

# VeinCore

Endoscopic vein harvesting tool



Manufactured by JJ. NYCE Vascular  
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Clemson, SC 29632



# VeinCore

ENDOSCOPIC VEIN HARVESTING TOOL

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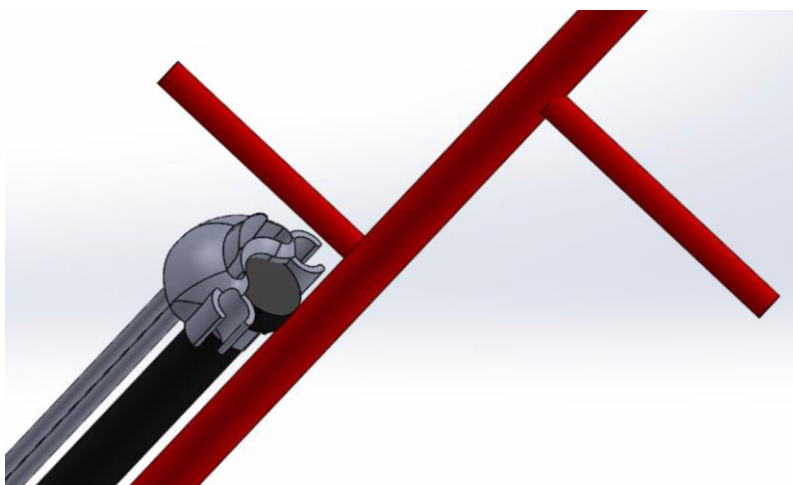
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## Device Description

VeinCore is a fully mechanical device to be used during Endoscopic Vein Harvesting procedures preceding a Cardiac Artery Bypass Graft procedure. VeinCore allows a clinician to sever the connective tissue around the outside of a target vein in order to extract the vein for the bypass.

The device is intended to simplify the vein harvesting procedure in order to lessen the learning curve amongst users, and as a result increasing graft patency while decreasing the harvesting time duration. The device is inserted into a small incision site. Once it is at the desired location the user extends the blade to begin severing the surrounding connective tissue. Once all of the desired connective tissue is severed, the user retracts the blade into its protective casing and safely removes it from the patient. The target vein can then be extracted. The device assists in preventing the user from accidentally cutting or nicking the vein of interest during the vein extraction.



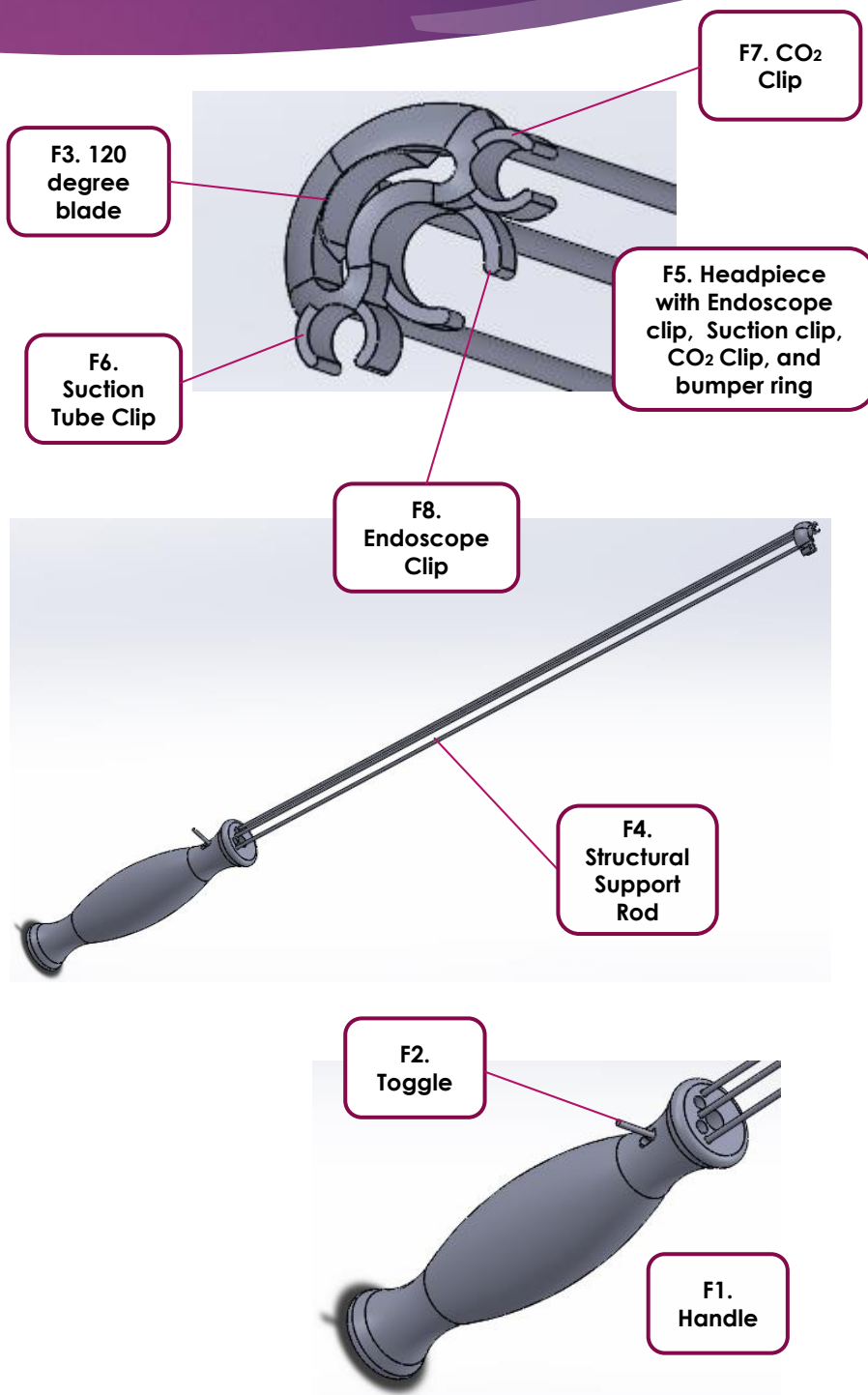
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## Device Description

The handle of the device (**F1**) contains a toggle mechanism (**F2**) in order to operate the retractable and extendable 120 degree blade (**F3**). The center support rods of the device (**F4**) hold the structure of the device, and when encased in a sheath-like outer covering, will hold the suction cords and the structural rod that allows the blade extension to operate. The headpiece of the device (**F5**) contains the 120 degree retractable blade as well as clips for both the suction and Carbon Dioxide attachments on either side of the headpiece (**F6** and **F7**). The endoscope clip sits in the center of the arc of the headpiece (**F8**). The headpiece also features a bumper ring for protection of the vein from contacting the blade.



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## Indications for Use

VeinCore is indicated for use in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extra peritoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels, and other tissues of the chest wall.

## Contraindications

- ▶ VeinCore should not be used if the patient is allergic to the device materials
  - ▶ If allergy is suspected, tests should be done prior to use to confirm the presence of the allergy, or lack thereof
- ▶ The device should not be used if the target vein possesses a pre-existing condition rendering it unviable for further bypass procedures
- ▶ Procedures outside the scope of the Indications for Use

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## Warnings

- ▶ Do not use if the package is damaged, broken, or unsealed
- ▶ Do not re-sterilize this device or use twice
- ▶ Read instructions thoroughly before use of device
- ▶ If not used properly, device can injure the patient or user due to sharp components



## Precautions

U.S. Federal law restricts this device to sale by or on the order of the physician

- ▶ Hazards associated with this device include, but are not limited to, inflammatory response and various device malfunctions
- ▶ Vein graft viability is to be assessed by the clinician post-vein harvest and prior to Cardiac Artery Bypass Graft procedure
- ▶ After use, the device will present a biohazard and must be disposed through the proper and nationally accepted channels
- ▶ Due to the presence of a sharp blade, caution must be used when operating the device so as not to injure/damage the patient or user

R<sub>x</sub>  
ONLY

## Adverse Events

- ▶ Cutting of the target vein
- ▶ Inflammatory response
- ▶ Sticking/breaking of toggle system
- ▶ Failure of blade to extend or retract
- ▶ Blade fracture from device
- ▶ Infection of the surgical site

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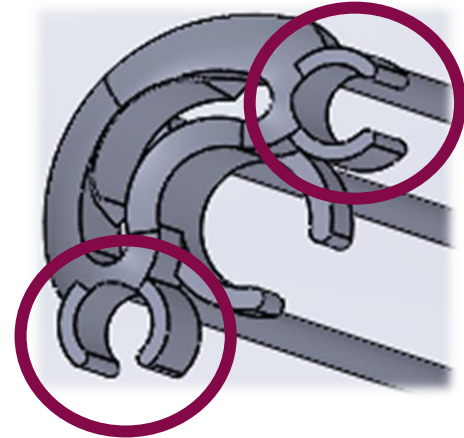
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## Directions for Assembly and Use

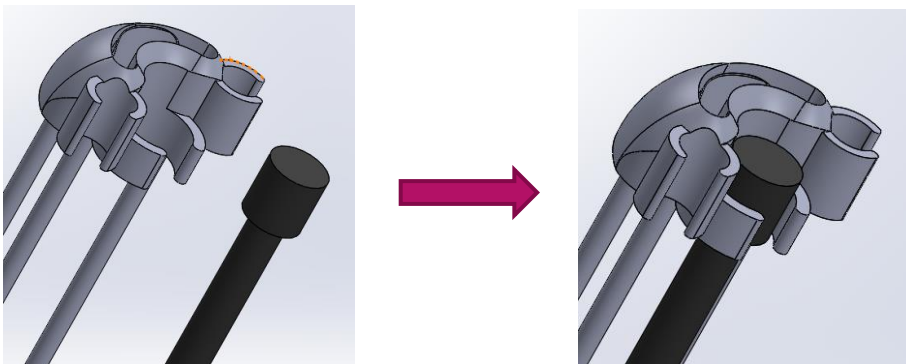
1. Pick up device by ergonomic handle.
2. Attach suction tube and CO<sub>2</sub> to device by inserting the suction tube into the clip on the headpiece
3. Fasten endoscope to clip on headpiece



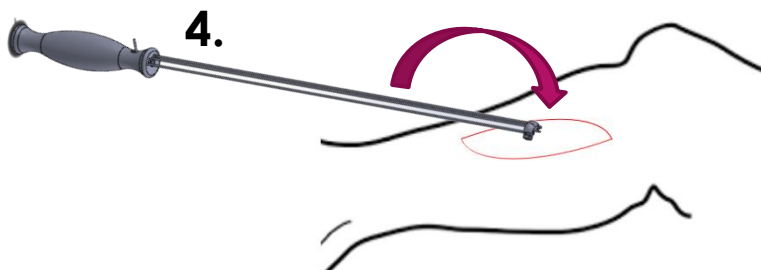
2.



3.



4. Insert device into incision



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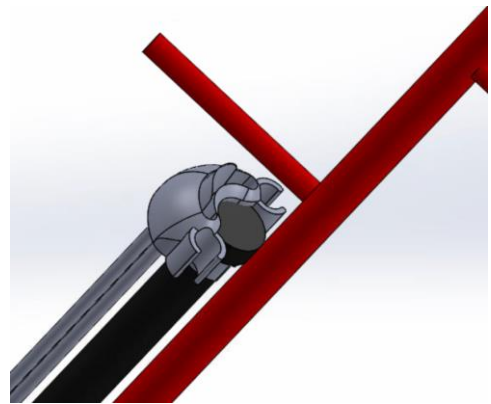
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## Directions for Assembly and Use

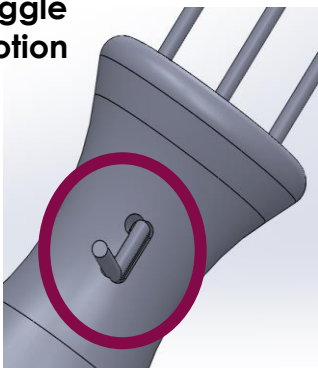
**5.** Position device headpiece with bumper ring and endoscope adjacent to target vein

**6.** Press toggle upward to extend the blade

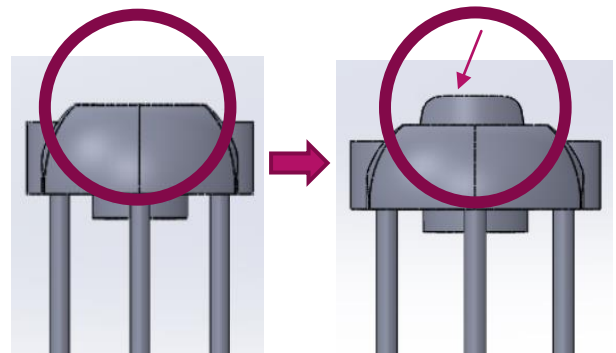
**5.**



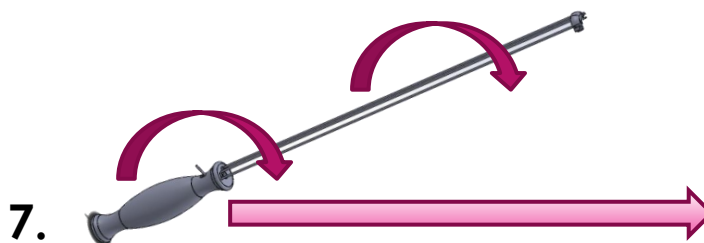
**6.**  
Toggle  
Motion



**6.**  
Resulting  
Blade  
Motion



**7.** Move the whole device forward while rotating wrist when necessary to sever all connective tissues



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## Directions for Assembly and Use

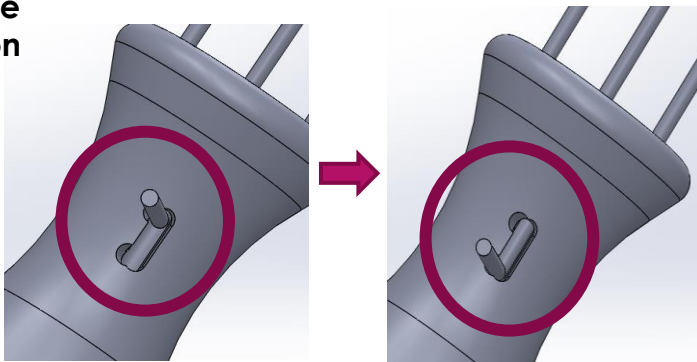
**8.** If necessary, press and hold the suction pedal on the suction pump to suction the blood away from the procedural space and increase visibility or operate the CO<sub>2</sub> valve to insufflate the leg cavity for visibility

- release the suction pedal or CO valve when the space is as desired or to switch between these two mechanisms

When procedure is complete:

**9.** Press toggle downward to retract the blade

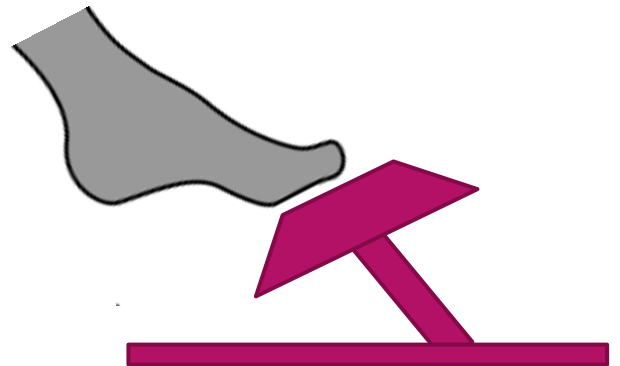
**9.**  
**Toggle**  
**Motion**



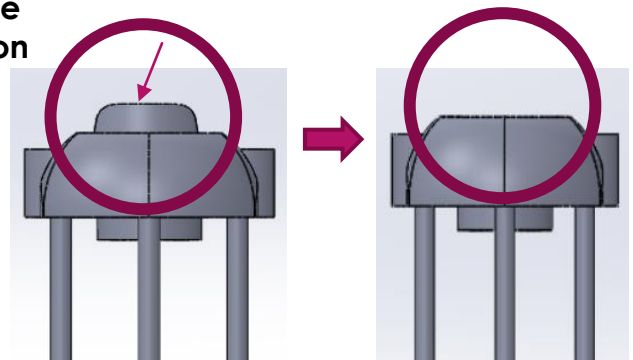
**10.** Remove the device from the surgical space



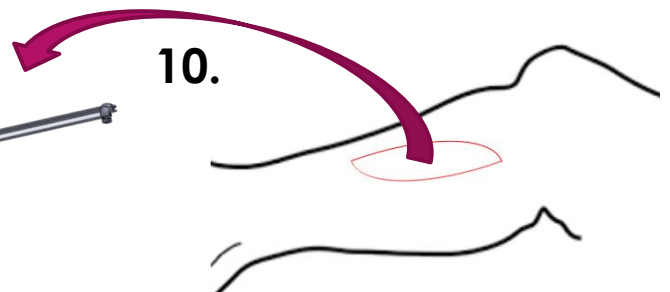
**8**



**9.**  
**Resulting**  
**Blade**  
**Motion**



**10.**



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## Cleaning

This device does not require a cleaning procedure as it is a disposable product. After use, discard device in appropriate medical waste receptacle.



## Storage

VeinCore should be kept in a dry space at approximately room temperature so as to prevent rusting of the metal components. The device should remain in original packaging and unassembled until time of use.



## Sterilization

This device is provided sterile in packaging that should not be opened until ready for use. VeinCore is disposable and should not be used and re-sterilized.



## Material Specifications

- ▶ Handle: Nylon 12
- ▶ Body/structural rods: 316 L Stainless Steel
- ▶ Blade: 316 L Stainless Steel

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For addition information and inquiries regarding VeinCore please  
contact JJ. NYCE Vascular:

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