

INTENDED USE and INDICATIONS FOR USE

SoloSpecTM Disposable Anoscopes are intended for the examination and diagnosis or treatment of the anus and rectum and are for one-time use only.

The anoscopes may be used with or without a single-use light guide and approved light source.

SoloSpecTM Disposable Anoscopes: 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.

SoloSpecTM Disposable Anoscopes (Fig.1)

1. Insert single-use light guide (3) in GreenStarTM LED Endoscopic Illuminator (4) and then slide light-guide into block on anoscope body (2). Leave obturator (1) in place during insertion

A suitable lubricant may be applied to the tip of the obturator and device tube.

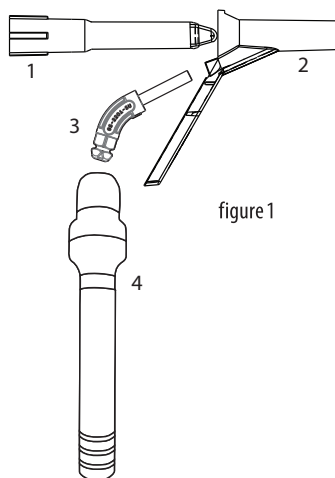


figure 1

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 anoscopes 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 anoscope in patient

CAUTION: SoloSpecTM Disposable Anoscopes 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(1,2)	SoloSpec TM Disposable Anoscope	II	Small	42301-1
		II	Medium	42301-2
		II	Large	42301-3
1(1,2)	SoloSpec TM Disposable Anoscope, Notched	II	Medium	40801-14-2
		II	Large	40801-14-3
1(1,2)	SoloSpec TM Disposable Anoscope, Bevel Tip	II	Medium	42301-2-5
1 (4)	Greenstar TM LED Endoscopic Illuminator	I	—	GS-LEI-A-HP
1 (3)	Single-use Light Guide	—	—	GS-2201-SU

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

REF Catalogue number

LOT Batch code

NON-STERILE Non-sterile

Manufacturer

UDI Unique device identifier

Temperature limitation

Keep away from rain

Protect from sunlight

Do not reuse

Use by the date

Consult instructions for use