

Field Safety Corrective Action

Recall Notification

FSCA-identifier : 2025-001

Marchaux-Chaudefontaine, July 23th, 2025

Scope : *Field Safety Corrective Action - RECALL*

Affected product :

- MICRODEEP® Depth Electrode
- References: D08-12AM

Affected batches :

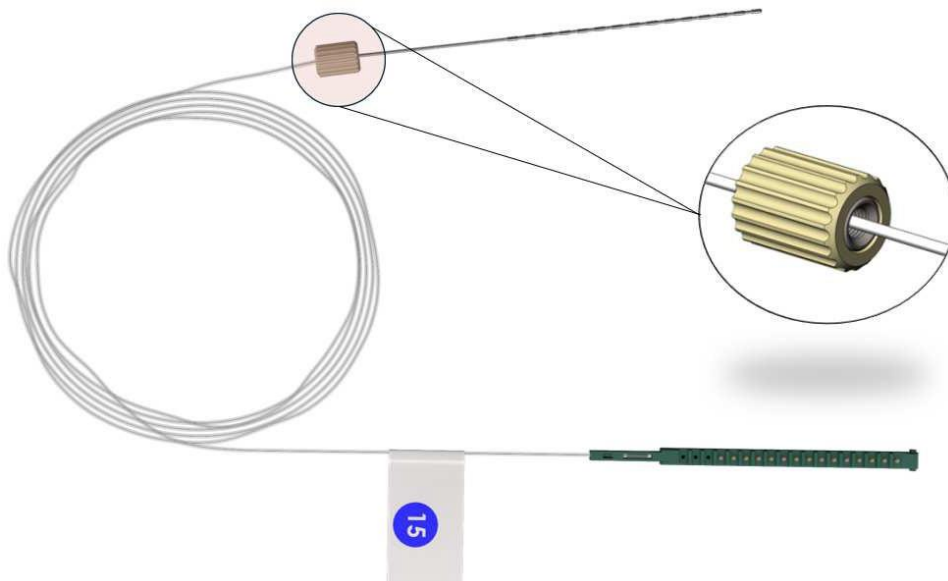
- Devices shipped after April 1st, 2025 (See attached list for your facility)

Dear Customer,

We would like to inform you that DIXI Medical S.A.S. is initiating a voluntary Field Safety Corrective Action (FSCA) as a precautionary measure regarding the devices listed above.

Description of the issue:


During a production quality control, an assembly defect was identified concerning the caps used in our devices. See image below.



The following issue has been observed:

- When mounted on MICRODEEP® depth electrodes: although the cap is screwed onto the guiding screw, it is possible for the electrodes to slip inside the cap. This means that the clamping function provided by the screw may not be fully effective, compromising the secure positioning of the device.

Actions Required:

1. Refer to the **attached list of affected devices** to identify those potentially impacted within your facility.
2. Immediately retrieve the identified devices, isolate and label them as "Non-Conforming".
 - If a device has already been implanted, we ask that you exercise increased vigilance, by regularly checking the positioning of the electrodes.
3. **Complete the attached form titled “EN-FSCA-07 Urgent Field Safety Corrective Action – Recall Response Form” to confirm receipt of this Field Safety Notice issued by DIXI Medical S.A.S.**
4. Return the completed form via email to the following address:
 quality@diximedical.com
5. Upon receipt of your response form, **DIXI Medical will send replacement devices.**
6. Finally, **collection of the affected products** will be arranged by DIXI Medical as soon as possible.

For any questions, please contact DIXI Medical at the following number: +33 3 81 88 90 89