B BRAUN
SHARING EXPERTISE

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Urgent Field Safety Notice
GELITA TAMPON
Return of the Medical Device to the manufacturer
Att. Users of above products

October 03rd, 2022

Dear Sir or Madam,

B. Braun Surgical, S.A.U. is voluntarily recalling Gelita Tampon product. Gelita Tampon is a spongy haemostat intended for control local haemorrhage and for filling dead spaces, made from hardened gelatin of porcine origin that is completely biologically degradable. Absorption takes place over a period of approximately 4 to 6 weeks as a result of phagocytosis and enzymatic degradation. The large surface area of the sponge-like structure favours the adhesion of platelets and thus, leads to a rapid coagulation of the blood. The gelatine additionally stabilizes the coagulum. Gelita Tampon is supplied as rectangular pieces of various sizes.

Gelita Tampon is indicated to stop venous-capillary or parenchymatous haemorrhage, when suture, ligature or electro-coagulation is not possible in: Neurosurgery, orthopaedic surgery, urology, vascular surgery, hepatic surgery, ear nose throat surgery, and for filling dead spaces and/or control bleeding in dental coagulum.

Identification of affected medical devices
Reference number and name:

Reference number	Reference name
2070014	GELITA-TAMPON 1 X 1 X 1 CM
2070103	GELITA-TAMPON 1 X 1 X 1 CM 045
2070154	GELITA-TAMPON 1,5 X 1,5 X 1 CM 045
2070600	GELITA-TAMPON 8 X 5 X 1 CM
2070707	GELITA-TAMPON 8 X 2 X 1 CM

Batch numbers: This recall is not limited to a particular batch number for the reasons described below. All products described above, still within shelf-life are being recalled. The shelf-life of these products is 5 years.

Description of the medical device deficiency
The supplier of Gelita Tampon product informed us that during a routine bioburden testing, the endotoxin concentration of the product in some samples has been measured above the limit. Since these "outliers" in testing cannot be reconciled at this time, it has been decided to take a very conservative approach and recall all product, even that found to be within specification.

Potential harms associated
Bacterial endotoxins, found in the outer membrane of gram-negative bacteria are members of a class of phospholipids called lipopolysaccharides (LPS). LPS are not exogenous products of gram negative bacteria. Endotoxin is commonly found everywhere in the environment, and it is the most significant pyrogen in parenteral drugs and medical devices. The release of LPS from bacteria takes place after death and lysis of the cell. Endotoxins can elicit a pyrogenic/inflammatory response from the human body. In rare cases, septic or anaphylactic shock might occur.
If the hospital uses a product affected by this issue, an acute pyrogenic reaction might be expected within 2-5 days after use. If the patient presents the complication described the hospital protocol for such situations will be acted upon accordingly. No further follow-up of the patient is required.

Actions to be taken
Please identify and quarantine if you still have the listed product in your warehouse.

Please check with your customers if they still have the listed product in their warehouse. If yes, ask them to send the product back to you immediately.

Once you have all affected units for return contact us for the management of the material.

Please, fill out the attached "FSCA/Recall Confirmation Form" and send the completed form to us by November 03rd, 2022.

This notice needs to be passed on all those who need to be aware within your organization and to any organization where the potentially affected devices have been transferred.

If you have any questions regarding this voluntary product recall, please contact us at the e-mail: vigilance_CT@bbraun.com.

We apologize the inconveniences we might have caused.
Thank you for your cooperation.

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