Exceed™

Patient Information

Please review this important information before beginning your treatment.

This patient information leaflet explains what to expect from a microneedling treatment of facial wrinkles and acne scars using the Exceed microneedling device.

If you have any questions relating to the information in this leaflet, please contact the Candela Corporation. The contact details are printed at the end of this leaflet.

Glossary

Acetaminophen: medicine used to treat pain and fever. It is typically used for mild to moderate pain relief.

Acne: Acne is a skin disease that occurs when hair follicles are clogged with dead skin cells and oil from the skin. It is characterized by blackheads or whiteheads, pimples and oily skin.

Adverse event or incident: an untoward side effect of the treatment

Anticoagulant therapies: often called blood thinners, these are chemical substances that prevent or reduce coagulation or clotting of blood. They are used to treat certain heart conditions.

Chemotherapy: treatment of a disease with chemical agents. Often used to treat cancers and kill malignant cells

Corticosteroids: a type of steroid. Steroids alter the immune response of the body and can be applied to the skin, taken in tablets, injected, inhaled or administered topically by cream.

Cosmeceuticals: type of cosmetic skincare product, often stronger than over-the-counter skincare

Diabetes: a condition where the sufferer has high blood sugars, caused by either the pancreas not making the hormone insulin or not making it in the correct amount or cells in the body not responding to insulin. This can lead to dangerously high blood sugar levels.

Eczema: a type of skin condition that leads to inflammation of the skin. These conditions are often characterized by itchiness, red skin and a rash.

Epidermis: upper layer of the skin.

Fitzpatrick skin types: a classification system of skin color in humans. The scale is used by skincare specialists to estimate the response of different types of skin to sunlight. Lower skin types represents lighter skin types. Higher values represent darker skin types.

Hemophilia: a genetic disorder that affects the body's ability to make blood clots, a process needed to stop bleeding. This results in people bleeding longer after an injury, are easily bruised, and have an increased risk of bleeding.

Hepatitis: inflammation of the liver tissue, predominantly caused by a virus.

Herpes simplex virus type 1: commonly known as the cold sore or fever blister virus, this is the virus that causes fever blisters.

HIV: human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS). The condition is caused by a virus. HIV is spread primarily by unprotected sex, contaminated blood transfusions, hypodermic needles, and from mother to child during pregnancy, delivery, or breastfeeding.

Keloid scars: type of scar that is formed after surgery or injury. Keloid scars are firm, rubbery shiny scars. A keloid scar is benign and not contagious. Studies have shown that subjects with darker skin color are at a higher risk of keloid scarring as a result of skin trauma.

Laser: a device that emits light through a process of amplification by the stimulated emission of radiation. It can be used for skin rejuvenation, cutting, and/or cauterization.

Malignancy: term often used to describe cancer or tumor that spreads versus a benign tumor

NSAIDs: Non-steroidal anti-inflammatory drugs (NSAIDs) reduce pain, decrease fever, prevent blood clots and, in higher doses, decrease inflammation

Pigmentation/pigmented: general term used to describe the darkening or lightening of an area of skin or nails caused by increased or decreased levels of melanin (a natural pigment that gives skin its color).

Radiofrequency: type of energy or current that generates heat and is used in a variety of aesthetic treatments to treat signs of aging.

Radiotherapy: type of therapy that uses ionizing radiation, generally as part of cancer treatment to control or kill malignant cells

Fitzpatrick skin types

Type I: always burns, never tans (pale white; blond or red hair; blue eyes; freckles)

Type II: usually burns, tans minimally (white; fair; blond or red hair; blue, green, or hazel eyes)

Type III: sometimes mild burn, tans uniformly (cream white; fair with any hair or eye color)

Type IV: burns minimally, always tans well (moderate brown)

Type V: very rarely burns, tans very easily (dark brown)

Type VI: never burns, never tans (deeply pigmented dark brown to darkest brown)

Aging skin

As we age, our skin shows visible signs of the aging process such as lines and wrinkles. Our skin loses its springiness and firmness and can appear blotchy or pigmented. Many treatments are available to help treat signs of aging. Some take the form of over the counter creams while others require treatments from a physician using drugs, and some products that may be referred to as cosmeceuticals or specialist treatments with devices such as lasers or radiofrequency.

The Exceed device is a type of microneedling device. A microneedling device is a medical device that is used by licensed healthcare providers to create many, tiny, microscopic punctures in the epidermis of the skin using very fine sterile stainless-steel microneedles. To do this, the device is moved over the skin repeatedly to puncture the epidermis. This creates many tiny wounds in the skin which has been reported to help smooth wrinkles.

There are many alternative treatments to the Exceed microneedling device and therefore, it's important that you discuss with your healthcare provider whether microneedling is right for you.

Indications for use

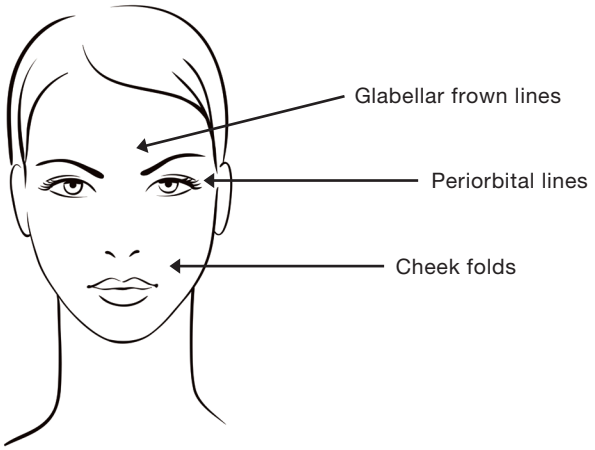
The Exceed is a microneedling device and accessories is intended for the treatment of wrinkles in Fitzpatrick skintypes I, II and/or III in the following facial areas: glabellar frown lines, periorbital lines and cheek folds in adults aged 22 years or older.

The Exceed is a microneedling device and accessories intended to be used as a treatment to improve the appearance offacial acne scars in Fitzpatrick skin types I, II, III and IV in adults aged 22 years or older.

Caution: Federal law restricts this device to sale by or on the order of a physician.

The Exceed microneedling device can be used to treat wrinkles in the following facial areas:

NOTE: This product is not intended for transdermal (under the skin)



delivery of topical products such as cosmetics, drugs, or biologics.

Is the treatment suitable for you?

The treatment may NOT be suitable for you if any of the following apply directly to you:

- You have a known history of clotting or bleeding disorders such as hemophilia.
- You suffer from uncontrolled diabetes.
- You are taking anticoagulant therapies such as warfarin or heparin or low dose aspirin as prescribed by your physician.
- You are suffering from an active skin infection including bacterial, viral, or fungal.
- You have eczema, psoriasis, rosacea, a collagen vascular disease, or skin rashes on the face.
- You are suffering from active acne of the face or you are currently taking acne medication with the ingredient isotretinoin (such as Accutane™).
- You have actinic (solar) keratoses, keloid scars (or a history of keloid scars), human papillomavirus warts (HPV) or birthmarks or moles in the treatment area.
- You are suffering from a known malignancy or are undergoing or about to undergo treatments using chemotherapy, radiotherapy or high dose corticosteroids.
- You suffer from a systemic infection such as hepatitis or human immunodeficiency virus (HIV).
- If you are pregnant or are currently breastfeeding.
- You are allergic to stainless steel or topical or local anesthetics or have a history of contact dermatitis to these products.
- You are allergic to or have a history of contact dermatitis to the ingredients in Supragel™ which consists of calcium chloride, propylene glycol, deionized water, sodium hydroxide, sucrose, pectin and cellulose gum (blanose)
- You have undergone plastic surgery of the face including dermal fillers within the last 12 months or have any facial surgical scars < 12 months old.
- You have undergone Botox® or other neuromodulator injections in the face within the last three months.

Patients with darker skin types

If you have darker skin (Fitzpatrick skin types IV, V, and/or VI), please talk to your healthcare provider to determine if treatment is right for you. This device has not been studied in patients with darker skin types (Fitzpatrick skin types IV, V, and/or VI).

How was the device studied?

The following is a summary of a clinical study that was performed to investigate the effectiveness and safety of the Exceed device for the treatment of facial wrinkles.

The objective of the study was to assess the effectiveness of the Exceed microneedling system in reducing the signs of skin aging as measured by the improvement in wrinkles, after 4 standardized treatment sessions and to assess the safety of the system as measured by the number of adverse events.

The study was conducted at a single center. Subjects were treated four times, 30 days apart (Day 0, 30, 60 and 90) with final assessment 60 days after the last treatment at 150 days.

Treatments were conducted by medically trained healthcare professionals.

How the study measured the effect of the treatment?

At each visit, digital photographic images were taken of the subject's face and the investigating physician assessed facial wrinkles using an authenticated (validated) scale. At the end of the study the digital images of the subject's face were collected, randomized and analyzed independently by three physicians using the same grading scale.

How the study measured safety – what side effects were seen in the clinical study?

Immediately after each treatment the physician was asked to grade the amount of visible skin redness in the treatment area. Grading was carried out using a grading scale where:

i. None: no skin redness Skin is normal color

ii. Minor: very faint skin redness

iii. Mild: blotchy, visible redness that does not cover the entire face

iv. Moderate: skin has a very definite redness to it

v. Severe: skin is severely red

Subjects also graded their skin redness immediately after each microneedling treatment and in addition graded pain and discomfort experienced during the treatment. A scale was used for subjects to evaluate their skin redness that contained photographs showing grades of skin redness in different skin types. This scale was also used for subjects to record their skin redness at home.

Pain and discomfort were recorded using a scale (0–10) where 0 was equivalent to "no pain" or "no discomfort" to 10, which represented "most intense pain ever" and "most discomfort ever". This grading structure was also used to record changes to pain and discomfort from the evening of the treatment to Day eight (seven days after the treatment). In addition, skin peeling was assessed by the subject from day three to day eight using a scale where 0 represented "no skin peeling or flakiness" to 10 "heavy skin peeling over the whole face."

During all times any potential adverse incidents were recorded by the research staff.

Results of winkles study

Safety – Physician reported outcomes

Nine treatment-related adverse incidents (side efects) and four non-treatment-related incidents were observed during this study.

There were 8/48 (17%) recorded adverse incidents, where the treatment triggered fever blisters (also called cold sores) due to the virus herpes simplex virus I (HSV I). Of the eight fever blister outbreaks, five occurred in subjects with Fitzpatrick skin type II, two occurred in skin type III and one occurred in skin type V. Thirteen, 13/48 (27%) of subjects reported a history of fever blisters at the beginning of the study. Within this population eight patients reported an outbreak of virus herpes simplex virus I (HSV I), this represented an occurrence rate of 62% or approximately 6/10 in people who have a history of fever blisters. Subjects who had a fever blister outbreak were treated using antiviral medication and for the rest of the study subjects were given antiviral medication to take before the microneedling treatment. There were no further reported outbreaks of fever blisters.

One subject reported extremely dry skin which did not need any further treatment from the doctor. The subject did not report dry skin again during the study. This subject's skin type was skin type II.

Patient reported outcomes

Subjects were also asked to grade their erythema immediately at the end of the treatment. Nineteen out of 48 (40%) subjects graded their skin redness as moderate and 29/48 (60%) subjects as severe (table 1).

Table 1: Erythema assessment by physician and subject immediately after treatment

Grading of erythema immediately after treatment	Grading		
	Minor	Moderate	Severe
Physician	34/48 (70%)	14/48 (30%)	0
Subject	0	19/48 (40%)	29/48 (60%)

Subjects indicated that although the treatment appeared to be moderately painful it was not particularly uncomfortable (table 2).

Table 2: Pain and discomfort experienced during the treatment

Subject assessment of pain and discomfort during the treatment (average over 4 treatments)	Pain score[1]
Pain during treatment	5.2 (3.8 to 6.1)
Discomfort during treatment	1.3 (<1 – 2.1)

1. based on a scale 0-10 0 - No pain or discomfort. 10 - Worst pain or discomfort ever

Redness (erythema), pain, discomfort, and skin peeling were recorded by the subjects up to eight days after treatment.

- Erythema was experienced by 48 out of 48 subjects (100%) immediately after the treatment lasting eight days. Eight days after the treatment, 39/48 (81%) subjects reported no erythema, 9/48 (19%) subjects reported minor erythema and 1/48 (2%) subjects mild erythema.
- Pain was experienced by 48 out of 48 subjects (100%) to some degree during the treatment lasting eight days. By day three, 37/48 (77%) of subjects still reported pain. By day eight, 2/48 (4%) still reported some pain. These symptoms can be alleviated with non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen.
- Discomfort was experienced by 48 out of 48 subjects (100%) to some degree during the treatment lasting eight days. Eight days after the treatment, discomfort was still reported by 9/48 (20%).
- Skin peeling was experienced by 48 out of 48 subjects (100%) from day three, lasting eight days. The amount of skin peeling reached a maximum of 3.4 by day 4. Skin peeling was still reported in 31/48 (65%) subjects by the evening of day 8. Figure i).

Figure i: Subject assessment of pain, discomfort and peeling immediately after the treatment up to day 8

What will the treatment accomplish, and what did the clinical study show?

Effectiveness – Physician reported outcomes

Three areas of the face were excluded for evaluation by the blinded physicians because they were difficult to assess by photography. The following 6 areas were therefore assessed for wrinkles: horizontal forehead lines, glabella frown lines, periorbital lines, cheek folds, nasolabial folds, and upper lip lines.

Of the six facial areas which were evaluated, three areas achieved a clinically meaningful result, while three areas did not show improvement. For glabella frown lines, periorbital lines and cheek folds the mean values of change showed ≥ 1 grade improvement in the grading scale. These changes were statistically significant. For horizontal forehead lines, nasolabial folds, and upper lip lines, the results did not demonstrate a clinically meaningful improvement at day 150. The number of subjects whose wrinkle grade improved by ≥ 1 as well as the number of subjects seeing no change in their wrinkle grade or whose wrinkles worsened is shown in table 3.

Table 3: Change in wrinkle grading from the beginning

	Glabella Frown Lines n(%)	Periorbital Lines n (%)	Cheek Folds n (%)
Subjects graded as having a ≥1 grade improvement	41/48 (85.4%)	42/48 (87.5%)	43/48 (89.6%)
Subjects graded as unchanged (Change = 0)	7/48 (14.6%)	6/48 (12.5%)	5/48 (10.4%)
Subjects graded as worsened	0/48 (0%)	0/48 (0%)	0/48 (0%)

of the study to two months after the last treatment

What happens during the treatment?

1. You will have your face cleansed to remove any traces of make-up.
2. You will have a numbing cream applied to your face. You will need to wait (typically 30 minutes) while the numbing cream works.
3. After your face is numb the cream is removed from your face and your face will be cleansed again.
4. You will undergo the treatment. The treatment involves making many, microscopic punctures into the epidermis of the skin using very fine sterile needles. To do this, the device is moved over your skin repeatedly to puncture the epidermis. People who experience the treatment say that it feels like their skin is being rubbed with fine sandpaper while others describe the feeling of an electronic toothbrush being moved across your skin.
5. The treatment takes 15–20 minutes. After the treatment, your skin will be cleansed again and a high sun protection factor (SPF) sunscreen will be applied to your skin.

What happens after the treatment?

During a clinical study on 48 subjects the following side effects were reported:

- Some pinpoint bleeding after the treatment, but this will stop within 5–10 minutes

Erythema, pain, discomfort and skin peeling were recorded by the subjects up to eight days after treatment. A full description of the side effects are described in “Patient reported outcomes”.

If you experience any side effects or symptoms that are NOT listed above and/or symptoms that appear to be worse than those listed above, please contact your physician immediately.

Please contact your physician if you have any concerns in general about the treatment.

Care of your skin after the treatment

a. Your physician may give a sunscreen to use after the treatment and a moisturizer to use only in extreme cases of your skin feeling excessively dry. Follow the instructions given to you by your healthcare provider.

b. Apply the sunscreen in the morning and if directly in the sun every two hours.

c. Pat the sunscreen onto the face for the first three days while the skin may be red and uncomfortable. DO NOT massage the sunscreen into the skin.

d. Avoid direct sun exposure for five days.

If you experience any side effects or symptoms that are NOT listed above and/or symptoms that appear to be worse than those listed above, please contact your physician immediately. Please contact your physician if you have any concerns in general about the treatment.

Acne Scars

Active acne is a very common problem affecting more than 90% of the adolescent population. Acne scars are usually the result of inflamed acne caused by skin pores enlarged with excess oil, dead skin cells and bacteria. Sometimes the pores become so large that they cause the follicle wall to rupture. Shallow lesions are usually minor and heal quickly. But if there is a deep break in the wall of the pore, infected material can spill out into surrounding tissue, creating deeper lesions.

The skin attempts to repair these lesions by forming new collagen fibers. These repairs usually aren’t as smooth and uniform as the original skin and so appear as indentations or scars.

Many treatments are available to help treat acne scarring. The majority of which are available from a dermatologist or skin specialist and include chemical peels and specialist treatments with devices such as lasers or radiofrequency.

The Exceed device is a type of “microneedling device”. A microneedling device is a medical device that is used by physicians to create many, very tiny, microscopic punctures in the epidermis of the skin using very fine sterile stainless-steel needles. To do this, the device is moved over the skin repeatedly to puncture the epidermis. This creates many tiny wounds in the skin which has been reported to help the acne scars and give the skin a more uniform appearance.

There are many alternatives treatments to the Exceed microneedling device and therefore, it’s important that you discuss with your physician whether microneedling is right for you.

Indications for use

The Exceed is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in Fitzpatrick skin types I, II, III and IV in adults aged 22 years or older.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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

Is the treatment suitable for you?

The treatment may NOT be suitable for you if any of the following apply directly to you;

- You have a known history of clotting or bleeding disorders such as hemophilia.
- You suffer from uncontrolled diabetes.
- You are taking anticoagulant therapies such as warfarin or heparin or low dose aspirin as prescribed by your physician.
- You are suffering from an active skin infection including bacterial, viral, or fungal.
- You have eczema, psoriasis, rosacea, a collagen vascular disease, or skin rashes on the face.
- You are suffering from active acne of the face or you are currently taking acne medication with the ingredient isotretinoin (such as Accutane™).
- You have actinic (solar) keratoses, keloid scars (or a history of keloid scars), warts (HPV) or birthmarks or moles in the treatment area.
- You are suffering from a known malignancy or are undergoing or about to undergo treatments using chemotherapy, radiotherapy or high dose corticosteroids.
- You suffer from a systemic infection such as hepatitis or human immunodeficiency virus (HIV).
- If you are pregnant or are currently breastfeeding.
- You are allergic to stainless steel or topical or local anesthetics or have a history of contact dermatitis to these products.
- You are allergic to or have a history of contact dermatitis to the ingredients in Supragel™ which consists of Calcium chloride, Propylene glycol, Deionized water, Sodium Hydroxide, Sucrose, Pectin and Cellulose gum (Blanose™).
- You have undergone plastic surgery of the face including dermal fillers within the last 12 months or have any facial surgical scars < 12 months old.
- You have undergone Botox or other neuromodulator injections in the face within the last 3 months.

Patients with darker skin types

If you have darker skin (Fitzpatrick skin types V, and/or VI), please talk to your doctor to determine if treatment is right for you. This device has not been studied for the treatment of acne scars in subjects with darker skin types (Fitzpatrick skin types V, and/or VI).

How was the device studied?

The following is a summary of a clinical study that was performed to investigate the effectiveness and safety of the Exceed microneedling device for the treatment of facial acne scars. The objective of the study was to assess the effectiveness of the Exceed microneedling system in reducing the appearance of acne scars after 4 standardized treatment sessions and to assess the safety of the system as measured by the number of adverse events side effects.

The study was conducted at a single center. Subjects were treated 4 times, 30 days apart (Day 0, 30, 60 and 90) with a final assessment of the subjects skin 12 weeks after the final treatment.

Treatments were conducted by a medical physician.

How the study measured the effect of the treatment?

At the beginning of the study and 12 weeks after the last treatment, digital photographic images were taken of the subject's face. At the end of the study, the digital images of the subject's face were collected, randomized and analyzed independently by 3 physicians using the same grading scale. In addition, subjects were asked a series of questions in relation to their perceptions of the treatment and its success.

How the study measured safety – what side effects were seen in the clinical study?

Subjects graded their skin redness, pain and discomfort on the day of the treatment and for the next 7 days. A scale was used for subjects to evaluate their skin redness that contained photographs showing grades of skin redness in different skin types.

Pain and discomfort were recorded using a scale (0–10) where 0 was equivalent to "no pain" or "no discomfort" to 10, which represented "most intense pain ever" and "most discomfort ever". This grading structure was also used to record changes to pain and discomfort from the evening of the treatment to Day 7.

During all times any potential adverse incidents were recorded by the research staff.

Results of the study

Fifty-six subjects participated in the study. Forty-seven subjects completed the study. There were 18 males and 38 females whose ages ranged from 18 to 62 years of age.

Safety – Physician reported outcomes

There were 26 adverse incidents (side effects) that were observed during the study that occurred in 18 of the subjects. Twenty-two of the events were expected, 4 events were unexpected (Table 1).

The most common adverse events were bruising (n=6) and swollen lymph nodes (n=6).

Hyperpigmentation was reported by 4 subjects, but this side effect did not persist.

Hyperpigmentation was seen in one subject whose Fitzpatrick skin type was type II, two subjects whose Fitzpatrick skin type was type III and one subject whose Fitzpatrick skin type was type IV.

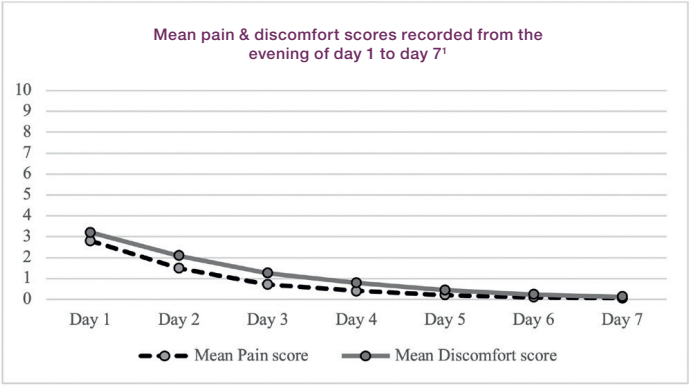
Table 1. - Adverse events

Adverse Event (AE) Category	Number of Adverse events	Number of subjects	Adverse events in relation to the device		Expected / Unexpected	Fitzpatrick skin type
			Related	Non-Related		
Bleeding 2 days post treatment	1	1	1 (100%)	0	Unexpected	FP III
Bruising	6	5	6 (100%)	0	Expected	4/5 FP II
						1/5 FP II
Fever and ague	1	1	0	1 (100%)	Unexpected	FP III
Flaking of the skin surface	3	1	3 (100%)	0	Expected	FP II
Headache	2	2	2 (100%)	0	Unexpected	1/2 FP II
						1/2 FP III
Herpes simplex	1	1	1 (100%)	0	Expected	FP III
	4	4	4 (100%)	0	Expected	1/4 FP II
						2/4 FP III
Pustules and rash	1	1	1 (100%)	0	Expected	FP III
Serous fluid leakage	1	1	1 (100%)	0	Expected	FP III
Swollen lymph nodes	6	3	6 (100%)	0	Expected	1/3 FP II
						2/3 FP III
All categories	26	18	25 (96%)	1 (4%)	–	–

Safety – Subject reported outcomes

Subject assessment of pain on the evening of the treatment showed an average pain score of 2.8 (the lowest score was 0 and the highest score was 9). Mean pain scores reduced to <1 by day 3 and were 0.05 by Day 7. Discomfort was highest on Day 1 with a mean score of 3.20 (the lowest score was 0 and the highest score was 10). Discomfort had receded to <1 by day 4 and receded further to 0.12 by Day 7 (Figure 1).

Figure 1. – Subject recorded mean pain and discomfort scores over 4 treatments



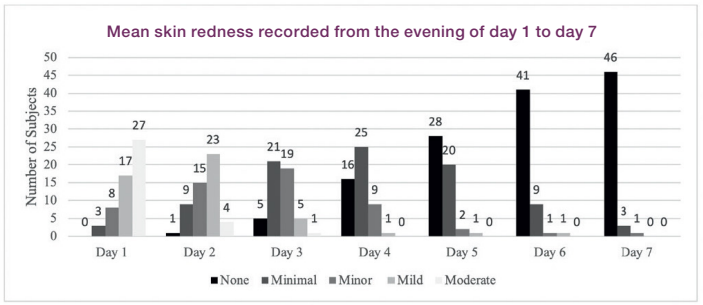
1. based on a scale 0-10 0 - No pain or discomfort. 10 - Worst pain or discomfort ever

Subject reported outcomes – Redness

Forty nine percent (49%) of subjects reported their skin to be moderately red on the evening of the treatment, the remainder reporting their skin redness to be mild or less than mild.

By day 5, 94% of subjects reported their skin redness as either minimal or absent (Figure 2).

Figure 2. – Subject recorded skin redness recorded from the evening of day 1 to day 7



What will the treatment accomplish, and what did the clinical study show?

Effectiveness – Physician reported outcomes

10/56 subjects could not be evaluated by the 3 blinded physicians at the final assessment. The reasons that 10 subjects could not be evaluated are listed below;
– 6 subjects did not complete all 4 treatments
– 3 subjects did not appear at the final follow-up
– 1 subject had no photographs at final follow-up

Treatment success was defined as subjects who improved by 1 grade as agreed upon by two out of 3 blinded physicians using the Acne Scar Assessment Scale (ASAS). The ASAS scale is a descriptive scale used to evaluate the number of visible acne scars. A 1 grade improvement was seen in 27/46 (59%) of subjects. The evaluation by the three blinded physicians indicated that 38/46 (83%) of subjects showed an improvement greater than 0 but less than 1 in their acne scars according to the ASAS scale. 8/46 (17%) subjects demonstrated no improvement from baseline. No subject's acne scars worsened over the study period (Table 2).

Table 2. – Change from Baseline of photograding of ASAS

Timepoint	n	Subjects improved 1 grade as agreed upon by 2 of 3 blinded physicans	Subject showed some improvement (improvement is greater than 0 but less than 1)	No improvement	Subject worsened	Mean change	Standard deviation	Range
Final follow up 3 months post treatment	46	27 (59%)	38 (83%)	8 (17%)	0	0.59	0.38	0 - 1

Of the 38 subjects that showed some improvement, 20/24(83%) subjects were Fitzpatrick skin type II, 14/18(78%) were Fitzpatrick Skin Type III and 4/4(100%) were Fitzpatrick skin type IV. Of the 17 subjects that improved by 1 grade; 8/24(33%) subjects were Fitzpatrick skin type II, 5/18 (28%) were Fitzpatrick skin type III and 4/4(100%) were Fitzpatrick skin type IV.

Effectiveness – Subject reported outcomes

Self-assessed Scar Improvement Scale (SASIS)

Subjects assessed their acne scarring compared to baseline using the Self-assessed Scar Improvement Scale (SASIS). Thirty-eight, 38/43 (88%) of subjects reported some improvement in their acne scarring. Five subjects 5/43 (12%) reported no improvement. No subjects reported a worsening of their acne scars (Table 3).

Table 3. – Self-assessed Scar Improvement Scale (SASIS)

Subject Global Aesthetic Improvement Scale (SGAIS)

Subjects also assessed their acne scarring compared to baseline using the Subject Global Aesthetic Improvement Scale (SGAIS). Thirty-three, 33/43 (77%) of subjects reported some improvement in their acne scarring. Ten subjects 10/43 (23%) reported that the appearance of their acne scarring was essentially the same as the original condition. No subjects reported that the appearance of their acne scars worsened (Table 4).

Table 4. – Subject Global Aesthetic Improvement Scale (SGAIS)

Subject Global Aesthetic Improvement Scale	Compared to the beginning of the study please rate your facial scars now?				
Grading	1 Very Much Improved: Optimal cosmetic result.	2 Much Improved: Marked improvement in apperance from the initial condition, but not completely.	3 Improved: Obvious improvement in apperance from initial condition.	4 No Change: The apperance is essentially the same as the original condition	5 Worse: The apperance is worse than the original condition
Number of Subjects (n=43)	0	4	29	10	0
% of Subjects	0.0	9.3	67.4	23.3	0.0

Additional questions of subject's satisfaction

1. Do you notice any improvement in how your acne scars look in the treated area?

Yes [N, (%)]	No [N, (%)]
37 (86%)	6 (14%)

2. How would you characterize your satisfaction with the treatment?

How would you characterize your satisfaction with the treatment?							
Grading	**Extremly satisfied**	**Satisfied**	**Slightly satisfied**	**Neither satisfied nor dissatsfied**	**Slightly dissatsfied**	**Dissatsfied**	**Extremly dissatsfied**
Number of Subjects (n=-43)	7	18	10	7	0	1	0
% of Subjects	16.3	41.9	23.3	16.3	0.0	2.3	0.0

3. Would you recommend this treatment to your friends and family members?

Yes [N, (%)]	No [N, (%)]
38 (88%)	5 (12%)

What happens during the treatment?

1. You will have your face cleansed to remove any traces of make-up.
2. You will have a numbing cream applied to your face. You will need to wait (typically 30 minutes) while the numbing cream works.
3. After your face is numb the cream is removed from your face and your face will be cleansed again.
4. You will undergo the treatment. The treatment involves making many, very tiny, microscopic punctures into the epidermis of the skin using very fine sterile needles. To do this the device is moved over your skin repeatedly to puncture the epidermis. People who experience the treatment say that it feels like their skin is being rubbed with fine sandpaper while others describe the feeling of an electronic toothbrush being moved across your skin.
5. The treatment takes 15–20 minutes. After the treatment your skin will be cleansed again, and a high sun protection factor (SPF) sunscreen will be applied to your skin.

What happens after the treatment?

During a clinical study on 56 subjects the following side effects were reported,

- Some pinpoint bleeding after the treatment, but this will stop within 5–10 minutes
- Bruising in the treatment area
- Swollen lymph nodes

Some skin redness, pain and discomfort may possibly persist up to 7 days after treatment. A full description of the side effects is described in **"Subject reported outcomes"**.

If you experience any side effects or symptoms that are NOT listed above and/or symptoms that appear to be worse than those listed above, please contact your physician immediately.

Please contact your physician if you have any concerns in general about the treatment.

Care of your skin after the treatment

a. Your physician may give a sunscreen to use after the treatment and a moisturizer to use only in extreme cases of your skin feeling excessively dry. Follow the instructions given to you by your healthcare provider.

b. Apply the sunscreen in the morning and if directly in the sun every 2 hours.

c. Pat the sunscreen onto the face for the first 3 days while the skin may be red and uncomfortable. DO NOT massage the sunscreen into the skin.

d. Avoid direct sun exposure for 5 days. If you experience any side effects or symptoms that are NOT listed in this information leaflet and/or symptoms that appear to be worse than those listed, please contact your physician immediately.

Please contact your physician if you have any concerns in general about the treatment.

Manufactured by:
MT.DERM GmbH
Gustav-Krone-Str. 3
14167 Berlin - Germany
Phone +49 30 76766220-4
Fax +49 30 76766220-5
info@mtderm.de

Distributed by:
Candela
251 Locke Drive
Marlborough, MA 01752
United States
Phone 508-358-7400 or 800-733-8550
candelamedical.com
info@candelamedical.com

CANDELA™
Science. Results. Trust.

© 2020 Candela Corporation. This material contains registered and unregistered trademarks, trade-names, service marks and brand names of Candela Corporation and its affiliates. All other trademarks are the property of their respective owners. All rights reserved. PU07675EN-NA, Rev. A