

PHS MEDICAL GMBH – EDERWEG 3 – 34277 FULDABRÜCK



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Date: 2017-02-02

URGENT: MEDICAL DEVICE RECALL Port Catheter Systems with F9.6 Silicone Catheters

Ref.: Complaint File No.: RKL036

Dear Device Customer/Distributor,

(1) Purpose of this letter

The purpose of this letter is to advise you that PHS Medical GmbH is voluntarily recalling specific NuPort^{CT} and C-Port^{CT} Port Catheter Systems containing F9.6 Silicone Catheters, Lot .01606081.

Note: Serious injuries and/or deaths have not occurred due to the failure mode associated with this recall.

(2) Reason for the Voluntary Recall:

Intravascular catheters are required to be radiopaque such that they can be visualized under radiographic imaging. PHS Medical specifies from its vendor of silicone catheters the addition of a radiopacifier (BaSO₄, 15%) to enhance visualization during implantation.

- We are aware of three product complaints associated with a limited radiodensity of the affected catheters resulting in the inability to visualize the catheter in-vitro during implantation. There are currently no adverse events associated with these complaints.
- Not all catheters of this lot are affected, however, the radiodensity of a random number of these catheters clearly show severely reduced radiopacity.

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(3) Risk to Health:

3a) There is currently no risk to the health of the patient as the limited radiopacity is identifiable during implantation via fluoroscopy or x-ray, which is standard for the procedure, and allows for immediate intervention.. The inability to visualize the catheter can lead to delays in the surgical procedures or other delays in treatment or therapy,

3b) The qualitative level of radiopacity is visually established during implantation, allowing for immediate replacement of the catheter with a different lot number. As stated above, not all of the lot of catheters involved are affected, however, as a precautionary measure, all catheters of this lot are subject to the recall.

(4) Actions to be taken by the Customer/User:

The following actions should be implemented:

- All ports as listed in the „Product and Distribution Table“ that have not been shipped to the end-user should be removed from inventory and placed in quarantine pending the return of the product to PHS Medical.
- All end-users are to be queried regarding any units which have not yet been implanted and instructed to place these in quarantine pending removal by the distributor.
- For units which have been implanted, the respective end-user should review the implanting documentation to determine if during the surgical procedure a radiographic visualization of the catheter position was performed. If the catheter was visualized, no further action is required. In those instances where this is not the case, the individual patient should be examined using radiopaque dye to confirm the proper location of the catheter. If the catheter is visible using contrast medium, the attending physician should determine, based on an individual basis, if it is beneficial for the patient to have the port explanted and replaced.
- If the removal of the product creates a shortage, we recommend the use of units containing the 8F silicone catheters until new replacement units can be provided.
- The distributor is requested to acknowledge receipt of this Medical Device Recall within 2 days after receipt in the space provided at the end of this letter.
- The distributor is instructed to complete and return within 7 days after receipt of this Medical Device Recall, the **Acknowledgement and Receipt Form** attached herewith.

(5) Product and Distribution Information: Our records indicate that the following affected units have been shipped to the distributor:

| Product and Distribution Information Table | | | | | |
|---|---------------|-------------------|-------------------------|----------------------------------|-------------------------|
| Product Name | Ref. | Lot Number | Quantity Shipped | Delivery Note to customer | Date of Delivery |
| C-Port-CT | CTKP-096IS-CA | A1635004 | 20 | 40192 | 14.09.2016 |
| NuPort-HP | PH-096IS-CA | A1635008 | 50 | 40192 | 14.09.2016 |
| C-Port-CT | CTKP-096IS-CA | A1639003 | 25 | 40374 | 19.10.2016 |
| NuPort-HP | PH-096IS-CA | A1639006 | 100 | 40373 | 19.10.2016 |

(6) Type of Action by the Company:

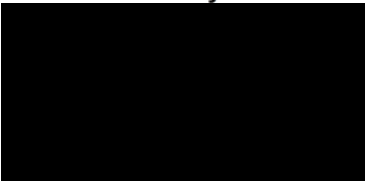
- Upon receipt of the **Acknowledgement and Receipt Form**, PHS Medical will contact the distributor with modality information regarding return and replacement of affected products.

- Failure investigation findings and corrective actions will be communicated to the distributor upon completion of investigation.

(7) CONTACT INFORMATION FOR QUESTIONS:

Should you require additional information, we may be reached from Monday through Friday, 8:30 AM to 4:30 PM CET via telephone, fax or email as listed above in the letterhead. All communications pertaining to this recall should reference the above complaint file number.

Authorized by:



The receipt of this Medical Device Recall is herewith acknowledged.

Date: _____

Authorized signature: _____

Name and title: _____

**MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form**

Response is Required

Customer Information:



**Port Catheter Systems with F9.6
Silicone Catheters, Lot 01606081**

| Product and Distribution Information Table | | | | | |
|--|---------------|------------|------------------|---------------------------|------------------|
| Product Name | Ref. | Lot Number | Quantity Shipped | Delivery Note to customer | Date of Delivery |
| C-Port-CT | CTKP-096IS-CA | A1635004 | 20 | 40192 | 14.09.2016 |
| NuPort-HP | PH-096IS-CA | A1635008 | 50 | 40192 | 14.09.2016 |
| C-Port-CT | CTKP-096IS-CA | A1639003 | 25 | 40374 | 19.10.2016 |
| NuPort-HP | PH-096IS-CA | A1639006 | 100 | 40373 | 19.10.2016 |

I have read and understand the recall instructions provided in the recall letter of 02.02.2017. Yes ___ No ___

Any adverse events associated with recalled product? Yes ___ No ___

If yes, please explain:

Was this device implanted? Yes ___ No ___

If yes, can the implant dates, the quantities implanted, and tracking information be made available if necessary? Yes ___ No ___

Affected Product Information: Include information that is applicable for affected product.

| Affected Product Information Table | | | | | |
|---|-----------------------------|--------------------------------|-----------------------|---------------------------------|-------------------------|
| Product Name) | Manufacturer's Product Ref. | Lot Number shipped to Customer | Quantity in inventory | Quantity removed from customers | Quantity to be returned |
| | | | | | |
| | | | | | |
| | | | | | |

Return Response Box:

Please provide any additional information, if applicable.

Distributors:

I have checked my stock and have quarantined inventory consisting of _____ units.

I have identified and notified my customers that were shipped or may have been shipped this product by **(specify date and method of notification)**.

Questions: (when applicable)

Please have Customer Service contact me.

Signature of Receipt _____

| | |
|---------------|--|
| Name/Title | |
| Telephone | |
| Email address | |

PLEASE FAX OR EMAIL COMPLETED RESPONSE FORM TO:

Fax: +49-561-99 85 97-199

Email: info@phs-medical.de

ATTN: XXXXXXXXXX