

Dec 8, 2011

Re: Grifols product stopper redesigned to address complaints related to latex-free stoppers used in 100, 50 and 25 mL product formats

Dear Customer:

Grifols Canada Ltd (formerly Talecris Biotherapeutics, Ltd) has initiated distribution of product with a redesigned 20 mm latex-free stopper.

Grifols Canada Ltd has previously communicated that when switching from a latex-containing stopper to a latex-free stopper, there were reports that these stoppers may be pushed into the vial, when using an IV spike to enter the stopper of the 100, 50 and 25 mL product vials. Grifols identified the root cause of this issue to be a change in the stopper material (from latex-containing to latex-free material) and in the stopper dimensions.

The majority (> 97 %) of the stopper complaints reported in Canada involve the Albumin 25%, 100 mL product. The reported failure rate is < 0.2 % for this product format. In all reports to-date, the impacted vial has been discarded or returned for evaluation, and the contents were not transfused.

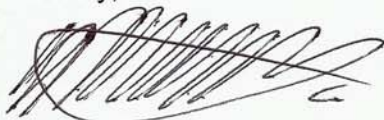
Grifols has previously communicated that the occurrence of this issue may be minimized by closely following the product monograph administration instructions (i.e., the stopper should be penetrated perpendicular to the plane of the stopper, within the area delineated by the raised ring) and by using an IV set that has a relatively smaller diameter (e.g., < 6 mm) and/or sharper stopper spike.

Grifols understands that this issue has inconvenienced and impacted its customers. To further minimize occurrence of this issue, Grifols has implemented a redesigned latex-free stopper that is more robust and compatible with IV spikes. Grifols is now manufacturing products using this redesigned stopper and has initiated distribution of products with the redesigned stopper to the Canadian market.

Grifols is committed to customer satisfaction; we apologize for any inconvenience that this issue has caused, and we appreciate your patience while we work to address this issue.

If you have any questions or concerns regarding this information, please do not hesitate to contact Grifols Medical Information at 1-866-482-5226.

Sincerely,



Mary Hughes, PhD MBA
Sr. Director Sales & Marketing