

Proctolux How To Use Guide

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.

The Proctolux proctoscope does not need to be fully inserted for examination or treatment of the patients rectum and anal cavity.

If the examination area is shallower than the 97mm and 80mm length of our Proctolux device then insert the scope up to desired depth and carry out the procedure as normal.

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 by gently rotating clockwise and anti-clockwise until it slides out freely** 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.

