

Reliability of HiRes Ultra 3D multi-magnet assembly to withstand 200 MRI cycles

INTRODUCTION

In the US alone, 40 million Magnetic Resonance Imaging (MRI) procedures are performed each year.¹ The demand for MRI investigations is rising and it can be attributed to technological advancements,² an aging population requiring more scans,³ increased awareness and accessibility,⁴ and research applications.

In the past, cochlear implants raised concerns regarding MRI safety due to potential adverse events such as dislocation of internal components and demagnetization.^{6,7,8} The forces imposed on these magnets required sturdy bandaging of the implant's magnet and were often reported to be very uncomfortable.^{9,10}

The HiRes™ Ultra 3D cochlear implant, introduced by Advanced Bionics in 2019, features a multi-magnet assembly designed to minimize these risks and avoid the need for a support bandage.^{11,12} This device has been designed to withstand the rigors of MRI scanning, a growing requirement for patients with cochlear implants.

The multi-magnet assembly includes four individual magnets in a friction-free rotating frame (see figure 1). The frame provides alignment to the MRI field along one rotational axis, while the individual magnets provide alignment along the second axis of the field, achieving alignment in the 3D space. This results in a low torque system, regardless of the angle of the device to the MRI field, which results in no pain or discomfort for the cochlear implant user.

This white paper reviews the findings from an internal engineering report documenting extensive testing performed on the HiRes Ultra 3D multi-magnet assembly, including rotation tests and MRI exposure cycles to assess the reliability of the implantable device.

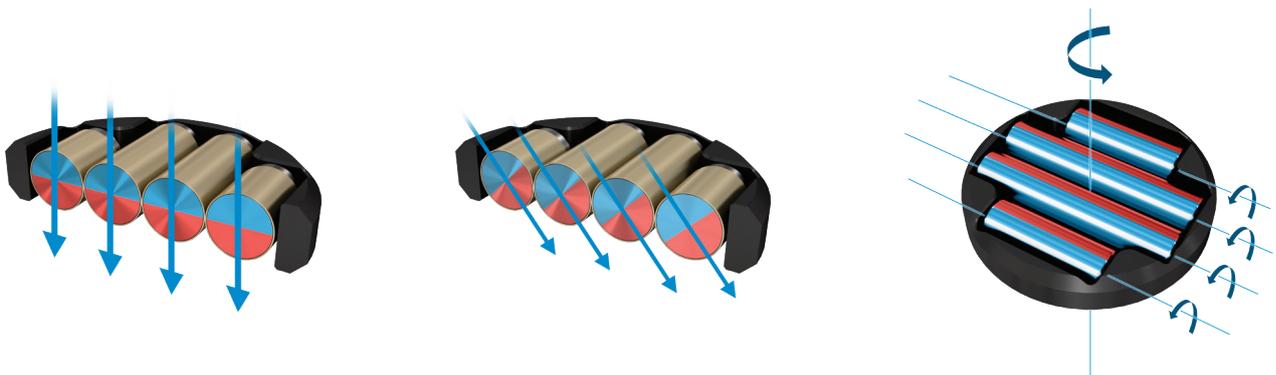


Figure 1: individual magnets alignment in three dimensions

METHODS

An average of 10 headpiece attachment and removal cycles per day is believed to occur at most. The alignment of the implant magnet to the headpiece results in a rotation in the magnet's depth axis. Reliability testing involved subjecting HiRes Ultra 3D multi-magnet assemblies to 1,182,500 rotation cycles to simulate more than 320 years of use. Furthermore, the HiRes Ultra 3D implant containing the aforementioned multi-magnet assemblies were inserted into and extracted from the centre of a 3 Tesla MRI scanner in an orientation to force the revolution of the magnets 200 times. Afterwards, their ability to rotate freely and keep a magnetic moment (strength) that met manufacturing specifications were confirmed.

RESULTS

All multi-magnet assemblies demonstrated a consistent magnetic moment, averaging 0.146 A-m² (SD 0.0004 A-m²) after 1,182,500 cycles. Additionally, following 200 cycles into and out of the MRI scanner, all implants passed electrical tests and remained fully functional as confirmed by post-scan testing.

CONCLUSIONS

The findings from the engineering report indicate that the HiRes Ultra 3D multi-magnet assembly is capable of withstanding significant mechanical and magnetic stress without failure. The results agree with the recent literature¹³ that supports the safety and efficacy of the HiRes Ultra 3D device in MRI environments.

The HiRes Ultra 3D multi-magnet assembly exhibits exceptional reliability after 200 MRI cycles. This performance exceeds by far the expected rate of MRI investigations undergone by a human in a lifetime, suggesting that the device can endure even more extensive MRI exposure without compromising patient safety or device functionality.

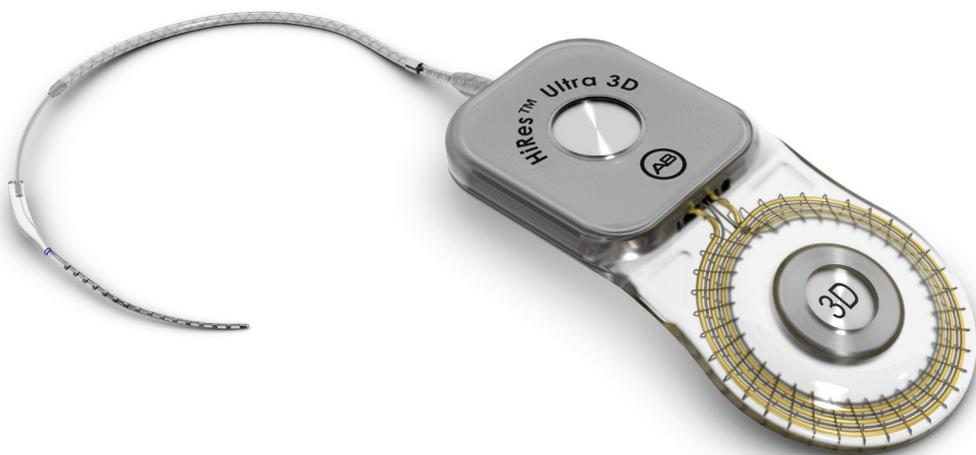


Figure 2: the HiRes Ultra 3D cochlear implant

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