

EntabiTM

PD Pack

for the ideal insertion of peritoneal dialysis catheter
(patent pending)

CAUTION: U.S. federal law restricts this device to sale by or on the order of a properly licensed practitioner.

DEVICE DESCRIPTION

The ENTABI PACK is an assembly of instruments that includes all components needed to place a peritoneal catheter at the bedside.



CAUTION

Read all instructions prior to use. It is strongly recommend that you watch the instructional video on our website before using the pack at www.entabiinnovation.com

While this pack allows for peritoneal dialysis catheter insertion at the bedside, bedside insertion requires high levels of experience and the availability of hospital backup in case of injury. It is recommend that the practitioner use it at an appropriate facility for the first few times before attempting it at the bedside.

The medical techniques, procedures and potential complications stated herein are mere suggestions. They are not a substitute for adequate training and sound medical judgment by a physician. This product is intended for use by physicians trained and experienced in diagnostic, interventional, and surgical techniques. Standard techniques and clinical considerations for placement of percutaneous catheters should be employed.

Catheter tubing can tear when subjected to serrated-jaw forceps, excessive force, repeated clamping, or rough tools. Forceps are typically unnecessary with this kit. However, if necessary, use ONLY smooth-jawed forceps or equivalent.

Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

- For single patient use only. Do not resterilize, reuse, or reprocess as that may compromise the structural integrity of the device and/or lead to device failure and infection. Do not use if packaging is opened, damaged or broken.
- Do not use after expiration date.
- Follow aseptic procedure standards when handling.
- Dispose of the sharp components (needles, scalpel, vial) in the appropriate sharps container. Follow your institutions recommendations on how to dispose other components that are contaminated by patient's bodily fluids and pose a hazard for infection. Especially, blood-borne viruses such as Hep C and HIV.
- Do no twist or rotate catheter during the implantation procedure, as that may lead to catheter damage and/or obstruction.

Common Q&A's

Why is the ENTABI PACK the best available kit for PD catheter placement?

- It is the most versatile and complete kit. It can be used in laparoscopic, image guided technique
- It allows the possibility of PD catheter insertion at the bedside under local anesthesia: the least invasive method of inserting PD catheter for the patient.
- Adds an additional layer of safety to any method of inserting PD catheter
- Avoids anesthesia and its accompanying risks
- Minimal post-procedure pain (most patients require no pain meds postop)
- Quickest method to insert a PD Catheter (10 minutes average)
- Dialysis can start immediately after insertion: The tunnel is dilated to snugly fit the catheter, thus it prevents leaks from around the catheter.
- The only kit that has everything you need to place a catheter at the bedside.
- Catheter may be removed at the bedside in case of infection/problems: It is very easy to remove the catheter and insert a new one. The ENTABI PACK catheter has one subcutaneous cuff. That makes removing it very easy and minimally invasive similar to removing a tunneled hemodialysis catheter.

In contrast, other single cuff catheters are designed to have the cuff placed in the muscle.

Thus, using other methods of inserting the catheter necessitates a trip to the operating room in a patient that is ill in order to remove the deep cuff within the muscle. When using the ENTABI PACK, there is no need for the deep cuff as the tunnel is tight enough around the catheter from the beginning. All that is needed is a simple skin incision to reach the cuff and remove the catheter when needed.

How does the practitioner know the location of the catheter tip in the abdomen?

In all methods of insertion, the practitioner can only control the trajectory of the catheter within the abdominal wall. The catheter tip is always free to move in the peritoneum.

In a traditional laparoscopic technique, the patient's abdomen is insufflated to create the working space. This distorts the abdominal wall curvature and can lead to an unnatural curvature of the catheter within the abdominal wall. This can create a torque force when the abdomen goes back to its natural state at the end of the procedure and may lead to catheter migration. On the other hand, the ENTABI PACK allows the physician to set the trajectory of the catheter within the patient's natural abdominal curvature. It does not involve insufflation or any alterations to the natural curvature of the abdominal wall. This allows a high rate of success in positioning the catheter where intended. It is also associated with least chance of catheter migration.

INTENDED USE

The ENTABI PACK is designed to enable the practitioner to place a peritoneal dialysis catheter at the bedside under local anesthesia. It includes all components needed. It may also be used in the operating room or at the interventional radiology suite or cath lab. NOTE: While this pack allows for peritoneal dialysis catheter

insertion at the bedside, bedside insertion requires high levels of experience and the availability of hospital backup in case of injury. It is recommended that the practitioner use it at an appropriate facility for the first few times before attempting it at the bedside.

CONTRAINDICATIONS

Do NOT use if the patient is not a suitable candidate for peritoneal dialysis therapy.

WARNINGS

All the parts are Latex free. However, possible allergic reactions should be considered.

PRECAUTIONS

According to Saber et al. 2004 For an average adult: The epigastric vessels are located around 4.5cm from the midline at the level of the xiphoid process. They deviate away from the midline as they go towards the patient feet.

At the symphysis pubis, the Inferior epigastric arteries were 7.5 cm lateral to the midline. Thus we recommend placing the catheter around 2-3 cm from the midline to avoid epigastric vessel injury.

POTENTIAL COMPLICATIONS:

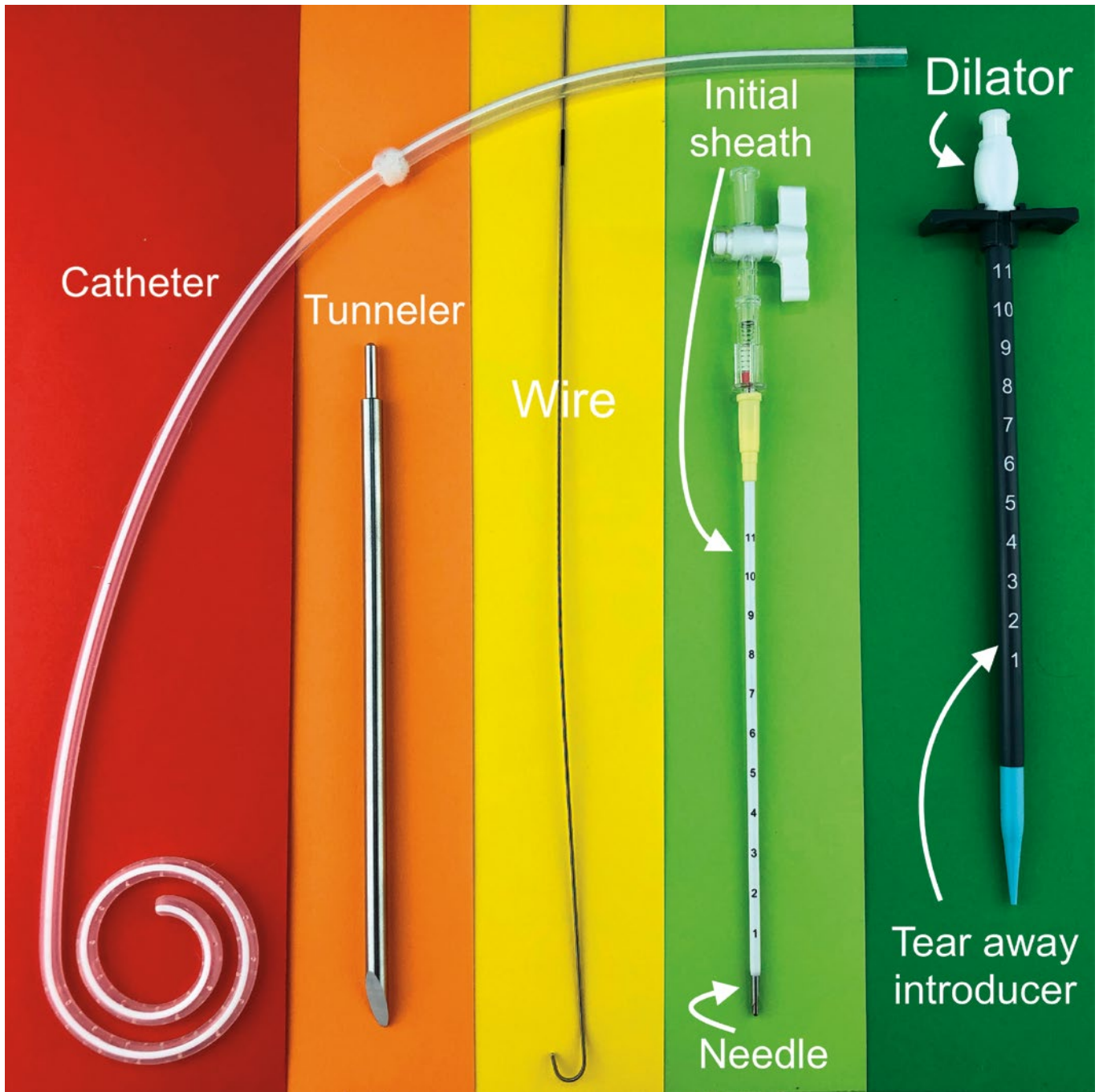
- Catheter obstruction (infow or outflow)
- Bleeding (subcutaneous or intraperitoneal)
- Cuff erosion
- Infections (exit-site or tunnel)
- Peritonitis
- Sepsis
- Bowel Perforation
- Leakage (initial or latent)
- Ileus

- Other risks normally associated with the insertion technique (laparoscopy or interventional radiology)

The ENTABI PACK may be used as intended (under local anesthesia only, at the bedside). However, it may be used in other settings, including:

- Laparoscopy
- Surgery (Open; Blind; Cut-down)
- Percutaneous (with or without ultrasound or fluoroscopy)

INSTRUCTIONS FOR USE CATHETER IMPLANTATION

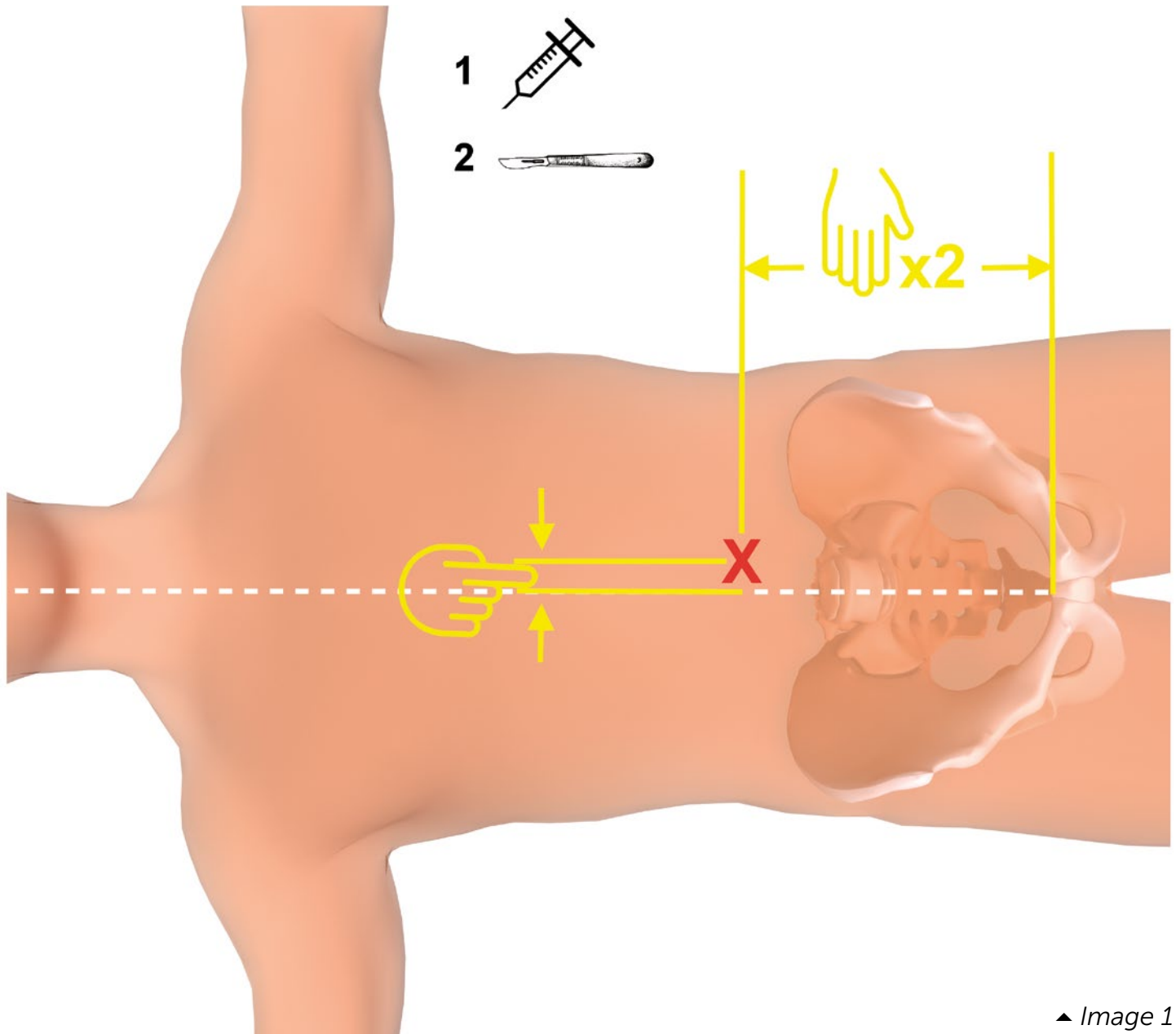


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SUGGESTED INSTRUCTIONS:

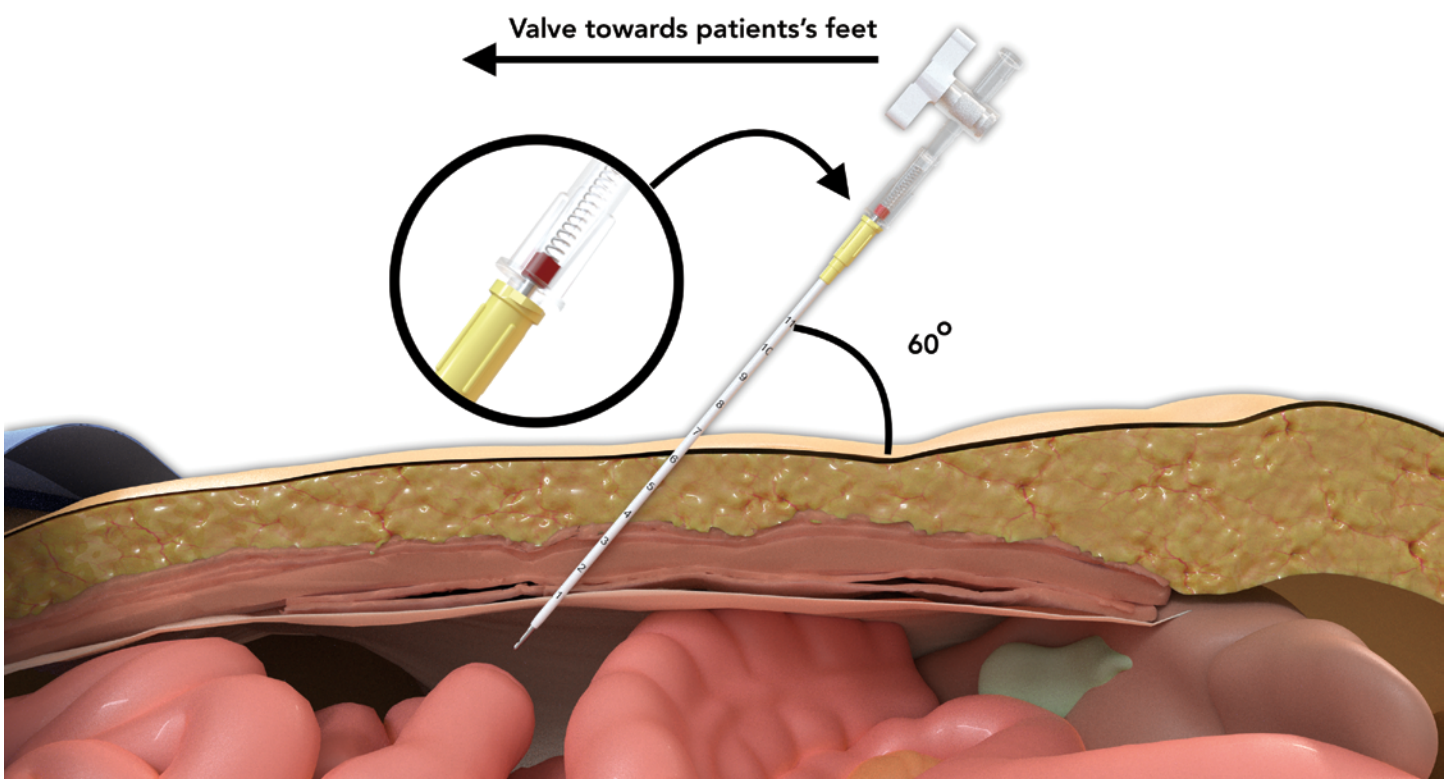
Gaining access to the peritoneum:



▲ Image 1

1 (Image 1) Patient should be lying supine for the entire procedure. Locate the area of the initial incision: Measure 15-20 cm (two hand widths) from the superior aspect of the pubic symphysis and 2-3cm (one to two finger width) off the midline. Don't rely on the position of the umbilicus as it changes with obesity and aging.

- Perform an antiseptic scrub of the skin over insertion and exit site areas and drape in a routine sterile fashion.
- Infiltrate sufficient local anesthesia at the intended puncture site and then make a 4-5 mm linear horizontal skin incision with a #11 blade.



▲ Image 2

2 (Image 2) This is the most critical part of the procedure:

Before beginning, make certain the needle BEVEL is in the correct direction (THE VALVE SHOULD BE TOWARD PATIENT'S FEET) and angle the insertion device at a 60° degree angle aiming at the pelvis.

During insertion, the practitioner should pay close attention to the red marker in the insertion device. The practitioner should be able to feel the resistance against their hand as they are pressing down. Between 2 to 4 clicks can be felt or seen before a complete loss of resistance is met. This indicates that the tip of the needle is in the peritoneal cavity (the resistance vary widely based on age, sex, and level of obesity). Ideally, the practitioner should feel complete loss of resistance before proceeding to the next step. NOTE: In very small patients, it is possible to puncture the retroperitoneum if the practitioner persists beyond the loss of resistance.

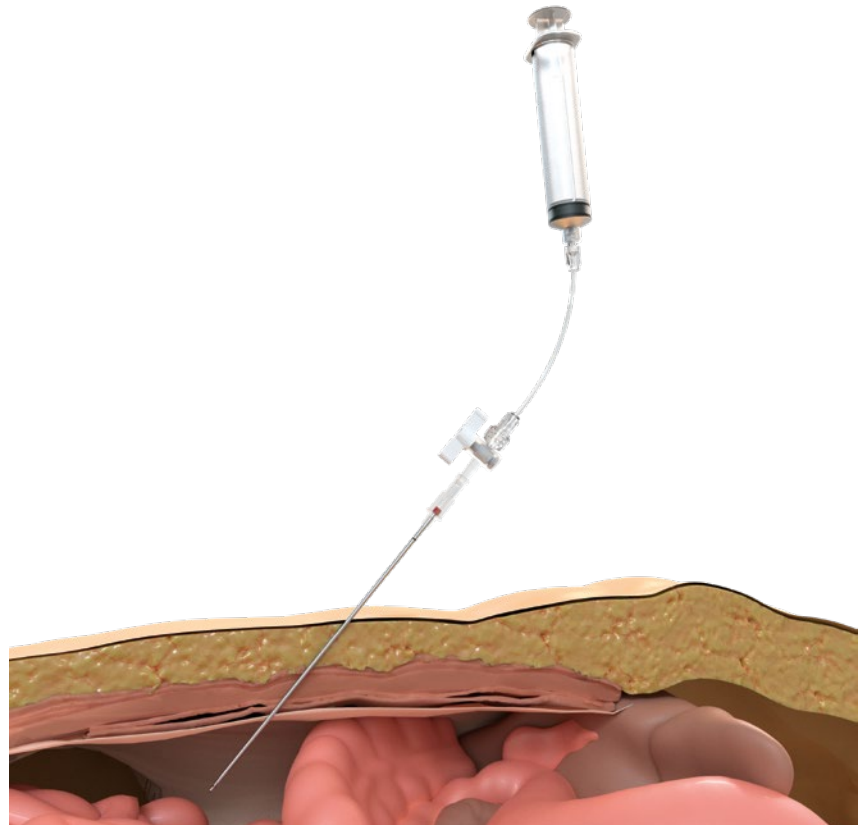
3 (Image 3) Once you feel the loss of resistance; you should run a position confirmation test.

Position confirmation test :

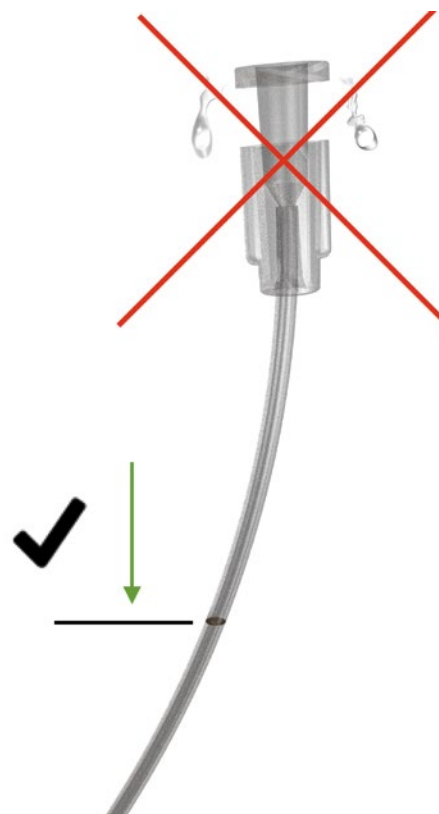
- Connect the provided tubing to the Insertion device
- Inject 10cc of saline.
- Straighten the tubing so that it is vertical to the patient's body
- Disconnect the syringe

(Image 3b) Watch the saline. Saline level in the tubing should drop. It should never spill from the top when you hold the tube vertically. This process may be repeated anytime there is doubt about the position of the catheter as the IV tubing connects to the initial sheath.

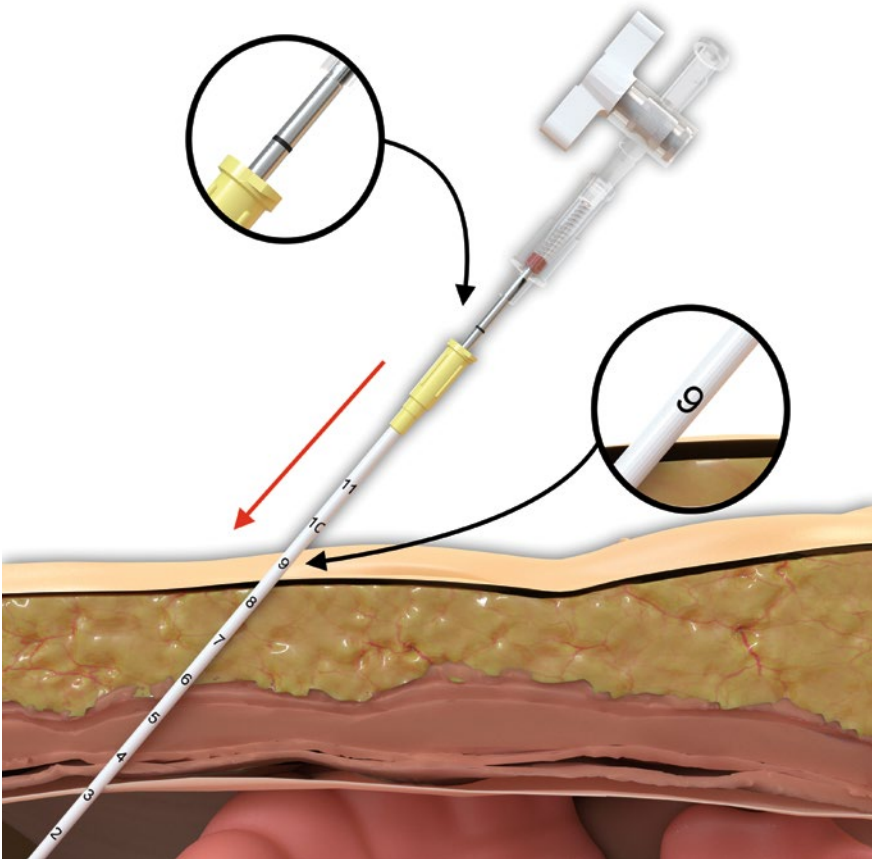
NOTE: if saline spills from the IV tubing or doesn't go down significantly after removing syringe, that means that the tip of the needle is not in the peritoneal cavity. Most of the time, it has traveled within the abdominal wall or in the Omentum. In that case, pull the insertion device out and start over again.



▲ Image 3



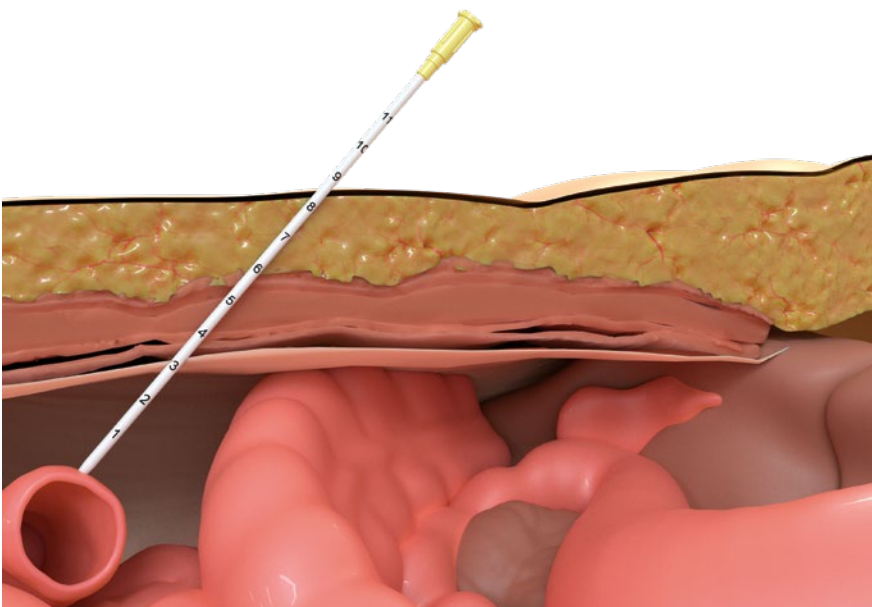
▲ Image 3b



▲ Image 4

4 (Image 4) After performing a successful position confirmation test using saline, the practitioner is confident that the tip is in the peritoneal cavity.

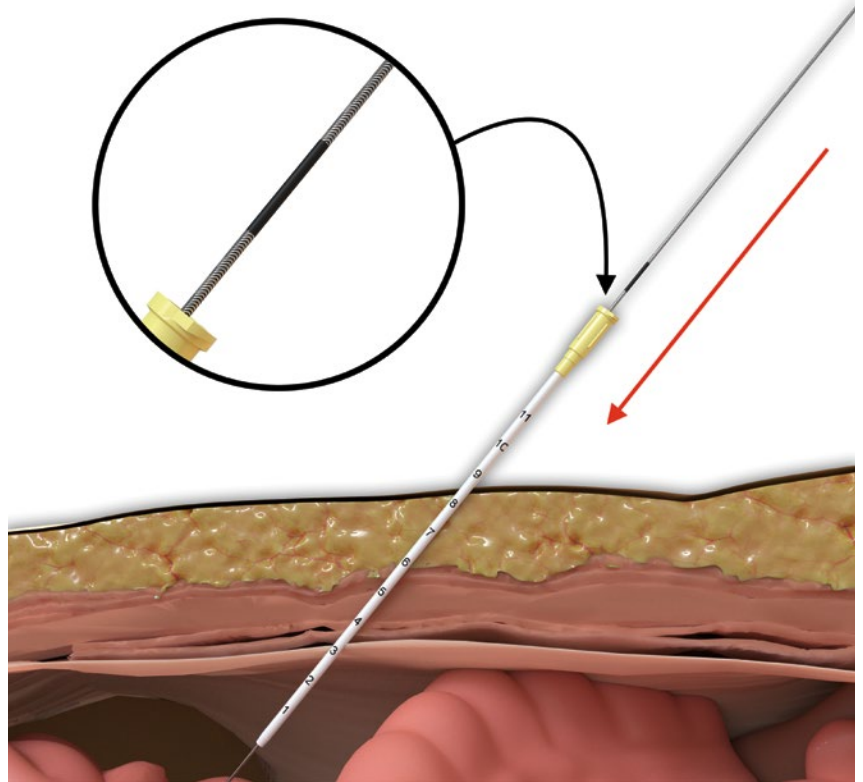
- Notice the number on the sheath that appears at the skin level and record it.
- While holding the needle in its position, slide the outer sheath down on the needle for a few millimeters until you see the black line on the needle.
- At this time, you may repeat the position confirmation test.



▲ Image 5

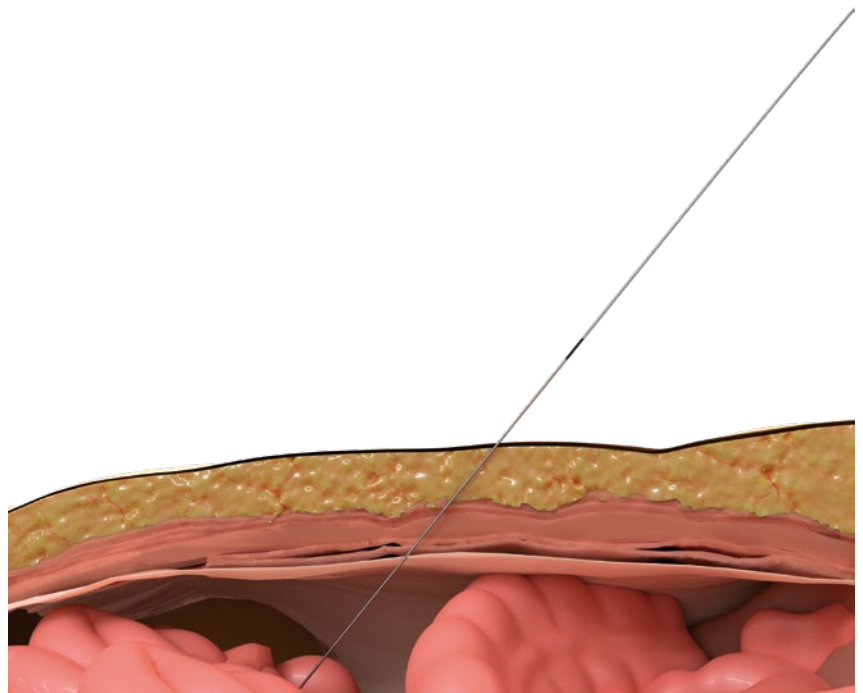
5 (Image 5) Now that you see the black line, hold the outer sheath in place and pull the needle out while holding the sheath in place.

6 (Image 6) Insert the wire through the sheath; advance it to a point where the black ring on the wire disappears in the sheath.



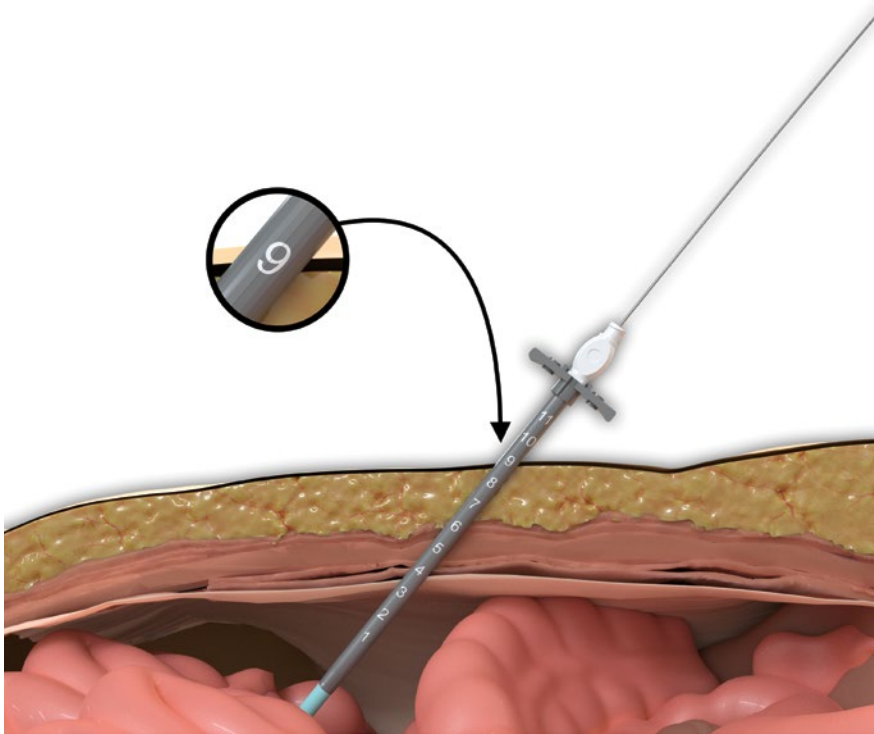
▲ Image 6

7 (Image 7) Hold the wire with one hand while you remove the sheath, leaving the wire in place.



▲ Image 7

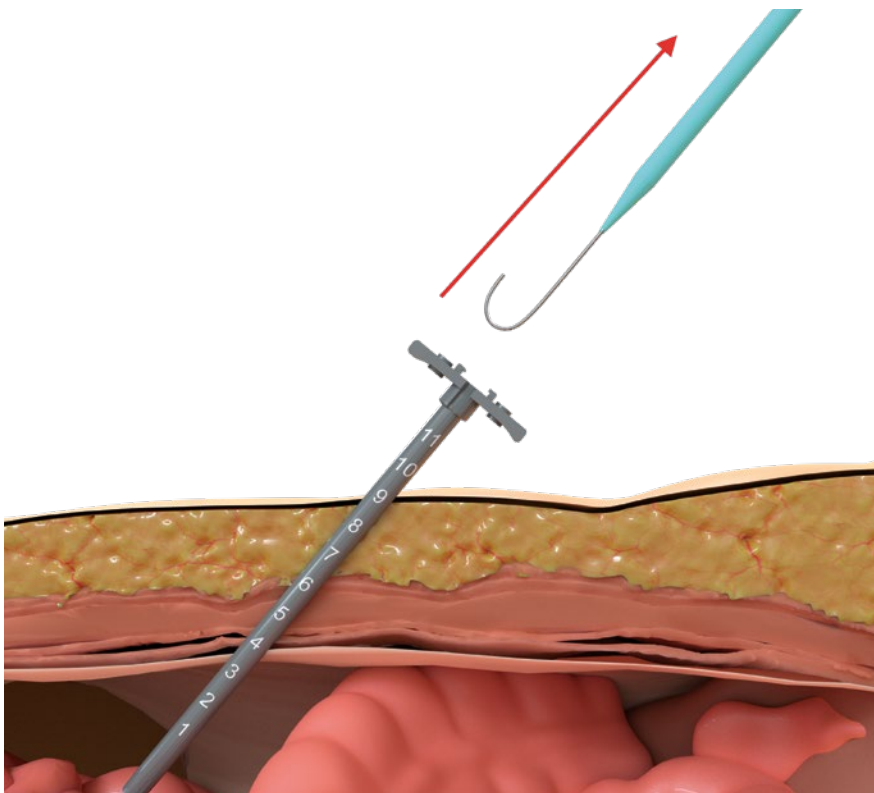
Catheter tip insertion:



▲ Image 8

8 (Image 8) Insert the tear away introducer/dilator assembly over the wire: Hold the tear away introducer/dilator assembly near its tip, and with a firm twisting motion, advance it into the peritoneal cavity. While advancing the assembly, move the wire back and forth slightly. That would insure that the introducer is advancing correctly. Advance beyond the same number you noticed on the initial sheath.

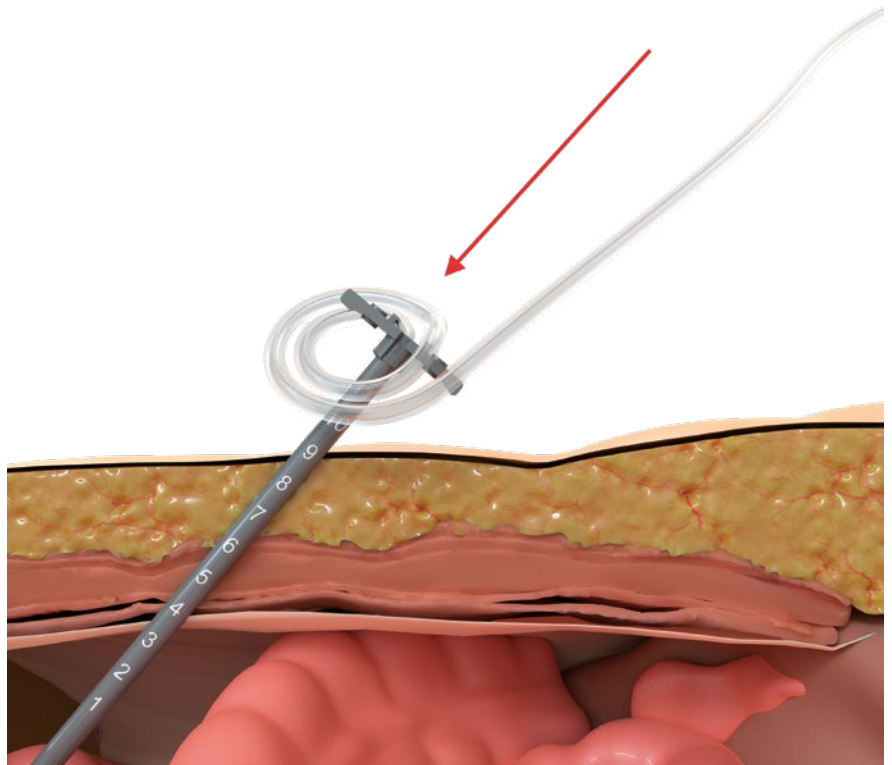
NOTE: the introducer can always insert deeper if there is no resistance or patient discomfort.



▲ Image 9

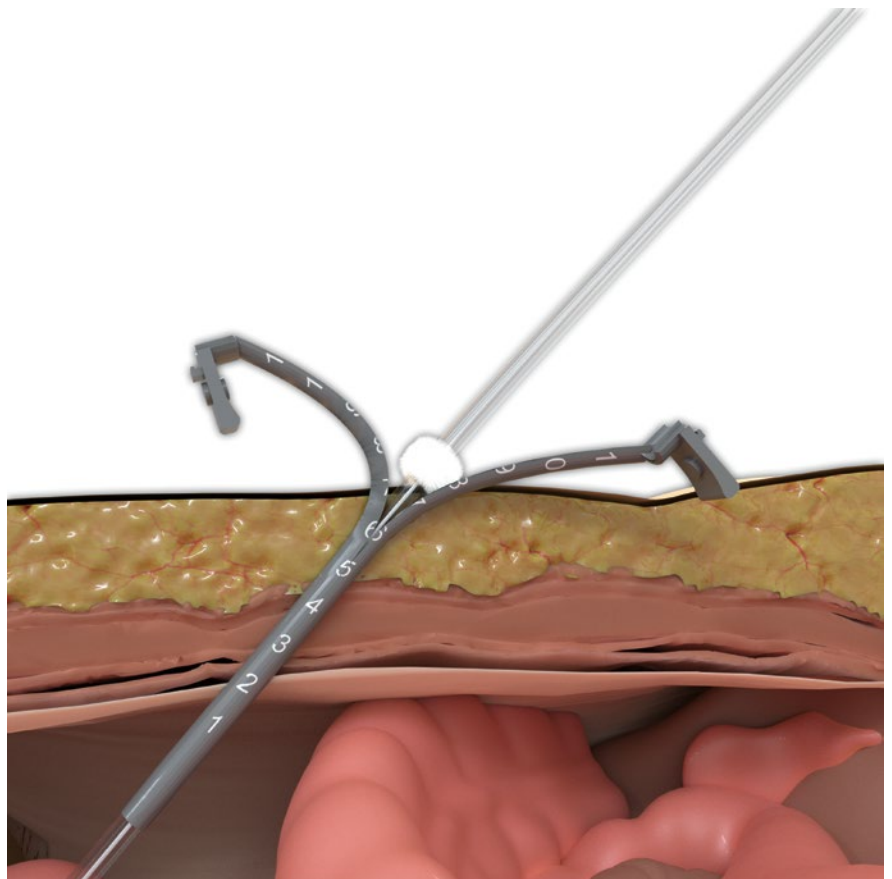
9 (Image 9) Turn and remove the dilator along with the wire while holding the tear away introducer in place.

10 (Image 10) Rinse the catheter and the tear away introducer with saline to help reduce friction and then insert the curved tip of the catheter through the tear away introducer. NOTE: Due to the tight fit, some resistance is normal. However, the resistance will decrease when the coiled portion of the catheter has advanced through the introducer. Advance until the cuff hits the introducer.

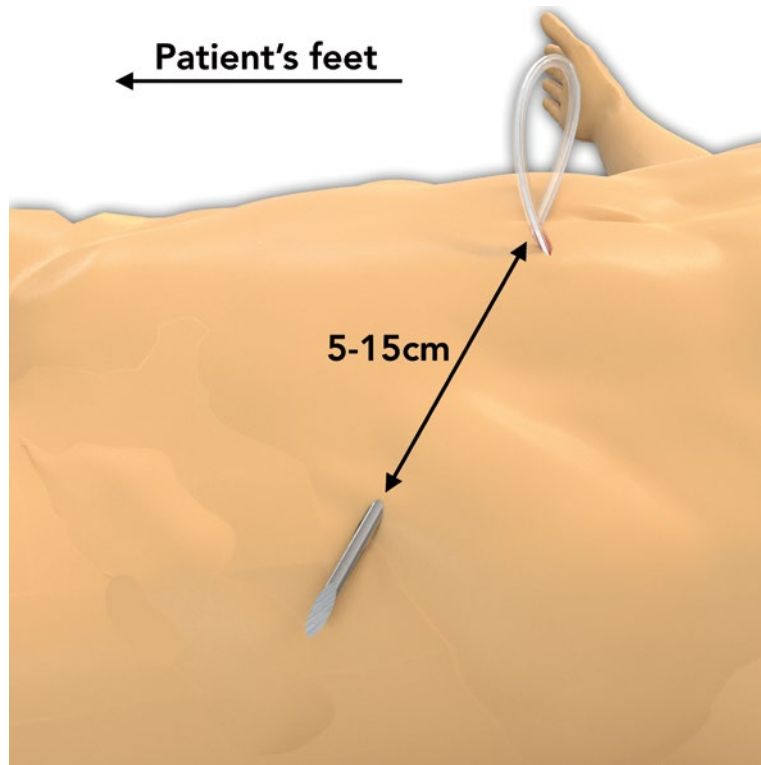


▲ Image 10

11 (Image 11) Now, separate the tear away introducer into 2 pieces by twisting the two handles away from each other. Place one finger on the catheter to push it down while removing the tear away introducer completely.



▲ Image 11



Tunneling:

Once the catheter tip has been properly placed in the peritoneum, the next step is to create the tunnel:

12. (Image 12) Plan the exit site: Typically 5-15cm lateral and towards the patient feet to the original insertion. Try to avoid the belt line.

- Infiltrate sufficient local anesthesia at the intended exit site
- Connect the blunt end of the tunneler to the catheter, the tubing of the catheter should encase the tunneler blunt tip.
- Insert the sharp end of the tunneler through the incision, adjacent to the catheter.
- Advance the tunneler in the subcutaneous tissue toward the intended exit site. Be careful to not go too deep and aim to stay within the subcutaneous tissue.
- At intended exit site, push the tunneler to puncture the skin with the sharp tip of the tunneler.

- Grasp the tunneler at the exit site and pull on the rest of the tunneler and catheter. Make sure the tension is enough to remove any possible redundancy or kinks. Pay attention to leave the cuff in the subcutaneous tissue around 2-5 cm from the exit site.

The cuff should now be well buried under the skin. There should now be at least 10cm of catheter outside of the abdomen at the exit site.

- Detach the tunneler from the catheter and discard.
- Place leur attachment and leur cap on the catheter tip
- Place the provided steri-strip to cover the initial incision: Place the steri-strip on one side of the incision, then pull it towards the other side and press it down to seal the incision.
- Place provided dressing to cover the catheter, insertion site, and exit sites.

The peritoneal catheter is now available for immediate use. Special attention should be paid to avoid applying undue tension during the first 2 months of use until the site is completely healed.

*Thank you for helping us improve
the health of our patients.*

Catheter Cleaning and Care

The ENTABI PACK catheter is made of silicone. Exit-site cleaning agents that are compatible with silicone are acceptable: Normal (sterile) saline; Antibacterial soap with triclosan, Hydrogen peroxide, Chlorhexidine or Sodium hypochlorite.

Do NOT use acetone or acetone-based products on any part of the catheter.

REFERENCES

***Ann Surg. 2004 Feb; 239(2): 182–185.**

WARRANTY

Entabi Innovation Inc. WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Entabi Innovation Inc. reserves the right to modify its products or contents in accordance with all relevant regulatory requirements.



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