

**B. Braun Australia Pty Ltd**

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16 September, 2026

For the attention of: The Chief Executive Officer, Chief Medical Officer
& Supply Chain Managers, Nurse Unit Managers

Urgent Recall**TGA Reference Number: RC-2026-RN-00715-1****ARTG 136029 RV1000NC SAFSITE VALVE VV/O EXTRA CAP**

Dear Valued Customer,

Product Catalog Number	Primary DI Number	Unit DI Number	Product Description	Lot Number	Distribution Range	Expiration Date
415068	04022495769862	04045928016067	RV1000NC SAFSITE VALVE VV/O EXTRA CAP	0061968348	06MAY2025 10NOV2025	31OCT2029
				0061966913	27MAY2025 02JUN2025	30SEP2029

The scope of this recall is to the hospital/healthcare level. This recall is being conducted following agreement with the Therapeutic Goods Administration (TGA).

Reason for the recall:

B Braun has identified through the investigation of customer complaints for leakage and backflow at the Safsite valve; that a potential problem may lead to valves remaining in the open position after disconnecting from the port.

Risk to Health:

To date, there have been no reports of death to patients, users, or third parties associated with the identified problem. There were 15 reports of injuries to patients associated with leakage/backflow which could cause a minor delay in treatment while replacing the device. If the valve contains hazardous medication, there is the potential for leakage of that medication with limited to significant exposure that may result in mild to severe injury to the patient, clinician or other. If the leakage is not evident, the valve may result in blood loss or be contaminated, potentially resulting in bloodstream infection.

Actions Required:

1. Review this recall notice, in its entirety, and ensure that all users in your organisation of the above-mentioned product, and other concerned people are informed about this recall. If you are a distributor and have further distributed the product, please forward

this notice to your consignees. The recall is to be extended to the hospital/healthcare facility level.

2. Determine your current inventory of the affected items within inventory of your facility, cease use and quarantine product subject to recall. Do not destroy any affected product.
3. Using the attached " Recall Response Form", record the total number of individual impacted units. If you have no inventory remaining, please enter zero (0) on the form.
4. Return the completed "Recall Response Form" to Icon Medical Supplies at:
cs@iconmedical.com.au

Kind regards,



Mr Geoff Brown
Managing Director
B. Braun Australia Pty Ltd

Att.

RECALL RESPONSE FORM

Product Catalog Number	Primary DI Number	Unit DI Number	Product Description	Lot Number	Distribution Range	Expiration Date
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Please complete this form and return to cs@iconmedical.com.au

We hereby confirm that we are aware of the Product Recall RC -2026-RN -00715-1

ARTG 136029 RV1000NC SAFSITE VALVE VV/O EXTRA CAP

Organisation:

Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature	
Product For return	
Lot Number	QTY
0061968348	
0061966913	