

URGENT ADVISORY 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.

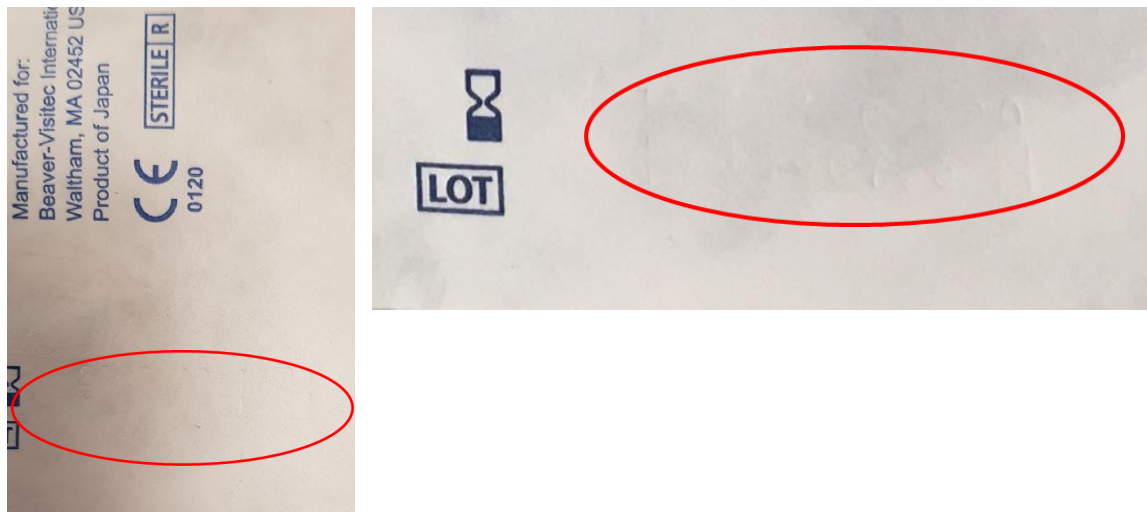


Figure 1: Example of illegible unit level package expiration date and LOT number



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
Urgent Advisory 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 have # of Shelf Pack (SP) Boxes. | I have # or unit level (units) | |
| 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>I have # of Shelf Pack (SP) Boxes.</i> | <i>I have # or unit level (units)</i> | |
|  | 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 | | |


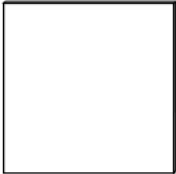
ATTACHMENT 1 - RESPONSE FORM
Product Information

| 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> |
| | 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 |
| 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 |