Instructions for use Retractor

UDI-DI	VARIANT	Ref	Blade Size
07350093650556	RetraLight LED Light Retractor 28mm	RL4000	28 mm
07350093650600	RetraLight LED Light Retractor (without Teeth) 28mm	RL4001	28 mm
07350093650617	RetraLight LED Light Retractor 20 mm	RL4002	20 mm
07350093650648	Retractor 20 mm	E4001	20 mm

Intended Use

To provide surgeons with the ability to illuminate the surgical field independent of an external light source or fiber optic cables. The lighted retractor is indicated for enhancing visibility to a surgical field through retraction of soft tissue and illumination of the surgical cavity. It is intended for but not limited to general, plastic, and reconstructive procedures in breast and open abdominal surgery procedures.

Description

It's a Medical Device product for transient use that delivers light and helps to visualize the surgical tissue or pocket. It is a simple design with no moving parts, composed of a rigid "L" shape handle and a light opposite to the handle where the device is inserted into the breast or surgical pocket.

It is an adjuvant for the medical practitioners as it helps to bright up the inside of the incision site. In this way it can shine the field from several different angles, eliminating shadows, reflections, and glare. Especially when the surgical access site is small, this can be a great advantage.

The use of a low temperature LED light features the avoidance of:
- costly and complicated reprocessing requirements of fragile fiber-optic cables
- high risk thermal injuries

Indications
A single use battery power light retractor is an adjuvant medical device used during breast mastectomies, lumpectomies, sentinel node biopsies and reconstruction procedures. It is intended to provide source of light to allow better visibility and access to the surgical tissue or pocket during pocket dissection of a breast augmentation procedure.

Intended Users
The Retractor is used in plastic, reconstructive and general surgeries by professional personnel. Not used by lay persons. Not used by patient. Operation Theatre sterile barrier use only.

Connection to other Devices and Accessories
No other devices are needed to be connected nor related to the Retractor; the device can be used totally independent. In case the customer would like to add a fume suction source, an adaptor to the hospitals suction source can be connected to the Retractor device. Not necessary and performance is not affected when the adaptor is or not used.

Risk with the use of the device
No residual risks, nor undesirable side-effects, have been noticed by the manufacturer

Physical characteristics	- The product consists of a single use cordless retractor. - Battery powered by a low temperature LED - Integrated smoke evacuation channel - Low voltage alkaline battery - Unique mechanical strength resistant nylon reinforced material - Specially designed rounded tip to improve atraumatic tissue grip for widening the breast pocket. - Ergonomic and lightweight for improvement surgeon maneuvering performance.
Battery Characteristics:	- Nominal voltage: 1.50V - Average Service capacity: 110mAh (rated capacity at 6.2kW load, cut off voltage 1.0V at 20°C)
Operating and Storage Temperature:	Temperature: 5 to 40°C
Humidity:	(10 ± 90)% RH
Shelf Life:	Please check package label
Performance Characteristics:	Lux 0.20

Contraindications
The use of the retractor may be contraindicated in situations where the tissue or the surgical pocket to be visualize is too friable implying sensible tissues such as nerves or open active bleeding wounds.

Warnings
1. Do not use in presence of flammable anaesthetics or gases.
2. The system should only be used by medical professionals with adequate training in general or plastic surgery.
3. Do not use the system in any other setting than a sterile OR environment where proper sterile technique can be applied.
4. If any malfunction or deformation is noted on the handpiece, the user should immediately exchange the components and return them to the producer for evaluation. No service of the equipment is to be carried out by the user.
5. No modification of this equipment is to be carried out by the user.
6. If leakage of battery fluid is detected, discard and replace the disposable handpiece.
7. Do not exchange batteries device is single use
8. Inspect sterile packaging prior to use. If packaging is damaged or compromised, discard disposable handpiece.
9. The handpiece unit is singe use only! DO NOT Re-sterilize.
10. Stacking or placing equipment adjacent to other devices is not recommended. Observe for reciprocal electrical interference posed by the presence of the device in the proximity of other electrical devices, if detected such interference, contact manufacture for advice.
11. Do not submerge the handpiece in water, ultra sonic cleaner, or disinfectant.

System components

Rigid “L” shape handle and a light opposite to the handle.

Guidelines to check proper functionality of the Retractor
A failure mode may be caused by end of life of the battery, improper use or improper storage. Careful inspection and functional test by turning ON/OFF the device before use is the best method determining the adequate safe and efficient performance of the device.

Typical failure modes
• Broken cables
• Battery reach end of life

Instructions For USE
1. Using sterile technique, open the sterile pack of the Retractor
2. After incision a proper cauterization shall be made.
3. Turn the power switch ON by pressing the button located at the top part of the retractor, no need to hold to continue being ON.
4. Turn OFF the LED light when needed by pressing again the button located at the top part of the retractor.
5. Use precautions according to hospital protocol for the operation and disposal of contaminated waste.

Battery Removal
1. Press the snap fit buttons on the side of the Handle to remove battery cap and pull out the Battery Pack.
2. Disconnect the small cable connection by pulling or cutting.

Disposal After USE
-Make sure to remove the battery pack in case of disposal.
-Ensure that the device is disposed of safely and in accordance with all current national and international waste disposal directives.
-Do not sterilize, nor submerge in water.
-For the correct method of disposal, please contact your local municipality, waste disposal services.

Please contact PulseLavage AB, in case of questions about setting up or operating the system. PulseLavage AB should be notified in the case of any unexpected operation or performance of the device.

(This IFU will be renewed on any significant change of product, product range, standards and laws, Change Management by date)

Symbols seen in the label:
Labelling Symbols


Patient information website


Unique Device Identification


Medical Device


Do not resterilize


Do not reuse


Manufacturer


Single sterile barrier system with protective packaging inside sterilized using ethylene oxide.


Humidity Limitation


Caution


Type BF APPLIED PART


Do not use if package is damaged


Consult instructions for use


Batch Code


Keep away from sunlight


Catalog Number


Use by date


Temperature Limit


Keep dry


Recycle alkaline battery

CLASS A GROUP 1

Reporting of Incident to Manufacturer (see below) & Competent Authority
In case any patient/user faces a serious incident, please IFU report the incident to the manufacturer, and the Competent Authority of the country where the user/patient resides.

Manufacturer:
Pulse Lavage AB
Rubanksgatan 8
74171 Knivsta, Sweden
Phone: +46-18-55 55 05
Fax: +46-18-51 50 50
E-mail: pulselavage@pulselavage.se
Web: www.pulselavage.se

CE
2862