Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Cooper Surgical HUMIDIFIER BOTTLES
Device Model	BT37 BT37 MKII
Lot No.	AY200246 AY102295
Manufacturer	Copper Surgical
Country of Origin	United Kingdom
Reference	attached
Reason of Recall	NHRA initiates this FSN due to of a potential breach to the sterile barrier due to packaging orientation of the filter box being shipped packaged inside the bottle packaging. The use of this product without confirming its sterile barrier is intact may result in use of an unsterilized device, potentially contaminating and may cause degradation or loss of embryo during incubation
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Gulf Corporation for Technology at quality@gctbahrain.com to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Recall 2022 0038

75 Corporate Drive
Trumbull, CT 06611

T 203 601 5200
www.coopersurgical.com

July 12th, 2022

URGENT: MEDICAL DEVICE SAFETY NOTICE

CooperSurgical HUMIDIFIER
BOTTLES FOR BT37/BT37 MKII

Dear Valued CooperSurgical Customer,

CooperSurgical is issuing a Medical Device Recall Notice for 5,988 units of the 6 pack of Humidifier Bottles for the BT37 and BT37MKII (the "Product"), (**CooperSurgical Part Number AY102295 for BT37 and AY200246 for BT37 MKII**). This action affects all product that was **distributed between June 21st, 2019, and December 9th, 2021**. Any unit distributed after December 9th, 2021, is corrected as the shipping packaging has been changed at that point. **(The list of potentially affected lots can be found on page 5 of this packet).** The AY200246 and AY102295 product codes refer to the sterile humidifier bottle pack of 6, including the syringe filters, for the BT37 and BT37MKII incubators.

Reason for Voluntary Recall:

CooperSurgical is issuing this notice to inform the affected customers of a potential **breach to the sterile barrier** due to packaging orientation of the filter box being shipped packaged inside the bottle packaging.

Risk to Health:

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

The use of this product without confirming its sterile barrier is intact may result in use of an unsterilized device, potentially contaminating and may cause degradation or loss of embryo during incubation.

Actions to be Taken:

Our records indicate that you may have purchased the affected Product from CooperSurgical. The affected product was distributed between June 21st, 2019, and December 9th, 2021.

- 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 Recall Notice
- When the completed form is received by CooperSurgical, arrangements will be made for return of affected product at no additional cost to you.

A corrective action has been initiated to ensure this failure does not reoccur.

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

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.

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 Recalled Product? Yes _____ No____

If yes, please explain: _____

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

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

☐ 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)
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: _____

Potentially Affected Lot numbers
05593V291121
18-1192
18-1265
1812-68
18-1268
18-1268/G004639
19-1030
E160415
E170306
G000575
G001261
G001771
G002256
G002404
G003077
G003341
G003811
G003893
G004517
G004637
G004638
G004639
G004874
G005109
G005476
G005723