



Dear Valued Partner,

Cochlear strives to always put our recipients at the forefront of each and every one of our decisions. Over 22 years ago, Cochlear was the first to introduce a key safety feature to ensure MRI compatibility for its implants: a removable magnet.

As the strength and use of MRIs increased over time, there was a desire to develop solutions that would allow for MR scans to be performed without the need to remove the magnet. In 2016, Cochlear received FDA approval for its Implant Bandage and Splint Kit (MRI Kit), enabling MRI access at 1.5 Tesla without removing the magnet for recipients with CI500 and CI24RE-series implants. In July 2019, the Nucleus Profile™ Plus implant was introduced, permitting MRI scans at 1.5 and 3.0 Tesla without the need to rely on compression wrapping with the MRI Kit or magnet removal.*

While the MRI Kit was originally intended to provide CI500 and CI24RE recipients with greater access to MRI, we have observed inconsistencies in its use by medical imaging professionals over time. These observations have led us to further assess post-market complaints and adverse event data, which also suggest inconsistencies with the patient experience and potential for pain and/or magnet dislodgement, sometimes requiring revision surgery including possible device explantation and reimplantation. Accordingly, we will discontinue the MRI Kit (P773147) effective January 6, 2020.

Cochlear recommends that all CI500 and CI24RE series implant recipients undergo magnet removal prior to MR scannings at 1.5 and 3.0 Tesla and has updated the device labeling and MRI Resource webpage to reflect this change.

*Please refer to our updated MRI Resource page for the full MRI Guidelines, found here: <https://www.cochlear.com/us/en/professionals/Resources/mri-guidelines>

We recognize that this may be considered an inconvenience for both you and your recipients, but we believe that this is the decision that puts our recipients first. Should you have any questions or require additional information, please contact your local Cochlear representative.

Sincerely,

Tony Manna
President – Cochlear Americas