

**** URGENT FIELD SAFETY NOTICE ****

February, 24th 2016

RE: Volcano R-100[®] Sterile Equipment Cover, Product REF numbers PBKBG and PBKGB-10
SpinVision[®] Sterile Equipment Cover, Product REF numbers 891BG and 891BG-10

Dear Volcano Customer:

Volcano Corporation is initiating a voluntary Field Safety Correction of all currently distributed **R-100 and SpinVision Sterile Equipment Covers** because an incorrect expiration date may be printed on an inventory label on the outer shipping box. This inventory label is intended for Volcano Corporation internal use and does not identify the product by part or lot number. Affected products are identified below:

REF Number	Device	Lot Number
PBKBG	R-100 Sterile Equipment Cover	All
PBKGB-10	R-100 Sterile Equipment Cover 10 pack	All
891BG	SpinVision Sterile Equipment Cover	All
891BG-10	SpinVision Sterile Equipment Cover 10 pack	All

We are initiating this recall as a precaution due to the potential that the product may be labeled beyond its expiration date. A number of units at the manufacturing facility may have been shipped in a package with the inventory label containing an expiration date that is one or more months later than the correct expiration dates shown on the product's primary and secondary packaging. The primary packaging (Figure A below) includes a label on each pouch containing individually packaged products. The secondary packaging (which is also the shipping box) also contains a label identifying the product by part and lot number (Figure B below). The correct expiration dates located on the labels of the primary and secondary packaging for these products is no earlier than March 2018, so prompt attention to this notice will prevent expired product from mistakenly remaining in inventory. While month and year are listed, the shelf life extends through the last day of the listed month.

Figure A



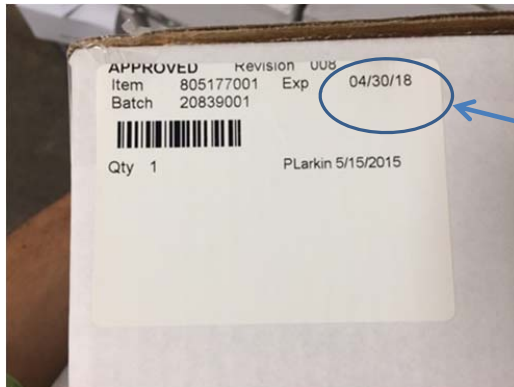
Figure B



Primary and Secondary Packaging with correct expiration dates

Potential confusion exists when comparing the primary and secondary packaging expiration dates to that of the smaller inventory label placed on the side of the secondary packaging (Figure C below). In some cases, this inventory label may indicate a later expiration date.

Figure C



Inventory label on
Secondary
Packaging with
Incorrect "Exp" Date

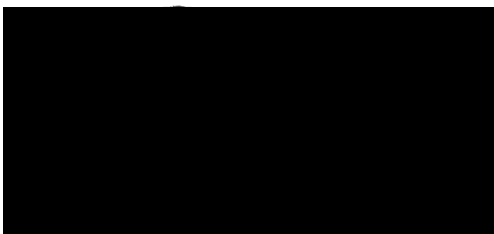
Although the risk of use of this product beyond its expiration date is low, we want to eliminate any confusion related to the correct expiration date of the products.

Should you identify any affected product, please remove the product from the secondary packaging/shipping box and discard the shipping box. The expiration date on the primary packaging is correct and may be relied upon. Once you have completed an inventory of your supply, please complete, sign, and return the attached form indicating that you have removed all products from the shipping box. If you no longer have inventory, please indicate that choice on the form. Sign and date the form and return the completed form to Volcano.

We recognize the inconvenience this may cause you, your staff, and your patients. However, this action reflects Volcano Corporation's commitment to patient safety and high quality standards. No other products are impacted.

Please ensure that a copy of this Field Safety Notice is provided to all personnel within your organization who handle these products. Thank you for your prompt attention to this important matter. On behalf of Volcano, we appreciate your partnership and your continued support.

Sincerely,



CUSTOMER ACKNOWLEDGEMENT

Hospital Name: _____

Hospital Address: _____

Country: _____

Contact Email: _____

Contact Phone: _____

1. Complete the information below.
2. Fax completed form to Volcano Customer Service (see list below) or e-mail to vefsca@volcanocorp.com

Italy	+390459971861
Spain	+34935207112
France	+33153010911
Germany	+493221122683167
Poland	+48123841700

	R-100 Sterile Equipment Cover (PBKBG or PBKBG-10)	SpinVision Sterile Equipment Cover* (891BG or 891BG-10)
Please indicate whether you have product on site:	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No *Do not include consideration of units packaged individually with the Revolution Catheter.
Confirm that all product in inventory has been removed from the shipping box and that the shipping box has been discarded.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Form Completed by:

Name and Title

Signature

Date