

Patient Information Sheet v2.0

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Prior to starting the assessment, your ear care provider (ECP) will discuss the aims and benefits of otoscopy, ear wax removal and hearing assessment. In order to check that it is safe to proceed you will be asked some questions about your ears and general health. It will also be necessary to carry out a detailed digital visual examination (otoscopy) of your ear(s) and confirm that wax is present. If safe to do so and clinically necessary, wax will be removed from your ear(s) using the most appropriate method according to the quantity and consistency of the wax discovered. Please note it is common for your consent to be taken by the ECP. This practitioner will be suitably trained and competent to take consent and to perform the procedure. You may have questions before starting, during or after your procedure. Please discuss any concerns about your treatment with your ECP. The risks quoted in this Patient Information Sheet assume that you have no additional factors, which would increase your risk.

1. Otoscopy (Examining your ears)

The ECP will ask for your permission to examine your ear(s) using the digital video otoscope called the Tympa device. This allows examination of the ear canal and eardrum. The assessment involves you sitting comfortably whilst allowing the ECP to gently insert the digital otoscope into your ear. The ECP will then explain what they see during the assessment. Depending on what is found, a further review with a general practitioner (GP), audiologist, or an ear, nose and throat (ENT) specialist may be required.

Common problems often found when examining the ear include:

1. Ear wax or foreign body that might be blocking the ear
2. Discharge – fluid coming out of the ear
3. Bulging eardrum – indicating that there is infected fluid in the middle ear
4. Dull eardrum – indicating uninfected fluid in the middle ear (glue ear)
5. Retracted eardrum – indicating that the Eustachian tube is not working properly
6. Perforated eardrum – a hole in the eardrum, with or without signs of infection

Risks

Common (Might happen – more than 1 in 20)

- **Mild discomfort when the otoscope is introduced / removed from the ear**

Rare (Probably won't happen – fewer than 1 in 100)

- Severe pain
- Trauma to the ear canal

2. Hearing Assessment

A hearing assessment involves placing headphones over both ears. The Tympa device will play a range of different sounds at varying loudness and pitch through the headphones. Each time you hear one of the sounds you will be asked to press a button on the Tympa screen. The assessment will start with louder sounds and get progressively quieter. The aim of the assessment is to establish the quietest sounds you can hear. Depending on what is found or based on what you report, a further review with a general practitioner (GP), audiologist, or an ear, nose and throat (ENT) specialist will be recommended.

If you have a device called programmable ventriculo-peritoneal (PVP) shunt then you **MUST** inform your ECP and **NOT** proceed with hearing assessment.

Risks

Common (Might happen – more than 1 in 20)

- Discomfort to some loud or high pitch sounds in the assessment, but this tends to be temporary

- Temporary worsening of pre-existing tinnitus

Rare (Probably won't happen – fewer than 1 in 100)

- Vertigo
- Permanent worsening of pre-existing tinnitus
- Triggering the onset of tinnitus

3. Ear Wax Removal

Ear wax removal maybe necessary to relieve fullness/blocked sensation of the ear, and/or to enable otoscopy and hearing assessment.

Pre-Procedure

You may be advised to soften the wax with olive oil prior to your appointment. Your ear(s) may feel blocked following application of an ear wax softener due to the expansion of the wax. If you are a hearing aid wearer it can be advisable to avoid wearing the hearing instrument/s when olive oil has recently been administered, therefore overnight application of an ear wax softener may be best. If you have a hole in your eardrum (current or previously) then do not use sodium bicarbonate based eardrops to soften the wax.

Procedure

Two methods of wax removal may be used during your appointment, microsuction and/or manual removal.

Removal of wax using manual extraction instruments

Fine hand-held instruments are introduced carefully into your ear and used to gently remove the wax from the ear canal. These will not be used when the wax is deeply situated in the ear canal.

Wax removal using microsuction

Wax is removed from the ear by a small suction tube which can be noisy.

Risks

Your ECP has undertaken training and is certified as competent in ear care and wax removal and will use best practice procedures to minimise any risk. However, even when performed with the utmost care, there are some risks involved in wax removal. These risks include:

Common (Might happen, more than 1 in 20)

1. Wax removal cannot be completed

Uncommon (Unlikely to happen, fewer than 1 in 20)

1. Discomfort / pain (minimised by application of olive oil prior to appointment)
2. Damage to skin of the ear canal (minimised by application of olive oil prior to appointment)
3. Bleeding from ear canal (abrasion or bruising)
4. Ear infection (minimised by water precautions post procedure)
5. Temporary reduction in hearing
6. Temporary hearing sensitivity
7. Temporary worsening of existing tinnitus
8. Temporary irritation to the throat or stimulation of cough

Rare (Probably won't happen, fewer than 1 in 100)

1. Damage to the ear drum during the procedure (minimised by restricting the depth of insertion of the suction tube)
2. Feeling Lightheaded
3. Temporary dizziness

Extremely rare (Probably won't happen, fewer than 1 in 1000)

1. Permanent hearing loss (minimised by limiting time of exposure to noise of suction machine and avoiding any contact with or trauma to the ear drum)
2. Permanent new tinnitus (minimised by limiting time exposure to noise of suction machine)
3. Fainting during or shortly after the procedure

4. Outcomes

If the wax cannot be removed

Depending on the amount and consistency of the wax and your own comfort, it may not be possible to remove all of the wax in a single appointment. A second or third appointment may be required with further softening of the wax for a few days between visits using alternative softeners as advised.

Onward referral

In some situations, wax removal may be deemed unsuitable or need to be abandoned during the procedure due to safety reasons. This is due to identified abnormalities of the ear which require further assessment by your GP or an ENT specialist, and hence making it inappropriate to proceed.

It may be necessary to refer you following the procedure for a follow up with a medical professional either directly (or via the “Tympa Panel” remote review system) for further management, advice, or a second opinion. Most commonly this is because:

1. Evidence of current or recent infection has been discovered
2. Evidence of current or previous damage to the ear has been discovered
3. Wax removal procedure has made you feel unwell
4. Wax has proven to be too difficult to remove safely or without causing discomfort
5. Foreign body has been discovered in the ear which cannot be removed safely

Media recorded

Before, during and after the procedure your clinician will record images and videos within your ear(s). This media may be used for the following reasons:

1. To request further advice or a second opinion from another suitably qualified medical professional
2. For training, education, research
3. For improving TympaHealth products
4. To ensure you, the patient, are as informed as possible

Aftercare

Keep ears dry for a minimum of 24 hours after the appointment. It can be helpful to use a cotton wool ball in the entrance to the ear canal with some petroleum jelly when showering. Inform your clinician and seek advice from an appropriately qualified medical professional immediately if any discomfort, pain, swelling, discharge, odour or disruption to your hearing is experienced following the procedure.

5. Consent

You will be asked to sign a consent form on the Tympa System. The full wording is as follows:

1. I understand that the ear care provider (ECP) will remove wax from my / the patient's ear as clinically appropriate, and;
2. I understand that the removal of wax may take more than one appointment and that it may be necessary to refer me / the patient to a medical professional if any complications arise, and;
3. I understand I can ask the ECP to stop the procedure at any time, for any reason, and;
4. I am 18 years old or over / I am a third party and have legal authority (see statements below) and hereby agree the services and give informed consent to the ECP to perform otoscopy / earwax removal / hearing assessment on my / the patient's ear(s) using the Tympa System, and;
5. By signing I confirm I have read the Patient Information Sheet version 2 above and understood the benefits and risks associated with otoscopy, ear wax removal by microsuction and hearing assessment. I have had the opportunity to discuss alternative options, including no treatment.

Consent for 18 years old and over:

I hereby give informed consent to the ECP to perform otoscopy / earwax removal / hearing assessment on my ear(s) using the Tympa System.

Consent for 18 years old and over and lacking capacity to consent:
(Ear care provider to complete)

I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of treatment. I believe the examination of the ear(s) including otoscopy / earwax removal / hearing assessment to be in the patient's best interest. Where possible I have consulted the patient's family members / carer or other form of legal authority.

Consent for under 18 years old:

(Parental or person with parental responsibility agreement to investigation or treatment for a child or young person under 18 years).

I agree for the ear care provider to perform otoscopy using the Tympa System and I confirm that I have 'parental responsibility' for this child. I hereby give the ear care provider informed consent. Your Relationship to the Child (Person with Parental responsibility) is one of the following: Mother / Father, legally appointed guardian, a Person with Residence order concerning the child, a local authority designated to care for the child, or a local authority of person with an emergency protection order for the child. The ear care provider confirms that prior consent has been obtained from a person with parental responsibility.

Data Protection Statement:

I understand that by consenting to this procedure, my / the patient's medical history, images, videos and hearing assessment will be shared with, and stored by Tympa Health Technologies Ltd (TympaHealth).

I understand that TympaHealth will not access my / the patient's identifiable information except for technical support issues or unless in the rare event it is deemed necessary in a safeguarding scenario or if an undiagnosed condition is discovered.

I understand that TympaHealth will use my / the patient's anonymised medical history, images, videos and hearing assessments to further product development and for research purposes. Further information on how TympaHealth processes your data can be found on TympaHealth's Privacy Notice at <https://tympahealth.com/privacy-notice>