



Trade Name: **ONETRAC<sup>®</sup>**

Description: Single-Use Cordless Retractor with Integrated LED Light Source

This IFU applies to all products with a **REF** beginning with "C10"

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

+1-978-291-6853

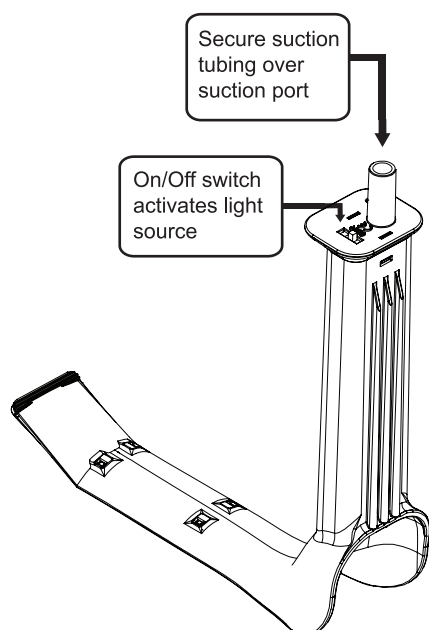
[www.obpmedical.com](http://www.obpmedical.com)



EMERGO EUROPE  
Prinsesgracht 20  
2514 AP The Hague  
The Netherlands

Australian Sponsor:  
Emergo Australia  
201 Sussex Street  
Docking Park, Tower II,  
Level 20  
Sydney, NSW 2000  
Australia

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



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

Slide switch on the bottom of the handle to activate light.

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

Light source duration is a minimum of 60 minutes at peak brightness. Turn light off when not in use to extend light duration.

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

Force at tip not to exceed 30 lbs. For soft tissue retraction only.

















Retractor is available in various sizes and styles with the same integrated light source functionality. Please visit [www.obpmedical.com](http://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, ER-SPEC and OfficeSPEC are registered trademarks of OBP Medical.

Patent information available at: [www.obpmedical.com/patents](http://www.obpmedical.com/patents)

PL-10-0113 REV F

## 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

**STERILE** Sterilized using ethylene oxide (only applicable to versions marked as sterile on unit packaging)

## Indications for Use

The OBP Medical ONETRAC single-use lighted retractor is indicated for use to retract soft tissue in order to enhance exposure during surgical procedures.

## Warnings and Cautions

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

**WARNING:** If a device is damaged, do not use any device 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 device in suitable disposal unit or in accordance with local regulations.


**WARNING:** Devices are not compatible with gamma radiation or autoclave sterilization and should never be resterilized by any method.

**WARNING:** No modification of this equipment is allowed

**WARNING - Risk of reuse:**

The strength of the device may be significantly compromised and the resulting risk to the patient and/or user is unknown.

The light may not function properly.

 **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](http://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

Device is 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 sterilized using ethylene oxide (ETO)



[www.obpmedical.com](http://www.obpmedical.com)

