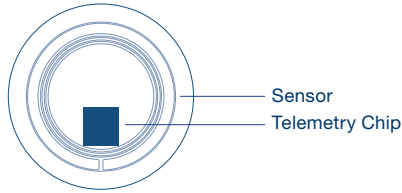


SENSIMED Triggerfish® Sensor

ST1001; ST1002; ST1003



Directions for Use

Carefully read these instructions for use and all contained warnings and precautions before using this product.

Product Description

The SENSIMED Triggerfish® Sensor (“the Sensor”) is a disposable silicone soft contact lens with a chip embedded in it, allowing the monitoring of changes in corneal curvature induced by intraocular pressure variation wirelessly.

The Sensor has the following properties:

- Diameter: 14.1 mm
- Base Curves: 8.4 (STEEP); 8.7 (MEDIUM); and 9.0 (FLAT)
- Lens material: Silicone
- Specific Gravity: 1.05
- Refractive Index: 1.43
- Light Transmission: Measures greater than 85% – dry
- Surface Character: Hydrophilic
- Water Content: Approximately 0.2%

Packaging and Sterility

Each Sensor is supplied sterile in a medical grade glass vial in a buffered saline solution. The vial is labeled with the Sensor parameters, expiry date, the manufacturing Lot Number, the Sensor ID and the product catalogue number.

NOTE Contents are sterile if package is undamaged or unopened. Do not use if package is open or damaged. Do not re-sterilize.

NOTE The packaging is designed to protect the Sensor from any damage.

Handling outside the package may result in damage of the Sensor. It is therefore recommended that the Sensor remains inside the package until use.

Symbols



Manufacturer:
 SENSIMED AG, 1003 Lausanne, Switzerland



The Sensor SENSIMED Triggerfish® is delivered sterilised. Autoclave sterilised.



Do not re-use



Caution, consult accompanying documents



CE Marking of conformity



Use by date (expiry date)



Batch code



Catalogue Number



Do not re-sterilise

Shelf Life

The recommended shelf life is marked on each package. Storage beyond the recommended time may result in Sensor deterioration. **Re-sterilization will not extend the shelf life.**

Safety

WARNINGS

- ▲ The Sensor is not designed for vision correction. It may have residual optical power.
- ▲ The patient must be instructed not to drive vehicles, crafts or handle dangerous machinery while wearing the Sensor.
- ▲ The Sensor is intended for use on the surface of the eye. Do not implant the Sensor.
- ▲ The patient must be instructed to contact the health care professional if the Sensor is displaced.
- ▲ Only a trained health care professional should manipulate the Sensor.
- ▲ The Sensor must never be manipulated by the patient.
- ▲ To avoid complications the Sensor should not be used simultaneously with any kind of contact lens or other device applied in the same eye.
- ▲ Environmental fumes, smoke, dust, vapors or windy conditions should be avoided in order to minimize the chances of Sensor contamination.
- ▲ Do not use a Sensor with exposed parts of the microchip.
- ▲ Eye irritation or infection may occur if cosmetics, lotion, soaps, creams, hair sprays or deodorants come in contact with the Sensor.
- ▲ Patients must be instructed to immediately contact the health care professional in case of complication.
- ▲ The Sensor is not intended for extended wear.
- ▲ Do not use a Sensor after the expiry date.
- ▲ Do not use a Sensor if the sterile packaging has been opened or if the seal is damaged.
- ▲ Do not re-sterilize the Sensor.
- ▲ Do not re-use the Sensor. It will not be sterile and there is a risk of eye irritation or infection including epithelial damages due to degraded hydrophilic coating. The Sensor may have intermittent loss of communication and compromise the sensing performance.
- ▲ Do not use a damaged Sensor.
- ▲ Do not use Sensor with exposed parts of the micro-chip.

PRECAUTIONS

- △ Do not use solutions for hard contact lenses with the Sensor.
- △ Sterile artificial tears are recommended while using the Sensor.
- △ Do not use tap water on the Sensor.
- △ According to surgeons, patients should not be monitored with the Sensor during the immediate post-operative period until the eye has completely healed.
- △ Tweezers or other tools should not be used to hold or remove the Sensor.
- △ Do not freeze the Sensor.
- △ Do not crush or flip the Sensor.
- △ For a proper fit of the Sensor, refer to the “Fitting Guide” section in this document.
- △ The Sensor may reduce or delay absorption of eye drugs during the 24 hours monitoring.
- △ Some patients may wear glasses under certain conditions to correct their nearsightedness, farsightedness or to offset refractive astigmatism.
- △ Patients must not wear glasses with full metal frame.

Direction for Use

The Sensor is indicated for continuous intraocular pressure monitoring up to 24 hours with glaucoma patients, patients at risk of glaucoma and/or patients with suspicion of high intraocular pressure.

Contraindications

The Sensor should not be used when one or more of the following conditions exist:

- Active eye disease, eye injury or eye abnormality affecting the cornea, conjunctiva, or eyelids
- Patient history of eye or eyelid infections including sties or history of adverse events associated with contact lens wear, or intolerance, or abnormal ocular response to contact lenses
- Active inflammation of the eye
- Active infection of the eye
- Corneal vascularisation
- Insufficiency of lachrymal secretion
- Corneal hypoesthesia
- Known allergy to silicone
- Patient inability or unwillingness to understand or comply with any warnings, precautions, restrictions or directions of the health care professional, because of age, infirmity, mental or physical conditions or an adverse working or living environment,

Complications / Adverse Events

The patient must immediately contact a health care professional or emergency health service (if after office hours) when one or more of the following events occur:

- Discomfort
- Dry eye sensation
- Foreign body sensation
- Excess tearing and/or other secretion
- Itching, burning, or gritty feeling
- Swelling of eyelids
- Pink eye (conjunctivitis)
- Eye infection
- Corneal abrasion
- Eye irritation
- Corneal ulcers
- Eye pain
- Contact lens related allergy
- Eye injury
- Allergy to silicone or allergic reactions to contact lens solution
- Blurred vision

Required Equipment

The Sensor provides the means for continuous intraocular pressure monitoring using the SENSIMED Triggerfish® Set (Medical Device class IIa). This set consists of the SENSIMED Triggerfish® Recorder (the "Recorder"), the SENSIMED Triggerfish® Software (the "Software"), the SENSIMED Triggerfish® Data Cable (the "Data Cable"), and the SENSIMED Triggerfish® Antenna (the "Antenna").

Sensor Handling

NOTE Wash your hands before handling the Sensor. Follow the hygienic standards appropriate to contact lens handling.





The products and procedures in this manual are recommended by the manufacturer for handling the Sensor. The Sensor must be rinsed with sterile artificial tears. The health care professional may recommend alternative products and procedures for contact lens handling. If other products and procedures are recommended under full liability of the health care professional, specific information for those products should be provided to the patient.

Fitting Guide

The Sensor is fitted similarly to a soft silicone contact lens. The following minimum procedure must be followed when fitting a Sensor in a patient's eye:

1. Conduct a proper eye inspection to exclude all contraindications.
2. Conduct a keratometry or topography to measure the Central Corneal Radius. Use the Flat Meridian in millimeters (mm) or diopters (D) as reference.
3. Evaluate the Corneoscleral Profile: distinguish between "Fluent" or "Marked" shape.

4. Choose the adequate Base Curve according to the following table:

Central Corneal Radius (Flat Meridian)	7.0–7.65 mm 48–44 D	7.65–8.4 mm 44–40 D		
Corneo-scleral Profile				
	Fluent	Marked	Fluent	Marked
Base Curve	8.4 (STEEP)	8.7 (MEDIUM)	8.7 (MEDIUM)	9.0 (FLAT)

Follow these recommendations to place the Sensor in the patient's eye:

- Inspect the vial and its seal to assure that it is not damaged.
- Wash your hands before handling the Sensor.
- Always handle the Sensor with care. Do not crush or flip the Sensor.
- To remove the Sensor from the vial pull out the holder and pull the lid to open it.
- Sterile artificial tears must be used to rinse the Sensor.
- Do not use tap water on the Sensor.
- Before placing the Sensor in the patient's eye, check that the Sensor does not show any damages on both sides.
- Carefully place the Sensor in the patient's eye.
- The Sensor should be well centered on the cornea and move about 0.5 mm with every eye blink and about 2 mm with a "push-up" test.
- Inform the patient about all risks associated with contact lens wear.
- Instruct the patient to immediately contact your office or the emergency service after office hours in case of incident.

Sensor Removal

The Sensor should only be removed by a trained health care professional. Refer to the recommended techniques generally used for the removal of soft contact lenses. Do not re-use the Sensor after removal. The Sensor should be discarded according to local hospital/clinical practice requirements. Finger cots or surgical gloves may be used to remove the Sensor.

In case of emergency, the following removal procedure is recommended:

1. With the middle finger, pull down the lower eyelid
2. Place the index finger on the Sensor's edge
3. Slide the Sensor on the sclera and pinch it slightly between the thumb and the index finger to remove it.

A topical anaesthesia can be used to make the process easier to remove the Sensor.

Patient Booklet

The Patient Booklet provides the Patient Logbook and Patient Information. The patient must fully understand all instructions. In addition, it is very important for the health care professional to give the Patient Booklet and review it with the patient. Copies of the latest applicable versions of the Patient Booklets are available free of charge from the www.sensimed.ch website or from the local SENSIMED representative (check the validity of the printed copy before using it).

Sensor ID Information

Every Sensor has a unique Sensor ID code. This alphanumeric code is printed on each vial. Refer to the User Manual's section "How to Perform a Monitoring Session" for detailed instructions.

This product is manufactured and sold under one or more of the following global patents: US7137952, EP1401327, PCT/EP2007/061244.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Prices, specifications and model availability are subject to change without notice.

Version ST1000-15.EU.E-B

Issued: February 2010

These Directions for Use supersede all prior instructions for this product.

Please read this information carefully and keep it for future use.

SENSIMED AG

Route de Chavannes 37
1007 Lausanne
Switzerland

Telephone +41 21 621 9191
Fax +41 21 621 9193
www.sensimed.ch