Ear-O-Care®: A Safer Earwax Removal Alternative

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Key Features and Benefits of Ear-O-Care®:

- Dual-action, soft silicone-based spiral and scoop tip
- Ten disposable tips for hygienic cleaning
- Patented 'safety stop' feature to protect the inner ear
- Portable and compact self-storing handle
- Safer earwax cleaning ability than Q-tips and ear picks
- Soft, flexible silicone tip ensures pain-free cleansing

Abstract

The buildup of cerumen, or earwax, in the ear canal is a common issue that can lead to hearing problems, itching, and irritation if it is not properly addressed. There are several self-cleaning techniques that are frequently used to cleanse the ear canal, such as wax-softening drops, cotton swabs (Q-tips), bulb syringes, and ear picks or scoops that are made from metal or hard plastic. Q-tip and cotton swab use is the primary cause of earwax impaction, which refers to excessive earwax buildup that leads to discomfort. Furthermore, ear cleaning tools with sharp, pointed, or blunt ends not only increase the risk of pushing earwax further into the ear canal but can also lead to eardrum perforation due to improper insertion. To resolve this issue, ND Products Inc. developed Ear-O-Care[®], a US-patented, silicone-based spiral and scoop ear cleaner that offers a safer alternative to cotton swabs and other hazardous tools that are associated with serious health problems, including earwax impaction, perforation, and infections. The unique 4-in-1 design features: 1) dual-action 360° cleaning; 2) a wide-flared base for safer insertion; 3) disposable, hygienic tips; and 4) a portable, self-storing handle. Ear-O-Care® offers a contoured flare tip, as well as an exclusive 'safety stop' feature at the base that prevents deep insertion into the ear canal. The anatomically designed 'safety stop' feature, in combination with the spiral and scoop tip, provides gentle, efficient, and hygienic earwax removal—positioning Ear-O-Care® to become the flagship 4-in-1 earwax cleaning kit.

Introduction

Cerumen, also known as earwax, is a naturally produced substance that serves as a protective barrier for trapping bacteria, germs, dust, and other foreign particles. The accumulation of earwax in small amounts is normal as skin cells within the ear canal and ear drum continuously migrate outward. Therefore, cleaning the ears regularly may not necessary for some people, while others may need to frequently remove excess earwax from the outer parts of the ear. In addition, some people may experience various health issues that arise in the ear canal, including boils, glandular tumors (abnormal cell growth in glandular tissue), and sebaceous

cysts (benign lumps under the skin) [1, 2]. However, the majority of individuals who report earrelated complaints struggle with the buildup or impaction of earwax [1].

Earwax impaction is characterized by earwax blockage that results in physical symptoms [2]. Impacted earwax may also hinder an ear examination and block or reduce hearing. Symptoms of earwax impaction include pain, discomfort, itching, hearing difficulties, tinnitus, dizziness, and a reflex cough [3]. This issue affects approximately 1 in 10 children, 1 in 20 adults, and 1 in 3 older individuals [4, 5]. In addition, earwax impaction accounts for about 12 million doctor visits and over 8 million earwax removal procedures each year [3].

Impaction typically occurs when the normal clearance of earwax is prevented by the use of certain devices, such as headphones, earplugs, and hearing aids, or by cleaning the ears with Q-tips, cotton swabs, ear fins, ear picks, or scoops made from solid material (Figure 1) [1].



Figure 1. Hazardous ear cleaning tools that are associated with an increased risk of eardrum and ear canal damage.

The most common self-cleaning technique that may lead to pain, bruising, bleeding, damage, otitis media (middle ear infection), and impaction involves repeated attempts to remove earwax with sharp, blunt, or pointed objects [6-9]. Furthermore, Q-tips and cotton swabs, which are designed to clean only the outermost region of the ear, are one of the primary causes of earwax impaction [2, 6]. Despite a warning listed on the label indicating that swabs should not be placed into the ear canal and should instead be used to clean the outer surface of the ear only, many people still experience impacted earwax and serious injuries from using Q-tips and cotton swabs incorrectly [7].

A more serious issue that may occur due to self-cleaning with sharp, blunt, or pointed tools (e.g., swabs, picks, scoops) is eardrum perforation (rupture), as this injury leads to hearing loss and requires medical treatment [8]. Due to these risks, health professionals emphasize the avoidance of placing pointed or sharp objects into the ears for earwax removal [2-6].

To provide consumers with a safer alternative to conventional self-cleaning tools, ND Products Inc. developed Ear-O-Care[®], a soft silicone-based spiral and soft scoop tip earwax removal kit. This US-patented innovation is an ideal solution to the current earwax cleaning problems.

Advantages of Ear-O-Care®

Ear-O-Care® is a hygienic, portable, pain-free ear cleaner that offers a safer alternative to Q-tips, cotton swabs, ear picks, and other hazardous objects that are commonly used to remove earwax buildup. The unique 4-in-1 technology offers:

- A dual-action spiral and scoop tip with exfoliating grooves that gently extract earwax
- A 'safety stop' feature consisting of a wide-flared base that is designed to reduce the risk
 of over insertion that is observed with swabs and ear picks
- Soft, silicone tips that are gentle on the ears and disposable for optimal hygiene
- A self-storing handle with a protective cap and two tip cartridges for a convenient, compact, and portable device

The base of the handle also contains an arrow that indicates the direction to rotate the device for proper cleaning of the ears once or twice a week as needed.

The exclusive design is based on years of research and development that incorporates key anatomical features of the ear into the finished product. This includes the structure of the outer ear (auricle), which includes the concha, tragus, and ear canal, as well as the distance between the auricle and the eardrum. The ear canal has a length of about 2.5 centimeters (cm) and a diameter of around 0.6 cm [9]. The shape of the ear canal is an elongated S. The outer region of the ear canal is cartilage, and the semicircular opening is positioned in the skull bone. In children, the outer cartilaginous region of the ear canal is nearly circular, but this region attains an oval shape as individuals get older [9].

Based on these anatomical features, the Innovative Team at ND Products Inc. developed Ear-O-Care® with a flared tip that accommodates the size and shape of an adult's ear. In particular, the length of the spiral and scoop tip is shorter than the length of the ear canal, thus preventing the tip from reaching the eardrum. Furthermore, the wide-flared base of the 'safety stop' helps users avoid excessive insertion by accounting for unexpected arm and hand movements. The black arrows in Figure 2 demonstrate how the tip base stops the user from excessive insertion.

Figure 2. The 'safety stop' feature is indicated by the black arrows on the outer region of the ear. The specific measurements of the ear for adults were incorporated into the design of the tip base to prevent users from excessive insertion, as the tip cannot reach the eardrum.

To further reduce the risk of injury and avoid any uncertainty, the material for Ear-O-Care® was selected by considering important factors that might affect human health. According to research, silicone is a favorable material as it is flexible and does not have harmful effects on the ear



canal [2, 9, 10]. Therefore, the soft silicone tip is anatomically designed to provide gentle earwax extraction without reaching the eardrum (Figure 3). Another key feature is the avoidance of falling earwax during removal [2, 10], which is avoided due to the spiral grooves on the tip (Figure 2). The spiral grooves and scoop tip trap earwax as the device is rotated in a unidirectional manner. This technique provides gentle, efficient removal of earwax without the risk of further impacting the ear canal.

Figure 3. Soft, silicone-based spiral and scoop tip traps earwax during unidirectional rotation for gentle, 360° earwax cleaning.

Similarly, research supports the use of more rigid material for the grip and stop of the handle to support the geometry of the ear removal tool without damaging the ear canal walls [2, 10]. The



grip and stop of the handle also ensure that the tip is introduced to the ear canal in the right path to avoid hurting or damaging the auricle. These properties formed the basis of the 'safety stop' feature, ensuring safer, more efficient, and more comfortable cleaning with Ear-O-Care® than other hazardous cleaning tools (e.g., swabs, ear picks). Most importantly, this feature circumvents the main issues associated with swabs, ear picks, and jet irrigators that often push earwax deeper into the ear (earwax impaction) or cause serious trauma, such as perforation.

Overall, this manual cleaning device negates the use of harmful earwax removal tools, thus solving serious problems that often develop with other devices, such as skin damage, impacted earwax, infections, and eardrum perforation.

Key Differences Between Safe Swab and Conventional Earwax Removal Techniques

One of the most frequently used self-cleaning techniques for earwax buildup involves Q-tips and cotton swabs [6, 11]. Research consistently shows that improper swab use is attributed to a lack of understanding regarding the risks associated with placing cotton swabs or other pointed objects into the ears [7, 8, 11]. Q-tips and cotton swabs are designed to clear earwax that has migrated to the outer region of the ear, with the instructions specifically stating, "Do not insert the swab into the ear canal as entering the ear canal could cause injury." An additional warning is to keep swabs out of the reach of children. However, most people use swabs by placing them into the ear canal and twisting the swab to collect earwax before removing it from the ear canal [11].

Ear picks are also commonly used for removing earwax buildup, particularly deep in the ear canal [2]. Kits that consist of an ear pick with a camera are currently marketed for the removal of impacted earwax, but this unsafe practice is linked to perforation, as small movements of the arm can transfer to the hand and device, leading to improper insertion A shift of less than one-half inch can cause excessive earpick insertion that results in eardrum damage [2, 8, 11]. Furthermore, this type of device requires wiring, the use of a phone, and an app, which makes the cleaning process cumbersome and less hygienic by using the same tip each time. These hazardous practices are linked to serious issues and warrant a safer alternative, such as Ear-O-Care[®].

The anatomically designed tip on the Ear-O-Care® handle is made from flexible silicone material that gently cleans the inside of the ear canal while reducing possible skin irritation, preventing further earwax impaction, and avoiding contact with the eardrum. The 'safety stop' feature and arrow on the base also offer an easy-to-use method for cleaning that can be performed by anyone without the need for medical qualifications. Furthermore, the flared-tip design of Ear-O-Care® contours to different ear sizes. By developing an anatomically designed device, this all-in-one earwax cleaner is gentler and safer than Q-tips, cotton swabs, and ear picks.

Another common earwax removal technique entails the use of wax-softening drops that typically consist of carbamide peroxide, sold under trade names that include Mollifene, Debrox, Murine, and Auraphene-B Ear Drops [12, 13]. Following the application of several wax-softening drops, the earwax may begin to slowly drain out of the ear canal, or the ears can be flushed with a bulb syringe. Improper use of the drops or bulb syringe may lead to failed earwax removal, pain, an ear infection, or eardrum perforation [12]. Placing too many drops into the ear canal, inserting the bulb syringe into the ear, and administering the flushing liquid (warm water) with too much force may lead to further impaction or injury. Some people also experience adverse reactions to carbamide peroxide and other substances in wax-softening drops, including itching, skin irritation, hives, swelling, blisters, and peeling skin [14].

Earwax removal kits that contain a jet irrigator that connects to a faucet for continuous water pressure present additional risks to various structures in the ear canal [12]. Oral jet irrigators are marketed as portable, fast, and inexpensive ear cleaning devices, but they can also cause serious trauma [2, 15]. The main issues that arise from jet irrigation are the occurrence of

dizziness and infection due to the use of tap water. More serious injuries that have been reported following the use of jet irrigation include [2, 15]:

- Tympanic membrane rupture (eardrum perforation)
- Ossicular disruption (separation of the middle ear bones)
- Subluxation of the stapedial footplate (dislocation of middle ear structures)
- Round and oval window fistulae (a defect in the membranes that separate the middle ear and inner ear)

Research shows that substantial percentages of individuals who used jet irrigators experienced a perforated eardrum with the power setting on the irrigator that was one-third full power or higher [2, 15].

An additional issue that is associated with the use of a bulb syringe or jet irrigator is temperature control. Water that is too hot or too cold may lead to dizziness or nausea. Warm water that is close to body temperature (98.6°F-100°F) is recommended, but in the absence of a temperature sensor, it is difficult to ensure the proper temperature of the water that is used for earwax removal [16]. Overall, these methods can be messy, unsafe, cumbersome, and time-consuming for people who are looking for a safer, quicker, and mess-free alternative.

The invention of Ear-O-Care® circumvents each of the risks that are associated with Q-tips, cotton swabs, ear picks, irrigators, and other hazardous ear cleaning tools that are currently on the market. The use of Ear-O-Care® does not require water, a camera, or any other attachments to facilitate earwax cleaning. Furthermore, its research-based design is not associated with any possible adverse events, including perforation, due to the dimensions of the tip and the wide-flared base.

Conclusions

Ear-O-Care® is a US-patented earwax removal kit that is unmatched in quality, safety, hygiene, and efficacy in comparison to conventional ear cleaning devices such as Q-tips, cotton swabs, sharp ear picks, blunt scoops, and jet irrigators. Furthermore, none of the frequently used ear cleaning tools have 'safety stop' features that prevent their dangerous insertion into the ear canal. The designers at ND Products Inc. developed this safety feature based on intensive research to produce a device that offers an efficient earwax cleaning solution for adults—another important aspect that conventional devices cannot offer. In addition, the spiral and scoop tip is a unique, dual-action feature that quickly and easily traps earwax for safer removal.

In 2016, the healthcare innovation team at ND Products Inc. invented Smart Swab[®], the world's first spiral ear cleaning device, and in doing so, established a new market sector. After more than seven years, Smart Swab[®] remains on the market with no reports of adverse events. Ear-O-Care[®] is a newer and more innovative design that exceeds the quality, safety, efficiency, ease of use, and portability of any other ear cleaning tool on the market, such as the hazardous

devices that consumers frequently use. These advantages are positioning Ear-O-Care® to become the flagship 4-in-1 earwax cleaning kit.

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