MED-EL Announces FDA Approval of New FLEX™24 and FLEX™28 Electrode Arrays

New Cochlear Implant Surgical Option Engineered for Atraumaticity

May 15, 2012 – (Durham, NC) – MED-EL Corporation announced today the U.S. Food and Drug Administration approval of the new FLEX™24 and FLEX™28 electrode arrays. The exciting new surgical option will be coming to the U.S. market soon for use with the MAESTRO™ Cochlear Implant System.

The FLEX electrode design incorporates FLEX-Tip™ technology and MED-EL’s exclusive wave-shaped wires. The electrode arrays feature paired electrode contacts for the seven basal channels and single electrode contacts for the five apical channels. This design creates an electrode that is narrower, tapered and more flexible on the apical end to better match the shape of most cochleae. Offered in two lengths, 28mm or 24mm, the new electrode arrays offer surgeons additional options for atraumatic insertion, which provides the best possibility for preserving the delicate structures in the cochlea.

All of MED-EL’s electrode arrays feature ultra-flexible wave-shaped wires, designed to significantly reduce rigidity in comparison to a straight-wire design. This design provides a better chance to preserve the integrity of neural tissue targeted for electrical stimulation. When considering that future hearing treatments may depend on preserving the anatomy, preservation of neural tissue becomes an important goal of electrode design and development. While MED-EL has always provided a number of options to best meet the unique needs of every candidate, the new FLEX electrode arrays are specifically engineered for atraumaticity during both insertion and extraction, if that is required. In addition to the new FLEX options, MED-EL will continue to offer the Standard, Medium and Compressed electrode arrays.

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"With today's rapidly changing technology, it's much more likely that patients will have more than one electrode insertion over their lifetime. A child implanted today will hopefully still be benefitting from cochlear implants or other innovative hearing implant technologies and treatments 80 years from now. So, patients and surgeons want to consider electrodes that are as gentle to insert and extract as possible," said Richard Collette, President and CEO, MED-EL Corporation USA.

"An atraumatic electrode is also very important when thinking about accessing developments on the horizon. Technologies being researched today, including stem cell treatments, genetic treatments, optical stimulation and drug delivery, will likely benefit from intact cell structures. We want to do all we can to help preserve that future potential for our patients, while still providing an opportunity to take advantage of all that our current cochlear implants have to offer," he continued.

In addition to helping to preserve the delicate neural structures for future innovations, many individuals with severe to profound hearing loss may still be able to hear some very loud sounds; this is referred to as residual hearing. Preserved residual hearing after implantation indicates that the electrode was atraumatic and that the surgical technique was excellent. FLEX electrodes are demonstrated to preserve residual hearing in a variety of peer-reviewed publications, thus supporting the goal of ensuring a hearing future for implant recipients.

For more information about ordering the FLEX®24 or FLEX®28 electrode array, visit www.medel.com, or call 888-MED-EL-CI (633-3524).

About MED-EL
Since its founders developed one of the world's first cochlear implants in the 1970s, MED-EL has set new standards in hearing implant technologies, developing and manufacturing technologically advanced hearing solutions for people with varying degrees of hearing loss. MED-EL Hearing Implant Systems, currently used in 96 countries, combine the latest scientific advances, engineering and manufacturing techniques for performance, safety and reliability. MED-EL offers the broadest portfolio of hearing implant systems, including the MAESTRO Cochlear Implant System for those with severe-to-profound sensorineural hearing loss and the unique Vibrant Soundbridge®, a middle ear prosthesis for the treatment of moderate to severe sensorineural hearing loss. The fast-growing medical technology company employs more than 1,000 people worldwide, more than 650 of whom are based at the company's headquarters in Innsbruck, where R&D and production are located.

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