



NuvoMed DisImpactor™ Tool User Guide



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The DisImpactor™ Tool is a single use manual gastroenterology instrument intended for use in the treatment of fecal impaction in patients 18 years of age or older with a clinically confirmed fecal impaction. The device is not intended to treat constipation and should not be used for that purpose.

EXCLUSION CRITERIA

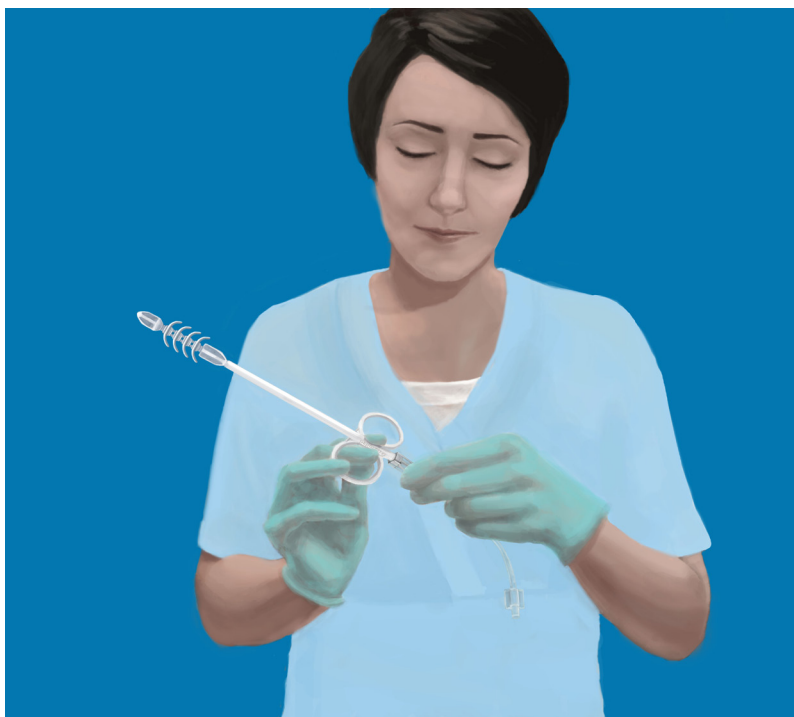
Hemodynamic instability, mental status changes, renal failure, hyperkalemia, active anticoagulation, known anal and/or rectal disease including neoplasm, active infection, active bleeding, inflammatory bowel disease, bowel obstruction, fissures, fistulae, or any other gastroenterological or systemic condition that may pose a risk to the patient.

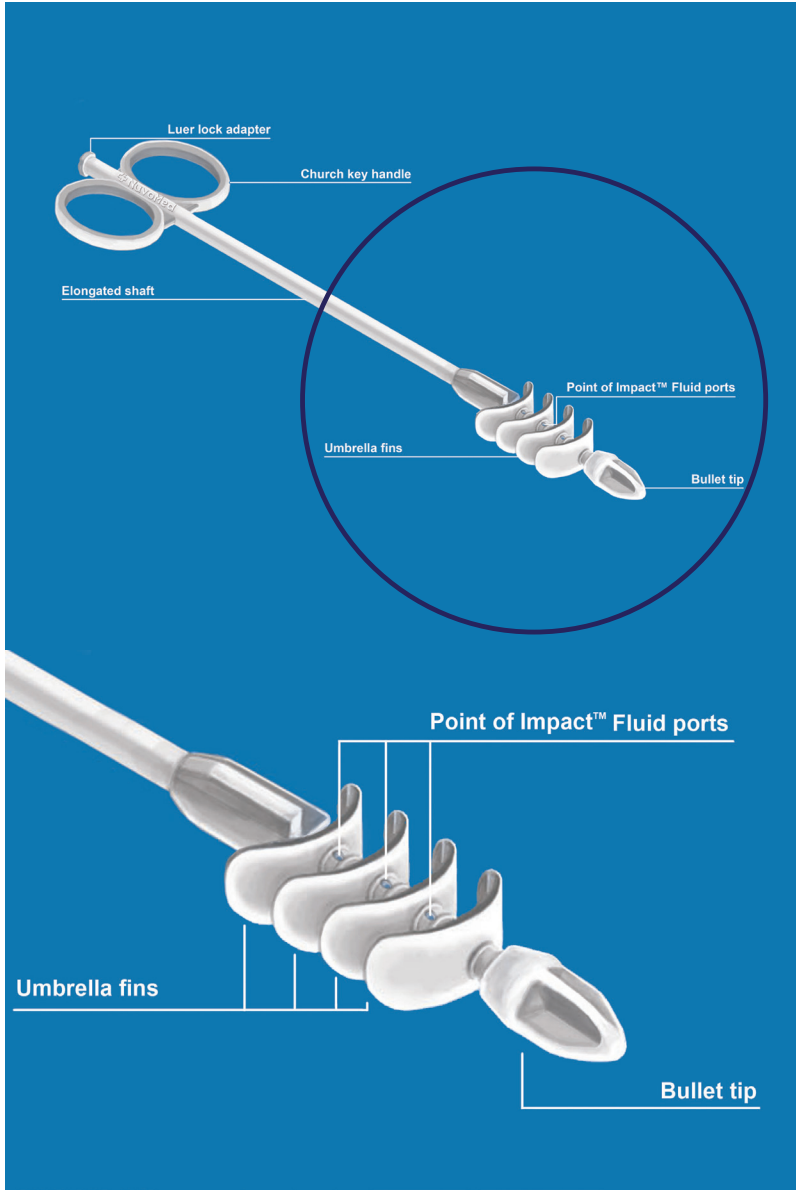
Manual disimpaction may fail when a clinician's single, gloved finger cannot gain a mechanical advantage against the impacted fecal load. The DisImpactor Tool is an instrument that provides an alternative to manual digital fecal disimpaction. The single-use design eliminates the need to clean the device and provides the convenience of disposability after use.

Use of a DisImpactor Tool facilitates the removal of a fecal mass through the combined effect of these elements:

- **Gripping of impaction.** The head of the DisImpactor Tool is designed to penetrate the impacted fecal mass in order to develop a mechanical grip that facilitates removal of the mass.
- **Fragmentation of impaction.** The soft, folding fins along the shaft of the device help to physically break up the mass and facilitate the removal of impacted stool.
- **Enema fluid delivery.** When used to deliver an enema, multiple fluid delivery ports on the DisImpactor Tool allow enema fluid to flow directly into the impacted mass and provide for a greater dispersion of the enema fluid. The design of the device allows for deep enema placement, particularly once the impaction has been disrupted and portions of the impacted stool have been removed.

Patients often experience pain with digital disimpaction when a clinician bends his or her finger to grasp impacted stool. This motion — intrinsic to the process of grasping and breaking up the fecal mass — causes further distention of the already distended bowel. This drawback to digital disimpaction may be avoided when using a DisImpactor Tool.





FEATURES

- Designed to be simple, safe and effective
- Bullet-nose tip for easy insertion
- Elongated, flexible shaft for improved access to fecal load
- Expandable umbrella fins provide traction during stool removal
- Point of Impact™ delivery system for deep enema penetration at site of impaction
- Double-ring “Church key” handles for safe control and manipulation
- Disposable, single-use

BENEFITS

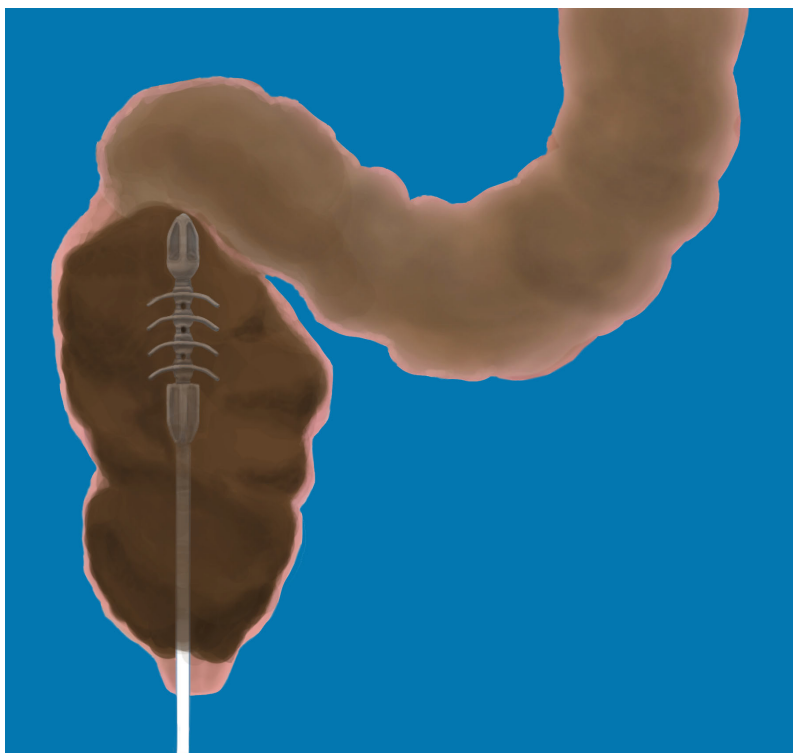
- Minimized pain and embarrassment of digital disimpaction
- Significant and rapid relief of pain
- Improved procedure for all involved
- Relief without hospitalization
- Cost-effective
- Non-digital impaction removal
- Makes enema more effective in removal of impaction
- No sterilization or cleaning required

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USER TRAINING

INTENDED USERS

Due to the possibility of serious injury to the patient, the DisImpactor Tool is intended for use by trained, medically qualified personnel only. The device is not intended for use by patients. All users must review the complete instructions for use prior to using the device.



OBJECTIVE OF USER TRAINING

After receiving instructions on proper usage of a DisImpactor Tool, a medically qualified person will be able to use the device with or without accompanying use of an enema procedure. Both a Quick Usage Guide and Full User Guide are available to explain proper use of the device. A web-based test and certification of training completion is available at www.NuvoMed.com/Training/certificate.

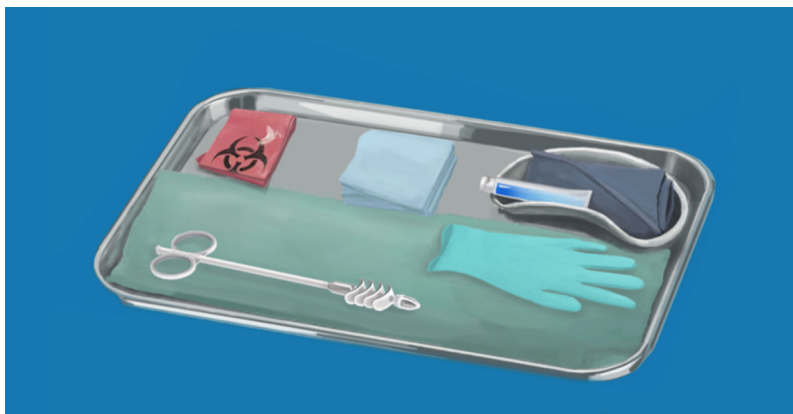
USER TRAINING OPTIONS

Multiple training options are available to users on the NuvoMed website (www.NuvoMed.com/Training) or provided by your NuvoMed distributor:

- User Guide
- Quick Usage Guide
- Online instructions for use
- Online Frequently Asked Questions (FAQs)

1. PREPARATION OF EQUIPMENT

Assemble and inspect all equipment including the DisImpactor Tool, IV extension tubing, water-based lubricant, patient drapes, gloves, and a disposal bag. At least three (3) DisImpactor Tools should be available at the bedside. Since most procedures will require enema fluid, prepare for the administration of enema fluid by emptying a standard 120 mL enema bottle into a small disposable basin. The fluid will then be used to fill two 60 mL Luer tipped syringes. During the administration of enema fluid, each syringe will be connected to the DisImpactor Tool via the included IV extension tubing.



Equipment laid out for use without enema



Equipment laid out for use with enema

2. PREPARATION OF PATIENT

- Explain the procedure to the patient and provide privacy.
- Position the patient lying on his or her side with the knees drawn to the abdomen.
- Drape the patient, and place several barrier pads underneath the buttocks to minimize soiling.
- Ask the patient to breathe deeply to promote relaxation.



3. USE WITHOUT ENEMA

- With the patient lying on his or her side, gently insert a gloved and lubricated finger into the rectum to confirm fecal impaction. A DisImpactor Tool may only be used when the fecal impaction is located in the rectum. Lubricate the anus with additional water-based lubricant.
- Remove the examining finger and ask the patient to gently bear down to relax the anal sphincter.
- With the patient still gently bearing down, carefully and slowly insert a well-lubricated DisImpactor Tool into the rectum utilizing light manual pressure and a gentle clockwise/ counterclockwise twisting motion. The DisImpactor Tool must remain within the center of the fecal mass and along the long axis of the rectal vault. The patient may now relax.
- Gently advance the DisImpactor Tool into the center of the fecal mass. The depth of penetration should be the minimal depth required to actively engage all of the tool's umbrella fins within the fecal mass. The depth of insertion may not exceed the length of the device, nor is full insertion of the device typically required. **DO NOT USE EXCESSIVE FORCE.**
- To begin the withdrawal of stool, ask the patient to bear down again while gently withdrawing the DisImpactor Tool and allowing it to pull stool out of the rectal vault. The combination of gentle traction and attempted defecation will facilitate the procedure. After the procedure is complete, remove the entire device, inspect its integrity, and place it into a biohazard container.
- Assessment after procedure without enema:
 - » Assess patient to determine if disimpaction procedure is successful.
 - » If a single round of disimpaction does not relieve the fecal impaction, use a second, fresh DisImpactor Tool to repeat the previous steps.

4. USE WITH ENEMA

- If fecal impaction persists after two attempts to remove the fecal mass, a new, fresh DisImpactor Tool can be used to facilitate the instillation of enema fluid.
- Fill both Luer-tipped enema syringes with enema fluid that has been emptied into a basin.
- Carefully and slowly insert a well-lubricated DisImpactor tool into the rectum utilizing light manual pressure and a gentle clockwise/counterclockwise twisting motion. The DisImpactor Tool must remain along the long axis of the rectal vault.
- Gently insert a DisImpactor Tool to an appropriate depth for enema administration. Do not withdraw the device. Connect the supplied IV extension tubing to the DisImpactor Tool. Attach the filled syringes, one at a time, to the DisImpactor Tool via the IV extension tubing. Gently infuse the enema solution using light pressure. **STOP THE PROCEDURE IF THE PATIENT HAS ANY DIFFICULTY TOLERATING ENEMA INFUSION.**
- Once the enema fluid has been infused, gently withdraw the DisImpactor Tool and catch any spillage on the drape. Discard the used device, tubing, and syringes into a biohazard container.
- Ask the patient to hold the enema fluid for at least 5 minutes, but only if able to do so. The patient may then use a bedpan or bedside commode for bowel evacuation. If necessary, the patient may be allowed to evacuate at an earlier interval.

- Assessment after procedure with enema:
 - » After performing the procedure with a DisImpactor Tool and enema, reexamine the patient. If the enema did not completely relieve the impaction, disimpaction may be performed again with another DisImpactor Tool to loosen the remaining softened stool.
 - » If residual impaction persists, a second enema using a different enema solution (e.g. soap suds) is typically effective. Administer the second enema via standard techniques without a DisImpactor Tool.
 - » If impaction persists following a second enema, additional adjunctive therapy (e.g. polyethylene glycol or magnesium citrate) may be considered when clinically indicated. Such therapy may be effective when the bulk of the impaction has been relieved.
 - » Most patients will experience relief of their impaction when the preceding steps are followed. In cases of incomplete relief, clinical judgment must be utilized to determine the best course of action for the patient.



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CUSTOMER SUPPORT

Customer Support for product questions and usage is available on the website and via phone:

Web: www.NuvoMed.com/Support

Phone: toll free 866-418-3772

