

EXPECTED LIFETIME OF IMPLANTABLE DEVICES

Retinal Implants (Scleral Buckles)

The expected lifetime of <u>Labtician's Retinal Implant Scleral Buckle</u>s is approximately 100 years, or the lifetime of the patient.

When **pure medical-grade silicone implants** are attached to the **sclera of the eye**, such as in the case of Labtician's Retinal Implants (**scleral buckling procedures**) used to treat retinal detachment, the material is expected to last indefinitely in most cases. Here's why:

Longevity in the Scleral Environment:

1. Biocompatibility:

- Medical-grade silicone is highly biocompatible and inert. It does not degrade or provoke a significant immune response in the ocular environment.
- Encapsulation by fibrous tissue, a common reaction, helps secure the implant and isolate it from other biological processes.

2. Minimal Mechanical Stress:

- The sclera is a relatively stable and protected environment with minimal mechanical stress compared to other implant locations like joints.
- Silicone's durability ensures it remains effective without breaking down over time.

3. Ocular Environment:

- The eye's low metabolic and enzymatic activity means the risk of degradation or chemical interaction with the implant is minimal.
- The scleral surface does not produce significant friction or pressure that could wear down the material.

4. Clinical Experience:

 In clinical practice, scleral buckles made of silicone have been observed to remain functional and intact for decades. With regards to Labtician's own Retinal Implants, data shows that patients who have had the procedure done in the 1960s, still have

- intact scleral buckles. In addition, Labtician has not received any data to demonstrate that the units were subjected to degradation.
- Cases of failure or removal are typically due to secondary factors, such as infection, extrusion, or patient-specific anatomical changes, rather than degradation of the silicone itself.

5. Studies and Reports:

 Long-term studies show that silicone scleral buckles often last for the lifetime of the patient, with no significant material changes noted upon removal in rare cases.

Gold Eyelid Load Weights

The expected lifetime of <u>Labtician's Gold Eyelid Load Weights</u> is approximately 100 years, or the lifetime of the patient.

When **gold** is used as a weight implanted in the **eyelid** to treat **lagophthalmos** (incomplete eyelid closure), it is also designed to last indefinitely under normal conditions. Here's a detailed explanation:

Longevity of Gold Weights in Eyelid Implants:

1. Material Properties:

- Gold is chemically inert: It does not corrode, degrade, or oxidize in biological environments, making it an excellent material for long-term implantation.
- It is biocompatible: Gold is well-tolerated by human tissues, minimizing the risk of adverse immune responses or degradation.

2. Anatomical Considerations:

- The eyelid is a relatively stable environment with limited mechanical stress compared to other parts of the body.
- o Gold weights are small and strategically placed to ensure proper eyelid function without excessive movement or strain.

3. Clinical Experience:

- Gold eyelid weights have been used for decades to treat lagophthalmos caused by conditions such as facial nerve palsy or Bell's palsy.
- Long-term studies and clinical reports indicate that these implants can remain in place for a lifetime without significant wear or material failure.

4. Potential Complications:

- While gold itself is durable and inert, complications requiring removal or replacement can arise, including:
 - **Extrusion**: Rare cases where the weight presses through the skin due to tissue thinning.
 - Infection: Although rare, infections may necessitate removal of the implant.
 - **Tissue irritation or scarring**: Can occur in some patients, though proper surgical technique and weight selection minimize this risk.
- These issues are typically related to patient-specific factors (e.g., anatomy, healing ability) rather than the material itself.

5. Specific Design for Eyelid Use:

- Gold weights are designed with smooth, rounded edges to reduce irritation and friction against the delicate eyelid tissues.
- They are typically secured within the eyelid through a surgical pocket or suture, ensuring long-term stability.

6. Monitoring and Maintenance:

- Routine follow-ups are essential to monitor the position of the gold weight and the condition of surrounding tissues.
- Adjustments or replacements are rare and are usually due to changes in eyelid function or anatomy over time rather than degradation of the implant.

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