CooperSurgical®

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July 12th, 2022

URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

CooperSurgical HUMIDIFIER
BOTTLES FOR BT37/BT37 MKII

Dear Valued CooperSurgical Customer,

As a valued customer, we would like to inform you that CooperSurgical is hereby issuing a Medical Device Field Safety Notice (FSN) for all the following Humidifier Bottles (used with the BT37 and BT37MKII) shipped between **June 21, 2019, and December 9, 2021**:

• 6-pack units of Humidifier Bottles with syringe filters, Part Number **AY102295** used with the BT37 Incubator and
• 6-pack units of Humidifier Bottles with syringe filters, Part Number **AY200246** used with the BT37 MKII Incubator.

A total of 5,988 units are a part of this FSN. The list of the affected lots is provided for your convenience on page 5 of this packet.

Reason for Voluntary Field Safety Corrective Action (FSCA):

CooperSurgical is issuing this FSN to inform our valued customers about a **potential breach to the sterile barrier** containing the Humidifier Bottles, due to the packaging of the filter box, located inside the bottle packaging.

Risk to Health:

The legal manufacturer has determined that this packaging orientation is unacceptable as it presents a risk of damage to the sterile barrier of the device.

Damage to the sterile barrier may result in an unsterilized device, which may cause contamination and degradation or loss of embryo during incubation.

Actions to be Taken:

Our records indicate that you may have purchased the affected Product from CooperSurgical between June 21st, 2019, and December 9th, 2021. Please take the following steps to ensure the safe return of the damaged device:

- Please inspect stock and quarantine affected product in your inventory.
- Complete the attached **Acknowledgement and Receipt Form.** Once completed please return the form to CooperSurgical to acknowledge receipt of the notice. If you do not have affected Product in inventory, please use the same enclosed Form to indicate that and return it to CooperSurgical so that we may document receipt of this FSN.
- When the completed form is received by CooperSurgical, arrangements will be made for return of affected product at no additional cost to you. Credit will be applied to your account for returned product under this action.

A corrective action has been initiated to ensure this failure does not reoccur and will not affect product shipped after December 9, 2021.

We sincerely apologize for any inconvenience caused by this notice. CooperSurgical is committed to high quality, safe and effective products. Please feel free to reach us at **203-601-5200** ext. **03300** or recall@coopersurgical.com.

Sincerely,
Edward Cook

Director, Senior Quality Systems

Acknowledgement and Receipt Form

IMMEDIATE RESPONSE REQUIRED-TIME SENSITIVE ACTION NEEDED

Please complete this form and return it via email: recall@coopersurgical.com or fax to **203.601.9870 ATTN: Product Surveillance.**

Customer Account #: _____ Account Name: _____

Street Address: _____ Town, State, Zip Code:_____

Contact Name: _____ Phone Number: _____

Email address: _____

I have read and understand the notice instructions provided in the July 12th, 2022, letter.
Yes _____ No___

Any adverse events associated with Affected Product? Yes _____ No____

If yes, please explain: _____

Affected HUMIDIFIER BOTTLES FOR BT37/BT37 MKII (PN: AY102295 and AY200246 – Lots on page 5) Product Information: Please check the appropriate box below and complete the table if applicable.

☐ We have no inventory within the scope of this action.

☐ We have the following affected product at our facility, will discontinue use and quarantine the affected product for return to CooperSurgical.

Part Numbers	Lot Numbers	Amount to be Returned
AY102295		
AY200246		

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at **203.601.5200** Ext. **3300** or email us at **recall@coopersurgical.com**. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Distributor Acknowledgement and Receipt Form

IMMEDIATE RESPONSE REQUIRED-TIME SENSITIVE ACTION NEEDED

Please complete this form and return it via email: recall@coopersurgical.com or fax to **203.601.9870 ATTN: Product Surveillance.**

FOR DISTRIBUTORS ONLY:

Customer Account #: _____ Account Name: _____

Contact Name/Title: _____ Phone Number: _____

Email address: _____

Affected HUMIDIFIER BOTTLES FOR BT37/BT37 MKII (PN: AY102295 and AY200246 – Lots on page 5) Product Information: Please complete the appropriate information below if applicable.

I have read and understand the notice instructions provided in the July 12th, 2022, letter. Yes __ No__

I have the following affected product at our facility, will discontinue use and quarantine the affected product for return to CooperSurgical.

Part Number	Lot Number	Amount to be Returned
AY102295		
AY200246		

Quantity shipped to Customer : _____

I have identified and notified my customers that were shipped or may have been shipped this Product by _____(Specify date and method of notification)

Or

Please notify the attached list of customers who received/may have received this Product.

Signature of Receipt: _____

Appendix A – Potentially Affected Product Lots	
Lot Number	
AY102295	**AY200246**
05593V291121	18-1265
18-1192	18-1268
1812-68	18-1268 / G004639
18-1268	G004637
G000575	G004638
G003811	G004639
G003893	
G004517	
G004874	
G005109	
G005476	
G005723	
E160415	