

### Rationale for single use of the SENSIMED Triggerfish® Sensor device in continuous IOP monitoring.

#### Introduction

The SENSIMED Triggerfish® Sensor device developed by SENSIMED AG is a contact lens capable of recording qualitative diurnal IOP profiles over a 24 hour period of normal behavior in patients with suspected IOP fluctuations. A strain gauge embedded in a soft silicone lens detects circumferential fluctuations in the area of the corneo/scleral junction, correlating directly with fluctuations in IOP, which are transmitted to a recorder via wireless telemetry. 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 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  $125 \times 10^{-9}$  units (and in places much more than this value). 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*.

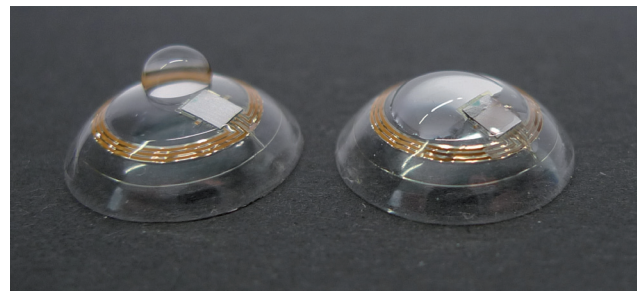


Fig 1. Left, The SENSIMED Triggerfish® Sensor with a degraded surface treatment clearly showing hydrophobicity. Right, The SENSIMED Triggerfish® Sensor with intact surface treatment demonstrates high wettability.

#### Conclusion

The SENSIMED Triggerfish® Sensor benefits the patient by monitoring the trend in IOP 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 24hrs 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.**