

SENSIMED Triggerfish® provides an automated recording of continuous ocular dimensional changes over 24 hours.

Technical white paper

Rationale for single use of the SENSIMED Triggerfish® Sensor.

Introduction

The SENSIMED Triggerfish® Sensor device developed by Sensimed SA is a contact lens capable of capturing spontaneous circumferential changes at the corneoscleral area over a 24 hour period. A strain gauge embedded in a soft silicone contact lens is highly sensitive and permits practitioners and patient not to influence the spontaneous eye behaviour. The device relies on the finest precision manufacturing and cutting edge technology. The Sensor, supplied in a pre-packed sterile delivery unit, has been designated as a single use device by the manufacturer.

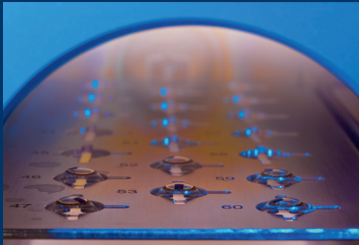
Rationale

Due to the very nature of the Sensor and its specific design, for patient safety the lens is made of silicone, which is highly permeable to oxygen. The Dk/t (oxygen permeability) measurement for the Sensor is 119 Dk/t. Although this property is highly desirable, the natural silicone material itself is hydrophobic. It is therefore necessary to treat the surface of the Sensor with oxygen plasma which creates a highly hydrophilic environment at the lens/cornea interface providing maximum patient safety and comfort. However, this treatment does not survive the first use of the device and thereafter reverts to a hydrophobic surface incompatible with clinical use (*Fig 1*). Therefore, never re-sterilize and never reuse. This can lead to an unacceptable level of both adherence to the cornea and discomfort for the patient, jeopardizing compliance and safety.

In addition, after the recording session, normal and recommended removal of the Sensor necessitates a more robust approach to handling and distorts the lens and the components within. Distortion of the connections can lead to false readings and may lead to complete failure in recording if it is attempted to re-fit the Sensor subsequent to removal. Moreover, there is a risk that breakage of a metal internal component could occur, protrusion of which through the silicone could lead to a corneal injury if re-use is attempted.



SENSIMED Triggerfish® Sensor in the eye.



The SENSIMED Triggerfish® relies on the finest precision manufacturing and advanced technology.

Conclusion

The SENSIMED Triggerfish® Sensor benefits the patient by monitoring the trend in ocular dimensional changes through a specific combination of safety, comfort and precision electrical engineering. These cornerstones are severely compromised by wear and removal. For these reasons the product has obtained CE-mark for single use up to 24 hours only. **Re-use of the Sensor is unsafe and off-label use**; it is the manufacturer's restriction that **re-use should never be attempted**.

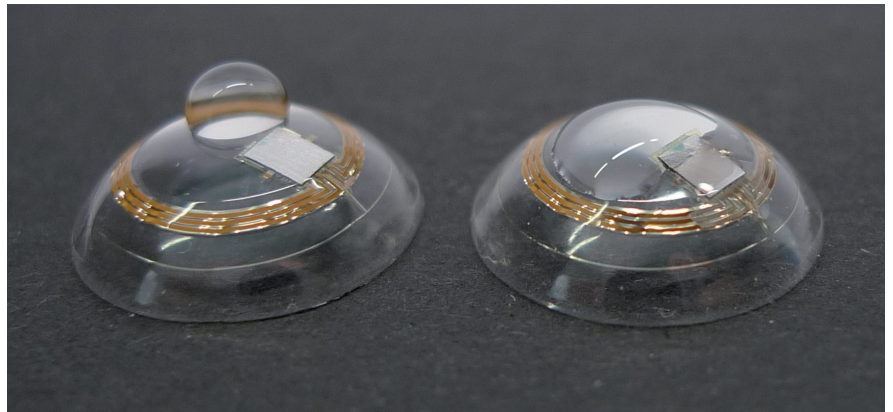


Fig 1. Left, The SENSIMED Triggerfish® Sensor with a degraded surface treatment clearly showing hydrophobicity.

Right, The SENSIMED Triggerfish® Sensor with intact surface treatment demonstrates high wettability.

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