

Advisory Notice

Customer Name

Street Address

City, State, Zip Code

Affected Product: GelPOINT® Path Transanal Access Platform

February 20th, 2019

Dear Valued Customer,

Applied Medical has identified a discrepancy on the labels of a single lot number of the GelPOINT Path Transanal Access Platform with Insufflation Stabilization Bag, 4cm. The GelPOINT Path system is CE approved and the device itself is not affected from a functional perspective; however, the labels and IFUs of the affected lot do not contain the required CE mark and Authorized European Representative information.

Our records indicate that you have received unit(s) from the affected lot. At this time, Applied Medical would like to offer you the choice of replacing the affected unit(s) at your earliest convenience.

Please note that the affected model number is **CNB10** and the affected lot is **1331395**.

If you choose to return the affected unit(s) immediately we ask that you please complete the following actions:

- Identify all unit(s) with the lot number 1331395.
- Complete the attached Advisory Notice Confirmation Form (Page 2) to acknowledge the notice and indicate that the affected unit(s) will be returned at this time.
 - Return the confirmation form to Applied Medical by emailing Reply-Europe@appliedmedical.com. Once we receive your confirmation form, we will expedite shipment of replacement unit(s) to your facility to minimize any interruption to your surgical cases. Please contact your local sales representative for any questions on replacement unit(s).
 - Return affected product and a copy of the confirmation form to Applied Medical. A box will be provided for each returning unit. Product Return Instructions are on Page 3.

If you choose to use the affected unit(s):

- Complete the attached Advisory Notice Confirmation Form (Page 2) to acknowledge the notice and indicate that the affected unit(s) will not be returned.

Applied Medical will ensure that the appropriate Regulatory Agencies have been notified. We apologize for any inconvenience this action may cause. Your immediate attention is appreciated.

your local representative.

Applied Medical Europe B.V.

Customer Advisory Notice CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND SEND TO:

Email: Reply-Europe@appliedmedical.com

Applied Medical "Sold To" Account Number:

Applied Medical "Ship To" Account Number:

INFORMATION FOR CUSTOMER FACILITY RESPONDING TO ADVISORY NOTICE:

Hospital Name: _____

Hospital Address: _____

RETURNING PRODUCT INFORMATION:

If no products are being returned, please check here: ☐

(If no products are returning, it is assumed that all products were previously used and are no longer available.)

| Model, Lot | Quantity of Units Being Returned |
|----------------|----------------------------------|
| CNB10, 1331395 | |

Please select credit or replacement: Credit ☐ Replacement ☐

If requesting replacement product, please include the No-Charge P.O. #: _____

INFORMATION ABOUT INDIVIDUAL COMPLETING THIS FORM:

Name: _____ Title: _____

Date: _____ Telephone: _____ Fax: _____ Email: _____

Product Return Instructions

(If returning affected units immediately)

A pick-up of the affected GelPOINT Path Transanal Access Platform(s) will be arranged by our Customer Service team after receiving the Advisory Notice Confirmation Form.

Please write the **RGA #** on the outside of the package which will be given to you by our Customer Service Department.

Please include a copy of the filled out Advisory Notice Confirmation Form (along with your returned product).

If you have any questions about the Advisory Notice Confirmation Form or how to return the product, please contact our **Customer Service Department** at:

Telephone number: -----

Email address: Reply-Europe@appliedmedical.com

If you have any regulatory questions, please contact:

Regulatory Department

Phone: +31 (0) 33422 90 40 – option 4

Email: RA-QA@appliedmedical.com