

# OfficeSPEC<sup>®</sup> / ER-SPEC<sup>®</sup>


Single-Use Vaginal Speculum with Built-In Light Source

## USER MANUAL


REV 08022016


**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.

**REF** Preceeds catalogue number.

 Indicates quantity.


 Fragile.

 Do not get wet.

 References other document

 Expiration Date

**LOT** Preceeds manufacture date.


 Preceeds manufactures contact infromation.

 Latex Free.

**Intended Use**

The OBP Medical ER-SPEC disposable vaginal speculum is indicated for use on women undergoing a procedure requiring vaginal access and exposure (e.g. for pelvic examination or Pap Smear). This device uses opposing bivalve plastic blades to separate the vaginal wall and is intended to expose the interior of the vagina and exterior of the cervix.

**Warnings and Cautions**


 **WARNING:** This speculum 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:** Specula, when in transit or storage, may be subject to damage beyond the control of the manufacture or supplier.

**WARNING:** Inspect each speculum prior to use.

**WARNING:** Treat used vaginal speculum as bio hazardous infectious material. Dispose of used vaginal speculum in suitable disposal unit or in accordance with local regulations.


**WARNING:** This speculum 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.


**CAUTION:** To prevent patient injury this speculum is designed to break outside of the patient at handle when overstressed.


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**Sterilization:**

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

OBP Medical Inc  
360 Merrimack St.  
Building 9  
Lawrence, MA 01843  
USA



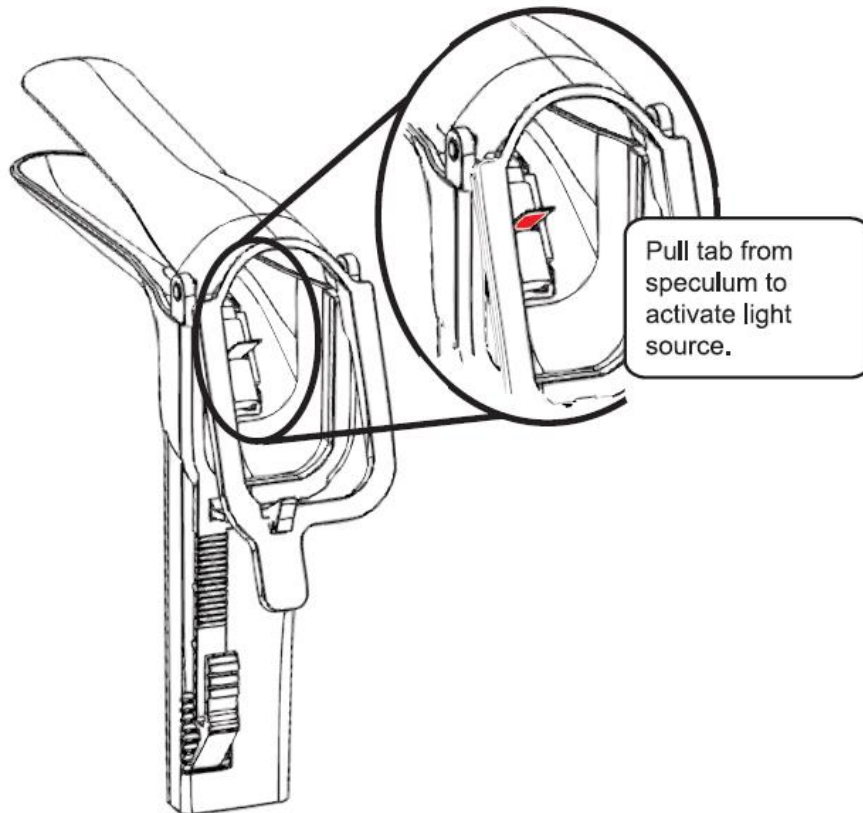
EMERGO EUROPE  
Molenstraat 15  
2513 BH, The Hague  
The Netherlands  
Tel: +31 (0)70 345 8570  
Fax: +31 (0)70 346 7299



## Product Overview

- ✓ **Entirely Single-use:** OfficeSPEC/ER-SPEC eliminates the time and expense of reprocessing, reducing the risk of cross-contamination by obsoleting rechargeable and plug-in light sources. Each OfficeSPEC/ER-SPEC comes with a built-in LED light source. The entire device is single-use; the facility incurs NO additional expenses.
  
- ✓ **Zero assembly:** OfficeSPEC/ER-SPEC comes out of the package ready for use. Each OfficeSPEC/ER-SPEC 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 OfficeSPEC/ER-SPEC comes with a built-in targeted LED light source. The OfficeSPEC/ER-SPEC 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:** OfficeSPEC/ER-SPEC reduces the risk of cross-contamination from poorly cleaned reusable parts and components.

## Instructions for Use – Light Source

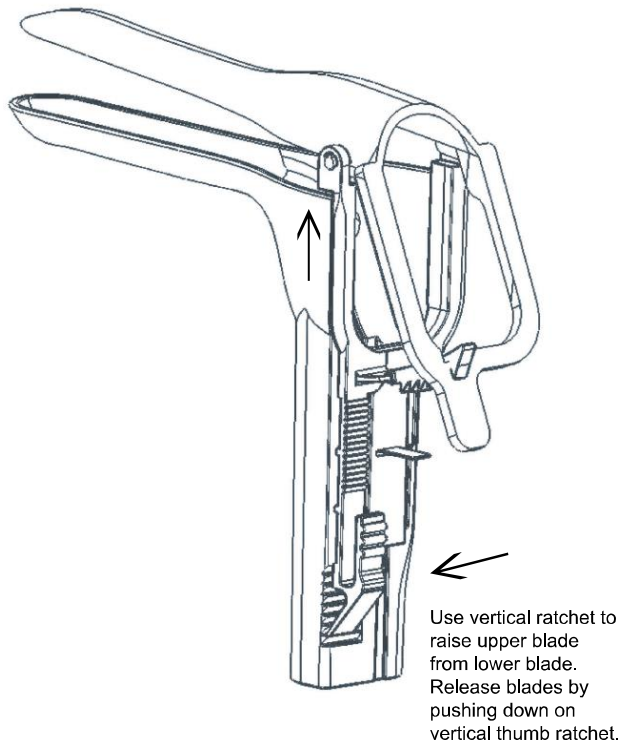
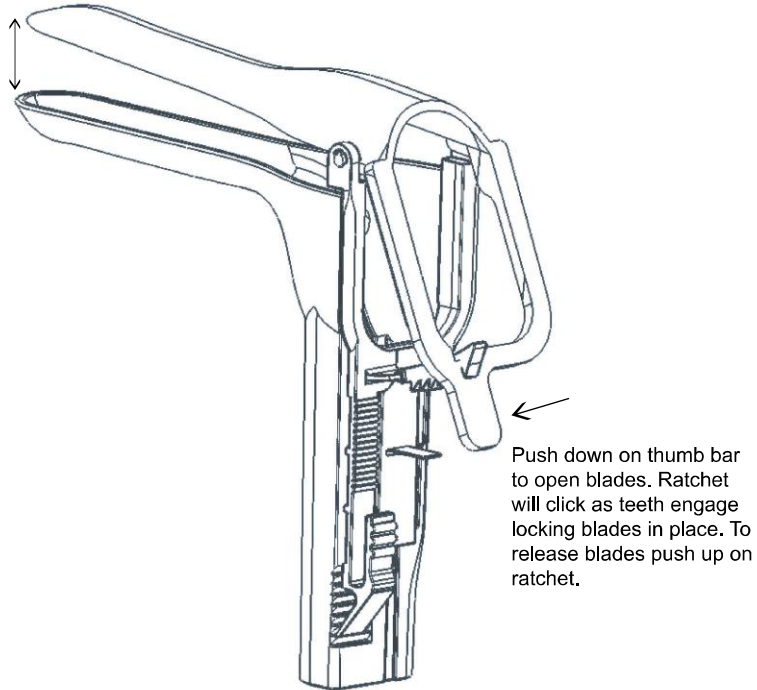


Light source is for single use and of limited duration. Do not pull tab until ready to use.

Simply pull tab to activate light source.

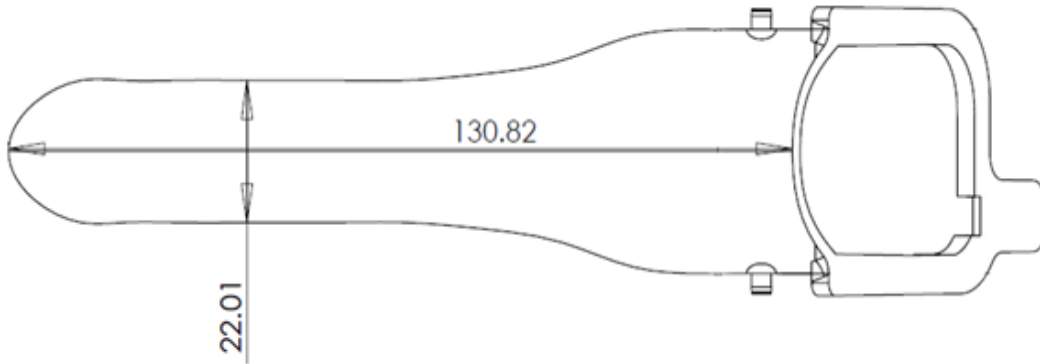
Light source will produce 30+ minutes of peak light.

## Instructions for Use – Blades

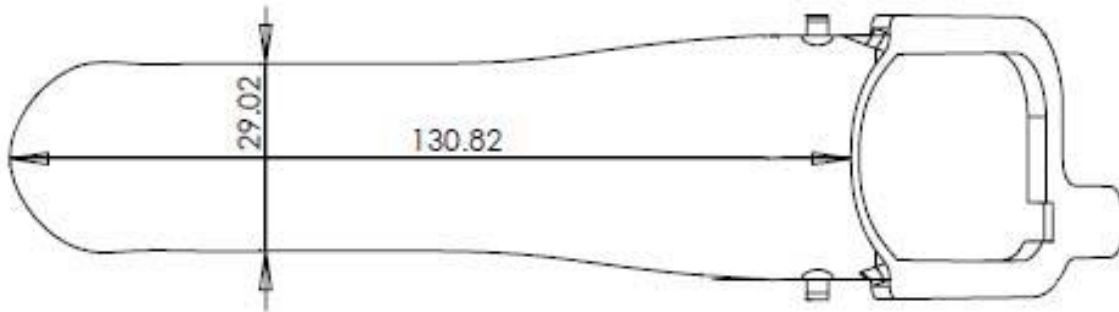


## Blade & Handle Specifications

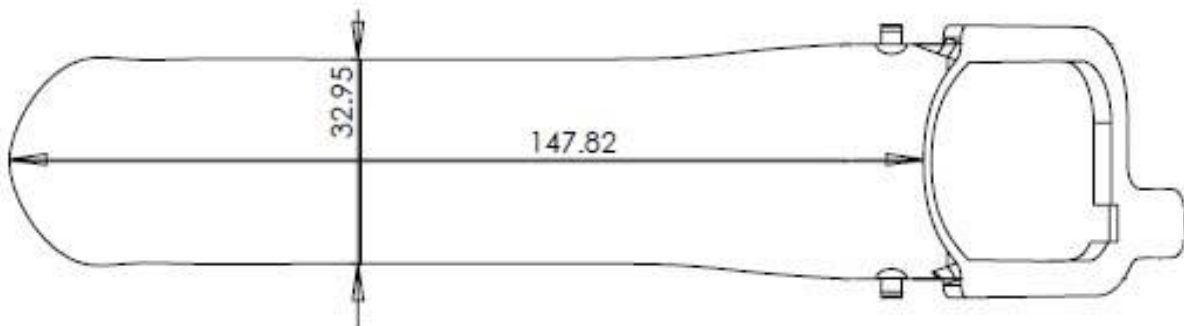
### OfficeSPEC/ER-SPEC Small



### OfficeSPEC/ER-SPEC Medium



### OfficeSPEC/ER-SPEC Large



## Batteries

The Office-SPEC/ER-SPEC 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. OfficeSPEC/ER-SPEC 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 of sterilization for OfficeSPEC/ER-SPEC 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](mailto: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

OfficeSPEC/ER-SPEC is available as follows:

- **Small** – Item # C020100-1
- **Medium** – Item # C020110-1
- **Large** – Item # C020120-1
- **Medium Side-Opening** – Item # C020001
- **Small (Sterile)** – Item # C020300
- **Medium (Sterile)** – Item # C020310
- **Large (Sterile)** – Item # C020320
- **Vaginal Exam Kit (Sterile)** – Item # C070100
- **IUD Insertion Kit (Sterile)** – Item # C070110

For additional information contact OBP Medical:



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