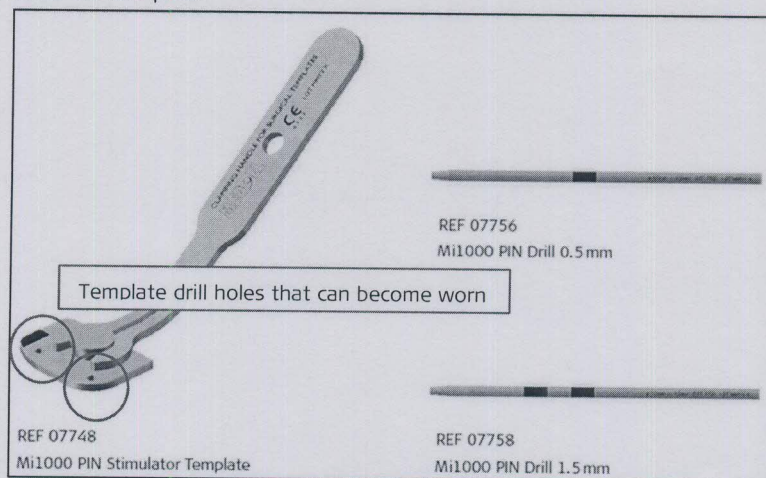


## Urgent—Medical Device Field Safety Notice (FSN) Voluntary Withdrawal of Mi1000 PIN Drills (REF 07756 and REF 07758)

Dear Madam or Sir,

MED-EL is voluntarily notifying surgery staff of a potential hazard that can occur with the Mi1000 PIN Drill Guide after repeated use and if wear is undetected. MED-EL has determined that the Mi1000 PIN drills must no longer be used during cochlear implant surgery in the ENT clinic to prevent any harm arising from undetected wear. This letter requests your immediate action to identify and discard these drills.

The Mi1000 PIN Drill Guide (REF 07613) is an optional, reusable surgical tool that can be used by ENT surgeons during Mi1000 CONCERTO PIN surgeries. The Mi1000 PIN Drill Guide (pictured below) consists of Mi1000 PIN Stimulator Template (REF 07748) consisting of a titanium base and clamping handle (left) and two drills (right) for 0.5mm (REF 07756) or 1.5mm (REF 07758) drilling depth. The purpose of this tool is to determine the correct distance between drill holes for the pins.



If the holes of the Mi1000 PIN Stimulator Template are damaged or excessively worn after repeated use, this can lead to enlarged drill holes. If this occurs and the included stainless steel Mi1000 PIN Drills are used with a worn template, the integrity of the stopper function of MED-EL supplied drills might be compromised and allow the drills to penetrate beyond the indicated depth. This specific combination of factors can create a potential hazard whereby the stepped drill can penetrate more deeply into the bone than intended, and possibly cause damage to anatomical structures during the use of the Mi1000 PIN Drill Guide. The current Instructions for Use (IFU) of Mi1000 PIN Drill Guide (AW7616) contain the following precautions and warnings:

*"Before use each component shall be visually inspected for damage, excessive wear or corrosion. Damaged, worn or corroded parts should not be used".*

All lot numbers are affected by this potential condition; therefore all drills in distribution are affected.

Because repeated use can enlarge the Template drill holes and the required visual inspection of these parts may prove to be challenging due to the small size of the holes, MED-EL, as a precautionary measure, has determined that the Mi1000 PIN drills must no longer be used to prevent the possibility of such an occurrence. The Mi1000 PIN Stimulator Template and handle (left, above) can still be used to mark the distance and location of the holes to be

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