

# Peristeen® Plus Transanal Irrigation System

## Patient training checklist

**Note:** This form is intended as a checklist for the clinician during initial Peristeen Plus patient training. It is recommended to provide a copy of this form to the patient for future reference upon completion of the training.

### PATIENT INFORMATION

Name \_\_\_\_\_ Date of birth \_\_\_\_\_

Date of training \_\_\_\_\_ Training clinician name \_\_\_\_\_

Name of facility \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_

Completed	Action	Clinician initials
<input type="checkbox"/>	I have reviewed the precautions, contraindications and potential complications with the patient and/or caregiver, and Instructions for Use.	
<input type="checkbox"/>	I have reviewed information with the patient/caregiver on how to safely use Peristeen Plus	
<input type="checkbox"/>	I have demonstrated to the patient/caregiver on how to safely use Peristeen Plus	
<input type="checkbox"/>	I have provided the patient/caregiver with information on Coloplast Care program and have reviewed the privacy statement listed on the Care enrollment form	
<input type="checkbox"/>	Per clinician guidance, the following should be used for Peristeen Plus _____ mL water _____ pumps in balloon Catheter size: _____ small _____ standard	

Before starting Peristeen Plus, patients must undergo a medical evaluation by a qualified healthcare professional to ensure they have no conditions that preclude using transanal irrigation or require further investigation. Transanal Irrigation with Peristeen Plus should always be performed with care. Prior to the first transanal irrigation with Peristeen Plus, a bowel clean-out should be carried out as prescribed by the physician. A digital rectal examination is also mandatory to check for any potential issues.

**Contraindications:** Transanal irrigation must not be used in the following situations: (Check any that apply.)

Yes No

- |                          |                          |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Known anal or colorectal stenosis   |
| <input type="checkbox"/> | <input type="checkbox"/> | Colorectal cancer (active/recurrent), radiotherapy to the pelvis, and recent abdomino-perineal surgery  |
| <input type="checkbox"/> | <input type="checkbox"/> | Active inflammatory bowel disease   |
| <input type="checkbox"/> | <input type="checkbox"/> | Acute diverticulitis, severe diverticulitis, previous diverticulitis and diverticular abscess   |
| <input type="checkbox"/> | <input type="checkbox"/> | Chronic symptomatic diverticular disease  |
| <input type="checkbox"/> | <input type="checkbox"/> | Complex diverticular disease  |
| <input type="checkbox"/> | <input type="checkbox"/> | Within 3 months of abdominal, anal or colorectal surgery  |
| <input type="checkbox"/> | <input type="checkbox"/> | Within 4 weeks of endoscopic polypectomy, recent colonic biopsy, recent endoscopic mucosal resection (EMR) and recent endoscopic sub-mucosal dissection (ESD) |
| <input type="checkbox"/> | <input type="checkbox"/> | Severe autonomic dysreflexia  |
| <input type="checkbox"/> | <input type="checkbox"/> | Ischemic colitis  |
| <input type="checkbox"/> | <input type="checkbox"/> | During spinal cord shock phase  |
| <input type="checkbox"/> | <input type="checkbox"/> | In patients who are pregnant and have not used the system before*   |

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

\*If the patient is pregnant and has never used transanal irrigation before, they should not start the irrigation procedure during pregnancy.

**Precautions:** Special caution must be shown if you have or have had any of the following: (Check any that apply.)

Yes No

- |                          |                          |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Any anorectal condition, which may cause pain or bleeding e.g. anal fissure, anal fistula or third or fourth degree hemorrhoids  |
| <input type="checkbox"/> | <input type="checkbox"/> | Fecal impaction/heavy constipation. If you are heavily constipated (fecally impacted) an initial clean-out of your bowels is mandatory before starting up transanal irrigation procedure |
| <input type="checkbox"/> | <input type="checkbox"/> | Irradiation therapy in the abdominal or pelvic region  |
| <input type="checkbox"/> | <input type="checkbox"/> | Diverticular disease   |
| <input type="checkbox"/> | <input type="checkbox"/> | Previous anal or colorectal surgery  |
| <input type="checkbox"/> | <input type="checkbox"/> | Previous major pelvic surgery  |
| <input type="checkbox"/> | <input type="checkbox"/> | Mild or moderate autonomic dysreflexia   |
| <input type="checkbox"/> | <input type="checkbox"/> | Long term corticosteroid therapy   |
| <input type="checkbox"/> | <input type="checkbox"/> | Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel)   |
| <input type="checkbox"/> | <input type="checkbox"/> | Concurrent use laxatives   |
| <input type="checkbox"/> | <input type="checkbox"/> | Changed stool pattern such as sudden diarrhea of unknown origin. The cause for diarrhea must be identified   |
| <input type="checkbox"/> | <input type="checkbox"/> | Rectal medication, since the effect of such medication may be reduced by transanal irrigation  |
| <input type="checkbox"/> | <input type="checkbox"/> | Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)  |
| <input type="checkbox"/> | <input type="checkbox"/> | Cancer in the abdominal or pelvic region   |
| <input type="checkbox"/> | <input type="checkbox"/> | Severe cognitive impairment (unless caregiver is available to supervise/administer)  |

Patient or legal guardian signature, complete A or B in the section below

<b>A:</b> I confirm that I am 18 years of age or older, have read and understood this document, and consent to the collection, use, transfer and processing of my information as described above:	
Signature: _____	Date: _____
<b>B:</b> I confirm that I have the legal right and authority to grant consent on behalf of the above end user to the collection, use, transfer and processing of the end user's information as described above:	
Full name: _____	Signature: _____
Basis for Signature Authority: _____ (Examples: parent of the above minor child, power of attorney, legal guardianship, court order, etc.)	

Clinician signature : \_\_\_\_\_ Date: \_\_\_\_\_

**Warning:** Transanal irrigation procedure should always be carried out with caution. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation and will require immediate admission to a hospital, often requiring surgery. Possible symptoms of bowel perforation:

- Severe or continued pain in the abdomen or back area, especially if fever and/or severe anal bleeding are present
- Rectal pain and abdominal pain
- Blood in feces

If any of these symptoms occur, contact your healthcare provider or urgent care immediately as it may require admission to the hospital and surgery if bowel perforation is confirmed.

[illegible]

**Contraindications:** Peristeen Plus Transanal Irrigation must not be used in the following situations: known anal or colorectal stenosis, colorectal cancer (active/recurrent), radiotherapy to the pelvis, and recent abdomino-perineal surgery, active inflammatory bowel disease, diverticulitis and ischaemic colitis, chronic and complex diverticular disease, abdominal, anal or colorectal surgery within the last 3 months, within 4 weeks of endoscopic polypectomy, recent colonic biopsy, recent endoscopic mucosal resection (EMR) and recent endoscopic sub-mucosal dissection (ESD), severe autonomic dysreflexia, or during spinal cord shock phase. Product must not be used in patients who are pregnant and have not used the system before\*. Since the list is not exhaustive, the healthcare professional should always consider individual patient factors as well.

**Warning:** Peristeen® Plus transanal irrigation procedure should always be carried out with caution. Bowel perforation is an extremely rare, but serious and potentially lethal complication to transanal irrigation and will require immediate admission to a hospital, often requiring surgery. See the device manual for complete user instructions, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Coloplast Corp at 1-855-605-7594 or consult the company website at [www.coloplast.us](http://www.coloplast.us). **Caution: Federal law restricts this device to sale by or on the order of a physician.**