

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Palm Cups® and ACE® MDI Spacers with Incorrect Shipping Box Labels

Date: March 26, 2021

Type of Action: Removal

Attention: Clinical Users of, and Distributors of Palm Cups and ACE MDI Spacers

Affected Devices: Specific lots of Palm Cups (Large) and ACE MDI Spacers with Small Masks potentially affected by this issue are listed in Table 1 below.

Table 1: List of Affected Devices

Model Number	Product Name	Lot Number
11-1122	ACE MDI Spacer with Small Mask	3809856
55-4090	Palm Cups (Large)	3768545

Dear Customer,

The purpose of this Field Safety Notice is to advise you that Smiths Medical has initiated a Field Safety Corrective Action (FSCA) for one lot of ACE MDI Spacers with Small Masks and one lot of Palm Cups (Large) listed in Table 1.

REASON FOR FIELD SAFETY CORRECTIVE ACTION

Smiths Medical became aware via complaints that one lot of ACE MDI Spacers with Small Masks and one lot of Palm Cups (Large) may have incorrect shipping box labels. The labels on the devices are correct. If an incorrect label was affixed to the shipping box you may have received the wrong product. If the correct product was received, it can continue to be used. The correct labels for the potentially affected devices are illustrated in Figure 1-4.



Figure 1 - Correct Label for ACE MDI Spacer with Small Mask Model 11-1122



Figure 2 - ACE MDI Spacer with Small Mask Model 11-1122

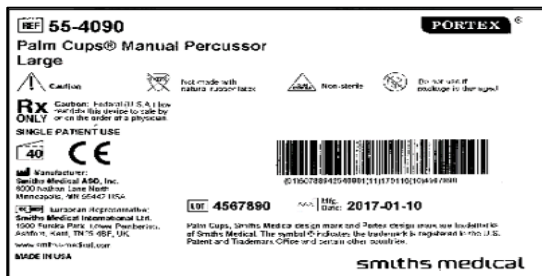


Figure 3 - Correct Label for Palm Cups Model 55-4090



Figure 4 - Palm Cups Model 55-4090

This Field Safety Corrective Action is being performed with the knowledge of the appropriate regulatory authorities.

RISK TO HEALTH:

If the device was packaged in a shipping box with the incorrect label, the shipping box may contain the wrong product, which could lead to a delay in therapy.

Smiths Medical has received no reports of deaths or serious injuries related to this issue.

INSTRUCTIONS:

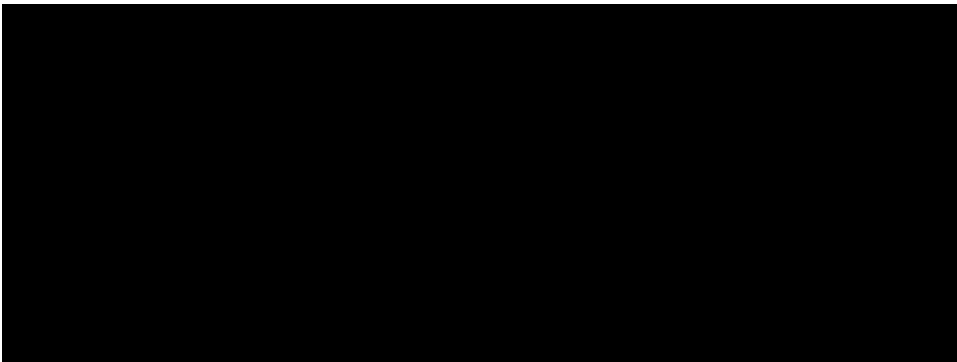
1. Identify and quarantine potentially affected devices in your possession by referring to Table 1: List of Affected Devices included on page 1 of this Field Safety Notice.
2. Inspect the potentially affected devices to determine if the device labels match the shipping box labels. Please refer to Figure 1 through Figure 4 for pictures of the potentially affected devices and their correct device labels.
3. Only affected device need to be returned to Smiths Medical. If the correct product was received it can continue to be used. Your completion of a Field Safety Notice Response Form will be required even if the devices in your possession are correctly labeled.
4. Complete the Field Safety Notice Response Form (Attachment 1) and return the form to fieldactions@smiths-medical.com within 10 days of receipt. The attached form must be returned even if you do not have any affected devices in your possession.
5. After the completed Field Safety Response Form has been submitted to fieldactions@smiths-medical.com, you will be contacted to arrange for return of any affected product.

Distributors: If you have distributed potentially Affected Devices to your customers (refer to Table 1: List of Affected devices on Page 1), please immediately provide them a copy of this Field Safety Notice and the accompanying Field Safety Notice Response Form.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

If you have any questions regarding this notification, please contact Smiths Medical via email at fieldactions@smiths-medical.com.

Sincerely,



Enclosure:

Attachment 1 – Field Safety Notice Response Form

ATTACHMENT 1

MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM

Palm Cups® and ACE® MDI Spacers with Incorrect Shipping Box Labels

Please acknowledge receipt of the accompanying Urgent Medical Device Field Safety Notice by completing and returning this Field Safety Notice Response Form to fieldactions@smiths-medical.com within 10 days. The Response Form must be completed and returned to Smiths Medical even if you have no Affected Product (Refer to Table 1 in the attached Field Safety Notice) in your possession.

DISTRIBUTORS – Please provide a copy of this Response Form and the accompanying Field Safety Notice to any of your customers to whom you distributed affected product, and complete Page 2 of this Response Form.

- I have affected product in my possession which has the incorrect label. *Please complete the Affected Product Table below.*
- I have no affected devices in my possession with the incorrect label.

Affected Product Table		
Product Number	Lot Number	Quantity of Affected Devices with Incorrect Shipping Box Label (individual units)

I certify that I have read and understand the information in the attached Field Safety Notice:

Name and Title (Please Print)	Signature and Date	Customer Number	Facility Name and Ship To Address*
Email Address	Telephone Number		

*If you are submitting a response form for multiple locations, please include the address for each facility you are responding for on the form or in an attachment.

For Distributors Only

I have identified and notified my customers that were shipped or may have been shipped this product

Distributor Name _____

Distributor Address _____

Distributor Email Address/Phone Number _____