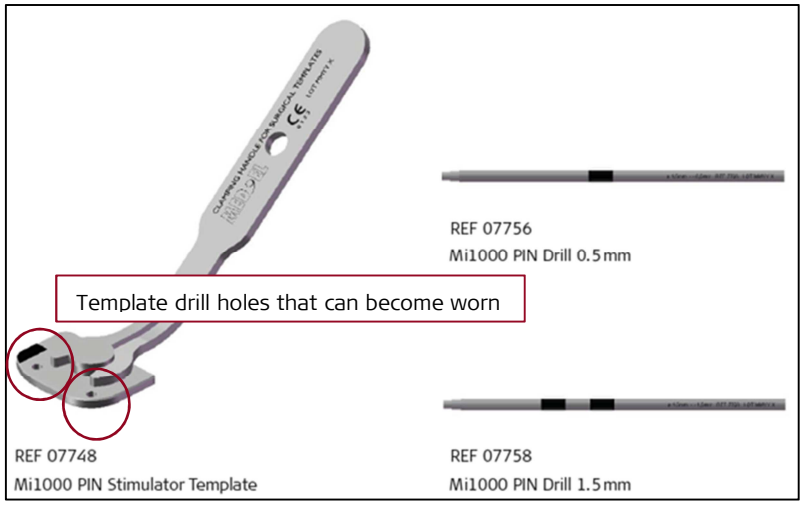
Urgent—Medical Device Field Safety Notice (FSN)
Voluntary Withdrawal of Mi1000 PIN Drills (REF 07756 and REF 07758)

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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drilled for the Mi1000 CONCERTO PIN implantations. Any potential enlargement of the template holes described above would not adversely impact the surgeon's ability to use the template for marking the correct distance between the pin holes, as it cannot significantly alter this distance beyond its acceptable tolerance. Standard, commercially available diamond burrs should be used to drill the holes after the location is marked, under full visualization, following standard clinical practice.

The instructions below should be followed using the Mi1000 PIN Stimulator Template and handle for marking of the pin distance.

General information about use

The Mi1000 PIN Drill Guide is used after the successful opening of the operation field and the flattening of temporal bone in the area in which the stimulator will be placed.

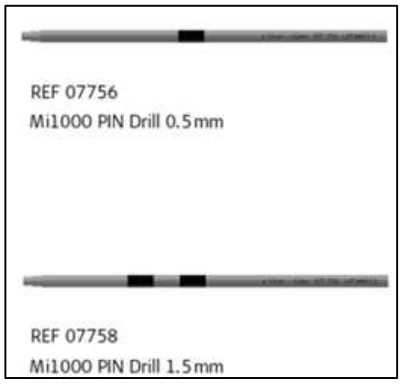
1. Assemble the Drill Guide by clipping the Clamping Handle onto the Mi1000 PIN Stimulator Template.
2. Place the Mi1000 PIN Drill Guide on the proposed stimulator site with the template's guide holes being adjacent to the mastoidectomy edge.
3. Mark the correct pin distance using the holes of the Mi1000 PIN Stimulator Template as a guide.
4. Removing the Mi1000 PIN Stimulator Template, drill holes with a standard 1.0mm diamond burr to a depth of about 1.5 mm.
5. MED-EL recommends checking the hole distance and depth using the related Implant Template.

For patients with skull thickness of less than 1.5mm, it is recommended to drill only 0.5mm deep holes. This is to avoid any possible damage to the dura. A pre-operative assessment of the skull thickness is recommended.

MED-EL is informing the Competent Authorities and/or Ministries of Health that we are initiating a Field Safety Corrective Action (FSCA).

This FSCA includes the following scope and request for actions:

- **Immediately stop use and/or distribution of the Drills** (REF 07756 and REF 07758, right) in any surgical kit product configuration.
- Please examine your inventory immediately to determine if you have any of the drills cited above. Please promptly destroy or return any affected drills in your possession.
- Report the number of affected units within your possession and actions taken (destroy or return) with these units.
- ***Please share this notice with anyone who might be affected by action, including all personnel/hospitals/clinics that may have this surgical tool as part of any MED-EL surgical tool kit.***



For marking the pin distance for Mi1000 CONCERTO PIN implantation surgeries, two options remain:

1. Use of the modified instructions above with the current Mi1000 PIN Stimulator Template to mark the pin hole distance, OR
2. The PIN Drill Guide SI (Small Incision) (REF 09906, pictured right) can be used in countries where this variant is approved and available. This variant does not include drills.

If you have further questions regarding how to return product or other issues, please contact: FSN@medel.com

We kindly ask you to report to MED-EL, within 7 working days of receipt that you have received this alert. You may report receipt of this notice to MED EL via scan/email or fax to:

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Fax: +43 512 288889 690

Mail:
FSN Coordinator
MED-EL Elektromedizinische Geräte GmbH
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We sincerely apologize for any inconvenience this notification may cause and thank you for your quick action to this important notification. We hope this information will help you provide the best care for your patients and continued safe use of MED-EL implants and accessories.

Respectfully,

[redacted]

Corporate Director, Regulatory Affairs & Quality Assurance