Important Safety Information

Voluntary Recall of Lot FBD82, I/A System single use BSD 515

Issued by

Bürki inno med AG
Industriestrasse 67
9443 Widnau
Switzerland

Dear distributors, dear users,

In internal tests based on user feedback, we observed reduced irrigation flow in two BSD 515 irrigation handpieces of the production lot FBD82 (date of production: 2024-06-26).

While the other tested irrigation handpieces were fully compliant, we cannot exclude that there are other handpieces from the batch FBD82 that show the same characteristics. There are no reports of any health impact on patients. However, the duration of the irrigation/aspiration process may be prolonged. The performance of the irrigation handpiece may feel unexpected for surgeons.

Our analysis showed that traces of solid and biocompatible adhesive, which is used in production to glue the cannula to the handle, was found in the cannula, creating a slight constriction of the cannula, i.e. a small section with a reduced diameter. We conclude that the observation relates to an automated equipment that was used for this particular lot.

As a measure of precaution, we voluntarily recall all remaining products of the lot FBD82.

Therefore, we kindly ask you

a) As a distributor, please no longer ship products of lot FBD82 to users.
b) As a healthcare institution, please make sure that all users of the product and other involved personnel are informed about this important safety notice.
c) As a user, please no longer use products of the batch FBD82.
d) As a distributor and as healthcare institution, please send back products of the lot FBD82 that you may still have in stock to support our root-cause-analysis.

Please don’t hesitate to contact us for further coordination and questions.

With best regards

Bürki inno med AG, Manufacturer
(Date, Signature)

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