

**A Moldable Magnet System To Treat Auricular
Hematoma (Cauliflower Ear)**

&

**A Better Ear Plug Utilizing the same Moldable
Magnet System**

Dr. Donald Solomon, Dr. Neal Lemon, & Joe Boland



- “Build a better mousetrap and the world will beat a path to your door.”

- Ralph Waldo Emerson

And just look at that ear!

- **Dr. Donald Solomon, MD** (Director of Pediatric Otolaryngology at Cooper University Health Care, specializing in Adult & Pediatric Otology, as well as a former college wrestler and youth wrestling coach)
 - **Email: solomon-donald@cooperhealth.edu**
- **Dr. Neal Lemon, PhD, MBA** (Cooper Innovation Center)
- **Joe Boland** (Cooper Innovation Center)
- **Mike Wiley and the New Jersey Health Care Fund**
- **Merge Medical Device Studio - Tanner Hargens CEO**
 - **Nicolo Garbin PhD, Engineering Director**
 - **Kim Leon, Senior Engineer**



Lead PI: Dr. Solomon

We're a wrestling family, inevitably the ears suffered...



Auricular Hematoma Obstacle and Opportunity

The **Obstacle**: restoring normal appearance of the ear after auricular hematoma (ear blood clot) via a non-invasive method.

The **Opportunity**: creating a reliable, non-invasive pressure device to treat auricular hematoma that restores the ear to its pre-injury form.

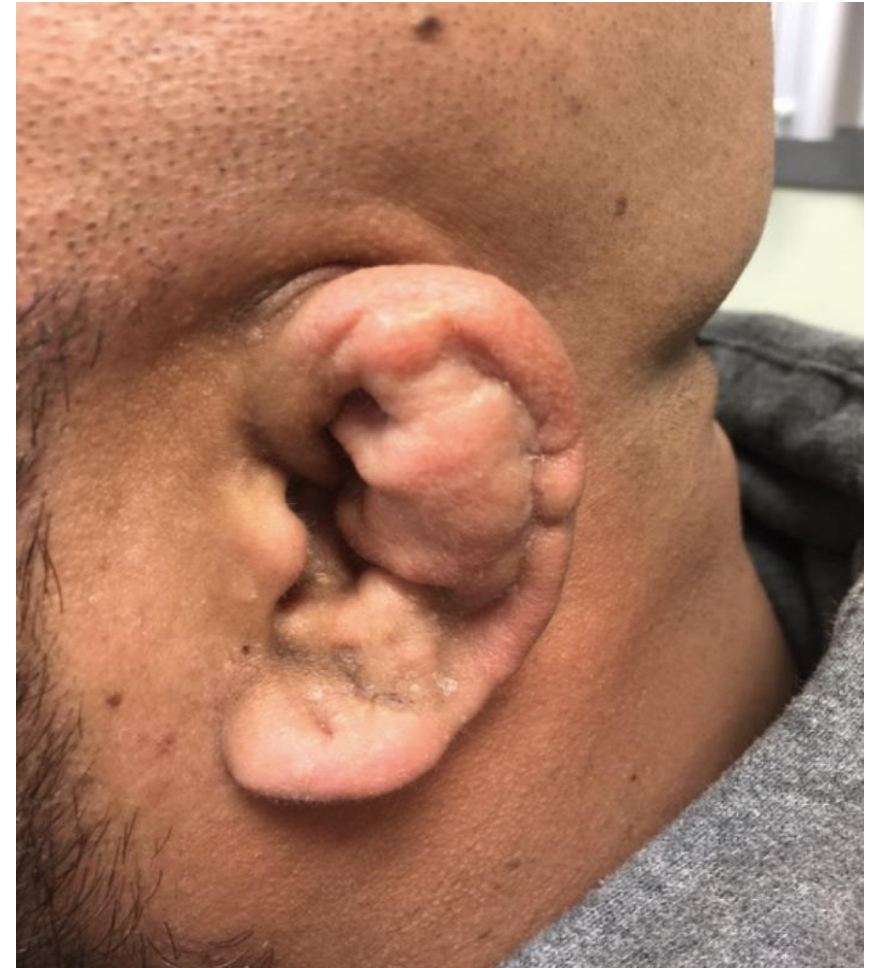
The Problem: Auricular Hematoma

- A blood clot between the ear cartilage and the overlying lining (perichondrium) caused by blunt force trauma.
- Individuals at highest risk for auricular hematoma are athletes involved in contact sports such as wrestling, mixed martial arts, boxing and rugby.



Untreated auricular hematoma leads to permanent deformity – cauliflower ear.

The blood clot within the ear fibroses over time and becomes firm and unsightly.



Effective treatment involves draining the blood clot and applying a pressure dressing.

Current methods to maintain pressure after drainage are flawed.

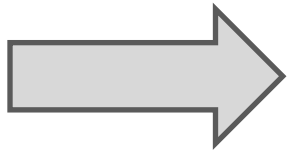


MPCO
www.mpcomagnetics.com



Initial Prototype Design:

Prototype created with a balloon and a variety of ferrous substrates. Best moldable substrate was balloon filled with iron shavings. Other ferrous attractive options exist.



Moldable balloon in the conchal bowl of the ear

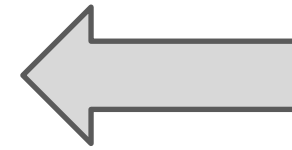


Date of first drawing:

January 2024

Date of construction of device:

February 2024



Backside disc magnet holding the conchal bowl balloon in-place

Current Technology:

Gold standard current treatment for auricular hematoma involves drainage then placement of an invasive bolster on each side of the ear. Alternative treatment involves placement of magnetic compressions discs on each side of the ear after drainage of the hematoma. Both methods have inherent disadvantages.

The invasive bolster can return the ear to its pre-injury form, however, it is painful to apply as it requires needles and stitches through the ear cartilage. The bolster also risks infection as the stitches must stay in place for a week and it requires antibiotic therapy while in place. Then it must also be removed in the office one week after placement.

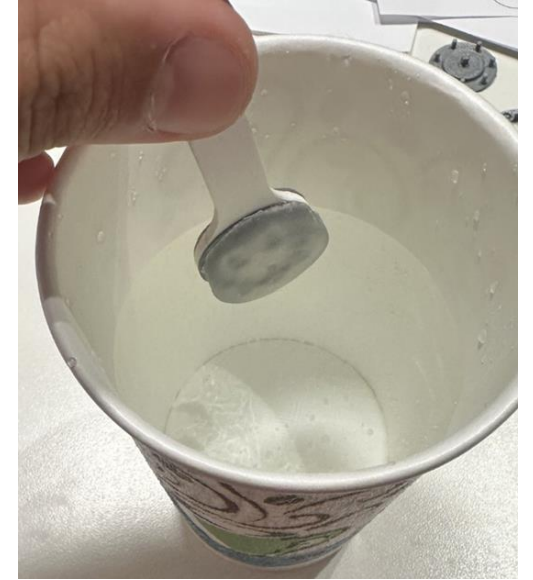
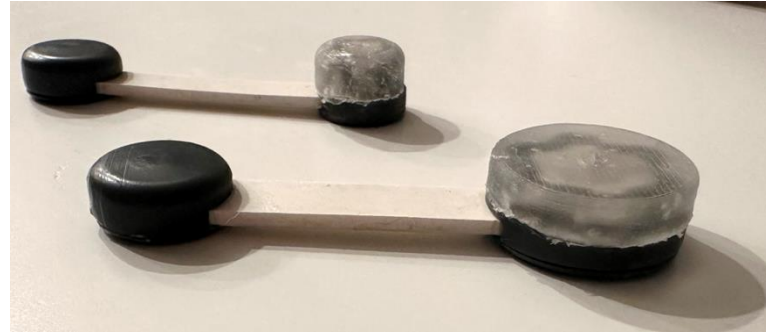
Non-moldable magnetic discs for pressure are non-invasive but the current ones on the market are rigid and do not mold to ear contours, so they don't return the ear to its pre-injury form and appearance.

The Solution: A Moldable Magnet System

A moldable magnet system - a device comprised of a back and front side magnet with overlying heat moldable EVA, a plastic material that molds to the natural contours of the ear while acting as a compression device to restore the ear to its pre-injury form without stitches. This product will improve patient outcomes while minimizing discomfort, risks of cartilage suturing, infection, pain and poor cosmetic results.

Magnetic Auricular Hematoma Treatment Device

- Dual magnet ear compression device with overlying EVA (heat moldable plastic material) allowing molding to the ear's natural contours.
- Has shown success on multiple patients in Dr. Solomon's clinic.

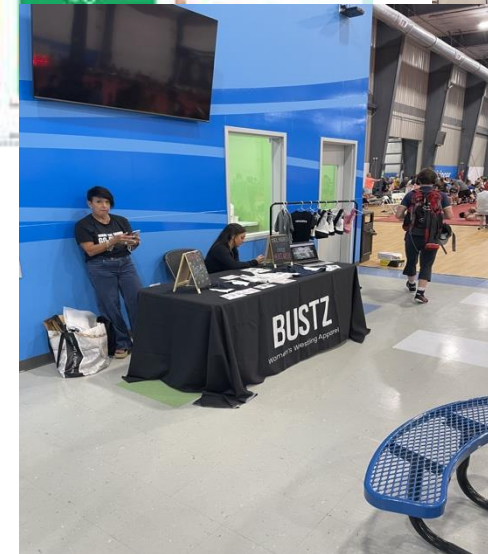


Many Options Exist For Sales & Marketing

Direct to Providers



Direct to Consumer



Intellectual Property

- Patent Pending

1. Ales BL, inventor; Ales BL, assignee. Pressure bearing auricular hematoma appliance. United States patent US 10,154,935 B1. 2014 May 27
2. Hay DM, Hay BD, inventors; Hay DM, Hay BD, assignees. Ear compression device. United States Pub No. US 2008/0086067 A1. 2006 Oct 10
3. Hay DM, Hay BD, inventors; Hay DM, Hay BD, assignees. Device and Method for Treating Ear Injuries. United States Pub No. US 2009/0182255 A1. 2009 Jul 16
4. Koehler RG, inventor; Koehler RG, assignee. Support assembly for an ear. United States patent US 8,627,824 B2. 2014 Jan 14

Market Participants

Rank order of Assignees in tech space based on a Patsnap semantic search of US10154935B1:

Ales Bryan L., Hay, Duff M; Hay, Benjamin D., Koehler, Robert Grant

Note: all patents withdrawn or inactive (nonpayment)

Market Competitors:

CauliBuds, Caulicure, MagnetRx, Earies, EarSplintz, Earlox

Exit:

License of technology or acquisition of startup showing initial sales by market participant (above)

Competitor Pricing

Product Name	Retailer	Price	Description
EarSplintz	Website	\$112	Kit includes support for right and left ear, base and catalyst to make mold, and head wrap
CauliBuds	Amazon	\$44.95	One large and one small size, a front and back magnet per size, magnets are disc shaped
MagentRX	Amazon	\$34.95	Eight magnets in various sizes & shapes and eight adjustable rubber spacers for tailored compression.
Earies	Amazon	\$29.95	One set of disc-shaped magnets, connected by a strap to prevent separation of magnets
Earlox	Amazon	\$35.99	One large and one small size, a front and back magnet per size, magnets are disc shaped

Regulatory Process, Risks, and Strategy

Phase III: Class I device – register with FDA

Cost & Time: ~\$30,000, 1 month for our Class I device

(Registration fee cost is \$7,653, average of \$20-50K, and 1 month (FDA, Credevo, Pathway Medtech))

Ear Hematoma Incidence: unknown due to lack of studies in the general population

- Risk increases with high level competition in wrestling, boxing, martial arts and rugby
- 96% of Finnish martial artists, 55.5% of high-level judo practitioners (StatPearls)
- Most high level sport practitioners in above will experience an auricular hematoma at one point in their career, often multiple

US & International Ear Hematoma Addressable Patient Population: 4.38M (estimation)

- Assumption that 20% of each population playing at a high school varsity to pro level will experience an auricular hematoma
- Total population of wrestlers: 1.9M (Statista) → 380K
- Total population of non-casual boxers: 5M (Statista) → 1M
- Total population of martial artists: 6.6M (Statista) → 1.32M
- Total population of rugby players: 8.4M (World Rugby) → 1.68M
- *Girls High School Wrestling – it's the fastest growing sport in the United States

Serviceable Available Market: ~\$262.8 - \$525.6 Million

4.38 Million and \$120 per mold = \$525.6M SAM (luxury pricing strategy)

4.38 Million and \$60 per mold = \$262.8M SAM (affordable pricing strategy)

Serviceable Obtainable Market: ~\$78.6 - \$157.7 Million

Initial: 30% percent market share in US and Europe for cauliflower ear use is ~\$157.7M in sales (1.31M cases at \$120 per unit)

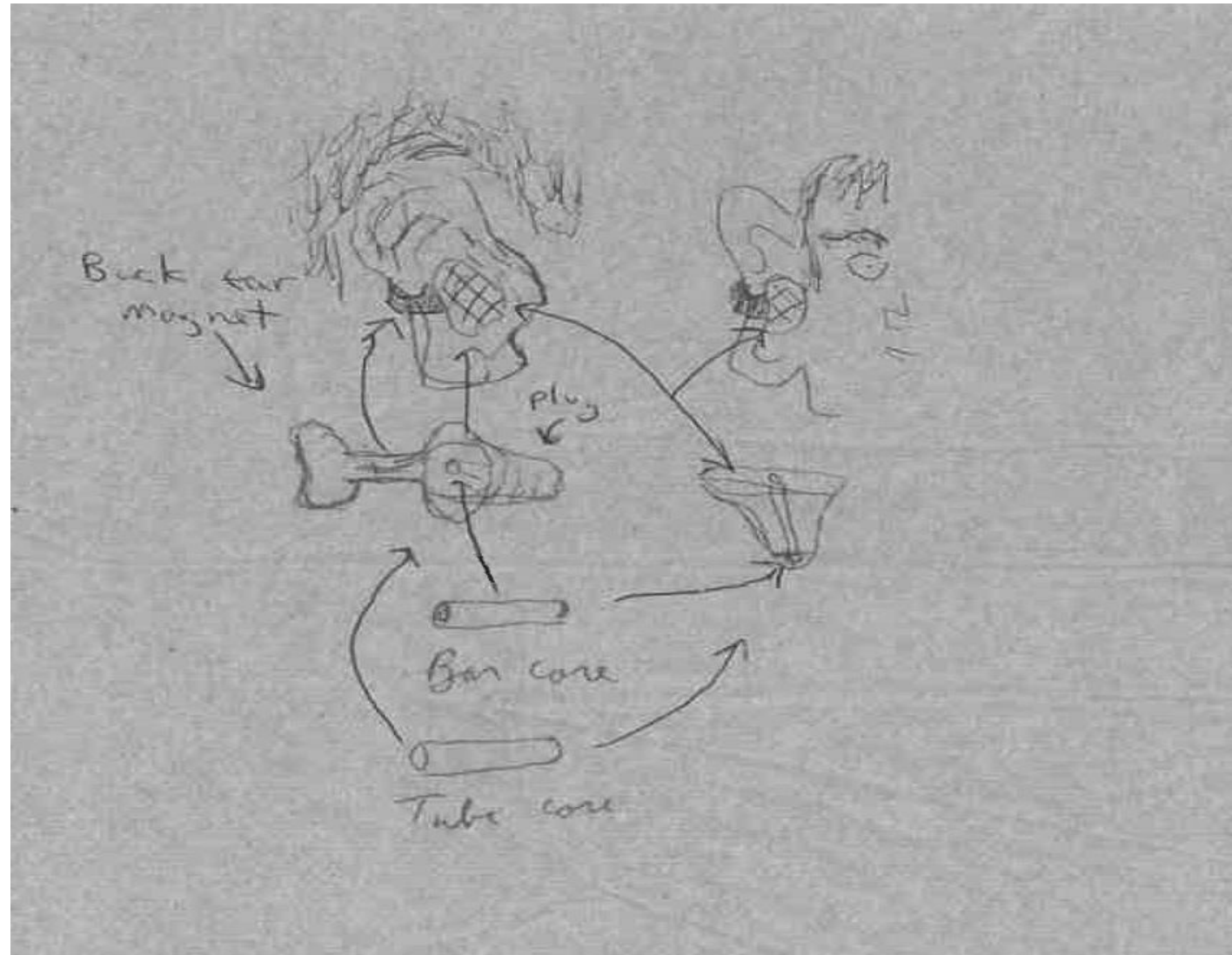
Alternate: 30% percent market share in US and Europe for cauliflower ear use is ~\$78.6M in sales (1.31M cases at \$60 per unit)

SWOT Analysis (Strength, Weakness, Opportunity and Threat)

Strengths • Clinician driven innovation • Facilities and expertise to test • Sizeable market • Moldable to ear contours	Weaknesses • Early Stage • Skeptical Target Market
Opportunities • Familiar technology components • Expanding market • Fragmented Market	Threats • Active market players with adoption • Benefit must be worth cost • Likely to fail without KOL adoption • No current large medical device company interest in licensing

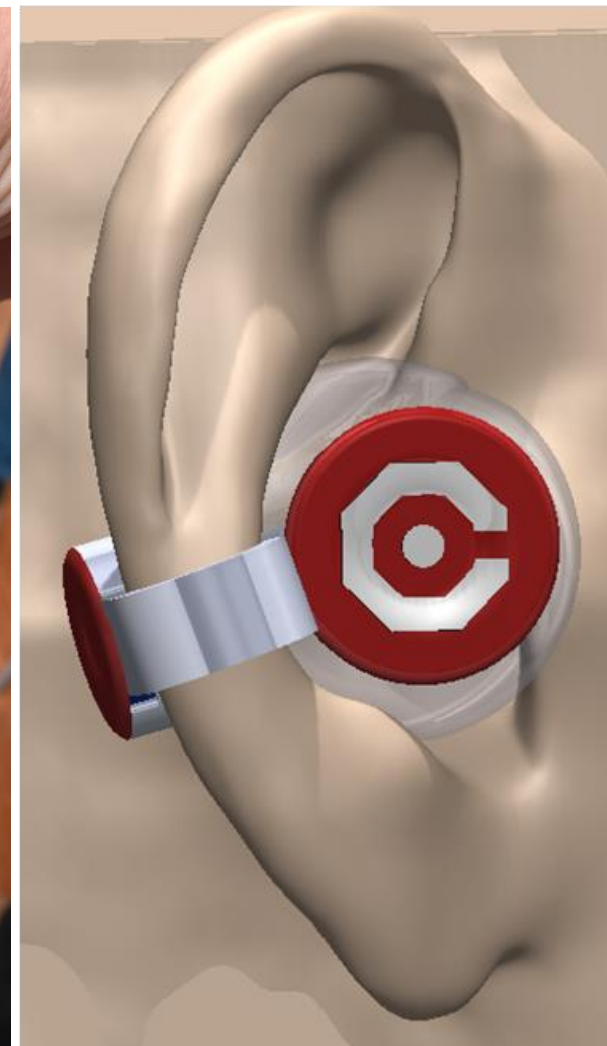
- **During creation of the moldable magnet system to treat auricular hematoma a new idea was born...**
- **A Better Ear Plug – one that is custom moldable, water-proof, sound-proof or both depending on patient needs, and held to the ear via a magnetic attachment system that prevents dislodgement.**

Back of the Napkin Renderings... Literally



A Custom Moldable Ear Plug with Magnetic Attachment

- Custom moldable ear plug utilizing EVA material – molded at home with heat like a mouthpiece.
- Provides sound dampening effects or water protection or both based on buyer / patient desire.
- Similar to custom hearing aid mold (left picture).
- Magnetic attachment prevents dislodgement during activity.



Ideas From Our Engineering Team...

MAGNETIC MOLDABLE EAR PLUGS

Custom fit. Secure. Reusable.



MOLDABLE BALL with embedded magnet

MOLDABLE BALL with embedded magnet

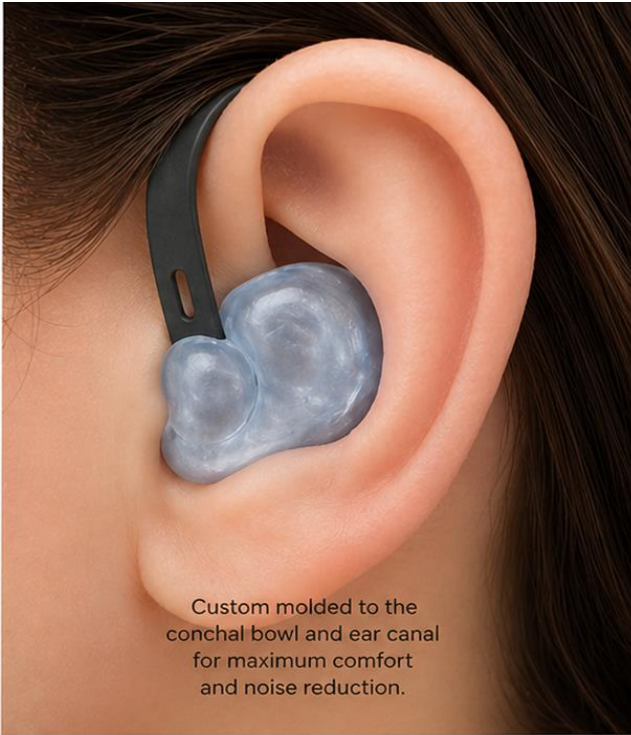
SILICONE STRAP

HEAT in hot water

MOLD to your ear

MAGNETIC connection

REUSABLE & durable



Custom molded to the conchal bowl and ear canal for maximum comfort and noise reduction.

- 1** HEAT in hot water for 30 sec
- 2** Magnetically form to ear canal. Wait to cool off.
- 3** ENJOY Custom fit. Secure. Comfortable. Noise reduced.



Molded to the unique shape of your ear. Easy to clean. Reheat and remold.

Advantage Over the Competition

- Silicone plugs – not reusable, can break off in the ear canal
- Foam plugs – don't protect against water
- Decibullz ear plugs – heat molded ear plugs intended only for sound dampening, not water protection and no magnetic or otherwise attachment system.
- Surf Ears – not custom moldable and not magnetically attached, intended for water protection only.



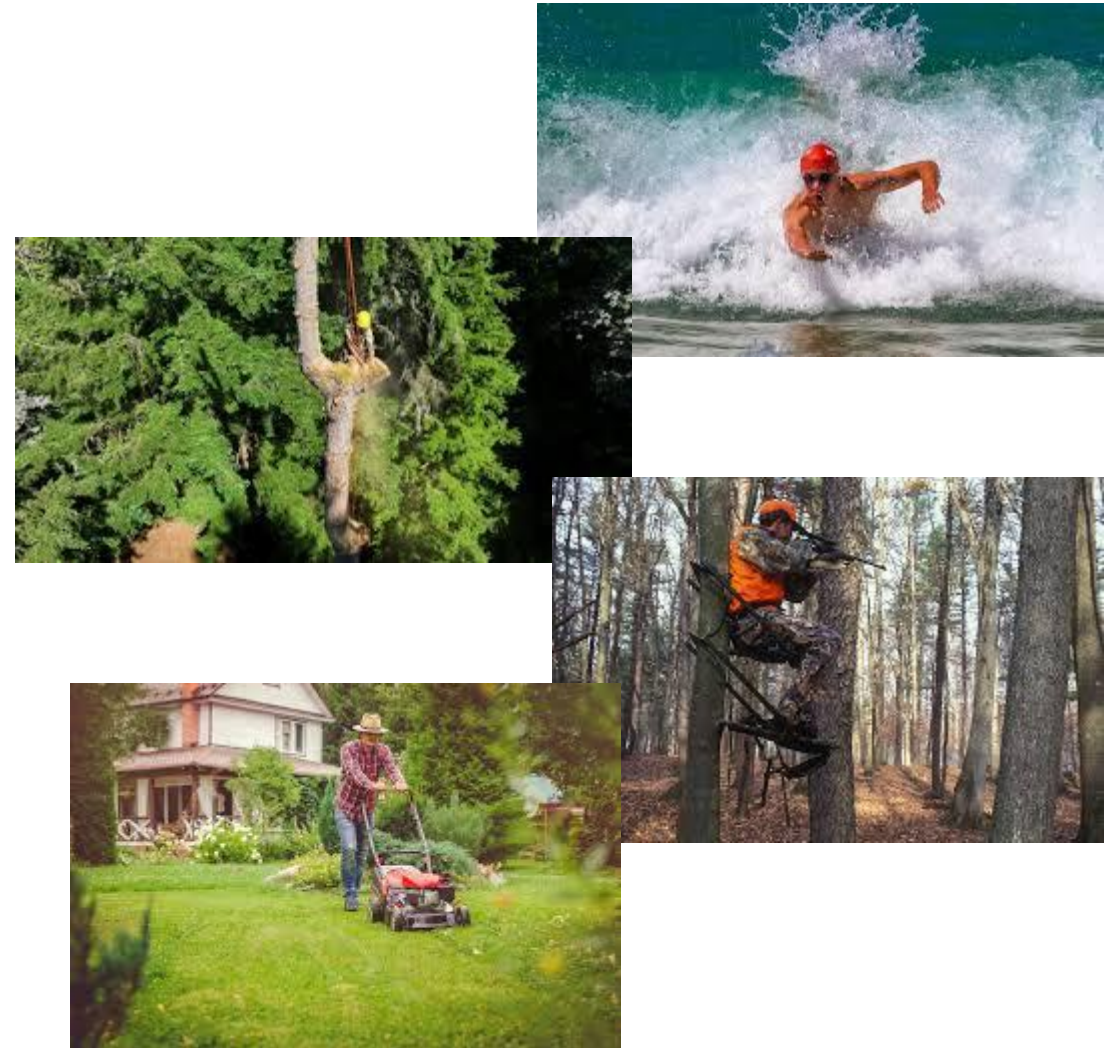
Professional Custom Molded Ear Plugs

- Molded by an audiologist.
- Can be used for sound reduction and water protection.
- Cost \$75 - \$500 each ear depending on where they are obtained.



Primary Use Cases & Market Opportunities

- The magnetic advantage
 - Prevents dislodgment during activities
 - Lanyard around neck or clip allows for easy on and off between use



Additional Use Cases & Market Opportunities

- Water protection
 - Children with ear tubes – prevents water related infections and discomfort from swimming and bathing
 - But our device can still allow sound transmission
 - Ear tube placement = most common surgery performed in the US – 700,000 procedures annually
 - Could market to surgeons / families - surgeon could mold device for small children while in the OR under anesthesia during the ear tube procedure, parents bring the plug to surgery with them, labeled left and right

Additional Use Cases & Market Opportunities

- The Comfort Version
 - For sleep and at home quiet activities
 - No magnet, just soft EVA
 - The equivalent of silicone ear plugs, but non-disposable without the risk of dislodgement into the ear canal.

- Combining a moldable magnetic compression device to treat auricular hematoma & a moldable non-disposable ear plug with a magnetic attraction component to create...
- **Ear Armor** – A company dedicated to advancing ear health through innovative, non-invasive technologies that protect, treat, and improve the health of the ear. Beginning with custom ear protection and auricular hematoma solutions, our vision is to build the leading portfolio of products for athletes, patients, and everyday consumers.

- Achieve optimal product development combining functionality and aesthetics for both the auricular hematoma compression system and the magnetic attraction ear plugs.
- Create a company management structure, sales plan and web interface all leading to sales and growth with a goal of offering better auricular hematoma treatment and ear protection to the public and returning value to investors.

