

## CATHETER INSERTION

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### Following initiation of a Stool Modification Plan (SMP) in candidate patient:

1. Position patient properly to insure maximal sphincter relaxation (preferred position - left lateral, knee-chest; alternate position – supine with hips flexed).
2. Digital Rectal Exam
  - Refer to chart for findings from admission physical rectal exam.
  - Assess rectum and anal canal for pathology / size / stool / fecal impaction.
  - Rectum should be cleared of stool.
  - Pre-dilate and lubricate anal canal (sphincters).
  - Determine Catheter length required (per Instructions for Use).
3. Analgesia considerations (similar to anoscopy).
  - Combative patient or patient with anal pain – sedation often required.
  - Alert and anxious – topical agent, extra reassurance, sedation occasionally required.
  - Alert and cooperative – good technique sufficient.
  - Sedated and unconscious - good technique sufficient.
4. Confirm Catheter functionality – intraluminal balloon, retention cuff and irrigation lumen.
5. Connect to Collection Bag (close-off Collection Bag drain tube with red clamp).
6. Inflate intraluminal balloon (25cc of air).
7. Fully collapse retention cuff.
8. Generously lube Catheter and patient (**CAUTION: TO AVOID DAMAGE TO RETENTION CUFF OR INTRALUMENAL BALLOON, DO NOT CONTACT EITHER WITH ANY SHARP EDGE INCLUDING THE ENCLOSED LUBRICATING JELLY PACKET.**)
9. Grip Catheter directly behind retention cuff with triple lumen connector tubing oriented anteriorly.
10. Insert Catheter while maintaining anterior orientation of triple lumen connector tubing.
11. Inflate retention cuff (35cc to 40cc of water).
12. Deflate intraluminal balloon.
13. Confirm tension free fit (1cm or greater gap between anchor strap faceplate and anus).
14. Secure Catheter (as needed) with anchor straps to “seat” retention cuff on rectal floor.
  - Apply skin care dressing (e.g. Stomahesive®, DuoDerm®, Tegaderm™).
  - Insure Catheter is not twisted.
  - Tape anchor straps to skin care dressing.
  - Insure straps DO NOT apply tension on Catheter.
15. Hang Collection Bag and position Catheter to facilitate gravity drainage.
16. Patency Confirmation Irrigation - insure System patency with open flow configuration (i.e. intraluminal balloon deflated) irrigation (per Instructions for Use).

# BOWEL MANAGEMENT SYSTEM INSERTION

## ROUTINE MAINTENANCE

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- Strict adherence to Stool Modification Plan (SMP) and irrigation protocol (reference Stool Modification Guidelines).
- Monitor deflated state of intraluminal balloon (via pilot balloon) minimally 3x /day.
- Rinse Catheter a minimum of 2x / day, with water via flush / sampling port.
- Weekly verification of retention cuff volume.
  - *Aspirate all fluid from retention cuff and disconnect syringe.*
  - *Verify deflated state by observing collapsed pilot balloon.*
  - *Re-fill retention cuff with 35cc – 40cc of water.*

## TROUBLESHOOTING

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### **Leakage around Catheter during irrigation.**

- *Position patient such that gravity and colonic anatomy facilitates the flow of irrigant into (i.e. supine with slight head down and / or slightly tilted to the left), and the drainage of irrigant and feces out of (i.e. supine with slight head up) the patient.*
- *Apply gentle traction to “seat” the retention cuff on the rectal floor.*
- *Add an additional 10cc of water to retention cuff (remove added water after irrigation as described in Instructions for Use).*
- Volume of stool in rectum close to defecatory response trigger. Upon initiation of irrigation the defecatory response is triggered resulting in the relaxation of anal sphincters and rectal contraction.
  - *Deflate intraluminal balloon and aggressively douche to break stool up in rectum. Additional irrigant may have to be infused to facilitate douching.*
- Reactive contraction of the rectum / colon from irrigation that is infused too rapidly, is too voluminous, and / or is too cool. This may or may not be associated with patient cramping.
  - *Optimize rate, volume and temperature of irrigation.*
- Little or no sphincter tone.
  - *Completely deflate retention cuff and reinflate with 50cc of water (following irrigation, completely deflate retention cuff and reinflate with 35cc to 40cc of water).*
  - *Application of traction may lead to Catheter expulsion.*

### **Lack of drainage and / or leakage around Catheter when not irrigating**

- Manage small volume perianal mucous or feces leakage with routine hygiene and absorbent pads.
- Intraluminal balloon inflated.
  - *Deflate intraluminal balloon.*
- Transsphincteric zone tubing twisted.
  - *Straighten tube and stabilize Catheter with anchor straps. Prior to using anchor straps check for anterior positioning of triple lumen connector tubing. Proper Catheter orientation is required to use anchor straps.*

# N, MAINTENANCE & TROUBLESHOOTING

- Stool occluding Catheter.
  - *Instill 300ml – 500ml of lukewarm irrigant with intraluminal balloon deflated and douche until significant amounts of stool begin to exit Catheter. Additional irrigation may be required to clear rectum of stool.*
  - *Check stool consistency. More aggressive Stool Modification Plan / irrigation protocol or Catheter removal may be required (reference Stool Modification Guidelines).*
- Retention cuff migrated inward.
  - *Use external retention straps to “seat” retention cuff on rectal floor.*
  - *If 3cm or greater gap between anchor strap faceplate and anus, consider removing Catheter and replacing with shorter Catheter (e.g. replace 6cm Catheter with 4cm Catheter).*
- Retention cuff lost volume.
  - *Completely deflate retention cuff and re-inflate with 35cc – 40cc water (reference Routine Maintenance section).*
- Fighting gravity.
  - *Reposition and / or milk Catheter to facilitate the drainage of irrigant and feces into the Collection Bag.*
- Transsphincteric zone tubing or retention cuff damaged.
  - *If all other measures have failed to resolve leakage, remove Catheter and check integrity of transsphincteric zone tube and retention cuff.*

## Irrigant will not infuse or infuses slowly

- Irrigation lumen occluded.
  - *Squeeze gravity Bag to clear occlusion.*
  - *Use large bore syringe to clear occlusion.*
  - *Put 100ml – 200ml of irrigant into Catheter through flush / sampling port, milk across anal canal and douche to clear occlusion.*

## Odor

- Stool may be accumulating too long in Catheter.
  - *Rinse Catheter more frequently.*

## Expulsion of Catheter

- Application of too much traction (tube is pulled out of patient).
  - *Insure no external traction is being applied to Catheter (e.g. patient’s leg, unsupported weight of Collection Bag, Catheter caught in bed linens).*
  - *Insure Catheter fit is tension free (1cm or greater gap between anchor strap faceplate and anus).*
  - *Reduce the amount of traction applied during irrigation.*
- Little or no sphincter tone.
  - *After rinsing Catheter, reinsert (per Instructions for Use) and inflate retention cuff with 40cc of water.*
- Volume of stool in rectum triggers defecatory response resulting in the relaxation of anal sphincters, rectal contraction and Catheter expulsion.
  - *Perform digital rectal exam to insure no impaction or stool is present in the distal rectum.*
  - *After rinsing Catheter, reinsert (per Instructions for Use).*
  - *Irrigate patient with the intraluminal balloon deflated and aggressively douche during irrigation to clear rectum.*
  - *Check stool consistency. More aggressive Stool Modification Plan / irrigation protocol may be required (reference Stool Modification Guidelines).*

**If expulsion frequency or leakage is excessive, consider discontinuing use of BMS.**

## IMPACTED

**Disimpaction, aggressive stool modification and irrigation required**

## FIRM

**Aggressive stool modification and irrigation required**

## SOFT

**Moderate stool modification with irrigations every 12 hours**

## LOOSE

**Maintenance stool modification and minimally daily irrigation**

## DIARRHEA

**Treat cause of diarrhea; daily irrigation to flush system**

## WHERE TO START

- Upon identification of a candidate patient, a pro-active **Stool Management Plan (SMP)** needs to be initiated prior to BMS insertion.
- To optimize BMS performance, the colon should be evacuated of formed stool prior to BMS insertion.
- **In ALL cases, the rectum should be cleared of stool prior to BMS insertion.**
- Patients who have not had a bowel movement for 2 or more days should be considered to have **FIRM** stool.

*Note: Federal (USA) law restricts this device to sale by or on the order of a physician. All patient care decisions should be made by the prescribing physician or designated healthcare professional. The following guidelines may be consulted in order to achieve optimum performance of the Bowel Management System. Refer to the complete BMS Instructions for Use supplied with the product for device contraindications, warnings, precautions and directions on how to properly use the product.*

# BOWEL MANAGEMENT SYSTEM ST

- The patient **Stool Modification Plan (SMP)** and irrigation protocol should take into consideration the patient history:
  - Stooling history (recent and longer term).
  - The functional status and integrity of the GI System.
  - Medical conditions that affect stool consistency.
  - Pharmacologic agents and fluids that affect stool consistency.
  - Fluid and electrolyte balance.
  - Diet / Nutritional support.
  - Tolerance of irrigation.
  - Recent bowel preparations.

## SUGGESTED STOOL MODIFICATION INTERVENTIONS

- **Irrigation:**
  - Lukewarm water or saline; usual volume 300ml, 500ml, 1000ml; usual frequency q 8, q 12, q 24 hrs; volume and frequency may be adjusted independently.
- **Aggressive Irrigation:**
  - Larger volumes of irrigant (e.g. 1000ml) with douching (ref. BMS Instructions for Use). The addition of 100 mg Ducosate (Colace®) or Glycerol to irrigant may be helpful.
- **Stool Modification Plan (SMP)** requires the administration of one or two of the following agents:
  - Fiber:**
    - Can be administered with tube feeding or as a bulk laxative (e.g. Citrucel® (methyl cellulose), Psyllium); always add additional dietary free water; Prune Juice – 180ml (6 oz) q 8 hrs.
  - Softeners:**
    - Ducosate (Colace®) 100 to 200 mg q 12 hrs.
  - Osmotic Laxatives:**
    - Lactulose 30 ml q 12 hrs; MiraLax™ 17 gms q day for 14 days or as directed by physician.
- **Aggressive SMP:**
  - Requires the administration of high dosages of multiple agents.

**Note:** Increasing the frequency and / or dose of stool modifying agents may improve results.

### IMPACTED

**The BMS is contraindicated for use in patients with IMPACTED stool.**

- **To use product on IMPACTED patients:**
  1. Disimpact patient.
  2. Initiate aggressive SMP to achieve **LOOSE** stool.
  3. Place Catheter and follow up with aggressive irrigation.
  4. If stool remains **LOOSE** manage as noted below. If stool begins to **FIRM**, irrigate q 12 to q 8 hour and continue aggressive SMP to maintain **LOOSE** stool.
- **If IMPACTED stool is identified after BMS placement:**
  1. Remove Catheter to clear impaction and proceed as noted above.

# STOOL MODIFICATION GUIDELINES

## FIRM

**FIRM**, well-formed, dry stool with large pieces of roughage may block the BMS and may present as leakage.

- **To use the product on patients with FIRM stool:**
  1. Remove stool with enemas or laxatives.
  2. Initiate aggressive SMP to achieve **LOOSE** stool.
  3. Place Catheter and follow up with aggressive irrigation.
  4. If stool remains **LOOSE** manage as noted below. If stool begins to **FIRM**, irrigate q 12 to q 8 hour and continue aggressive SMP to maintain **LOOSE** stool.
- **If Catheter becomes occluded (i.e. stool begins to FIRM) after BMS placement:**
  1. Clear Catheter with aggressive irrigation.
  2. If unsuccessful, remove Catheter and clear stool with enemas or laxatives and proceed as noted above.

## SOFT

**SOFT**, semi-formed stool can easily be irrigated out through the BMS Catheter with douching.

- **To evacuate SOFT stool:**
  1. After Catheter placement, follow up with aggressive irrigation and initiate SMP using Fiber and/or Softeners (with Osmotic Laxatives if more aggressive SMP is needed).
  2. Irrigate q 12 hour to maintain **LOOSE** stool.
- **If Catheter becomes occluded after BMS placement:**
  1. Clear Catheter occlusion with additional irrigation and douching.
  2. If occlusions persist increase aggressiveness of SMP (e.g. add Osmotic Laxative, increase dietary free water, increase the frequency and / or dose of current stool modifying agent(s)).

## LOOSE

**Ideal stool consistency for BMS use.**

- **Maintain SMP / irrigation regimen that is responsible for LOOSE stool (e.g. full support Tube Feed with fiber).**
  1. Remove anti-diarrheal and stool stiffeners if in place.
  2. Irrigate minimally q 24 hour to maintain **LOOSE** stool.
- **Small chance of Catheter occlusion with stool unless stool begins to FIRM. In which case, increase aggressiveness of SMP (e.g. add Softeners and extra dietary free water).**

## DIARRHEA

**Liquid stool is well managed by the BMS.**

- **No SMP is required to evacuate DIARRHEA.**
  1. Treat the cause of the diarrhea per physician orders.
  2. Irrigate q 24 hour to keep system clean to maintain **LOOSE** stool.
- **If patient presents with DIARRHEA after BMS placement:**
  1. Treat the cause of the **DIARRHEA** per physician orders.
  2. Be aware of increases in stool consistency with successful treatment that would require addition of stool modification (e.g. Fiber or Softeners) to maintain **LOOSE** stool.