

12th September 2011

Information for Cochlear Implant Recipients Voluntary Recall for Nucleus CI500 cochlear implant range

Questions you might have:

Question - I have a Nucleus CI512 implant should I have it explanted?

Answer – No. There is no need to have your working implant explanted and you should continue to use your system as normal. The incidence of the failure is very low – approximately 0.6% of registered CI512 devices globally so we expect most recipients will not be affected by this failure.

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

Answer – In the unlikely event the implant fails it will shut down safely. If you experience any issues in sound quality then this is most likely to be associated with your external sound processor. You should follow the normal sound processor troubleshooting which will almost certainly rectify the problem

Question - How do I know if I have a CI512 implant?

Answer – You may have received a CI512 implant if you received a Nucleus 5 System. Your clinic will be able to confirm this. If you or your child has a Nucleus Freedom, Sprint or an Esprit 3G sound processor you will not have a CI512 implant. The following implants **are not** affected by this recall, the Nucleus Freedom range (RE CA, RE ST), the Hybrid L24 electrode, the Nucleus CI422 slim straight electrode, the CI24 R CA, CI24 R ST, CI24 R CS the Nucleus 24M double array or the Nucleus ABI 24M.

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

Answer – 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 Nucleus Freedom implant. The Nucleus Freedom implant is fully compatible with the Nucleus 5 Sound Processor system.

Question – I am looking to get an implant for myself/my child. I really like the Nucleus 5 system, when will it be back on the market?

Answer – The Nucleus Freedom implant is fully compatible with the Nucleus 5 Sound Processor System which is not affected by this recall. This combination of Nucleus Freedom and Nucleus 5 sound processor system does not sacrifice any of the performance benefits of the Nucleus 5 processor system. It is difficult to say at this stage the timing for the return of the Nucleus CI500 implant range.

If you have any other questions please do not hesitate in contacting Cochlear Customer Service on 0800 444 819.