

**URGENT
PRODUCT
RECALL**

Subject: Recall of FlowCOUPLER Device

Dear Customer,

Synovis Micro Companies Alliance, Inc. (a subsidiary of Baxter International Inc.) is conducting a voluntary recall of the FlowCOUPLER Device.

What is the FlowCOUPLER Device?

The FlowCOUPLER Device is a single use, implantable device that is intended to be used in the end-to-end anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures. The FlowCOUPLER Device includes a pair of permanently implanted rings which secure the anastomosis and a removable Doppler probe that is press-fit onto one of the rings. When the FlowCOUPLER Device is used in conjunction with the FlowCOUPLER Monitor, the FlowCOUPLER System is intended to detect blood flow and confirm vessel patency intra-operatively and post-operatively at the anastomotic site.

What is the reason for the recall?

This recall is being conducted as a precautionary measure due to the possibility that some units may not maintain electrical continuity during handling intra-operatively and post-operatively, resulting in a loss of Doppler signal. This may result in the inability to monitor anastomotic patency, with the possibility that blood flow may not be appropriately monitored.

The root cause of this issue is currently under investigation, and appropriate actions will be taken to correct the problem and prevent recurrence.

What is the safety risk?

Because the FlowCOUPLER Device is a monitoring device, and is used in conjunction with other anastomotic patency monitoring techniques, it is unlikely that a malfunction of the device will result in patient harm. The IFU indicates that in the event a Doppler signal is lost, clinical indications of external Doppler probe should be relied upon for patient status. There have been no adverse events reported related to this issue.

What action does my facility need to take?

Our records indicate that you have received shipments that may be impacted by this issue. **A complete list of affected product codes and lot numbers affected by this recall is attached.** Synovis MCA is asking you to take the following actions:

- Please check your inventory for the lot numbers indicated on the next page, and complete and return the attached Inventory Response Form, even if the inventory is zero (0).
- Please discontinue use of any affected inventory.
- Contact the Synovis MCA Customer Service unit at 1-800-510-3318 or 205-941-0111 for instructions on how to return affected product.
- Replacement product will be sent to you.

What if I am a distributor?

If you further distribute this product, please notify your accounts of this recall immediately.

Has the FDA been informed?

The FDA has been informed of this recall. Other Regulatory Authorities have been informed per local requirements.

Who do I contact for questions or additional information?

If you have any questions regarding this recall or the use of the FlowCOUPLER Device, please contact the Synovis MCA Customer Service unit at 1-800-510-3318 or 205-941-0111.

We apologize for any inconvenience this recall may have caused, and are working to correct the issue.

Sincerely,



Les Vincent
Senior Quality Director,
Baxter Healthcare

FlowCOUPLER Lots Affected by the Recall

Part Number	Lot Number
5151-01200-010	SPSGT14-02B0027a
5151-01200-010	SPSGT14-04D0005
5151-01200-010	SPSGT14-04D0023
5151-01250-010	SPSGT14-02B0026
5151-01250-010	SPSGT14-04D0015
5151-01250-010	SPSGT14-04D0026
5151-01300-010	SPSGT14-02B0028
5151-01300-010	SPSGT14-02B0033
5151-01300-010	SPSGT14-04D0014
5151-01300-010	SPSGT14-04D0027
5151-01300-010	SPSGT14-05E0005

Inventory Response Form: FlowCOUPLER

Please complete and return this form via email to:
terry_harrell@baxter.com

Facility/ Institution:	
Address:	
Contact Person:	
Telephone:	

Our inventory

- We do not have any unit of the affected lots in our inventory.
- We do have the affected lots in our inventory, which have been quarantined, and will be returned:

Part Number	Lot Number	Quantity in Inventory
5151-01200-010	SPSGT14-02B0027a	
5151-01200-010	SPSGT14-04D0005	
5151-01200-010	SPSGT14-04D0023	
5151-01250-010	SPSGT14-02B0026	
5151-01250-010	SPSGT14-04D0015	
5151-01250-010	SPSGT14-04D0026	
5151-01300-010	SPSGT14-02B0028	
5151-01300-010	SPSGT14-02B0033	
5151-01300-010	SPSGT14-04D0014	
5151-01300-010	SPSGT14-04D0027	
5151-01300-010	SPSGT14-05E0005	