AMECATH

PERITONEAL CATHETERS

Guides & Instruction for use
AMECATH PERITONEAL DIALYSIS CATHETER

Guides & Instruction for use

Indications and intended use:
A tube channel placed in the peritoneal cavity for patient in need for peritoneal dialysis

WARNING
➢ The implantation technique has a significant influence on the complications and outcome of the chronic peritoneal catheter. To achieve good long-term results, implantation must be performed by a competent and experienced catheter insertion team. Inexperienced personnel should not be permitted to perform the implantation except under the direct supervision of an experienced physician or surgeon.
➢ For single product and patient use only. Do not re-use, reprocess or re-sterilize. Do not use catheter or accessories if any sign of product damage is visible.
➢ Reprocessing or Re-sterilization may damage the catheter and affect its integrity which may when re-used lead to sever deterioration in health and safety of patients.
➢ The catheter does not have any metallic components and can be exposed to various environmental conditions including thermal ignition source (during MRI) as long as no metal component is attached to it. If the catheter has been repaired by a repair kit containing a metallic part this repair extension should be removed prior to MRI exposure.

Device description

Acute semi rigid catheter
Straight tube like catheter comprises side holes at its distal part. The catheter is supplied with a metallic pointed stylet to facilitate its advancement into the peritoneal cavity.

Permanent soft Catheter

Straight: The straight tube like catheter, which can be utilized in combination with almost all extraperitoneal designs It comprises side holes to enhance flow in and out of the peritoneal cavity.
Coiled: The coiled catheter design provides an increased bulk of tubing to separate the parietal and visceral layers of the peritoneum. Flow in and out of the tip of the catheter is more protected and there are more side holes for outflow.

How Supplied:
The acute catheter is supplied with its metallic stylet and extension line in a sterile package. The permanent catheter is supplied either individually packed sterile with female luer end and clamp or in a kit sterile package containing accessories for percutaneous placement (blind method seldinger method mentioned below). Catheters are available in many sizes and length.

Warning:
➢ Improper selection of the catheter size or length my result in improper function of the catheters with diminished flow or kink.

CATHETER INSERTION
Ideally, catheter insertion should be undertaken under operating room, sterile conditions. This can be done on either an inpatient or an outpatient basis. Several placement techniques are described and practiced:

2. Surgical placement by dissection
3. Blind placement using guidewire (Seldinger technique).
**PRECAUTIONS:**

- The incidence and nature of complications should be described to the patient and all questions answered in a reassuring way, allowing a change to HD if not satisfactory.
- Presurgical Assessment: Presurgical assessment of the patient is essential, searching for herniation, eventration, and weakness of the abdominal wall. If present, it may be possible to correct these at the time of catheter insertion. Peritoneal dialysis should then not start during the first 4 weeks, due to increased risk of leakage.
- Determination of the Exit Site: Prior to insertion, the exit site should be identified and marked on the skin. This can be done by the operating surgeon, the nephrologist, or an experienced PD nurse. It is advisable to avoid locations where there may be pressure during daily activities.
- The exit site should be: either above or below the belt line, should not lie on a scar, or should not be in abdominal folds. The umbilicus should not be used as a reference mark. Determined with the patient in an upright (seated or standing) position. Placed laterally.

**CATHETER INSERTION**

Ideally, catheter insertion should be undertaken under operating room, sterile conditions. This can be done on either an inpatient or an outpatient basis. Several placement techniques are described and practiced:

1. Surgical placement by dissection.
2. Blind placement using Tenckhoff trocar.
3. Blind placement using guidewire (Seldinger technique).
5. Other modifications (Moncrief and Popovich, presternal).

**Pre implantation Preparation**

**PRECAUTION**

- The procedure, including the incidence and nature of complications, should be described to the patient and all questions answered in a reassuring way, allowing a change to HD if not satisfactory.

**Pre surgical Assessment:**

Pre surgical assessment of the patient is essential, searching for herniation, eventration, and weakness of the abdominal wall. If present, it may be possible to correct these at the time of catheter insertion.

**WARNING**

- Peritoneal dialysis should then not start during the first 4 weeks, due to increased risk of leakage around the catheter and immature cuff tissue in growth that may lead to catheter migration in the abdomen.

**Determination of the Exit Site:**

Prior to insertion, the exit site should be identified and marked on the skin. This can be done by the operating surgeon, the nephrologist, or an experienced PD nurse. It is advisable to avoid locations where there may be pressure during daily activities.

The exit site should be:

1. Either above or below the belt line, should not lie on a scar, and should not be in abdominal folds. The umbilicus should not be used as a reference mark; 2. Determined with the patient in an upright (seated or standing) position; 3. Placed laterally. A stencil can be applied to demarcate the tunnel and exit site clearly (as is the case for the Swan neck catheter insertion).

**Skin Preparation:**

On the morning of the operation, the patient should bathe or have a shower with chlorhexidine soap. If necessary, abdominal hair should be clipped. Patient’s nares may be swabbed to determine nasal carriage of Staphylococcus aureus.
Bowel Preparation:
Bowel preparation and the avoidance of constipation are of paramount importance. Similarly, emptying the bladder before the procedure is mandatory.

Prophylactic Antibiotics before Implantation: There is some recent evidence that prophylactic antibiotics prevent subsequent catheter infections, peritonitis, and wound sepsis

CATHETER IMPLANTATION TECHNIQUE

WARNING
- The implantation technique has a significant influence on the complications and outcome of the chronic peritoneal catheter. To achieve good long-term results, implantation must be performed by a competent and experienced catheter insertion team. Inexperienced personnel should not be permitted to perform the implantation except under the direct supervision of an experienced physician or surgeon.

PRECAUTIONS
- The implantation must be performed by a competent and experienced operator, in a planned manner. The procedure must be regarded as an important surgical intervention demanding care and attention to detail equal to any other surgical procedure.
- Peritoneal entry should be lateral (deep cuff in or below the rectus musculature), or paramedian (deep cuff at the medial edge of the rectus muscle), to give good deep-cuff fixation and minimize herniation and fluid leaks. Other entry sites (midline through the linea alba) are used with trocar insertions.
- The deep cuff should be placed in the musculature of the anterior abdominal wall or in the preperitoneal space. Good results have also been obtained with the cuff placed within the posterior rectus fascia. The deep cuff should never be placed within the peritoneal cavity. After proper positioning of the catheter tip, the peritoneum is closed tightly around the catheter below the level of the deep cuff using a purse-string suture.
- The subcutaneous cuff should be located near the skin surface and at a distance of at least 2 cm from the exit site. Care should also be taken to avoid mechanically stressing the cuff material.
- Avoid acute angling of the catheters at tunnel inlet or exit.
- The exit site should be facing downwards or be directed laterally. Upward-directed exit sites should, in general, be avoided.
- The intraabdominal portion of the catheter should be placed between the visceral and parietal peritoneum toward the pouch of Douglas and should not be placed within loops of bowel or directly in omental tissue.

A. Blind technique using stylet (suitable for acute catheter):
1) Maintain full sterile technique, wear mask, cap, gown and sterile gloves. Drape the skin overlying the desired insertion site.
2) Lie the patient supine with both hand elevated above the head.
3) Anesthetize the full depth of the abdominal wall at the desired site using approximately 10 ml of local anesthetic agent
4) Make 0.5 cm skin incision over the desired abdominal entry site by using No. 11 scalpel blade. The insertion sites: either a midline or a lateral abdominal entry sites can be chosen. The midline site is about 3 cm. below the umbilicus. The lateral site is just lateral to the border of the rectus muscle, on a line between the umbilicus and anterior superior iliac spine. (Macbourny’s site)
5) While asking the patient to tense his abdominal wall, while place fingers of one hand on the catheter to resist extra pushing, push the stylet – catheter by the other hand through the abdominal wall aiming 20 degrees of the perpendicular toward the patient’s coccyx.
6) After entering the peritoneal cavity, hold the catheter in place by one hand and withdraw the stylet from the catheter for 1 cm by the other hand.
7) Advance the catheter over the stylet down into the abdominal cavity without advancing the stylet itself until the catheter meets firm resistance.
8) Remove the stylet, connect the catheter to the peritoneal dialysis tubing, observe and immediately start infusing dialysis fluid.
Warning:

- Connector of the catheter as being not glued should be fixed properly. Any excessive traction is to be avoided otherwise it will be dislodged with consequences catheter infection.

9) Examine the outflow of the catheter after infusing about 1 liter for flow rate, presence of blood or any other abnormality. If no outflow or weak outflow occurs withdraw the catheter slightly or change its position.

B- Surgical placement by dissection (suitable for permanent soft catheters):

Points for consideration:

a) The implantation must be performed by a competent and experienced operator, in a planned manner. The procedure must be regarded as an important surgical intervention demanding care and attention to detail equal to any other surgical procedure.

b) Peritoneal entry should be lateral (deep cuff in or below the rectus musculature), or paramedian (deep cuff at the medial edge of the rectus muscle), to give good deep-cuff fixation and minimize herniation and fluid leaks. Other entry sites (midline through the linea alba) are used with trocar insertions.

c) The deep cuff should be placed in the musculature of the anterior abdominal wall or in the preperitoneal space. Good results have also been obtained with the cuff placed within the posterior rectus fascia. The deep cuff should never be placed within the peritoneal cavity. After proper positioning of the catheter tip, the peritoneum is closed tightly around the catheter below the level of the deep cuff using a purse-string suture.

d) The subcutaneous cuff should be located near the skin surface and at a distance of at least 2 cm from the exit site. Care should also be taken to avoid mechanically stressing the cuff material.

c) Check for catheter patency. The catheter should be tested to ensure that there is adequate inflow and outflow without leakage. Techniques to accomplish this include infusing 1 L of peritoneal fluid over 5 minutes and allowing an equal time for drainage, or injecting 60 mL of 0.9% saline and observing if 30 – 40 mL is easily aspirated.

f) The exit site should be facing downwards or be directed laterally. Upward-directed exit sites should, in general, be avoided.

![Diagram of catheter placement](image)

**Figure 1**

**WARNING**

- The intra-abdominal portion of the catheter should be placed between the visceral and parietal peritoneum toward the pouch of Douglas and should not be placed within loops of bowel or directly in omental tissue. This maneuver has been shown to be facilitated by the use of a bent stylet or any device that will add rigidity to the catheter.
C- Blind Placement Using the Seldinger Technique:

1) This technique is somewhat similar to the split-sheath technique used for subclavian or internal jugular catheters
2) This technique involves passing a guide needle, attached to a syringe with 2 – 3 mL of saline, through the linea alba or the dissected rectus muscle sheath into the peritoneal cavity, with the syringe contents being injected after appreciating the “give,” indicating entry into the peritoneal cavity. A Seldinger guide wire is passed through the needle, which is then removed.
3) A tapered dilator with surrounding scored sheath is passed caudally over the wire, which is in turn removed. The Tenckhoff catheter is then inserted through the guide and the sheath is split to allow the cuff to reach the outer surface of the fascia. With the catheter held in place, the catheter guide is stripped away.

Warning:
- Connector of the catheter as being not glued should be fixed properly. Any excessive traction is to be avoided otherwise it will be dislodged with consequences catheter infection.

CATHETER NONINFECTIOUS (MECHANICAL) COMPLICATIONS
The most important noninfectious complications during PD are abdominal wall-related hernias, leakage of dialysis fluid, and in/outflow malfunction of the catheter.

Incisional Hernia
Incisional hernia through the catheter placement site, is more frequent if the implantation of the catheter is made through the midline, instead of a paramedial approach through the rectus muscle.
A significant hernia should primarily be repaired surgically; if not, the risk of enlargement of the hernia sac with inadequate drainage of the dialysis fluid from the abdominal cavity will significantly increase. After surgical repair, intermittent PD may be continued postoperatively using low volumes in a supine position. However, one should consider 3 – 4 weeks of HD after surgery in order to minimize the risk for recurrent or relapsing herniation.

Leakage
This complication is related to the catheter implantation technique, trauma, and/or patient-related anatomical abnormalities. It can occur early (<30 days), or late (>30 days), after implantation following the start of PD, and can have different clinical manifestations depending on whether the leak is external or subcutaneous.
Early Leakage (<30 days): This is usually external, appearing as fluid through the wound or the exit site.
When PD is commenced soon after catheter implantation, subcutaneous leakage may develop at the site of the incision and entry into the peritoneal cavity. If the leakage is apparent at the exit site or through the wound, the risk of a tunnel infection and/or peritonitis is increased. Prophylactic antibiotic therapy needs to be considered.
Peritoneal dialysis should be interrupted when early subcutaneous leakage develops. It may seal off during a prolonged rest period. Genital swelling as part of a subcutaneous early leak through the intra-abdominal wall is often a sign of a large leakage and should, in most cases, result in an exploration of the incision site. The other cause of genital swelling is a patent processus vaginalis; computerized tomography will usually differentiate between the two.

RECOMMENDATIONS
1. A period off PD (1 – 2 weeks) should be instituted during which the patient, if needing dialysis, is maintained on hemodialysis. Limited, small-volume supine PD may suffice.
2. For a recurrent leak, surgical repair is essential and the site of the leak may be localized using computerized tomography.
Late Leakage (>30 days): Late dialysis fluid leakage into the subcutaneous tissue is sometimes occult, difficult to diagnose, and may present as a diminished drainage, which might be mistaken for ultrafiltration failure. Exploration of the area of the inner cuff only rarely results in an identification of the leakage site. The management is essentially as above. If this is not effective the catheter must be removed.

Outflow/Inflow Obstruction
Outflow and inflow obstruction are the most frequently observed early events within 2 weeks after catheter implantation, although these complications can be seen later during PD-related complications such as peritonitis. It is important to differentiate between the various causes
1. Mechanical obstruction (tip migration, kink in external tubing, clamp)
2. Constipation
3. Catheter blockage
Outflow Obstruction
Outflow obstruction (one-way obstruction) is the most frequent problem characterized by poor flow and failure to drain the peritoneal cavity. The pathogenesis includes intraluminal catheter factors such as debris (blood clot or fibrin), or extraluminal factors that comprise the following:
1. Stool-filled bowel enwrapping the catheter (constipation)
2. Occlusion of the catheter holes from pressure exerted by adjacent organs.
3. Omental wrapping.
4. Catheter tip dislocation out of the true pelvis.
5. Tip entrapment in peritoneal pockets conditional on adhesions.
6. Incorrect catheter placement at implantation.
Although one-way obstruction is the most common form, two-way obstructions do exist. Also, a reversed one-way obstruction is known, wherein the fluid can be drained but the next infusion cannot be performed due to a clot within the catheter lumen (Twardowski and Pasley, 1994).
Inflow Obstruction: Inflow obstruction is related to either kinking of the catheter, often in the subcutaneous tunnel, or intraluminal debris.

RECOMMENDATIONS
Before treating a catheter obstruction, the type of obstruction must be established, if necessary, by catheter fluoroscopy. The treatment includes:
Conservative or noninvasive approaches such as body position change, walk on staircases, laxatives, flushing with heparinized saline (“push-and-suck” maneuver) should be undertaken. If these fail, then instillation of fibrinolytic agents (urokinase, streptokinase 10 000 U in 2 mL left in the catheter for 2 hours) may be tried. In the case of recurrent fibrin clots, heparin in doses of 500 – 2000 U/L dialysis fluid may prevent obstruction.

Catheter range:
SHORT TERM (ACUTE) PERITONEAL CATHETER KIT

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LONG TERM (STRAIGHT) PERITONEAL CATHETER KIT

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Precaution:

- Do not use absolute alcohol or acetone based product on the catheter. 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution.
- If you catheters experience color discoloration, close monitoring is necessary for possible catheter leak or crack.

Catheter disposal

Used sheath should be disposed in sanitary container to prevent possible contamination and cross infection.

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