



**PRODUCT  
RECALL**

## Urgent Field Safety Notice

**NEUROTUBE  
FA-2023-015  
Recall**

April, 2023

Dear Sir/Madam,

**Affected  
Product**

<b>Product Code</b>	<b>Product Description</b>	<b>Lot Number</b>	<b>BUDI</b>
5311-01240-010 (GEM0240NT)	NEUROTUBE, 02X40, RP, CE	19012112	478180000000000000001317P

**Problem  
Description**

Baxter Healthcare Corporation is issuing a Recall to the user level for the NEUROTUBE Lot number 19012112 due to the product being brittle and potentially crumbling upon handling or when being removed from its package.

**Hazard  
Involved**

A brittle or crumbling NEUROTUBE could lead to delay in therapy, insufficient therapy and/or additional mechanical stress to patient tissue(s). The harm to the patient can vary from transient symptoms that may require medical and/or surgical intervention, to more permanent impairment. However, the defect is most likely to be noticed prior to patient use. Baxter has not received any reports of serious injury related to this issue.

**Action to be  
taken by the  
user**

Baxter is kindly asking that you take the following actions:

1. Immediately locate, isolate, and cease all use of the affected lot number of the product. The product code and lot number can be found on the individual product and shipping carton.
2. Contact Synovis MCA to arrange for return and replacement of the product. Synovis MCA can be reached at 800-510-3318 or 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 [natasha\\_strong@baxter.com](mailto:natasha_strong@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 distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.

**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,

  
Director, Product Quality  
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form