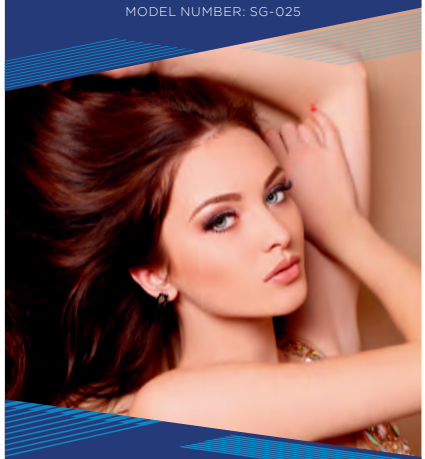
SERUGLOW™
MICRO INFUSION SYSTEM

SYMBOLS LEGEND			
	Manufacturer		Date of Manufacture
REF	Catalog Number		Consult Instructions for Use
QTY	Quantity	LOT	Lot Number
	Caution		Do not reuse
	Keep Dry	STERILE EO	Sterilized by ethylene oxide
	Do not resterilize		Fragile, handle with care
	Not made with natural rubber latex		Keep away from sunlight

P/N 7287 REV. 00
SERUGLOW INSTRUCTIONS FOR USE United States P/N: 7287 Rev: 00

SERUGLOW™
MICRO INFUSION SYSTEM
MODEL NUMBER: SG-025



INSTRUCTIONS FOR USE

SERUGLOWMD
MICRO INFUSION SYSTEM

DEVICE DESCRIPTION

The SeruGlow Micro Infusion system is a hand-held manual microneedling sterilized device. The product contains a needle head and an attached glass vial for optional use of solutions. The needle head contains 20 (0.25mm maximum) stainless steel microneedles that have been electropolished with nickel and 24k gold.

INDICATIONS FOR USE

The SeruGlow product is a single use microneedling device indicated for facial aesthetic use to facilitate exfoliation and improve the appearance of the skin. The device uses needles to mechanically puncture the stratum corneum of the skin for a potential desired facial aesthetic improvement.

CONTRAINDICATIONS

- Patients who suffer with eczema, psoriasis, dermatitis, acne, inflammatory skin conditions, active herpes labialis or any other infection in the treatment area, keloid predisposition, sun burned or broken skin, immunosuppression, and hemorrhagic (bleeding) disorder or hemostatic (bleeding) dysfunction.
- Patients who have hypersensitivity to any of the device materials (see 'Materials' section).

NOTE: This product is not intended for transdermal (under the skin) delivery of topical products such as cosmetics, drugs, or biologics.

PRECAUTIONS ⚠

- Always check with your physician if you have any skin conditions or are taking any medications that may prohibit use of exfoliation or microneedling devices.
- Microneedling should not be used within the orbital rim, such as the eyelids.
- Patients should avoid excessive sun exposure 24 hours prior to procedure.
- Patients who have had a recent skin resurfacing treatment, skin should be healed prior to treatment.
- Check with your healthcare provider if you are pregnant or breastfeeding.
- Do not use if any part of the device is broken, bent, cracked, crazed or dislodged.
- Do not use if the sterile packaging is compromised.

ADVERSE REACTIONS

- Bleeding, allergic reactions and skin redness.

DIRECTIONS FOR USE

1) Pre-Procedure

   a) Explain the procedure to the patient and set expectations.
   b) Have patient complete consent form. While wearing sterile, single use, non-latex gloves, cleanse the patient's face to effectively remove makeup, sunscreen, and surface oils.
   c) Open the microneedling device by peeling back the sterile backing and pushing the bottom of the device up and out of the blister pack.
   d) Remove safety cap.

2) During Use

   a) Using manual force and while holding the skin taut, gently stamp the device over the area to be treated. Be sure the device is always perpendicular to the skin with the bottom of the device facing up.
   b) Continue to methodically stamp the treatment area avoiding the area within the patient's orbital rim and mucus membranes.

3) Post-Procedure

   a) Gently use sterile gauze to pat down the affected area.
   b) Until the treated area has completely healed, patients should avoid excessive sun exposure, tanning beds, saunas, steam rooms and other facial aesthetic treatments.

STORAGE:

Store in a cool, dry environment out of direct sunlight.

MATERIALS

- Glass Vial
- Needles: 304 stainless steel, electropolished in nickel and 24k gold.
- The device does not contain natural latex rubber.
- The device does not contain phthalates (DEHP).

HOW SUPPLIED

- The device is a micro needle stamper that is sealed in a blister pack and placed into individual cartons.
- The device is intended for single use on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.
- The device is supplied sterile (ethylene oxide). Do not resterilize.

DISPOSAL:

The SeruGlow device is not intended to be reused. After use, dispose of the device in an appropriate biohazard sharps container.

CUSTOMER SERVICE & WARRANTY

The device is warrantied for use for the shelf-life of the product. The warranty does not cover defects due to negligence, abuse, misuse, alteration, or modification. Contact Suneva Medical Customer Service at (858) 550-9999 for inquiries.

The device is manufactured by WOW Facial Ltd., 207 Regents Street, London W1B 3HH, United Kingdom. www.wowfacial.co.uk

The device is distributed by Suneva Medical Inc.,
5870 Pacific Center Blvd., San Diego, CA. 92121,
United States of America. www.sunevamedical.com
Customer Service: (858) 550-9999

Ordering: In the United States or Canada, order by calling Suneva Medical Customer Service toll-free at +1-858-550-9999. Orders may also be sent by fax to 858-550-9997 or email to orders@sunevamedical.com.