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16/4/2015

URGENT FIELD SAFETY NOTICE- Thorametrix chest drainage system- recall notification

Dear Customer,

Biometrix is requesting that you cease use of the products referenced above and detailed in the table below. These products are the subject of a Field Safety Corrective Action/Recall and must be quarantined until further notice from Biometrix. Please read the remaining information for an explanation of this request.

A customer complaint has been received concerning lot DB142556 describing the failure of the device to perform suction due to a defective negative valve area.

Investigation of the complaint:

Verification of the batch records of production lots surrounding DB142556 revealed that defects of this kind were discovered but led to the decision of performing visual inspection of this area in all products as part of the process.

Statistical sample of the remaining stock showed no evidence of leaking devices. The decision to recall these lots is based on suspicion only.

Part number	Recalled Lots
NC-5512	DB142556
NC-7514	DB142487
NC-7514	DB142488
NC-5512	DB142526
NC-5512	DB142527
NC-3311	DB142534
NC-3311	DB142536

Root cause:

- Reduced mechanical strength of the negative valve assembly area:

  The production process is a mechanically assisted assembly and solvent bonding of the negative pressure relief valve mechanism to the main device's body. When the geometric fit combination is extreme, the solvent bonding process becomes sensitive and may reduce the mechanical strength of the area, thus making it temporarily brittle. Environmental Stress Cracking – ESC can develop and cause leakage from this area.

- Inspection method to identify the above cracks was not completely effective:

  Since the finding of the problem a 100% visual inspection was conducted in production. However, the test was performed before the complete drying of the solvent and therefore did not identify all possible defects.

- Samples that were produced as part of experiments in this period in attempt to strengthen the area might have mixed up with the legitimate production of the complaint's lot.

Corrective and Preventive Actions:

- Adjustments of the geometric shapes of the parts and reinforcement of the area that tend to develop the cracks were performed.
- Improvement and refining of the bonding process.
- Procedure which describes the steps to be taken when experiments of this kind are conducted during production will be implemented for all production sites.

What you need to do

Please locate and quarantine the product/products listed in the appendix below. The products can be identified by the reference number and lot number printed on the product/box labels.

Please complete and return the attached Recall Response Card to Biometrix. Upon receipt of the Recall Response Card we will quickly contact you to make the necessary arrangements for the replacement of products.

Note: please complete the Recall Response Card even if you do not carry stock of the affected lots.

Please forward this information immediately to all your customers /departments within your organization who may be using, or ordering these products. Additionally, please ensure that a copy of this letter is provided to any other organizations to which the affected devices have been transferred.

Please accept our apologies for the inconvenience caused by this action.

If you have any questions regarding this please contact the following telephone number: +972-73-2257101.

Adaya Lachman Eliahu

QA Manager