



Morgan Stout:

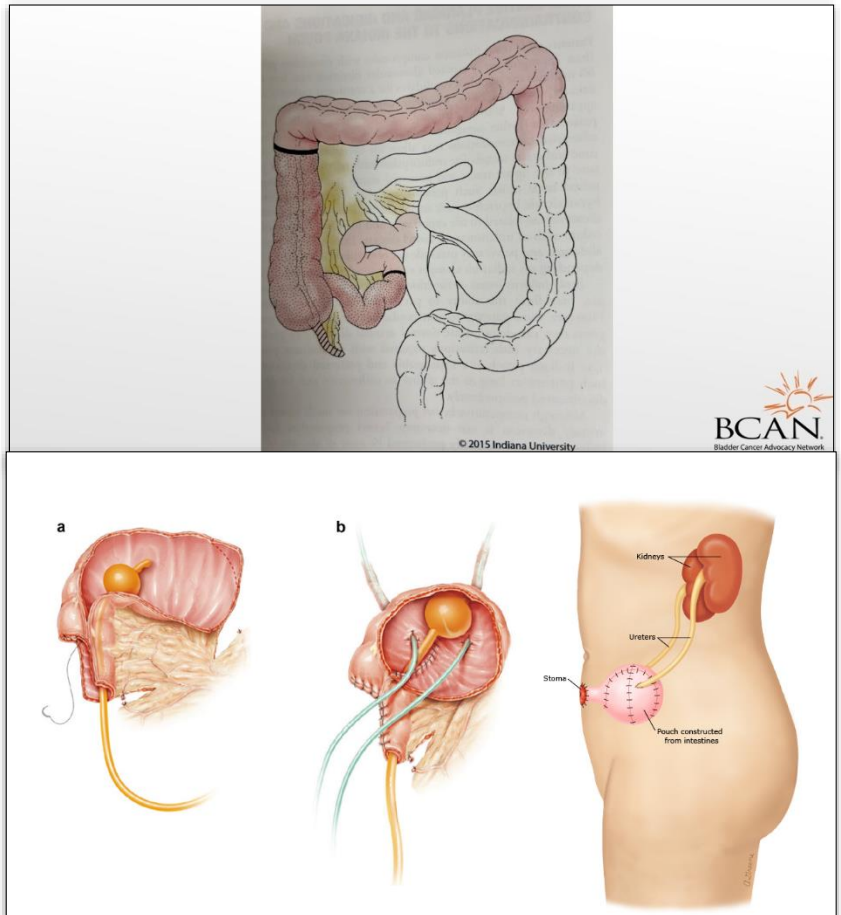
Bladder cancer will affect over 80,000 people every year of those 80,000 new diagnoses, about 25,000 people will be diagnosed with muscle invasive bladder cancer. Bladder removal is a common treatment for muscle invasive bladder cancer. And one of the diversion options after bladder removal is an Indiana Pouch sometimes called a continent cutaneous pouch. The Indiana Pouch was pioneered in 1985 at the Indiana University School of Medicine. My name is Morgan Stout and I'm the outreach and education manager at Beacon. I'm joined today by Dr. Aaron Laviana from Dell Medical School at UT Austin and our patient advocates, Scott and Cindy. Welcome. First, I will hand it over to Dr. Laviana to talk about the medical aspect of creating and caring for an Indiana Pouch. And then we'll hear from Scott and Cindy about the lived experience. With that, I will hand it over to you, Dr. Laviana.

Dr. Aaron Laviana:

Perfect. Thank you so much, Morgan. And it's really an honor to be here today and this evening, and thank you for taking the time to be a part of this. And so I'm just going to share my screen here with everybody. Hopefully you can see this. So we, this past weekend we had our annual American Urologic Association conference and one of the highlights of that always is what's called the Whitmore Lecture as part of the Society of Urologic Oncology and Dr. Eila Skinner is the chair at Stanford, and she gave the talk this year. And one of the things she focused on was just the differences between conduits, Indiana Pouches and neobladders. And one of the lines that really resonated with me was she said, you can talk any patient into getting an Ileal conduit if you want them to get an Ileal conduit. And it really strikes a cord there because Indiana Pouches in particular are very underutilized. And how much of that is just with people being uncomfortable with the operation or just not having exposure to them.

And so I definitely think this is a very underutilized operation here, and the more we can give exposure to it for the right patient, I think it can really go a long way. And a lot is not tonight too, is I want the patient experience to really be emphasized for both Cindy and Scott who have both undergone this operation and can share their experiences. Because at the end of the end of the day, I think that is what is most important. And so I would just like to thank our treatment talk sponsors here as listed above. And then I want to start by just giving an overview of what an Indiana Pouch actually is.

And so this is a picture here of both the small intestine and the colon. And so the Indiana Pouch is actually a combination of the two of them. As you transition from the small intestine over to the colon, there's something called an ileocecal valve. And that valve is what's used in this operation to actually provide the continents mechanism or that's what helps prevent the leakage of urine after this operation. So approximately 50 centimeters of small intestine are harvested or cut and then the rest of the bowel is sewed back together. And you can see this better in the next slide here. And so this picture on the left here, that's labeled A, on the right part of that screen, that is the actual pouch. And you can see the Foley catheter with the balloon going into the pouch. And then that area on the farther left there is where it narrows and comes out to the skin.



Dr. Aaron Laviana:

However, it's that's sort of that junction there of where that ileocecal valve is that provides the continents. If you move over to B here, you can see sort of how big this pouch is. Those blue tubes are the stents coming from the ureters into the pouch and the yellow thing is the catheter that comes out to the skin. Then finally, on the right side here, this is the last picture of the Indiana Pouch. You can see the pouch on the inside, and then you can see the "stoma" on the patient's outside that they then have to catheterize through. And so what actually is the Indiana Pouch here, is it's basically considered an artificial bladder that's inside of your body. That one empties with a detachable catheter, typically called also known as sometimes a Foley catheter or a red rubber, or a silicone catheter. There's many different names, or an in and out catheter, but it's something that does not stay inside. And it helps wearing it helps avoid wearing an external urine bag and results or hopefully results in normal urinary control.

What to expect during an Indiana Pouch

- The urologists build a "new" bladder, or pouch, from your colon and small intestine
- The pouch then connects to a piece of intestine instead of the urethra
- This intestine routes to the skin, where it ends at a dime-sized opening called a stoma
- Patients drain urine from the pouch by placing a catheter into a stoma every 4-6 hours. The stoma is usually located in the right lower abdomen
- Catheterizing is not painful

And so what to expect during an Indiana Pouch, and so the urologist or team urologists, which is often the case, builds a new bladder pouch from your colon and small intestine. That pouch then connects to a piece of intestine instead of your urethra. It comes through the skin, typically it's a dime size opening, many people do refer to it as a stoma, and then you drain, you drain urine from the pouch by catheterizing the stoma. This will change over time, but ultimately once you hit this sort of equilibrium, you catheterize every four to six hours. Most oftentimes it's located in the right lower abdomen. And typically catheterizing is not a painful experience.

Dr. Aaron Laviana:

So what are the benefits of an Indiana Pouch versus an Ileal conduit or neobladder compared to an Ileal conduit? It ideally avoids having a urostomy bag, you have normal urinary control during the day and night. You can also, depending on your preferences, place it below the belt line and so it's not visible such as when you're at the beach. And then it's also good option when the cancer has spread to the urethra and you can't do a neobladder. In females as well, it's sometimes a better option because anytime you get a neobladder, you have to be consulted on the need for self catheterization, which can be much more difficult with a neobladder as opposed to an Indiana Pouch. And last but not least, it does have the highest urinary control satisfaction. The ileal conduit obviously will leak continuously. Neobladders almost assuredly will leak at night, at least for the first year, and sometimes there's problems with daytime continence as well. So in Indiana Pouch, when it goes well, definitely has the highest urinary control satisfaction.

Now on the converse side, why don't we just give everyone an Indiana Pouch and some of the disadvantages here are, by having this pouch, you're never going to be able to urinate normally, the only way to evacuate your urine is to catheterize, and you're going to have to catheterize for the rest of your life. And typically it's every four to six hours, but that may vary. Also because of the large size of the intestines involved, in particular the colon as well, you need to rinse and irrigate

Benefits of an Indiana Pouch

- You avoid a urostomy bag
- You have normal urinary control during the day and night
- The stoma can be placed below your belt line and the stoma will not be visible when you're shirtless, such as when at the beach
- It's a good option when cancer has spread to the urethra, and a neobladder reconstruction cannot be performed
- Highest urine control satisfaction after surgery



Disadvantages of an Indiana Pouch

- You cannot urinate normally and need to empty your pouch using a catheter
- You need to rinse/irrigate out your stoma daily since it makes mucus
- It's a complex surgery

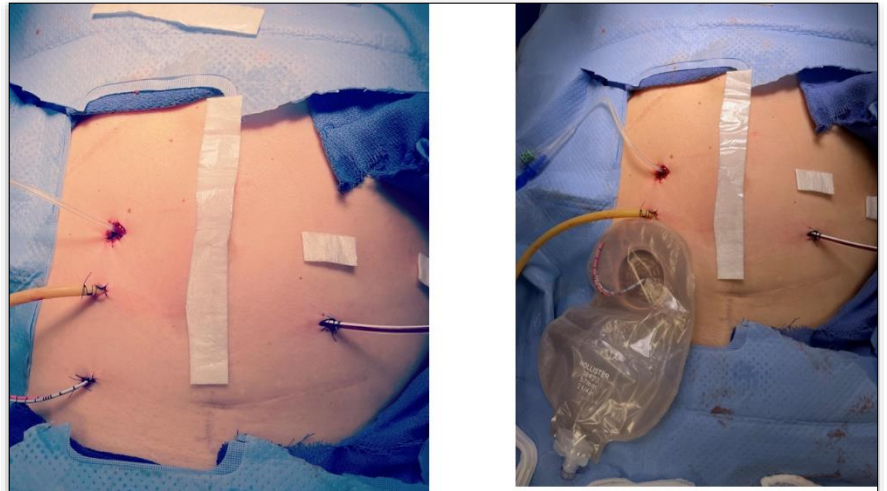


out your stomach day waste since it makes mucus. Now, some of this mucus production will go down over time, but for many people, they have to continuously irrigate this Indiana Pouch for their entire life. It's also a complex surgery as I'll show you a few pictures and diagrams here. When you wake up after surgery, you have many tubes and drains.

Some of these can get clogged, some of these can change angles. Sometimes the catheterization can get difficult and there's a potential for side effects. And the extra hours of doing this can take a toll on the body. So it's not for everybody.

Dr. Aaron Laviana:

So this picture here on the right and left is a picture of a patient I performed in Indiana Pouch on several months ago. And this was in the initial postop period here. So on the top left here, this is the stoma. This is where the patient ultimately catheterized through. However, to wake up and to make sure that the Indiana Pouch is adequately draining, also placed what's called a 24 French Malecot catheter. And that's basically a large port catheter that goes into the Indiana Pouch and that gets removed.



Below that and the lower left side are two urinary stents, and those are draining the kidneys in ureters to divert as much of that urine as possible in the initial period. I do this operation robotically for the most part here. So he has several tiny incisions from a robotic ports. And on the right side of the screen, that drain is just draining abdominal fluid. And then as you can see on the right side of this, on the right photo here, it's the same picture, but you can see the catheter draining where you're going to catheterize through the stoma. And then the bottom left piece is just a bag to collect the urine in the initial postoperative period.

So what to expect after going an Indiana Pouch. But so after going to Indiana Pouch, you're going to wake up with a lot of tubes and drains that can be confusing for yourself, but also for many of the nurses and other hospital staff, as if this operation's not done very often. People may not be used to seeing all these tubes and drains and so one of the things that's important is that they're all labeled appropriately and that everyone has a great understanding of what purpose each of them serve. The patients will typically recover in the hospital for about a week after surgery plus or minus based on how they're doing with

After undergoing an Indiana Pouch

- You have tubes connected to your body to various fluids, such as urine and mucus
- Patients typically recover in the hospital for a week with the bottleneck being having a bowel movement
- You return to the office for an X-ray to make sure the pouch is sealed. Once it is, the catheters begin to be removed
- Patients typically lose about 10-15 pounds during recovery as their bodies adjust -> weight stabilizes around 6-8 weeks after surgery

the, I always say the real bottleneck of this surgery is waiting for the patient to have a bowel movement, because you have to cut a segment of bowel, reconnected as goes with any cystectomy.

Dr. Aaron Laviana:

Sometimes you can get swelling at that staple site, and until the patients are able to pass a bowel movement, that's typically when they're able to go home. Now this can vary from practice to practice, but typically we keep the drains in for about three weeks and then get an x-ray something called a pouchogram to make sure the pouch is sealed and that there's no leaks. Once there's no leak then we can begin to take these catheters out one at a time here, sort of saving one as a safety or a pacifier. God forbid, there's any issues with catheterizing the stoma. And then it's also important to note that the surgery does take a toll on the patient, patients typically lose about 10 to 15 pounds during the recovery, but it takes a full almost two months for weight to stabilize, if not longer. And so it's always important to counsel for patients before going through this operation.

About one and a half to two months in, you should be able to go back to your normal activities. It typically takes though about eight weeks since you wake up and you feel like you've never had an operation, which can be a substantial amount of time. And then over the next year, you can slowly wait longer and longer to empty urine as your pouch stretches in the beginning. We want you emptying that pouch every two hours, just to

make sure it doesn't stretch out too quickly, both from a leak standpoint and then just from a retention of urine standpoint. Then eventually your pouch will be able to hold as much as a normal bladder. Sort of the sweet spot here is being able to catheterize every four to six hours for residuals of about five to 600cc or milliliters of urine. As you go over that you're at higher risk of getting bladder stones or pouch stones, which then may lead to further interventions and operations.

After undergoing an Indiana Pouch

- After about 1.5 months, you should be back to your normal activities
- Over the next year, you can wait longer and longer to empty urine as your pouch stretches. Eventually, your pouch will be able to hold as much as a normal bladder



Dr. Aaron Laviana:

So how does someone with this artificial bladder know if they need to urinate? And so most people will feel abdominal tightness or mild cramps that should not be particularly painful, but they typically feel uncomfortable sort of as having a full bladder. And then some patients will see their stomach sticking out on their right side, where their pouch is located when very full, but that's not everybody. What about needing to wear pads or an adult diaper? So if you're undergoing a neobladder, we always counsel patients on this that they're a high likelihood of leaking. And as I said earlier, you're definitely going to leak at night.

For an Indiana Pouch however, you should be able to wear regular underwear. And most

people wear a bandaid or a small pad to keep the amount of mucus that the stoma makes from getting on their underwear. Now, in the beginning phases of this though, it is common to leak urine, especially as that neobladder is expanding. And so in that case, you may wear pads, or you even may wear a conduit bag over it in the beginning until you sort of get in your routine and you're comfortable with how you're living your daily activities. For instance, if you know you're going to be out and about for several hours or even longer than that, you may want more wear a more protective barrier until you sort of get used to everything, but it's definitely person dependent there.

How do I know when I need to urinate?

- Most people feel abdominal tightness or mild cramps that should not be painful
 - Typically feels as uncomfortable as having a full bladder
 - Some patients will see their stomach sticking out on the right side, where the pouch is located, when full

Do I have to wear pads or an adult diaper?

- No – you should be able to wear regular underwear
 - Many people wear a Band-Aid or small pad to keep the small amount of mucous that the stoma can make from getting on their underwear

Dr. Aaron Laviana:

And what are a few other things to consider about an Indiana Pouch? Well, for starters, it's not uncommon to have urinary tract infections. You basically have an artificial bladder made out of intestine, which can have some bacteria in it, and you're also holding urine. And sometimes, especially the more urine you hold, the more prone you can become to infections. And when you

tie the... Or sew the ureters into this pouch, you can also have reflux of urine back the ureters and into the kidneys and that can also cause infections.

It's really important that you know how to irrigate with the Neobladder as the mucus can build up. It can not only clog the catheters, but can also lead to kidney stone formation. And you'll have to continuously irrigate that pouch to drain the mucus and help prevent these stones. Another thing is because of a large amount of intestine, you have to take to build this, that sometimes it leads to more acid reabsorption, and you have too much acid in your blood. And as a result, you have to take something called bicarbonate or bicarb to help counteract all the acid buildup in your blood. You can also have something called vitamin B12 deficiency and some other vitamin deficiencies, so it's important that you get your labs checked routinely as well.

Dr. Aaron Laviana:

A few other things is that leakage from the stomach may occur and the mucus may leak out. Not all these unfortunately are perfect and a lot of this comes down to the mechanism of how you sort of buttress the ileocecal valve I talked about, and that part's very important. Some do work better than others and so for some patients will leak more than other patients. But hopefully as it matures and gets to its steady state here, the leakage is not a huge problem. You can also get stoma narrowing, so on

What are a few things to consider about an Indiana Pouch

- You may have urine infections
- Mucus can build up and clog catheters/lead to stone formation
- You will have to irrigate your Indiana pouch to drain the mucus and prevent stones
- You may have too much acid deposited in your blood with an Indiana pouch and must take tablets
- Vitamin deficiencies may occur



What are a few things to consider about an Indiana Pouch

- Leakage from the stoma may occur and mucus may leak out
- If stomal narrowing occurs, it can make it difficult to catheterize and empty the pouch
- You will have to schedule emptying of your Indiana pouch during the night, especially in the beginning
- Consider getting a medical alert bracelet



the outside where you're catheterizing, that area can narrow and stricture down and that can make it difficult to catheterize and empty the pouch. Sometimes that needs to be revised. Also, you can get what's called a parastoma hernia, or it's sort of a muscle laxity or fascial defect around there where the intestines in the Indiana Pouch actually push out against your skin. And that can change the angle for catheterizing that can make it more and more difficult.

The other thing is you have to schedule emptying of your Indiana Pouch during the night, especially in the beginning, as it goes along, I do have some patients who absolutely refuse to get up to empty their Neobladder. But you have to understand that's putting you a little more at risk of having urinary tract infections and getting stones. Another important thing to consider is just getting a medical alert bracelet. God forbid, you ever run into trouble depending on what hospital or urgent care or freestanding emergency room you go to, many of the providers may not be familiar with Indiana Pouch. It's not uncommon that these providers have never even seen one. And so just making them aware, especially if you get any imaging studies done from the radiologist standpoint too, that they fully understand what you had done and what your anatomy is supposed to look like.

Now, what about these adjustment phases here? So with regard to leaking, especially in the beginning, as your pouch is learning how to hold urine as it's growing in size, it's normal that it's going to leak. This is normal and not something to necessarily panic over in the beginning. It should get better and oftentimes does. What about irritability? So there's times, especially when

you're learning to catheterize here, that you've been on a very regular schedule, let's say catheterizing every four hours, days, even weeks, maybe a month, and then all of a sudden, out of nowhere, you have to increase the frequency of catheterizing. Sometimes there's more swelling around the pouch that can cause this and this is not unusual, as the pouch is learning its new function, but you also may have a mild urinary tract infection that doesn't present with fevers and chills, but with just frequency or maybe change of odor. And in that case, antibiotics will help fix that.

Adjustment phases

- Leaking – It is not unusual while the pouch is learning to hold urine, it may leak. **This is normal**
- Irritability – There may be times when you have been on a somewhat regular schedule for days/weeks and then must increase the frequency of catheterizing
 - Not unusual
 - A) Pouch is learning its new function
 - B) Mild infection

Dr. Aaron Laviana:

What about difficulty passing the catheter? And so one of these things is from "trauma" of the catheterization this can actually cause swelling there, and that can be normal, it just may take more time to catheterize yourself, but it eventually will resolve. You also may feel the contours of the limb. So the limb is the piece that connects the pouch to the skin and they're all different shapes and sizes, especially as it sort of scars in. And so you may feel that as it passes around corners. And then oftentimes when you enter the pouch, you do feel a pop and that's the pop going through that valve, that ileocecal valve, that is the continent mechanism, but that can be alarming to patients, especially in the beginning. One of the tricks here to help facilitate or to help ease with inserting the catheter is to roll the catheter between your fingers, which may help.

Then also another thing is straining or bearing down can make it more difficult as that pressure of the intraabdominal pressure from straining can compress that limb, make it difficult to pass the catheter. So in that case, it's always a good idea to try to relax your abdomen and your core as much as possible to place that catheter. And then also in the beginning, waters soluble lubricants, such as KY jelly, Surgilube can help pass the catheter. Your limb and the pouch are natural lubricants, so often with time, you don't even need a lubrication, but the key here don't use Vaseline as that can plug that can plug the catheter.

And what about for other troubleshooting? So it's not unusual to see flecks of blood in the urine, and this is normal. You also may see it on any pads you're using to cover your stoma. It can sometimes get irritated and scraped from the catheter. And then what about failure to adequately empty the pouch? This can lead to some frustration and unfortunately it can be normal. You may... Not every pouch is a perfect sphere, and you may have little segments of small pouch components that you have to maneuver the catheter around to different areas, to fully drain that Indiana Pouch. And some of that improves with different positions, some do better with standing, some sitting, some hunched over, but

Adjustment Phases continued

- Difficulty passing the catheter
 - With frequent catheterizations, the stoma and channel leading to the pouch may have some swelling which is normal
 - It may take more time to catharize yourself but will eventually resolve
 - One may feel the contours of the "limb" as it passes around corners
 - Once it enters the pouch, you may feel a "pop"
- Rolling the catheter between your fingers as you push may help facilitate insertion
- Straining or bearing down can make passing the catheter more difficult as the pressure compresses the limb
- Use a water-soluble lubricant such as K-Y jelly, Surgilube, or Lubrafax. Do NOT use Vaseline as it can plug the catheter



Troubleshooting

- Occasional flecks of blood in the urine – normal
 - May also see it on the pad covering your stoma. The stoma and/or channel sometimes gets irritated or scraped from the catheter
- Failure to adequately empty pouch – normal
 - Takes time, practice, and patience to know when the pouch has been completely emptied
 - Position used (standing, sitting) may have some effect as well
 - Gentle pressure may help



the patient sort of gets to know that with time. And then gentle pressure on the area of that pouch may also help.

Dr. Aaron Laviana:

And then what about thick mucus? So you may notice the change in the consistency of your mucus. One of the most common causes of this is just from not drinking enough fluids. And so patients will know the difference in their mucus thinning by the more water they drink, just they loop the mucus. And so it's recommended drink 8 to 10 glasses of water or fluids in total per day. I have some patients who drink upwards of 15 plus of fluids. If you're going

to go super high, it's just good to check your labs and make sure all of your electrolytes are intact. But for most of those patients, it's not an issue. And then leaking at night can also occur. And one of the main culprits there is just drinking up until bedtime. So any diuretics such as coffee or alcohol will increase urine production, especially at night, and then not cutting off fluids or having fluids right before you go to bed will obviously make more urine at night and that can lead the problems also.

And then what about irrigation of an Indiana Pouch? I just wanted to go over this because I think it's important how to actually irrigate and the purpose of irrigating is to... For starters, minimize that mucus building up and getting that out of it. And as we talked about helps prevent stone formation and also prevents infection. Now, this is typically done one to two times per day, but if you're one who has more mucus, some patients are doing this more than twice a day.

Troubleshooting Continued

- Thick mucous – usually from not drinking enough fluids
 - Try to drink 8-10 glasses of water/fluids per day
- Leaking at night – often due to drinking up until bedtime



Irrigation of Indiana Pouch

- Purpose
 - Minimize mucus build up
 - Help prevent stone formation
 - Help prevent infection
- Maintenance Procedure
 - 1-2 times/day or more often if mucus build up



So what are the steps here? So the irrigation steps in general are first, just gather all the equipment and make sure you have everything ready to irrigate, wash your hands thoroughly, and then cleanse the end of the catheter with at least 70% alcohol, and then rinse it off with warm water and shake off any excess. You can lubricate the catheter if you're not using pre lubricated catheters, but over time, this often is not needed as your channel's naturally lubricated and then insert the catheter into the stoma and advance until there's a return of urine.

If the catheter isn't draining well, or if there's nothing back, remove the catheter and run it under hot water to remove any potential mucus plugs and then reinsert. And then with a Toomey, it's also known as a catheter tip or and Piston Syringe, draw up 60cc of saline and instill into the pouch. You can buy the saline or some people actually make their own saline, and then let the fluid drain by gravity. After the drainage just stopped, you always want to rotate the catheter about a quarter of the way turn and withdraw it and then push it back in and this helps you get some of these other pouches that may have been missed with the initial catheter because you basically want to just sweep the entire pouch at least twice to try to drain all that excess urine. And then you can remove the catheter.

Typically, patients like folded catheter on the way out, and that's just to prevent it from leaking and splashing all over. Some patients do reuse the catheters. Many have those one time disposable use catheters, but some who do reuse it, they actually migrate the catheters once per week, however one at a time so that they're not melting all together. And that's about it for the overview now, and now I just wanted Scott and Cindy to sort of share their experiences and sort of keep this as an Q and A session here, just to chime in and we can answer any questions about this. And if anyone's exploring an Indiana Pouches or on the fence about it, happy to answer any of those questions also.

Irrigation steps

- 1) Gather all equipment
- 2) Wash hands thoroughly
- 3) Cleanse the end of the catheter with 70% alcohol; rinse off under warm water and shake off excess
- 4) Lubricate catheter, if desired (over time may not be needed)
- 5) Insert catheter into stoma and advance until return of urine
 - If the catheter drains slowly, or not at all, remove the catheter and run under hot water to remove mucus plug. Reinsert



Irrigation steps

- 6) With a Toomey (piston/catheter tip) syringe, draw up 60cc of saline and instill into pouch
- 7) Fluid can drain by gravity
- 8) Once drainage has stopped, rotate catheter about ¼ turn and withdraw 2-3 inches. Push catheter back into pouch and continue to do this until you have "swept" the pouch at least twice in order to drain all the pockets
- 9) Remove the catheter, first by folding the catheter on itself to prevent leaking
- 10) Clean the catheter, if reusing (some microwave catheters once/week one at a time)



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