November 7, 2012

URGENT FIELD CORRECTION NOTICE

5283
SAFETY OFFICER
UAB MEDICAL CENTER
701 19TH ST
BIRMINGHAM AL 35294

SUBJECT: Door Hinge Replacement Needed – Certain Forma CO2 Incubators Manufactured Between April 2001 to September 2009

Dear Customer:

We write to alert you to a possible problem involving the metal coated outer door hinges for the following incubator models:

CO2 Incubators Manufactured between April 2001 and September 2009:
- Forma branded SteriCult models 3307, 3308, 3310, and 3311
- Thermo Scientific NAPCO 8000 models 3584, 3585, 3598, and 3599
- Thermo Scientific Series 8000 models 3540, 3541, 3542, and 3543
- Forma branded SteriCycle models 370, 371, 380, and 381

In very rare reported instances, the hinges have failed in the field. If the hinge fails, the door may fall and could cause injury. In one case, a laboratory worker has reported a serious injury from a falling door.

Our records indicate that you may have purchased one of the above models. Please respond to this letter by completing the attached Acknowledgment Form indicating whether the incubator(s) listed above are still in your possession and in active use. Customers with units still active will be sent replacement stainless steel door hinges, free of charge, along with easy step by step replacement instructions. In addition, qualified product support technicians will be available to address any questions about the hinge replacement process, at our toll free support number 1-888-964-3766 within the USA. Outside the USA, customers should contact the nearest distributor or request assistance at www.unitylabservices.com on the ‘contact us’ section and a customer service representative will contact you.

Our product design has since been upgraded with stainless steel outer door hinges, so only the models listed above are affected by this corrective action.

To summarize:

Thermo Fisher will provide:
- Parts at no cost and easy to follow replacement instructions

You should:
- Locate all affected incubators still in service
- Return the Acknowledgment Form in order to get replacement hinges and instructions
- Replace the hinges upon receipt of the replacement hinges and instructions

We appreciate your immediate attention to this field correction. We have reported this issue to the US FDA. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

Sincerely,

Bill Burnett
Quality Manager
ACKNOWLEDGMENT & RECEIPT FORM

EMAIL this completed form to servicedispatchfax@thermofisher.com OR
FAX this completed form to USA 888-618-2682
Attention: Technical Service

Affected Product: CO2 Incubators Manufactured between April 2001 and September 2009. Specifically,
- Forma branded SteriCult models 3307, 3308, 3310, and 3311
- Thermo Scientific NAPCO 8000 models 3584, 3585, 3598, and 3599
- Thermo Scientific Series 8000 models 3540, 3541, 3542, and 3543
- Forma branded SteriCycle models 370, 371, 380, and 381

Please provide the model and serial numbers of affected units still in service requiring hinge replacements.

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Use additional sheet(s) if necessary.

We do not have any affected incubators still in service as described above. _____ (initials)

UPON RECEIPT OF THIS ACKNOWLEDGMENT FORM, YOU WILL RECEIVE NEW STAINLESS STEEL HINGES & REPLACEMENT INSTRUCTIONS. PLEASE PROVIDE THE LOCATION & ADDRESS TO WHICH THE REPLACEMENT HINGES SHOULD BE SENT.

CONFIRMATION OF RECEIPT

I have read and understand the attached Customer Letter and instructions provided: _____ (initials)

Company Name _____________________________________________________________

Shipping Address, State, Zip ________________________________________________

Your Name (please print) ____________________________________________________

Signed ________________________________________________________________

Position ________________________________________________________________

Date ____________________________

Email Address/Telephone Number ____________________________________________