

For Immediate Release

MED-EL's COMBI 40+ Cochlear Implant Receives FDA Approval for 1.5T MRI with the Internal Magnet in Place



Approval Provides Historic Access to MRI for Cochlear Implant Recipients

July 14, 2016 – (DURHAM, NC) – Global hearing implant manufacturer MED-EL announced today the FDA approval of its COMBI 40+ cochlear implant as conditionally safe with 1.5T MRI with the magnet in place. The approval demonstrates MED-EL's unprecedented legacy commitment to their recipients. The COMBI 40+ received FDA approval in August 2001,ⁱ and was the first MED-EL cochlear implant offered in the United States.

"From the very beginning, MED-EL has engineered our cochlear implants to be future-ready so that our recipients can access the latest technology as it becomes available. As a company, we continuously strive to support our recipients through the life of their implant. This FDA approval demonstrates an unprecedented level of support in the cochlear implant industry. There is simply no other company that goes to this length to ensure that their end users can access technological advancements, including MRI," said Raymond Gamble, CEO & President, MED-EL North America.

Magnetic Resonance Imaging (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.

MED-EL stands alone in its leadership in pursuing MRI compatibility for its implant recipients. All MED-EL cochlear implants have been FDA approved for 0.2T scans without surgical removal of the magnet since 2001. In June 2013, the company was granted FDA approval for PULSAR, SONATA and CONCERT cochlear implants as conditionally safe for 1.5T MRI with the magnet in place. In January 2015, MED-EL announced the FDA approval of the SYNCHRONY cochlear implant, the first and only implant conditionally approved for high-resolution 3.0T MRI with the magnet in place, considered a breakthrough in MRI and cochlear implant technology.

MRI capability is an important issue for people who have cochlear implants. People who live with chronic conditions, such as heart disease, stroke, cancer and neuromas may require the regular use of MRI technology. Diagnostics with MRI were not routine at the time of the COMBI 40+ approval, however, usage has increased at a rate of 10% per year since 1996.ⁱⁱ In 2015, an estimated 37.8 million MR procedures were performed in approximately 8,465 sites in the United States.ⁱⁱⁱ

Trent Bensheimer of Greenwood, IN, was just 15 months old when he received a COMBI 40+ in his left ear as a part of the MED-EL clinical trials in February 2000. In 2007, Trent received a Pulsar cochlear implant in his right ear. Now 17 years old, Trent is still hearing with his original cochlear implants.

"Trent has always enjoyed sports and being active," said his father, Michael Bensheimer. "There are times that we've wondered about whether or not he would need an MRI and what decisions we would have to make if and when the time came. Having the peace of mind that now Trent can undergo a 1.5T MRI with the internal magnet in place is reassuring to me as a parent, and to Trent as a young adult."

People 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 infection, and add unnecessary cost from the surgery (including a new, sterile magnet) as well as lost wages during recovery. Because no additional surgery is necessary for any of 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. The time separated from hearing is only a matter of the length of the MRI scan, as opposed to days waiting for a surgical incision to heal.

"I'm constantly amazed at the life MED-EL's cochlear implant has enabled my son to have. When Trent first received the COMBI 40+ sixteen years ago, MRI compatibility was not a consideration. The fact that he can have a 1.5T scan today without additional pain and expense of surgery to remove the internal magnet on his original implant is pretty astounding. It just exceeds our expectations," Michael said. "The fact that MED-EL has not left us behind in technology just shows how much this company cares about its recipients."

Medical professionals can download the latest MED-EL MRI safety guidance here:

<http://www.medel.com/us/isi-cochlear-implant-systems>

About MED-EL

Austria-based MED-EL Medical Electronics is a leading provider of hearing implant systems with 29 subsidiaries worldwide. The family-owned business is one of the pioneers in the industry. The two Austrian scientists Ingeborg and Erwin Hochmair developed the world's first microelectronic-multichannel cochlear implant in 1977. The cochlear implant was and remains the first replacement of a human sense, the sense of hearing. In 1990 they laid the foundation for the successful growth of the company when they hired their first employees. To date, the company has grown to more than 1500 employees around the world.

Today MED-EL offers the widest range of implantable solutions worldwide to treat various degrees of hearing loss including cochlear and middle ear implant systems. People in over 100 countries enjoy the gift of hearing with the help of a product from MED-EL. www.medel.com

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ⁱ U.S. Food and Drug Administration.

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm085394.htm> Accessed May 2, 2016.

ⁱⁱ 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.

ⁱⁱⁱ IMV. <http://www.imvinfo.com/index.aspx?sec=mri&sub=def> Accessed May 2, 2016.