

Contra-indications

Peristeen® Plus Transanal Irrigation must not be used in the following situations as the mechanical obstruction or the weakened tissue in the colon caused by any of the below would increase the risk of bowel perforation, trauma or bleeding:

- Known anal or colorectal stenosis
- Colorectal cancer (active/recurrent)
- Within 3 months of anal or colorectal surgery
- Within 4 weeks of endoscopic polypectomy
- Ischaemic colitis
- Acute inflammatory bowel disease
- Acute diverticulitis

Since the list is not exhaustive, the physician/healthcare professional should always consider individual patient factors as well.

Cautions specific for healthcare professionals

Prior to the first Peristeen® Plus Transanal Irrigation procedure, a careful review of the patient's medical history as well as a digital rectal examination must be performed to explore any potential contra-indications, warnings or cautions.

A physician experienced in the use of Peristeen Plus Transanal Irrigation must evaluate patients who may have a fragile bowel anatomy (for instance, due to previous anal, colorectal or pelvic surgery and/or radiation therapy).

Endoscopy, defecography or comparable procedures should be used to determine whether the patient's bowel could withstand the Peristeen Plus Transanal Irrigation procedure, including (if using a balloon catheter) how much the balloon shall be (if at all) inflated.

Besides observing the contra-indications and warnings, special caution must be shown if the patient has or has had any of the following:

- Any anorectal condition, which may cause pain or bleeding e.g. anal fissure, anal fistula or third- or fourth-degree
- haemorrhoids
- Faecal impaction/heavy constipation. If the patient is heavily constipated (faecally impacted) an initial clean-out of his/her
- bowels is mandatory before starting up Peristeen Plus Transanal Irrigation procedure
- Irradiation therapy in the abdominal or pelvic region
- Severe diverticulosis or diverticular abscess
- Previous anal or colorectal surgery
- Previous major pelvic surgery
- Severe autonomic dysreflexia
- Long term corticosteroid therapy
- Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel)
- Changed stool pattern such as sudden diarrhoea of unknown origin. The cause for diarrhoea must be identified
- Rectal medication, since the effect of such medication may be reduced by transanal irrigation

(Please refer to the 'instructions for use' leaflet supplied with the product for further information.

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