

ADVISORY NOTICE

Visitec® VisiwipeTM Instrument Wipe 7.3 x 7.3cm (2 7/8 x 2 7/8 in) REF #: 581047

29 March 2019

Re: ATTENTION & ACTION REQUIRED

Dear Doctor and Customer,

This notice is to inform you that Beaver-Visitec International, Inc. (BVI) is issuing this Advisory Notice for Visitec® Visiwipe™ Instrument Wipe 7.3 x 7.3cm (2 7/8 x 2 7/8 in) due to a potential illegible expiration date and lot number embossed on the individual (Figure 1). We are advising you to check your inventory of the REF#: 581047 involving ONLY the following Lot Numbers (Table A):



Figure 1: Example of illegible expiration date and lot number

Lot Number	Expiration Date
18B0431	2023-02-13
18B0542	2023-02-21
18C0753	2023-03-20
18F1889	2023-06-29
18J2671	2023-09-18

Table A: Lot numbers and correct expiration dates

You may not actually have any product remaining in your inventory however, we asking you to **complete** the attached response form below (Attachment 1).

The Visiwipe™ Instrument Wipes are intended to be used to wipe instruments prior to surgery and are routinely used to clean delicate surgical instruments and gem blades.

The Issue: The expiration date and lot number embossed on the individual packs are difficult to read.

Health Hazard Assessment: It has been determined by BVI's medical experts that there is no intrinsic risk to patient (hazard) associated with this notification.



Please be advised you may choose to discard/destroy these products according to your facilities policy.

BVI is asking that you take the following action:

1) Immediately evaluate all of your inventory for Visitec® Visiwipe™ Instrument Wipe REF#: 581047 and the Lots in the table:

Lot Number	Expiration	
	Date	
18B0431	2023-02-13	
18B0542	2023-02-21	
18C0753	2023-03-20	
18F1889	2023-06-29	
18J2671	2023-09-18	

2) Please complete **Attachment 1** and return the attached form to assist us in confirming that all affected customers have been made aware of this issue. Please **return Attachment 1 – Response Form** to BVI by emailing the attached to <u>SSupportInternational@bvimedical.com</u>

We value your business and apologise for any inconvenience this may cause. If you have questions regarding this matter, please call Customer Service Department, "use regional phone number"

Sincerely,

Beaver-Visitec International, Inc. (BVI)



Attachment 1 - Response Form ADVISORY NOTICE

Please complete and return this response form no later than 30 April 2019

BVI Visitec® Visiwipe™ Instrument Wipe 7.3 x 7.3cm (2 7/8 x 2 7/8 in)				
REF #: 581047				
Lot Number	Expiration Date			
18B0431	2023-02-13			
18B0542	2023-02-21			
18C0753	2023-03-20			
18F1889	2023-06-29			
18J2671	2023-09-18			

D.				
Please of	check the appropriate	response(s)		
STEP 1				
□ I have	e No product on hand	[Complete information in S	Step 2]	
OR				
	e read the information ete information in Step	related to this matter and u 2].	inderstand this product i	Advisory Notice
□ I have	e chosen to destroy ur	nits & lots as identified below	w and complete informa	ation in Step 2.
	# of Units Destroyed	Lot Number	Expiration Date	
		18B0431	2023-02-13	
		18B0542	2023-02-21	
		18B0542 18C0753	2023-02-21 2023-03-20	
		18B0542 18C0753 18F1889	2023-02-21 2023-03-20 2023-06-29	
		18B0542 18C0753	2023-02-21 2023-03-20	
STEP 2		18B0542 18C0753 18F1889	2023-02-21 2023-03-20 2023-06-29	
	Company name:	18B0542 18C0753 18F1889	2023-02-21 2023-03-20 2023-06-29	
		18B0542 18C0753 18F1889	2023-02-21 2023-03-20 2023-06-29	
	Company name:	18B0542 18C0753 18F1889	2023-02-21 2023-03-20 2023-06-29	

STEP 3

Please **return the completed Attachment 1-Response Form** to BVI by email to <u>SSupportInternational@bvimedical.com</u>

______ Email: _____

*****Thank you for your assistance in this matter****