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Disposable Ophthalmic Instruments

ENGLISH EN

INSTRUCTIONS FOR USE (IFU)

Electronic version

This information provided by HASA OPTIX (manufacturer) to inform the user of Ophthalmic Surgery Instruments' intended purpose and proper use and of any precautions to be taken.

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1. DESCRIPTION

The sterile/nonsterile, single use ophthalmic surgery instruments are made of **medical grade stainless-steel**, which are manually operated, 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. ***See Label on package for technical description (sterile or nonsterile, single use, description of instrument, shape characteristics & dimensional characteristics) of the package content.***

2. 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 QUALIFIED OPHTHALMOLOGIST 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.

3. USE WITH OTHER DEVICES OR EQUIPMENT

Ophthalmic surgery instruments are designed to perform their intended function alone without combination of other devices or equipment.

4. LIMITATION OF LIFE / SHELF-LIFE / STERILITY

Ophthalmic surgery instruments are intended for SINGLE USE Only. Shelf-Life is claimed as 3 years. Instruments remain sterile until primary package (blister) is intact. The **Red circle** on the secondary packaging label indicates that the packaging is sterile.

5. INDICATIONS & CLINICAL BENEFITS

Eye injury or disease requiring an ophthalmologist's intervention and selection of suitable ophthalmic surgery instrument.

6. CONTRAINDICATIONS, UNDESIRABLE SIDE EFFECTS & PATIENT TARGET GROUP

As determined by the physician performing the related intervention, including information to be conveyed to the patient in this regard.

7. PERFORMANCE & SAFETY CHARACTERISTICS

Ophthalmic surgery instruments fulfil PERFORMANCE requirements in compliance with harmonized standards EN ISO 7153-1:2016, ISO 7151:1088 and ISO 7741:1986 respectively. Ophthalmic surgery instruments fulfil SAFETY requirements in compliance with harmonized standard BS EN ISO 13402 for resistance against autoclaving, corrosion, and thermal exposure.

8. USE INSTRUCTIONS

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 of malfunctions prior to use. Also, ensure the sterile barrier has not been compromised.

9. 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.

10. DEVICE WITH MEASURING FUNCTION AND GAUGE INDICATION

For instrument having measuring function, the degree of accuracy is indicated on Label of each package. There are three types of coloured circles used on the label of primary or secondary packaging for the ease in identification of the number of gauge(G) required for intended use.

I. Orange circle with **23G**
II. Blue circle with **25 G**
III. Purple circle with **27 G**

11. 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. Single use instruments if reused, may not function as intended and may pose risk of injury or disease to patient, user, or other medical staff.

12. WARNINGS

Do not use if package is damaged or unintentionally opened before use and consult electronic instructions for use (eIFU).

Do not use after expiry date.

Keep dry, storage in moist / humid environment may cause rusting of instruments.

Keep away from sunlight.

Fragile, handle with care

The Sterile instruments are delivered in sterile condition which are ready to use and intended for single use only.

Before using, examine the instruments. Do not use instruments that show problems or defects.

Remove the plastic protective cap from the instrument before use.

During use, if you observe malfunction of instrument or changes in its performance that may affect safety, please STOP use of instrument and report to Hasa Optix.

Do not reuse, reuse may result in infection or injury.

Do not reprocess or re-sterilize instruments.

Instruments must be used for their specified purpose; incorrect use may damage the instrument or may cause injury to patient, user, or other medical staff.

Ophthalmic surgery instruments are made of stainless steel (metal). The accuracy of electromagnetic navigation systems may be affected substantially by the size, type, proximity, and shape of metal object.

13. STORAGE

Before use, store the sterile instruments at ambient conditions in dry place away from sunlight in a manner that protects the sterile packaging and reduces the possibility of contamination. Instruments are fragile, handle with care.

14. DISPOSAL

After use, sharp instruments should be disposed of in a sharp's disposal container. All used instruments having potentially infectious substances from human origin, should be disposed of in a biomedical waste stream in compliance with hospital's waste management program & local regulatory requirements. Packaging may be disposed of in normal waste streams with no additional precautions.

15. QUALITY STANDARDS

HASA OPTIX is committed to providing the highest quality ophthalmic surgery instruments. **HASA OPTIX** maintains a Quality Management System in compliance with **EN ISO 13485:2016**, Medical Device Directive **93/42/EEC & Regulation (EU) 2023/607** of amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for **certain medical devices** and *in vitro* diagnostic medical devices. (Article 120)

16. WARRANTY

HASA OPTIX warrants that this medical device is free from defects in both materials and workmanship. **ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED**. Suitability for use of this medical device for any specific surgical procedure should be determined by the user in conformance with the best knowledge of ophthalmic surgery techniques. **THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF**.

17. IMPORTANT NOTICE TO USER

ANY SERIOUS INCIDENT THAT HAS OCCURRED IN RELATION TO OPHTHALMIC SURGERY INSTRUMENTS SHALL BE REPORTED TO THE MANUFACTURER (HASA OPTIX) OR THE CONCERNED COMPETENT AUTHORITY OF THE MEMBER STATE AS PER THEIR NATIONAL REGULATION.

18. CONTACT FOR TECHNICAL ASSISTANCE

Tel: +32 2 524 63 88

E-mail: info@hasaoptix.com

19. MANUFACTURER

HASA OPTIX

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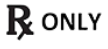
20. EXPLANATION OF SYMBOLS USED ON LABEL (EN ISO 15223-1:2020)

SYMBOL	TITLE OF SYMBOL	DESCRIPTION OF SYMBOL	SYMBOL NO.
	Manufacturer	As defined in Regulation (EU) 2017/745: natural or legal person who has a device designed, manufactured, and markets that device under its name or trademark	5.1.1 of EVS-EN ISO 15223-1 :2021
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information	5.7.10 of EVS-EN ISO 15223-1 :2021
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	5.1.6 of EVS-EN ISO 15223-1 :2021
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or LOT can be identified	5.1.5 of EVS-EN ISO 15223-1 :2021
	Cautions	Indicates the need for the user to consult the instruction for use for important cautionary information such as warnings and precautions.	5.4.4 of EVS-EN ISO 15223-1 :2021
MD	Medical Device	To include here the definition of the symbol + make the link with the document listing in details for each article what information to be indicated on Line 1/Line 2 and Line 3	5.7.7 of EVS-EN ISO 15223-1 :2021

SYMBOL	TITLE OF SYMBOL	DESCRIPTION OF SYMBOL	SYMBOL NO.
	Consult instruction for use	Indicates the need for the user to consult the instruction for use	5.4.3 of EVS-EN ISO 15223-1 :2021
	Sterilized using Irradiation	Indicates a medical device that has been sterilized using irradiation	5.2.4 of EVS-EN ISO 15223-1 :2021
	Non-Sterile	Indicates a medical device that has not been subject to a sterilization process	5.2.7 of EVS-EN ISO 15223-1 :2021
	Single sterile barrier system	Indicates a single sterile barrier system is used as sterile packaging.	Ref No 5.2.11 of EVS-EN ISO 15223-1 :2021
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system is used as sterile packaging with protective packaging outside.	Ref No 5.2.14 of EVS-EN ISO 15223-1 :2021
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	5.4.2 of EVS-EN ISO 15223-1 :2021
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized	5.2.6 of EVS-EN ISO 15223-1 :2021
	Do Not Use If Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8 of EVS-EN ISO 15223-1 :2021
	Keep dry	Indicates a medical device that needs to be protected from moisture	5.3.4 of EVS-EN ISO 15223-1 :2021
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed	5.3.7 of EVS-EN ISO 15223-1 :2021
	Keep away from sunlight	Indicates a medical device that needs protection from light source. This symbol also means keep away from heat.	5.3.2 of EVS-EN ISO 15223-1 :2021
	Fragile, Handle with Care	Indicates a medical device that can be broken or damaged if not handled carefully	5.3.1 of EVS-EN ISO 15223-1 :2021
	Date of Manufacture	Indicates the date when the medical device was manufactured	5.1.3 of EVS-EN ISO 15223-1 :2021
	Use By Date	Indicates the date after which the medical device is not to be used	5.1.4 of EVS-EN ISO 15223-1 :2021
	Distributor	As per Article 2 of MDR 2017/745, any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting it into service.	5.1.9 of EVS-EN ISO 15223-1 :2021
	Importer	As per Article 2 of MDR 2017/745, 'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market.	5.1.8 of EVS-EN ISO 15223-1 :2021
	Translation	To identify that the original medical device information has undergone a translation which supplements or replaces the original information.	Ref No 5.7.8 of EVS-EN ISO 15223-1 :2021
	Prescription use only	Federal law restricts this device to sale by or on the order of a physician	21 CFR 801.109
	CE Mark	Product Complies with requirements of Directive 93/42/EEC and 4-digit number (0068) reflects identification number of notified body. **MTIC InterCert S.r.l via G. Leopardi, 14, 20123, Milano (MI), ITALY**. Tel. +39 02 97071 800 - Fax +39 02 930 8176 Email: info@mticert.org www.mticert.org	Annex XII of Directive 93/42/EEC
(01) 00000000000000		14 Digit Basic UDI-DI Code (GS1-GTIN)	
(10) 00000000		Lot Number	
(11) YYYYMMDD		Date of manufacture	
(17) YYYYMMDD		Use by Date (not applicable for nonsterile product)	
		UDI-DI (GS1-GTIN) + UDI-PI in GS1-Datamatrix	
		QR code indication for registered website of HASA Optix	

SYMBOL	TITLE OF SYMBOL	DESCRIPTION OF SYMBOL	SYMBOL NO.

Languages & Code in Europe

Language	Code	Language	Code
Bulgarian	BG	Irish	GA
Croatian	HR	Italian	IT
Czech	CS	Latvian	LV
Danish	DA	Lithuanian	LT
Dutch	NL	Maltese	MT
English	EN	Polish	PL
Estonian	ET	Portuguese	PT
Finnish	FI	Romanian	RO
French	FR	Slovak	SK
German	DE	Slovenian	SL
Greek	EL	Spanish	ES
Hungarian	HU	Swedish	SV

Code of Language in Europe

NA