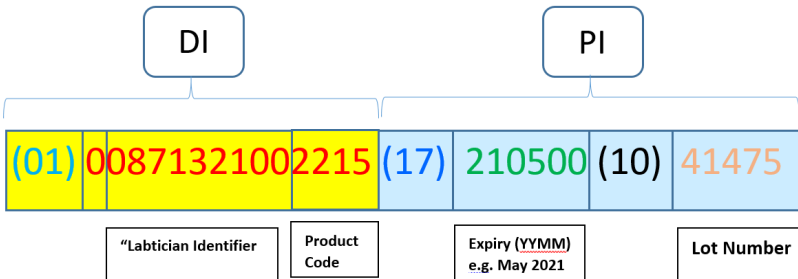


## Summary of Safety and Clinical Performance

Medical Device:	Labtician Gold Lid Loads
Manufacture:	Labtician Ophthalmics, Inc
Address:	2140 Winston Park Drive, Unit 6 Oakville, Ontario, L6H 5V5
SRN:	CA-MF-000012242

### Unique Device Identifier (UDI)

#### Format:



#### Device UDI:

Model	Description	UDI-DI
SG06	Labtician Lid Load™ 0.6 grams	00871321001058
SG08	Labtician Lid Load™ 0.8 grams	00871321001065
SG10	Labtician Lid Load™ 1.0 grams.	00871321001072
SG12	Labtician Lid Load™ 1.2 grams	00871321001089
SG14	Labtician Lid Load™ 1.4 grams	00871321001096
SG16	Labtician Lid Load™ 1.6 grams	00871321001102
SG18	Labtician Lid Load™ 1.8 grams	00871321001119
SG20	Labtician Lid Load™ 2.0 grams	00871321001126
SG22	Labtician Lid Load™ 2.2 grams	00871321001133

Model	Description	UDI-DI
SG24	Labtician Lid Load™ 2.4 grams	00871321001140
SG26	Labtician Lid Load™ 2.6 grams	00871321001157
SG28	Labtician Lid Load™ 2.8 grams	00871321001164
SGP06	LLL Proportional 0.6 grams	00871321002390
SGP08	LLL Proportional 0.8 grams	00871321002406
SGP10	LLL Proportional 1.0 grams	00871321002413
SGP12	LLL Proportional 1.2 grams	00871321002420
SGP14	LLL Proportional 1.4 grams	00871321002437
SGP16	LLL Proportional 1.6 grams	00871321002444
SGP18	LLL Proportional 1.8 grams	00871321002451
SGP20	LLL Proportional 2.0 grams	00871321002956

**Intended Purpose of Device:**

Labtician Lid Loads/ Proportional Lid Load Implants are used to treat lagophthalmos.

**Contraindications:**

Labtician Lid Loads/ Proportional Lid Loads should not be used for patients who have a known sensitivity to gold.

**Target Populations:**

The target group for this device are people who develop Lagophthalmos, which may occur due to:

- Trauma—for example, a facial laceration or a blow to the head that fractures the base of the skull, or a punch in the jaw that fractures the mandible
- Graves' disease and other related thyroid disease
- Heredity
- Möbius' syndrome, a rare, congenital disease that frequently causes facial palsies
- Damage to any of the layers of tissue that comprise the eyelids
- Complication of eyelid surgery

Bell's palsy, a poorly understood form of facial palsy and frequent cause of Lagophthalmos.

**Device Description:**

Composed entirely of gold (99.99%) the Labyrinth Lid Load Gold Eyelid Weight Implants, surgically implanted in the upper eyelid, work by gravity to restore a functional blink mechanism in the patient with lagophthalmos resulting from temporary or permanent facial paralysis, specifically the orbicularis oculi muscle. This paralysis may be the result of Bell's palsy or from surgical trauma to the facial nerve.

The patient with lagophthalmos is unable to close the eyelid completely because of partial or complete paralysis to the facial nerve. This paralysis may be the result of Bell's palsy or from surgical trauma to the facial nerve. The condition of paralysis can be either permanent or transient.

**Possible Diagnostic or Therapeutic Alternatives:**

Many patients benefit from a gold weight placed in the upper eyelid by an oculoplastics specialist. One problem with this option is the weights sometimes close one eye more than the other one. Gold weight implantation is usually well tolerated, but it can produce blurry vision from corneal astigmatism and bulging of the implant.

- If gold is not tolerated, some eyelid weights are made from other metals such as platinum.
- Lubricants/gels: For mild lagophthalmos, the first treatment to try is the use of an ointment when the symptoms occur more frequently. For nocturnal lagophthalmos, patients can apply the ointment at night to protect the eye. However, some patients complain on the way it feels or experience blurriness upon waking. If lagophthalmos also occurs during the day, a lubricant that is not as thick as a nighttime ointment may be the answer, such as Refresh Celluvisc (Allergan, Irvine, Calif.) or GenTeal Gel (Novartis Ophthalmics, East Hanover, N.J.).
- Taping of the lids: Taping the eyelids closed at night with a tape similar to the one used during surgery. A weighted piece of tape such as that made by MedDev Corp. (Sunnyvale, Calif.) is another option, because it drops the eyelid to achieve full closure. While taping is a good short-term solution, patients usually get skin redness and irritation if it is used for more than a couple of days.
- Treating the related dry eye: Some patients will feel relief from their irritation with a typical course of treatment for dry eyes. This can include artificial tears, Restasis (cyclosporine, Allergan) and punctal plugs.
- Nighttime moisture goggles: A product called tranquileyes (Eye Eco, Murrieta, Calif.), which Dr. Latkany described as "a fancy sleep mask," can also provide more moisture to patients with nocturnal lagophthalmos. TranquilEyes are a soft, flexible goggle that create a moist environment around the eye and prevent evaporation of natural tears. Patients can wear the goggles while sleeping, relaxing, or in an environment where dry-eye symptoms are at their worst.
- Tarsorrhaphy: is a surgical procedure in which the eyelids are partially sewn together to narrow the eyelid opening. It may be done to protect the cornea in cases of corneal exposure, as a treatment for Graves' ophthalmopathy, Möbius syndrome or after corneal graft surgery, Aside from an occasional unacceptable cosmetic result, [tarsorrhaphy] is usually quick and

reversible and has few complications. Reducing the outer lid aperture yields a smaller exposed ocular surface area and facilitates management of ocular surface problems.

- Prevention and surgery: A lagophthalmic patient who is considering refractive surgery, blepharoplasty, or Botox may benefit from seeing a corneal and external disease specialist first. Although it is not a given that patients will experience lagophthalmos after these procedures, the specialist can evaluate signs of a dysfunctional tear film that may be exacerbated.

#### Harmonised Standards and CS Applied:

ISO 13485: 2016  
ISO 10993:2018  
ISO 11607-1:2019  
ISO 11135:2014  
ISO 15223-1:2021  
ISO 11607-2:2006  
ISO 14971:2019  
ISO 14630:2012  
ISO 20417:2021  
MEDDEV 2.7.1 Rev 4  
ASTM F2503-13

#### Summary of Clinical Evaluation and Relevant Information on PMCF

The Gold Lid Loads meet safety and performance requirements with respect to its intended purpose from the clinical evaluation study. The risks identified in the Risk Analysis File have been addressed and all risks are acceptable, the residual risks are below the acceptance criteria.

So, the overall Clinical Evidence demonstrates that:

- Literature references cited are related to clinical safety and performance of the product which has very well established the mechanism of action and intended use of Labtician Gold Lid Loads supporting its clinical performance and safety.
- Attributes such as Biocompatibility and Sterility proves the clinical safety and performance thereby highlighting the clinical benefits of the device.
- Internal test reports and risk control measures adopted by Labtician are also high standard references for the product's safe clinical performance.
- Information from the scientific literatures has positive feedback about clinical performance and safety of the device among European population.
- No manufacturing and quality issues were detected, no risks were identified which required further reduction and the product is deemed safe for clinical usage.
- The PMS study of Labtician Gold Lid Loads for the period has provided positive feedbacks of the Labtician Gold Lid Loads such as satisfactory customer feedback, effective instructions for use, improved product quality and market viability, acceptable risk management and sufficiently good device performance on different user population. Strict monitoring of PMS activity will be continued to detect any kind of adverse events.

- PMCF studies have not been required due to the maturity of this technology/procedure. Labtician intends to perform a PMCF review annually.

**Suggested Profile and Training for Users**

Implanting of Labtician’s Gold Lid Loads should be performed by surgeons who are training in the eyelid weight loading procedure.

**Residual Risks, Undesirable effects, Warnings and Precautions**

- a. Extrusion of the lid load through the skin.  
 In patients in whom the prosthesis was not attached to the tarsus, the gold implant extruded through the skin four to six months after surgery<sup>17</sup>.

Probability:	4.2%
Extent Duration:	The implant was removed; and immediately reinserted correcting the deficiency.
Frequency:	Unreported with regards to Labtician’s Lid Loads

- b. Misplacement of the lid load – impairing good closure of the eyelid.

Probability:	4.2%
Extent Duration:	The implant is removed; and immediately reinserted correcting the deficiency.
Frequency:	Unreported with regards to Labtician’s Lid Loads

- c. Reaction to gold. Persistent edema of the upper eyelid impeding wide opening of the eye

Probability:	4.2%
Extent Duration:	The implant was removed
Frequency:	Unreported with regards to Labtician’s Lid Loads

d. Conjunctivitis resulting from incomplete eyelid closure

Probability:	2.8%
Extent Duration:	N/A
Frequency:	Unreported with regards to Labtician's Lid Loads

e. Keratitis caused by a fifth nerve palsy and lack of corneal reflex in spite of optimal eyelid movements.

Probability:	2.8%
Extent Duration:	N/A
Frequency:	Unreported with regards to Labtician's Lid Loads

f. Spontaneous extrusion of the prosthesis.

Probability:	1.4%
Extent Duration:	N/A
Frequency:	Unreported with regards to Labtician's Lid Loads

g. Infection.

Probability:	0% (from observed data <sup>17</sup> ).
Extent Duration:	N/A
Frequency:	Unreported with regards to Labtician's Lid Loads

Prepared by: Phil Cuscuna, Director of Quality Assurance and Regulatory Affairs  
Date: April 3, 2023