



New Device Approvals

MED-EL COMBI 40+ Cochlear Implant System - P000025

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: MED-EL COMBI 40+ Cochlear Implant System with C40+, C40+S, and C40+GB Implants, CIS-PRO+ and TEMPO+ speech processors
Manufacturer: Med-El Corporation
Address: 2222 E. Highway 54, Suite B-180, Durham N. Carolina, 27713
Approval Date: August 20, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/P000025a.pdf>

What is it? The MED-EL COMBI 40+ is a cochlear device implant system that allows patients with severe hearing loss to understand speech and environmental sounds. It has two parts:

- An external part that receives and interprets sound and sends the sound to an internal part.
- An internal part that is implanted under the skin behind the ear and attaches to the cochlea in the inner ear. For a picture of the inner ear go to <http://www.nlm.nih.gov/medlineplus/ency/imagepage/1092.htm>

How does it work? Using a small microphone, the external part picks up sound from the patient's surroundings, interprets it, and sends it to an internal receiver in the implanted part of the device. This receiver separates the sound into groups of sounds, which it sends to the cochlea. The cochlea sends these sounds through the auditory nerve to the brain, allowing the patient to hear.

When is it used? The device is used when patients have extremely poor hearing (severe to profound hearing loss) and do not receive enough benefit from hearing aids.

What will it accomplish? It can provide awareness and understanding of environmental sounds, including speech.

When should it not be used? This device will not work for patients who have:

- A damaged or missing 8th cranial nerve (auditory),
- A central auditory pathway (nerve pathway to the brain) that is not normal,
- A poorly developed cochlea,
- No inner ear
- Frequent or long-lasting ear infections

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/P000025.html>

Other: National Institutes of Health, National Institute on Deafness and Other Communication Disorders (NIDCD):

- General information on hearing, smell, taste: <http://www.nidcd.nih.gov/health/hb.htm>
- Information on the cochlear implant: http://www.nidcd.nih.gov/health/pubs_hb/coch.htm
- Glossary of hearing-related terms from A to W
<http://www.nidcd.nih.gov/health/glossary/glos1.htm>

(Updated 8/19/2002)