PROCTOLUX™

INSTRUCTIONS FOR USE

19MM OR 25MM PROCTOSCOPES WITH LIGHT SOURCE

Product Description and Appropriate Application

PROCTOLUX™ is a range of single use, fully disposable and self-illuminating rigid Proctoscopes. These devices are used during either rectal examination or rectal surgery for use in examination, diagnosis and treatment in the anal cavity and rectum.

PROCTOLUX™ comes in two sizes, 19mm and 25mm diameters.

All PROCTOLUX™ devices are shipped ready for use.

Should light output become impaired in use due to debris or smoke obscuring the light output, the end of the light guide can be cleared by wiping.

Re-use of this device represents an unnecessary and avoidable risk of cross infection to the patient.

Application

The G+N Medical PROCTOLUX™ and associated Illuminator are intended to provide a means of speculum to the anal cavity and rectum. PROCTOLUX™ supplies effective illumination thus permitting direct visual examination and treatment by a suitably qualified and experienced Healthcare Professional.

The key functions of PROCTOLUX™ are:

1. To enable trained Healthcare Professionals to effectively inspect and perform invasive investigational procedures to the anal cavity and rectum.
2. Reduce the complexity and increase the ease of use by having a light source directly attached to the device. This enables the area to be viewed by the operator facilitated by an internal light source that can illuminate the area without the need for extra equipment.

Intended Use

The G+N Medical 19mm and 25mm PROCTOLUX™ is intended to provide means of rigid endoscopic access to the patient's rectum and anal cavity. The supply of effective illumination permits direct visual examination by a suitably qualified and experienced Healthcare Professional.

Indications

The G+N Medical 19mm and 25mm PROCTOLUX™ is indicated for use when a suitably qualified and experienced Healthcare Professional requires to perform either a direct rectal examination, or surgery of the patient using a suitable rigid Proctoscope.

Instructions for Use

1. Remove the device from its packaging by separating the peel pouch and removing the product. Discard the package. Examine the pack before use. The pack shall not be issued nor the Proctoscope used if the wrapper or seal is broken. DO NOT USE IF PACKAGING OR PROCTOSCOPE IS DAMAGED.
2. Pull out the blue tab in the light pack located in the device handle to activate the light source, before insertion into the patient. Maximum illumination intensity is maintained for a minimum of 30 minutes. The light pack will operate for a considerably longer period, with gradually diminishing intensity.
3. Ensure that the appropriate size of Proctoscope is selected before commencing the procedure.
4. Apply a suitable lubricant to the outer aspect of the Proctoscope and then gradually and gently insert the Proctoscope into the anal canal and rectum.
5. When the Proctoscope is in the required position, remove the inner obturator and begin examination.
6. If rotation or repositioning of the Proctoscope is required, reinsert the obturator.
7. Upon completion of the examination, gradually and gently withdraw the Proctoscope from the anal canal and then confirm that the patient is comfortable.
8. After use, ensure that the product is disposed of safely into an appropriate clinical waste container in accordance with local policies and procedures as described below.

Warnings and Precautions

- For hygienic reasons always wear rubber gloves when handling the device before and after use. The device will come into contact with biological fluids which are potentially infectious.
- Do not use damaged Proctoscopes.

Storage

Store devices in their original packing at room temperature and normal air humidity.

The shelf life is indicated on the product.

Disposal

Discard the Proctoscope with the light pack still attached, as "clinical waste" according to hospital, or local protocols. Note: If required the light pack can be removed by firmly pulling the entire pack downwards. Do be careful as it may well release suddenly. Dispose of the light pack responsibly.

2	Do not re-use		Do not use if package is damaged
REF	Catalogue number		Keep dry
LOT	Batch number		Shock protection (Type BF Applied Part)
	Use by date	Rx	Federal or EU Law restricts this device to be sold by or on the order of a licensed Health Practitioner
	Date of manufacture		Warning/caution consult accompanying documents
3.6v	Direct electrical current at voltage shown		Consult instructions for use/consult operating instructions
LATEX	Not made with natural rubber latex	NON STERILE	Non-sterile
	Do not look directly into the light source		Manufacturer and address of the manufacturer
	Fragile – handle package carefully	1	Number of items per pack
DEHP	No DEHP	IP30	IP rating

Description	Model Size	Product Code Number
PROCTOLUX™	19mm	702000
PROCTOLUX™	25mm	702010

Contraindications: None

WARNINGS:

Before each use carefully examine the instrument to ensure that there are no visible scratches, chips, voids, etc. These could cause the instrument to lose its stability potentially compromising safety. The patient should be informed when the Proctoscope is to be introduced and removed.

Adjustments may be necessary to provide improved comfort.

The device is a single use device and should be disposed of after use.

WARNING: ⚠ Inspect each device and packaging for damage prior to use.

WARNING: ⚠ If a device or packaging is damaged, do not use any devices from the same box.

WARNING: ⚠ When in transit or storage, device may be subject to damage beyond the control of the manufacturer or supplier.

WARNING: ⚠ Never use device with laser equipment.

WARNING: ⚠ Device is not compatible with gamma radiation or autoclave sterilization.

WARNING: ⚠ No modification of this equipment is allowed.

Precautions:

The size and shape of the Proctoscope is determined by the patient's anatomy and need for investigational procedure. Never use an ultrasonic cleaner for the device, the device should not be cleaned or sterilised in any way as it is provided in a clean hygienic form for single use only.

FOR SINGLE USE ONLY: The G+N Medical device is designed for single use only; do not reuse device. G+N does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination. Reuse may result in infection, serious injury, or patient death. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations

CAUTION: Use by trained personnel only.

CAUTION: Federal (USA) and European Union law restricts this device to sale, distribution and use by or on the order of a physician.

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Manufactured by G+N Medical