbers between "00001" and "02279-T" are <u>not</u> equipped with the spill collection drainage system. These should be returned to Stericycle as instructed below.

Rear view of OrthoPAT device

Serial numbers "00001" through "02279-T"

PLEASE RETURN

<u>ACTION REQUIRED:</u> <u>FAX confirmation of your possession of OrthoPAT devices.</u>

Our records show that your facility is in possession of the OrthoPAT device(s). Please confirm your possession of the device(s). Record the serial number of all devices in your possession, sign the acknowledgement and fax it to Stericycle at 1-866-792-5450. Upon receipt of the Customer Confirmation sheet, Stericycle will supply you with a customer return kit. If you do not have a device, please indicate on the Customer Confirmation sheet that a device is no longer in your possession.

If you have any questions, please call Stericycle at 1-866-918-8736.

<u>ACTION REQUIRED:</u> <u>RETURN OrthoPAT devices NOT equipped with spill collection drainage system.</u>

FOR INSTRUCTION ON HOW TO ARRANGE RETURN OF ORTHOPAT DEVICES, CALL A STERICYCLE REPRESENTATIVE AT 1-866-918-8736. To facilitate your discussion, please have the serial numbers of your OrthoPAT devices handy for your call.

To assist you with these recall actions, a Haemonetics representative will be in contact with your facility within the next 14 working days.

As part of our recall efforts, Haemonetics will replace returned devices with OrthoPAT devices equipped with a spill collection drainage system. Our supply of these devices is limited, so there may be some delays in replacement. We apologize for any inconvenience. Haemonetics is planning to incorporate additional improvements to the OrthoPAT device to further protect it

against fluid intrusion. These planned improvements will not require any additional training or instruction.

Thank you for your attention.

Sincerely,

Warren Nighan, R.N
Haemonetics Corporation
VP Worldwide Quality and Regulatory

Haemonetics Corporation April 2011

ORTHOPAT® RECALL
IMPORTANT – CUSTOMER CONFIRMATION

Facility Name _____

City, State _____

Please record the serial number of all OrthoPAT devices <u>WITHOUT</u> the spill collection system located in your facility. THESE ARE TO BE <u>RETURNED</u> TO STERICYCLE.

_____ _____ _____ _____

_____ _____ _____ _____

_____ _____ _____ _____

Please record the serial number of all OrthoPAT devices <u>WITH</u> the spill collection system that are located in your facility. THESE MAY REMAIN IN USE:

_____ _____ _____ _____

_____ _____ _____ _____

_____ _____ _____ _____

☐ ***We are no longer in possession of the OrthoPAT® device(s).**

PLEASE SIGN AND DATE BELOW

We acknowledge receipt of OrthoPAT recall notice CL101099-US (AC) and confirm that the above OrthoPAT devices between the serial number range of 00001 and 02279-T will be returned to STERICYCLE.

_____ _____
Customer Signature **Date**

_____ _____
Print Name Print Title

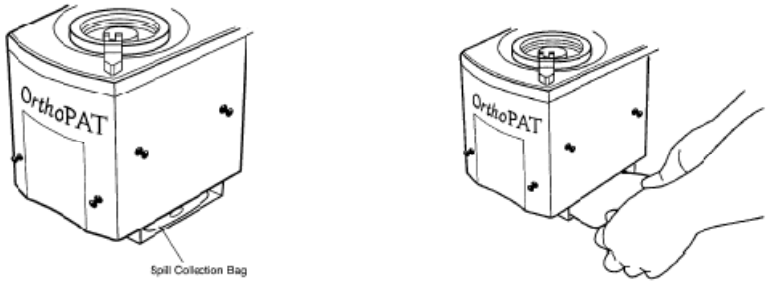
FAX THE COMPLETED FORM TO STERICYCLE AT 1-866-792-5450

INSTRUCTIONS:
DEPLOYMENT OF SPILL COLLECTION DRAINAGE SYSTEM

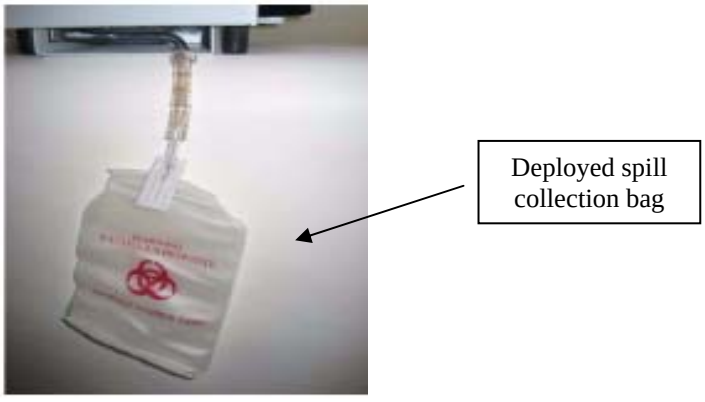
OrthoPAT® Orthopedic Perioperative Autotransfusion System

The following is important product information about OrthoPAT devices equipped with the spill collection drainage system. These devices are not subject to return, but we want to remind you of their proper operation. KEEP THESE INSTRUCTIONS WITH YOUR ORTHOPAT DEVICE. Haemonetics will be delivering an updated Operations Manual, Quick Reference Guide, and training video with this information within the next 60 days.

1. **The spill collection bag should be deployed as part of the setup of the device and should remain deployed in order to assure that fluid spills in the centrifuge are captured. To deploy the spill collection bag:**
   a. **Remove the spill collection bag from the tray on the underside of the Base Unit**



   b. **Ensure there are no kinks or twists in the tubing and allow the bag and its tubing to hang from the drain tube attached to the Base Unit.**
   c. **Open the slide clamp and leave it open.**
   d. **!Caution! The spill collection bag should remain deployed from the tray at all times**



2. If blood spills into the centrifuge area, the following warnings and procedures must be observed.

!Warning!

Leakage of fluids into the interior of the device may create the risk of an electric spark or fire. In the event of a blood spill or leak from the disk, immediately turn the power off and unplug the device from the AC electrical outlet.

Contact a Haemonetics service representative for return of the device to Haemonetics for service

(1-800-537-2802)

!Warning!

Follow universal blood precautions by wearing gloves and protective eyewear when cleaning up a blood spill in the system. Dispose of all cleaning materials as bio-hazardous waste.

i. **Turn off the device and unplug the device from AC electric power.**
ii. **Make sure the spill collection bag is unfolded and hanging from the base unit tray and that the slide clamp is open.**
iii. **Remove all blood from the centrifuge spill containment well using absorbent cloths and exercising care to ensure that blood does not splash up under the centrifuge rim. Do not irrigate the area.**
iv. **Clean the device using absorbent cloths.**
v. **Replace the spill collection bag.**
vi. **Return the device to Haemonetics for service.**

KEEP THESE INSTRUCTIONS WITH YOUR ORTHOPAT DEVICE.

FOR ASSISTANCE, CONTACT HAEMONETICS CUSTOMER SERVICE

1-800-537-2802