



Urgent Field Safety Notice
1882900 DRILL MINI-TREPHINATION 2.0mm
Recall

March 2019

Medtronic reference: FA862

Dear Healthcare professional,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling the listed Mini-Trephination 2.0mm Drill model 1882900.

Issue Description:

The Frontal Sinus 2.00mm Mini-Trephine Drill is an interchangeable drill bit intended for use with the Xomed XPS System and Drill Guide with Skin Protector. The 2.0mm reusable drill is packaged singly and provided sterile for first time convenience. The Frontal Sinus MiniTrephination Drill is indicated for use in incising or removing bone and tissues in ear, nose, and throat, including sinus and rhinology surgery.

The issue is that the drill may not cut properly. The hazardous situation that may occur if the Mini-Trephination Drill does not function properly is that the procedure being performed may be delayed, causing extended exposure to anesthesia for the patient.

Product Scope:

CFN	GTIN	Lot Number
1882900	00681490047241	0215115425
1882900	00681490047241	0215115426
1882900	00681490047241	0215142888
1882900	00681490047241	0216403765
1882900	00681490047241	0216439625

Actions:

Our records show that you were shipped affected product. We are requesting your assistance by performing the following:

- Examine your inventory immediately and quarantine the device.
- Return your affected device(s) to Medtronic. Your Medtronic Representative can assist you in returning the device(s).

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Medtronic has notified the Competent Authority of your country (JAZMP) of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,

Local/BU Manager