



For Immediate Release

MED-EL Announces FDA Approval of PULSAR, SONATA and MED-EL CONCERT Cochlear Implants for 1.5T MRI

Durham, NC – (June 14, 2013) – MED-EL USA announced today the U.S. Food and Drug Administration (FDA) approval of the PULSAR, SONATA and MED-EL CONCERT cochlear implants for use with 1.5 Tesla (T) MRI systems without the need for surgical removal of the internal magnet. MED-EL's cochlear implants are the only implants available in the United States with this approval. Patients with one of these MED-EL cochlear implants will be able to obtain 1.5T MRI scans upon final labeling approval by FDA, expected by the end of summer 2013.

Magnetic Resonance Imaging (MRI) capability is an important issue for people who have cochlear implants. The FDA approval for MRI imaging at 1.5T without the surgical removal of the magnet is a major breakthrough for people who live with chronic conditions, such as heart disease, cancer and neuromas that may require the regular use of MRI technology. All MED-EL cochlear implants have been FDA approved for 0.2T scans without surgical removal of the magnet since 2001. The addition of 1.5T MRI means that physicians will be able to obtain even higher resolution imaging, allowing better diagnosis and treatment using the most popular scan resolution currently used in the USA.

Pete Unger, a member of MED-EL's Patient Support Team, is one such case. After having surgery to remove a tumor in 2004, Pete's doctors recommended periodic MRIs to monitor the area where his tumor was removed. The surgery left Pete completely deaf on his right side and he soon lost most of his hearing on his left side due to Meniere's disease. Pete says that MRI capability without magnet removal was a primary reason why he chose a MED-EL implant in 2007.

"It's reassuring to know that my MED-EL implant has not only given me my hearing back, but has now given me peace of mind during my follow up care," he added.

Patients with other brands of cochlear implants must have surgery to remove the internal magnet before undergoing an MRI scan and a second surgery is required to replace the magnet after the scan has been obtained. Even surgeries described as "minimally invasive" can cause pain and discomfort, come with an increased risk of surgical side effects such as scarring, and add unnecessary cost from the surgery (including a new, sterile magnet) and lost wages during recovery. Because no additional surgery is necessary for MED-EL's implant users to receive an MRI, there is also no time, aside from actually receiving the MRI, when the recipient needs to go without their audio processor (which must be removed for MRI scanning).

MRI machines are available in a range of strengths, called Tesla (T). The current standard strength is 1.5T in the United States and the vast majority of MRIs performed are done with 1.5T machines. More than 32 million MRIs were performed in the USA in 2011.(IMV) Recent data show that MRI use in the United States has increased by approximately 10% annually between 1996 and 2010.(JAMA)

People who have a MED-EL PULSAR, SONATA or MED-EL CONCERT cochlear implant will not need special permission from the company prior to undergoing an 1.5T MRI; warranties for internal equipment will continue

-more-

to be valid as long as the company's recommendations for scanning are followed. These recommendations will be available on the company's website in the near future. It is important to note that all cochlear implants, including those manufactured by MED-EL, remain contraindicated for MRIs at 3.0T strength in the USA.

While other manufacturers may claim MRI compatibility, MED-EL is the only company that has received FDA approval for patients to undergo 1.5T MRIs without additional surgery to remove the magnet.

About MED-EL

MED-EL Medical Electronics is a leading provider of hearing implant systems worldwide offering the broadest portfolio of hearing implant solutions. The company was founded by Austrian scientists and industry pioneers Ingeborg and Erwin Hochmair, who together developed the world's first microelectronic, multichannel, cochlear implant. In 1990, they laid the foundation for the successful growth of the company when they hired their first employees. To date, the privately held company has more than 1,400 employees around the world.

The cochlear implant was and remains the first replacement of a human sense, the sense of hearing. Today, MED-EL offers the widest range of implantable solutions worldwide to treat the various degrees of hearing loss, including cochlear and middle ear implant systems.

MED-EL's mission is to overcome hearing loss as a barrier to communication and quality of life. Individuals in more than 100 countries enjoy the gift of hearing with a MED-EL Hearing Implant System.

#

Press contact

Rebecca Novak Tibbitt

Ph: (704) 341-1544

Email: Rebecca@RNTCommunications.com

Sources:

IMV 2012 Market Outlook Report. <http://www.imvinfo.com/index.aspx?sec=mri&sub=dis&itemid=200085>
Accessed May 23, 2013.

Smith-Bindman R. et. al. "Use of diagnostic studies and associated radiation exposure for patients enrolled in large integrated health care systems, 1996-2010." *JAMA*. 2012 June 13;307(22):2400-9.

*****FOR DISTRIBUTION IN THE UNITED STATES ONLY*****