

Phonak Lyric™

**Healthy Ears for Lyric Wearers:
A review of key contributing factors**

**Michelle Wiebke, AuD
Lyric Clinical Manager**



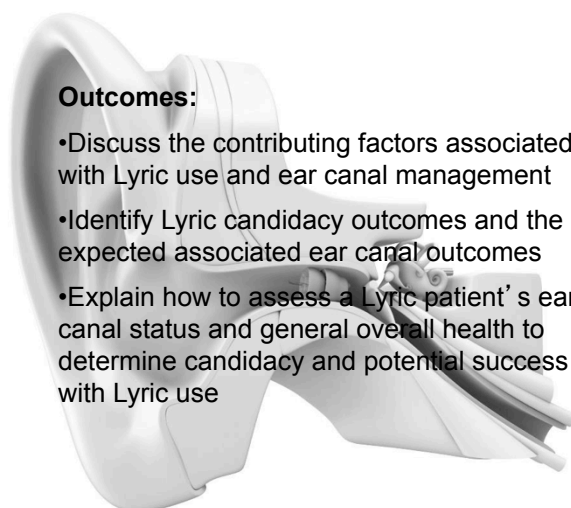
*this presentation is a summary of Phonak Insight: Phonak Lyric Clinical and Medical Review by Jacob Johnson, M.D., June 2019
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Phonak Lyric™

**Healthy Ears for Lyric Wearers:
A review of key contributing factor:**

Outcomes:

- Discuss the contributing factors associated with Lyric use and ear canal management
- Identify Lyric candidacy outcomes and the expected associated ear canal outcomes
- Explain how to assess a Lyric patient's ear canal status and general overall health to determine candidacy and potential success with Lyric use



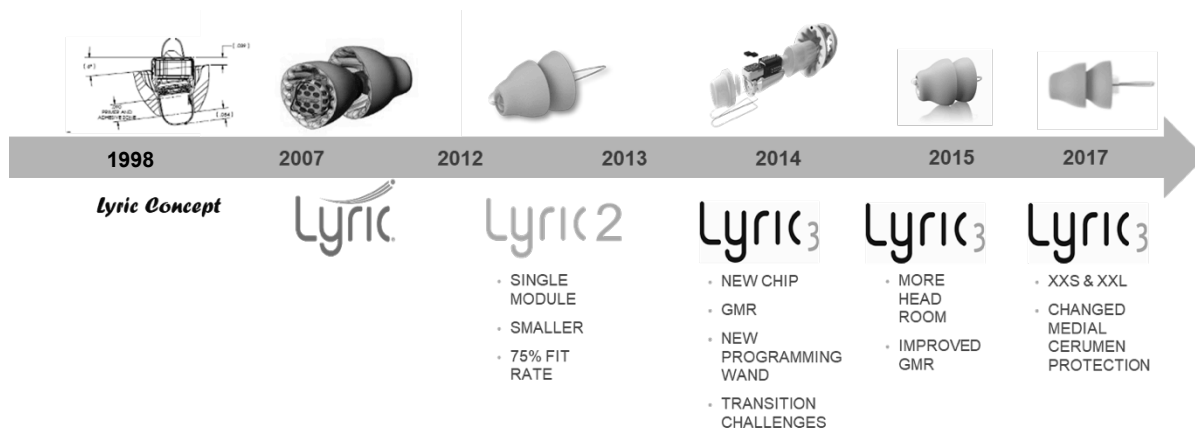
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Lyric – product evolution

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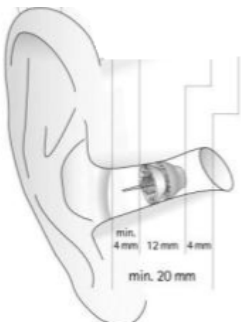
- Since the commercial launch of Lyric in 2008, more than 1.5 million Lyric fittings have taken place. With over 10 years of clinical data monitoring, and more than 320,000 Lyric fittings in 2017, Lyric has continued to show that it's a safe and effective hearing solution for patients with mild to moderately-severe hearing loss.

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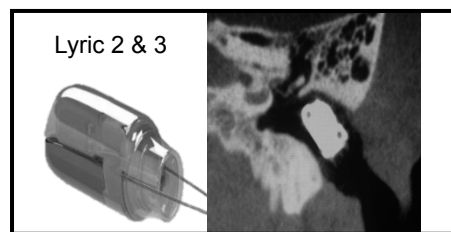
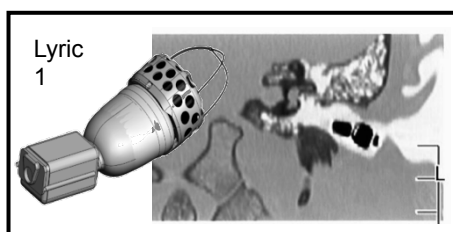
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Lyric – design concepts

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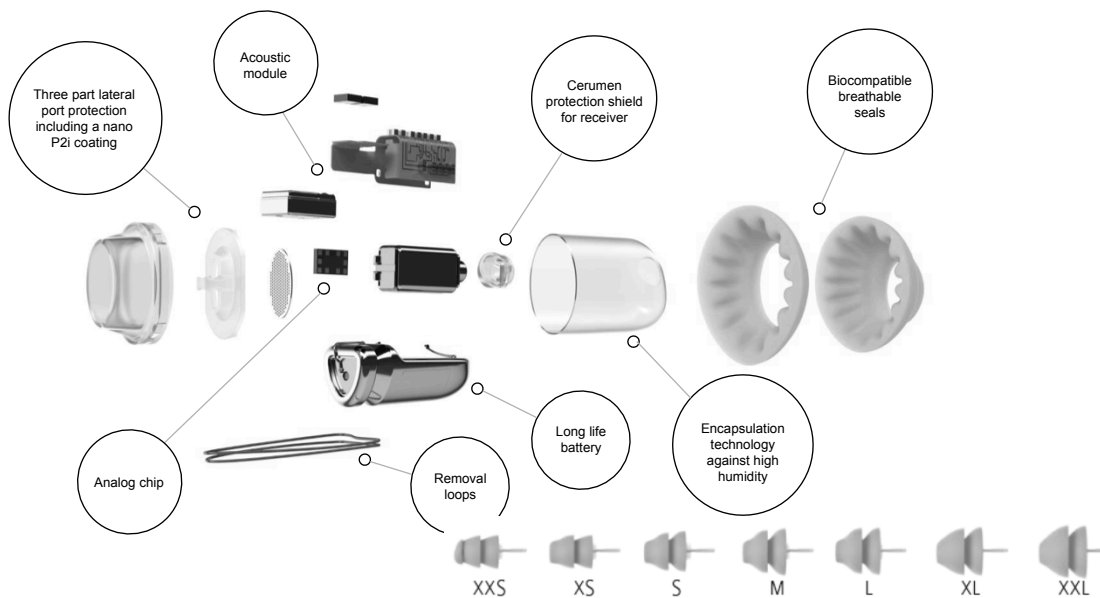


1. Avoid excessive pressure
2. Breathability
3. Device placement in the bony portion of the canal



Lyric – design concepts – microengineering at it's best

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Lyric candidacy assessment

- Use the Lyric Candidacy Form to help make an informed recommendation

Medical clearance is recommended for the following conditions:

- Uncontrolled diabetes
- Bleeding disorder
- Anti-coagulation therapy
- Age under 21 years old
- Immunodeficiency (including chronic steroid use)
- Currently wearing an implantable medical device

Lyric is **contraindicated** in patients with previous head and neck radiation therapy and active middle ear issues, such as tympanic membrane perforation, cholesteatoma or PE tubes.

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Lyric Candidacy		Lyric [®]	
Patient name:	Date:	DOB:	
Contraindications		Medical Clearance Suggested	
Has the patient ever had radiation therapy to the head or neck?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the patient have diabetes?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient have any middle ear conditions (TM perforation, cholesteatoma, PE tubes)?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the patient take prescription anticoagulant medication?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Recovery Considerations		Does the patient have a compromised immune system (chemotherapy within the last 6 months, lipos, WBC, etc)?	
Does the patient need regular MRI testing?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the patient have a bleeding disorder (hemophilia)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient regularly swim underwater?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Does the patient have an implantable medical device?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient scuba dive or sky dive?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the patient under the age of 21?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the patient have any skin sensitivities?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Based on the above, can the patient wear Lyric?			
<input type="checkbox"/> Yes <input type="checkbox"/> No, due to:			
<input type="checkbox"/> Obtaining medical clearance due to:			
Physician name/specialty:			
Audiogram		Lyric First Fit Checklist	
Right	Left	<input type="checkbox"/> Validate comfort, feedback, and sound quality (make adjustments as necessary) <input type="checkbox"/> Show patient counselling video/highlight link to view at home <input type="checkbox"/> Give patient new Lyric Fitting Kit (show medical alert card, Lyric user guide and MyLyric registration card) <input type="checkbox"/> Show SoundSync removal tool and instruct patient on use <input type="checkbox"/> Discuss topics of itching, water, sleeping, MRI, and what to do if device is weak, dead, or has unusual sounds <input type="checkbox"/> Let patient know how to reach you if there are any issues <input type="checkbox"/> Provide guidance on the expectation for refit appointments <input type="checkbox"/> Schedule a 1-week follow-up appointment <input type="checkbox"/> Prepare patient for a phone call or email within 24 hours	
Measured insertion depth (mm)		Preferred Method and Time to Contact:	
Actual insertion depth (mm)			
Device size			
Lubrication used			
Cerumen removed			

Lyric candidacy assessment

- Consider the entire patient!

A study conducted by the Lyric Research and Development team in 2018 found that that participants with poorer general health, have a greater incidence of ear health issues when compared with participants with fewer general health concerns.

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Lyric Candidacy		Lyric [®]	
Patient name:	Date:	DOB:	
Contraindications		Medical Clearance Suggested	
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Does the patient have any skin sensitivities?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
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Measured insertion depth (mm)		Preferred Method and Time to Contact:	
Actual insertion depth (mm)			
Device size			
Lubrication used			
Cerumen removed			

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Clinical presentation patterns

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Temporary ear skin issues can occur in a small percentage of Lyric users and resolve by removing the Lyric and resting the ear.

The review of the ear health status data shows two primary patterns of ear skin issue presentation:

Discomfort or pain

Non-infectious Otitis Externa

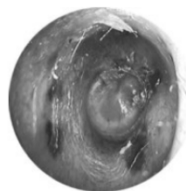
Clinical presentation patterns

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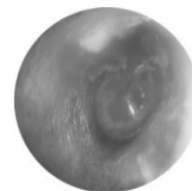
Discomfort or pain

Discomfort or pain which typically presents within the first 1–2 weeks of placement, especially with new users. The five main reasons for discomfort leading to removal within the first two weeks are:

- Traumatic insertion
- Sizing error
- Poor placement leading to motion or pressure
- Poor cerumen management prior to insertion
- Patient manipulation of the device



Abrasion following Lyric removal



Ear canal after 10 days rest

In these cases, a hematoma or abrasion may develop on the skin in the ear canal. Most of these skin issues will resolve within 7–10 days of rest and typically do not require medical intervention.

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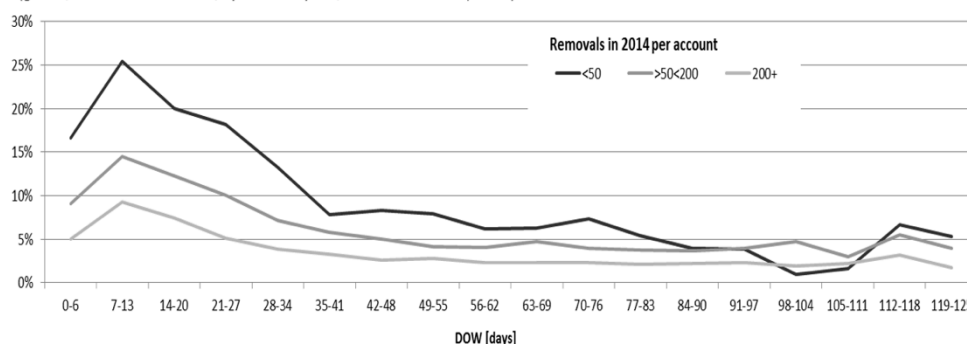
Clinical presentation patterns



Discomfort or pain

Removals in 2014 which are NOT OK FOR IMMEDIATE REFIT by DOW & customer volume

(global, n=207'000 removals, Lyric2.3 & Lyric3, trials and subscriptions)



Recommendations for ear canal issues



Discomfort or pain

Abrasion and/or hematoma:

Allow the ear canal to rest 7–10 days and ask the patient to return for re-examination, and if cleared, re-fit the Lyric device. Counsel patient not to manipulate the device. While the device can be removed by the patient, most practices prefer to schedule proactive removals with lubrication or loosening the seal to promote comfortable device removals.

Bleeding:

Place cotton with a lubricant or Afrin on the area for approximately 3-5 minutes, and repeat until bleeding stops. Remove fresh blood with cotton, Q-tip or oil-based ear drops to prevent blood from drying in the ear canal. Rest the ear (7-10 days) and re-insert Lyric device only when ear is free of bleeding and abrasion.

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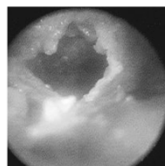
Clinical presentation patterns

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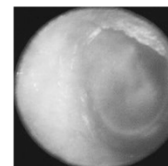
Non-infectious otitis externa

Non-infectious otitis externa will typically occur within 2–3 weeks post placement, and the patient will report a weak or malfunctioning device. The ear canal, in these cases, may reveal ear canal moisture with keratin consistent with non-infectious otitis externa.

The differentiation between non-infectious and infectious otitis externa is that there is no cartilaginous ear canal swelling and there is no pain with non-infectious otitis externa after Lyric removal even though the ear canal has moisture, edema and keratin debris in the medial canal.



Noninfectious Otitis Externa



After five days rest without medical intervention

Clinical presentation patterns

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Non-infectious otitis externa

- Longitudinal study from San Francisco Audiology Research Center shows that many subjects are tested with positive bacterial/fungal culture prior to wearing Lyric!

- **No clear correlation for bacterial or fungal results to ear health observation**

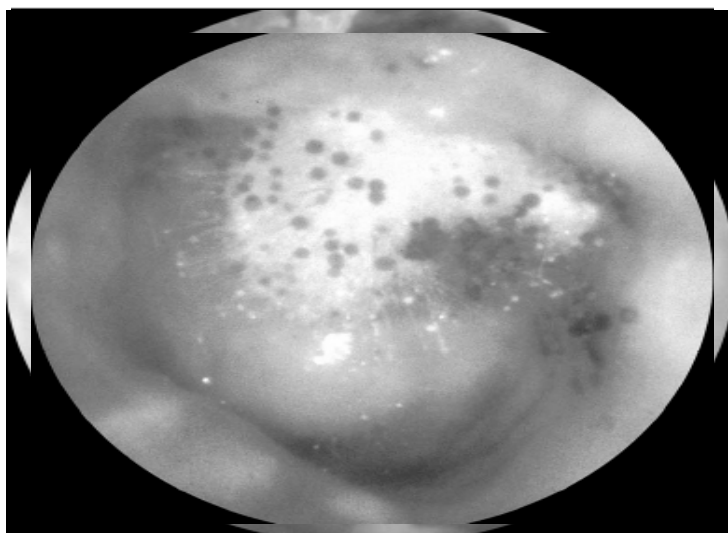
- Majority of subjects (both healthy and unhealthy) do not have any detectable bacterial and/or fungal growth from microbiome culture data

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Clinical presentation patterns

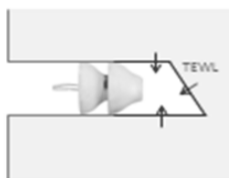
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Clinical presentation patterns

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Non-infectious otitis externa

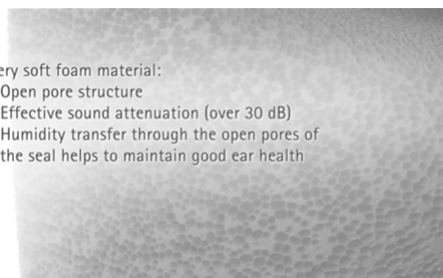


Importance of sufficient moisture vapor transfer through seals:

- Skin releases moisture continuously (transepidermal water loss TEWL)
- Seals need to transmit humidity outward

Very soft foam material:

- Open pore structure
- Effective sound attenuation (over 30 dB)
- Humidity transfer through the open pores of the seal helps to maintain good ear health



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Clinical presentation patterns



Non-infectious otitis externa

					A= Healthy			
					B = Unhealthy			
	EH Observations - BOTH EARS - ACA (N=38)							
	RH %							
SIZE	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90-94
XS		B	BBBB	BBAB	AB	B		
S	A	AA		A	B			
M	AA	A	AAA	AB	BA	A	B	A
L	B			B				B
XL		A	AB	A			B	B
	EH ZONE	GOOD	MEDIUM	POOR	Smaller ear (device) sizes have lower tolerance for high relative humidity levels in terms of ear health observations			
	A - HEALTHY	12	3	4				
	B - UNHEALTHY	2	4	13				
	TOTAL	14	7	17				
	<u>PROBABILITY FOR EH ISSUE</u>	14%	57%	76%				

Recommendations for ear canal issues



Non-infectious otitis externa

Allow the ear canal to dry prior to device replacement, typically requiring ear rest for 5–10 days.

Attempt to determine what might have caused the non-infectious otitis externa and adjust fitting to remove the suspected cause:

- Over lubrication.
- Excess medial moisture from allergies.
- Excess medial moisture as skin heals from trauma possibly caused by cerumen removal, irritation, or abrasion.
- Excess external moisture saturating lateral seal from sauna, sweat, shower, swimming, etc.
- Poor fit of device or recent upsize.
- Higher humidity level due to normal makeup of patients skin in the ear canal.
- Overall generally poor health or patient battling another skin condition

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Ear canal health: best practices



- If a Lyric user has repeat ear canal issues, they should be transitioned to a daily wear device.
- An audiogram, tympanogram, Lyric medical candidacy evaluation and ear canal/ tympanic membrane photo-documentation is recommended prior to initial Lyric fitting and annually.
- Instruct the user to return to the clinic if they have any discomfort or pain. Re-adjust, replace or resize Lyric if there is discomfort or pain. Counsel the user not to manipulate the device themselves.
- Generally, ear canal lubrication is not needed for Lyric placement. If the ear canal is very dry or the device provides a lot of resistance during placement, then water or glycerin may be used.
 - Take care to judiciously use lubricants as to not saturate the seals or occlude the microphone or receiver.

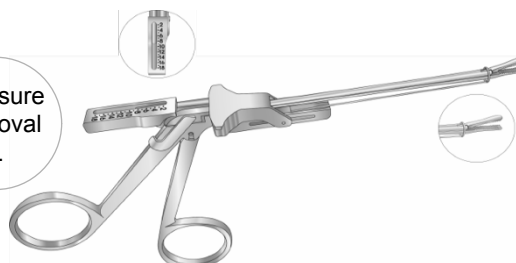


Ear canal health: best practices



- During removal, if the device provides a lot of resistance:
 - Add lubrication to the ear canal.
 - Use a thin metal curette to gently break the seal between the device and the ear canal skin.
 - Slowly remove the device with alligator forceps with the patient slowly opening and closing his/ her jaw.

Pro-tip: use the Lyric slider forceps to measure the depth of the device prior to device removal to determine if any migration has occurred.



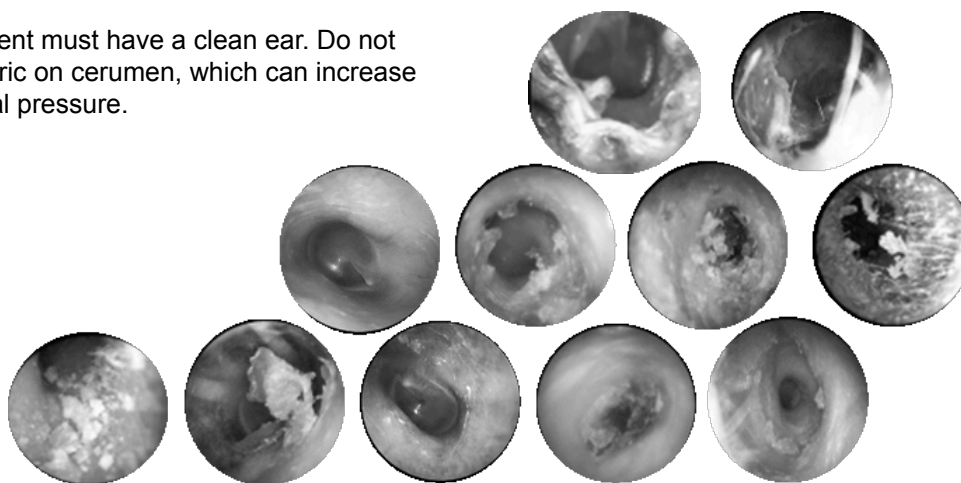
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Ear canal health: best practices

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- The patient must have a clean ear. Do not place Lyric on cerumen, which can increase ear canal pressure.



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•Additional recommendations and general considerations

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Recommendations for ear canal issues



Ulcer (small break in skin):

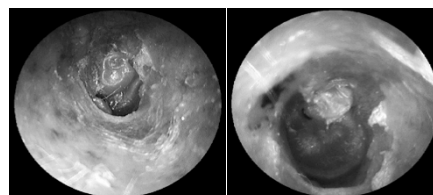
An ulcer may take weeks to heal and the otolaryngologist may need to clean debris from the base of the ulcer to promote healing.

- Review medical clearance and ensure a clean ear canal with each fitting.
- Surgery is not needed to treat ulcers.

Medial bulge/growth:

This has been observed in a small percentage of patients. The ear canal will resolve with rest and does not require medical treatment, but should be closely monitored to track healing progress.

- Differential diagnosis between medial ear canal growth and other more serious medical conditions (e.g., cholesteatoma, tumors) should be carefully considered.
- If removal of the device and ear canal rest does not promote healing, the patient should be referred to an otolaryngologist familiar with Lyric ear health presentation patterns. If not familiar with Lyric, then he/she should be made aware of the timing of the medial bulge so to avoid unnecessary medical procedures.
- Photo-documentation is helpful in guiding care decisions.



After
1
week
rest

Recommendations for tympanic membrane issues



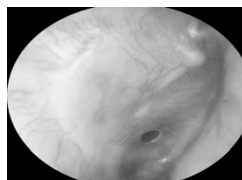
- Fully visualize the tympanic membrane at each visit and obtain one pre-fit tympanogram. Lyric should be removed to evaluate the tympanic membrane and to perform tympanograms.

Hematoma:

- Allow the ear to rest for 7–10 days and ask the patient to return for re-examination, and if cleared, refit the Lyric device.
- At refit, resize the device, do not fit the device as deep and counsel the patient not to manipulate the device.

Persistent Perforation: To date, no cases of persistent perforation have been reported.

- The few reported acute cases (no photo documentation) have healed with no surgical intervention. In these cases, tympanometry/exam notes indicated a perforation prior to Lyric fitting, or significant history of middle ear issues and pressure equalization tubes prior to Lyric use.



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Recommendations for middle ear issues

To date, no cases of ossicular injury have been reported. If a patient reports middle ear issues, assess the complaint as usual and obtain medical support if needed.

Hearing aid use, including extended wear, is not related to eustachian tube dysfunction or otitis media. The barometric pressure is equalized by the porous foam seals.

Recommendations for inner ear issues

To date, no cases of dizziness, tinnitus, sensorineural hearing loss or inner ear injury have been reported. If a patient reports inner ear issues, assess the complaint as usual and obtain medical support if needed.

Lyric is NOT contraindicated for vestibular schwannoma “acoustic neuroma” related hearing loss, unless the patient has received radiation therapy for the neuroma.

General considerations



Quality and longitudinal data has shown that Lyric is a safe, long-term solution, with many current Lyric users having worn devices for over 10 years.

•**Temporal-mandibular joint (TMJ):** To date, there have been no reports that Lyric has persistently exacerbated TMJ issues in patients, but chronic ear or jaw pain is a precaution for fitting Lyric.

•**Trauma:** Lyric should be removed if there is ear and/or head trauma. Ear canal and tympanic membrane should be evaluated as usual.

•**Vaso-vagal Episodes:** It is very rare, but it is possible for a vaso-vagal episode to be initiated in some patients during examination of the ear, cerumen management, performance of an audiogram or tympanogram, manipulation of the ear canal, or placement and removal of Lyric. If this occurs, the patient will feel warm, get nauseous, and faint. Place the patient in a lying position with head down and feet up, provide reassurance and place cool paper towels on his/her head or chest. If the patient does not start to improve within a few minutes, obtain appropriate medical support.

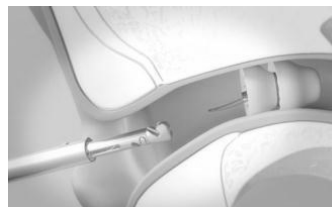
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General considerations



- **Pacemakers, ventricular shunts, deep brain stimulators:** The Lyric programming wand and SoundLync contain a magnet that may interfere with other medical devices. As a general rule, the Lyric SoundLync and programming wand should not be brought within 1cm of implantable medical devices.
- **Magnetic Resonance Imaging (MRI), surgery, Hyperbaric Oxygen Therapy (HBO), Electroconvulsive Therapy (ECT):** As a general rule, the Lyric device should be removed for these tests or therapies.

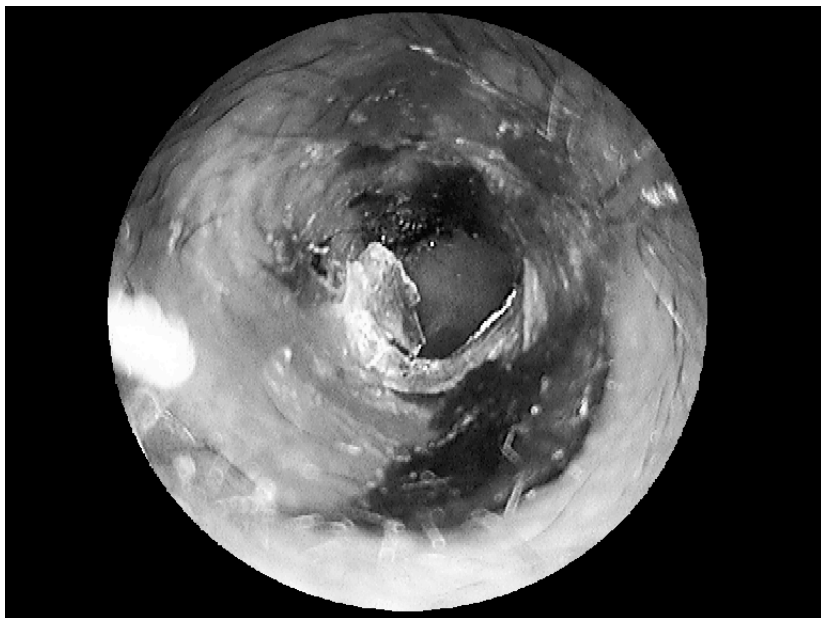


•Case studies

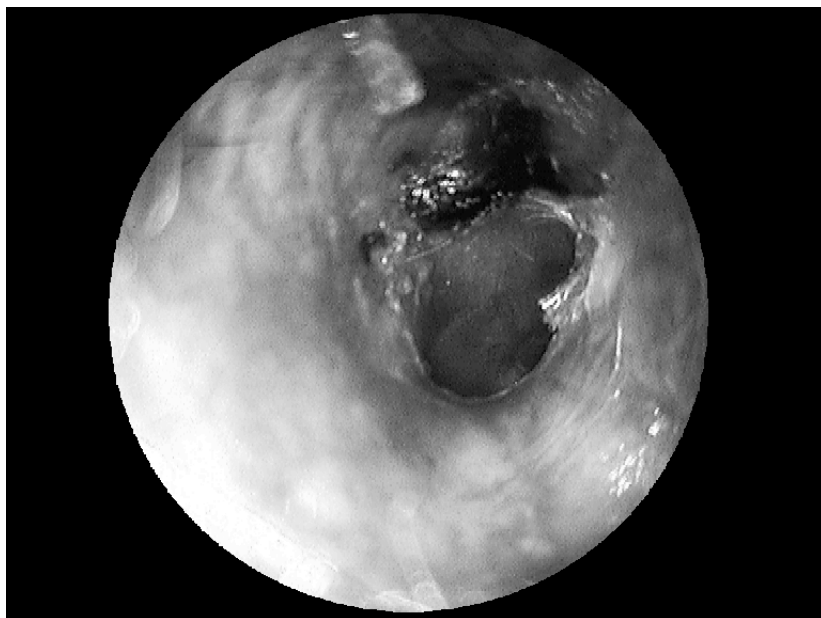


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- » Tourist case
- » Pt reported no cleaning prior to fit 1 wk ago
- » Lyric died

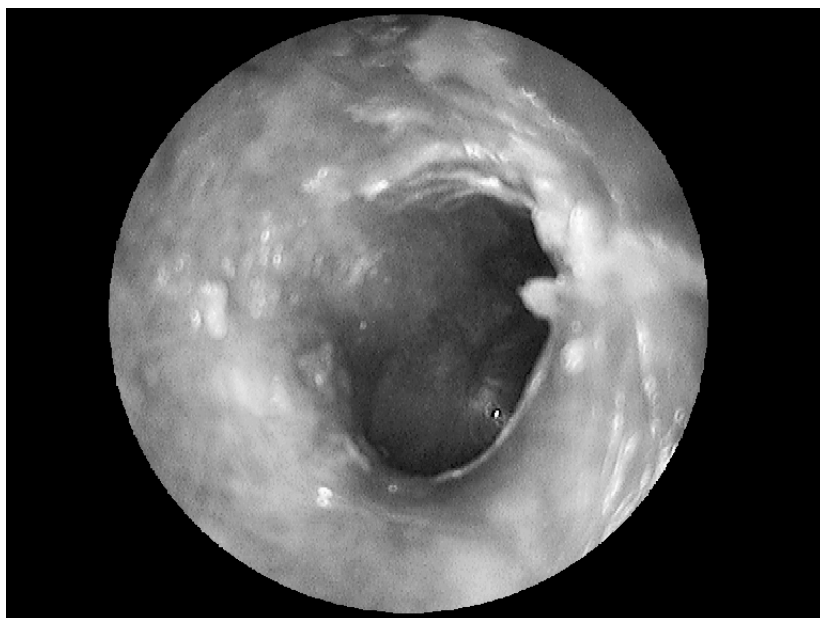
Case Studies**PHONAK**
life is on**Case 1**

- » Softened with mineral oil
- » Partially cleaned with instrumentation and suction

Case Studies

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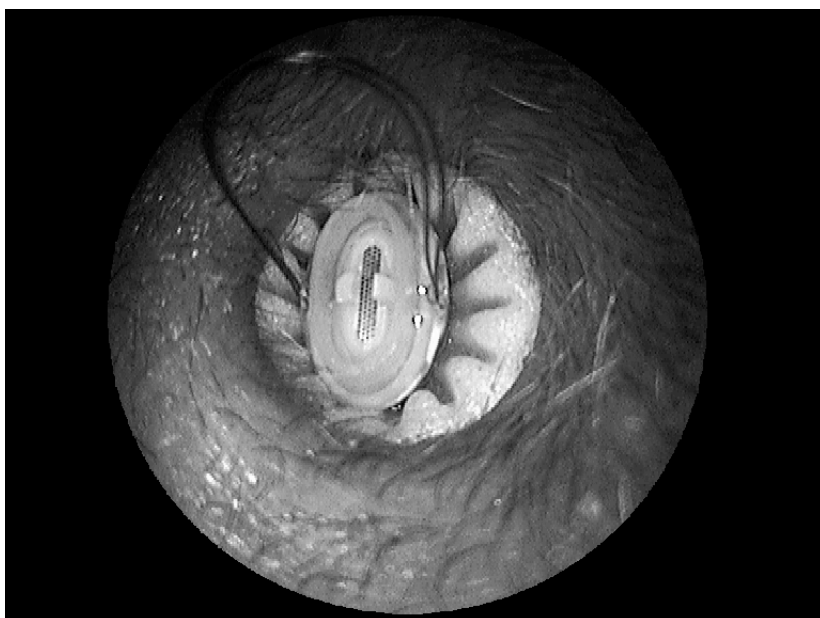


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Case 1

» Canal appropriate for fitting

Case Studies



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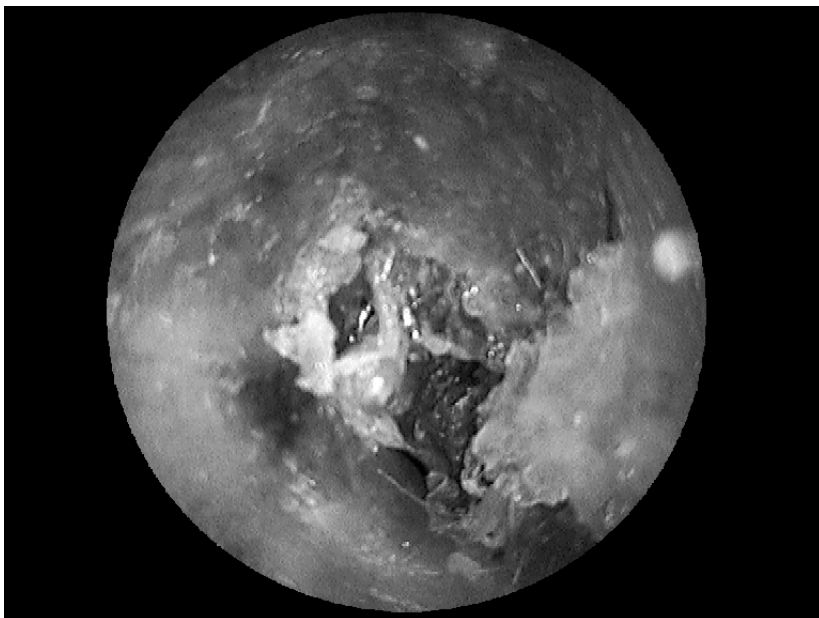
Case 2

» Newly inserted L Lyric

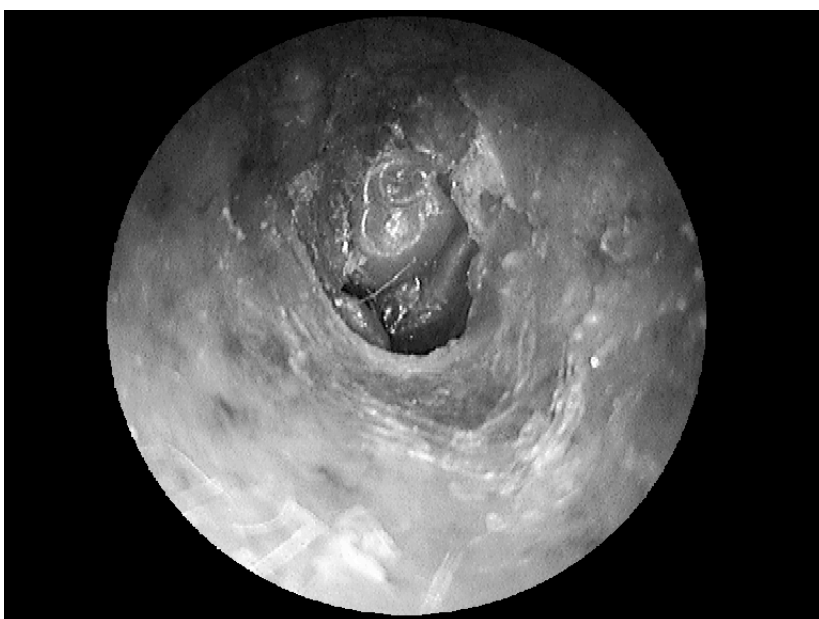
Case Studies

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**PHONAK**
life is on**Case 2**

- » Lyric removed due to reduced volume

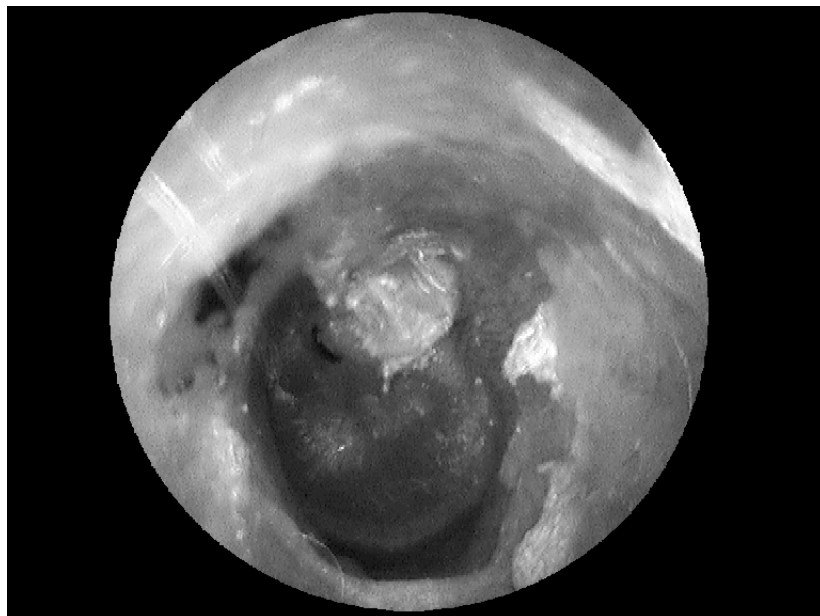
Case Studies**PHONAK**
life is on**Case 2**

- » Medial growth
- » After cleaning

Case Studies

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**PHONAK**
life is on**Case 2**

- » Medial growth
- » After 1 wk rest

Case Studies**PHONAK**
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- » Scheduled Lyric removal

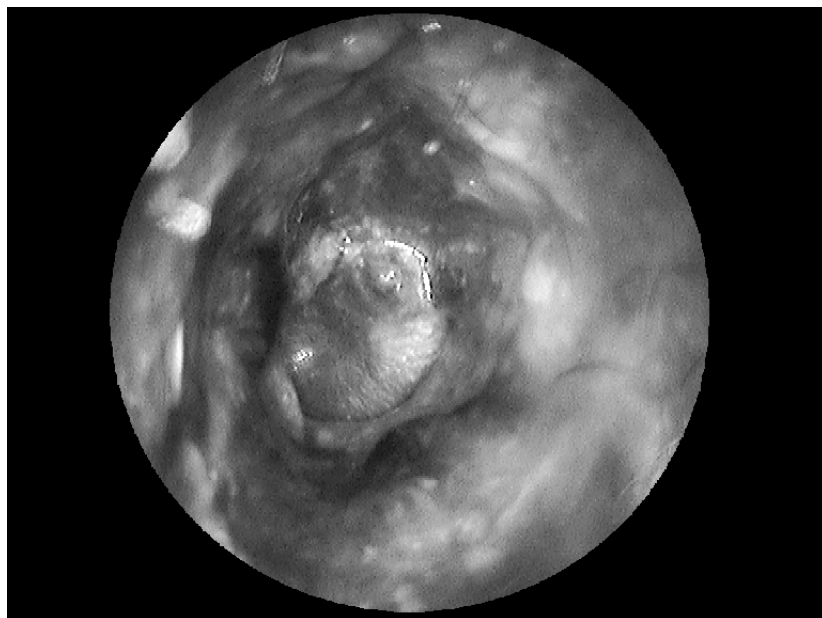
Case Studies

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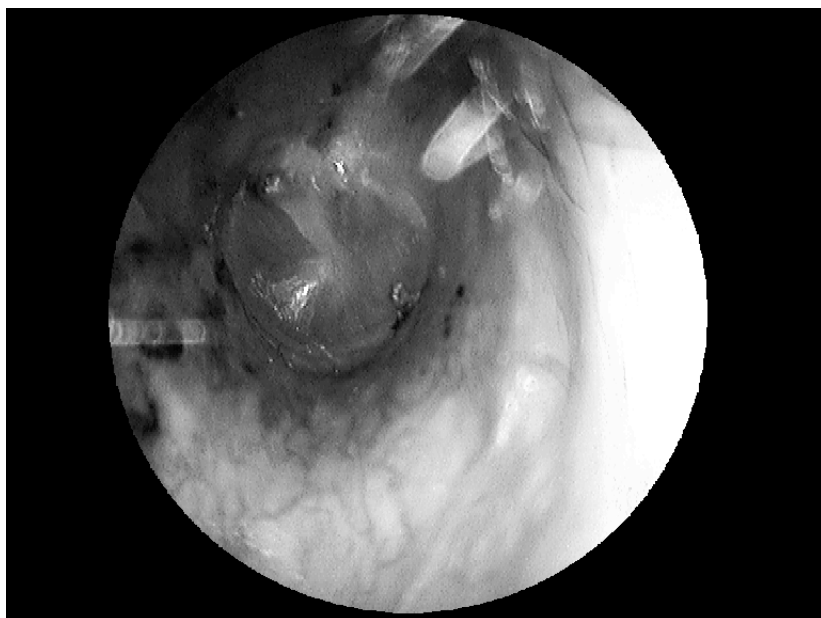
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- » Lyric has stopped working
- » Pt manipulates device
- » Pt having difficulty removing device

Case Studies**PHONAK**
life is on**Case 4****Case Studies**

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Case 4

» 2 wks after rest and cleaning

Case Studies



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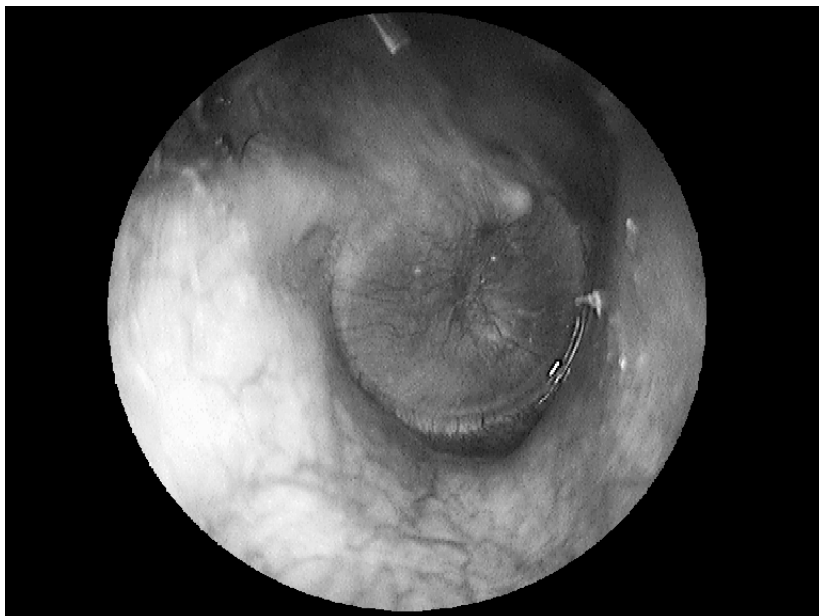
Case 5

» dried blood after Lyric removal

Case Studies

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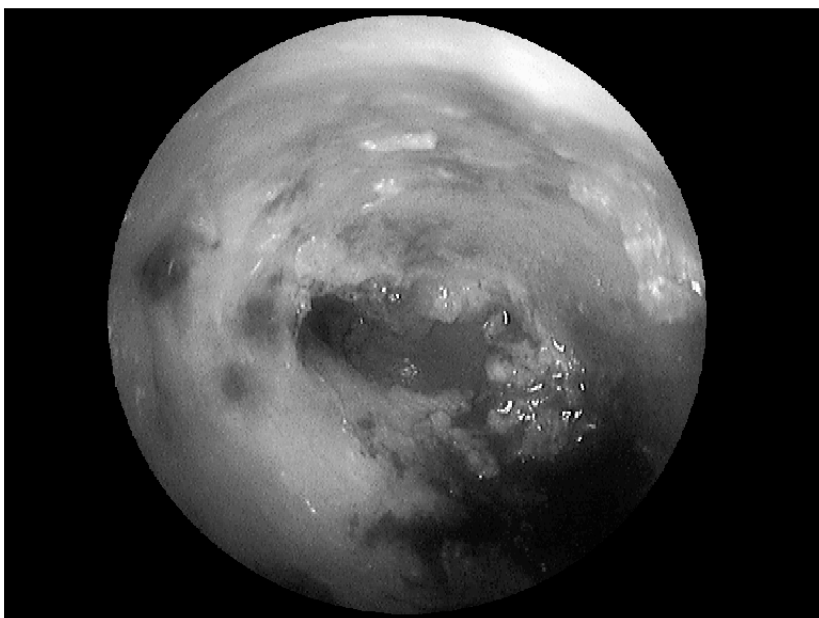


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Case 5

» 2 wks after removal

Case Studies



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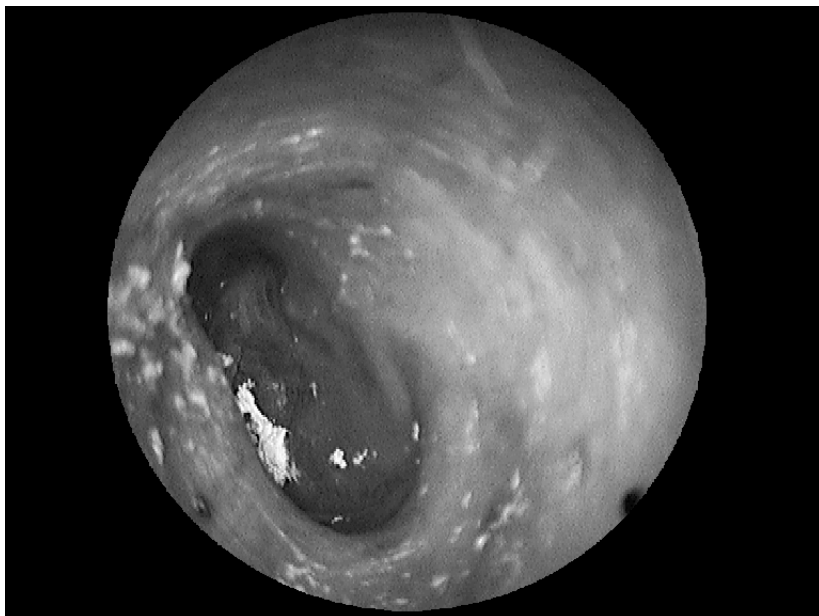
Case 6

» 97 y.o male
» dedicated Lyric user
» vulnerable skin
» Lyric removal for weak device

Case Studies

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- » 97 y.o. male
- » ear still healing at 1 wk
- » needs to continue resting

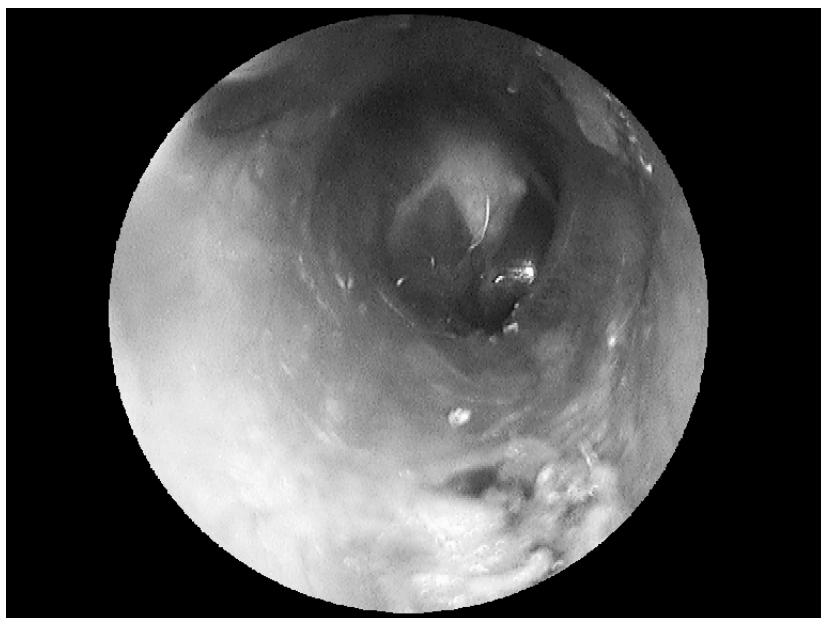
Case Studies**PHONAK**
life is on**Case 7**

- » 50 y.o. male
- » Note pre-existing TM abnormality

Case Studies

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PHONAK
life is on

Case 7

» small ear canal ulcer will
need to heal prior to refit

Case Studies

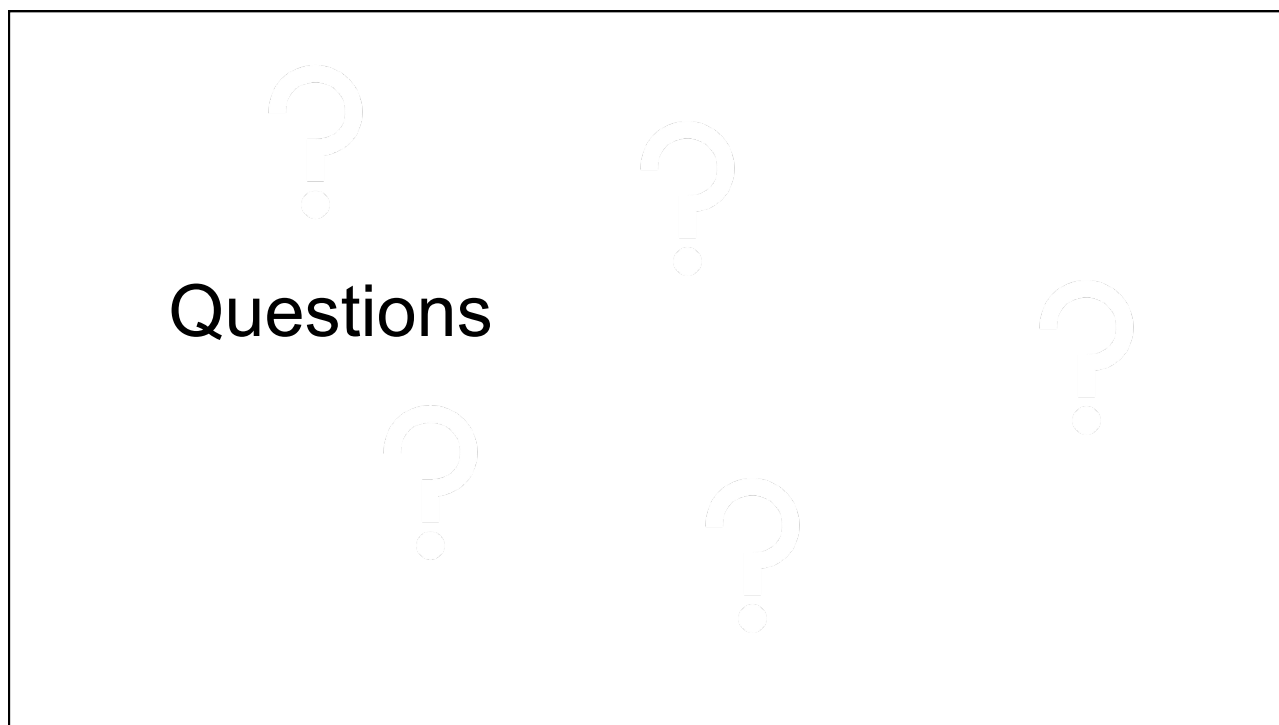
Key takeaways

PHONAK
life is on

- **Lyric is the only product available to replace hearing 24/7, except Cochlear Implants.**
 - Why give up hearing for 10-12 hours a day or more?
- To be good at something new, you have to be dedicated to spend time to become proficient – and Lyric is something new even though it's a hearing aid.
 - If you are afraid, you won't be successful for your patients.
- **The ear canal is skin - skin heals.**

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