Rev 1: September 2018
FSN Ref:

FSCA Ref: CAPA 26044

Date: 24/Sep/2026

Urgent Field Safety Notice
Cochlear Nucleus CI612 & Cochlear Nucleus Nexa CI1012

For Attention of*:[Hospital Name,
User Name,
Department,
Customer address,
Zip Code, City,
Country]

Contact details of local representative (name, e-mail, telephone, address etc.)*
[Name of Contact, e-mail, telephone] Cochlear Deutschland GmbH & Co. KG, Mailänder Straße 4 a, 30539 Hannover GERMANY

Urgent Field Safety Notice (FSN)
Cochlear Nucleus CI612 & Cochlear Nucleus Nexa CI1012
Potential incomplete electrode welds in CI612 and CI1012 cochlear implants

1. Information on Affected Devices*	
1.	**1. Device Type(s)***
	Cochlear Nucleus CI612 cochlear implant with Contour Advance electrode & Cochlear Nucleus Nexa cochlear implant with Contour Advance electrode (CI1012)
1.	**2. Commercial name(s)**
	Cochlear Nucleus CI612 cochlear implant with Contour Advance electrode & Cochlear Nucleus Nexa cochlear implant with Contour Advance electrode (CI1012)
1.	**3. Unique Device Identifier(s) (UDI-DI)**
	As per below.
1.	**4. Primary clinical purpose of device(s)***
	The CI600 Series and CI1000 Series Cochlear Implants are intended for long term implantation in the mastoid region of either side of the head and are intended to restore a level of hearing via electrical stimulation of the cochlea.
1.	**5. Device Model/Catalogue/part number(s)***
	As per below.
1.	**6. Software version**
	N/A
1.	**7. Affected serial or lot number range**

Part Number	Serial Number
P774600 - CI612	1020240595667
P1979576 - CI1012	1020210078740
P1979576 - CI1012	1020210072076

1.	**8. Associated devices**
	None

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	**1. Description of the product problem***
	A production team member identified that they had not consistently performed all required weld steps in accordance with the manufacturing electrode weld work instruction. Investigation determined that this may have resulted in electrode rings being processed without the intended weld between the wire and ring, creating a potential risk of open circuits.

2.	**2. Hazard giving rise to the FSCA***
	Based on the information available, no immediate direct risk to patient health has been identified. However, the long-term performance of potentially affected devices is currently unknown. The most likely time for an open circuit to develop is during implantation, where the electrode is under the most stress, and this issue may be identified during intraoperative testing. However, the potential for this issue to result in a latent failure mode, and any long-term performance impacts, has not been fully characterised.
2.	**3. Probability of problem arising**
	The identified manufacturing deviation may have resulted in some affected devices containing one or more electrode rings without the intended weld connection between the wire and ring. Not all devices within the affected serial number population are expected to be affected. Where present, the issue is most likely to develop during implantation when the electrode is subjected to mechanical stress and would ordinarily be detected during intraoperative testing.
2.	**4. Predicted risk to patient/users**
	No immediate direct risk to patient health is anticipated. If multiple electrode contacts were to develop open circuits in an implanted device, clinical performance could be reduced and, under worst-case circumstances, permanent loss or degradation of device function could occur, potentially requiring revision surgery and device replacement. However, the most likely time for an open circuit to develop is during implantation, and the issue would ordinarily be identified during intraoperative testing.
2.	**5. Further information to help characterise the problem**
	N/A
2.	**6. Background on Issue**
	At the time of issuing this notice, no complaints or adverse events related to this manufacturing deviation have been identified in the affected population. Following initial assessment, Cochlear initiated an investigation to determine the root cause and potential impact. While the investigation remains ongoing, Cochlear has undertaken this FSCA out of an abundance of caution. Traceability review confirmed the affected serial numbers and enabled direct notification of impacted healthcare facilities.
2.	**7. Other information relevant to FSCA**
	This FSCA applies only to the identified serial number population. Products outside the affected serial number range are not impacted by this action.

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device
	☐ On-site device modification/inspection
	☐ Follow patient management recommendations
	☐ Take note of amendment/reinforcement of Instructions For Use (IFU)
	☐ Other ☐ None
	Provide further details of the action(s) identified.

	All affected healthcare facilities have been directly notified and instructed to identify, quarantine, and return impacted products. Routine patient management practices should continue unchanged.	
3.	**2. By when should the action be completed?**	As soon as possible
3.	3. **Particular considerations for**: Implantable device **Is follow-up of patients or review of patients' previous results recommended?** No No patient follow-up or review of previous patient results is required. This FSCA is limited to the retrieval of affected non-implanted devices. There are no known implanted devices within the EU associated with the affected serial number population. All affected healthcare facilities have been directly notified and instructed to identify, quarantine, and return impacted products. Routine patient management practices should continue unchanged.	
3.	4. Is customer Reply Required? * (If yes, please acknowledge receipt of this letter with your designated contact and confirm that the device has been identified, quarantined, and returned to Cochlear)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Cochlear is conducting a voluntary Field Safety Corrective Action (FSCA) involving the identification and removal of all affected non-implanted devices from the field. Affected healthcare facilities are being directly notified and provided with instructions to identify, quarantine, and return impacted products.	
3	**6. By when should the action be completed?**	As soon as possible
3.	**7. Is the FSN required to be communicated to the patient /lay user?**	No
3	**8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?**	
	Choose an item. Choose an item.	

	4. General Information*	
4.	**1. FSN Type***	New
4.	**2. For updated FSN, reference number and date of previous FSN**	N/A
4.	**3. For Updated FSN, key new information as follows:**	
	N/A – Initial Notification	
4.	**4. Further advice or information already expected in follow-up FSN? ***	Not planned yet
4	**5. If follow-up FSN expected, what is the further advice expected to relate to:**	
	N/A	
4	**6. Anticipated timescale for follow-up FSN**	N/A
4.	**7. Manufacturer information** **(For contact details of local representative refer to page 1 of this FSN)**	
	a. Company Name	Cochlear Limited
	b. Address	1 University Avenue, Macquarie University NSW 2109 AUSTRALIA
	c. Website address	www.cochlear.com
4.	**8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. ***	
4.	**9. List of attachments/appendices:**	If extensive consider providing web-link instead.
4.	**10. Name/Signature**	Marcus Ignacio Director Regulatory Affairs EMEA

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.