English	en

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CooperSurgical®

ER-SPEC™ Single-Use Vaginal Speculum with Integrated LED Light Source
HER-SPEC™ Single-Use Click-Free Vaginal Speculum with Integrated LED Light Source
OFFICESPEC™ Single-Use Side-Opening Vaginal Speculum with Integrated LED Light Source

MD R_xOnly

CE UK CA

Instructions for Use

REF **ER-SPEC: C020100-1 • C020110-1 • C020120-1 • C020130-1 • C020140-1**
HER-SPEC: C020500 • C020510 • C020520
OFFICESPEC: C020001

R_xOnly CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

DEVICE DESCRIPTION
The lighted vaginal speculum devices are single-use, non-sterile disposable vaginal speculums made from a clear rigid polymer with an integrated bright white light-emitting diode (LED) light source to enhance visualization.
Each device consists of a standard two-blade design with fixable and releasable vertical translation and angulation mechanisms for the upper blade.
The light source is activated by removing a tab allowing connection of the circuit which powers the LED for 30 or more minutes.

INTENDED USE
The lighted vaginal speculum devices are intended to aid in the visual examination of the vagina and cervix and to provide access to the cervical canal and uterus for the implementation of various diagnostic and therapeutic procedures.

INDICATIONS FOR USE
The single-use lighted vaginal speculum is indicated for use on women undergoing a procedure requiring vaginal access and exposure (e.g. for pelvic examination or Pap Smear). The device uses opposing bi-valve plastic blades to separate the vaginal wall and is intended to expose the interior of the vagina and exterior of the cervix. It may be used with or without a removable light source.

CONTRAINDICATIONS
None.

PATIENT TARGET GROUPS
The lighted vaginal speculum devices are intended to be used with adult women, who meet the indications for use at the discretion of the healthcare provider.

INTENDED USERS
The lighted vaginal speculum devices are intended to be used by qualified healthcare professionals.

⚠ WARNINGS
- Inspect each device for damage prior to use.
- Never use device with laser equipment.
- Treat used devices as bio hazardous infectious material. Dispose of used devices in suitable disposal unit or in accordance with local regulations.
- No modification of this equipment is allowed.
- Risk of Reuse: The strength of the device may be significantly compromised and the resulting risk to the patient and/or user is unknown. For single use only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury. Reuse, reprocessing or re-sterilization may create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

⚠ PRECAUTIONS
- Confirm functionality of the light prior to use of the device with the patient.
- Light source is single-use and of limited duration. Do not activate light source until you are ready to use the device.

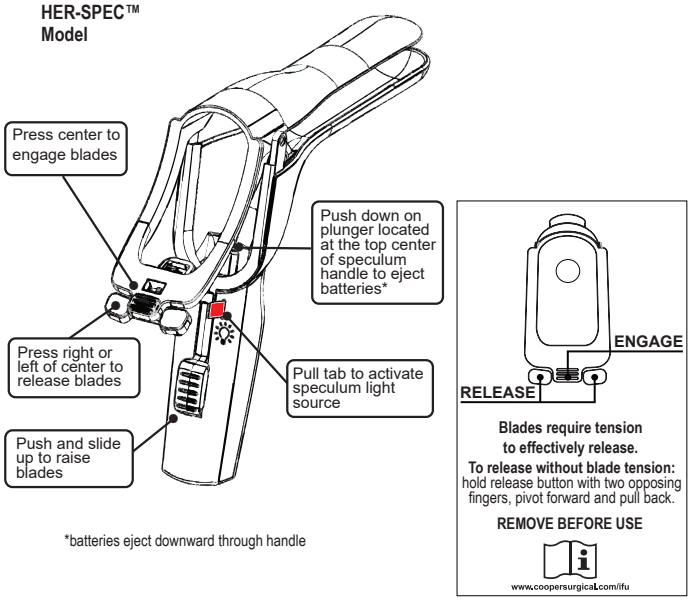
ADVERSE EFFECTS
None.

DEVICE LIFETIME
Vaginal speculums are non-sterile, single-use, disposable devices. The LED will remain illuminated ≥30 minutes.

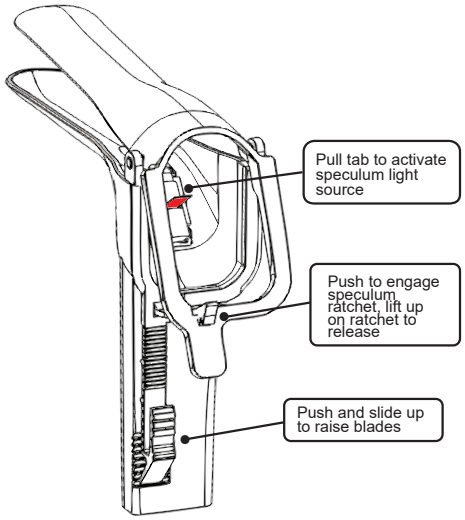
HOW SUPPLIED / STORAGE CONDITIONS
The lighted vaginal speculum devices are supplied non-sterile. Store in the original packaging at room temperature and away from sunlight or UV light.

INSTRUCTIONS FOR USE

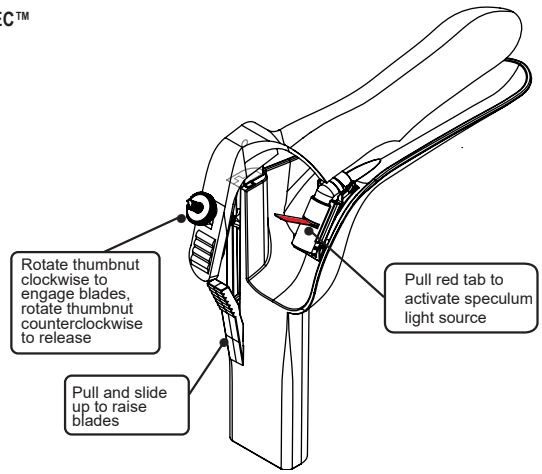
HER-SPEC™ Model



ER-SPEC™ Model



OFFICESPEC™ Model



PERFORMANCE CHARACTERISTICS
These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

EXPECTED CLINICAL BENEFIT(S)
The single-use lighted vaginal speculum is indicated for use on women undergoing a procedure requiring vaginal access and exposure (e.g. for pelvic examination or Pap Smear). Therefore, no direct clinical benefit is derived from these instruments that could be observed in the form of measurable performance outcomes, as the benefit is derived from the medical procedure.

DISPOSAL OF DEVICE
This device must be handled and disposed of as healthcare medical waste in accordance with hospital procedures and applicable regulations.
Any device that has been contaminated with potentially infectious substances of human origin (such as bodily fluids) must be handled according to hospital protocol for infectious medical waste.

REPORTING OF SERIOUS INCIDENTS
If a serious incident is suspected from using the vaginal speculum, report the details of the incident to CooperSurgical via the online complaint form https://www.coopersurgical.com/contact-us/customer-complaint-form-med-dev, by email at ProductSurveillance@coopersurgical.com , or by phone number +1 203-601-5200 Ext. 3100 and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

WARRANTY
Please visit www.coopersurgical.com "Terms and Conditions" page for warranty information. CooperSurgical®, Inc. should be notified immediately via phone or email of any defective units.

Glossary of Symbols
Source: ISO 15223-1 and ISO 7000

Symbol	Title
	Packaging unit
	Catalogue number
	Batch code
	Country of manufacture ("CC" shall be replaced by either the two letter or the three letter country code)
	Use-by date
	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Medical Device
	Product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Non-Sterile
	Caution
	Consult instructions for use or consult electronic instuctions for use
	Authorized representative ("XX" shall be replaced by either the two letter or the three letter country code)
	Importer
	Manufacturer
	The product conforms to the UK Device Medical Regulation 2002, as amended. The product can be freely marketed in Great Britain (England, Wales and Scotland)
	Date of manufacture
	Fragile, Handle with care
	Keep away from sunlight
	In order to preserve, protect and improve the quality of the environment, protect human health and utilize natural resources prudently and rationally - do not dispose of waste electrical or electronic equipment (WEEE) as unsorted municipal waste. Contact local WEEE disposal sites.

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