

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Level 1® Foley Catheters with Temperature Sensors Shipped Without Current EC Certification

Affected Device: Level 1® Foley Catheters with Temperature Sensors

Type of Action: Removal

Date: September 17, 2018

Attention: Clinical Users of, and Distributors of affected Level 1® Foley Catheters with Temperature Sensors

Affected Models: Model Numbers and associated Lots affected by this issue are listed in Table 1. An image of the affected product is shown in Figure 1.

Table 1 – Affected Models and Lots

Product Number	Lot Number
FC400-8	971005
FC400-10	971024
FC400-12	971001
FC400-14	971002
	971017
FC400-16	971003
	971122
	971123
FC400-18	971023

Figure 1 – Affected Product



Dear Customer,

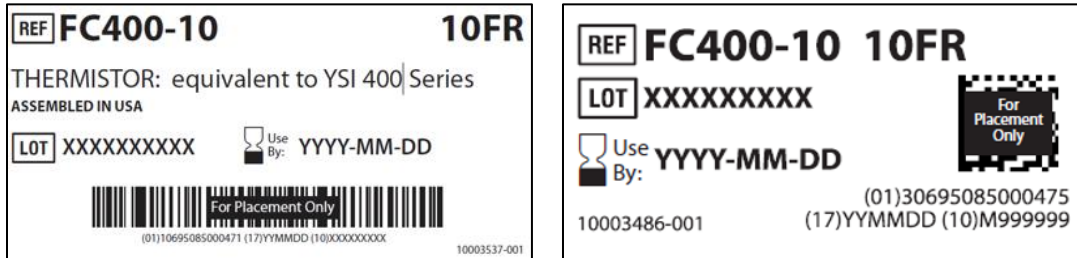
The purpose of this Field Safety Notice (FSN) is to advise you that Smiths Medical has initiated a voluntary Field Safety Corrective Action (FSCA) for specific models and lots of Level 1® Foley Catheters with Temperature Sensors. A total of 1,580 devices are included in this FSCA. Model and Lot number information of affected product shipped to your facility can be found on the Response Form accompanying this FSN.

REASON FOR FIELD SAFETY CORRECTIVE ACTION:

Smiths Medical became aware that the devices listed in Table 1 were inadvertently shipped to European countries without current EC Certification.

A representative image of affected device labeling is shown in Figure 2 below.

Figure 2 – Affected Product Labeling



RISK TO HEALTH:

The product itself has no known quality or safety issues and was manufactured to specification. There is no known patient risk and **Smiths Medical has received no reports of deaths or serious injuries related to this issue.**

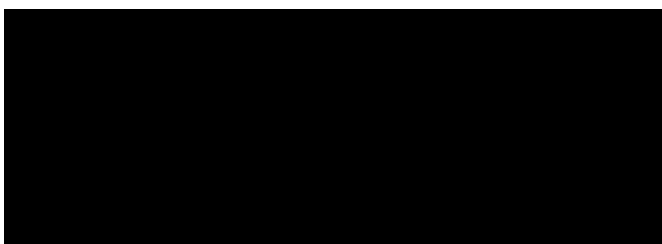
INSTRUCTIONS TO CUSTOMERS:

1. Locate and determine the number of affected products in your possession by referring to Table 1.
2. Complete the attached Response Form within 10 days and return it to fieldactions@smiths-medical.com, even if you do not have any of the affected product in your possession.
3. Return affected product to Smiths Medical utilizing the pre-paid shipping labels included with this notice. Include a copy of your completed Response Form inside EACH BOX of returned product to facilitate processing of credit. Ensure boxes are sealed and labeled with your facility name prior to shipping.
4. **DISTRIBUTORS:** If you have distributed potentially affected devices to your customers, please immediately notify them of this Field Safety Corrective Action.

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,



Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442

Enclosure: Field Safety Notice (FSN) Response Form
Product Return Labels