



**Distributed by:**  
Tiger Aesthetics Medical, LLC  
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# Cannula Kit

## Manufactured by:

Tiger Aesthetics Medical, LLC  
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STERILE UNLESS OPENED OR DAMAGED PRODUCT  
SINGLE PATIENT USE PRODUCT



## FDA Codes:

GEA – Cannula, Surgical, General & Plastic Surgery  
GES – Blade, Scalpel

## Product Codes:

ALC100S – Cannula Kit Standard w/ Scalpel  
ALC200S – Cannula Kit Spatula w/ Scalpel  
ALC300S – Cannula Kit Cobra w/ Scalpel

## Contents

This Cannula Kit product unit contains (1) Cannula and (1) Thumb Scalpel that are terminally sterilized using irradiation. These items are packaged within a blister with a Poly/Tyvek back seal. The contents of this package will include the cannula, the thumb scalpel, patient labels sheet, and product kit IFU.

## Product Description and Indications:

The cannula is a manual, sterile, single use device intended for general surgical applications and to manually facilitate the delivery of product from an 18mm diameter supply container.

The thumb scalpel is a manual, sterile, and single use device intended for creating incisions in general surgical applications.

## Regulatory Classification:

All cannula kit items are distributed in accordance with the U.S. Food and Drug Administration (FDA) requirements and State Regulations by Tiger Aesthetics Medical, LLC.

Federal law restricts this product for sale by or on the order of a licensed medical practitioner and/or clinician.

## Sterilization:

All cannula kit items are terminally sterilized using gamma irradiation in accordance with ANSI/AAMI/ISO 11137, meaning the product will be provided sterile to the end user.

## Precautions:

Prior to usage, inspect items and box packaging to ensure the product is not damaged.

**DO NOT USE** if the packaging shows evidence of being opened, damaged, or otherwise compromised.

**DO NOT USE** if the cannula or scalpel shows evidence of being opened, damaged or, otherwise compromised.



UNTHREADED



THREADED

**Note:** Align cannula volumetric indicators slightly to the right of the cannula supply container to ensure that when threaded together, all volumetric indicators are aligned.

## Instruction for use:

1. Remove scalpel and cannula from sterile packaging using aseptic techniques.
2. Attach cannula to cannula supply container.
3. Remove scalpel sheath and create incision.
4. Deliver product to desired areas.

**Note:** Cannula kit items are for SINGLE PATIENT USE ONLY. Cannula and scalpel should be disposed of in approved sharps container.

### Applications:

Cannula kit items should be operated and handled by healthcare professionals. Items in the cannula kits should be used for their intended surgical purposes. Federal law restricts this product for sale by or on the order of a medical practitioner.

### Storage and Handling:



Cannula kits must be stored in original unopened packaging and not to be used after the expiration date listed on product labels.



Cannula kits must be stored at ambient temperatures (59-86°F / 15-30°C) until ready for use.

### Packaging and Labeling:

The cannula and thumb scalpel are packaged in an inner blister pack with a Poly/Tyvek back seal. The inner blister pack is sealed in a second blister tray with a Poly/Tyvek back seal to create a sterile double-barrier system. The final sealed product is then placed within the final product packaging box and sealed with the product label. The final packaging box is terminally sterilized using gamma sterilization. Any damage or breaking of this seal will result in compromising of product sterility and product returns will not be accepted.

Each cannula kit is identified using the product label which contains the product unique identifier number (UDI), product identification number, product lot number, expiration date, and storage information.

### Expiration Date:

Product has a 36-month shelf life. See package label for expiration date. It is the responsibility of the end user to maintain this instrument kit in the appropriate storage conditions prior to usage and to track the expiration date accordingly.

### Contraindications:

Both the cannula and scalpel are not intended to be used for activities not listed in these instructions for use.

### Disposal and Return of Instruments:

#### Disposal:

If for any reason the cannula kit is opened and not used, it should be disposed of properly. In general, surgical instrumentation disposal shall be in accordance with local, state, and federal regulations. Product that cannot be used because it is defective or it does not meet the specification requirements, should be returned to Tiger Aesthetics Medical, LLC following appropriate return procedures described below.

#### Returns:

If for any reason, the instrument kit must be returned, a return authorization must be obtained from Tiger Aesthetics Medical, LLC prior to shipping the instrument kit. Cannula Kits will not be accepted if the original packaging has been opened, compromised or if the cannula kit has exceeded the printed expiration date. It is the responsibility of the healthcare institution or healthcare provider returning the cannula kit to adequately package and label the cannula kit for return.

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### Warnings:



Read these instructions completely prior to kit usage.



Do not re-sterilize the product. The cannula and scalpel are intended for SINGLE PATIENT USE ONLY.



Please exercise caution when handling cannula and scalpel to avoid unintended puncture.

### Adverse Effects:

All adverse outcomes potentially attributed to these instruments must be promptly reported to Tiger Aesthetics Medical, LLC.

Possible adverse events specific to the use of the cannula and thumb scalpel include but are not limited to superficial or deep wound infection, allergic reactions, instrument breakage, contamination, and patient or packaging puncture.

### Product Inquiries or Complaints:

For product information, sales inquiries, customer service or to obtain a printed IFU, contact Tiger Aesthetics Medical, LLC. Any healthcare professionals or patient who has any complaints or is dissatisfied with this product should notify Tiger Aesthetics Medical, LLC.

Tiger Aesthetics Medical, LLC

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Franklin, WI 53132

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### Warranty:

Tiger Aesthetics Medical, LLC recognizes its responsibility to replace products if proven to be defective. Tiger Aesthetics Medical, LLC does not accept liability for any damage or loss, either direct or consequential, stemming from the use of or inability to use the products as described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

Symbol	Symbol Title
	Manufacturer
	Date of Manufacture
	Use-by Date
	Batch Code
	Catalog Number
	Do Not Re-use
	Do Not Resterilize
	Sterilized Using Irradiation
	Do Not Use if Packaging is Damaged
	Double Sterile Barrier System
	Fragile, Handle with Care
	Consult Instructions for Use
	Caution
	Keep Away from Sunlight
	Keep Dry
	Prescription Only
	Ambient Temperature