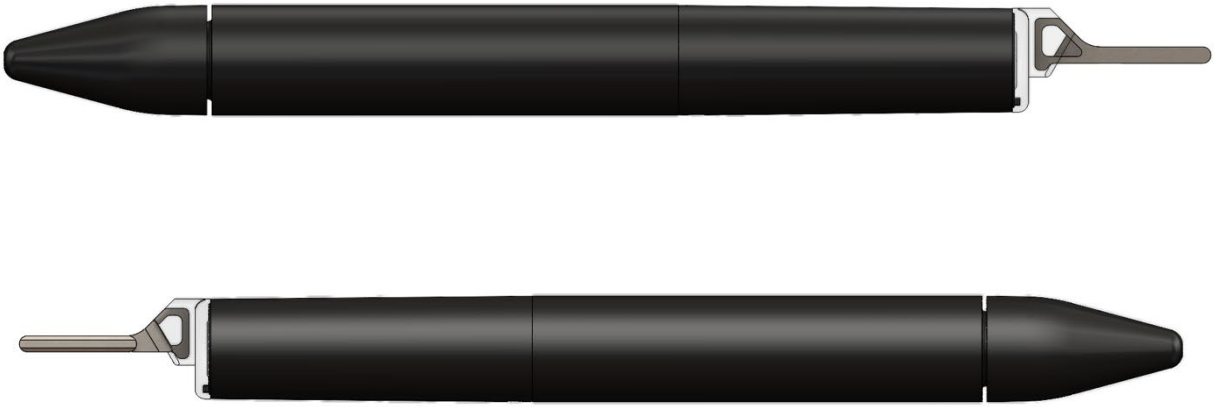
lumohs™ SCALPEL HANDLE - INSTRUCTIONS FOR USE - SURGICAL USE

DESCRIPTION



WHAT IS THE lumohs™ SCALPEL HANDLE - SURGICAL

Surgical scalpels consist of two parts, a blade and a handle. The handles are reusable, with the blades being replaceable. In medical applications, each blade is only used once (even if just for a single, small cut).

The **lumohs™ scalpel handle** ('lumohs') has twin led's, battery, and an electrical circuit within the scalpel handle that provides light during use of the scalpel by a physician. The on-off switch for the lumohs light is located at the end of the lumohs opposite the blade attachment and is denoted by the symbols shown in Table 2. Rotating the end clockwise towards the 'on' symbol turns the lumohs 'on' and rotating the end counter-clockwise towards the 'off' symbol turns the lumohs off. The lumohs™ scalpel handle is made primarily from medical grade autoclavable plastic (UDEL) and includes electrical parts that support the function of the device.

CONTENTS

The package contains one **lumohs™ scapel handle** and one **lumohs™ authorized battery pack**.

INDICATIONS AND INTENDED USER

INTENDED USE

The lumohs™ scalpel handle provides a means for attaching the blades listed below and the combination is intended for dermatology, reconstructive, cosmetic or similar surgical procedures that require a sharp surgical blade to puncture or cut tissue.

INTENDED USER

Intended to be used by Healthcare Professionals.

BLADES, BLADE REPLACEMENT, AND DISPOSAL

The following blades can be used with the lumohs™ scalpel handle: #15, #10, #11, #12, and also# 18,# 20, #21, #24 and # 6, #14, #19 , #25 and #10, #10 R, #10 D, #10 S,

CAUTION:

Blade should be attached to handle using proper instruments and should not be attached using hands and fingers.

For removing blades, normally use blade remover devices such as: Swann-Morton Scalpel Blade Remover; Feather Surgical Blade Remover (2990); Integra™ Miltex™ Blade-Safe Surgical Blade Remover; or Tiemann Scalpel Blade Remover (105-60). If such a device is not available blades can be removed by using artery forceps or needle holders to grasp the end of the blade nearest the handle on the blunt edge. Lift up the blade, bending it slightly (while being careful not to snap the blade) and slide it forward and off the handle, always pointing away from you and others.

Dispose of filled blade remover devices such as the Swann-Morton Scalpel Blade Remover according to facility protocol and all applicable federal, state, regional, and/or local laws and regulations. Dispose of individual blades in an approved puncture resistant sharps container and dispose of the sharps container in a similar manner as the filled blade remover devices.

BATTERIES

The lumohs authorized battery pack are made up of two AAAA alkaline batteries that are in a specific packaging configuration for optimal use in the lumohs™ scalpel handle. The rating of the battery combination is 3V DC. It is recommended that you ONLY use the lumohs authorized battery pack as the use of any other batteries will void the warranty. Note that the chemical make-up of different batteries can affect the lighting life expectancy or safety of the lumohs scalpel handle.

To prolong battery life, switch the lumohs light off when not in use. Store unused battery packs in a cool dry location. Temperature and humidity affect the life of the lumohs battery pack.

BATTERY INSTALLATION AND REPLACEMENT

Unscrew (twist counter clockwise) the rear end cap opposite the blade side of lumohs™ scalpel handle. Remove the rear end cap. The battery pack is located in the barrel of the lumohs. Remove the battery pack and dispose according to facility protocol. Insert a new battery pack into barrel following the orientation symbol on the barrel. Ensure spring on circular metal end plate is positioned in the back of the rear end cap with the spring in the center of the end cap. Screw rear end cap back into place by twisting end cap clockwise. The last quarter turn clockwise will cause lumohs to turn on. Turn lumohs device on and off to ensure that battery replacement was done correctly.

ATTENTION:

USE ONLY AUTHORIZED LUMOHS BATTERY PACKS.

DO NOT USE NICKEL HYDRIDE RECHARGEABLE BATTERIES. DO NOT USE LITHIUM BATTERIES. USE ONLY THE LUMOHS BATTERY PACKS.

DO NOT INSTALL A BATTERY PACK INTO THE LUMOHS HANDLE UNTIL THE HANDLE IS FULLY COOLED AFTER MOIST HEAT STERILIZATION.

DO NOT INSTALL THE BATTERY PACK BACKWARDS- SEE DIRECTIONAL DIAGRAM ON HANDLE.

WARNING:

EXPLOSION HAZARD – REMOVE BATTERY PACK BEFORE STERILIZATION. DO NOT AUTOCLAVE WITH THE BATTERY PACK IN THE HANDLE OF LUMOHS DEVICE.

EXPLOSION HAZARD - DO NOT CHARGE BATTERIES. DO NOT PUT BATTERIES IN A FIRE OR MIX WITH OTHER BATTERY TYPES AS THIS MAY CAUSE EXPLOSION OR LEAK CAUSING INJURY. DO NOT OPEN OR MANIPULATE LUMOHS BATTERY PACKS.

PROCESSING BEFORE INITIAL USE

WARNING:

THE PACKAGED LUMOHS SCALPEL HANDLE WHEN RECEIVED IS **NOT STERILE**.
PREPARE FOR STERILIZATION BY ENSURING THAT THE **LUMOHS BATTERY PACK IS REMOVED** AND STORED. FOLLOW THE **STERILE WRAP FOR STERILIZATION**, **STERILIZATION**, **AND STORAGE** STEPS BELOW.

PROCESSING AFTER USE

ATTENTION: START THE CLEANING PROCESS AS SOON AS POSSIBLE AFTER THE PROCEDURE IS COMPLETED **BUT NO MORE THAN ONE HOUR** AS RESIDUAL MATERIAL MAY DRY AND AFFECT CLEANING EFFICACY.

CLEANING

The following steps should be followed:

PRE-TREATMENT

1) For cleaning, follow your facilities recommendations regarding personal protective equipment for blood removal.
2) **Remove** gross contamination by rinsing with a shower or spray gun, or similar
3) **Remove** remaining excessive soiling from the exterior of the lumohs™ scalpel handle with disposable wipe(s).

REMOVAL OF BLADE AND BATTERY ASSEMBLY

4) **Remove** and **Dispose** of blade. (See Blades and Blade Replacement.) Dispose of blade in an approved puncture resistant sharps container according to facility protocol and all applicable federal, state, regional, and/or local laws and regulations.
5) **Unscrew and Remove** battery assembly from device. (See Battery Installation and Replacement)
6) **Clean** battery assembly with disposable wipe(s), if soiled, and store.
7) **Screw** rear end cap back fully on the lumohs™ scalpel handle.

CLEANING

8) **Prepare** a cleaning solution (Enzymatic/Detergent) proven efficacy and neutral pH 7~9 in accordance to the manufacturer's instructions.
9) **Follow** manufacturer's instructions concerning materials, temperature, water quality, and cleaning method.
10) **Immerse** the soiled lumohs™ scalpel handle to ensure that all surfaces have contact with the enzyme solution for at least four (4) minutes.
11) **Brush** the lumohs™ scalpel handle with clean soft bristled brush to remove all traces of blood and other matter for at least two (2) minutes **finishing with focused brushing at any crevices of the device**.
12) **Flush** and rinse the lumohs™ scalpel handle in cold tap water for at least one (1) minute.

STERILE WRAP FOR STERIZATION

1) **Unscrew** rear end cap from the lumohs™ scalpel handle and separate the lumohs into two parts.

2) **Place** the two parts of the lumohs in a sterilization wrap. Use only a FDA-cleared sterilization wrap and should be double wrapped (reference ISO 11607-1).

STERILIZATION- Moist Heat Sterilization - Prevacuum

Follow the sterilization protocol for your facility but for reference the following are the sterilization guidelines from the CDC for prevacuum sterilization.

TABLES AND FIGURE: TABLE 1
CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

Minimum cycle times for steam sterilization cycles - Prevacuum

Type of Sterilizer	Item	Exposure time at 270^0 F (132^0 C)	Drying time
Dynamic-air-removal (e.g. prevacuum)	Wrapped instruments	4 min	30 min

MOIST HEAT STERILIZATION VALIDATION – lumohs™ Scalpel Handle

Within the barrel of the lumohs™ scalpel handle was placed a biological indicator (BI) inoculated with more than one million (10^6) resistant spores (Geobacillus stearothermophilus) . This location represented a challenging location for sterilization. Both the barrel of the lumohs handle and end-cap were placed within a sterilization wrap system meeting ISO 11607-1, *Packaging for terminally sterilized medical devices -Part 1*. The sterilization wrap was loaded in an empty chamber of the steam sterilizer and was validated to a 10^{-6} sterility assurance level (SAL) by the overkill method where a half-cycle resulted in total kill of all Bi's in accordance with Annex D of ISO 17665-1, *Sterilization of health care products – moist heat*.

STORAGE

After sterilization, the lumohs™ scalpel handle should be stored in the sterilization wrap in a dry and dust free place. The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions and handling. A maximum shelf life for sterilized reusable instruments before use should be defined by each health care facility. Instruments must be examined for possible damage before use.

INSPECTION AND REASSEMBLY PRIOR TO USE

Reassemble the lumohs™ scalpel handle by inserting lumohs battery packs into barrel following the orientation symbol on the barrel. Ensure spring on circular metal end plate is positioned in the back of the rear end cap with the spring in the center of the end cap. Screw rear end cap back into place by twisting end cap clockwise. (Note- The last quarter turn clockwise will cause lumohs scalpel handle to turn on.) Turn lumohs device on and off to ensure that the battery replacement was done correctly and that the light is working correctly. See battery installation and replacement instructions. Install correct blade using proper instruments. Blade should not be attached using hands and fingers.

WARNING: ACCIDENTAL DROP OR MECHANICAL IMPACT

IF THE LUMOHS™ SCALPEL HANDLE IS DROPPED OR MECHANICALLY IMPACTED, EXAMINE THE TIP WHERE THE BLADE IS ATTACHED FOR DAMAGE. REMOVE THE LUMOHS DEVICE FROM SERVICE IF THE TIP IS DAMAGED. IF THE TIP APPEARS UNDAMAGED, UNINSTALL AND/OR INSTALL A NEW BLADE TO CONFIRM THAT BLADE PLACEMENT IS CORRECT. IF BLADE PLACEMENT IS NOT CORRECT, REMOVE THE LUMOHS DEVICE FROM SERVICE. REPEAT THE CLEANING AND STERILIZATION STEPS IF THE LUMOHS DEVICE IS USABLE AFTER BEING DROPPED OR MECHANICALLY IMPACTED.

EXPECTED SERVICE LIFE

The expected service life for the for the lumohs™ scalpel handle has been verified up to twenty-five (25) CLEANING and STERILIZATION cycles. Service life may be longer however this has not been verified.

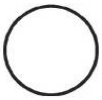
DISPOSAL INFORMATION

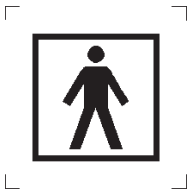
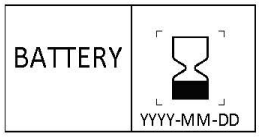
The lumohs™ scalpel handle when disposed of represents a potential biohazard, since it may be contaminated with blood or other body fluids, bone or other tissue. Handle and dispose of this product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

Any sharp objects should be disposed of immediately after use into a sharps container conforming to national, state and local laws. The sharp object must not be bent, broken or resheathed prior to disposal.

INFORMATION

Symbols Glossary

Symbol	Title and Designation Number for Standard	Title of Symbol and Reference No.	Symbol Meaning
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Attention ISO 7000-0434A	Device use needs operator awareness or operator action to avoid undesirable consequences"
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Consult instructions for use ISO 7000-1641	Consult instructions for use
	IEC 60417: Graphical symbols for use on equipment 5-102	Battery orientation IEC 60417, No. 5002	Proper orientation of anode and cathode of battery within well
	IEC 60417: Graphical symbols for use on equipment 5-102	On power IEC 60417, No. 5007	'On' power symbol to denote switch position that turns the device on
	IEC 60417: Graphical symbols for use on equipment 5-102	Off power IEC 60417, No. 5008	'Off' power symbol to denote switch position that turns the device off
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	LOT symbol ISO 7000-2492	Version, month, and year of lot manufacture for device
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Non sterile ISO 7000-2609	Indicates device is not sterilized

Symbol	Title and Designation Number for Standard	Title of Symbol and Reference No.	Symbol Meaning
	ISO 15223 – 1: Medical devices – Symbols to be used with information supplied by the manufacturer Part 1 5-134	Medical Device ISO 15223-1, 5.7.7	Medical Device
	IEC 60417: Graphical symbols for use on equipment 5-102	Direct current symbol IEC 60417, No. 5031	Direct current
	IEC 60417: Graphical symbols for use on equipment 5-102	Battery symbol IEC 60417, No. 5001B	Battery operated
$R_{x\ only}$	21 CFR 801.109 (b)(1)	Prescriptive device symbol	Symbol meaning – Caution: Federal law restricts this device to sale by or on the order of a physician (or dentist)
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Fragile, handle with care ISO 7000-0621	Indicates a medical device that can be broken or damaged if not handled with care.
	IEC 60417: Graphical symbols for use on equipment 5-102	Type BF Applied Part IEC 60417, No. 5333	Indicates that the applied part provides a higher degree of protection against electrical shock than Type B. Not suitable for cardiac application.
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Battery Expiration Symbol ISO 7000-2607	Indicates lumohs battery is not to be used after the date indicated under the hour glass.
IP_{22}	IEC 60529	Ingress protection rating	Protected against solid foreign objects ≥12.5mm. Protected against vertically falling water drops with enclosure tilted at 15 degrees.

Symbol	Title and Designation Number for Standard	Title of Symbol and Reference No.	Symbol Meaning
	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Keep packaging dry ISO 7000-0626	Keep packaging dry to protect medical device.
			Recycle symbol
+50^0 C  - 18^0 C	ISO 7000: Graphical symbols for use on equipment- Registered symbols 5-124	Transport or storage temperature range ISO 7000-0632	Indicates that the lower temperature range for storage/transport is -18^0 C and the upper is +50^0 C
	Not Applicable	SGS NRTL Mark Mark is a proprietary mark of SGS	Indicates that device was tested and found to comply with ANSI/AAMI ES60601-1:2005/A2:2021 and CAN/CSA-C22.2 No. 60601-1:14

SAFETY INFORMATION

- Protection Against Electric Shock (Section 6.2, IEC 60601-1) - The classification of the lumohs™ scalpel handle is as an INTERNALLY POWERED ME EQUIPMENT with Type BF Applied Part.

- Protection Against Harmful Ingress of Water and Particulate Matter (Section 6.3, IEC 60601-1) - The classification of the lumohs™ scalpel handle is IP_{22}.

- Mode of Operation (Section 6.6, IEC 60601-1) - The mode of operation of the lumohs™ scalpel handle is CONTINUOUS OPERATION.

WARNING: NO MODIFICATION OF THE DEVICE IS ALLOWED. THERE ARE NO SERVICEABLE PARTS OTHER THAN BATTERY REPLACEMENT.

ELECTROMAGNETIC COMPATIBILITY

FCC:

Supplier's Declaration of Conformity
47 CFR § 2.1077 Compliance Information

Unique Identifier: lumohs™ Scalpel Handle

Responsible Party – U.S. Contact Information

Nano Surgical LLC
230 George Bush Blvd., Suite B
Delray Beach, FL.
33444 USA

1-888-586-6478; www.lumohs.com

FCC Compliance Statement:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IEC 60601-1-2 (CISPR 11):

The lumohs™ Scalpel Handle is a Class B, Group 1 Device (§5, CISPR 11) and meets the limits shown for electromagnetic radiation disturbance. [Class B equipment is equipment suitable for use in locations in residential environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.]	Frequency Range MHz	Quasi-peak dB(uV/m)*
	30 – 230	40
	230 - 1000	47

*3m measuring distance applicable to *small size equipment*.

ESSENTIAL PERFORMANCE - The essential performance of the lumohs™ scalpel handle is as a means for attaching scalpel blades. The LED light function is not part of the essential performance of the device.

WARNING: USE OF THIS EQUIPMENT ADJACENT TO OTHER EQUIPMENT SHOULD BE AVOIDED BECAUSE IT COULD RESULT IN IMPROPER OPERATION. IF SUCH USE IS NECESSARY, THIS EQUIPMENT AND OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THAT THEY ARE OPERATING NORMALLY.

Nano Surgical LLC, 230 George Bush Blvd., Delray Beach, Florida 33444

WARNING: DO NOT USE WITH HF SURGICAL EQUIPMENT AS COMPATIBILITY HAS NOT BEEN DETERMINED.

GENERAL SPECIFICATIONS

ELECTRICAL

Operating Voltage - 3V
Current - ~ 100mA

LUMINOSITY

LED Brightness– @39-41 lumen (minimum)
Estimated Run Time – @5 hours
Intensity at 1" from target tissue- @800 lux (minimum)

MECHANICAL

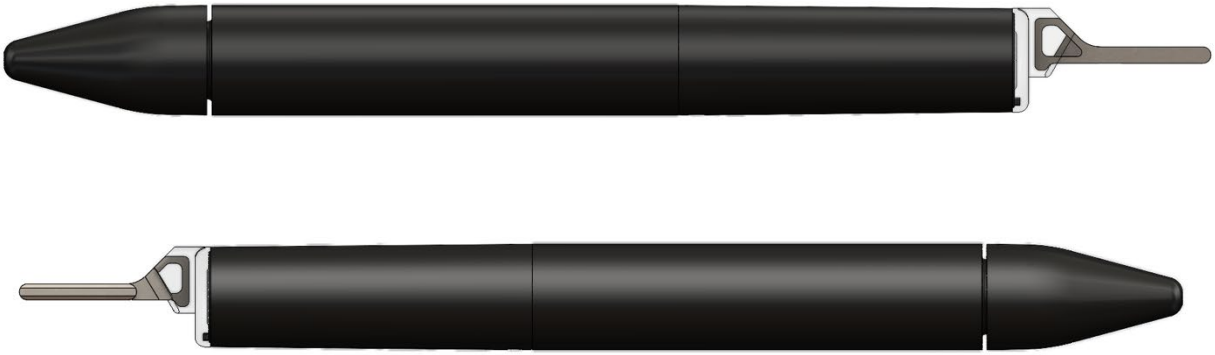
Meets ISO 7740: 1985 – Instruments for surgery – Scalpels with detachable blades – Fitting dimensions

ENVIRONMENTAL

Operating Temperature - +5^{o} C to + 40^{o} C
Transport Temperature - -18^{o} C to +50^{o} C
Humidity - 15% to 90% noncondensing

lumohs™ SCALPEL HANDLE (DERMAPLANE) - INSTRUCTIONS FOR USE

DESCRIPTION



WHAT IS THE lumohs™ SCALPEL HANDLE (DERMAPLANE)

The lumohs™ scalpel handle used by estheticians, dermatologists, or cosmetic surgeons in a dermaplane cosmetic procedure is exactly the same device physically, mechanically, and electrically as the lumohs™ scalpel handle used for surgical use. There are certain labeling differences.

CONTENTS

The package contains one **lumohs™ scapel handle (Dermaplane)** and one **lumohs™ authorized battery pack**.

INDICATIONS AND INTENDED USER

INTENDED USE

The lumohs™ scalpel handle (Dermaplane) is used in a cosmetic procedure (Dermaplaning) that removes the top layer of dead skin cells with typically a 10-gauge blade attached to the lumohs™ scalpel handle. This method of exfoliation is performed by a certified esthetician,dermatologist, or cosmetic surgeon. The lumohs™ scalpel handle used in combination with a blade for this cosmetic purpose is not a medical device as it does not diagnose, treat, prevent, cure or mitigate any disease.

INTENDED USER

Intended to be used by a certified esthetician, dermatologist, or cosmetic surgeon performing exfoliation for cosmetic purposes.

BLADES, BLADE REPLACEMENT, AND DISPOSAL

The following blades can be used with the lumohs™ scalpel handle (Dermaplane): #10, #10 R, #10 D, #10 S, and #14.

CAUTION:

Blade should be attached to handle using proper instruments and should not be attached using hands and fingers.

For removing blades, normally use blade remover devices such as: Swann-Morton Scalpel Blade Remover; Feather Surgical Blade Remover (2990); Integra™ Miltex™ Blade-Safe Surgical Blade Remover; or Tiemann Scalpel Blade Remover (105-60). If such a device is not available blades can be removed by using artery forceps or needle holders to grasp the end of the blade nearest the handle on the blunt edge. Lift up the blade, bending it slightly (while being careful not to snap the blade) and slide it forward and off the handle, always pointing away from you and others.

Dispose of filled blade remover devices such as the Swann-Morton Scalpel Blade Remover according to facility protocol and all applicable federal, state, regional, and/or local laws and regulations. Dispose of individual blades in an approved puncture resistant sharps container and dispose of the sharps container in a similar manner as the filled blade remover devices.

BATTERIES

The lumohs authorized battery pack are made up of two AAAA alkaline batteries that are in a specific packaging configuration for optimal use in the lumohs™ scalpel handle (Dermaplane). The rating of the battery combination is 3V DC. It is recommended that you ONLY use the lumohs authorized battery pack as the use of any other batteries will void the warranty. Note that the chemical make-up of different batteries can affect the lighting life expectancy or safety of the lumohs scalpel handle.

To prolong battery life, switch the lumohs light off when not in use. Store unused battery packs in a cool dry location. Temperature and humidity affect the life of the lumohs battery pack.

BATTERY INSTALLATION AND REPLACEMENT

Unscrew (twist counter clockwise) the rear end cap opposite the blade side of lumohs™ scalpel handle (Dermaplane). Remove the rear end cap. The battery pack is located in the barrel of the lumohs. Remove the battery pack and dispose according to facility protocol. Insert a new battery pack into barrel following the orientation symbol on the barrel. Ensure spring on circular metal end plate is positioned in the back of the rear end cap with the spring in the center of the end cap. Screw rear end cap back into place by twisting end cap clockwise. The last quarter turn clockwise will cause lumohs to turn on. Turn lumohs device on and off to ensure that battery replacement was done correctly.

ATTENTION:

USE ONLY AUTHORIZED LUMOHS BATTERY PACKS.

DO NOT USE NICKEL HYDRIDE RECHARGEABLE BATTERIES. DO NOT USE LITHIUM BATTERIES. USE ONLY THE LUMOHS BATTERY PACKS.

DO NOT INSTALL A BATTERY PACK INTO THE LUMOHS HANDLE UNTIL THE HANDLE IS FULLY COOLED AFTER MOIST HEAT STERILIZATION.

DO NOT INSTALL THE BATTERY PACK BACKWARDS- SEE DIRECTIONAL DIAGRAM ON HANDLE.

WARNING:

EXPLOSION HAZARD – REMOVE BATTERY PACK BEFORE STERILIZATION. DO NOT AUTOCLAVE WITH THE BATTERY PACK IN THE HANDLE OF LUMOHS DEVICE.

EXPLOSION HAZARD - DO NOT CHARGE BATTERIES. DO NOT PUT BATTERIES IN A FIRE OR MIX WITH OTHER BATTERY TYPES AS THIS MAY CAUSE EXPLOSION OR LEAK CAUSING INJURY. DO NOT OPEN OR MANIPULATE LUMOHS BATTERY PACKS.

PROCESSING BEFORE AND AFTER INITIAL USE

INITIAL USE

The packaged lumohs™ scalpel handle (Dermaplane) when received has not been cleaned or disinfected for use. As applicable, follow state or local regulatory guidelines for cleaning and disinfecting instruments for cosmetology to process the lumohs scalpel handle for initial use.

CLEANING AND DISINFECTING AFTER INITIAL USE

As applicable, follow state or local regulatory guidelines for cleaning and disinfecting instruments for cosmetology during the life of the lumohs™ scalpel handle (Dermaplane)

WHEN SURGICAL STERILE TECHNIQUE IS REQUIRED : CLEANING AND STERILIZATION BEFORE AND AFTER INITIAL USE

If cleaning in combination with moist heat sterilization (autoclave) is required as part of your professional practice please see all of the instructions and information for *PROCESSING AFTER USE* in the lumohs™ scalpel handle (surgical) section of this instructions for use. This specific form of cleaning and sterilization is the ONLY method that has been validated.

ATTENTION:

IF IMMERSING THE LUMOHS™ SCALPEL HANDLE (DERMAPLANE) UNSCREW AND REMOVE THE BATTERY ASSEMBLY FROM THE DEVICE. FOR BATTERY REMOVAL AND REPLACEMENT SEE BATTERY *INSTALLATION AND REPLACEMENT* ABOVE.

WARNING: ACCIDENTAL DROP OR MECHANICAL IMPACT

IF THE LUMOHS™ SCALPEL HANDLE (DERMPLANE) IS DROPPED OR MECHANICALLY IMPACTED, EXAMINE THE TIP WHERE THE BLADE IS ATTACHED FOR DAMAGE. REMOVE THE LUMOHS DEVICE FROM SERVICE IF THE TIP IS DAMAGED. IF THE TIP APPEARS UNDAMAGED, UNINSTALL AND/OR INSTALL A NEW BLADE TO CONFIRM THAT BLADE PLACEMENT IS CORRECT. IF BLADE PLACEMENT IS NOT CORRECT, REMOVE THE LUMOHS DEVICE FROM SERVICE. REPEAT APPLICABLE CLEANING AND/OR DISINFECTION STEPS IF THE LUMOHS DEVICE IS USABLE AFTER BEING DROPPED OR MECHANICALLY IMPACTED.

DISPOSAL INFORMATION

Follow state or local regulatory guidelines for disposing of the lumohs™ scalpel handle (Dermaplane). Any sharp objects should be disposed of immediately after use into a sharps container conforming to national, state and local laws. The sharp object must not be bent, broken or resheathed prior to disposal.

INFORMATION

See Symbols Glossary above at pp. 6-9 for a definition of symbols used on the lumohs™ scalpel handle (Dermaplane) device and packaging. This includes specific information for the device and packaging. Please note that the following symbols do not apply to the lumohs™ scalpel handle (Dermaplane) as it is not a medical device:

Rx

GENERAL SPECIFICATIONS

ELECTRICAL

Operating Voltage - 3V
Current - ~ 100mA

LUMINOSITY

LED Brightness– @39-41 lumen (minimum)
Estimated Run Time – @5 hours
Intensity at 1" from target tissue- @800 lux (minimum)

MECHANICAL

Meets ISO 7740: 1985 – Instruments for surgery – Scalpels with detachable blades – Fitting dimensions

ENVIRONMENTAL

Operating Temperature - +5° C to + 40° C
Transport Temperature - -18° C to +50° C
Humidity - 15% to 90% noncondensing

ADVERSE INCIDENT REPORTING

FOR ALL USERS, IF ANY SERIOUS INCIDENT HAS OCCURRED IN RELATION TO THE DEVICE , IT SHOULD BE REPORTED TO THE MANUFACTUREER AND COMPETENT AUTHORITY IN WHICH THE USER OR PATIENT IS ESTABLISHED.

FOR FURTHER INFORMATION, PLEASE CONTACT:

Nano Surgical LLC
230 George Bush Blvd., Suite B
Delray Beach, FL. 33444 USA
1-888-LUMOHS-8
www.lumohs.com

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