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About this guide

This guide is for healthcare professionals using the Cochlear™ Contour Advance® Depth Gauge.

Note
• The depth gauge is a single-use, sterile surgical instrument.
• Refer to the relevant sections for cautions and warnings relating to the use of the depth gauge.

Symbols used in this guide

Note
Important information or advice.

Caution (no harm)
Special care to be taken to ensure safety and effectiveness. Could cause damage to equipment.

Warning (harmful)
Potential safety hazards and serious adverse reactions. Could cause harm to person.
Cochlear Contour Advance Depth Gauge

(Z179994)
Intended purpose

The Contour Advance Depth Gauge is intended to be used to check the patency of the cochlea lumen and assess whether an adequate depth of electrode insertion can be achieved during a cochlear implantation surgical procedure.

Indications

The Contour Advance Depth Gauge is indicated for when there is evidence that the cochlea is obstructed in a way that may prevent successful electrode insertion or when pre-operative imaging to assess cochlea patency is not conclusive or unavailable.

The Contour Advance Depth Gauge can be used to assess the cochlea patency for the following implants:

- CI24RE Series Implants: CI24RE (CA)
- CI500 Series Implants: CI512
- CI600 Series Implants: CI612.
Contraindications

The use of the Contour Advance Depth Gauge is contraindicated unless there is evidence of obstruction or malformation of the cochlea. The use of a depth gauge is contraindicated when attempting to preserve residual hearing.

Intended patient population

The intended patient population are recipients of compatible Cochlear hearing implants undergoing implantation. There are no restrictions for the intended patient population of the devices in terms of age, weight, health or other condition.

Intended users

The intended users who have direct interaction with these devices include qualified medical professionals such as surgeons and surgical nurses.

Benefits

The Contour Advance Depth Gauge may aid the surgeon in providing appropriate treatment by determining more information about the cochlea to assist with implantation.
Warnings

- For temporary use only. Not for implantation.
- Supplied sterile. Sterilised in ethylene oxide. Do not resterilise.
- Single-use item. Do not use more than once. Re-use could cause infection.
- Do not use if packaging is damaged.
- Do not use if gauge becomes non-sterile e.g. if dropped or mishandled in theatre after removal from packaging.

Note
Dispose of used depth gauge according to your institution’s policy for the disposal of biohazardous waste.
Opening the package

The depth gauge is supplied in a sterile packaging.

Non-sterile field

1. Remove the cardboard box (outer packaging).
2. Break the seal on the outer tray, and confirm that:
   • exposure to ethylene oxide processing is indicated by a green dot on the outer tray
   • the inner tray is not damaged.

   Warning
   If the sterile pack is damaged or opened unintentionally, do not use the depth gauge.

Sterile field

3. Break the seal on the inner tray.
4. Lift the depth gauge from the tray.
5. Confirm the depth gauge is not damaged.
Using the depth gauge

The depth gauge is designed to replicate a Contour Advance electrode.

To use the Contour Advance Depth Gauge:

1. Insert the depth gauge electrode into the cochlea. For electrode insertion steps refer to a *Physician's Guide* for an implant with Contour Advance electrode.
2. Count the number of electrode bands visible outside the cochleostomy.
3. Subtract this number from 22, the total number of active electrodes.

If eight or more bands are outside the cochlea, leaving 14 or less active bands for insertion, consider implant choice and alternative surgical techniques.
Other Information

Transport and handling
Transport and store the depth gauge at temperatures from -10 °C to +55 °C (+14 °F to +131 °F).
For long term storage, store at ambient room temperature. Keep dry.

Specifications
Product component measurements for the Contour Advance Depth Gauge.

<table>
<thead>
<tr>
<th>Weight</th>
<th>Thickness</th>
<th>Width</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 g</td>
<td>3 mm</td>
<td>20 mm</td>
<td>97 mm</td>
</tr>
</tbody>
</table>

Safe disposal
Dispose of used items according to your institution’s policy on the disposal of biohazardous waste.
Summary of safety and clinical performance

A summary of the safety and clinical performance of the Cochlear Contour Advance Depth Gauge can be found at https://ec.europa.eu/tools/eudamed
Labelling symbols

The following symbols may appear on the depth gauge and/or packaging.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>📚</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>⚠️</td>
<td>Specific warnings or precautions associated with the device, which are not otherwise found on the label</td>
</tr>
<tr>
<td>🟡</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🕒</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>⌛️</td>
<td>Use by date</td>
</tr>
<tr>
<td>🕒</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>🧽</td>
<td>Do not resterilise</td>
</tr>
<tr>
<td>🟡 🤚 REP</td>
<td>Authorised representative in the European Community/European Union</td>
</tr>
<tr>
<td>🟡 🤚 REP</td>
<td>Authorised representative in Switzerland</td>
</tr>
<tr>
<td>UDI</td>
<td>Unique Device Identification</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td>MD</td>
<td>Medical Device</td>
</tr>
<tr>
<td>REF</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code</td>
</tr>
<tr>
<td>CE</td>
<td>CE registration mark</td>
</tr>
<tr>
<td>CE₀₁₂₃</td>
<td>CE registration mark with notified body number</td>
</tr>
<tr>
<td>Rx Only</td>
<td>By prescription</td>
</tr>
<tr>
<td>📘</td>
<td>Sterile barrier</td>
</tr>
<tr>
<td>STERILE EO</td>
<td>Sterilised using ethylene oxide</td>
</tr>
<tr>
<td>🔄</td>
<td>Recyclable material</td>
</tr>
<tr>
<td>⚫️</td>
<td>Keep dry</td>
</tr>
<tr>
<td>🥕</td>
<td>Fragile</td>
</tr>
</tbody>
</table>
Serious incidents

Whilst serious incidents in relation to medical devices are rare, it is acknowledged that incidents may happen. As an organisation, Cochlear recognises the potential for harm and will respond to any reported serious incident.

What is a serious incident?

A 'serious incident’ means any event that directly or indirectly has caused or could have caused an unexpected or unwanted event including any of the following:

• The death of a patient, user or other person,
• The temporary or permanent serious deterioration of a patient’s, user’s or other person’s state of health,
• A serious public health threat.

Reporting a serious incident

There is no definitive list of events or incidents that constitute a serious incident, however all serious incidents should be reported to:

• your local Cochlear office
  www.cochlear.com/intl/contact/global-offices
• For users within the European Union, you should also report serious incidents to your National Competent Authority,
• For users outside of the European Union, if applicable, report serious incidents to your National Competent Authority,
• For users within Australia, report serious incidents to the Therapeutic Goods Administration
  https://www.tga.gov.au
Trademark legal notice

ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BC Drive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, Cochlear SoftWear, Contour, コントゥア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Invisible Hearing, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, Soundband, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.