

Material Selection for the Oxygen Enriched Atmosphere

2013

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Faculty Disclosure

Richard C. Barry, BBA, CHT-A is the Vice President of Safety & Technical for Healogics

- Employed by Healogics
- Spouse is employed by Healogics

Committee Member:

- NFPA 99 Health Care Facilities: Hyper/Hypobarics
- NFPA 53 Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres
- UHMS Material Testing Advisory Committee
- UHMS Accreditation Team Member
- National Board of Diving and Hyperbaric Medical Technology
- ASTM G04 Committee: Compatibility and Sensitivity of Materials in Oxygen Enriched Atmospheres

Discussion Points

- Future State
- Why you need to know this
- What is *safe* and *safety*
- History
- Tools and resources
- Current day practice
- Products
- Process

Future State

UHMS Material Testing Advisory Committee (MTAC)

- Develop standard test;
- Petition ASTM to recognize;
- Petition NFPA to cite; and
- Industry requirement.

Why you need to know this

- To make informed decisions regarding items you will **or** will not allow in your chamber
- To protect patient, staff, and equipment
- To protect the industry of hyperbarics
- NFPA 99 Code requirement...*physician and safety director*
 - 2012 edition: 14.3.1.5.4.3
 - 2005 edition: 20.3.1.5.4.4
- Because patients happen
- No simple answer or conclusive test
- No recognized listing of *approved* products...but there is a prohibited list

Why you need to know this (cont.)

The physician in charge, with the concurrence of the HSD, shall be permitted to use prohibited items in the chambers that are of the following:

- **Suture Material**—Used for wound closure, suture material comes in 3 classes; collagen, synthetic absorbable, and non-absorbable. The United States Pharmacopeia classification is as follows:
 - Class I - Silk or synthetic fibers of monofilament, twisted, or braided construction
 - Class II - Cotton or linen fibers or coated natural or synthetic fibers in which the coating contributes to suture thickness without adding strength
 - Class III - Metal wire of monofilament or multifilament construction
- **Alloplastic Devices**—Non biologic material such as metal, ceramic, and/or plastic.
- **Bacterial Barriers**—Latex gloves, silver dressings...something that blocks bacteria.
- **Surgical Dressings**—Dressing placed at time of surgery.
- **Biological Interfaces**—Interface refers to the boundary between two parts. External fixators, Ostomy bags....
- **Synthetic Textiles**—refers to any material made of interlacing fibers. *Fabric* refers to any material made through weaving, knitting, crocheting, or bonding. *Cloth* refers to a finished piece of fabric that can be used for a purpose such as covering a bed. For use in hyperbarics this refers to dressing (4 x 4s and the like), linens, and gowns...to name a few items.

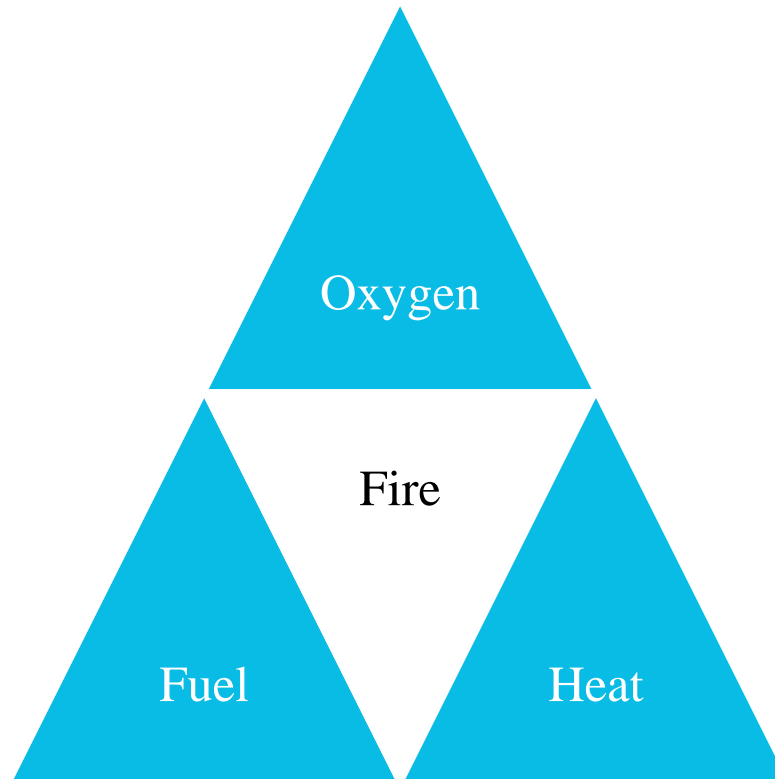
History

- Hyperbaric and hypobaric chamber fires: a 73-year analysis
 - Sheffield, P.J., & Desautels, D.A. (1997). Undersea and Hyperbaric Medical Society, Inc.
- May 2009 – Lauderdale-by-the-Sea
 - April 2012: Manslaughter and Aggravated Manslaughter
 - Broward County Arrest Affidavit
- February 2012 – Ocala, FL.
 - Class C explosion
 - 1 staff killed
 - OSHA

Tools and Resources

- NFPA 99 Health Care Facilities
- NFPA 53 Recommend Practice on Materials, Equipment, and Systems Used in OEA
- ASTM G04 Committee: Compatibility and Sensitivity of Materials in Oxygen Enriched Atmospheres
- ASTM Safe Use of Oxygen and Oxygen Systems
- Material Safety Data Sheet (MSDS – SDS)... 1 ata in air
- Food and Drug Administration (FDA)
- Approved and Prohibited Items (local list)
- Product Manufacturer (Tech Support)
- Peers (with justification)

Do you have these elements present?



Building The Picture



Building The Picture (cont.)

- Data collection takes time
- Start a terms and definition summary
- Web searches
- Ask questions
- Leave the product out if you are not positive it is safe

Current Day Practice

- Placing items in a chamber based on:
 - Historical experience
 - Known physical properties
 - Test data...does it apply?
 - Education of decision makers (on location)
 - Manufacturer support
 - 3M Skin & Wound Care Division
 - Medtronic, Inc.
 - Hydrofera Blue®

Products

- Dressings
 - Grafts
 - Wraps
 - Gels and ointments
- Materials
 - Pillow and mattress
 - Linens
- Equipment
 - External fixator
 - Internal device
 - Medical device

Products (cont.)

Know the product in order to understand the concern. If you cannot define the concern, you cannot determine if it is safe or not.

- Will this cause heat?
- Will pressure affect the product?
- Will a patient issue have an impact on the product?
- Is static a potential...how much?
- Is it...*fill in the blank?*

Process

- Develop a method for determining;
 - Approved/Prohibited at your facility
 - Document both for future reference
 - Not a blanket statement until added to your listing
 - PUT IT IN WRITING
- Develop a standard data collection process;
- Determine where to locate results;
- Determine how to disseminate the information within the facility; and
- Determine when to add to your listing.

Collect data - HSD

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graph TD; A[Collect data - HSD] --> B[HSD & Physician review]; B --> C[Determine - Approve/Prohibit]; C --> D[Document];
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HSD & Physician
review

Determine –
Approve/Prohibit

Document

Process (cont.)...document

Product Data Collection Form

Facility: _____ Date: _____

Product: _____

Manufacturer: _____

Test data: _____

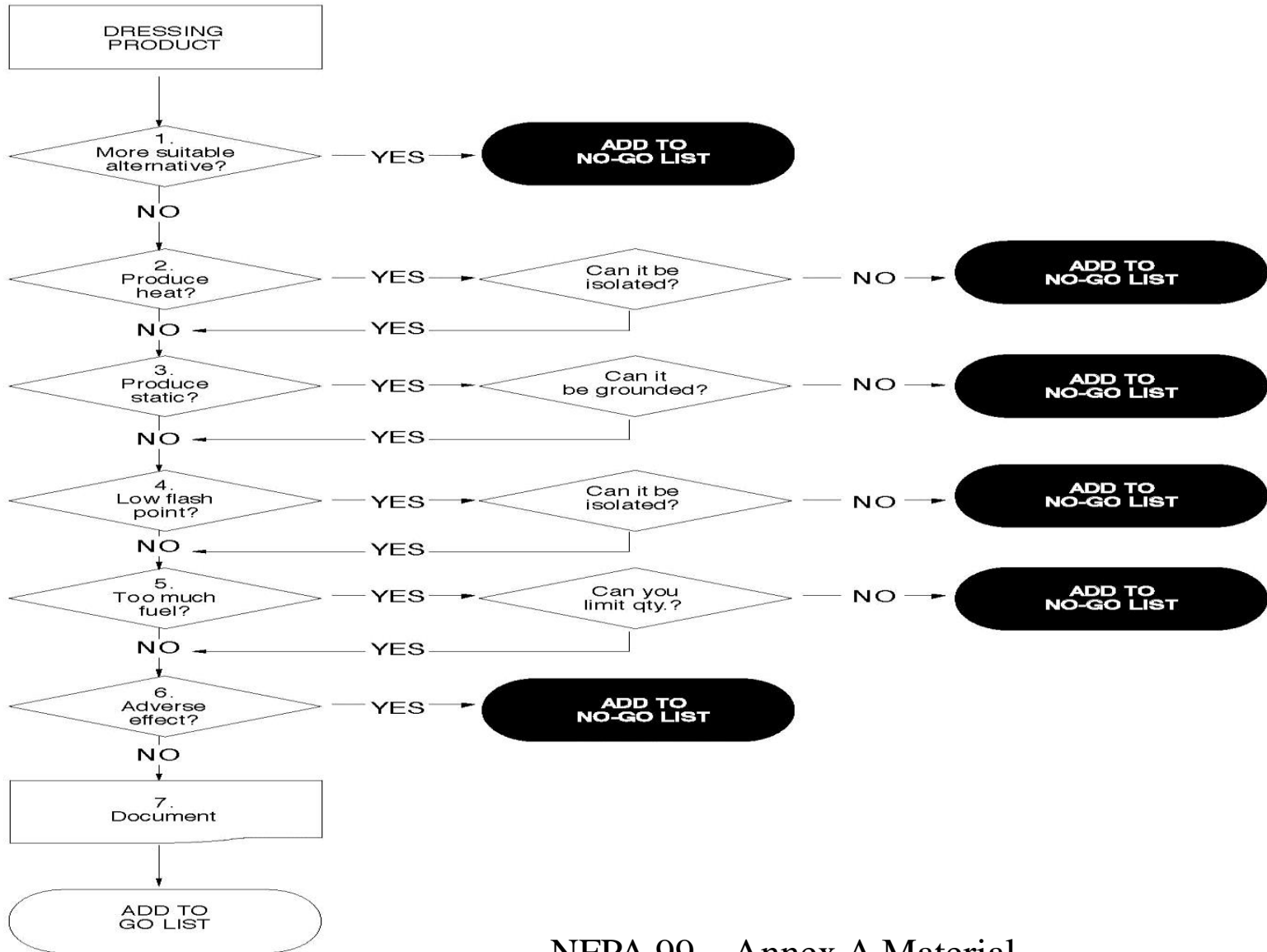
MSDS - SDS: Yes / No

Tech Support Response: _____

Signature: Physician in Charge & HBO Safety Dir.

Process (cont.)

1. The following is a list of products allowed or not allowed inside the hyperbaric chamber...
 - As determined by...Medical Dir./Physician & HBO Safety Dir.
2. Through the process of...
 - Describe the evaluation method
 - Show forms, if utilized
3. The results will be located...
4. Hyperbaric staff will be informed of updates by...
5. Products will have interim status until...



NFPA 99 – Annex A Material

Process (cont.)

- Effected by pressure?
 - Flammable?
 - Solid, liquid, gel, or gas?
 - Metal or non-metal?
 - Removable?
 - Prescribed item?
 - Quantity?
 - Cosmetic?
 - Heat producing?
 - Static producing?
 - Strong odor?
 - Purpose of item?
 - Alternative?
 - Electrical?
 - Tech Support Info?
 - Gas environment?
 - Material?
- Ask yourself, “What is my concern with this product?”***

Understand what you are reading

XYZ Lab considered Material X to exhibit a low probability of self-ignition and high severity of ignition. This high level of severity is consistent for all nonmetallic materials that are exposed to HBO.

The high severity of ignition rating is associated with the flammability of the material. The material will burn if exposed to a sufficiently strong ignition source and the fire could lead to a catastrophic event in HBO. Therefore, preventing exposure of this material to ignition sources is the safe and necessary risk mitigation approach.

Hyperbaric Oxygen Therapy and Flammability of Topical Skin Care Products

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Abstract

Product selection may determine whether or not proper skin care can be safely provided during hyperbaric oxygen therapy. Independent studies were conducted comparing the oxygen compatibility for six leading skin care products currently on the market. Oxygen compatibility was determined via autogenous ignition temperature (AIT) testing, oxygen index (OI) testing and heat of combustion (HoC) testing. AIT is a relative indication of a material's propensity for ignition, OI is a relative indication of a material's flammability, and HoC is the absolute value of a material's energy release upon burning. Products with a high AIT, a high OI and a low HoC are recognized as being more compatible for application in oxygen-enriched environments. Furthermore, an Acceptability Index based on the above factors is used to rank overall oxygen compatibility. By way of example, the HoC value of Aquaphor Healing Ointment[®] from Beiersdorf AG, was

more than five times greater than Remedy Skin Repair Cream[™] from Medline Industries, Inc. Subsequently, Skin Repair Cream[™] received an Acceptability Index rating approximately 25 times better than Aquaphor[®]. Additional skin care products included in the study were Aloe Vesta 2-in-1 Protective Ointment Skin Protectant[®] from Convatec, Remedy Calazime Protectant Paste[®] from Medline Industries Inc., Critic Aid Clear Moisture Barrier Ointment[®] from Coloplast, Nutrashield Cream[™] from Medline Industries, Inc. and Secura Protective Ointment[®] from Smith & Nephew. Application of flammable products during hyperbaric oxygen therapy imposes significant risks associated with ignition and is therefore strongly discouraged. Further studies are recommended to determine which products can provide proper skin protection and healing during hyperbaric oxygen therapy while maintaining strict fire safety standards.

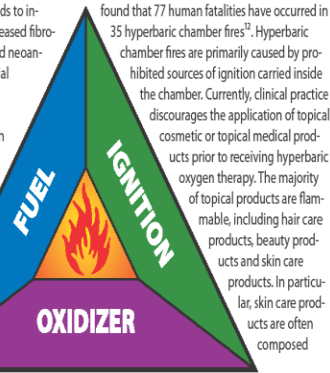
Background

Hyperbaric oxygen therapy has been found useful in the treatment of wounds and wound infections^{1,2,3}. The therapy consists of 60-120 minute periods of breathing 100% oxygen in a chamber pressurized between 2.0-2.4 ATA⁴. Periodic breathing of high oxygen concentrations increases the transmission of oxygen into the wound. The arrival of excess oxygen stimulates the production of such oxidants as hydrogen peroxide. Oxidant production leads to increased growth factor levels, increased fibroblast collagen synthesis, increased neoangiogenesis, and increased bacterial phagocytosis^{5,6,7}.

The antioxidant status of the plasma^{4,8,9}. In fact, hyperbaric oxygen therapy is increasingly used in pediatric medicine to safely treat neonates and children^{10,11}. However, there are significant external risks associated with the flammability in oxygen-enriched hyperbaric chambers.

Fire is catastrophic in the confined space of a hyperbaric chamber. A study published in 1997 found that 77 human fatalities have occurred in 35 hyperbaric chamber fires¹². Hyperbaric chamber fires are primarily caused by prohibited sources of ignition carried inside the chamber. Currently, clinical practice discourages the application of topical cosmetic or topical medical products prior to receiving hyperbaric oxygen therapy. The majority of topical products are flammable, including hair care products, beauty products and skin care products. In particular, skin care products are often composed

Physiological risks associated with proper hyperbaric oxygen treatment remain minimal. Numerous studies confirm that hyperbaric chamber sessions do not cause adverse effects on platelet aggregation, platelet metabolism, erythrocyte or lymphocyte numbers, or



Background Continued

of petrolatum or petrolatum fractions such as paraffin. Petrolatum and petrolatum fractions are a semi-solid mixtures of hydrocarbons obtained by the fractional distillation of petroleum¹³. Hydrocarbon-oxygen mixtures are extremely explosive, especially in confined spaces^{14,5}. Flammability risks associated with certain topical products have prevented the use of even oxygen compatible skin care products during hyperbaric oxygen therapy.

Utilizing advanced water and silicone-based creams instead of petrolatum-based products diminishes risks associated with flammability. Water and silicone-based products that have undergone compatibility

testing for use in oxygen-enriched environments have attained promising results^{16,17}. In fact, selected silicone creams were found to be five times less combustible than popular petrolatum-based products¹⁸.

Silicone creams may provide a safe means of treating peri-wound skin during hyperbaric oxygen therapy. Silicones are currently used in numerous specialized delivery systems, catheters and specialized medical devices^{19,20}. Providing proper skin protection and nutrition while stimulating wound oxidant production deserves consideration. Safely combining effective treatment methods may promote improved healing and wound closure.

Results

MATERIAL	AIT (°C)	HoC (CALORIES/GRAM)	OI (%)
Aloe Vesta 2-in-1 Protective Ointment Skin Protectant [®]	198	7735	30
Aquaphor Healing Ointment [®]	186	10869	25
Calazime Protectant Paste [®]	170	5915	25
Critic Aid Clear Moisture Barrier Ointment [®]	193	8879	21
Nutrashield Cream [™]	224	2111	55
Secura Protective Ointment [®]	205	10973	30
Skin Repair Cream [™]	179	1989	50

Table I. AIT indicates a material's propensity for ignition; HoC is an absolute value of a material's energy release upon burning; OI indicates a material's flammability. Oxygen compatible materials maintain high AITs, high OIs, and low HoC values¹⁶.

Figure I. AIT is a relative indication of a material's propensity for ignition. Materials with high AITs result in higher Acceptability Indices^{16,17,18}.

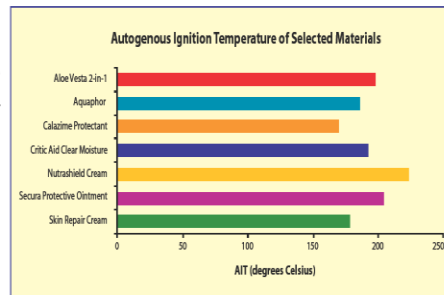


Figure II. HoC is an absolute value of a material's energy release upon burning, which is an indication of its damage potential. Materials with low HoC values result in higher Acceptability Indices^{16,17,18}.

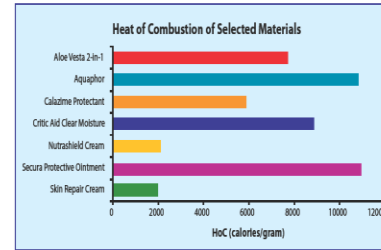


Figure III. OI is a relative indication of a material's flammability. Materials with high OIs result in higher Acceptability Indices^{16,17,18}.

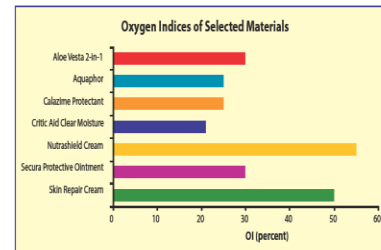
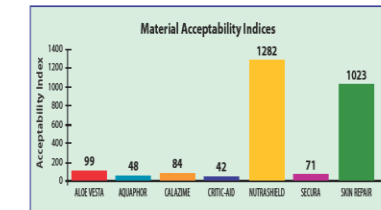


Figure IV. Acceptability Indices are used to rank the oxygen compatibility of various materials. The Index is based on the following equation^{16,17,18}: $[(OI)^2 \times (AIT)] / (HoC)$



Conclusions

The results displayed a wide range of AIT, HoC, and OI values, corresponding to significantly different Acceptability Indices. In particular, the HoC and OI values varied greatly among the seven skin care products tested. It seems that maintaining high OI values while preserving low HoC values is the characteristic most required for oxygen compatibility. During testing, a sustained fire was not achieved for Skin Repair Cream[™]. Although Skin Repair Cream[™] achieved momentary flash-point behavior, the material would self-extinguish soon after the promoter flame was removed¹⁹. The water and silicone base of Skin

Repair Cream[™] is most likely responsible for the product's self-extinguishing behavior. In contrast, the petrolatum, paraffin and/or mineral oil base of certain other products tested is likely to be responsible for the corresponding decrease in oxygen compatibility. Oxygen compatibility testing should be considered as an appropriate method of determining whether certain skin care products can be used safely and effectively during hyperbaric oxygen therapy. Further research concerning oxygen compatibility and product acceptability is suggested.

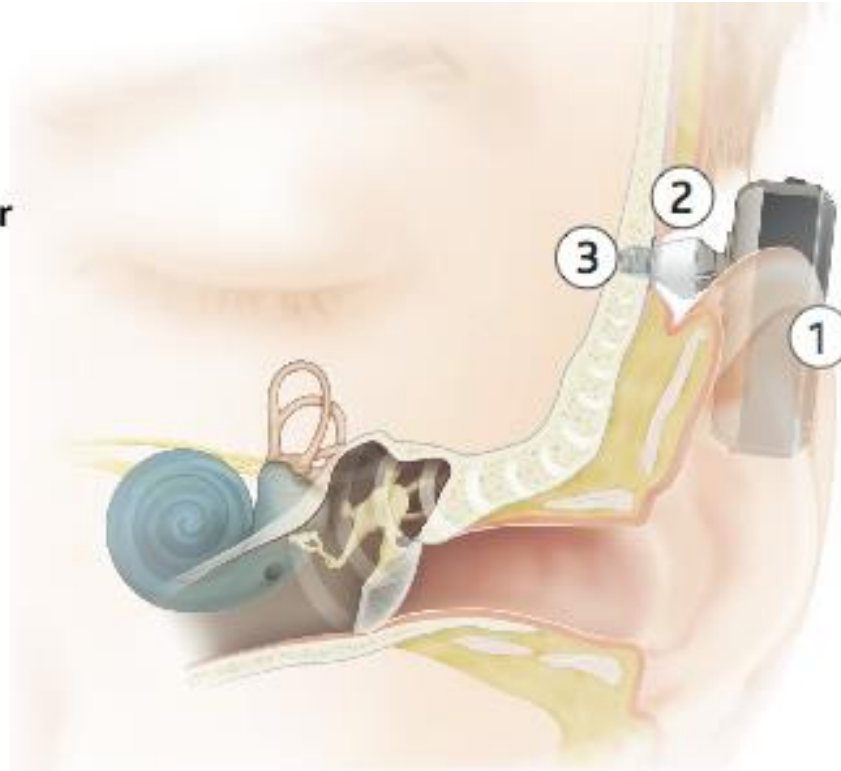
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BAHA – 3



① processor

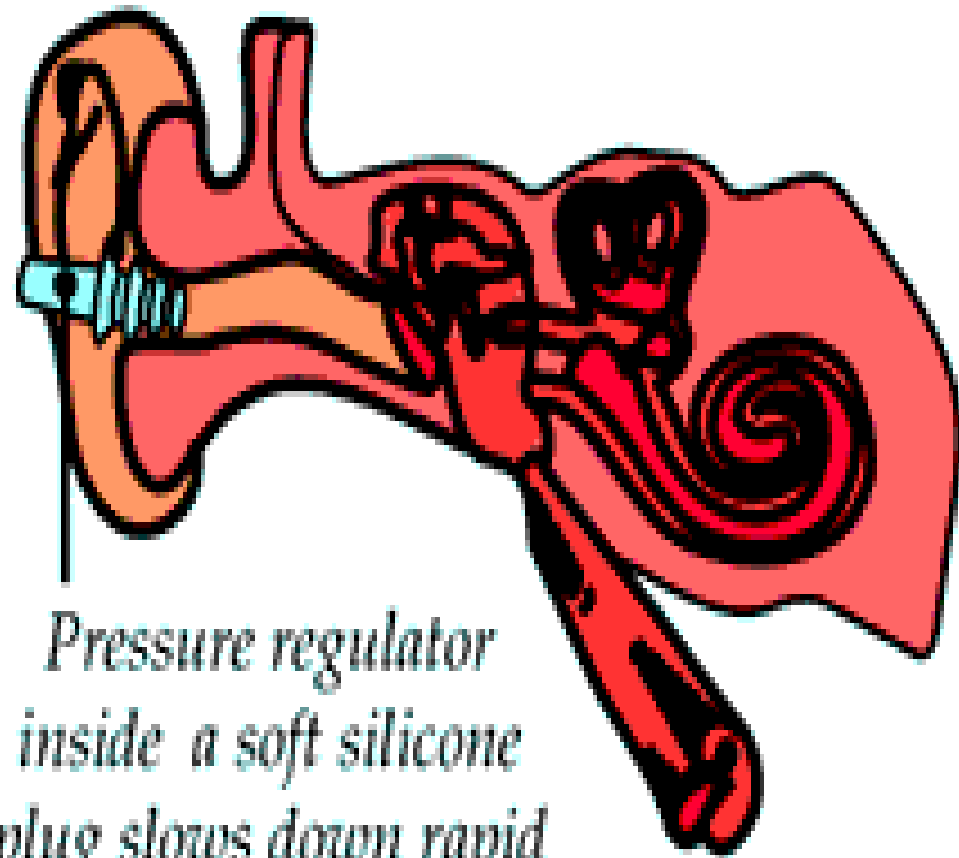


② abutment



③ titanium implant





Pressure regulator inside a soft silicone plug slows down rapid pressure changes that cause discomfort.

Completing The Picture

