

URGENT ADVISORY NOTICE

**Visitec® Visiwipe™ 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)**:

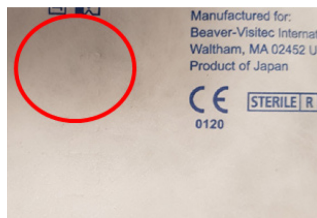


Figure 1: Example of illegible expiration date and lot number

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 SSupportInternational@bvimedical.com

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,

Regina Shih
VP Global Regulatory & Quality Affairs
Beaver-Visitec International, Inc. (BVI)



**Attachment 1 - Response Form
URGENT ADVISORY NOTICE**

Please complete and return this response form **as soon as possible**

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

Please check the appropriate response(s)

STEP 1

I have **No** product on hand [Complete information in Step 2]

OR

I have read the information related to this matter and understand this product Advisory Notice [Complete information in Step 2].

OR

I have chosen to destroy units & lots as identified below and complete information in Step 2.

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

STEP 2

Company name: _____

Address: _____

Telephone: _____

Contact name: _____

Title: _____ Email: _____

STEP 3

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

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