Field Safety Corrective Action

Direct Customers

Recall Notification

FSCA-identifier : FDS MED 3130

Marchaux-Chaudefontaine, November 22nd, 2021

Scope : FSCA – DIRECT CUSTOMERS

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 between January 1st, 2018 and October 19th, 2021.

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. Complete the attached *"FSCA 3130 MICRODEEP - Response Form"* to acknowledge that you have received this DIXI Medical FSCA and, if applicable, indicate on the form the reference and serial numbers of devices in your stock.
3. <u>Email the completed *"Response Form"* to DIXI Medical S.A.S (quality@diximedical.com). Upon receipt of this document, DIXI Medical S.A.S will organize the shipment of new devices.</u>
4. Once you receive new placement devices from DIXI Medical SAS, arrange the product returns to DIXI Medical S.A.S. 2A Route de Pouligney, 25640 Marchaux-Chaudefontaine, France. Please use the TNT account number **7921936.**

IMPORTANT NOTE : if a surgery is scheduled and you cannot ship back some devices, then a control of the packaging has to be performed before the surgery by the medical staff based on the instruction that we will provide you. If a specific training is required DIXI Medical is at your disposal to organize specific training or to answer all questions.

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.

<u>Transmission of this Field Safety Corrective Action</u>

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.

Cédric Boesch
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