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URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

CADD®- Solis VIP Ambulatory Infusion Pump

Affected Devices:	**CADD®- Solis VIP Ambulatory Infusion Pumps**
Type of Action:	**Removal**
Date:	**March 18, 2020**
Attention:	**Clinical Users, Distributors, and Health Care Providers overseeing the use of the CADD®- Solis VIP Infusion Pump**
Affected Devices:	**See Attached for List of Affected Serial Numbers**

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 serial numbers for CADD®- Solis VIP Ambulatory Infusion Pumps.

REASON FOR FIELD SAFETY CORRECTIVE ACTION:

Smiths Medical became aware that specific CADD-Solis VIP Ambulatory Pumps may exhibit intermittent performance in the AILD (Air in Line Detector) function. If an AILD does not sufficiently discern fluid from air in line, an air in line event may not be recognized by the pump and may not alarm to notify the clinician.

RISK TO HEALTH:

Failure to adequately detect air in line could lead to a potential increase in the risk of an air embolism.

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

All competent authorities have been notified of this action.

INSTRUCTIONS TO CUSTOMERS:

1. Complete the attached Response Form within 10 days and return it to Caddsolis@smiths-medical.com. Please complete and return the form even if you do not have any of the affected product in your possession
2. Once the Response form has been acknowledged, customer services will contact you to arrange collection of your device/s. However, please do not return any accessories as they will not be replaced. Please be sure to include a completed response form in each box of product that is returned.
3. Once the Response form has been acknowledged, customer services will contact you to arrange collection of your device/s. However, please do not return AC Adaptors or power cords as they will not be replaced. Please be sure to include a completed response form in each box of product that is returned.
4. **DISTRIBUTORS or Pharmacy Suppliers: If you have distributed potentially affected devices to your customers, please immediately notify them of this field notification by providing the information detailed in the Field Safety Notice, with the accompanying Response Form 1a. All communication to Smiths Medical**

must be completed by the Distributor or supplier. Please do not permit your end user to respond directly or return devices for replacement.

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 Caddsolis@smiths-medical.com.

Sincerely,

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

Enclosures: Attachment 1 – Field Safety Notice (FSN), Response Form, Response From 1a (Distributors and Suppliers)