Instructions for

Primaeva Medical, Inc.

Miratone™

System

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Chapter 1
General Information

Introduction

Thank you for selecting the Primaeva Medical Miratone™ System.

Please read all sections of this manual in their entirety and familiarize yourself with any appendices before using the system. This investment of your time will reward you with a better understanding of the system and the ability to operate it safely, effectively, and efficiently.

- **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Company Contact Information

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Chapter 2
Intended Use

The Miratone System is intended for use only by qualified physicians licensed by the law of the State/Country in which they practice to use or order the use of the device. If you are not appropriately qualified, do not attempt to operate the Miratone System for any reason. The treating physician bears sole responsibility for determining the applicability of Miratone treatment for any patient or condition and for the clinical effects of any treatment delivered.

Indication for Use

The Primaeva Medical Miratone System is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles.

Contraindications

The Primaeva Medical Miratone System is contraindicated for patients with the following conditions:

-An implanted electronic device (i.e. pacemaker, etc.)

-Active skin infection(s)

-Collagen vascular disease

-A known bleeding disorder

-A history of keloid formation

-A history of hypertrophic scarring

-Accutane use in the previous 12 months

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Chapter 3
Professional Information on Clinical Applications

Scope

This information is intended to provide background information and instruction in the clinical use of the Miratone system for the treatment of skin wrinkles of the face.

Training

Before using the Miratone system, the physician must be familiar with the device, method of use, indications for use, contraindications, warnings, and precautions. It is recommended that physicians receive preceptor training from an experienced user and be required to receive in-service training from Primaeva personnel in the correct use of the equipment and clinical techniques. The suitability of the Miratone procedure for all patients should be individually assessed by the physician on the basis of medical history, indication suitability, and contraindications.

General Discussion

The Miratone System is a minimally invasive device delivering bipolar non-ablative radiofrequency (RF) energy to the dermal layers of the skin. The Treatment Applicator inserts an array of microneedle electrode pairs into the superficial layers of the skin. RF energy is delivered through the distal section of each microneedle pair during treatment, heating collagen in the skin[1]. Surface cooling is applied during treatment above the area being heated using a separate cooling assembly. Clinical studies suggest the thermal effects of treatment induce a healing response resulting in skin remodeling and the production of collagen, elastin and hyaluronic acid in the treated skin[2].

The microneedle electrodes of the Miratone System are insulated at the proximal end while leaving the distal end exposed. During treatment, current passes between the exposed lengths of the electrodes of a pair. Energy is delivered directly within the target tissue in a volume largely defined by the geometry of the individual microneedle pair. The spacing between adjacent lesions is determined by the

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electrode cartridge type and the separation between successive treatment applications. The Treatment Applicator deploys the microneedle electrodes through the epidermis at a nominal angle of 20° to the skin surface. When deployed correctly, the electrode tips are positioned at a vertical distance of approximately 2 mm from the epidermal surface. Within each pair, a temperature sensor is located at the distal tip of the electrode to provide real-time feedback of target tissue temperature from within the forming lesion. This temperature feedback system allows lesion temperature to function as the control parameter, and allows for pre-selection of target lesion temperature.

Prior to delivery of RF energy to the electrodes, a low energy test current is briefly passed between the electrodes to measure target tissue impedance. The control system uses this pre-treatment impedance value and those obtained during treatment to confirm the measured impedance is in a range expected for dermal tissue, and to optimize the heating algorithm. Microneedle pairs with measured impedance out of the anticipated range for dermal tissue are disabled. The impedance values are reported for each electrode pair following each treatment to help guide physician electrode deployment technique. Each of the electrode pairs is controlled independently by the generator during all treatments.

Clinical Discussion

The clinical literature suggests the mechanism for observed clinical improvement following non-ablative RF treatment of wrinkles involves dermal remodeling and wound healing processes initiated by thermal denaturation of dermal collagen[1-6], and collagen contraction during denaturation[6]. Denaturation of dermal collagen has been documented to occur above temperatures of 58°C[1,7]. Histological evidence of focal dermal collagen denaturation has been reported using the Miratone system for treatment temperatures from 60°C to 80°C[1]. Hantash et al[2] demonstrated the generation of collagen, elastin and hyaluronic acid following thermal denaturation of dermal collagen at 72°C. Clinical testing of the Miratone System has shown clinical improvement in facial wrinkles for treatment temperatures from 62°C to 78°C.

The treatment dose is controlled by the physician using three primary parameters:

- Lesion Temperature
- Treatment Duration
- Treatment Density

Clinical testing of the Miratone System suggests that collagen coagulation occurs at temperatures above 60°C, and that higher temperatures primarily increase lesion size by expanding the volume of the coagulation temperature isotherm. Within the 62°C to 78°C temperature range tested *in vivo* for the treatment of facial wrinkles, the treatment temperature has not been shown to directly correlate with clinical outcome. Similarly, treatment duration will influences individual lesion dimensions, with conduction associated with longer exposures resulting in larger lesions. Within the 3 to 5 second treatment duration range tested *in vivo* for the treatment of facial wrinkles,

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treatment duration was not shown to correlate with clinical outcome. The size of treatment lesions as a function of treatment parameters is detailed in Chapter 6.

The density of lesions deposited within the skin and the corresponding percentage of skin treated is controlled by the choice of electrode cartridge type and by the adjusting the spacing between successive applications of the device. Treatment density is a primary treatment parameter under direct physician control during delivery of treatment applications. The treatment density is the parameter most commonly varied over the treatment area based on the severity of the baseline condition in the area being treated. Physicians will typically deliver higher density treatments in areas of more baseline involvement, and lower density treatments in areas of less baseline involvement according to the treatment parameter guidance provided in Chapter 6: Treatment Instructions of this document.

The table below summarizes the clinical results of facial wrinkle improvement using the Primaeva Medical Miratone System:

Summary of Facial Wrinkle Improvement
(Results based on 3 independent physician graders using Fitzpatrick Wrinkle Assessment Scale)

Time period	Number of subjects	Subjects with partial or no improvement	Improvement seen by 2 of 3 evaluators	Improvement seen by 3 of 3 evaluators
3 months	53	3	14	36
6 months	42	1	15	26

Patient Selection

The Primaeva Medical Miratone System is intended for use on patients who are in good health. The suitability of the Miratone procedure for all patients should be individually assessed by the physician on the basis of medical history, indication suitability, and contraindications. The assessment of a patient's baseline wrinkle condition should include evaluation of the origin and nature of the wrinkles, and an assessment of severity using standardized metrics (Fitzpatrick Wrinkle Assessment Scale[8], Alexiades Comprehensive Grading Scale[5]).

The suitability of Miratone treatment for each patient should be considered within the context of all treatment alternatives. Dynamic wrinkles associated with underlying muscle activity may be amenable to neurotoxin treatment, while wrinkles associated with superficial actinic damage may be amenable to ablative laser resurfacing. The Miratone system is designed to generate treatment lesions in the reticular dermis. Consequently, wrinkles with reticular dermal involvement, including wrinkles associated with intrinsic aging, may be most amenable to treatment. Clinical improvement in wrinkles has been observed during clinical testing of the Miratone system for patients with baseline Fitzpatrick Wrinkle Assessment Class I – III and Score 3 - 9.

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It is important to set realistic expectations for treatment with Miratone for all patients. Treatment of wrinkles with Miratone is intended to improve a patient's condition. Clinical testing of the Miratone system suggests a one grade improvement in wrinkles, as assessed by Fitzpatrick Wrinkle Assessment Score, is achievable for many patients, although individual results may vary.

Patient Skin Type

Clinical testing of the Miratone system for the treatment of wrinkles has been performed for Fitzpatrick Skin Types I – IV patients. Radiofrequency heating of collagen in the reticular dermis does not involve melanin as a treatment chromophore, and the clinical literature suggests that noninvasive radiofrequency treatment can safely treat darker skin types, however, no literature or clinical testing data presently details the efficacy levels and side-effect profile, including the incidence of post-inflammatory hyperpigmentation, which may follow minimally-invasive radiofrequency treatment of skin type V and VI patients with the Miratone system.

- **CAUTION** The side-effect profile associated with the treatment of Fitzpatrick skin type V and VI patients, including the incidence of post-inflammatory hyperpigmentation has not been assessed in clinical testing and may differ from the reported during clinical testing of the Miratone system on skin type I – IV patients. Caution is advised when treating Fitzpatrick skin type V and VI patients.

Treatment Discomfort

Miratone treatment can involve mild to moderate discomfort during microneedle insertion. Heating dermal tissue to collagen denaturation temperatures will result in significant to severe discomfort during application of energy. Post-procedure discomfort has been reported as none to moderate.

All patients should receive anesthetic medication to minimize discomfort during energy application. Topical anesthetic alone, while sufficient to minimize discomfort associated with microneedle insertion, is typically insufficient to manage discomfort during treatment. Regional blocks are effective in removing all discomfort associated with microneedle insertion and treatment in anatomical zones accessible to regional blocks. A combination of topical anesthetic and regional blocks has been successfully employed to manage treatment discomfort for patient willing to tolerate brief periods of moderate discomfort outside of the regions covered by the regional blocks.

Infiltration with dilute local anesthetic (¼% lidocaine w/ 1:400,000 epinephrine) was employed as the preferred anesthesia technique during clinical testing of the Miratone system. Local anesthetic eliminates all discomfort in regions infiltrated. Inclusion of epinephrine may help minimize bruising associated with anesthetic infiltration and/or

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microneedle insertion. Patients may experience brief periods of moderate discomfort during treatment outside of infiltrated regions and in skip zones within the infiltrated field.

Oral analgesics and sedatives can also be considered to manage discomfort and patient anxiety. The choice of anesthesia for any particular patient is left to patient preference and to the medical judgment of the treating physician based on specific patient needs, and may include topical, local, and regional anesthetics, and systemic analgesics.

Complications and Adverse Effects

Any procedure perforating the skin can cause discomfort, pain, bleeding, infection, swelling, edema, scar formation, permanent marking, and pigment alteration. Potential risks which could result from the Miratone treatment include discomfort during and after the procedure, pain, infection, scarring, swelling or edema, permanent discoloration, nerve damage, and/or loss of sensation.

- **CAUTION** There may be risks associated with bi-polar RF energy delivery to the skin that are yet unknown.

■ **Warning!** Improper use of any of the Miratone System components could result in an adverse event.

Expected treatment side effects include:

- Pain during treatment: Topical, regional and local anesthetics are recommended to minimize treatment discomfort.
- Bleeding at insertion locations: Small beads of blood at insertion points frequently develop several seconds following retraction of the microneedle electrodes. These beads are good markers from which to judge the position of the next device application. If the beads do not develop, pressure adjacent to the treatment site may help them appear if desired to guide the next application. Occasionally more noticeable bleeding occurs, which is normally controlled by pressure for several seconds. It is recommended to have sterile gauze available during treatment.
- Erythema and redness immediately following treatment: These will typically resolve within several hours.
- Focal edema or induration at treatment sites: Focal edema at treatment sites typically develops 2 to 10 minutes follow treatment and can remain visible for 24 to 48 hours. Induration is often palpable for 5 to 10 days following treatment, and has been reported by patients as persisting 30 days.
- Bruising: All patients develop mild to significant bruising throughout the treatment area. During clinical testing of Miratone bruising was reported as

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none – 8%, few/isolated – 48%, many/isolated – 25%, and generalized – 19%. Bruising develops following treatment and is typically most noticeable 24 to 48 hours after treatment. Bruising typically resolves in 5 to 10 days but has been reported to persist 15 days.

- Visibility of insertion locations: Small crusts at insertion locations occasionally develop at microneedle insertion locations and typically slough in 12 to 48 hours for facial skin.
- Generalized swelling: Mild to significant swelling throughout the treatment area is expected developing 6 hours to 48 hours following treatment. Swelling typically resolves in 3 to 7 days but has been reported to persist 20 days.
- Discomfort following treatment: Patients have described post treatment discomfort during the first 24 hours as none to moderate. 8% of patients have reported taking Tylenol for discomfort following treatment.
- Discomfort on skin palpation: Most patients report skin sensitivity/discomfort to firm pressure in the treatment area that persists for 14 to 28 days.
- Itch, twinge and tingle sensations during healing: Patients have reported occasional spontaneous brief itch, twinge or tingle sensations in the treated area beginning 5 to 7 days following treatment, becoming infrequent 30 to 45 days following treatment.
- Temporary loss of sensation: Patients have infrequently reported a slight loss of sensation in some regions of the fields infiltrated with local anesthetic and treated. This loss of sensation, when reported, typically persisted 5 to 20 days.
- Pigmentation change: Pigmentation change, including hypopigmentation, hyperpigmentation and post-inflammatory hyperpigmentation was reported during clinical testing of the Miratone system for the patient skin type I – IV population investigated. Pigmentation change is a potential side effect of treatment and is more likely to occur for skin type V and VI patients. Caution is advised when treating skin type V and VI patients.

Preoperative Patient Consultation

The treating physician should conduct a patient consultation prior to treatment to provide the patient information on treatment options, risks, benefits, possible complications, and anticipated outcome. The consultation should include a medical history and exam. The patient should be informed that that no specific level of outcome can be assured.

Patients should be advised to avoid use of non-steroidal anti-inflammatory drugs (NSAIDs) for 2 weeks prior to treatment to minimize the potential for bruising, unless the medications involved are prescribed for the treatment of an existing medical condition.

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Preexisting lesions and/or textural change in the areas to be treated should be documented in the patient chart prior to treatment. Patients will generally inspect the treated area more closely after treatment than before and may attribute preexisting textural change to Miratone treatment. Standardized before and after photography is strongly recommended to document changes that are attributable to the Miratone treatment and to assess clinical improvement. Patients will frequently forget the severity of their baseline condition and may underestimate the clinical benefit that develops during the 3 to 6 month dermal remodeling process.

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Chapter 4
System Information

System Description

The Miratone system is comprised of an RF Generator system with Graphical User Interface (GUI), a reusable Treatment Applicator, a Cooler Controller and reusable Cooling Applicator, and disposable Electrode Cartridges. RF energy is delivered from the RF Generator, through the Treatment Applicator, to electrodes in the Electrode Cartridge that are deployed into the dermal layers of the skin. Bi-polar RF energy is delivered between independent electrode pairs.

RF Generator

The RF Generator is the energy source for the Miratone system. See Primaeva RF Generator User Manual for further operating instructions.

Treatment Applicator

The Treatment Applicator is a handheld electro-mechanical device that is used to insert the array of microneedle electrodes, at an acute angle, into the skin tissue. The device has a mechanism to deploy and retract the electrodes when actuated by the user. There is a cable and connector that interfaces with the RF Generator.

Cooling Applicator and Controller

The surface cooling system is a solid state cooler with an independent temperature control loop. The cooling device is placed on the skin surface during the treatment cycle.

Electrode Cartridges

Three disposable electrode cartridges types are available with the Miratone system, designated C1, W1, and S1. All electrode cartridges feature five independently controlled and electrically isolated electrode pairs. The geometry of each electrode pair is identical for all cartridge types. Energy is delivered directly within the

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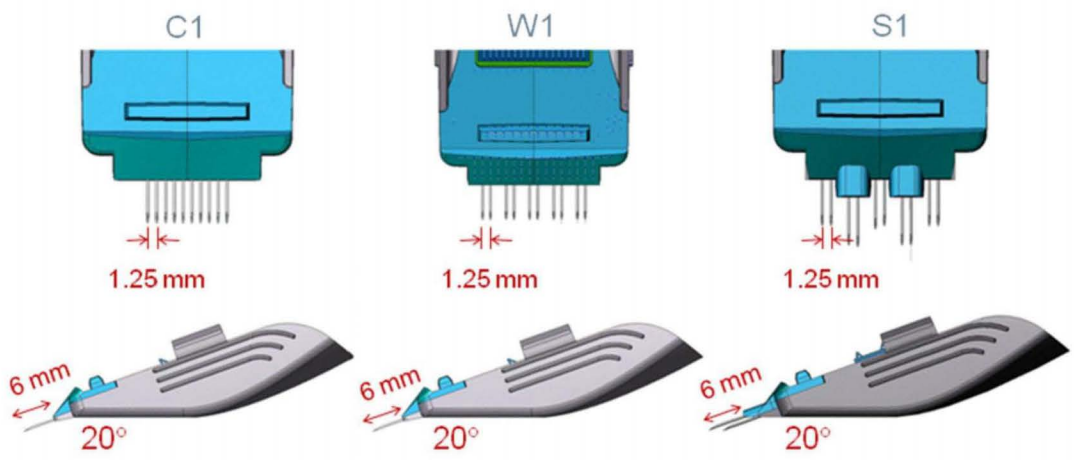
target tissue in a volume defined primarily by the geometry of the microneedle pair which is identical for all cartridge types.

Each electrode of a pair is designed to penetrate 6 mm within the skin at an angle of 20° to the surface of the skin. The proximal 3 mm of each electrode is insulated to protect the epidermis. The distal 3 mm of each electrode is the active portion of the electrode and is exposed to the dermis extending from 1 mm to 2 mm beneath the skin surface. The distance between the centers of all electrode pairs is 1.25 mm. All electrodes pairs are designed to be the same and will create identical treatment zones, regardless of the type of cartridge that is used. Electrode Cartridges vary only in the spatial location of the electrode pairs relative to each other as follows:

C1 Close spacing - adjacent electrode pairs are separated by 1.25 mm

W1 Wide spacing - adjacent electrode pairs are separated by 2.50 mm

S1 Staggered spacing - adjacent electrode pairs are separated by 2.50 mm; entry point into the skin of adjacent pairs is staggered by 2.50 mm



The lateral spacing between adjacent lesions within the skin is determined by the electrode cartridge type and is the same for the W1 and C1 cartridges.

■ **Warning!** The electrodes have sharp tips and can cause injury.

• **CAUTION** The electrodes tips can dull with repeated insertions. Do not exceed the recommended number of insertions to prevent electrode tip damage. The recommended maximum number of insertions is one hundred (100) per cartridge.

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Storage

Store the Treatment Applicator, Cooling Applicator and Electrode Cartridges in a cool dry place.

Do not use the disposable Electrode Cartridges if packaging appears damaged or the sterile barrier is compromised.

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Chapter 5
System Set-Up

RF Generator and Cooler Controller

See Primaeva Medical Miratone System User Manual for RF Generator and Cooling Applicator Controller set-up details.

Preliminary Inspection

DO NOT USE the Miratone System if you believe it is damaged or not functioning correctly.

DO NOT USE any sterile Electrode Cartridge if its packaging or contents appears damaged or if the packaging has been opened.

DO NOT USE any sterile Electrode Cartridge if its packaging labels are illegible or missing.

DO NOT USE any sterile Electrode Cartridge if its "Use by" date has passed.

DO NOT USE the Miratone System if any of the components or accessories are contaminated or not cleaned.

Cooling Applicator

Remove reusable Cooling Applicator from the shipping/storage box. Clean the Cooling Applicator. A 70% isopropyl alcohol solution or a germicidal wipe may be used to clean all outer surfaces of the device and cable.

- **CAUTION** Do not spray or pour liquids directly on the Cooling Applicator. Do not allow fluids to enter the Cooling Applicator. The Treatment Applicator is not sterilizable.

Cover the patient contact surface of the Cooling Applicator with a sterile probe cover or cut sterile surgical drape (Ioban® or equivalent) to fit the patient contact

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surface of the device and apply adhesive backing to skin contact surface of the device. Preserve the cleanliness of the draped skin contact surface prior to patient treatment.

Set the cooler controller temperature to 15°C.

Reusable Treatment Applicator

Remove reusable Treatment Applicator from the shipping/storage box. Clean Treatment Applicator. A 70% isopropyl alcohol solution or a germicidal wipe may be used to clean all outer surfaces of the device and cable.

- **CAUTION** Do not spray or pour liquids directly on the Treatment Applicator. Do not allow fluids to enter the Treatment Applicator. The Treatment Applicator is not sterilizable.

Cartridge Connection to Treatment Applicator

Select appropriate cartridge C1, W1 or S1 according to clinical need or preference.

■ **Warning!** Care should be taken when handling the Treatment Applicator when the Electrode Cartridge is attached. The electrodes have sharp tips and can cause injury.

- **CAUTION** All disposable Electrode Cartridges are supplied sterile and are for single patient use only. Cartridges cannot be re-sterilized.

- **CAUTION** Make every effort to preserve the sterility of the electrodes and skin contact portion of the device. Do not use the device if sterility is not maintained prior to treatment.

Open the Electrode Cartridge packaging and remove the sterile pouch. Open the sterile pouch to remove the Electrode Cartridge. Remove the protective shipping cover from top of the cartridge by depressing the sides of the cartridge assembly. Discard the protective shipping cover.

Verify that the electrodes are in the fully retracted position. Press the black button on the Treatment Applicator to fully retract the deployment mechanism. While holding the Treatment Applicator in one hand, place the cartridge assembly into position with the connector facing the bottom of the Treatment Applicator. Press together until the cartridge is securely fastened to the Treatment Applicator.

Press the blue “release” button to deploy the electrodes. Verify that the electrodes fully deploy and the mechanism is functioning properly. Confirm the thermocouples are measuring room temperature for all channels.

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Chapter 6
Treatment Instructions

Patient Preparation

Prior to treatment, the patient's skin should be cleaned of all material including all makeup. The patient's hair should be secured out of the treatment field using an appropriate hair restraint. The patient should be placed is in a supine position to allowing access to treatment location. It is recommend that a gown or drapes be used to cover the patient's clothing to prevent inadvertent soiling with skin cleansing solutions or blood.

If using topical anesthetic, clean treatment area with isopropyl alcohol or acetone to degrease skin, and apply the anesthetic following labeling instructions. Application 30-50 minutes prior to treatment may be appropriate. After the appropriate application, remove all residual topical anesthetic from the skin before continuing.

Clean the skin with Betadine or Hibiclens (or equivalent) prior to starting treatment to minimize any risk of local infection

If using local or regional anesthetics, infiltrate the treatment area following standard anesthetic practices.

Make a plan for the treatment considering anatomical regions to be treated, the severity of the baseline condition, cartridge selection, treatment parameters, orientation of insertions, and spacing between successive insertions. It is normally recommended that treatments be delivered in rows parallel to anatomical contours (the line formed by the insertion locations of the microneedle electrodes will be perpendicular to the anatomical region margin) as illustrated in Figure 6-1, which shows a sample treatment guide for a 52 application/per side treatment of the lateral lower face. In delivering treatments, it is recommended to start medially and move laterally from the prior insertion location so direct visualization of the prior insertions can guide spacing of subsequent applications (Figure 6-2).

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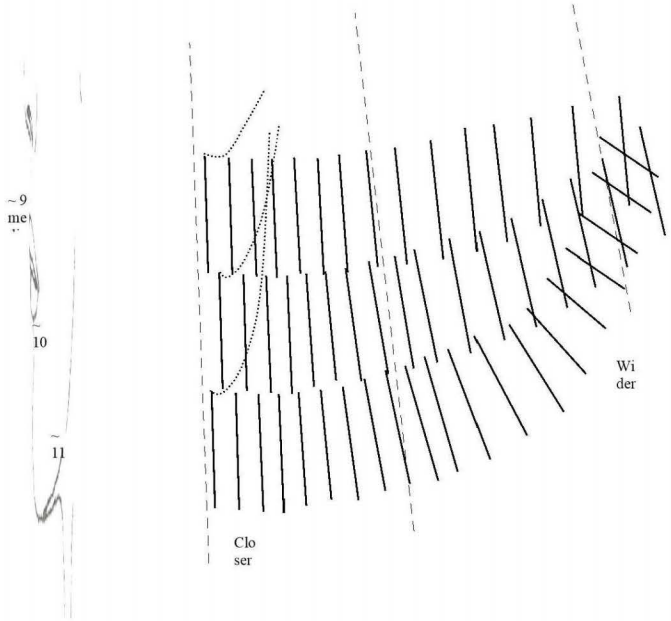

Figure 6-1

52 application/per side lateral lower face treatment guide for W1 and S1 Electrode Cartridge

Figure 6-2

Delivering a row of treatment parallel to the jaw line moving laterally from the prior insertion location so direct visualization of the prior insertions can guide spacing of subsequent applications.

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Treatment Guidelines

The following information is intended to provide guidance only and is not prescriptive for any class or category condition. The operative needs of each patient should be individually evaluated by the treating physician based on the indication, treatment location, and on the patient's medical and wound healing history. If uncertain of expected clinical response, choose conservative temperature, duration and treatment density settings and adjust as necessary to achieve the desired treatment coverage and clinical endpoint.

■ **Warning!** The Miratone system is not intended for the treatment of periocular or lid skin within the orbital rim, and is not intend for the treatment perioral or lip skin within the vermillion border.

Table 6-1 provides parameter guidance for the treatment of facial wrinkles. These settings are recommended for most patient treatments. Only W1 and S1 electrode cartridges are recommended for the treatment of facial wrinkles.

Table 6-1

Recommended Treatment Parameters
W1 and S1 Cartridges

Anatomical Region	Temperature	Duration
Mid and lower lateral face	**70°C**	**4 sec**

The approximate size of dermal lesions associated with treatment using W1 or S1 electrode cartridges at a temperature setting of 70°C for treatment durations from 3 to 5 seconds are shown in Table 6-2.

Table 6-2

Approximate Lesion Size for each Electrode Pair
Length x Width x Height mm
W1 and S1 Cartridges

Temperature	Treatment Duration		
	3 sec	**4 sec**	**5 sec**
70°C	2.8 x 1.6 x 1.0	2.9 x 1.7 x 1.3	2.9 x 1.7 x 1.4

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The density of lesions and corresponding percentage of fractional skin coverage is controlled by the adjusting the spacing between successive applications. The spacing between applications is the treatment parameter most commonly varied based on the severity of the baseline condition. The spacing density is shown in Tables 6-3.

Table 6-3

Typical Application Spacing
W1 and S1 Electrode Cartridges

Spacing	Density
3-4 mm	High
5-6 mm	Medium
8-10 mm	Low

Higher density treatments are typically delivered in areas of more baseline involvement, and lower density treatments in areas of less baseline involvement. For a fixed set of treatment parameters, changes in total dose are made by adjusting treatment spacing. Table 6-4 provides guidance on application spacing based on anatomical location and baseline severity of wrinkles.

Table 6-4

Application Spacing Guidance
W1 and S1 Electrode Cartridges

Anatomical Region	Baseline Condition	Density
Mid and lower lateral face	**Mild**	**Low**
	Moderate	**Medium**
	Significant	**High**

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Treatment Delivery

Make a plan for the treatment considering anatomical regions to be treated, the severity of the baseline condition, cartridge selection, treatment parameters, orientation of insertions, and spacing between successive insertions. Identify the treatment area. If desired, use a sterile marking pen to draw a treatment template to help guide electrode insertion locations.

1. Select treatment parameters using the RF generator GUI.
2. Reset the insertion counter to zero.
3. In open air, deploy and retract electrodes to confirm that the Treatment Applicator mechanism is functioning correctly.
4. Visually inspect the electrode tip and the coating to confirm that there is no damage to the electrode tip and the coating is completely intact. The coating should completely insulate the proximal 3 mm of the electrode.

- CAUTION Visually inspect the electrode tips and coatings to confirm that there is no damage to the electrode tip and that coating is completely intact before first use and between each insertion.

5. Verify the temperature sensors in the needle tips are reading room temperature (GUI).
6. Press the Retract Button (black) on the left hand side of the device, to arm the device (Figure 6-3). Press the button completely inward until the round lock is engaged. The Release Button should arm with a click sound.

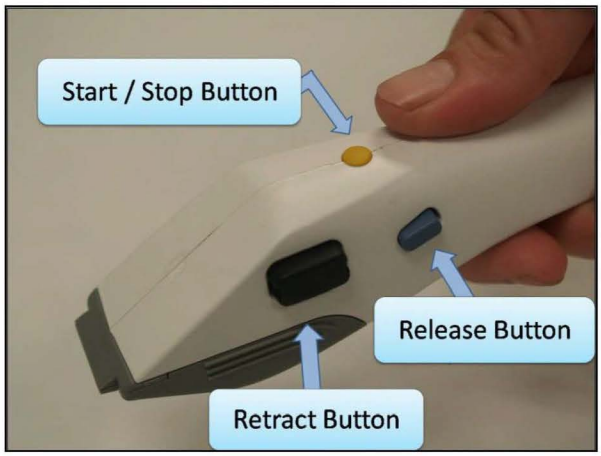

Figure 6-3

Treatment Applicator

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7. Firmly place the Treatment Applicator against the skin being aware that, when deployed, the electrodes will advance from the device approximately 6 mm at a 20 degree angle into the dermis.

■ **Note:** The treatment zone will extend approximately from 3 mm in front of the Treatment Applicator to 6 mm in front.

DEPLOY ELECTRODES:

8. Using your 2nd hand, or with the help of an assistant, apply mild retraction of the patient's skin behind an in front the Treatment Applicator to hold the skin taught and limit the skin movement as the electrodes deploy (Figure 6-2).
9. Press the deploy/release button.
10. Verify the needles have advanced completely and the lock is engaged.
11. If the needles are fully deployed and not fully inserted into the skin (the skin moved away from the Treatment Applicator during deployment), push forward on the Treatment Applicator until the needles are fully inserted.

• **CAUTION** You must visually inspect the electrode insertion on every insertion. The electrodes must be fully deployed and completely within the skin. No portion of the electrode should be exposed. The electrodes must be inserted evenly and at consistent depth. Note insertions that appear to be too deep and/or too shallow. IF THE ELECTRODES ARE NOT CORRECTLY DEPLOYED AND FULLY INSERTED INTO SKIN AT THE CORRECT DEPTH, DO NOT APPLY TREATMENT.

■ **Warning!** Superficial insertions may result in an epidermal burn that may be slow to heal. If visual inspection suggests the electrodes are deployed too superficially or incompletely inserted DO NOT APPLY TREATMENT: Retract electrodes and re-deploy.

• **CAUTION** It is important to hold the Treatment Applicator steady after the electrodes have been inserted to avoid damage to the dermis.

12. Position the Cooler Applicator in contact with the skin surface, directly above the electrodes. Verify the Cooler Controller is indicating that the surface temperature is at the control temperature.

START TREATMENT:

13. Press yellow Start/Stop Button on the Treatment Applicator or click "Start" on the Graphical User Interface to initiate treatment. The RF Generator will beep while treatment is delivered.

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Ex. 2151-023

- **CAUTION** Leave the Cooler Applicator on the skin for 2 to 4 seconds beyond the completion of each treatment application.

14. Following the completion of the heating cycle, leave the Cooler Applicator on the skin for an additional 2 to 4 seconds as heat conduction to the skin surface will lag dermal heating. Then remove the Cooler Applicator.

WITHDRAW ELECTRODES:

15. Remove the microneedle electrodes from the skin by withdrawing the Treatment Applicator in the opposite direction of the electrode insertion.

- **CAUTION** Do not rearm the device in skin to withdraw the electrodes.

16. Visually inspect the electrode tips and coating after every treatment cycle.
17. Rearm the device in open air after removing from the skin retracting the microneedle electrodes.

- **CAUTION** It is important to rearm the applicator to retract and protect the microneedle electrodes. Exposed microneedles are both subject to damage and represent a sharps hazard to the operator.

18. Visually inspect the treatment area. Note any superficial burns.
19. Minor beading of blood at insertion location is expected and somewhat desirable as it gives a visual indication of the insertion location from which the distance to the next can be gauged. If bleeding occurs, pressure applied for several seconds with sterile gauze may be required.

BETWEEN TREATMENT APPLICATIONS:

20. Review the treatment data collected during the prior treatment that is displayed on the RF Generator GUI. Note tissue impedance values for each electrode pair and any system warning or alerts.

■ **Note:** The RF Generator will not deliver treatment energy to any electrode pair where an impedance value above 3000 ohms or below 300 ohms is detected. These channels are highlighted in red, and re-enable automatically on the next clinical cycle.

Clinical testing of the Miratone with W1 and S1 electrode cartridges for the treatment of wrinkles of the lower face has suggested that impedance values in the range 500 to 2000 ohms are typical. Higher impedance values tend to correlate with deep insertions and lower impedance values tend to correlate with more superficial insertions. Significant patient to patient variations, facial region

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variation and needle pair to needle pair variations do occur. Rely primarily upon correct treatment technique (applicator flat against skin and mild counter traction) and on visualization correct insertion to ensure correct treatment depth. Use the tissue impedance values reported to provide guidance on trends within one patient, rather than on an absolute scale.

■ **Note:** Correct treatment technique (applicator flat against skin with mild counter traction) and direct visualization correct insertion is the principal method of ensuring correct treatment depth.

21. Relocate the Treatment Applicator 3-8 mm from the previous insertion based on the desired density (see Table 6-3) for the condition being treated. It is normally preferred to deliver applications in rows parallel to anatomical contours work medially to laterally so the prior insertion location can be directly viewed to guide positioning of the next application.
22. Repeat above steps until the desired treatment zone has been covered.

• CAUTION The electrodes tips can dull with repeated insertions. Do not exceed the recommended number of insertions to prevent electrode tip damage. The recommended maximum number of insertions is one hundred (100) per cartridge.

TREATMENT COMPLETE:

23. Set the Treatment Applicator and the Cooling Applicator clear of the patient.
24. Clean the patient's skin with sterile gauze wetted with normal saline to remove any dried blood or residual Betadine.

■ Note: It is recommend cleaning the skin before showing the immediate postoperative skin appearance.

25. If desired, take immediate postoperative photographs to document the treatment.
26. Show the patient the immediate postoperative treatment appearance of the skin.
27. If appropriate or desired, apply a thin coat of antibiotic or healing ointment (Aquaphor or equivalent) to the treated area.
28. Give the patient verbal and written postoperative instruction.

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Postoperative Instructions

Patients should be advised of the expected healing sequence and expected treatment side effects as detailed in Chapter 3. The patient should be advised to wash normally using mild cleansers or soaps and avoid wash cloths and harsh cleansers until all transient healing processes have resolved naturally. Patients should avoid excessive sun exposure on the treatment area and use a sun screen (SPF 15+) for one (1) month following the procedure. Patients should be advised to contact the office if they have any concerns about how their skin is responded to treatment or is healing.

Retreatment

Clinical testing of the Miratone system suggests wrinkle improve can continue to develop for 3 to 6 months following treatment. Clinical literature suggests that the dermal remodeling process following non-ablative RF treatments can continue for 6 to 12 months. Retreatment with Miratone is not recommended prior to 6 months following the initial treatment.

Post Treatment Protocol

Remove the used electrode cartridge from the Treatment Applicator and discard in sharps container for biological hazardous waste.

Clean all outer surfaces of the Treatment Applicator and cable using a germicidal wipe (PDI Super Sani Wipe or equivalent) removing all visible contaminates and leaving surfaces wetted for the period specified by the manufacturer of the wipe.

Remove and discard the drape covering the patient contact surface of the Cooling Applicator. Clean all outer surfaces of the Cooling Applicator and cable using a germicidal wipe (PDI Super Sani Wipe or equivalent) removing all visible contaminates and leaving surfaces wetted for the period specified by the manufacturer of the wipe.

- **CAUTION** Do not spray or pour liquids directly on the Treatment or Cooling Applicators. Do not allow fluids to enter the Treatment or Cooling Applicators. The Treatment and Cooling Applicators are not sterilizable.

Return the Treatment and Cooling applicators to their storage boxes.

Turn off the RF generator and Cooling Applicator Controller.

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Chapter 7

Labels and Symbols

Single Patient Use only	STERILE R **Radiation Sterilized**	**Manufacturer** Primaeva Medical, Inc. 4160 Hacienda Drive Suite 100 Pleasanton, CA 94588 (925)621-6100
Expiration Date	LOT **Lot Number**	REF **Catalogue Number**
Attention: **See Instructions for Use**	**Manufactured Date**	

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