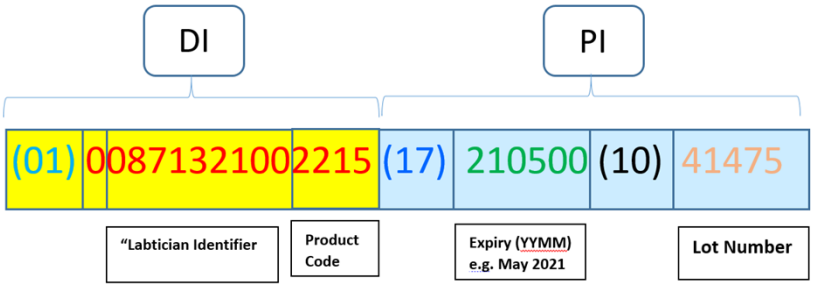
Summary of Safety and Clinical Performance

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.

For a more complete picture on causes of lagophthalmos, this list could also include other causative aetiologies.

- Acoustic Neuroma (Vestibular Schwannoma) - This is a benign tumor that can affect the facial nerve, leading to facial palsy and potentially causing lagophthalmos.
- Infection - Severe infections like Herpes Zoster Ophthalmicus can damage the facial nerve, leading to lagophthalmos.
- Neurological Disorders - Conditions like stroke or multiple sclerosis can lead to facial nerve paralysis, resulting in lagophthalmos.
- Radiation Therapy - Radiation treatment for head and neck cancers can sometimes damage facial nerves, leading to lagophthalmos.
- Tumors - Tumors of the parotid gland or other nearby structures can compress the facial nerve, leading to facial weakness and lagophthalmos.

Note that the list of causes for lagophthalmos can always change or widen to capture more causes of the condition. While this list of lagophthalmos cause can expand the indication of use of gold eyelid implants to treat lagophthalmos is not widening. The indication of use of the device remains the same.

Device Description:

Composed entirely of gold (99.99%) the Labtician 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 having a gold weight implanted in the upper eyelid by an oculoplastics specialist. However, the weight can sometimes cause one eye to close more than the other. While generally well tolerated, it may cause blurry vision due to corneal astigmatism or bulging of the implant. Current options as alternatives are:

Weights made of other materials: If gold is not tolerated, platinum and other metals can be used for eyelid weights.

Lubricants/gels: For mild lagophthalmos, ointments can be applied when symptoms are more frequent. For nocturnal lagophthalmos, patients can apply ointment at night, though some experience discomfort or blurriness upon waking. During the day, lighter lubricants like Refresh Celluvisc or GenTeal Gel can be helpful.

Eyelid taping: Eyelids can be taped shut at night using surgical tape or a weighted option like MedDev Corp's tape. This is effective short-term, but prolonged use can cause skin irritation or redness.

Dry eye treatment: Relief may come from artificial tears, Restasis (cyclosporine), or punctal plugs to treat the dry eye symptoms associated with lagophthalmos.

Nighttime moisture goggles: Products like TranquilEyes provide a moist environment around the eyes during sleep, preventing tear evaporation and easing dry eye symptoms.

Tarsorrhaphy: A surgical procedure where the eyelids are partially sewn together to reduce the eye's exposure. It's a quick, reversible procedure with minimal complications, though some cosmetic concerns may arise.

Some additional considerations as alternative options to gold implant could be:

- **Hyaluronic acid gel injections**: A non-surgical option where gel is injected to weigh down the eyelid, aiding in closure. Useful for patients who are not candidates for gold weight implants.
- **Implantable electromagnetic actuator**: A device powered wirelessly to aid eyelid closure, designed for patients with severe facial nerve paralysis, offering a more dynamic and controllable solution than traditional methods.

Prevention and surgery: Patients considering refractive surgery, blepharoplasty, or Botox should consult with a corneal specialist to assess tear film dysfunction, which may worsen after these procedures.

Harmonised Standards and CS Applied:

ISO 13485: 2003
ISO 10993:2009
ISO 11607-1:2006
ISO 11135:2014
ISO 15223-1:2016
ISO 11607-2:2006
ISO 14971:2012
MEDDEV 2.7.1 Rev 4
EN 1041:2008
ASTM F2182-11a

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. The risks identified in the Risk Analysis File have been addressed and all risks are acceptable, the residual risks are within the acceptability range.

So, the overall Clinical Evidence demonstrates that:

- Literature references cited are related to clinical safety and performance of the product, which have 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 confirm the clinical safety and performance thereby highlighting the (continued) clinical benefits of the device and reassures that the benefits indeed outweigh any risks.
- Internal test reports and risk control measures implemented by Labtician serve as high-quality references for ensuring the products' safe clinical performance.
- Information from the scientific literatures has positive feedback about clinical performance and safety of the device among different populations including 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 ending January 2024 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 and to guide measures that can be implemented to prevent them when possible.
- PMCF reviews have determined that clinical studies are not required at this time.

Suggested Profile and Training for Users

Implanting of Labtician's Gold Lid Loads should be performed by surgeons who are either fully trained or are in training with accredited professionals 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.

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).
Extent Duration:	N/A
Frequency:	Unreported with regards to Labtician's Lid Loads

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Approved by: Phil Cuscuna, Director of Quality Assurance and Regulatory Affairs.

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Date: August 31, 2024