ORDERING

In the UK call Circa Skin customer service team on **+44 7506 517274** or email **info@circaskin.co.uk**

CUSTOMER SERVICE & WARRANTY

The device is under warranty for use of the product for the duration of the shelf-life.

The warranty does not cover defects due to negligence, abuse, misuse, alteration, or modification.

Contact Circa Skin customer services on **+44 (0)7506 517274.**

KEEP OUT OF THE REACH OF CHILDREN

Do not use if you have any known allergies to any of the component parts.

CAUTION

This product is restricted for sale to medical professionals or licensed practitioners only.

Dispose appropriately after use.

DISPOSAL

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

WOW® *fusion*

Manufactured by Circa Skin Ltd.
70 Curzon Road, London. W5 1NF.

A British Brand
www.circaskin.com

WOW® *fusion*

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The WOW Fusion® device is a hand-held manual micro needling device designed for use by licensed healthcare practitioners or individuals directed by practitioners. The device incorporates a sterile single patient use, microneedle head attached to a glass vial. The microneedle head has twenty needles in a circular array. The needles are solid stainless steel with a bevelled tip. The maximum needle penetration depth is the same as the needle length. The device is available in two models.

MODEL	DESCRIPTION	NEEDLE LENGTH
WOW060	0.60mm WOW Fusion® device	0.60mm
WOW070	1.00mm WOW Fusion® device	1.00mm

INDICATIONS FOR USE

The WOW Fusion® product is a single use micro needling device indicated for facial aesthetic use to facilitate exfoliation and improve the appearance of the skin. The device uses needles to mechanically puncture the epidermis for a potential desired facial aesthetic improvement in adults aged 18 years or older.

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

CONTRAINDICATIONS

- Patients who suffer with eczema, psoriasis, dermatitis, sun-burned or broken skin, inflammatory or irritated skin conditions, active cold sores, acne, skin cancer or are taking any prescribed medication for their skin or any skin disease.
- Patients who have had a recent laser skin treatment.
- Patients who have hypersensitivity to any of the device materials (see 'Materials' section).
- Patients who have a haemorrhagic (bleeding) disorder or haemostatic (bleeding) dysfunction.

PRECAUTIONS ⚠

- Always check with your patient if they have any skin conditions or are taking any medications that may prohibit use of exfoliation or micro needling devices.
- Micro needling should not be used within the orbital rim of the eye such as the eyelids.
- Patients should avoid excessive sun exposure 24 hours prior to procedure.
- 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 extended skin redness.

DIRECTIONS FOR USE

1) Pre-Procedure
   - **a)** Explain the procedure to the patient and set expectations.
   - **b)** While wearing sterile, single use, non-latex gloves, cleanse the treatment area with a gentle cleansing complex to effectively remove makeup, sunscreen and surface oils.
   - **c)** Ensure you are using the correct needle length.
   - **d)** Open the micro needling device by peeling back the sterile backing and pushing the device up and out of the blister pack from the bottom of the glass vial.
   - **e)** Remove the 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 patient's eyes and mucus membranes.
3) Post-Procedure
   - **a)** Advise the patient on the post procedure avoidance of sun tanning, sunbeds, saunas and steam rooms.
   - **b)** Advise the patient on when it's appropriate to continue with other facial aesthetic treatments.

STORAGE

Store in a dry environment out of direct sunlight.

SHELF LIFE

When the device is properly stored and handled, the device remains suitable for its intended use for the shelf-life of the product. Do not use after the 'use by' date provided on the product label.

MATERIALS

- Glass vial with medical grade plastic.
- Needles: 304 stainless steel, electroplated in nickel and 24k gold.
- The device does not contain natural latex rubber.
- The device does not contain phthalates (DEHP).

HOW SUPPLIED

- The WOW fusion® is a micro needling device 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. Do not re-sterilize.

Symbols Legend			
	Manufacturer		Date of Manufacture
	Catalogue or Model #		Lot #
	Quantity		Configuration
	Consult Instructions for Use		Use by date
	Caution		Keep away from sunlight
	Keep Dry		Fragile, handle with care
	Do not reuse		Do not re-sterilise
	Sterilised by ethylene oxide		Do not use if package is damaged
	Not made with natural rubber latex		Does not contain phthalates (DEHP)