

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Smiths Medical Procedure Kits Containing Paper Kidney Bowls

AFFECTED DEVICE: Smiths Medical Procedure Kits Containing Paper Kidney Bowls

TYPE OF ACTION: Removal

DATE: January 7, 2020

ATTENTION: Clinical users of, and Distributors of, Smiths Medical Procedure Kits Containing Paper Kidney Bowls

AFFECTED MODELS: All Lots of the Model Numbers Listed Below:

CARFC06006	CARFC70002	RADFC17902
CARFC06007	CARFC70003	RADFC17903
CARFC19505	CARFC73701	RADFC17904
CARFC19506	CARFC92901	RADFC18002
CARFC19508	CARFC96101	RADFC18003
CARFC19509	CARFC98501	RADFC18004
CARFC32001	CVPFC01001	RADFC21501
CARFC32002	CVPFC07102	SMA-292
CARFC32901	EPIFC00901	SPIFC00601
CARFC61602	I-09-4201-025	

Dear Customer,

The purpose of this Field Safety Notice is to advise you that Smiths Medical has initiated a voluntary field safety corrective action for certain Smiths Medical Procedure Kits containing Paper Kidney Bowls.

REASON FOR FIELD SAFETY CORRECTIVE ACTION:

Smiths Medical has become aware that the model numbers of procedure kits listed above contain a supplied paper component used for waste collection that may not be adequately sterilized. A non-sterile kit component could potentially result in exposure to infectious agents.

This field safety corrective action is being performed with the knowledge of the appropriate regulatory authorities.

RISK TO HEALTH:

Exposure to infectious agents due to a non-sterile product could potentially result in infection. Smiths Medical has not received any reports of deaths or serious injuries related to this issue.

INSTRUCTIONS TO CUSTOMERS:

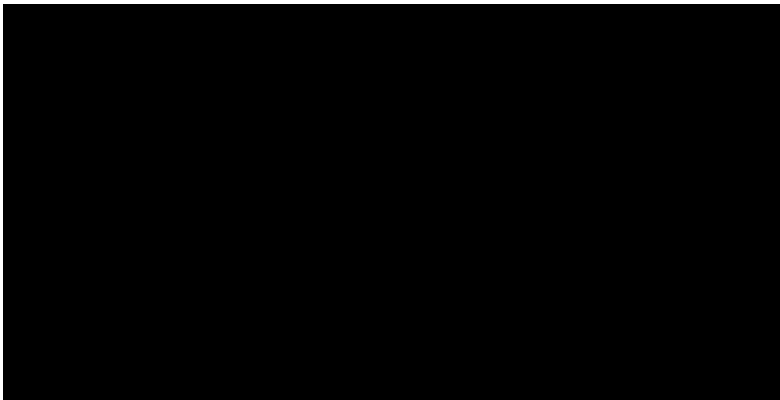
Smiths Medical is asking all customers in possession of affected models (listed above) of Procedure Kits containing Paper Kidney Bowls to immediately return these products to Smiths Medical. Please follow the steps below to complete this process.

1. Locate and quarantine all affected models of Procedure Kits containing Paper Kidney Bowls in your possession. The model number of a procedure kit can be identified by reviewing the outer packaging.
2. Determine the number of affected devices in your possession. Complete the attached Field Safety Notice Response Form within 10 days of receipt, returning it to fieldactions@smiths-medical.com even if you do not have any affected product in your possession. All affected product must be returned for processing.
3. Upon returning the Response Form, Smiths Medical will provide a shipping label to return the affected product. Include a copy of your completed Response Form inside each box of returned product to facilitate processing. Ensure boxes are sealed and labeled with your facility name prior to shipping.
4. If you have distributed any of the potentially affected products identified in this Field Safety Notice, please immediately notify the recipients of the potentially affected products by forwarding them a copy of this Field Safety Notice.

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

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE
RESPONSE FORM**Smiths Medical Procedure Kits Containing Paper Kidney Bowls**

Please assist us in making this field safety corrective action process as efficient and convenient for you as possible by completing and returning this form via email to fieldactions@smiths-medical.com within 10 calendar days of receipt of the Urgent Medical Device Field Safety Notice. This will serve as confirmation that you have received and understand the notification and will allow us to ensure that we have reached all customers who may be affected by this field safety corrective action.

Model Number(s) to be Returned	# of Units to be Returned

**Please attach list of any additional model numbers if necessary*

Name and Title (Please Print)	Signature	Date
Email Address	Telephone Number	