

Instruction for use

OPHTHALMIC KNIVES

No.	Product name	Global code
1.	15 deg. Ophthalmic Knife	8065921501
2.	20 ga.V-Lance - FullHandle	8065912001
3.	23 ga. MVR Blade Vit Ret Handle	8065912301
4.	25 ga. MVR Blade Vit Ret Handle	8065912501
5.	Straight Satin Crescent Knife	8065990001
6.	Bevel Up Satin Crescent Knife	8065990002
7.	ClearCut Dual Bevel 1.0mm Angled Sideport Knife	8065921540
8.	ClearCut Dual Bevel 1.5mm Angled Sideport Knife	8065921542
9.	ClearCut Dual Bevel 3.0 mm Angled Slit Knife	8065993047
10.	ClearCut HP2 Dual Bevel 2.2 Angled Slit Knife for Intrepid MicroCoaxial System	8065982265
11.	ClearCut HP2 Dual Bevel 2.4 Angled Slit Knife for Intrepid MicroCoaxial System	8065982465
12.	ClearCut HP2 Dual Bevel 2.6 mm Angled Slit Knife	8065982665
13.	ClearCut HP2 Dual Bevel 2.8 mm Angled Slit Knife	8065982865
14.	2.6mm Clearcut Angled Satinslit Knife	8065992645
15.	Clearcut Dual Bevel 2.6 mm Angled Slit Knife	8065992647
16.	Clearcut HP Dual Bevel 2.6 mm Angled Slit Knife	8065992648
17.	Clearcut Dual Bevel 2.75 mm Angled Slit Knife	8065992747

Description

Ophthalmic knives are sterile, single-use, manual ophthalmic surgical instruments used by surgeons to create surgical incisions during ophthalmic surgical procedures.

They consist of a variety of stainless steel surgical knives having variations in cutting edge positioning and point designs at the distal end, attached to a handle at the proximal end.

All of the knives are single use devices, which are packaged and terminally sterilized.

Intended use

Ophthalmic knives are intended for use only by a ophthalmic surgeon who is skilled and trained in surgical procedures.

Indications

To be used by surgeons to create surgical incisions during ophthalmic surgical procedures.

Instruction for use

Use in ophthalmic surgical procedures.

For single use only. Not reusable.

There is no specific direction for use. Ophthalmic knives must be used only by a ophthalmic surgeon who is skilled and trained in surgical procedures.

Do not use if package is damaged or the sterility has been compromised.

Contraindications

There are no known contraindications to the use of ophthalmic knives.

Warnings and Precautions

For single use only. Not reusable.

User should be trained to handle the ophthalmic knife appropriately.

Do not use if package is damaged or the sterility has been compromised.

Adverse Reactions

The overall rate for adverse events reported to Alcon was low. The reported adverse events include: miscellaneous event-ocular, eye injury, corneal Descemet's detachment, corneal/eye tissue injury other, user injury, Toxic Anterior Segment Syndrome, Endophthalmitis, Metal dust or particulates, Surgical Complication, Corneal Wound Leakage, Iris prolapse.

Serious Incident Reporting

Any serious incident that may reasonably be regarded as device related should be reported to Alcon Laboratories, Inc.:

By Phone:

International - Contact the local country office.

In USA – call 1 (800) 757-9780

By Email:

In Vietnam: complaint.vietnam@alcon.com

In the EU: qa.complaints@alcon.com

Website:

<http://www.alcon.com/contact-us/>

Each ophthalmic knife is identified by a serial number which provides traceability, and this information should be given to Alcon.


Warranty

Not applicable for single use product.

Storage condition

Store in room temperature.

Shelflife and expiration date

The expiration date  is listed on the outside of the packaging. Do not use after expiration date.

Made in USA by:

Alcon research, LLC

714 Columbia Ave.,

Sinking Spring, PA 19608, USA.

Legal manufacturer:

Alcon Laboratories, Inc.

6201 South Freeway

Fort Worth, TX 76134, USA.

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