

CLEARCUT™ S Incisional Instruments

Instructions for Use

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INSTRUCTIONS FOR USE

Alcon Laboratories, Inc.

CLEARCUT™S INCISIONAL INSTRUMENTS

Caution: Federal (USA) law restricts this device to the sale by or on the order of a physician.

DESCRIPTION

The ClearCut™S family of incisional instruments are manual ophthalmic surgical instruments used by surgeons to create surgical incisions during ophthalmic surgical procedures. This family of instruments consists of a variety of stainless steel surgical knives having variations in cutting edge and point design at the distal end, and attached to a polycarbonate handle at the proximal end. The device is not made with natural rubber latex.

Incisional instruments incorporating sharps protection features provide injury prevention to those who come in contact with the device. The instruments are designed with an integral guard that can be actuated to place the blade in a safe or exposed condition. These devices are intended for use during a single procedure with the capability of exposing and guarding the blade multiple times during the surgical session. The device is delivered to the user terminally sterilized by means of either gamma irradiation or ethylene oxide sterilization methods.

Table below depicts detailed product description by product type.

Product Type	Product Group	Product Sub-group
Slit Knives	CLEARCUT™ Slit Safety	CLEARCUT™ Safety INTREPID™ Micro-coaxial System (Single Bevel)
		CLEARCUT™ Safety INTREPID™ Micro-coaxial System (Dual Bevel)
		CLEARCUT™ Safety SATINSLIT™
Crescent Knife	CLEARCUT™ Crescent Safety	CLEARCUT™ Safety Crescent
Sideport Knives	CLEARCUT™ Sideport Safety	CLEARCUT™ Safety Sideport
		CLEARCUT™ Safety Sideport SAB
Detailed Product Description		
<p>CLEARCUT™ Safety INTREPID™ Micro-coaxial System single bevel knives have a sharps protection feature, a tapered designed distal tip, and 2.2 mm and 2.4 mm widths. These knives provide a 2 mm depth indicator line at the distal tip. A blue depressible button is located on the handle.</p>		
<p>CLEARCUT™ Safety INTREPID™ Micro-coaxial System dual bevel knives have a sharps protection feature, a tapered designed distal tip, and 2.2 mm and 2.4 mm widths. These knives provide a 2 mm depth indicator line at the distal tip. A blue depressible button is located on the handle.</p>		
<p>CLEARCUT™ Safety SATINSLIT™ single bevel knives have a sharps protection feature, a distal tip with parallel cutting sides, and 2.6 mm and 2.75 mm widths. A blue depressible button is located on the handle.</p>		
<p>CLEARCUT™ Safety Crescent single bevel knives have a sharps protection feature, a rounded surface distal tip with parallel cutting sides, and a 2.3 mm width. A green depressible button is located on the handle.</p>		
<p>CLEARCUT™ Safety Sideport knives have a sharps protection feature, a sharp distal tip, and 1.0 mm and 1.2 mm widths. A yellow depressible button is located on the handle.</p>		
<p>CLEARCUT™ Safety Sideport SAB knives have a sharps protection feature and 15° or 30° cutting edge angles. A purple depressible button is located on the handle.</p>		

INDICATIONS

ClearCut™S incisional instruments are single-use, manual ophthalmic surgical instruments intended for use by trained ophthalmic surgeons to create incisions during ophthalmic surgical procedures. These instruments have a sharps protection feature to prevent accidental injuries during the surgery.

TARGET POPULATION

The intended use of these devices includes no special target population, but rather includes all patients undergoing ophthalmic procedures in which these devices are needed.

CONTRAINDICATIONS

There are no known contraindications.

CLINICAL BENEFIT

The ClearCut™S family of incisional instruments (Safety Knives) are designed with an integral blade guard to reduce the risk of sharps injury to those who use or handle the device. The benefit of the use of such devices is supported by the general need for improved sharps safety in the healthcare setting, particularly in regard to scalpel injuries, which may result in serious tissue injury and/or exposure of both patient and surgical staff to transmissible disease.

PERFORMANCE CHARACTERISTICS

The ClearCut™S Incisional Instruments (Safety Knives) are manual ophthalmic surgical instruments used by surgeons to create surgical incisions during ophthalmic surgical procedures. Incisional instruments incorporating sharps protection features provide injury prevention to those who come in contact with the device. The instruments are designed with an integral guard that can be actuated to place the blade in a safe or exposed condition. An overall residual risk evaluation has been performed and has concluded that the benefits provided by Alcon Sharps Protection significantly outweigh the risks associated with their use.

WARNING

1. DO NOT re-use this product. This product is for SINGLE patient use only and should not be used in more than one patient. Reuse of this single-use device may result in serious injury, such as infection.

PRECAUTIONS

1. Read all instructions prior to use. Surgeon familiarity and training associated with ophthalmic surgery is required before attempting use of this device.
2. As with any surgical procedure, risk is involved. Potential complications resulting from use of this blade during ophthalmic surgery include, but are not limited to: infection, tissue damage, inflammation, edema, hyphema, hypopyon, secondary surgical re-intervention, and wound leak repair. Consult the labeling of all other devices and products used in conjunction with the surgery to more fully understand other risks that may be involved.

3. Assure that the protective shield is locked in the guarded position whenever the device is passed from one person to another and that aseptic handling techniques are observed during surgery.
4. As an added precaution, continue safe handling practices used for unguarded sharps instruments even when using ClearCut™S incisional instruments.
5. After use, place the product in a container designed for secure disposal of sharps instruments.
6. Do not reuse this device. Degradation of the sharpness of the precision cutting edge occurs after initial use.
7. Reuse may lead to wound irregularities and/or cross contamination between patients.
8. If the sterile packaging is damaged or unintentionally opened, potentially compromising sterility before use, do not use

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.

By Email:

In the EU: qa.complaints@alcon.com

Website:

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

NOTE: In the EU, these serious incidents must also be reported to the competent authority for medical devices of the appropriate Member State.

HOW SUPPLIED

ClearCut™S Incisional instruments are supplied in a PETG thermoformed tray with a sealed TYVEK* lid. The product is delivered sterile and must be opened only under aseptic conditions.

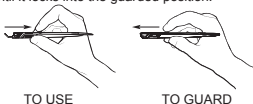
EXPIRATION DATE

Sterility is guaranteed unless the packaging is damaged or opened. The expiration date is clearly indicated on the packaging.

INSTRUCTIONS FOR USE



















TO USE: To unlock the shield and move it from the guarded to the unguarded position, depress the button on the handle to release the lock. Slide the shield away from the blade until it locks into the unguarded position.

TO GUARD: To unlock the shield and move it from the unguarded to the guarded position, depress the button on the handle to release the lock. Slide the shield toward the blade until it locks into the guarded position.



LOCK CONFIRMATION: To confirm that the shield is locked:
STOP: Feel that the shield motion has stopped and cannot be moved any further.
LOOK: Observe that the button is not recessed into the handle and has returned to its original position.
LISTEN: A click can be heard as the shield lock engages into the guarded and unguarded positions.

DEFINITION OF SYMBOLS

SYMBOL	ENGLISH
	Manufacturer
	Date of manufacture
	Authorized representative in the European community
	Consult instructions for use or consult electronic instructions for use
	Do not re-use
	Do not re-sterilize
	Caution
	Do not use if package is damaged
	Open Here
	Use by
	Medical device
	Batch code
	Catalog number
	Quantity
	Single sterile barrier system
	Ethylene oxide sterilized
	Gamma irradiation sterilized
	Sterile

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