

12 September 2011

Information for cochlear implant users and parents

Voluntary recall of Cochlear™ Nucleus® CI500 Series cochlear implant

While less than 1% of Nucleus CI500 Series implants have failed since launch in 2009, Cochlear has identified a recent increase in the number of implant failures where the implant shuts down safely and ceases to function. Exercising the greatest caution and with utmost concern for our recipients in mind, Cochlear is undertaking a voluntary recall of **unimplanted** Cochlear Nucleus CI500 Series cochlear implants. This means that until further notice, the CI500 Series cochlear implants are not available for implantation. The Nucleus CI24RE Series implants are recommended instead.

Questions you might have:

Question - I have a Nucleus CI500 Series implant. Should I have it removed?

Answer – No. There is no need to have your working implant removed and you should continue to use your system as normal. Less than 1% of Nucleus CI500 Series implants have failed since launch in 2009 so we expect most recipients will not be affected by this failure. In the unlikely event of the implant failing, it will shut down safely and cease to function.

Question – How will I know if my implant is failing?

Answer – In the unlikely event the implant fails it will shut down safely and cease to function. If you experience any issues in sound quality, this is most likely to be associated with your external sound processor. You should follow the normal sound processor troubleshooting process to identify any problems with the sound processing unit, coil, cables, batteries or whether the microphone protectors require changing. This will almost certainly rectify the problem. In the unlikely event that these steps do not solve the issue, you should contact your clinic.

Question - How do I know if I have a CI500 Series implant?

Answer – If you or your child has used or continues to use a Nucleus Freedom™, SPrint™ or an ESPril™ 3G Sound Processor you will most likely not have a CI500 Series implant.

You may have received a CI500 Series implant if you received a CP810 Sound Processor at first fitting. Only the CI512, CI513, CI551 and the ABI541 are affected by this recall. No other implants are affected. You may consult your Patient Identification Card to determine the type of your implant.

If you are currently using the CP810 Sound Processor with another implant, you are not affected by this recall.

Question – What happens if my or my child’s implant fails?

Answer – Less than 1% of Nucleus CI500 Series implants have failed since launch in 2009. In the rare circumstances your implant fails then you should contact your clinic. The implant is covered under normal warranty conditions and can be replaced with a CI24RE Series implant. The CI24RE is fully compatible with the Cochlear Nucleus CP810 Sound Processor and does not compromise any of the usability and hearing performance benefits of the Nucleus 5 System.

Question – I am considering a cochlear implant for myself or my child and I like the Nucleus 5 System. What should I do?

Answer – Cochlear is recommending use of a Nucleus CI24RE Series implant instead. These cochlear implants are fully compatible with CP810, the latest Nucleus 5 Sound Processor. The combination of a CI24RE Series implant and the CP810 Sound Processor does not compromise any of the usability and hearing performance benefits of the Nucleus 5 System.

It is difficult to say at this stage the timing for the return of the Nucleus CI500 Series implants.

If you have any other questions, please do not hesitate to contact your local Cochlear office.