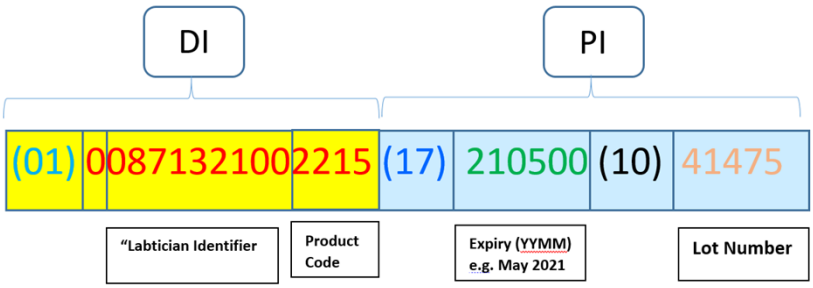
Summary of Safety and Clinical Performance

Medical Device:	Labtician's Retinal Implants
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
S 1981-4	Oval Sponge	10871321001178
S 1981-5	Oval Sponge	10871321001185
S 1981-7	Oval Sponge	10871321001192
S 1981-7.5	Oval Sponge	10871321001208
S 1982-1.5	Round Sponge 1.5mm	10871321001215
S 1982-2	Round Sponge 2mm	10871321001222
S 1982-2.5	Round Sponge 2.5mm	10871321001239
S 1982-3	Round Sponge 3mm	10871321001246
S 1982-4	Round Sponge 4mm	10871321001260
S 1982-5	Round Sponge 5mm	10871321001277
S 1982-5T	Round Tunnel Sponge 5mm	10871321001291
S 1982-7	Round Sponge 7mm	10871321001307
S 1982-7.5	Round Sponge 7.5mm x 50mm	10871321001314

S 1983-2.3	Grooved Sponge	10871321001321
S 1983-2.5	Grooved Part Thickness Sponge	10871321001338
S 1983-2.8	Grooved Part Thickness Sponge	10871321001345
S 1983-3	Grooved Sponge	10871321001352
S 1983-3.2	Grooved Sponge	10871321001369
S 1983-3.5	Grooved Sponge	10871321001376
S 1983-4	Grooved Sponge	10871321001383
S 1983-5	Grooved Sponge	10871321001390
S 1983-7.5	Grooved Sponge	10871321001406
S 1984-2.5	Part Thickness Sponge	10871321001413
S 1984-3	Partial Thickness Sponge	10871321001420
S 1984-3.3	Partial Thickness Sponge	10871321001437
S 1984-5	Partial Thickness Sponge	10871321001444
S 1984-7.5	Partial Thickness Sponge	10871321001451
S 1985-5	Scholda Partial Thickness	10871321001468
S 1985-7	Scholda Partial Thickness	10871321001475
S 1986-3.5	Oblong Sponge	10871321001482
S 1986-4	Oblong Sponge	10871321001499
S 1987-7	Accessory Sponge	10871321001505
S 1987-8	Accessory Sponge	10871321001512
S 2950	Circling Band	10871321001543
S 2965	Silicone Strip	10871321001550
S 2967	Silicone Strip	10871321001567
S 2968	Silicone Strip	10871321001574
S 2969	Circling Band	10871321001581
S 2970	Silicone Strip	10871321001598
S 2971	Silicone Strip	10871321001604
S 2976	Silicone Button	10871321001611
S 2977	Silicone Tire 10mm	10871321001628
S 2978	Meridional Implant - Flat	10871321001635
S 2986	Silicone Tire 7mm	10871321001642
S 2987	Circling Band	10871321001659
S 2988	Meridional Implant	10871321001673
S 2989	Boat	10871321001680
S 2991	Silicone Tire 9mm	10871321001697
S 2992	Silicone Strip	10871321001703
S 2993	Pad	10871321001727
S 2994	Silicone Tire 6.0mm	10871321001734
S 2995	Silicone Tire 8.5mm	10871321001741
S 2996	Silicone Tire 10mm	10871321001758
S 2996 L	Silicone Tire 10mm LG	10871321001765
S 2997	Silicone Tire 12.5mm	10871321001772

S 2998	Silicone Strip	10871321001789
S 2999	Silicone Tire 7.0mm	10871321001796
S 2999 L	Silicone Tire Wide Groove	10871321002281
S 3004	Silicone Tire 9mm	10871321001802
S 3010	Silicone Tire 6mm	10871321001819
S 3012	Boat	10871321001826
S 3013	Silicone Strip	10871321001833
S 3014	Silicone Tire 7mm	10871321001840
S 3014 L	Silicone Tire 7mm WG	10871321001857
S 3016	Silicone Tire 10mm	10871321001864
S 3017	Silicone Tire	10871321001871
S 3018	Silicone Sleeve	10871321001888
S 3019	Silicone Sleeve	10871321001895
S 3020	Meridional Implant	10871321001901
S 3021	Wedge	10871321001918
S 3022	Wedge	10871321001925
S 3025	Wong Meridional Implant	10871321002236
S 3071	Silicone Sleeve	10871321001932
S 3083	Labtician Oval Sleeve™	10871321001949
S 3084	Labtician Oval Sleeve™	10871321001956
S 3093	Labtician Buckling Sleeve™	10871321002380
S 3094	Labtician Buckling Sleeve™	10871321002342
S 4050	Silicone Strip	10871321001963
S 4055	Silicone Strip	10871321001970
S 4060	Silicone Strip	10871321002267
S 4065	Silicone Strip	10871321001987
S 5020	Silicone Lace™ 2mm	10871321002014
S 5025	Silicone Lace™ 2.5mm	10871321002021

Intended Purpose of Device:

Labtician Retinal Implants are indicated for use on the sclera to aid in retinal reattachment.

Contraindications:

Labtician retinal implants should not be used for patients who have a known sensitivity to silicone polymers.

Target Populations:

A retinal detachment can occur at any age, but it is more common in people over age 40. It affects men more than women and Whites more than African Americans.
A retinal detachment is also more likely to occur in people who:

- Are extremely nearsighted
- Have had a retinal detachment in the other eye
- Have a family history of retinal detachment
- Have had cataract surgery
- Have other eye diseases or disorders, such as retinoschisis, uveitis, degenerative myopia, or lattice degeneration
- Have had an eye injury

Device Description:

Retinal Implants are used in the surgical treatment of retinal detachments. The implant creates an indentation in the sclera and choroid which approximates the retina to the pigment epithelium. This procedure is accomplished by local indentation or through the use of an implant that encircles the globe. Circling Bands and Silicone Strips encircle the eye and are used alone or in combination with other Implants. Grooved Strips are designed for narrow or wide beds or for high scleral buckles. Tire shaped Implants and Wedges are used under encircling elements for wide scleral beds; for breaks near the ora serrata; for multiple breaks; and for high scleral buckles. Sleeves are used to secure the encircling elements. Buttons are indicated for use under grooved strips to produce higher buckles. Meridional Implants give additional buckling in the meridional direction, and are used under curved or grooved implants. The Pad is used to close scleral ruptures. Silicone Sponge Implants are used alone or in combination and are often indicated for segmental buckling procedures.

Previous Generations/Variants: None
Description of differences between Variants: N/A
Description of Accessories, other Devices intended to be used with Device: N/A

Possible Diagnostic or Therapeutic Alternatives:

The availability of small-gauge instrumentation, wide-angle viewing systems, high-speed cutters, and better illumination have made pars plana vitrectomy PPV much easier (and therefore a better option). Surgeons may also lack confidence in their skills with indirect ophthalmoscopy.

Nevertheless, many continue to use scleral buckling because this approach works well in appropriately selected cases; it involves no intraocular surgery, results in no cataractogenesis, and necessitates no postoperative positioning; it restores vision more quickly; it leads to better outcomes if patients are not corrected in a single procedure; and it is economically cost-effective

Harmonised Standards and CS Applied:

ISO 13485: 2016
ISO 10993:2018
ISO 11607-1:2019
ISO 11135:2014
ISO 15223-1:2021
ISO 14630:2012
ISO 14971:2019
MEDDEV 2.7.1 Rev 4
EN 1041:2008

Summary of Clinical Evaluation and Relevant Information on PMCF

The Retinal Implants 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 Retinal Implants supporting its clinical performance and safety.
- Attributes such as Biocompatibility, Sterility, Encircling Scleral Buckling, Medical grade silicon, Device Design contribute to lowering the chances of post surgical issues such as refractive changes, extrusion, Infections, cataract progress, ocular motility disturbance, (recurrent) subconjunctival hemorrhages and, impingement on the optic nerve. This confirms the clinical safety and performance of the device and at the same time highlights that the clinical benefits of the device outweigh the 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 scientific literature has positive feedback about clinical performance and safety of the device among several populations including the 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 Retinal Implants for the period ending January 2024 has provided positive feedbacks of the Labtician Retinal Implants 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 prevent any foreseeable adverse events if feasible.
- PMCF reviews have indicated that clinical studies are not required at this time.

Suggested Profile and Training for Users

Retinal implants are intended to be used by surgeons who are trained (or are in training) in the scleral buckling procedure.

Residual Risks, Undesirable effects, Warnings and Precautions

a. The most common cause of failure in surgery for retinal detachment is a type of scarring on the retina, called proliferative vitreoretinopathy (PVR) that can cause the retina to detach again. PVR usually requires additional treatment, including vitrectomy surgery.

Probability:	Of developing PVR - 23.1%; Retinal detachment caused by PVR – 7.5%; note the scleral buckling procedure was found to have higher rates of anatomical success compared with pars plana vitrectomy PPV alone.
Extent Duration:	N/A
Frequency:	Unreported with regards to Labtician's SB

b. Detachment of the choroid (a part of the tissue that forms the eyeball) or swelling in the retinal area may delay healing.

Probability:	"Common" (not quantified by literature)
Extent Duration:	Develops 1 or 2 days following surgery; heals on its own within two weeks.
Frequency:	Unreported with regards to Labtician's SB

c. The pressure of the scleral buckle can raise the fluid pressure inside the eyeball. People with glaucoma may have a higher risk of this complication.

Probability:	1.4 – 4.4%
Extent Duration:	Resolves spontaneously within several weeks
Frequency:	Unreported with regards to Labtician's SB

d. Bleeding in the eye can impair vision.

Probability:	1%
Extent Duration:	Transient
Frequency:	Unreported with regards to Labtician's SB

e. The eye may become infected. The patient may need antibiotics and corticosteroids to reduce redness or discharge from the eye and treat the infection. Sometimes it is necessary to remove the buckling implant to treat the infection.

Probability:	Removal of SB from infected eye - 1%

Extent Duration:	Transient with antibiotics; may require surgery.
Frequency:	One case (infection not resulting from Labtician's device); reported out of a base of 2.6 million units.

f. The buckling device may rub on other parts of the eye, or move out of place. In some cases, the buckling device may need to be removed.

Probability:	Rare (note that one author reported this as "rare" however the literature search did not seem to reflect this).
Extent Duration:	N/A
Frequency:	Unreported with regards to Labtician's SB

g. Since a scleral buckle pushes in on the eye, it can change the shape of the eye. Good vision depends on the shape of the eye. The change caused by a scleral buckle may cause a refractive error that can affect vision. Vision may change for several months after scleral buckling surgery.

Probability:	Not enough data in literature to adequately determine probability; One small (12 patient) study comparing PPV vs PPV+SB did report an effect
Extent Duration:	N/A
Frequency:	Unreported with regards to Labtician's SB

h. The scleral buckle can affect the eye muscles and how well they control the movement of the eyes. This can lead to misaligned eyes (strabismus) and double vision (diplopia).

Probability:	1.46%
Extent Duration:	Approximately 3 months; requires explantation
Frequency:	Unreported with regards to Labtician's SB

i. Scleral Erosion.

Probability:	Rates of scleral erosion have been reported, symptomatically at .09% (N=4400) and at higher rates including symptomatic and asymptomatic occurrences, but appear to vary widely by practitioner, practise, and the use of rod elements.
Extent Duration:	N/A
Frequency:	Unreported with regards to Labtician's SB

j. Ocular torsion may occur by interference of the musculature (superior oblique, inferior rectus) associated with the procedure or implant.

Probability:	This complication was presented in a single paper in the literature search, and was essentially absent from the

		discussions of outcomes data from all sources, noting that general scleral buckling procedure descriptions identify that interference of the musculature is to be avoided by positioning the implant elements underneath these muscles (i.e. proximal to the sclera).
	Extent Duration:	N/A
	Frequency:	Unreported with regards to Labtician's SB

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