

Urgent - Field Safety Notice
MEDICAL DEVICE RECALL
GLIDESCOPE® GVL 2 STAT

Wednesday 1 March 2017

Dear Valued GlideScope Customer,

The purpose of this letter is to advise you that Verathon® Inc. is voluntarily recalling one (1) lot number (lot # GC32825) of GlideScope GVL® size 2 Stats.

Our records indicate that your facility has received one or more of the products affected by this notice. Please identify the lot number of your GlideScope GVL® size 2 Stats located on the packaging as described on page 4 of this letter and follow the instructions on the following pages that apply to your device(s).

This Field Safety Notice is being conducted with the knowledge of the applicable Regulatory Authorities. Please report any suspected malfunction or adverse event related to any GlideScope device to Verathon Customer Care at CustomerCareEU@verathon.com.

Thank you for your immediate attention to this matter. Verathon is committed to providing products of the highest quality and we regret any inconvenience these actions may cause. We encourage you to contact us if you need assistance or further information.

Sincerely,

.....

Urgent - Field Safety Notice

MEDICAL DEVICE RECALL

Wednesday 1 March 2017

Affected product: GlideScope® GVL 2 Stats, lot number GC32825 Note: Does not apply to any other GlideScope GVL 2 Stat lot numbers					
Product Name	Part number		Lot Number	Lot Number Count	Dates of Distribution
	Single Stat	Box of 10			
GVL® 2 Stat	0574-0027	0270-0429	GC32825	1	October 2016 - December 2016

The GlideScope® GVL size 2 Stat is used in conjunction with the GlideScope® Video Baton 1-2 as part of the GlideScope® Single Use system which is intended for use by qualified medical professionals to obtain a clear, unobscured view of the vocal cords for medical procedures.

Reason for the Voluntary Correction:

Verathon Inc. has become aware that product labelled as GVL® size 2 Stat lot GC32825 was physically packaged with GVL® size 1 Stats. As a result, patients for intubation with a GVL® size 2 Stat may inadvertently be intubated with a smaller GVL® size 1 Stat.

Risk to Health:

The identified risk to health is remote. There have been no reported patient incidents associated with the mislabeling of this lot, worldwide. The problem was identified during a pre-procedure inspection of the product at a customer site.

The recommended patient weight ranges for the GVL® Stat 1 and 2 overlap between 1.8 - 3.8 kg. The population at greatest risk are those patients greater than 3.8 kg and up to 10kg and with a known or anticipated difficult airway. In this remote scenario, the unintended use of a GVL® 1 Stat may result in inadequate visualization of the patient airway during first intubation attempt, thus requiring a secondary attempt with the correct size of Stat or alternative intubation device.

How to Recognize that the Device May Fail:

There is no size identification marker directly on the GVL® Stat 1 or 2. A medical professional trained on GlideScope video intubation is familiar with the range of sizes by their visual appearance and is expected to have inspected their equipment prior to use. A medical professional should recognize the unexpected attachment of a GVL® 1 Stat, based upon the differences in the stat tip dimensions of a GVL® 1. The most prominent feature difference between the two Stat sizes (1 and 2) is a 13 mm difference in stat tip length.

Page 2 of 6

The stat tip length for the GVL® 1 Stat is 15 mm and the stat tip length for GVL® 2 is 28 mm. The photograph below illustrates the mislabeled product.

Affected product (Lot GC32825)
is labeled as GVL* 2 Stat



Affect product (Lot GC32825) in
the package is a GVL* 1 Stat



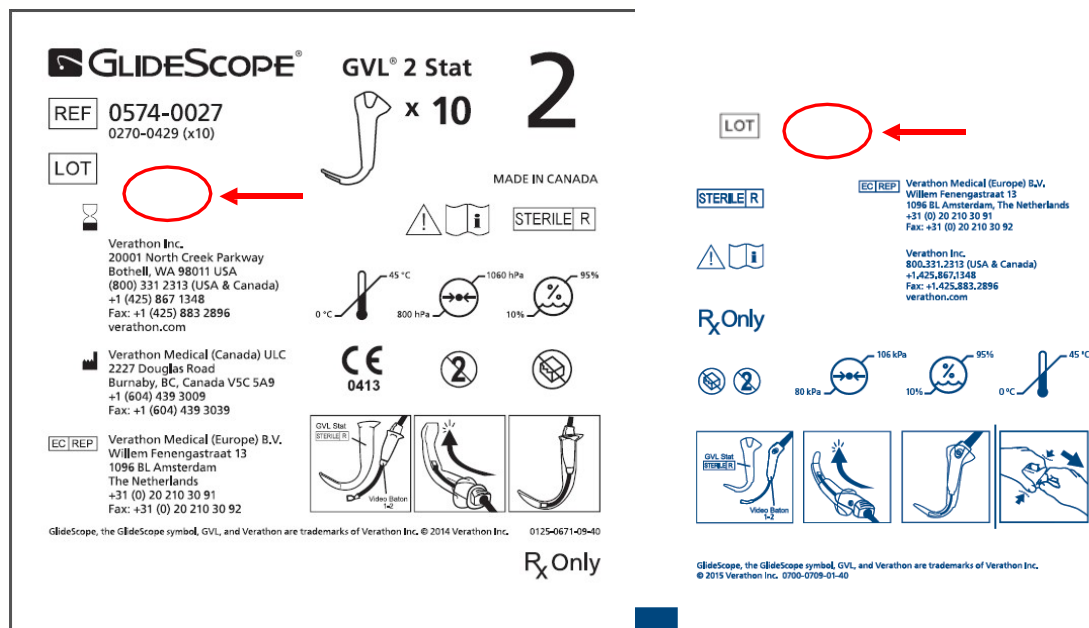
Actions to be Taken by the Customer/Distributor:

Our records indicate that your facility has received one or more of the products affected by this Field Safety Notice. Please identify the GVL® size 2 Stat lot number GC32825 either on the label of each individually pouched sterile Stat or on the outer label of the packaged box (quantity of 10 Stats per box). Follow the instructions below once the affected product has been identified.

Verathon will replace all affected GlideScope GVL® size 2 Stats that remain in your facility's inventory with new products that have been screened to ensure correct sizing per the label. The lot number for your GlideScope GVL® 2 Stat is located in two places:

1. on the outer carton/packaging label for a box of ten (10) stats (**left image below**) and
2. on the immediate sterile packaging label for each individual GVL® size 2 Stat (**right image below**).

The lot number is a seven (7) alphanumeric characters sequence located on the upper left corner of the label next to the lot number symbol **LOT**. The red circle and arrow in the figure below will assist you in locating the lot number:



To comply with this Field Safety Notice for the affected GlideScope GVL® 2 Stats, please take the following actions:

1. Fill out the attached Field Safety Notice Reply Form and return it to Verathon by fax: +31 (0) 20 210 30 92, or email: CustomerCareEU@verathon.com. Please return the form even if you do not have any Stats subject to this Field Safety Notice.

2. Quarantine and dispose all the remaining affected GVL® size 2 Stats.
3. Contact Customer Care to arrange for delivery of replacement Stats for affected GlideScope GVL® size 2 Stats that remain in your facility's inventory.

Should you have any questions about this Field Safety Notice, please contact your Verathon representative or Verathon Customer Care at CustomerCareEU@verathon.com.

Field Safety Notice Reply Form: Response Required

Please complete the form

Our records indicate that your facility has received one or more boxes of GlideScope® GVL size 2 Stats with lot number GC32825. Please fill out and return this **Field Safety Notice Reply Form**.

FIELD SAFETY NOTICE REPLY FORM: RESPONSE REQUIRED		
Affected Devices: GlideScope® GVL 2 Stats, lot # GC32825		
Product		GVL® size 2 Stat
Part Number	Single Stat	0574-0027
	Box of 10	0270-0429
	GlideScope AVL Video Baton 1-2 Kit	0270-0662
Lot Number		GC32825

1. I have reviewed and understand this Field Safety Notice, and have received a customized list of products shipped to me.

☐ YES ☐ NO If NO, please explain: _____

2. ☐ We no longer have GlideScope GVL size 2 Stats, lot # GC32825, in our inventory.

3. ☐ We do have GlideScope GVL size 2 Stats, lot # GC32825, and will contact Verathon Customer Care to arrange for replacement Stats. All these remaining GVL size 2 Stats, lot # GC32825, will be disposed.

List the number affected devices in your possession, in the table below.

GVL 2 Stat PN 0574-0027	
LOT number	GC32825
Number of Single Stats	

4. ☐ We confirm we have disposed all the remaining GVL size 2 Stats, lot # GC32825 that were still in our possession.

Business Name:	
Address, City, Post Code, Country:	
Signature:	Phone:
Printed Name:	Date:

5. Please e-mail or fax the completed form to Verathon:

Fax: +31 (0) 20 210 30 92

E-mail: CustomerCareEU@verathon.com

Page 6 of 6

verathon.com