ZERO-IN™

COMPREHENSIVE CLINICAL SOLUTIONS PROGRAM

Fecal Incontinence Patient Selection Assessment Table

FI Assessment Parameters	Assessment Criteria		
Patient History and Physical Assessment	• Determine underlying type and cause of fecal incontinence • Evaluate potential cause(s) of fecal incontinence and associated complications • Assess for medical conditions, contraindications and warnings to all interventions • Use appropriate Pain Scale or Assessment Tool to detect pain per facility policy		
Abdominal Assessment	Assess abdomen for stool impaction, abnormalities and pain		

Rectal Assessment	• Assess fecal output for stool frequency, consistency and volume
	• Obtain stool culture if stool consistency is semi-liquid to liquid (diarrhea) or if ileus is suspected
	  ◦ If diarrhea present, initiate and document Contact Precautions until resolved
	• Conduct digital rectal exam to determine rectal tone, sensation, abnormalities and to detect stool impaction
	  ◦ If stool impaction, disimpact per facility policy		

Skin Assessment	• Assess skin for injury, abnormalities and dehydration		
Risk Parameters	**Risk Levels for Developing Complications Associated with FI**		
	At Risk	**Moderate Risk**	**High Risk**
Stool Frequency	< 3 stools in 24 hrs	3-6 stools in 24 hrs	> 6 stools in 24 hrs
Stool Consistency	Solid to Semi-Solid	Semi-Solid to Semi-Liquid	Semi-Liquid to Liquid
Bristol Stool Form Scale Score	Type 1-4 Hard (impacted) to Normal	Type 4-6 Normal to Loose stool	Type 6-7 Loose stool to diarrhea
Stool Culture	Negative	Negative/Positive	Positive
Braden Scale Score	18-15	14-13	12 or <
IAD Risk Level	No Risk Skin Intact	High Risk to Early IAD Skin Intact, Erythema, No Blisters	Moderate to Severe IAD Skin NOT Intact

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Indications: The BARD® DIGNISHIELD® Stool Management System (SMS) with odor barrier properties is intended for fecal management by diverting and collecting liquid or semi-liquid stool in bedridden patients and to provide access for the administration of medications.

Contraindications: The device should not be used for more than 29 consecutive days, on patients with certain medical conditions including rectal or anal abnormalities, or on patients who have had lower large bowel or rectal surgery within the last year. Do not use on patients with indwelling rectal or anal device, delivery mechanisms, or enemas in place.

Warnings and Adverse Events: There is a potential risk of misconnections with connectors from other healthcare applications. As with the use of any rectal device, adverse events can occur including: leakage of stool, loss of anal sphincter muscle tone, pressure necrosis, infection, bowel obstruction, and perforation of the bowel. Changes to the patient including: rectal bleeding indicating possible pressure necrosis, abdominal distention, cuff migration, and rectal pain should be investigated.

Please consult package insert for more detailed safety information and instructions for use.