

**URGENT: MEDICAL DEVICE REMOVAL**

## PCNL Balloon/Inflation Device Kit

Product Name	Model/Catalog Number	Lot Number(s)	UDI PI	Distribution Range
Nephro-EZDilate Kit 24Fr (8mm) x 15cm Nephrostomy balloon catheter and Inflation Device	BPCN0815K	25037006	00821925033016	May 28, 2025 to August 29, 2025

Date: 17-Oct-2025

Attention: Urology Department, Risk Management

Dear Healthcare Professional:

Olympus is writing to inform you of a Medical Device Removal Action pertaining to the PCNL Balloon/Inflation Device Kit with the lot numbers listed in this letter. These products are intended for dilatation of the nephrostomy tract. The Nephro-EZDilate nephrostomy balloon catheter is recommended for dilatation of the nephrostomy tract and gaining working access to the kidney.

**Reason for Action:**

It was identified that the PCNL Balloon/inflation Device kits contained the 4mm x 4cm urinary tract balloon catheters (BURS0404) instead of the correct 8mm x 15cm nephrostomy tract balloon catheter (BPCN0815). The root cause was identified as operator error. All other components in these impacted kits were correctly included and packaged in the kit.

As a result of this issue, Olympus is requesting customers to return affected products.

**Risk to Health:**

The potential consequence of receiving the incorrect balloon within the PCNL kit is that the correct product may not be immediately available for use.

Although no adverse events directly related to this issue have been reported, potential patient risks include delay in starting a procedure or minimal prolongation of a procedure in progress.

**Actions Required:**

Our records indicate that your facility has purchased one or more of the affected products. Therefore, Olympus requires you to take the following actions:

1. Examine your inventory and quarantine the above-listed device with the affected batch number.
2. **Cease usage of the product immediately.**

3. Olympus requests that you return any remaining affected product. Please contact Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization. Olympus will issue a credit to your facility upon return of your affected product.
4. Olympus requests that you acknowledge receipt of this letter through our recall web portal:
  - a. Go to <https://olympusamerica.com/recall>
  - b. Enter the recall number: "0479"
  - c. Complete the form.
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

Olympus requests you to report any complaints to our Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact directly by phone at (647) 999-3203 or by e-mail [Cynthia.Ow@Olympus.com](mailto:Cynthia.Ow@Olympus.com).

Sincerely,

*Cynthia Ow*

Cynthia Ow  
Sr. Manager, Field Corrective Action, Americas