Field Safety Corrective Action

End Users level

Recall Notification

FSCA-identifier : FDS MED 3130

Marchaux-Chaudefontaine, November 22nd, 2021

Scope: FSCA – END USER

Affected product:

- MICRODEEP®
- References: D08-05AT, D08-08AT, D08-10AT, D08-12AT, D08-15AT, D08-18AT, D08-05AM, D08-08AM, D08-10AM, D08-12AM, D08-15AM, D08-15BM, D08-15CM, D08-18AM, D08-18CM.

Affected Lots :

- Devices shipped after January 1st, 2018.

Dear Customer,

This is to inform you that DIXI Medical S.A.S. has initiated a voluntary Field Safety Corrective Action (FSCA) of the MICRODEEP® from the market as a precautionary measure.

Description of the issue :

The sterile barrier of the MICRODEEP® deep electrodes is provided by a double packaging consisting of a blister pack with a Tyvek seal (primary packaging) then a Tyvek bag (secondary packaging).

This recall has been initiated due to a partial and localized deformation of the primary packaging which may be accompanied by perforation in a limited number of cases. This issue could cause a defect in the maintenance of the sterile barrier of the device causing potential severe complications for the patient. The secondary sterile barrier composed of the Tyvek bag remains compliant.

No case of postoperative complication or injury has been reported to date. In addition, sterility tests have been carried out in collaboration with an accredited laboratory and no device with an integrity defect has been declared "non-sterile".

DIXI Medical S.A.S is recalling these lots in an effort to provide our customers and their patients with the highest quality product possible. We take this matter very seriously and we are committed to ensuring our products meet the highest quality and safety standards.

Actions to be taken - For devices currently in <u>your stock</u>:

1. If you have devices in stock, stop using immediately, quarantine and keep the MICRODEEP® electrodes in a secure location to prevent further usage.
2. Follow the instruction communicated by your local DIXI Medical Affiliate or Distributor.

In an effort to ensure continuity of supply and limit the inconvenience to your service, DIXI Medical S.A.S will replace, free of charge, your impacted products.

Transmission of this Field Safety Corrective Action

Please forward this information to your staff and biomedical engineers that may use the MICRODEEP® lot(s) in your healthcare facility.

We sincerely regret any inconvenience this may cause and appreciate your cooperation with this matter.

This recall is being made with the knowledge of National Competent Authorities.

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