

ANOSPEC[®]

Single-Use Anoscope with Built-In Light Source

USER MANUAL

REV 09232015

ENGLISH

Symbols Description

-  In this document, indicates conditions or practices that may lead to injury, illness, or death ("WARNING").
-  In this document, indicates conditions or practices that could damage the equipment or other property ("CAUTION").
-  On the product means consult other accompanying documentation.
-  Do not reuse.
-  Preceeds catalogue number.

-  Indicates quantity.
-  Fragile.
-  Do not get wet.
-  References other document
-  Expiration Date
-  Preceeds manufacture date.
-  Preceeds manufactures contact infromation.
-  Latex Free.

Intended Use

The AnoSPEC Disposable Anoscope with light is intended for physician use to examine the anal sphincter, anus, rectum, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Warnings and Cautions

-  **WARNING:** This anoscope is not for use with laser equipment. It may reflect, transmit, or absorb laser or other photocoagulation energy, possibly resulting in combustion or emission of irritating gases.
- WARNING:** Anoscope, when in transit or storage, may be subject to damage beyond the control of the manufacture or supplier.
- WARNING:** Inspect each anoscope prior to use.
- WARNING:** Treat used anoscope as bio hazardous infectious material. Dispose of used anoscope in suitable disposal unit or in accordance with local regulations.
- WARNING:** This anoscope is not compatible with gamma radiation or autoclave sterilization.
- CAUTION:** Used by trained personnel only.
-  **CAUTION:** Rx only. U.S. federal law restricts this device to sale by or on the order of a physician.

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Sterilization:

Anoscope in manufactured in accordance with FDA GMP Quality System Regulations, 21 CFR, Part 820. Anoscope is not supplied sterile.

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Product Overview

- ✓ **Entirely Single-use:** ANOSPEC eliminates the time and expense of reprocessing, reducing the risk of cross-contamination by obsoleting rechargeable and plug-in light sources. Each ANOSPEC comes with a built-in LED light source. The entire device is single-use; the facility incurs NO additional expenses.

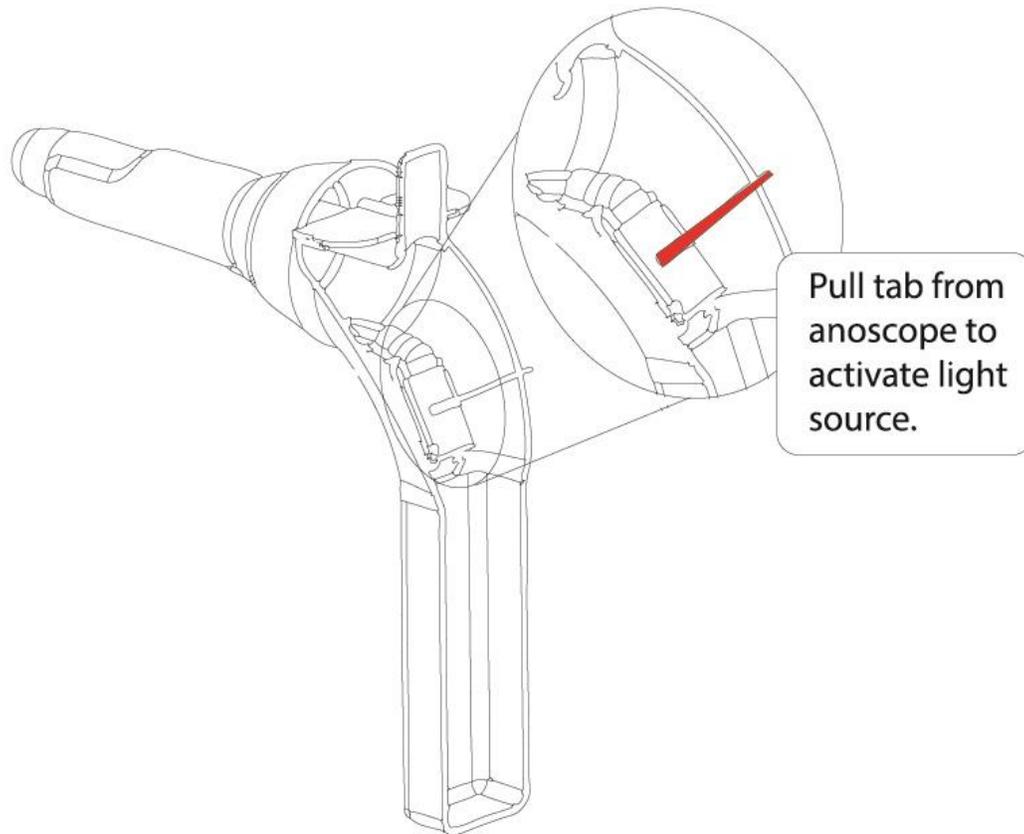
- ✓ **Zero assembly:** ANOSPEC comes out of the package ready for use. Each ANOSPEC units comes with a built-in ultra-bright single-use LED light source. No additional parts or components (replacement bulbs, light sources, chargers, etc.) are required.

- ✓ **Built-in Targeted Light Source:** Never worry about a reusable light source again. Each ANOSPEC comes with a built-in ultra-bright LED light source. The ANOSPEC light source does not utilize a light pipe of any kind so the maximum power of the light source is fully realized. High-powered illumination is achieved without generating any damaging heat.

- ✓ **Save Time/Increase efficiency:** Never worry about searching for, replacing, or cleaning a reusable light source again.

- ✓ **Reduce Risk of Cross-Contamination:** ANOSPEC reduces the risk of cross-contamination from poorly cleaned reusable parts and components.

Instructions for Use – Light Source



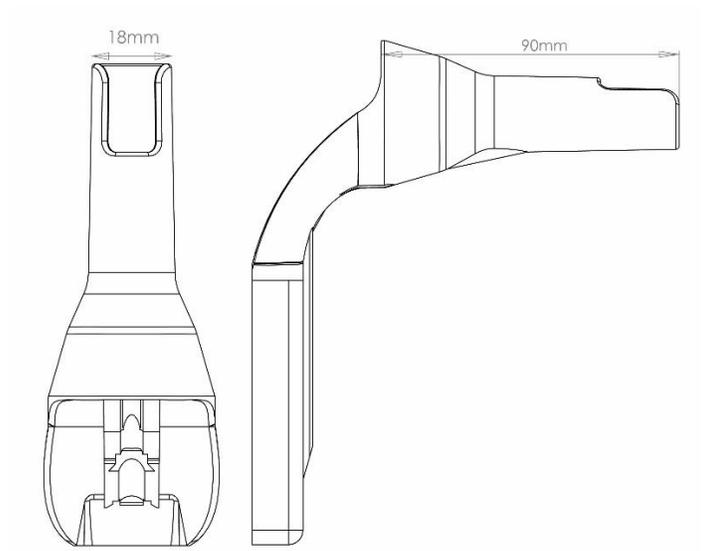
Light source is for single use and of limited duration. Do not pull tab until required.

Simply pull tab to activate light source.

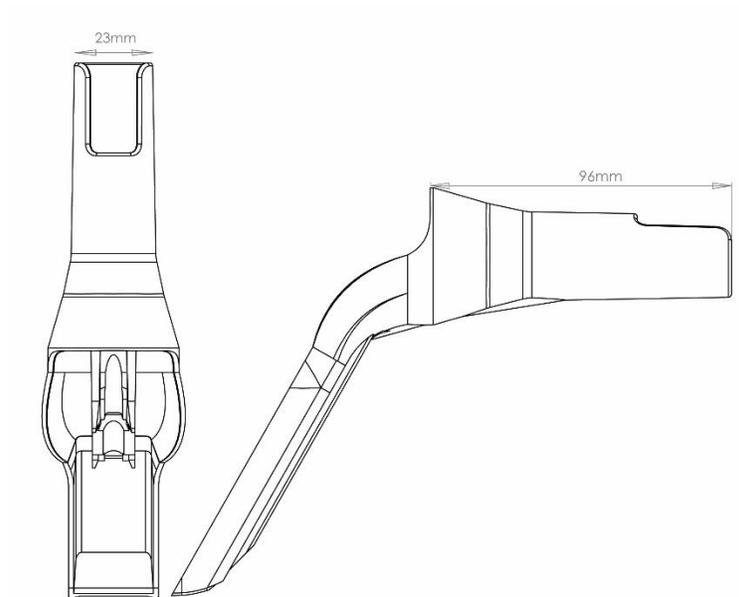
Light source will produce 30+ minutes of peak light.

ANOSPEC Specifications

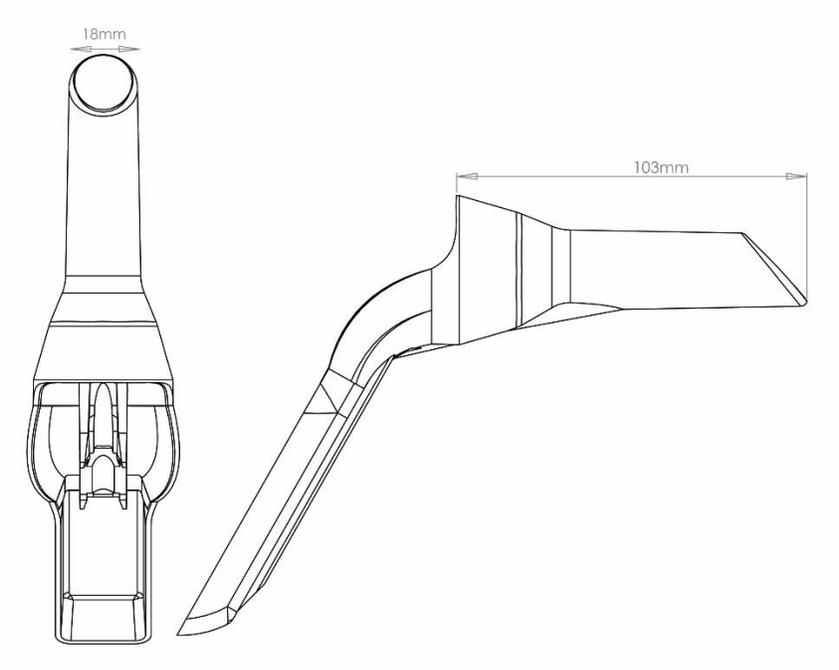
90mm x 18mm slotted



96mm x 23mm slotted



103mm X 18mm bevel



Batteries

The ANOSPEC light source contains modern Alkaline batteries.

Alkaline batteries do not contain toxic materials per federal E.P.A. guidelines.

Alkaline batteries are not regulated hazardous waste.

“Button” style AG3 batteries contain only enough chemistry for a single use.

Batteries comply with European directive 2006/66/EC and amendment

For additional information visit:

<https://obpmedical.com/company/disposable-medical-device-batteryinformation>

Disposal

Check with your Environment, Health, & Safety department regarding your facilities battery disposal policy. ANOSPEC device is considered a biohazard after use. Follow good hospital practices and local ordinances in the disposal of this device after use.

Sterilization

The only acceptable form sterilization is Ethylene Oxide (EtO). EtO parameters are as follows:

Sterilization method	Ethylene Oxide (EtO)
Concentration	100%
Exposure time	8 hrs

Technical Assistance

For additional product information please contact OBP Medical at **1-978-291-6853** or via email at **info@obpmed.com**.

Return Policy

- Accept eligible returns within 30 days of customer receiving order.
- Returns are only accepted for defective products.
- Defective product complaints may be communicated via telephone (888-300-2946) or via email at info@obpmed.com.
- Customer must provide the lot number of defective product when issuing complaint.
- Used or opened product will not be accepted under any circumstances due to contamination risks.
- An unopened product from the same lot number or batch may be returned for evaluation.
- Whenever additional information is required, "good faith" effort will be made to obtain such information, and a reasonable number of attempts will be made to contact the reporter either by phone, fax or letter.
- Following evaluation of complaint, if product is proven to be defective by OBP Medical Quality Assurance, product will be replaced or a full refund will be made at customer's discretion. Refunds will be applied in the same form customer payment was issued.

Product Ordering Information

ANOSPEC is available in 3 sizes:

- **90mm x 18mm slotted** – Item # C060100
- **96mm x 23mm slotted** – Item # C060110
- **103mm x 18mm bevel** – Item # C060120

For additional information contact OBP Medical:



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