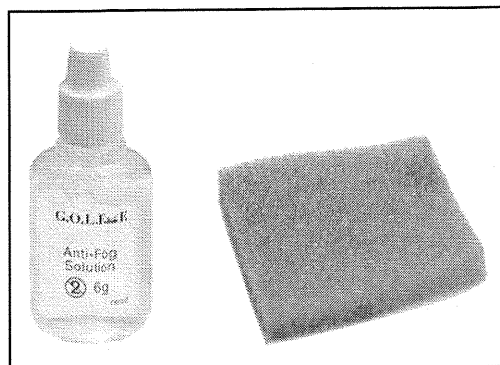


September 18, 2014

FIELD SAFETY NOTICE

Device No.: GOLFF-R0
Device Name: G.O.L.F.F.™ (ANTI-FOG SOLUTION)
LOT NO.: 49691



Type of action: Device Destruction

Dear Valued *Batrik* Distributor,

Batrik is committed to offering quality products and superior customer service. We evaluate all non-conformances and we take every effort to conduct a thorough investigation of each incident.

As a result of an investigation following a customer complaint for the GOLFF-R0 (G.O.L.F.F.™ -ANTI-FOG SOLUTION) lot no. 49691, we have uncovered that the labels on the sterile pouches **may have an expiry date error of 2018-14**. The reason we say, "may", is due to the fact that after carefully inspecting our inventory of the above-mentioned lot no., we found that the outer boxes have the correct expiry date: 2018-04, however, some pouches within these boxes have been labeled correctly with the correct expiry date being: 2018-04 **and some have been labeled incorrectly with the incorrect expiry date being 2018-14**.

There is no potential hazard/risk associated with the immediate use of the G.O.L.F.F.™ (ANTI-FOG SOLUTION) lot no. 49691 as the product is sterile and only expires in 2018-04, however, it is important that you communicate with all your customers and review your current stock to ensure destruction of all incorrectly labeled product showing an expiry date of 2018-14. As such, we request that you identify and quarantine the above lot no. immediately and that one of the following two options be taken by our Distributors as well as by your customers;

OPTION 1

Review your current inventory and that of your customers having received the GOLFF-R0 (G.O.L.F.F.™ -ANTI-FOG SOLUTION) lot no. 49691 by opening all outer boxes (irrespective of the expiry date) and inspecting each pouch for the expiry date, all the while segregating the correct labeled pouches/boxes with the expiry date being: 2014-04. You will be requested to sign the "Confirmation of Inspection Form" provided attached, along with the "Certificate of Destruction" form also provided attached, required for all incorrectly labeled pouches/boxes with the incorrect expiry date of 2018-14 that must be discarded.



● ● ● Medical Manufacturing

OPTION 2

Review your current inventory and that of your customers having received the GOLFF-R0 (G.O.L.F.F.™ -ANTI-FOG SOLUTION) lot no. 49691 without physically opening the boxes, and provide the attached "Certificate of Destruction" form duly completed.

All product quantities indicated (Option 1 & 2) on the "Certificate of Destruction" will be replaced at no charge.

This notice must be passed on to all those who need to be aware within your organization and to any customer where the potentially affected device has been transferred/sold to.

Please provide the completed forms attached **no later than October 15, 2014** to ensure effectiveness of the corrective action.

We wish to sincerely apologize for any inconvenience caused as a result of this Field Safety Notice. If you have any questions or concerns arising from this Field Safety Notice, please contact me directly;

Suzy Bairos, Vice President
Batrik Medical Manufacturing Inc.
850 Halpern ave, Dorval, Quebec, Canada, H9P 1G6
Email: sbairos@surgmed.com
Fax: +1-514-631-7741 Tel: +1-514-631-7988 extension no. 21

As per the MEDDEV 2 12-1 rev. 8 Vigilance 49, we confirm that we have notified the appropriate Regulatory Agencies.

Sincerely,

Suzy Bairos
Vice President
www.batrik.com



FIELD SAFETY NOTICE

CERTIFICATE OF DESTRUCTION

Form

Device No.: GOLFF-R0, **Device Name:** G.O.L.F.F.™ (ANTI-FOG SOLUTION), **LOT NO.:** 49691

Further to our enclosed Field Safety Notice, you are requested to complete the following if you choose;

→**OPTION 1.** Have inspected and found incorrectly labeled pouches with the expiry date of 2018-14.

→**OPTION 2.** To count your current inventory and that of your customers, but will not physically open the boxes to inspect.

Our records show that you have received the above mentioned product and lot no. on the below shipments:

Posting Date	Item No.	Document No.	Your PO No.	Source No.	Customer Name	Lot No.	Invoiced Quantity
Total:							

Based on the above, I, _____, _____
(name) (title)

of _____ confirm that the entire above-mentioned product shipped to my company
(Company name)

as well as to my customers, has been traced back and the customers have used and no longer have in their possession
_____ boxes of 20 pouches, therefore these boxes will be kept on record.
(qty)

I hereby certify that our company as well as our customers have a total of _____ boxes of 20 pouches that can
(qty)

potentially be **incorrectly labeled with the expiry date of 2018-14 and these have been destroyed in an appropriate manner, hereby releasing BATRIK MEDICAL MANUFACTURING INC. from all liability concerning this quantity for the above-mentioned lot no.**

We require _____ boxes of 20 pouches replaced at no charge. My replacement p.o. no. _____ is attached.
(qty)

(Signature)

date (MM/DD/YYYY)



FIELD SAFETY NOTICE
CONFIRMATION OF INSPECTION
Form

Device No.: GOLFF-R0, Device Name: G.O.L.F.F.™ (ANTI-FOG SOLUTION), LOT NO.: 49691

Further to our enclosed Field Safety Notice, you are requested to complete the following inspection if you choose **OPTION 1** to physically inspect the entire below-mentioned product shipped to your facility as well as that of your customer's.

Our records show that you have received the above mentioned product and lot no. on the below shipments:

Posting Date	Item No.	Document No.	Your PO No.	Source No.	Customer Name	Lot No.	Invoiced Quantity
Total:							

Based on the above, I, _____, _____
(name) (title)

of _____ confirm that the entire above-mentioned product shipped to my company
(Company name)

as well as to my customers, has been traced back and the customers have used and no longer have in their possession

_____ boxes of 20 pouches, therefore, these boxes cannot be inspected and will be kept on record.

(qty)

Furthermore, our company as well as our customers have opened each outer box of the above-mention lot no. that is currently in stock (irrespectively of the expiry date indicated on the outer box) and carefully inspected each pouch and have found a total of;

_____ boxes of 20 pouches that are **correctly labeled with the expiry date of 2018-04** and a total of

(qty)

_____ boxes of 20 pouches that are **incorrectly labeled with the expiry date of 2018-14, for which a "Certificate of**

(qty)

Destruction" Form will also be completed.

(Signature)

date (MM/DD/YYYY)