

Urgent Field Safety Notice**GEM Microvascular Anastomotic COUPLER
FA-2020-008
Product Recall**

March XX, 2020 (to be adapted locally)

Dear Sir/Madam

**Affected
Product**

Product Code	Product Description	Lot Number	Expiration Date
5111-00250-060	COUPLER, 2.5MM,6PK GEM2753	SP19J11-1402242	8/28/2024
		SP19J11-1402246	8/28/2024
5111-00250-010	COUPLER, 2.5MM,1PK GEM2753	SP19J11-1402265	8/28/2024
5111-00200-060	COUPLER, 2.0MM,6PK GEM2752	SP19J08-1401476	9/3/2024
		SP19J09-1401614	9/3/2024
5111-00200-010	COUPLER, 2.0MM,1PK GEM2752	SP19J09-1401617	9/3/2024
		SP19J08-1401480	9/3/2024

**Problem
Description**

Synovis Micro Companies Alliance (MCA), Inc., a subsidiary of Baxter International Inc., is issuing a voluntary product recall to the user level due to a customer complaint regarding a GEM Microvascular Coupler Device in which the Coupler size labeling of the outer tray did not match the Coupler size of the inner tray. Please see above for a list of product codes and lot numbers potentially affected by this issue.

**Hazard
Involved**

The mislabeling of a Coupler tray may lead to a delay in therapy; however, this issue is not expected to result in adverse health consequences. There have been no reports of patient injury associated with this issue.

**Action to be
taken by the
user**

Baxter is kindly asking that you take the following actions:

1. Locate and remove the affected product lots from your facility. The product code and lot number can be found on the individual product packaging.
2. Contact Synovis MCA to arrange for return and replacement of the product. Synovis MCA can be reached at 205-941-0111 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday. Please have your Synovis MCA account number, product code, lot number, and quantity of product to be returned ready when calling.



3. Complete the enclosed Baxter customer reply form and return it to Baxter by faxing it to 224 270 5457 or scanning and e-mailing it to fca@baxter.com, even if you do not have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. If you purchased this product from a distributor, contact your supplier to arrange for return and credit. Please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please conduct a consumer-level recall of the affected product that you distributed to customers and check the associated box on the reply form.

**Further
information
and support**

For general questions regarding this communication, contact Synovis MCA at 205-941-0111, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

xxx

Synovis MCA, Inc., a subsidiary of Baxter International Inc.

Enclosure: Baxter Customer Reply Form

