

URGENT FIELD SAFETY NOTICE
ATTENTION & ACTION REQUIRED

Beaver-Visitec International, Inc (BVI) Sponge Products

April 24, 2019

RE: BVI Ophthalmic Instrument Wipes, Wicks and Corneal Light Shield Sponge Products

Dear Doctor and Customer,

This notice is to inform you that Beaver-Visitec International, Inc. (BVI) is issuing this Advisory Notice for a select group of **BVI Visitec®VisiWipe or Merocele® ophthalmic instrument wipes and/or wicks, corneal light shield sponge products** because of a potentially faint or illegible embossed expiration date and LOT number on the individual unit level package (Figure 1). While BVI does not feel there is a safety concern and we value you as a customer we are recommending you keep the individual packages in their original shelf pack box (Figure 2) that has the legible expiration date and lot number.

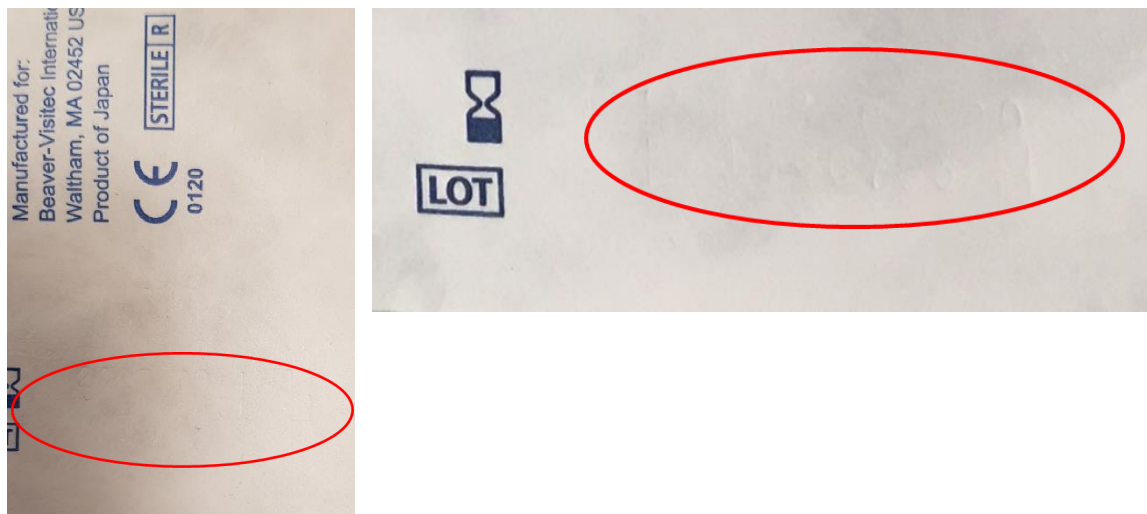


Figure 1: Example of illegible unit level package expiration date and LOT number



Figure 2: Example of a Shelf Pack (SP) box with legible expiration date and LOT number

We advise you to check your inventory using the Product Information sheets in Attachment 1 to identify the impacted REF(s) # and associated LOT(s) #.

Product Intended Use:

- BVI Visitec® Visiwipe or Merocel® Instrument or Adhesive Wipes are intended to be used to wipe delicate ophthalmic surgical instruments.
- BVI Visitec® or Merocel® Eye Wicks are for draining fluid away from the ophthalmic surgical site.
- BVI Merocel® Corneal Light Shields are intended to protect the eye during ophthalmic surgeries.

The Issue: The expiration date and lot number embossed on the individual unit level package may be difficult to read or illegible.

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.

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

Because we value our customers, and should this incident have an impact on your product needs, please contact BVI’s customer service.

Sincerely,

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



ATTACHMENT 1 - RESPONSE FORM
Field Safety Notice Instructions

Please complete and return this response form **no later than 10 May 2019**

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] and consulted **Product Information sheets in Attachment 1** to inform BVI of checked stock on-hand.

STEP 2

Company name: _____

Address: _____

BVI Customer Account # (if known): _____

If purchased through a distributor, include distributor name: _____

Telephone: _____

Contact name: _____

Title: _____ Email: _____

Date completed: _____

STEP 3

BVI outside USA customers, please **complete and return the ATTACHMENT 1 - RESPONSE FORM** to BVI by one of these methods:

UK - English

Fax: + 44 1865 595 761

Email: ordersuk@bvimedical.com

French

Fax: + 33 4 88714057



Email: commandes@bvimedical.com

German

Fax: + 49 622 13929883

Email: bestellungen@bvimedical.com



Italian

Fax: + 39 02 44386868


Email: ordini@bvimedical.com

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


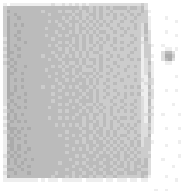
ATTACHMENT 1 - RESPONSE FORM
Product Information

REF# & Description	Lot Number	Expiration Date	Customer checked stock. Quality on-hand.	
			<i>I have # of Shelf Pack (SP) Boxes.</i>	<i>I have # or unit level (units)</i>
90900 Instrument Wipe 76.2 x 76.2 mm (3 x 3 in), 2 mm thick (20 units/box) 	16M5110	2019-12-20	_____ #SP	and/or _____ #units
	17C0906	2020-03-13	_____ #SP	and/or _____ #units
	17D1440	2020-04-19	_____ #SP	and/or _____ #units
	17E1872	2020-05-25	_____ #SP	and/or _____ #units
	17F2173	2020-06-23	_____ #SP	and/or _____ #units
	17G2598	2020-07-25	_____ #SP	and/or _____ #units
	17H2993	2020-08-22	_____ #SP	and/or _____ #units
	17K3694	2020-10-17	_____ #SP	and/or _____ #units
	17M4247	2020-11-30	_____ #SP	and/or _____ #units
	17M4427	2020-12-13	_____ #SP	and/or _____ #units
	18B0285	2021-02-01	_____ #SP	and/or _____ #units
	18B0558	2021-02-23	_____ #SP	and/or _____ #units
	18C0898	2021-03-26	_____ #SP	and/or _____ #units
	18D1183	2021-04-24	_____ #SP	and/or _____ #units
	18F1753	2021-06-18	_____ #SP	and/or _____ #units
	18F1899	2021-06-29	_____ #SP	and/or _____ #units
	18J2669	2021-09-18	_____ #SP	and/or _____ #units
	18K2855	2021-10-04	_____ #SP	and/or _____ #units
18M3598	2021-12-11	_____ #SP	and/or _____ #units	
90910 Instrument Wipe 76.2 x 76.2 mm (3 x 3 in), 1 mm thick (20 units/box) 	16M4967	2019-12-05	_____ #SP	and/or _____ #units
	16M5111	2019-12-20	_____ #SP	and/or _____ #units
	17B0409	2020-02-01	_____ #SP	and/or _____ #units
	17C0907	2020-03-13	_____ #SP	and/or _____ #units
	17C0957	2020-03-16	_____ #SP	and/or _____ #units
	17E1873	2020-05-25	_____ #SP	and/or _____ #units
	17G2599	2020-07-25	_____ #SP	and/or _____ #units
	17J3187	2020-09-05	_____ #SP	and/or _____ #units
	17J3349	2020-09-19	_____ #SP	and/or _____ #units
	18D1184	2021-04-24	_____ #SP	and/or _____ #units
	18H2397	2021-08-22	_____ #SP	and/or _____ #units
	18J2670	2021-09-18	_____ #SP	and/or _____ #units
	18K2856	2021-10-04	_____ #SP	and/or _____ #units
	18M3599	2021-12-11	_____ #SP	and/or _____ #units
19A0276	2022-01-17	_____ #SP	and/or _____ #units	

ATTACHMENT 1 - RESPONSE FORM
Product Information

REF# & Description	Lot Number	Expiration Date	Customer checked stock. Quality on-hand.		
			<i>I have # of Shelf Pack (SP) Boxes.</i>	<i>I have # or unit level (units)</i>	
223620 Instrument Wipe 76.2 x 76.2 mm (3 x 3 in) (20 units/box) 	16L4829	2019-11-30	_____ #SP	and/or _____ #units	
	17B0402	2020-02-01	_____ #SP	and/or _____ #units	
	17C0905	2020-03-13	_____ #SP	and/or _____ #units	
	17C0949	2020-03-16	_____ #SP	and/or _____ #units	
	17D1363	2020-04-12	_____ #SP	and/or _____ #units	
	17F2169	2020-06-23	_____ #SP	and/or _____ #units	
	17G2546	2020-07-25	_____ #SP	and/or _____ #units	
	17H2887	2020-08-16	_____ #SP	and/or _____ #units	
	17J3345	2020-09-19	_____ #SP	and/or _____ #units	
	17K3701	2020-10-17	_____ #SP	and/or _____ #units	
	17M4252	2020-11-30	_____ #SP	and/or _____ #units	
	18A0137	2021-01-16	_____ #SP	and/or _____ #units	
	18C0772	2021-03-15	_____ #SP	and/or _____ #units	
	18C0833	2021-03-23	_____ #SP	and/or _____ #units	
	18D1158	2021-04-24	_____ #SP	and/or _____ #units	
	18F1738	2021-06-18	_____ #SP	and/or _____ #units	
	18F1868	2021-06-29	_____ #SP	and/or _____ #units	
	18H2253	2021-08-07	_____ #SP	and/or _____ #units	
	18H2368	2021-08-22	_____ #SP	and/or _____ #units	
	18J2664	2021-09-18	_____ #SP	and/or _____ #units	
	18K2849	2021-10-08	_____ #SP	and/or _____ #units	
	18L3356	2021-11-15	_____ #SP	and/or _____ #units	
	18M3647	2021-12-13	_____ #SP	and/or _____ #units	
	19A0269	2022-01-17	_____ #SP	and/or _____ #units	
	16L4829	2019-11-30	_____ #SP	and/or _____ #units	
	17B0402	2020-02-01	_____ #SP	and/or _____ #units	
	223621 Wipe with Wick 76.2 x 76.2 mm (3 x 3 in) (20 units/box)	16M4912	2019-12-05	_____ #SP	and/or _____ #units
		16M5105	2019-12-20	_____ #SP	and/or _____ #units
17B0403		2020-02/01	_____ #SP	and/or _____ #units	
17C0758		2020-03-01	_____ #SP	and/or _____ #units	
17C0759		2020-03-01	_____ #SP	and/or _____ #units	
17C0950		2020-03-16	_____ #SP	and/or _____ #units	
17E1865		2020-05-25	_____ #SP	and/or _____ #units	
17F2170		2020-06-23	_____ #SP	and/or _____ #units	
17G2547		2020-07-25	_____ #SP	and/or _____ #units	
17H2888		2020-08-16	_____ #SP	and/or _____ #units	
17J3192	2020-09-05	_____ #SP	and/or _____ #units		



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Product Information

REF# & Description	Lot Number	Expiration Date	Customer checked stock. Quality on-hand.		
			I have # of Shelf Pack (SP) Boxes.	I have # or unit level (units)	
	17J3353	2020-09-19	_____ #SP	and/or _____ #units	
	17M4420	2020-12-13	_____ #SP	and/or _____ #units	
	18A0138	2021-01-16	_____ #SP	and/or _____ #units	
	18B0552	2021-02-23	_____ #SP	and/or _____ #units	
	18B0564	2021-02-23	_____ #SP	and/or _____ #units	
	18C0834	2021-03-23	_____ #SP	and/or _____ #units	
	18D1159	2021-04-24	_____ #SP	and/or _____ #units	
	18F1739	2021-06-18	_____ #SP	and/or _____ #units	
	18J2665	2021-09-18	_____ #SP	and/or _____ #units	
	18K2850	2021-10-04	_____ #SP	and/or _____ #units	
	18L3349	2021-11-15	_____ #SP	and/or _____ #units	
	18M3472	2021-12-03	_____ #SP	and/or _____ #units	
	19B0413	2022-01-31	_____ #SP	and/or _____ #units	
	223622 Merocel® Instrument Wipe Kit Includes: 1 - wipe with wick 1 - eye drain 1 - corneal light shield (20 units/box) 	16L4826	2019-11-30	_____ #SP	and/or _____ #units
		16M4913	2019-12-05	_____ #SP	and/or _____ #units
16M5106		2019-12-20	_____ #SP	and/or _____ #units	
17B0404		2020-02-01	_____ #SP	and/or _____ #units	
17C0760		2020-03-01	_____ #SP	and/or _____ #units	
17C0761		2020-03-01	_____ #SP	and/or _____ #units	
17C0951		2020-03-16	_____ #SP	and/or _____ #units	
17D1435		2020-04-19	_____ #SP	and/or _____ #units	
17E1866		2020-05-25	_____ #SP	and/or _____ #units	
17F2171		2020-06-23	_____ #SP	and/or _____ #units	
17G2382		2020-07-06	_____ #SP	and/or _____ #units	
17H2866		2020-08-16	_____ #SP	and/or _____ #units	
17H2990		2020-08-26	_____ #SP	and/or _____ #units	
17M4253		2020-11-30	_____ #SP	and/or _____ #units	
18B0282		2021-02-01	_____ #SP	and/or _____ #units	
18B0553		2021-02-23	_____ #SP	and/or _____ #units	
18C0835		2021-03-23	_____ #SP	and/or _____ #units	
18D1160		2021-04-24	_____ #SP	and/or _____ #units	
18F1740		2021-06-18	_____ #SP	and/or _____ #units	
18F1869		2021-06-29	_____ #SP	and/or _____ #units	
18H2369	2021-08-22	_____ #SP	and/or _____ #units		
18J2666	2021-09-18	_____ #SP	and/or _____ #units		
18K2851	2021-10-04	_____ #SP	and/or _____ #units		
18K3172	2021-10-31	_____ #SP	and/or _____ #units		


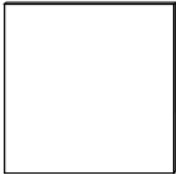
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REF# & Description	Lot Number	Expiration Date	Customer checked stock. Quality on-hand.	
			I have # of Shelf Pack (SP) Boxes.	I have # or unit level (units)
	18L3350	2021-11-15	_____ #SP	and/or _____ #units
400117 Merocel® Eye Kit Includes: 1 - wipe with wick 1 - corneal light shield (20 units/box)	16M4936	2019-12-05	_____ #SP	and/or _____ #units
	16M5109	2019-12-20	_____ #SP	and/or _____ #units
	17C0762	2020-03-01	_____ #SP	and/or _____ #units
	17C0952	2020-03-16	_____ #SP	and/or _____ #units
	17E1867	2020-05-25	_____ #SP	and/or _____ #units
	17G2552	2020-07-25	_____ #SP	and/or _____ #units
	17K3686	2020-10-17	_____ #SP	and/or _____ #units
	18B0283	2021-02-01	_____ #SP	and/or _____ #units
	18B0554	2021-02-23	_____ #SP	and/or _____ #units
	18C0773	2021-03-15	_____ #SP	and/or _____ #units
	18C0844	2021-03-23	_____ #SP	and/or _____ #units
	18D1165	2021-04-24	_____ #SP	and/or _____ #units
	18F1741	2021-06-18	_____ #SP	and/or _____ #units
	18M3654	2021-12-13	_____ #SP	and/or _____ #units
	400200 Instrument Wipe 92.1 x 76.2 mm (3.625 x 3 in) (20 units/box)	16L4828	2019-11-30	_____ #SP
16M5136		2019-12-22	_____ #SP	and/or _____ #units
17B0406		2020-02-01	_____ #SP	and/or _____ #units
17C0765		2020-03-01	_____ #SP	and/or _____ #units
17C0888		2020-03-10	_____ #SP	and/or _____ #units
17C0889		2020-03-10	_____ #SP	and/or _____ #units
17C0954		2020-03-16	_____ #SP	and/or _____ #units
17D1437		2020-04-19	_____ #SP	and/or _____ #units
17E1869		2020-05-25	_____ #SP	and/or _____ #units
17E1904		2020-05-25	_____ #SP	and/or _____ #units
17F1987		2020-06-05	_____ #SP	and/or _____ #units
17G2558		2020-07-25	_____ #SP	and/or _____ #units
17J3193		2020-09-05	_____ #SP	and/or _____ #units
17K3688		2020-10-17	_____ #SP	and/or _____ #units
17K3703		2020-10-17	_____ #SP	and/or _____ #units
17M4422		2020-12-13	_____ #SP	and/or _____ #units
18B0560		2021-02-23	_____ #SP	and/or _____ #units
18C0775		2021-03-15	_____ #SP	and/or _____ #units
18C0849		2021-03-23	_____ #SP	and/or _____ #units
18D1168		2021-04-24	_____ #SP	and/or _____ #units
18F1743	2021-06-18	_____ #SP	and/or _____ #units	
18F1879	2021-06-29	_____ #SP	and/or _____ #units	

ATTACHMENT 1 - RESPONSE FORM
Product Information

REF# & Description	Lot Number	Expiration Date	Customer checked stock. Quality on-hand.	
			<i>I have # of Shelf Pack (SP) Boxes.</i>	<i>I have # or unit level (units)</i>
	18H2274	2021-08-08	_____ #SP	and/or _____ #units
	18H2371	2021-08-22	_____ #SP	and/or _____ #units
	18J2667	2021-09-18	_____ #SP	and/or _____ #units
	18K2853	2021-10-04	_____ #SP	and/or _____ #units
400207 Instrument Wipe 76.2 x 76.2 mm (3 x 3 in) (20 units/box) 	17B0408	2020-02-01	_____ #SP	and/or _____ #units
	17C0767	2020-03-01	_____ #SP	and/or _____ #units
	17E1871	2020-05-25	_____ #SP	and/or _____ #units
	17G2561	2020-07-25	_____ #SP	and/or _____ #units
	17K3690	2020-10-17	_____ #SP	and/or _____ #units
	18B0436	2021-02-14	_____ #SP	and/or _____ #units
	18B0557	2021-02-23	_____ #SP	and/or _____ #units
	18C0851	2021-03-18	_____ #SP	and/or _____ #units
	18D1170	2021-04-24	_____ #SP	and/or _____ #units
	18F1745	2021-06-18	_____ #SP	and/or _____ #units
	18K2854	2021-10-04	_____ #SP	and/or _____ #units
	18L3353	2021-11-15	_____ #SP	and/or _____ #units
	18M3550	2021-12-06	_____ #SP	and/or _____ #units
	400210 Wipe with Wick 92.1 x 76.2 mm (3.625 x 3 in) (20 units/box) 	17C0768	2020-03-01	_____ #SP
17C0769		2020-03-01	_____ #SP	and/or _____ #units
17C0956		2020-03-16	_____ #SP	and/or _____ #units
17D1362		2020-04-12	_____ #SP	and/or _____ #units
17E1639		2020-05-09	_____ #SP	and/or _____ #units
17F2172		2020-06-23	_____ #SP	and/or _____ #units
17G2562		2020-07-25	_____ #SP	and/or _____ #units
17G2563		2020-07-25	_____ #SP	and/or _____ #units
17K3691		2020-10-17	_____ #SP	and/or _____ #units
17L4056		2020-11-15	_____ #SP	and/or _____ #units
17M4424		2020-12-13	_____ #SP	and/or _____ #units
18C0878		2021-03-26	_____ #SP	and/or _____ #units
18F1880		2021-06-29	_____ #SP	and/or _____ #units
18H2373		2021-08-22	_____ #SP	and/or _____ #units
18J2668		2021-09-18	_____ #SP	and/or _____ #units
18L3198		2021-11-02	_____ #SP	and/or _____ #units
18M3642		2021-12-13	_____ #SP	and/or _____ #units
17C0768	2020-03-01	_____ #SP	and/or _____ #units	
581047	16L4827	2021-11-30	_____ #SP	and/or _____ #units
	17A0329	2022-01-26	_____ #SP	and/or _____ #units

ATTACHMENT 1 - RESPONSE FORM
Product Information

REF# & Description	Lot Number	Expiration Date	Customer checked stock. Quality on-hand.	
			<i>I have # of Shelf Pack (SP) Boxes.</i>	<i>I have # or unit level (units)</i>
Instrument Wipe 7.3 x 7.3 cm (2 7/8 x 2 7/8 in) (20 units/box) 	17B0715	2022-02-23	_____ #SP	and/or _____ #units
	17C1076	2022-03-30	_____ #SP	and/or _____ #units
	17D1439	2022-04-19	_____ #SP	and/or _____ #units
	17E1640	2022-05-09	_____ #SP	and/or _____ #units
	17F2006	2022-06-07	_____ #SP	and/or _____ #units
	17F2175	2022-06-23	_____ #SP	and/or _____ #units
	17G2578	2022-07-25	_____ #SP	and/or _____ #units
	17J3185	2022-09-05	_____ #SP	and/or _____ #units
	17J3186	2022-09-05	_____ #SP	and/or _____ #units
	17J3347	2020-09-19	_____ #SP	and/or _____ #units
	17K3692	2022-10-17	_____ #SP	and/or _____ #units
	17L4057	2022-11-15	_____ #SP	and/or _____ #units
	17M4425	2022-12-13	_____ #SP	and/or _____ #units
	18K3171	2023-10-31	_____ #SP	and/or _____ #units
581076 Adhesive Wipe 7.6 x 4.5 cm (3 x 1 3/4 in) (20 units/box) 	17E1641	2022-05-09	_____ #SP	and/or _____ #units
	17G2582	2022-07-31	_____ #SP	and/or _____ #units
	17H2992	2022-08-19	_____ #SP	and/or _____ #units
	17J3348	2022-09-19	_____ #SP	and/or _____ #units
	17K3693	2022-10-17	_____ #SP	and/or _____ #units
	17M4426	2022-12-13	_____ #SP	and/or _____ #units
	18B0437	2023-02-14	_____ #SP	and/or _____ #units
	18C0892	2023-03-26	_____ #SP	and/or _____ #units
	18D1179	2023-04-24	_____ #SP	and/or _____ #units
	18F1893	2023-06-29	_____ #SP	and/or _____ #units
	18H2377	2023-08-22	_____ #SP	and/or _____ #units
18K3111	2023-10-24	_____ #SP	and/or _____ #units	