Field Safety Corrective Action

Distributor level

Recall Notification

FSCA-identifier : FDS MED 3130

Marchaux-Chaudefontaine, November 22nd, 2021

Scope : FSCA – DISTRIBUTOR

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> (distributor level):

1. If you have devices in stock, stop shipping immediately, quarantine and keep the MICRODEEP® electrodes in a secure location to prevent shipping to an end user.
2. Follow the instruction "*FSCA 3130 MICRODEEP - Blister Control Protocol*" in order to carry out the required visual checks and identify the impacted blisters. DIXI Medical is at your disposal to organize specific training or to answer all your questions if required.
3. 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 impacted (with a visible deformation).
4. Email the completed *"Response Form"* to DIXI Medical S.A.S (quality@diximedical.com). If you have any urgent scheduled delivery please contact (abed.hammoud@diximedical.com)
5. Arrange the product returns to DIXI Medical S.A.S. 2A Route de Pouligney, 25640 Marchaux-Chaudefontaine, France

Actions to be taken - For <u>unused devices in the field (hospital level):</u>

- Communicate the "*FSCA 3130 MICRODEEP - End Users*" provided by DIXI Medical to all your customers.
- Confirm with each of your customers which option you want to follow:

Option 1:

1. Ask the hospital to send you all their unused stock of MICRODEEP®
2. Organize the replacement of their stock according to the priorities of each customer.
3. Follow the instruction " *FSCA 3130 MICRODEEP - Blister Control Protocol*" in order to carry out the required visual checks and identify the impacted blisters.
4. Complete the attached *"FSCA 3130 MICRODEEP - Response Form"* and indicate on the form the reference and serial numbers of devices impacted (with a visible deformation).
5. Email the completed *"Response Form"* to DIXI Medical S.A.S (quality@diximedical.com)
6. Arrange the product returns to DIXI Medical S.A.S. 2A Route de Pouligney, 25640 Marchaux-Chaudefontaine, France

IMPORTANT NOTE : if a surgery is scheduled and your customer 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 provided you. If a specific training is required DIXI Medical is at your disposal to organize specific training or to answer all questions.

Option 2:

1. Carried check the stock of MICRODEEP® at the end user by one of your employees who has read and understood the control instruction *("FSCA 3130 MICRODEEP - Blister Control Protocol")*. Complete the attached *"FSCA 3130 MICRODEEP - Response Form"*
2. Organize the replacement of the impacted devices.
3. Email the completed *"Response Form"* to DIXI Medical S.A.S (quality@diximedical.com)
4. 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.**

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.

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.

…