

OBP[®]

M E D I C A L

Simple. Bright. Ideas.

Trade Name: **ANOSPEC[®]**

Description: Single-Use Anoscope with Integrated LED Light Source

This IFU applies to all products with a **REF** beginning with "C06"



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OBP Medical is proud to be an ISO 13485 certified company.

OBP Medical Single-Use Anoscope with integrated LED Light Source comes ready to use out of the package. There are no additional accessories, parts or components required.

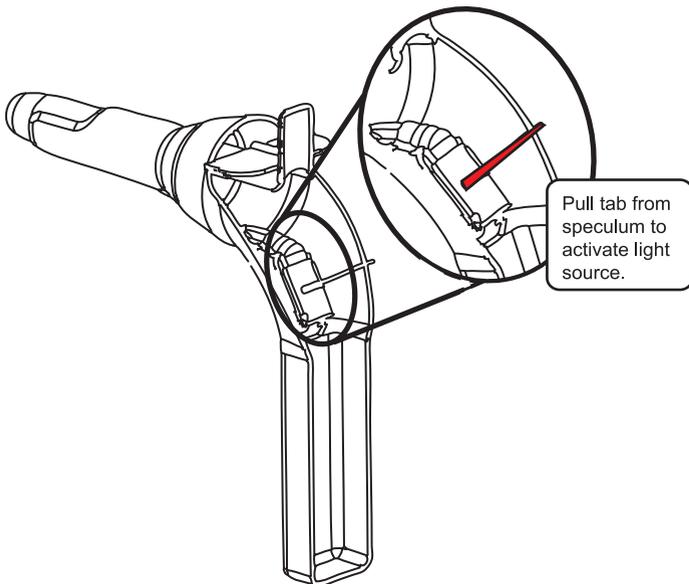
Pull red tab to activate light source. Dispose of red tab immediately once pulled.

Light source is single-use and of limited duration. Do not pull red tab to activate light source until you are ready to use the device.

Light source will last at peak brightness for up to 30 minutes and will fade gradually thereafter.

LED light source generates no harmful heat and is safe to dispose of while lit.

Anoscope is available in various sizes and styles with the same integrated light source functionality. Please visit www.obpmedical.com to see all options.



OBP Medical assumes no responsibility for any injury to anyone, or for any illegal or improper use of the product, that may result from failure to use this product in accordance with the intended use, instructions, cautions, or warnings. OBP Medical, ANOSPEC is a registered trademark of OBP Medical.

Patent information available at: www.obpmedical.com/patents

PL-06-0001 REV D

Symbol Descriptions

	In this document, indicates conditions or practices that could lead to illness, injury, or death ("WARNING").
	In this document, indicates conditions or practices that could damage the equipment or other property ("CAUTION").
	Consult Instructions for Use
	Do not re-use, Single use device
	Catalogue Number (Reorder #)
	Lot Number
	Use By Date
	Manufacture Date
	Quantity
	Manufacturer's contact information
	Not made with natural rubber latex
	Fragile
	Temperature limit
	Humidity limitation
	For Professional Use
	Do not use if package is damaged

Indications for Use

The OBP Medical ANOSPEC single-use lighted Anoscope is intended for physician use to examine the anal sphincter, anus, rectum, and, using additional devices, to perform various diagnostic and therapeutic procedures.

Warnings and Cautions

 **WARNING:** Inspect each device for damage prior to use

WARNING: If a device 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: Treat used devices as bio hazardous infectious material. Dispose of used devices in suitable disposal unit or in accordance with local regulations.

WARNING: Devices are not compatible with gamma radiation or autoclave sterilization.

WARNING: No modification of this equipment is allowed

 **CAUTION:** Use by trained personnel only.
CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician.

Warranty

Please visit www.obpmedical.com "Terms and Conditions" page for warranty information.

OBP Medical should be notified via phone or email of any defective product and the item should be securely packaged and immediately returned with prepaid postage from OBP Medical

Manufacture & Sterilization

Device is manufactured in accordance with FDA GMP Quality System Regulations, 21 CFR, Part 820. Device is supplied non-sterile.

Device is manufactured and assembled in a strict clean-room environment.



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