

INTERI™ SYSTEM

HEALTHCARE PROFESSIONAL USER GUIDE

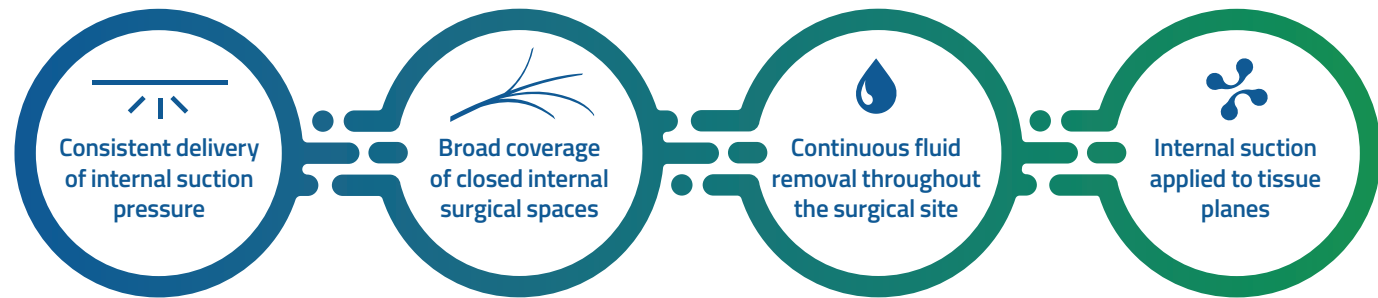
This guide is intended as a high-level overview for Healthcare Professionals in their use of Interi and as they train patients. Prior to clinical use, please review the Interi System Instructions for Use. Please refer patients to the Interi System Patient Guide for complete instructions, along with the Interi System User Video.



WHAT MAKES INTERI UNIQUE?

The Interi System assists with internal wound control by delivering continuous suction pressure to internal surgical spaces.

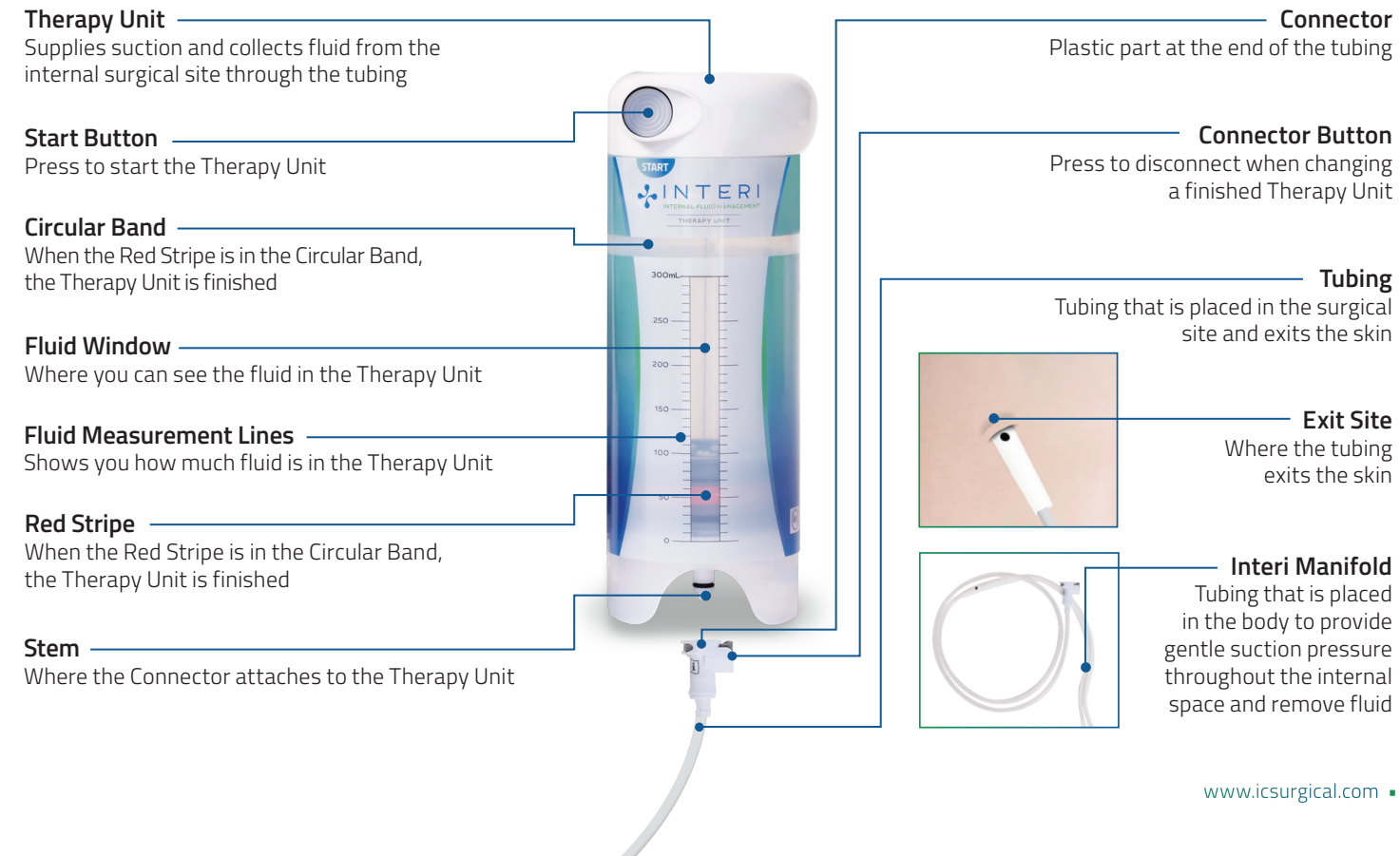
The Interi System Mechanism of Action



Interi is designed to:

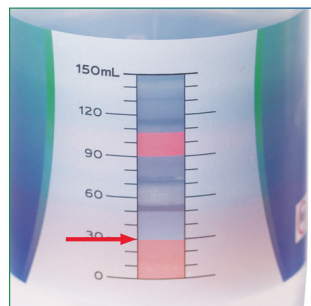
- Reduce dead space and potential for fluid accumulation
- Access broad internal spaces with a single exit site
- Reduce risk of post-surgical complications such as seroma
- Make post-surgical care as simple and hassle-free as possible for patients

INTERI SYSTEM OVERVIEW

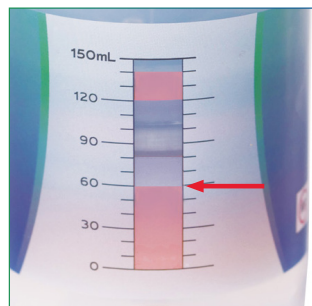


Monitor the System Every 4 Hours While Awake

1. CHECK for fluid flow: READ and RECORD the fluid level. COMPARE it to the last number recorded. If the fluid level is not higher, troubleshoot for a potential problem, see page 11 for instructions.



Fluid level is 30 mL.



Fluid level is 60 mL which is higher than the last number recorded. Fluid is flowing.

2. DETERMINE if the Therapy Unit is finished. If the Red Stripe is in the Circular Band, it is finished and must be changed.



NOT Finished



Finished

Monitor the System Every 4 Hours While Awake (continued)

3. CHANGE the Therapy Unit when it is finished.



Wash your hands thoroughly. Remove the used Therapy Unit by pressing the gray Connector Button. Hold the Connector upright as shown.



Attach a new Therapy Unit by pressing the Connector onto the Stem until you hear a click.



Gently tug on the tubing to make certain the connection is secure.



Press the Start Button to activate. You should hear a click.

Upon Arrival

1. CONFIRM the Start Button on the Therapy Unit is pressed.
2. CHECK that there is a secure dressing on the exit site.
3. CHECK the Therapy Unit is secured in the Carrying Case.
4. MAKE SURE there are no pinches, kinks, or clots in the tubing.
5. MONITOR the System routinely while the patient is in the PACU.
See page 4 for instructions.
6. If you are concerned that fluid is not flowing, see page 11 for instructions.



Interi Carrying Case

When Transferring the Patient to the Floor



Interi Therapy Units –
individually packaged

Prior to transfer:

- Do a final check of the Interi System
- If the Therapy Unit is finished, change to a new one

Be sure that supplies travel with the patient to the floor:

- a. Extra Therapy Units
- b. Patient Guide
- c. Healthcare Professional IFU
- d. Carrying Case

Things to Do

1. Train the patient or family member on all aspects of the Interi System using the Patient Guide and Interi System videos.
2. Check the fluid level in the Therapy Unit and change to a new one if the Therapy Unit is close to finished with the Red Stripe near the top of the fluid window.
3. Make sure the patient has all of their supplies:
 - a. Two or more new Therapy Units
 - b. Patient Guide
 - c. Carrying Case in place with Therapy Unit secured
 - d. Link to the training video on YouTube



Interi System
User Video



Carrying Case

Reminders for Patients



Therapy Unit is FINISHED

Using Interi at home:

1. MONITOR Interi every 4 hours while awake.
2. CHECK for fluid flow. Read and record the fluid levels and COMPARE it to the last number recorded.
3. DETERMINE if the Therapy Unit is finished.
4. CHANGE the Therapy Unit when the Red Stripe is in the Circular Band at the top.
5. Press the Start Button after connecting a new Therapy Unit.

Other Things to Remind Patients Before Discharge



You may not get a rush of blood or fluid when you start the Therapy Unit and the flow may vary.



Never pull on the tubing or the exit site.



Check your exit site and notify your doctor if the exit site appears inflamed/red or is leaking fluid.



Always keep your Therapy Unit in the Carrying Case. This will reduce pulling at your exit site.



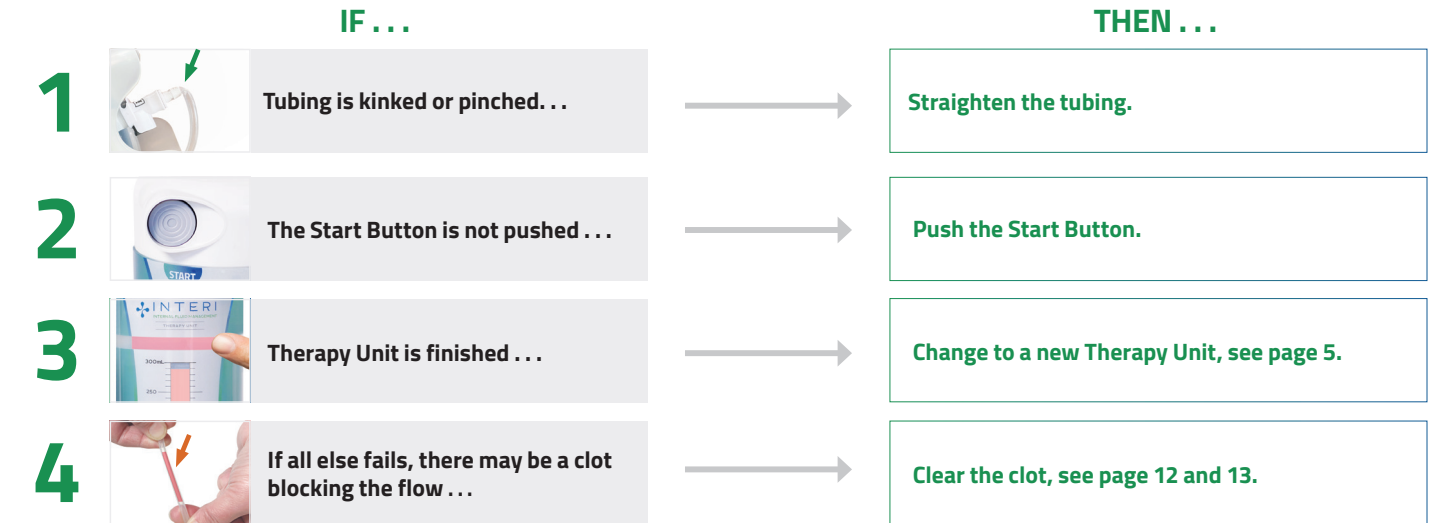
Never push the Stem at the bottom of the Therapy Unit.



If Connector does not click into place, apply your thumbnail to gray horizontal line to pop the gray button back into position.

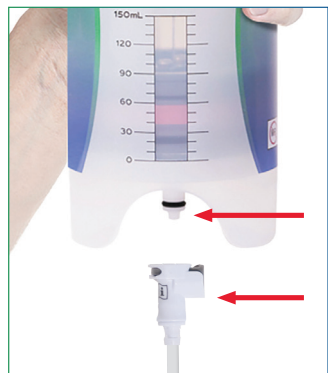
No Fluid Flow

If you are concerned the fluid is not flowing, verify **4** things:



Wait 1 hour and recheck to verify fluid flow. Fluid may flow slowly but you should see an increase in the amount of fluid in the Therapy Unit.

Check the Connector and Stem for a Clot



The arrows identify the Stem on Therapy Unit and the Connector

1. Wash your hands thoroughly.
2. Disconnect Therapy Unit from the Connector. Do not push on the Stem.
3. Hold the Connector upright as shown.
4. Carefully wipe away any clots from both the Stem on the Therapy Unit and the Connector on the tubing.
5. Re-connect the Therapy Unit.
6. Wait one hour and check if the fluid level is higher to confirm fluid flow.



Interi System
Managing Clots Video

If there is a Visible Clot in the Tubing, Strip the Tubing

1. Before stripping, be sure the Therapy Unit is attached and is not finished. If it is finished, change it.
2. Use one hand to firmly pinch the tubing at its exit site near the skin.
3. The other hand is used to strip away from the first hand in an even sliding motion. An alcohol wipe may be used to assist with sliding motion.
4. The first hand then comes and pinches at the advanced location away from the body, then the second hand continues to strip away.
5. Progress is made down the tubing to “milk” a column of fluid and any clot or obstruction down to Therapy Unit.
6. This process can be repeated in order to clear the System of any clots.
7. Wait one hour and check if the fluid level is higher to confirm fluid flow.



Pinching with one hand while other hand strips the tubing

If all steps above fail, it is possible a clot remains in the Therapy Unit Stem. Replace the Therapy Unit with a new one.

Topic	Considerations
Fluid does not appear to be flowing through the tubing	<ul style="list-style-type: none"> Check for pinches or kinks. Ensure Start Button is pushed. Ensure Therapy Unit is not finished. There may be a clot blocking flow.
There may be a clot in the Connector or Stem	<ul style="list-style-type: none"> Disconnect Therapy Unit. Carefully wipe away or gently remove any clots from both the Connector and the Stem. Reconnect Therapy Unit. Wait 1 hour and check Therapy Unit fluid level. If fluid level is not increasing, replace the Therapy Unit.
There is a clot visible in the tubing	<p>Strip the tubing to clear the clot:</p> <ul style="list-style-type: none"> Before stripping, be sure the Therapy Unit is attached and is not finished. Follow instructions on Page 13.
Therapy Unit has some air in the Fluid Window	It is not unusual for some air to be present in the Therapy Unit.
Therapy Unit is partially or completely filled with air	<p>This indicates a lack of air-tight System.</p> <ul style="list-style-type: none"> Check that Connector is secure to the tubing. Check that exit site and incision site are tightly closed and the dressings are sealed. Remind the patient not to push on the Stem. <p>If Therapy Unit is finished, replace it with a new one.</p>

Topic	Considerations
Therapy Unit needs to be temporarily disconnected	<p>Therapy Unit and Connector have one-way valves and can be safely disconnected. If patient disconnects from the Therapy Unit:</p> <ul style="list-style-type: none"> Do not let the Connector dangle, and cover it in the shower. Carefully reconnect ensuring that the Stem is not accidentally pushed.
Connector is accidentally pulled off the tubing	<p>Clinicians should clean the Connector with Isopropyl Alcohol 70%, cut off a few centimeters of tubing, and reattach the Connector.</p> <p>Patient should be instructed to contact their doctor's office for instructions if this happens at home.</p>
The Therapy Unit drops while connected and pulls the exit site	<p>Check dressings at the exit site for signs of bleeding. If there is any pain or bleeding, patient should contact their surgeon's office for instructions.</p> <p>It is important to keep the Therapy Unit in the Carrying Case to prevent accidental drops or kinking of the tubing.</p>
Some fluid dripped during Therapy Unit change	To prevent dripping in the future, always hold the Connector upright when disconnecting from the Therapy Unit.
How to clean the Therapy Unit and external Manifold Tubing	<p>Use a solution of either:</p> <ul style="list-style-type: none"> Isopropyl Alcohol, 70% 1.5 tsp dishwashing liquid in 2 cups of water

WARNING, CAUTIONS, AND IMPORTANT INFORMATION


- Do not use Therapy Unit if the tamper resistant seal has been broken or there is any suspected damage.
- Do not connect any other negative pressure or suction device to the tubing other than the Therapy Unit.
- System tubing is a strangulation hazard. Keep out of reach of small children.
- Keep the exit site protected from contamination or injury. Follow instruction provided by the surgeon for cleaning the exit site. Notify the surgeon if the exit site appears inflamed/red or is leaking fluid.
- Do not expose the tubing and Therapy Unit to temperatures below 68°F/20°C or above 86°F/30°C.



The Manifold and Manifold Connector are MR Safe and are safe for MRI Scanner room.



The Therapy Unit is MR Unsafe. Disconnect the Therapy Unit and leave it outside of MRI Scanner room as it could present a projectile hazard.

- The Therapy Unit is for single use only. 
- Once activated the Therapy Unit cannot be emptied or reset.
- Therapy Unit must be changed after 7 days of continuous use, even if it is not finished.
- If the Manifold Connector is temporarily disconnected from the Therapy Unit, it will hold suction until the Manifold Connector is re-connected.
- The System components are supplied ready to be used. Do not attempt to sterilize any of the components.
- To clean any part of the System:
 - Wash your hands with soap and water.
 - Clean the Therapy Unit and Manifold tubing with one of the following solutions: Isopropyl Alcohol, 70% OR 1-½ tsp of dishwashing liquid in 16 ounces (2 cups) of water
 - Do not use other chemicals, solutions, or methods as this could cause damage or contamination of the system.
- Dispose of used Therapy Unit per your facility protocol.
- If body fluid drips from the system, clean it up as directed by your health care provider.

Questions: 1-833-615-1143



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