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Cochlear advises of FDA approval for four new products, advancing performance and connectivity

- Cochlear receives FDA approval for the Nucleus® Kanso® 2 Sound Processor, Nucleus® 7 Sound Processor for Nucleus 22 implant recipients, Custom Sound® Pro fitting software and the Nucleus® SmartNav system
- New technology showcases Cochlear's commitment to improving hearing outcomes and quality of life for people with moderately severe to profound hearing loss and enhancing support for healthcare professionals

Cochlear Limited, the global leader in implantable hearing solutions, has obtained US Food and Drug Administration (FDA) approval for four new products, adding to its suite of hearing technology solutions. The Nucleus® Kanso® 2 Sound Processor, Nucleus® 7 Sound Processor for Nucleus 22 implant recipients, Custom Sound® Pro fitting software and the Nucleus® SmartNav system reflect Cochlear's ongoing commitment to innovation in hearing technology. The four new systems will be commercially released in the US and Western Europe in the next few months, subject to local approvals.

Nucleus® Kanso® 2 Sound Processor

The Nucleus Kanso 2 Sound Processor is the world's smallest¹ off-the-ear cochlear implant sound processor with proven hearing performance technologies²⁻⁵. It is the first and only off-the-ear cochlear implant sound processor to offer direct streaming from compatible Apple or Android™ devices, and is compatible with the Nucleus Smart App, enabling control of device settings, functions and information.

Cochlear's CEO & President, Dig Howitt said, "The Nucleus Kanso 2 Sound Processor showcases Cochlear's latest and most advanced hearing performance technology. With our latest connectivity features and a simple design that is comfortable and discreet, it really is designed to help cochlear implant recipients enrich their lives."

Nucleus® 7 Sound Processor for Nucleus 22 implant recipients

The Cochlear Nucleus 7 Sound Processor is now compatible for cochlear implant recipients with a Nucleus 22 implant. This means that Nucleus 22 implant recipients can now upgrade to Cochlear's latest behind-the-ear sound processor and, for the first time, access direct smartphone connectivity and streaming from compatible Apple or Android™ devices.

Mr Howitt said, "The Nucleus 22 implant was Cochlear's first commercial implant, released in 1982. There are more than 17,000 people around the world with a Nucleus 22 implant. This upgrade means that for the first time people who have benefitted from their implant for almost 40 years can access direct smartphone connectivity as well as a smaller and lighter design."

Custom Sound® Pro fitting software

Custom Sound Pro supports clinicians in fitting Cochlear's sound processors. The software harnesses almost 40 years of experience and input from thousands of clinicians worldwide.

The Custom Sound Pro fitting software keeps the patient at the centre of care with a new dashboard and Patient Goals feature, promoting patient engagement and facilitating more effective tracking of progress between appointments¹. With an intuitive layout, an integrated workflow for bilateral fittings and increased on-air time, the software is designed to enhance the fitting experience for clinicians and their patients.

Mr Howitt said, "To help patients experience the best possible hearing performance, it's important that programming software for cochlear implant sound processors provide flexibility and be easy to use. The new Custom Sound Pro fitting software was created by clinicians, for clinicians, enabling hearing health professionals to deliver tailored care for every patient."

Nucleus® SmartNav system

The Nucleus SmartNav system is a new tool to support surgeons in optimising electrode placement during cochlear implant surgery.

The Nucleus SmartNav system delivers wireless, actionable intraoperative insights to support electrode insertion with real-time navigation, providing surgeons with added assurance of a successful surgical outcome for their patients. The system consists of an innovative iPad-based solution and a surgical sound processor that presents an intuitive workflow to support surgery, giving surgeons additional feedback for in-theatre decision making.

Mr Howitt said, "The Nucleus SmartNav system provides new and valuable insights to assist in optimising placement of Cochlear's implant electrode during surgery."

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This announcement is authorised by the Continuous Disclosure Committee.

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Nucleus® Kanso® 2 Sound Processor references

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