

Update - Field Safety Notice

Heparin syringe compatibility with 4008H, 4008B, 4008S (excl. S V10), Art (Standard/Universal) and Prometheus

Date: January XXth, 2025

Dear Valued Customer,

Fresenius Medical Care is contacting you because you have been identified as a user of the no longer sold 4008H, 4008B, 4008S (excluding S V10), Art (Standard/Universal), or Prometheus dialysis machines.

During our post-market surveillance activities Fresenius Medical Care received reports that the replacement BD Plastipak 30ml LL syringe (article code F00012137) is not locking properly into the heparin syringe tray of the following devices (see Table 1):

Table 1. Affected Products

Product Name	Product Code
4008H	M20068(1) 4008H
4008B	M20011(1) 4008B
4008S (excluding S V10!)	M20066(1) 4008 S Standard
	M20067(1) 4008 S (Standard + CDS)
	M20084(1) 4008 S (Standard + ONLINEplus)
	M20085(1) 4008 S (Standard + CDS + ONLINEplus)
Art (Standard/Universal)	9798931 Art Standard
	9798941 Art Universal
Prometheus	M201231 Prometheus Standard Hepa
	M201241 Prometheus Standard CiCa

Currently the BD Plastipak 30ml LL syringe is the only approved 30ml heparin syringe for use with the affected devices following the phase-out of its predecessor.

Due to a smaller outer diameter (as compared to the Fresenius Medical Care predecessor), the syringe may fall out of the syringe pump tray during treatment by applying a small amount of force, e.g. when adjusting the disposable / consumables. There has been no change to the BD Plastipak 30ml LL syringe.

The heparin line is placed after the blood pump on the arterial blood line. The positive pressure at this point may cause blood in the heparin line to rise and push the syringe plunger out of

the syringe. This may result in an uncontrolled loss of blood and can lead to serious patient harm.

Fresenius Medical Care recommends that healthcare providers do the following:

Stop using the BD Plastipak 30ml LL syringe with the above-mentioned Fresenius Medical Care devices.

Please apply adequate anticoagulation according to prescription by other means. Consult the responsible physician.

We sincerely apologize for any inconvenience this may cause. Fresenius Medical Care is committed to ensure that our products and services consistently meet the highest standards of quality and safety for patients and healthcare providers.

Please distribute this Safety Notice to all those within your organization who need to be aware of it.

In case of any further questions do not hesitate to contact:

Name (*Please adapt locally*)

Telephone (*Please adapt locally*)

E-mail XXX@freseniusmedicalcare.com (*Please adapt locally*)

Sincerely yours,

Name and Signature (*please adapt locally*)