

# Physician Medical Clearance Form



Date: \_\_\_\_\_

RE: Medical clearance for: \_\_\_\_\_

To: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Your patient, \_\_\_\_\_ is interested in being fit with Lyric extended wear hearing aids. Because these hearing aids are placed deep in the ear canal and are worn 24/7 for months-at-a-time, they present unique fitting requirements. Lyric is worn successfully by patients who are generally healthy with normal ear canal anatomy and good skin quality. Your patient has reported the condition indicated below. Please evaluate and determine if you feel he/she is an appropriate candidate for Lyric extended wear hearing aids.

## Immune System

Lyric should be contraindicated if a patient's immune system is significantly impacted by an underlying condition and/or they present with recurrent infections.

- Diabetes** - Is the diabetes managed with no concerns of complications?  YES  NO
- Compromised immune system** - Is the immune system at a managed state with no concerns of recurrent infections?  YES  NO
- Chemotherapy within 6 months** - Has the immune system recovered?  YES  NO

## Coagulation System

Lyric is placed deep in the ear canal and replaced every few months. Lyric should be contraindicated if the patient has a history of spontaneous bleeding and/or very easy bruising.

- Anticoagulation medications** - Is the patient monitored with no concerns of spontaneous bleeding or very easy bruising?  YES  NO

## Electromagnetic Interference

Lyric is programmed and adjusted via a magnet. Patients are instructed to keep the SoundLync magnet more than 1cm from the implantable device or its control port to avoid interference. The Lyric device itself poses no electromagnetic interference.

- Implantable medical device:** \_\_\_\_\_
  - Given the above implantable medical device, does the patient understand to keep the SoundLync magnet more than 1cm away from the implantable device or its control port?  YES  NO

## Pediatric Patients

All persons under the age of 21 require medical clearance before being fit with hearing aids. The pediatric user must be able to understand safe Lyric use.

- Minor under the age of 21** - Does the patient sufficiently understand safe Lyric use?  YES  NO

If any of the above question(s) were answered **"No," Lyric use is not recommended.**

If all the above questions were answered **"Yes," is the patient cleared for Lyric hearing aid use?**  YES  NO

Physician Signature: \_\_\_\_\_

Printed Name \_\_\_\_\_

Please fax or email this completed form to our office at \_\_\_\_\_

Attached you will find further information on Lyric hearing aids. Should you have any questions or need additional information, please do not hesitate to contact me.

Regards,

\_\_\_\_\_

## 24/7

Uniquely bio-engineered to be worn 24/7 for up to 120 days. Patients wear Lyric during their daily activities - sleeping, showering, exercising and talking on the phone.

## Effortless

Lyric uses the pinna to naturally direct sound into the ear canal. There are no batteries to change, no maintenance is needed, and no daily insertion or removal is required. While patients can remove the Lyric devices, the insertions are performed by a Lyric trained professional.

## Invisible

Lyric is the only invisible, extended-wear hearing device, and is placed approximately 4mm from the tympanic membrane.

## Lyric Materials

### Seals

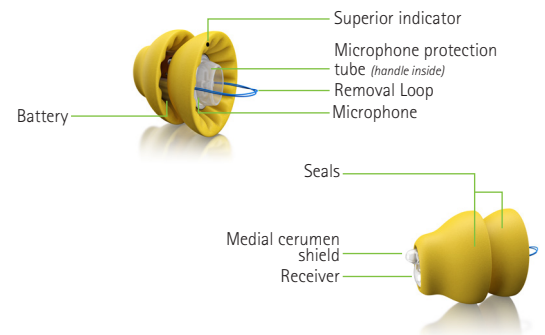
- Polyurethane foam with silicone coating provides a moisture vapor transfer rate (MVTR) that ensures ear canal ventilation and barometric pressure change relief
- Silver oxide antimicrobial coating to mitigate risk of infection
- Yellow No. 5 dye

### Battery

- Does not contain mercury

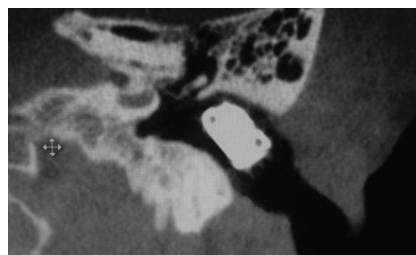
### SoundLync

- Contains a magnet that allows the patient to change the volume and put the device into sleep, off or on modes
- Minimal magnetic field strength at a distance over 1 cm
- Small hooks on the other end to allow the patient to self-remove the device if needed



## Additional Information

Lyric has been commercially fit since 2007 and over 200,00 Lyric fittings occurred worldwide in 2013. Clinical data monitoring since 2001 shows no permanent complications. A small percentage of patients experience reversible ear canal or tympanic membrane inflammation.



Visualization (diagram and CT\*) of Lyric placement in the ear canal, approximately 4mm from the tympanic membrane

\*CT not needed for Lyric evaluation or placement confirmation