**URGENT FIELD SAFETY NOTICE**
**EZee Retrieval (550-000-000) RECALL**

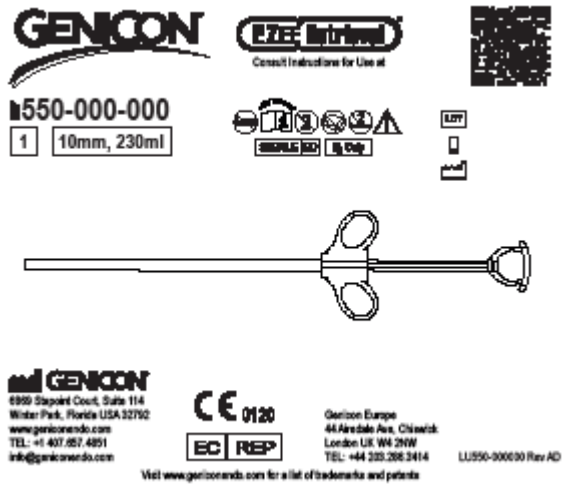
March 29, 2018

[CONTACT NAME OR DEPT]
[FIRM NAME]
[ADDRESS]
[CITY | STATE | ZIP]

Dear [NAME],

This is to inform you of a product recall involving:

Specimen Retrieval | EZee Retrieval | GENICON Single Use Poly Specimen Retrieval Bag | 550-000-000 | Lots I8095/2017-11-08 | I8162/2018-01-09 | I8162/2020-01-09.
See enclosed product label.




This recall has been initiated due to broken thumb loops on the product. Use of this product may cause delays in procedure time and/or additional surgical intervention to remove the specimen from the patient.

We began shipping this product in November 2016.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

All product with lots I8095/2017-11-08 | I8162/2018-01-09 | I8162/2020-01-09 shall be returned to GENICON via FedEx Ground on GENICON's account (297603345). No other lots of 550-000-000 are impacted by this removal. Please only return the lots listed above.

This recall should be carried out to the user level.

Your assistance is appreciated and necessary to prevent the above referenced potential health hazard. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please complete and return the enclosed response form as soon as possible.

If you have any questions, call GENICON Customer Service at 407-657-4851 x800.

This recall is being made with the knowledge of the Food and Drug Administration and appropriate National Competent Authority(ies) and Regulatory Agencies.

Katlyn Kachman
Regulatory Compliance

Enclosure(s)

550-000-000
I8095/2017-11-08 | I8162/2018-01-09 | I8162/2020-01-09

Please check ALL appropriate boxes:
☐ I have read and understand the recall instructions provided in the [DATE] letter.
☐ I have checked my stock and have quarantined inventory consisting of _____ units.

Indicate disposition of recalled product:
☐ Returned (specify quantity, date and method)/held for return: _____
☐ Destroyed (specify quantity, date and method): _____
☐ Relabeled (specify quantity and date): _____
☐ Quarantined pending correction (specify quantity): _____
☐ Transfused – Blood or blood products (specify date and quantity): _____
☐ Implanted (specify date and quantity): _____

Indicate furthur notification:
☐ I have identified and notified my customers that were shipped or may have been shipped this product by (specify date and method of notification): _____
☐ Attached is a list of customers who received/may have received this product. Please notify my customers

Any adverse events associated with recalled product? ..... ☐ Yes ☐ NO
If yes, please explain: _____

Please check the appropriate box(es) to describe your business:
☐ Wholesaler/Distributor ☐ Retailer ☐ Manufacturer ☐ Hospital Pharmacies
☐ Food Service/Restaurant ☐ Repacker ☐ Pharmacy (retail) ☐ Hospital/Medical Facility
☐ Medical laboratory ☐ Grocery Corporate Headquarters
☐ Other: _____

Name: _____ Title: _____
Phone: _____
Firm Name: _____
Address: _____

PLEASE FAX COMPLETED RESPONSE FORM TO Tel. # 407-677-9773, ATTN: REGULATORY
OR MAIL TO:

GENICON
ATTN: Regulatory
6869 Stapoint Court Suite 114
Winter Park, FL 32792 USA