Quickloop™ Abscess Treatment Device

Read this entire package insert carefully prior to use.

Quickloop is a single use device. Do not resterilize any portion of this device. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

Indications
Quickloop is intended to provide percutaneous drainage of subcutaneous fluid collections.

Quickloop devices with the irrigation feature are intended to provide percutaneous irrigation of the subcutaneous cavity.

℞ only

Contraindications
- Due to the rare association of incision and drainage of abscesses with mycotic aneurysm, fine-needle aspiration for blood, diagnostic imaging, and/or angiography may be indicated prior to delivery of the device.
- Patients with bleeding disorders may need additional testing and/or administration of medication or blood products prior to procedure.
- The device is contraindicated for patients with known allergies to PVC found in the device, and/or tapes or adhesives used to fix the device to the patient post-procedure.

Warnings
- If the packaging is open or shows any signs of being compromised, discard the device, and replace with a new one.
- Do not reshape or bend the introducer (metal component). Any bending risks device fracture and possible injury to the patient.
- Consider the size of the loop created by the tubing before closing the hub cover. If the tube is looped too tight it may create areas of necrosis or poor healing between incision sites.
- When dressing the Quickloop in place, the tubing should lie flat and in line with the skin exit areas.
- Do not leave the device installed longer than 28 days.

Precautions
- Avoid creating a sharp bend in or otherwise kinking the tubing. Any kinking will restrict or limit the irrigation potential of the device.
- Do not attempt to take the irrigation hub off the tubing. The hub is permanently fixed onto the tubing.
- Do not attempt to reopen the irrigation hub cover once it has been closed. It is designed for a single closure.
- Do not add additional irrigation holes.
- Do not suture through the tubing.
- In the event of occlusion of the irrigation holes, device may be submerged in warm water for 15 minutes after which irrigation may be reattempted. If occlusion persists, the device may be left in place without the use of the irrigation feature.
- Leaving the tubing implanted for a length of time could cause tissue in-growth around the tubing which can interfere with easy removal and affect performance of irrigation. The health care professional should monitor the healing progress.

General Instructions For Use
It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect the success of the procedure.

- All users are expected to read the Instructions For Use that accompany the device.
- Devices should be stored in their original packaging in a dry, temperature-controlled environment, away from corrosive or oily chemicals.
- Do not resterilize the device.
- Inspect the product, including all packaging and labeling materials carefully:
  - Do not use past expiration date specified on the product label
  - Do not use if the device or packaging is damaged
  - Do not use if there are discrepancies in label information
- Promptly report all product defects and patient adverse events to the manufacturer (see Product Complaints section).

Pre-Procedure
The patient or patient representative must be made aware of the risks and benefits of the device and procedure, as listed below, prior to consenting. The patient must also be made aware of the care of the device post-procedure.

The following is a list of intra-procedural and post-procedural complications and adverse reactions that may require further medical or surgical interventions.

- Device failure
- Device disassembly
- Pain, possibly severe in nature
- Epidermis and/or dermis tear or contusion, soft tissue erosion
- Injury to superficial nerves, blood vessel damage, hematoma, significant blood loss
- Secondary wound infection – deep or superficial
- Delayed wound healing, non-healing cutaneous fistula
- Foreign body reaction to the device which may include localized inflammation, scarring or keloid formation

Intra-Procedure/Device Placement
Ensure that patient has appropriate anesthesia and/or procedural sedation as per standard practice. The procedure must be performed in sterile fashion per typical standard of care practices.

- Ensure Quickloop is free of obstructions or knots and that irrigation hub cover is open.
- Using a needle driver, grasp the device on the needle just in front of the blade. Do not hold the device by the blade. Doing so can stress the device and cause it to bend or fracture.
- When inserting the device, care should be taken to avoid using excessive force. Doing so has the potential to cause damage to the device or surrounding tissue.
- Centrally position the Quickloop within the abscess, keeping the entry and exit points equidistant from the outer edge. Insert the needle point within the edge of the subcutaneous cavity and advance through to the opposite side. The incisions should be positioned close enough to the edge to allow for subsequent use of instruments to break up locations if necessary.
- Upon the needle point protruding through the distal boundary, reengage the needle driver at the needle point and pull the device through the cavity until only the tubing is within it.
- Position the tubing so it creates an appropriately sized loop with the distal irrigation hub.
- Remove the introducer by cutting the tube near the introducer with scissors.
- Discard the introducer in a standard sharps container.
- Consider the size of the loop created by the tubing before closing the hub cover. If the tube is looped too tight it may create areas of necrosis or poor healing between incision sites.
- Position the free end of the tubing within the trough of the irrigation hub taking care to ensure some tubing sticks out of the hub.
- Close the hub cover and trim excess tube from distal end.
- Connect a 20-50ml Luer Lock syringe filled with irrigation solution to the irrigation hub.
- Position the tube's irrigation holes within the subcutaneous cavity and begin irrigating by depressing the syringe.
- The contents of the subcutaneous cavity should exit the proximal and distal holes during irrigation. Gentle traction of the device away from the skin may be needed to increase the size of the incisions to accommodate thicker drainage material.
- A blunt instrument may be used to break up loculations as needed by carefully inserting it into the incision adjacent to the tubing.
- After irrigation, adjust the tubing so that the fenestrations reside outside of the subcutaneous cavity to prevent obstruction.
- Adhere the device temporarily to the patient's body so that it won't catch on objects but can be accessed by the patient for irrigating at home.

Post-Procedure
The health care professional must provide clear directions and warnings and obtain verification of patient understanding for patient post-procedure compliance. Post-procedure care and the patient's ability and willingness to follow instructions are extremely important aspects of successful healing. Device presence may cause pain, discomfort, abnormal sensations, and increased risk of progression of infection if not used as intended or in accordance to the Instructions For Use. Proper supplies for home care, irrigation, and dressing changes should be made available to the patient as determined by the treating health care professional. The patient is to be advised of the need for regular post-procedure irrigation and dressing care as determined by the treating health care professional.

Furthermore:

- Caution the patient against leaving the device exposed to rubbing or catching on external objects.
- Instruct the patient to seek medical attention if sudden changes in appearance at the procedure site are noticed or if an unexplained increase in pain is experienced.
- Instruct patient of the need to keep the incision and device clean.
- The tubing should be adjusted so that the fenestrations reside outside of the subcutaneous cavity to prevent tubing occlusion.
- Affix the device to the patient's body taking care not to leave portions of the device exposed to catch on external objects.

Device Removal
To remove the device, cut the tubing with sterile scissors and pull the tubing out of the incision. Inspect the incisions for signs of healing or infection and treat as necessary. Discard the device in accordance with local, state and federal regulations or requirements.

Product Complaints
Complaints or dissatisfaction with the device quality, safety, reliability, durability, effectiveness and/or performance, brought forth by a health care professional, whether via a customer or user of the product, should be immediately conveyed to the attention of the manufacturer via telephone, fax, or written correspondence to feedback@emdevicelab.com or by express mail. It is important to note that when filing a complaint, the following information must be included to properly respond to the complaint:

Name and address; nature of the complaint; the product name and catalog number; applicable lot number(s).

Manufacturer
EM Device Lab, Inc.
6303 Mountain Park Cove
Austin, TX 78731
(737) 243-9701 Main | (737) 273-7431 Fax
info@emdevicelab.com | emdevicelab.com

Symbol Use Table:

Symbol Definitions					
REF	Catalog Number	LOT	Batch Number	QTY	Quantity
	Use-By Date	℞only	Prescription Use Only	2	Do Not Reuse
STERILE EO	Sterilized Using Ethylene Oxide	2 STERILIZE	Do Not Resterilize		Do Not Use If Package is Damaged
	Caution - Sharp		Consult Instructions For Use		Manufacturer