



Health Technology Review	
Technology Ref.:	HTA23030
Technology Name:	EarWell® (nonsurgical infant ear deformity correction device)
Approvals by International Bodies:	FDA
Company name:	MEDICAL IDEA MEDICAL SURGICAL ARTICLES & REQUISITES TRADING L.L.C
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Short Description of the Technology:	<p>EarWell® Infant Ear Correction System is the first and most advanced non-surgical infant ear deformity device to correct infants ear deformities without surgery or incision. In the clinic and without any type of Anesthesia, it is fixed on the infant ear, starting by mounting the posterior shell to surround the ear and held on position by non-allergic adhesive tape, then retractors are placed and fixed around the helical rim to mould the ear into the desired position. After that the conchal formers are placed to shape the conchal crus. The last step is applying the outer lid to hold all components securely in place. It depends on the flexibility of the ear cartilage at the early weeks after birth (1-16 week) without the need for waiting till the age of 5 to do invasive surgery and with high acceptance & convenience usage.</p>
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>The technology is a non-invasive auricular corrective system (ear moulding) to use for the correction of ear deformities in infants. It depends on the softness of children's ears and the capableness of their cartilages to correct the shape of the auricle. It mostly effective when its applied in early infant age (less than three weeks of age). The early application of this technology can avoid long-term surgical treatment and psychological damage. The technology is FDA approved and it's been used in USA, UK and other countries.</p>	
Advantages	Disadvantages
Scientifically proven effectiveness in reshaping and adjust infant ears deformities in early neonatal stage.	The successful treatment with EarWell® depends on time of diagnosis, complexity of deformities and adherence to treatment plan.
As per provided studies, the early non-surgical treatment saves costs compared with school-aged surgery, reduces the incidence of complications, and avoids the pain of invasive treatment	More effective on infants less than three weeks of age, while in bigger age the desired results will be less.
FDA approved technology	Minor side effect and complications like skin eczema, irrigation and pressure sores.

Non-invasive & Safe approach; no risk on patients neither professionals.	Treatment timeline (4 to 6 weeks) and could be longer base on infant age.
Easy to use and could be applied in doctor office	Required training for the healthcare professionals

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

1. Approval on the use of EarWell® Infant Ear Deformity Correction System version BE-450 & BE-400
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.

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



Fig. 1. The EarWell Infant Ear Deformity Correction System (Model BE-450) with and without ear deformity. The



Population, setting and intended user for Technology “EarWell® (nonsurgical infant ear deformity correction device)”

- **Population/ Intended User;**
 - Infant with ear deformities at early age (up to three weeks)
- **To be performed by:**
 - By Healthcare Professional
- **Clinical Setting:**
 - At doctors’ clinic.
- **Condition of use:**
 - As per the manufacturer instruction and doctor prescription.
- **Exclusion criteria:**
 - Other conflicting medical issues