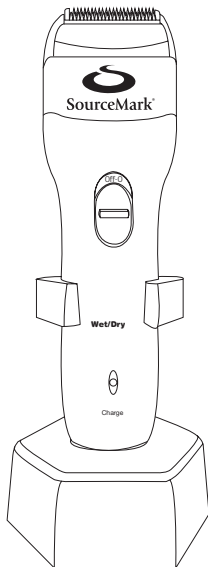




SourceMark®

SOURCEMARK ELECTRICAL CLIPPER WITH CHARGING BASE

INSTRUCTIONS FOR USE



REF SMCLIPPER

REF SMHANDLE

ELECTRICAL CLIPPER WITH CHARGING BASE

REF SMCLIPPER – Electric Surgical Clipper and Charging Base

REF SMHANDLE – Electric Surgical Clipper

REF SMBLADEU – Universal Blade Attachment

REF SMBLADEC – Coarse Hair Blade Attachment

REF SMBLADEN – Narrow Blade Attachment

REF SMBLADEUF – Universal Clipper Blade, Flat Style

REF SMBLADECF – Coarse Hair Clipper Blade, Flat Style

REF SMBLADENF – Narrow Clipper Blade, Flat Style

IMPORTANT: Read all instructions thoroughly before using this product.

PRODUCT DESCRIPTION:

The Electric Surgical Clipper is a cordless, rechargeable, battery-operated clipper with single patient use disposable blades. The charging base is a separate unit with an attached electrical cord. The blade attachments are interchangeable to fit onto the Electric Surgical Clipper, depending on the use of the attachment.

INDICATIONS FOR USE:

The Electric Surgical Clipper is intended for the removal of body hair from patients as required prior to surgery or other minor procedures.

The clipper is safe to use with wet or dry hair. For best performance, clip wet hair. To avoid cross contamination, use a new blade for each patient.

WHAT BLADE TO USE:

REF SMBLADEU – Universal Attachment – for all hair clipping.

REF SMBLADEC – Coarse Hair Attachment – for coarse or thicker hair clipping. Primarily used for scalp hair. Important to pull

skin taut when using this blade.

REF SMBLADEN – Narrow Area Attachment – for clipping hair in narrow areas and crevices. Important to pull skin taut when using this blade.

REF SMBLADEUF – Universal Flat Style Blade.

REF SMBLADECF – Coarse Hair Flat Style Blade.

REF SMBLADENF – Narrow Flat Style Blade.

WARNINGS:

When using this surgical clipper, basic precautions should always be followed. Please read and understand all safety information before using.

1. Use this clipper only for its intended use as explained in this insert.
2. The clipper must only be used with the charger provided.
3. Do not submerge charging adapter in water or any other liquid. Do not store the charging adapter near water. Should the charging adapter fall into water or any other liquid, immediately unplug the charger from the wall unit before attempting to retrieve the adapter.
4. If hands are wet, do not attempt to plug or unplug the charger from an electrical unit.
5. Keep the charging adapter cord away from heated surfaces.
6. Do not replace the supply cord.
7. Always unplug the charger prior to cleaning.
8. If blade becomes damaged, do not use. Replace blade according to instructions.
9. Do not sterilize blade or charger.
10. To avoid risk of fire or explosion, do not use near flammable anesthetics, aerosol sprays, or oxygen-administering equipment other than those administered via nasal cannulas or masks.
11. This product has been tested according to Electromagnetic Compatibility Testing per IEC60601-1-2. This unit does not run the risk

of discharging radiation and affecting other equipment. If undesirable performance is experienced, discontinue use of product.

- 12.** Do not use or charge the clipper if it has a damaged plug or cord.
- 13.** Do not charge in the vicinity of the patient.
- 14.** To turn off charging adapter, disconnect the plug from the main power source.
- 15.** Do not use clipper on injured skin.
- 16. WARNING:** No modification of this equipment is allowed.

INSTRUCTIONS FOR USE:

To charge the clipper body:

Your surgical clipper may initially arrive with a limited charge. Before use, it should be charged for 12 hours. To recharge, place clipper in charging adapter. Make sure the indicator light is on to ensure proper connection to the charging adapter. A completely depleted battery will require 12 hours of charging time. Damage will not result from over-charging the battery.

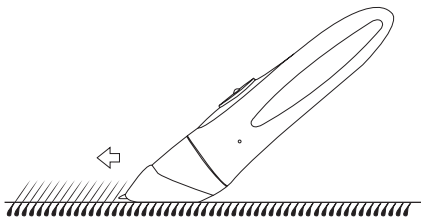
To attach blade:

Make sure that the on/off switch is in the off position.

Line up the small line on the side of the clipper blade with the first (upward) small line on the clipper handle. Fit the blade on the handle by pushing downward until the line on the clipper blade lines up with the second (lower) line on the clipper and it will click into place.

To use clipper:

Patient's skin should be clean. Attach blade per instructions. Place On/Off switch in the on position. Hold the clipper body so that the blade assembly is flat against the patient's skin and use short gentle strokes. For best results, clip against the direction of hair growth. For problem areas, stretch the skin taut while clipping. When finished, place On/Off switch in the off position. Remove blade when not in use.

**To remove blade:**

Make sure the On/Off switch is in the off position. Position the clipper over an appropriate waste receptacle with the metal part of the blade facing downward and the back of the clipper facing up. Push the blade away from the clipper to release the blade. When not in use, after cleaning and drying, place clipper body in the charging adapter for charging and safe storage. Contact your Representative to order replacement blades. The blades are intended for single patient use.

Item numbers:

SMBLADEU: Surgical Clipper
Universal Single-Use Blades, 50/case.

SMBLADEC: Surgical Clipper
Coarse Hair Single-Use Blades, 50/case.

SMBLADEN: Surgical Clipper
Narrow Area Single-Use Blades, 50/case.

SMBLADEUF: Surgical Clipper
Universal Clipper Blade, Flat Style, 50/case.

SMBLADECF: Surgical Clipper
Coarse Hair Clipper Blade, Flat Style, 50/case.

SMBLADENF: Surgical Clipper
Narrow Clipper Blade, Flat Style, 50/case.

Wall Mount Instructions: (Optional)

To install optional wall mount:

1. Select an appropriate location on the wall using the screws provided.
2. Attach the detachable wall mount with screws making sure that the arrow on the back (flush part) points up.
3. Slide the charging adapter grooves downward into the wall mount until it clicks. To remove the charging adapter from the wall mount, disengage and slide the adapter upward.

Care and Cleaning of the Clipper Body:

Always unplug the charging adapter before cleaning. To remove loose hair and other gross debris from clipper, place under running water or soak in a water bath. Wipe the clipper with a damp cloth containing a non-corrosive disinfectant, such as: Isopropyl-Alcohol, OPA (Ortho-phthaldehyde), 2% glutaraldehyde or any other non-corrosive disinfectant wipe. Dry clipper with a clean towel. Return clipper to either the charging adapter or to a storage area.

Specifications:

Power Source: AC 100 – 240V 50-60Hz 0.2A

Charger Output/Clipper Input: DC 3.3V 100mA

Motor Voltage: DC 2.4V

Mode of Operation: Continuous Operation

Battery: 2x Ni-MH (AA 600mAh - 1.2 Vdc)

Environment:	Operation	Storage Transport
Temperature:	+0°C to +40°C	-10°C to +60°C
Humidity:	30% - 75% RH	10% - 100% RH
Pressure:	700hPa – 1060hPa	500hPa – 1060hPa



Caution- Read accompanying documentation



Double Insulated

IPX7 Watertight equipment



Type B Applied Part

ETL CLASSIFIED



Intertek
4007556

SMCLIPPER/SMHANDLE SURGICAL CLIPPER WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI STD.ES60601-1 AND CAN/CSA STD. C22.2 NO.60601-1

Notes:

- Charge at room temperature of +41°F (+5°C) to +95°F (+35°C).
- Avoid charge in direct sunlight or near radiating heat.
- When not used for extended periods of time, charge every six months to preserve battery life.
- Clipper contains a Ni-Mh battery. Dispose of at an officially assigned location, if available.
- The battery in this clipper is not intended to be replaced by users.

Environmental Protection/Recycling of Material:

This clipper contains a nickel metal hydride battery, which does not need to be replaced. When discarding the clipper, it must be recycled or disposed of properly according to local ordinances.

Limited Warranty:

The surgical clipper is protected against defect in material and workmanship under normal use for a period of two (2) years from the date of purchase. This warranty does not cover damage caused by misuse, negligence, accident, abuse or alteration, modification of the units by anyone other than the original manufacturer, affixation of any accessory not distributed by SourceMark, or use of the surgical clipper with current or voltage other than that specified in the instruction insert. Medline is not liable in either tort or contract for any loss of damage, whether direct,

consequential, special, collateral, or incidental arising out of the use, misuse, or inability to use this product. For any questions, please contact your medline Representative.

This equipment has been tested and found to comply with the limits for the medical devices to the IEC60601-1-2, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to the other devices which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from the that to which the other device(s) are connected
- Consult the manufacturer or field service for help

EMC Information of Medline Electrical Clipper with Charging Base, SMCLIPPER/SMHANDLE Series

SourceMark Electrical Clipper with Charging Base, SMCLIPPER/SMHANDLE Series needs special precautions regarding EMC and needs to be used according to the following EMC information. Portable and mobile RF Communications equipment can affect SourceMark Electrical Clipper with Charging Base, SMCLIPPER/SMHANDLE Series. The Surgical Clippers have not been evaluated for proximity to RFID readers or NFC transmitters, hence, the clippers should not be used near RFID or NFC transmitters.

WARNING: The use of the charging adapter other than the SourceMark Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE series may result in increased emissions or decreased immunity of SourceMark Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE Series.

WARNING:

SourceMark Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE Series should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, SourceMark Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE Series should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration – Electromagnetic Emission –

SourceMark Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE Series is intended for use in the electromagnetic environment specified below. The customer or the user of SourceMark Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE Series should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance –
RF emissions CISPR 11	Group 1	SourceMark Electrical Clipper Charging Base, SMCLIPPER/ SMHANDLE Series uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	SourceMark Electrical Clipper Charging Base, SMCLIPPER/ SMHANDLE Series is suitable use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
RF emissions CISPR 11	Professional healthcare facility environment	Same as Group 1

Guidance and Manufacturer's Declaration – Electromagnetic Immunity –

SourceMark Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE Series is intended for use in the electromagnetic environment specified below. The customer or the user of SourceMark Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE Series should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance –
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV for differential mode	±1 kV for differential mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_T$ ($>95\%$ dips in U_T for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dips in U_T for 5 cycle	$<5\% U_T$ ($>95\%$ dips in U_T for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dips in U_T for 5 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c mains voltage prior to application of the test level			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity –

REF SMCLIPPER/SMHANDLE Series is intended for use in the electromagnetic environment specified below. The customer or the user of REF SMCLIPPER/SMHANDLE Series should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance –
Conducted RF IEC 61000-4-6	3 V/m 0.15MHz-80MHz 6 V/m ISM frequency band	3 V/m 6 V/m	Portable and mobile RF communications equipment should be used no closer to any part of SourceMark Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE Series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2700 MHz	3 V/m	

NOTE 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a.** Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which REF SMCLIPPER/SMHANDLE Series is used exceeds the applicable RF compliance level above, REF SMCLIPPER/SMHANDLE Series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation REF SMCLIPPER/SMHANDLE Series.
- b.** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 2 V/m.

Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and Medline Electrical Clipper Charging Base, SMCLIPPER/SMHANDLE Series

REF SMCLIPPER/SMHANDLE Series is intended for use in the electromagnetic environment in which RF disturbances are controlled. The customer or the user of REF SMCLIPPER/SMHANDLE Series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and REF SMCLIPPER/SMHANDLE Series as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separations Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 kHz to 800 MHz $d = 1.2 \sqrt{P}$	800 kHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.