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Rx ONLY

INSTRUCTIONS FOR USE

# Cannula with Guide

# CSK-6130, # CSK-6131

⚠**CAUTION:** Federal Law (US) restricts this device to sale by or on the order of a physician.

## DEVICE DESCRIPTION

The Cannula with Guide (CSK-6131) is provided STERILE in unopened, undamaged package. For single use only. Do not re-sterilize. Do Not Re-Use. This product may be used in conjunction with the following devices provided separately:

[1] EPi-Sense® Coagulation System, sterile, single-use (under separate IFU)

The Cannula is manufactured PVC free and is not made with natural rubber latex or phthalates.

## PRODUCT FEATURES

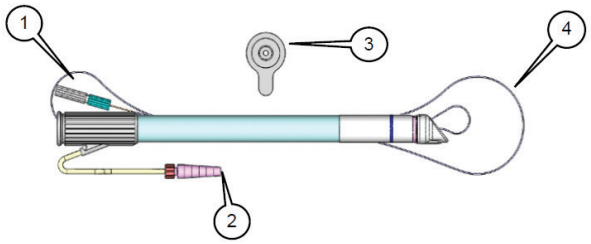


**Figure 1. Cannula (CSK-6131) with Guide Key Features**

[1] Torquer
[2] Vacuum Port
[3] Cannula Cap
[4] Guidewire - 0.026 in (0.66 mm) diameter

## INDICATIONS FOR USE

The Cannula with Guide is indicated for use in laparoscopic or general surgery to provide access for operative and diagnostic instrumentation in body cavity spaces.

## CONTRAINDICATIONS

There are no known contraindications.

⚠**WARNINGS**⚠

Insertion or removal of the Cannula with Guide while guidewire is extended may cause potential patient harm. Always fully retract the guidewire into the Cannula with Guide lumen.

The Cannula is provided sterile and is intended for single use only. Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.

Inspect the device packaging prior to use. If any breach of the packaging is found, the sterility of the product cannot be assured, and the product should not be used to prevent patient infection.

⚠**WARNINGS**⚠

Inspect the Cannula and guidewire prior to use. Ensure Cannula distal end and guidewire are smooth with no sharp edges. Sharp edge can cause potential patient harm. If sharp edge is found, device should not be used.

Care should be taken when inserting the Cannula. Applying excess force could cause potential patient harm. To reduce friction during insertion, lubricate the Cannula with sterile saline.

Care should be taken when manipulating the Cannula or guidewire. Always ensure no tissue is caught by the guidewire and brought into the Cannula with Guide lumen as this may cause altered hemodynamics or unintended tissue damage.

Care should be taken when manipulating the guidewire, scope, and any over-the-wire devices. Excessive forces may damage the Cannula and/or guidewire or cause unintended tissue damage. The Cannula with Guide has a limited functional life; if greater than 18 bend cycles of the Cannula, guidewire, or scope are intended, it is recommended to monitor for damage. If damage is observed, replace the device.

Avoid excessive pulling on the torquer. Excessive pulling on torquer may damage the Cannula and/or guidewire or cause patient injury.

⚠**WARNING**⚠

This device contains small amounts of Nickel (CAS# 7440-02-0). Do not use the device if the patient has sensitivity to Nickel as this may result in an adverse patient reaction.

⚠**CAUTIONS:**

- Avoid over-rotating the Cannula with Guide. Over-rotation can cause the vacuum tubing of the Cannula to kink, reducing the Cannula suction, thus causing reduced visibility.
- Avoid over-inserting the Cannula with Guide into patient body. Over insertion may reduce Cannula suction.
- Inspect the device prior to use. If any damage is found, the function of the product cannot be assured, and the product should not be used.

## ENVIRONMENTAL SPECIFICATIONS

| | Temperature | Humidity | Atmospheric Pressure |
|---|---|---|---|
| Operational | 10 to 40°C (50 to 104°F) | 30-75% relative humidity non-condensing | 700 to 1060 millibar (10 to 15 psi) |
| Transit | -29 to 55°C (-20 to131°F) | 30-85% relative humidity | N/A |
| Storage | -29 to 55°C (-20 to131°F) | 30-85% relative humidity | N/A |

## POTENTIAL COMPLICATIONS OF THE USE OF THE CANNULA SYSTEM

- Blunt trauma to adjacent organs
- Infection
- Pericardial effusion
- Vessel injury
- Tissue perforation
- Hemodynamic instabilities
- Arrhythmias
- Thromboembolic complication
- Hernia
- Pneumothorax
- Conversion to sternotomy

## REQUIRED EQUIPMENT AND SUPPLIES PROVIDED BY HOSPITAL

[1] Vacuum Tubing Set (Sterile)
[2] Vacuum regulated at -250mmHg

## RECOMMENDED EQUIPMENT

- 35 cm, 5 mm, and/or 10 mm Scope, depending on Cannula use
- 1000 mL 0.9% Normal Saline or Sterile Water

- Coagulation Device – Refer to Instructions for Use for the Coagulation Device when being used with the Cannula with Guide.

## INSTRUCTIONS FOR USE

### CANNULA SET UP

1. Inspect all pouches, cartons, and packaging to ensure there has been no package damage, which may result in product contamination. If package damage is discovered, do not use – replace the product.
2. Outside the sterile field, remove the pouched Cannula from carton.
3. Using sterile techniques remove Cannula and tray from the pouch and place near patient.
4. Remove Cannula, cap, and stopcock from tray.

**⚠WARNING⚠**

When removing Cannula from packaging, care should be taken to ensure guidewire and Cannula cap remain inside sterile field to reduce risk of infection.

5. Prior to inserting the Cannula into body cavity, examine the Cannula functionality to ensure no damage during shipping occurred.
6. Examine Cannula to ensure proximal end (Fig. 2) has no damage. If Cannula is damaged, do not use – replace the product.
7. Examine Cannula to ensure distal end and guidewire are not damaged and are smooth with no sharp edges. If Cannula is damaged or has sharp edges, do not use – replace the product.
8. If perfusion through the vacuum lumen is preferred, then attach a stopcock as shown in Fig 2. A stopcock is supplied. Connect perfusion tubing to perfusion port in Figure 2. Insert IV tubing into 0.9% normal saline.

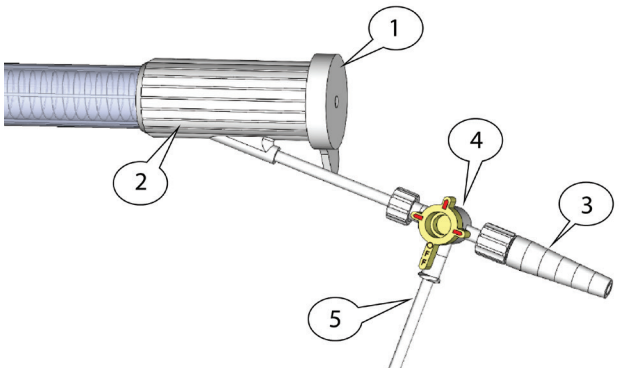


**FIGURE 2. PROXIMAL END OF CANNULA WITH GUIDE**

[1] Cannula Cap (Flat Valve)
[2] Cannula Grip
[3] Vacuum Port
[4] Stopcock
[5] Perfusion Port

### CANNULA DEPLOYMENT AND MANIPULATION

1. Remove torquer from the end of guidewire and thread guidewire through available hole in the center of the Cannula cap (Fig. 3). Replace torquer over proximal end of guidewire once guidewire is threaded through cap.

⚠**CAUTION:** Failure to place guidewire through hole in center of cap (puncturing cap or placing outside cap entirely) may reduce cap functionality.

⚠**CAUTION:** Failure to replace torquer exposes the sharp proximal end of the guidewire and may cause injury to patient and/or user.

2. Push cap onto end of Cannula grip.

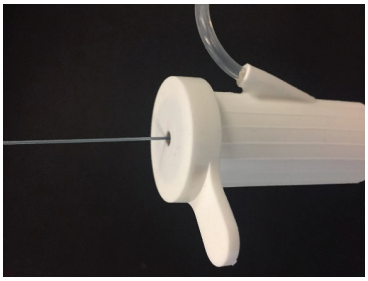

**FIGURE 3. CANNULA WITH GUIDE (CAP AND GUIDEWIRE)**

⚠**CAUTION:** Ensure Cannula cap is fully attached to the Cannula grip – failure to fully attach cap may reduce functionality of the Cannula cap.

3. Lubricate the exterior of the Cannula with sterile saline.
4. Fully retract the guidewire into the lumen of the Cannula with Guide (Fig. 4) prior to insertion into the body.


**FIGURE 4. CANNULA (CSK-6131) WITH GUIDE IN GUIDEWIRE DEPLOYMENT POSITION**

[1] Guidewire
[2] Distal End of Cannula

5. Before inserting instruments, lubricate Cannula lumen by injecting approximately 20mL sterile water or saline through hole in center of Cannula cap.
6. Insert scope into hole in Cannula cap as required for visualization. A blue line is on the outside of the Cannula (CSK-6131) as a landmark for scope retraction location to aid in visualization.
7. If resistance is felt as the scope is being inserted, pull back on the scope to readjust its position. Once the position has been adjusted re-insert the scope into the Cannula.
8. Insert the Cannula with Guide into the body as desired to create space and visibility. A blue marker line is indicated on the distal end of the Cannula, which may be used to facilitate orientation.

⚠**CAUTION:** Do not manipulate Cannula by grasping the tab of the Cannula cap. Doing so may loosen or remove Cannula cap from Cannula causing reduced functionality.

9. Use the guidewire to aid in visualization and in the positioning and manipulation of over-the-wire devices for operative or diagnostic procedures.
10. To use an over-the-wire device, remove the Cannula cap from the Cannula and Cannula guidewire. Follow device instructions for use for set-up/manipulation of the over-the-wire device.

**⚠WARNING⚠**

Cannula cap and torquer should be removed prior to insertion and removal of any over-the-wire devices – failure to remove cap prior to insertion may result in damage to the Cannula cap and/or the over-the-wire devices preventing application of the intended therapy.

⚠**CAUTION:** To avoid interruption of vacuum or perfusion flow, ensure tubing is not clamped or kinked during coagulation of tissue.

11. Connect one end of the vacuum tubing to vacuum port (Fig. 2, #3), and the other to the vacuum trap. Set vacuum pressure to -200 mmHg (-3.9psi, 26.7 kPA) to remove fluid. Suction saline to improve visibility.

⚠**CAUTION:** Do not set vacuum pressure outside the range of -225 to -275 mmHg (-4.35 to -5.32 psi; -30.0 to -36.7 kPa)

12. Retract surgical instruments from the Cannula lumen.
13. Retract the guidewire into the Cannula lumen.
14. Remove the Cannula with Guide from the body.

**⚠WARNINGS⚠**

Do not modify Cannula – modification could produce sharp edges resulting in unintended tissue damage.

Care should be taken when handling surgical instruments near the distal end of the Cannula – do not clamp the distal end of the guidewire with surgical instruments. Doing so may cut or break Cannula and cause tissue perforation or unintended damage or allow surgical instruments to stay outside the Cannula lumen during manipulation.

⚠**CAUTION:** Large blood clots and tissue particles may clog vacuum lumen and impair suction to Cannula with Guide.

**AT COMPLETION OF PROCEDURE**

Remove Cannula from tissue, disconnect all tubes, and discard Cannula and tubing sets following local governing ordinances and recycling plans for disposal or recycling of device components.

**⚠WARNING⚠**

Ensure device is disposed of following local governing ordinances and recycling plans to prevent biohazard exposure.

**RETURN OF USED PRODUCT**

If for any reason this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping. If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment. Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

**TROUBLESHOOTING**

| Symptom | Action |
|---|---|
| Not able to draw vacuum | • Check vacuum connections.<br>• Ensure vacuum regulator is set to -200 mmHg.<br>• Examine Cannula vacuum lumen for clots.<br>• If clogged, flush vacuum lumen with sterile water.<br>• If problem persists, replace Cannula. |
| Unable to advance instruments within Cannula lumen. | • Lubricate lumen with sterile water or normal saline.<br>• Ensure instruments are correct size. |

**LIMITED WARRANTY**

AtriCure warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. AtriCure's sole obligation under this warranty is limited to the repair or replacement of this instrument. AtriCure neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond AtriCure's control directly affect the instrument and the result obtained from its use. AtriCure assumes no liability with respect to instruments deliberately mis-used or those reused, reprocessed or re-sterilized and makes no warranties expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such mis-used or reused instruments. AtriCure shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the deliberate mis-use or re-use of this instrument.

**DISCLAIMER**

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used.

Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

**DISPOSAL**

After use this device should be treated as medical waste and disposed of following hospital protocol.

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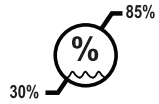
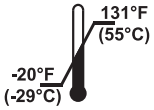
## SYMBOLS

| | | | |
|---|---|---|---|
|  | Manufacturer |  | Country and date of manufacture |
|  | Catalog Number |  | Caution |
|  | Batch code |  | Model Number |
|  | Unique device identifier |  | Prescription Use Only |
|  | Use-By Date |  | Do Not Resterilize |
|  | Do not re-use |  | Do Not Use if Package is Damaged |
|  | Single sterile barrier system with protective packaging inside |  | Single sterile barrier system with protective packaging outside |
|  | Sterilized using irradiation |  | Consult Instructions for Use |
|  | Not made with natural rubber latex |  | Contains hazardous substances |
|  | Non-pyrogenic |  | Does not contain Phthalates |
|  Transit/Storage Humidity limit | |  Transit/Storage Temperature limit | |


AtriCure Inc.
7555 Innovation Way
Mason, Ohio 45040 USA
+1 866 349 2342
+1 513 755 4100