

SoloSpec™

Disposable Sigmoidoscopes

Instructions for Use

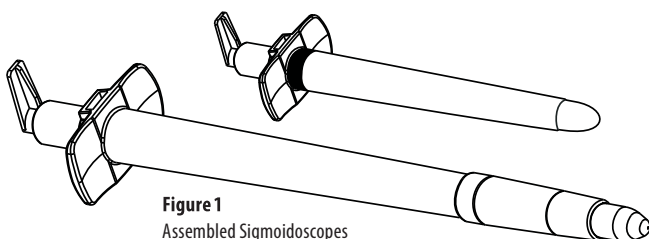


Figure 1
Assembled Sigmoidoscopes
(Body and Obturator), Small and Standard Sizes

by Orion Concepts Inc.
www.orionconceptsinc.com

INTENDED USE and INDICATIONS FOR USE

SoloSpec™ Disposable Sigmoidoscopes are rigid, graduated endoscopes intended for the examination and diagnosis or treatment of the anus and rectum and are for one-time use only.

The SoloSpec™ Disposable Sigmoidoscopes may be used with compatible, fiber-optic instrument heads and light sources approved for medical use.

Preparing & Using Instruments (Refer to Fig. #2 for details)

1. Remove Obturator (1) from SoloSpec™ Disposable Sigmoidoscopes Body (2) and attach body/tube to lighthead by pushing in fully & then twisting CW to secure.
2. Instrument Light-Head (3): Loosen screw on viewing window (3-2) and open window (3-1), Re-insert the obturator(1) through open window before inserting sigmoidoscope in patient. Insert stem of lighthead (3-3) until it latches in illuminator (4).

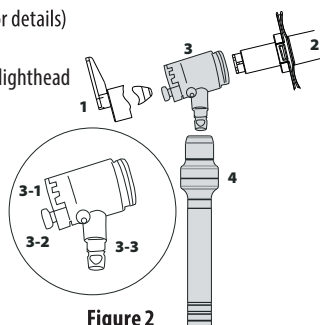


Figure 2

If required connect insufflation bulb to the lighthead. A suitable lubricant may be applied to the tip of the obturator and device tube.

3. Suggestions for use during examination: The window (Fig 2, 3-1) may be opened or closed at any time. Tightening the screw (Fig 2, 3-2) allows the instrument to be made airtight for insufflation.

Insufflation Sets

Orion Concepts Inc. single-use insufflation sets (Fig. 3) are recommended.

When compatible reusable insufflation sets Fig. 4 (1) are used the Orion Concepts Inc single-use filter Fig. 4 (2) prevents potential cross-contamination of the rubber insufflation bulb.

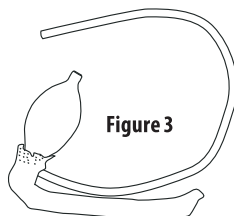


Figure 3

CLEANING PROCEDURE

Instrument head: Please consult the Instructions for Use supplied with such devices and strictly follow the manufactures guidelines for cleaning and reprocessing.

SoloSpec™ Disposable Sigmoidoscopes: These devices are supplied clean, non-sterile in a sealed bag and are meant for one-time use only. After use please dispose of in an approved manner.

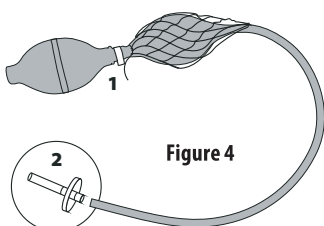


Figure 4

WARNINGS & CAUTIONS



WARNING: Devices are not for use with laser equipment. They may reflect, transmit, or absorb laser or other photocoagulation energy, possibly resulting in combustion or emission of irritating gases.

WARNING: Devices in transit or storage may be subject to damage beyond the control of the manufacturer or supplier.

WARNING: Inspect each device before use.

WARNING: Treat used sigmoidoscopes as bio-hazardous, infectious material. Dispose of in a suitable disposal unit and/or in accordance with local regulations.

WARNING: Devices are not compatible with gamma radiation or auto-claving.



CAUTION: To be used by trained personnel only

CAUTION: Rx Only. US Federal law restricts this device to sale by or on the order of a physician.

CAUTION: Obturator must be in place while inserting sigmoidoscope in patient

CAUTION: OCI recommends the use of either disposable insufflation sets or a disposable in-line filter for use with the sigmoidoscope and fiber-optic light head a to prevent contamination of the reusable style rubber insufflation bulb and possible cross contamination between patients.

CAUTION: : In-line filters are single-use only and must be disposed of after use to prevent possible risk of infection.

CAUTION: SoloSpec™ Disposable Sigmoidoscope are single-use only and must be disposed of after use to prevent possible risk of infection.

CAUTION: Protect from sunlight.

Reference Chart				
Figure No.	Device	Class	Size	Product Code
1	SoloSpec™ Disposable Sigmoidoscope	II	Small	42319-1
		II	Standard	42319-2
2 (4)	LED Endoscopic Illuminator	I	—	GS-LEI-A-HP
2 (3)	Fiber Optic Lighthead	I	—	GS-F0-RL
3	Single-use Insufflator Set	I	—	42316-1562
4 (2)	Single-Use Insufflator Filter	I	—	42316-1565

Symbols and Definitions



Alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.



Caution, consult accompanying documents



“WARNING” Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device



Date of manufacture (yyyy-mm)



Recyclable packaging materials



Catalogue number



Batch code



Non-sterile



Manufacturer



Unique device identifier



Temperature limitation



Keep away from rain



Protect from sunlight



Do not reuse



Use by the date



Consult instructions for use