



## INSTRUCTIONS FOR USE

### **Titanium And Stainless-Steel Sterile, Single Use Surgical Instruments (Class I, Class Is Medical Devices)**

#### **Description**

The single use surgical instruments are stainless-steel or titanium, manual, non-powered, non-active, hand-held instruments used in ophthalmic surgeries by ophthalmic professionals who have knowledge of the instrument features and their proper use. Instructions are intended for use only by persons with specialized training in the use of ophthalmic surgical instruments.

***The instruments are intended for single use only; do not reprocess or re-sterilize instruments.***

#### **Intended Use**

These instruments are designed for use by ophthalmic professionals who have knowledge of the instrument features and related surgical techniques. The instruments are selected at the discretion of the ophthalmic professional based on the most suitable instrument for the surgical technique being performed and based on his/her expertise and medical training. The instruments are used in a medical setting determined by the medical professional. The instruments are used primarily to facilitate the surgical treatment, mitigation, prevention, and/or diagnosis of ophthalmic diseases or conditions, often through manipulation of the lens nucleus, intraocular structures, sutures, foreign bodies, and/or intraocular implants.

#### **Quality Standards**

Stephens Instruments is committed to providing the highest quality ophthalmic surgical instruments. Stephens Instruments maintains a Quality Management System in compliance with ISO 13485(2016) requirements.

#### **Precautions**

Risks associated with surgical instruments include improper use or technique by an operator and transmitting infection or disease due to improper handling techniques. Improperly handled instruments may contribute to postoperative infections.

#### **Warnings**

The instruments are delivered sterile for single use; do not reuse. Reuse can result in infection or injury. Instruments must be used for their specified purpose; incorrect use could damage the instrument. Before using, examine the instruments. ***Do not use instruments that show problems or defects.***

#### **Use Instructions**

Before use, store the sterile instruments at ambient temperatures and humidity in a manner that protects the sterile packaging and reduces the possibility of contamination. Prior to use of any single use instrument, remove any protective tips or coverings and perform a visual inspection and functional evaluation, especially focusing on tips, teeth, blades, hollow areas, and moveable parts. Ensure no instruments have breaks, cracks, bends, or any other defects or malfunctions prior to use. Also, ensure the sterile barrier has not been compromised.



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### **Indications**

Eye injury or disease requiring an ophthalmologist's intervention

### **Contraindications**

As determined by the physician performing the related intervention

### **Potential Complications**

Potential complications are dependent on the eye disease or injury being treated, techniques used by the medical professional, proper use of the instruments, and the suitability of the instrument used relative to the eye disease or injury being treated

### **Disposal**

After use, sharp instruments should be disposed of in a sharps disposal container. All used instruments should be disposed of in a biomedical waste stream. Packaging may be disposed of in normal waste streams with no additional precautions.

### **References**

American Society of Cataract and Refractive Surgery, American Society of Ophthalmic Registered Nurses. Recommended practices for cleaning and sterilizing intraocular surgical instruments. J Cataract Refract Surg. 2007;33(6): 1095-1100.

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Atlanta, GA: Centers for Disease Control

ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance for healthcare facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation



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