Health Technology Review	
Technology Ref.:	HTA22024
Technology Name:	Auditory Brainstem Implant
Approvals by International Bodies:	FDA, CE.
Company name:	MedEl
Agent in UAE:	Cleveland Clinic Abu Dhabi
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Short Description of the Technology:	Auditory Brainstem Implant (ABI) bridges the connection between brain and cochlea when the cochlear nerve is absent. It provides a hearing impression for the patient, is helping with lip reading and can create in some patients a true hearing impression. It requires implant onto the brainstem itself where the origin of the cochlear function is located. It is placed after tumour resection on the area and based on the best available contacts by intra-operative electrophysiological stimulation.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The auditory brainstem implant (ABI) technology is CE certified and FDA approved technology, an (ABI) has two parts: an external part (the 'processor', worn on the ear) and the surgically implanted internal part. A microphone on the processor picks up the sound around it, and turns it from a sound wave into an electrical signal. The processor then transmits the sound signal to the internal part of the hearing implant. This consists of a receiver just below the skin, together with the implant array which is positioned within the brainstem. its applied for the people with severe hearing loss who can't benefit from a hearing aid or cochlear implant. This is most commonly due to a missing or very small hearing nerve or severely abnormal inner ear (cochlea). The auditory brainstem implant directly stimulates the hearing pathways in the brainstem, bypassing the inner ear and hearing nerve to help you detect sounds.

Due to the medical urgency, the fact that the application, the application comes from the most specialized healthcare provider in this field in Abu Dhabi and the fact that leading foreign regulatory bodies (FDA, NICE) have approved the use of this device, DoH did not consult further subject matter experts from the local market.

Advantages	Disadvantages
The ABI is a safe procedure when performed by an experienced surgical and rehabilitation team	Rare Expected side effects after the implantation procedure will be like: meningitis, leaks of fluid found in the brain and spine, facial nerve weakness, pain and dizziness.
Enhance the Patient Quality of life; ABI can restore meaningful sound awareness in most	Implant failure (failure to provide useful auditory sensations or movement/displacement

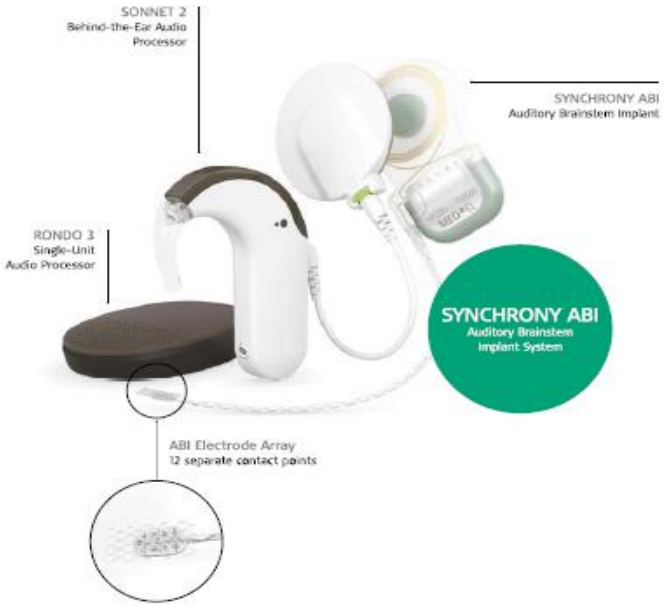
patients & Improve the ability to identify environmental sounds	of the electrodes).
Improve face-to-face communication by improving lip reading ability	It requires experts & Company approval on Surgical sites to perform the surgery
Good Alternative for Patients with hearing difficulties who can't benefit from a hearing aid or cochlear implant	
No history of post-market safety concerns could be located for this device.	
Current evidence on the safety and efficacy of auditory brain stem implants appears adequate to support the use of this procedure by surgical teams experienced in this technique	

We recommend an **approval of using this technology** with the following conditions:

1. The medical procedure shall be performed by Experienced trained professional limited to neurosurgical departments such as CCAD, SKMC and SSMC.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image



Population, setting and intended user for Technology "Auditory brainstem implant"

- **Population/ Intended User**;
  - ABIs for teens and adults are FDA approved only for those with profound hearing loss, usually found in patients with neurofibromatosis type 2
- **To be performed by**:
  - By neurosurgeons
- **Clinical Setting:**
  - Hospitals, special surgery centers
- **Condition of use:**
  - One main use of the auditory brainstem implant is for those with the condition Neurofibromatosis type 2 (NF2).
  - An auditory brainstem implant provides hearing to people with hearing loss who can't benefit from a hearing aid or cochlear implant. This is most commonly due to a missing or very small hearing nerve or severely abnormal inner ear (cochlear)
- **Exclusion criteria:**
  - Other conflicting medical issues