Peristeen[®] Plus transanal irrigation (TAI) Patient Assessment Checklist^{*}

Patient Name

patient information sticker

Contraindications	Yes	No	Precautions	Yes	No
Peristeen Plus <u>must not be used</u> in the following situations: Special caution for any of the following:					
Known anal or colorectal stenosis			Any anorectal condition, which may cause pain or		
Colorectal cancer (active/recurrent), radiotherapy to the pelvis, and recent abdomino-perineal surgery			bleeding e.g. anal fissure, anal fistula or 3 rd /4 th degree hemorrhoids		
Active inflammatory bowel disease		Fecal impaction/heavy constipation. If constipate			
Acute diverticulitis, severe diverticulitis, previous diverticulitis and diverticular abscess			impacted), an initial clean-out of the bowels is mandatory before starting up Peristeen Plus Transanal Irrigation procedure		
Chronic symptomatic diverticular disease			Irradiation therapy in the abdominal or pelvic region		
Within 3 months of abdominal, anal or colorectal			Diverticular disease		
surgery			Previous anal or colorectal surgery		
Severe autonomic dysreflexia			Previous major pelvic surgery		
Within 4 weeks of endoscopic polypectomy, recent colonic biopsy, recent endoscopic mucosal resection (EMR) and recent endoscopic sub-mucosal dissection (ESD)			Mild or moderate autonomic dysreflexia		
			Long term corticosteroid therapy		
			Bleeding diathesis or anticoagulant therapy (not including		
Ischemic colitis			aspirin or clopidogrel)		
During Spinal Cord Shock Phase			Changed stool pattern such as sudden diarrhea of unknown origin. The cause for diarrhea must be identified		
Complex diverticular disease			•		
Patients who are pregnant and have not used the system before*			Rectal medication, since the effect of such medication may be reduced by Peristeen Transanal Irrigation		
	•		Inflammatory bowel disease (e.g. Crohn's disease or		
Peristeen Plus is not recommended for:	Yes	No	ulcerative colitis)		
Children under the age of 2 years			Cancer in the abdominal or pelvic region		
*Current or planned pregnancy or nursing women			Severe cognitive impairment (unless caregiver is available to supervise/administer)		
Digital rectal examination (mandatory for all): Results/Comments		1	Yes		No
Does the patient have fragile bowel anatomy - previous anal, colorectal or pelvis surgery, and/or radiation therapy? Yes					\rceil_{No}
If yes, has an endoscopy or comparable examination been conducted to determine whether Peristeen Plus					1140
transanal irrigation (TAI) is safe for use?					No
Does the patient understand the possible risks and benefits of Peristeen Plus, and agree to initiate the therapy?					No
Is the patient able to perform Peristeen Plus independently?					No
If not, does the patient have a caregiver who will support with Peristeen Plus and get trained on the product use by a qualified HCP? Yes Name of the caregiver					No
Has the caregiver been trained?			Yes		No
Has the patient been trained?					No
Bowel clean-out program (mandatory if fecally impacted) Yes					No
Peristeen Plus Recommended for Use:				**	No
The Peristeen Plus Transanal Irrigation System is indicate	ad for us	e hy child	Iren (2 years - <12 years old) adolescent (12 years - <18 years	: old)	

Date

The Peristeen Plus Transanal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - <18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

If the patient is found suitable to initiate treatment with Peristeen Plus, remember to schedule the appropriate training and follow-up. The first irrigation must be supervised by a healthcare professional. A prior authorization from the patient's insurance provider may be required. Initial supply order will be shipped directly to the patient. Please advise your patients NOT to use the product until they have received thorough training from you.

*This checklist is NOT exhaustive; please consult the full instructions for use and the HCP Training Guide for further details.

This checklist is not intended to constitute medical advice or in any way replace the independent medical judgment of a trained and licensed physician with respect to any individual patient needs or circumstances.

**Please reference the Peristeen Plus Process Summary brochure for next steps after patient has been recommended

