INTERI™ SYSTEM

INSTRUCTIONS FOR USE

Healthcare Professional

IC SURGICAL
ADVANCING SURGICAL OUTCOMES

Intended Use

The Interi System is intended for the removal of surgical and bodily fluids from a closed wound following plastic and other general surgery forming large flaps for hemotoma and seroma prophylaxis. The system can be used in acute and home care settings.

Precautions

1. Please read all instructions prior to use.
2. Only physicians qualified in the appropriate surgical techniques should use this system.
   CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician.
3. Once activated, the Therapy Unit cannot be emptied or reset.
4. The fluid level in the Therapy Unit should be checked periodically during post-operative recovery to evaluate if fluid is flowing and if the reservoir is full.
5. There may not be a rush of blood or fluid when a Therapy Unit is connected and flow may vary.
6. The Manifold external tubing should be checked periodically during post-operative recovery to ensure that it is not clogged or kinked and fluid is flowing.
7. Used Therapy Units and Manifolds are to be disposed of according to regulations for biohazard disposal.

Warnings

- The system must be a closed system in order to preserve patency. The Manifold external tubing must not be occluded nor the Therapy Unit completely full in order to maintain system functionality.
- There must be an airtight seal where the Manifold molded junction exits the skin.
- Keep the Manifold exit site protected and clean. Consult CDC guidelines for information on surgical site care.
- An airtight seal between all system components (Therapy Unit, Connector and Manifold) is necessary for proper system function.
-  Do not use Manifold if the tamper resistant seal has been broken or any suspected damage has occurred to the packaging including damage to the sterile packaging.
- Manifold, trocar and Connector are provided sterile and non-pyrogenic. Do not re-sterilize the Manifold or the Connector.
- Trocar is sharp, use care when using trocar.
- Therapy Unit is provided non-sterile. **Do not sterilize the Therapy Unit.**

- Therapy Unit, Manifold, Connector, and trocar are for single use only.
- Do not use a Therapy Unit if the tamper resistant seal has been broken or any suspected damage has occurred.
- Do NOT place the Manifold against vascular or bowel anastomosis or other internal organs. The Manifold has not been studied for placement in organ spaces and should not be used in those anatomic spaces.
- The Manifold is not to be implanted for more than 30 days.
- Therapy Unit must be changed after 7 days of continuous use, even if it is not finished.
- No more than 4 Manifolds should be implanted into a single patient at a time.
- Do not connect any other negative pressure or vacuum suction sources to the Manifold other than the Therapy Unit except for the temporary use of wall suction after initial placement.
- Extreme caution should be used during post-operative recovery to ensure that there is no misconnection between the Manifold or Therapy Unit and any other medical device using similar tubing connections. Connecting the Manifold or Therapy Unit to any other device could result in harm.
- If hyperbaric therapy is required, the Therapy Unit should either be disconnected from the patient or accompany the patient into the chamber.
- System tubing is a strangulation hazard. Keep out of reach of small children.

Contraindications

Allergy or history of allergy to silicone-based products.

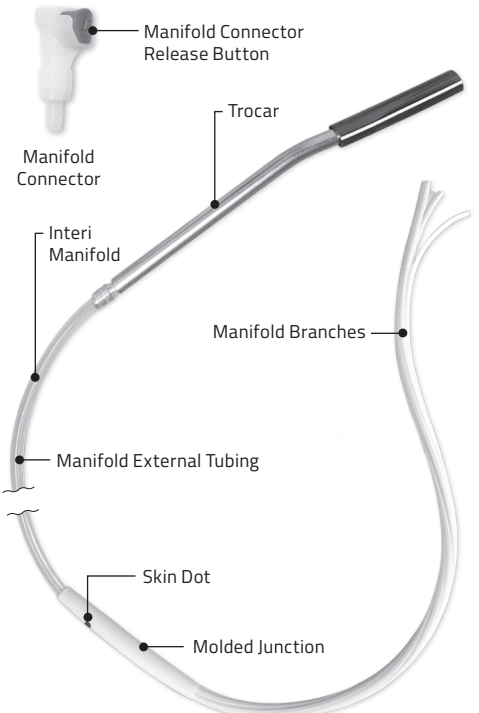
Do not use if there is the presence of:
- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in the surgical site
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site
- Exposed bone or tendons

Magnetic Resonance Imaging (MRI) Safety Information: The Manifold and Manifold Connector are MR Safe.

The Therapy Unit and trocar are MR Unsafe and must be removed prior to entering an MR environment as they may present a projectile hazard.

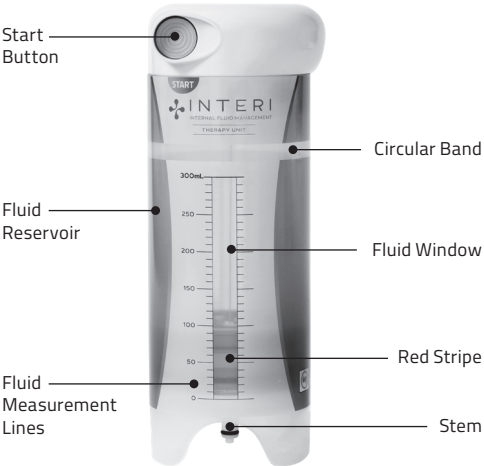
KIT SYSTEM COMPONENTS

Interi Manifold and Manifold Connector



- White sections of the Manifold (molded junction and branched portion of the Manifold) are radiopaque.
- The Manifold Connector contains an integrated backflow valve, as does the Stem that is pre-attached to the Therapy Unit.

Interi Therapy Unit



- Once activated, the Therapy Unit provides a negative pressure of 125 +/- 25 mmHg.

Carrying Case

Placement of the Interi Manifold

1. The surgeon should irrigate the wound with sterile fluid, then suction the irrigating fluid and gross debris from the operative site.
2. Open the secondary Manifold package.
3. Drop the internal package into the sterile field. Open the internal sterile Manifold package and remove both the Manifold with the pre-attached trocar and the Manifold Connector and then carefully drop them into the sterile field.
4. Inspect the Manifold tubing for nicks, cuts, or other potential damage. Do NOT use if any suspected damage has occurred.
5. Peel apart the Manifold branches as desired and place the Manifold into the body. Arrange the branches to ensure maximum suction coverage is achieved. If necessary, trim the branches to desired length as needed with sterile OR scissors.

   Note: Do NOT place the Manifold against vascular or bowel anastomosis or other internal organs. The Manifold has not been studied for placement in organ spaces and should not be used in those anatomic spaces.
6. Use the trocar to route the Manifold through the skin at a shallow angle (not straight out of the cavity). Aim for a shallow angle that routes through a minimum of 5cm of soft tissue.
7. Adjust the Manifold molded junction or clear silicone Manifold external tubing until the skin dot is aligned just outside of the exit site. This will help to ensure that the molded junction provides a good seal.

   Note: Both the surgical site and the Manifold external tubing exit site need to form an effective airtight seal for the system to function properly.
8. Cut the extra Manifold external tubing to the desired length. Ensure enough external tubing remains to allow patient movement without exerting tension on the exit site. Cutting to length will remove the trocar. Do not pull the trocar off the tubing as the section of tubing previously around the trocar is slightly stretched and may not hold onto the Manifold Connector securely.
9. Secure the Manifold molded junction to the skin with a large gauge permanent suture. Do not puncture the tubing with the suture.

10. Secure the Manifold external tubing outside of the exit site to the skin using tape or equivalent to prevent pulling and accidental Manifold displacement. Based on current practices, consider placing an antimicrobial or occlusive wound dressing at the exit site per site procedures and CDC recommendations.
11. **LOOSELY connect the Manifold to constant wall suction in order to remove any air or fluids.**
    Do NOT connect tightly, as it can cause injury.
    Do not exceed 180mmHg (24 kPa/3.48 psi) when using wall suction.
12. Close the body cavity, confirm that the surgical sites are sealed and that the Manifold is drawing fluid.
13. Repeat the procedure for each Manifold you intend to place.

Attach the Therapy Unit and Initiate Therapy

Note: Therapy Units and carrying cases are not sterile. Do NOT bring them into the sterile field.

1. Disconnect the Manifold tube from the wall suction.
2. Remove the sterile Manifold Connector from its packaging and push it onto the end of the Manifold external tubing. Ensure the barbs on the Manifold Connector are fully pushed into the external tubing.
3. Attach the Manifold Connector to the stem on the Therapy Unit. Do NOT use a Therapy Unit if any suspected damage has occurred.
4. Ensure the connections are secure by pushing the Manifold Connector together with the Therapy Unit stem until you hear a click. Perform a final inspection of the Manifold external tubing, connections and Therapy Unit to prevent leaks.
5. **Press the Start Button on the Therapy Unit.** Observe Manifold external tubing and Therapy Unit for fluid flow. **Once activated, the Therapy Unit cannot be emptied or reset.**
   Note: The Manifold Connector may be temporarily disconnected from the Therapy Unit. The Therapy Unit will automatically hold suction until the Manifold Connector is re-connected. NEVER touch or push the Stem at the bottom of the Therapy Unit.
6. There may not be a rush of blood or fluid when a Therapy Unit is connected and flow may vary.

7. There may be some air in the Therapy Unit which is normal.
8. Place the Therapy Unit into the carrying case and secure with the included Velcro strap. Route the tubing through the opening on the side of the carrying case before closing the cover. Make sure the tubing is not pinched inside the carrying case. Secure the carrying case so that it is not dislodged during patient transport. The carrying case can be worn around the waist or over the shoulder utilizing the adjustable straps.

End Therapy and Remove the Manifold

1. Disconnect the Therapy Unit from the Manifold Connector and dispose according to regulations for biohazard disposal.
2. Remove any tape adhering the Manifold external tubing to the skin.
3. Remove suture(s) securing the Manifold molded junction to the exit site.
4. If pain management is desired, use standard pain management protocols during Manifold removal.
5. GENTLY pull Manifold out of the body through the exit site.

   Note: DO NOT use sharp or toothed objects to pull the Manifold. This could damage the tubing or cause tubing fragments to be left inside the patient. If necessary, confirmation of the removal of all internal (white) tubing and branches can be done via X-ray (molded junction and Manifold branches are opaque).
6. Visually inspect the Manifold to confirm it is fully intact.
7. Dispose of the Manifold according to regulations for biohazard disposal.
8. Apply an antimicrobial dressing to the exit site per standard protocol.

Cleaning the Therapy Unit, Tubing and Carrying Case

Clean the Therapy Unit and External Manifold Tubing as necessary with one of the following solutions:

- Isopropyl Alcohol, 70%
- 1-1/2 tsp of dishwashing liquid in 16 ounces (2 Cups) of water (or 6 mL of dishwashing liquid in 400 mL of water)

Do not use other chemicals, solutions, or methods to clean the Therapy Unit or the External Manifold Tubing, as this could cause damage or contamination of the system.

Train Patients (or Caregivers) to Familiarize Users With:

- The features of the system and how to use it in a safe and effective manner.
- How to periodically record the volume of the fluid in the Therapy Unit.
- How to determine if the Therapy Unit is full.
- Handwashing prior to replacing a full Therapy Unit.
- Procedure for replacing a full Therapy Unit and initiating therapy with a new Therapy Unit.
- What to do with a used Therapy Unit.
- How to "strip" or "massage" the Manifold external tubing if the user suspects the tubing is clogged.
- Recommendation that only a healthcare professional should clean the Manifold exit site as needed.
- The importance of always holding the Manifold tubing upright and how to clean up drips from the system that might occur.

Storage conditions:
Temperature: 15 C – 30 C (59 F – 86 F)
Humidity: <= 90% RH

IC SURGICAL
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