smiths medical
bringing technology to life

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

GRIPPER® and PORT-A-CATH® Needles Shipped Without Current EC Certification

Affected Device: **GRIPPER® and PORT-A-CATH® Needles**

Type of Action: **Removal**

Date: **August 10, 2018**

Attention: **Clinical Users of, and Distributors of affected GRIPPER® and PORT-A-CATH® Needles**

Affected Devices: **The following Product Numbers and associated Lots affected by this issue are listed in Table 1 below:**

Table 1

Product Number	Lot Number	Product Number	Lot Number
21-2014-24	3550725, 3587313	21-2861-24	38X082
21-2714-24	3595538	21-2865-24	38X130
21-2715-24	38X153	21-2866-24	38X090
21-2718-24	38X254	21-2868-24	38X010
21-2720-24	3603299	21-2948-24	38X248
21-2733-24	3599339	21-2949-24	38X055
21-2734-24	3599337, 3599337	21-3271-24	38X059
21-2736-24	3595533	21-3277-24	38X004
21-2767-24	3618227	21-3362-24	38X261
21-3367-24	3599273	21-3363-24	38X278

Dear Customer,

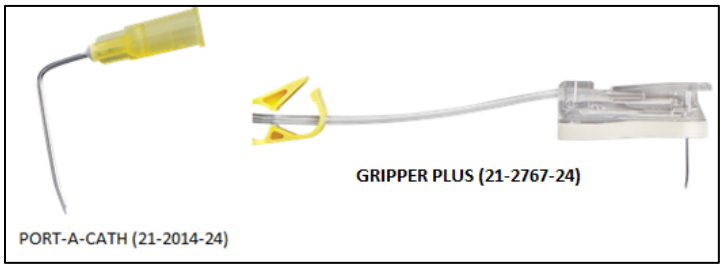
The purpose of this Field Safety Notice (FSN) is to advise you that Smiths Medical has initiated a voluntary Field Safety Corrective Action (FSCA) for specific GRIPPER® and PORT-A-CATH® Needles. A total of 29,292 devices are included in this FSCA. Product and lot number information of affected product in your possession can be found on the Response Form accompanying this FSN.

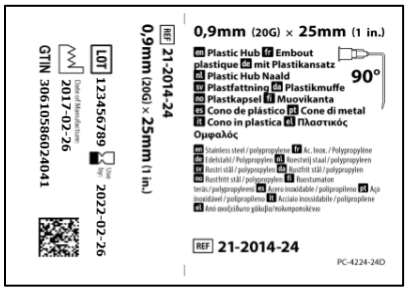
REASON FOR FIELD SAFETY CORRECTIVE ACTION:

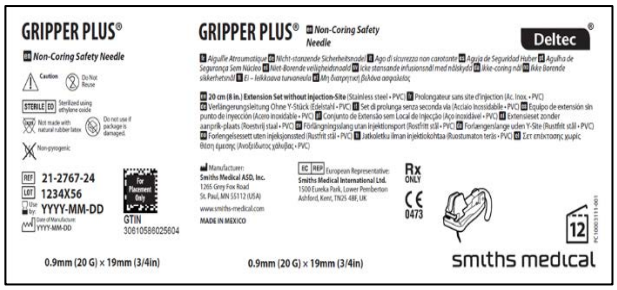
Smiths Medical became aware that the devices listed in Table 1 were inadvertently shipped to European countries without current EC Certification.

Representative images of affected device and examples of affected device labeling are shown in Figure 1.

Figure 1







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,

Dr. G. Barrett
VP Quality Systems, Regulatory and Compliance
Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442

Enclosure: Attachment 1 – Field Safety Notice (FSN) Response Form

Urgent Medical Device Field Safety Notice
Smiths Medical Ref # 3012307300-08/10/2018-009-R