B|BRAUN
SHARING EXPERTISE

B. Braun Surgical, S.A.U.
Carretera de Terrassa, 121
08191 Rubí
España
www.bbraun.com

Urgent Field Safety Notice
SURG LOOP SILIC YELLOW 1.5MM 2X45CM; reference B1095030 and batch 621202; and SURG LOOP SILIC YELLOW 1.5MM 75CM; reference B1095234 and batch 621156
Return of the Medical Device to the manufacturer
Att. Users of above products

November 2nd, 2021

Dear Sir or Madam,

B. Braun Surgical, S.A.U. is voluntarily recalling two reference/batches of Surgical Loop.

Surgical Loop is a special set for the intra-operative isolation, marking, mechanical support and looping of organs, blood vessels, tendons and nerves.

Identification of affected medical devices

Product name: SURGICAL LOOP SILICONE YELLOW 1.5MM 2X45CM
Reference; B1095030
Batch; 621202

and

Product name: SURGICAL LOOP SILICONE YELLOW 1.5MM 75CM
Reference; B1095234
Batch; 621156

Description of the medical device deficiency

An internal non-conformity is found in yellow silicone material affecting the above indicated Surgical Loop Silicone Yellow finished products. In particular, there was found a fungal contamination on the yellow silicone material that did not comply with the established biological requirements.

Potential harms associated

If a device has been manufactured with a raw material with non-compliant bioburden load, the sterilization process cannot be guaranteed. Therefore, in a worst-case scenario, a non-sterile product (but labelled as sterile) is placed in the sterile field or used during the surgery.

The use of this product could lead to provoke infection causing a risk of sepsis, allergic reaction, foreign body reaction that could lead to a life-threatening injury, need of treatment or reoperation.
Surgical Loop is intended for a single use, and it is not intended to remain in the body.

In those patients that the device has already been used, no additional follow-up is required, if the patient presents any of the complications described, the hospital protocol for such situations will be acted upon accordingly.

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 December 2nd, 2021.

This notice needs to be circulated to 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.

Yours faithfully,

B|BRAUN
B. Braun Surgical, S.A.
Carretera de Terrassa, 121
08191 Rubí (Barcelona)
Tel.: 93 586 62 00

Miguel Ángel Benade
Global Manager of Quality &
Technical Responsible (Spain)
B. Braun Surgical, S.A.U.

Martina Laporte
Quality and Regulatory Affairs Director
CoE OR Supply
B. Braun Surgical, S.A.U.