

Hair Removal Pre-Treatment Cautions

Read all additional Cautions as they appear throughout the Clinical Reference Guide and Operator's Manual. Before any Icon Aesthetic System Hair Removal treatment, a pertinent medical history should be obtained to determine whether any Cautionary Criteria or Contraindications are met. Pre-treatment cautions for light-based treatment includes, but is not limited to:

- **Allergies.** Ensure that those being treated are not allergic to medications, latex or other substances that may be used during treatment course.
- **Skin Type.** Evaluate and document the client's skin type. Verify that the client's skin type is appropriate for the handpiece you are using.
- **Test Spots.** Should always be administered before every treatment, on each client and at every visit. Doing so will help decrease or eliminate side effects.
- **Medications.** Review both prescription and non-prescription medications. Be sure to include herbal and natural remedies as some of these may cause photosensitivity. For those taking photosensitizing medication, perform test spots 24 hours up to one week before considering treatment.
- **Clients who are currently taking blood thinning medications** or anti-coagulants should be treated with caution. The client should discontinue the use of these medications if determined to be safe to do so by their prescribing physician. With the prescribing physician's approval, the client should stop taking the medication at least 2 weeks prior to and throughout the treatment course.
- **Blood Disorders.** Clients with conditions or taking medications that alters the ability of the blood to coagulate should be treated with caution after consultation with their managing physician.
- **Tretinoin and topical retinoids, e.g., Retin-A[®], Renova[®] and exfoliating products.** Although use in the area to be treated is not absolutely contraindicated, it is known to make skin more sensitive and prone to exfoliation. Candidates for Icon™ treatment should be advised to discontinue the use of exfoliating creams and other exfoliating products two (2) weeks prior to and during the entire treatment course.
- **Heat Urticaria.** Those with a history of heat urticaria may develop hives with exposure to light pulses.
- **Herpes I or II within the treatment area.** Before a treatment, candidates should consult their primary care physician for medical evaluation and possible prophylaxis to minimize the chance of a herpetic breakout. A small percentage of persons may experience an activation of oral herpes simplex virus infection within 5-10days after the procedure, even with appropriate prophylaxis.
- **Botulinums:** There is the possibility for increased diffusion of Botulinums, such as Botox[®], as a result of edema associated with facial light-based treatment, which may result in facial asymmetry when these procedures are performed at the same visit. Many physicians recommend waiting for a minimum of 2 weeks after a Botox injection before performing facial light-based treatments. Cynosure has conducted no clinical trials and cannot recommend any specific waiting time.

- **Diabetes.** Those to be treated should obtain clearance from their primary care physician.
- **Pigmented Lesions.** If treating over a pigmented lesion, the lesion must be diagnosed as benign by a qualified practitioner prior to treatment. Inaccurate diagnosis and inadvertent treatment of a skin cancer may lead to a delay in the person receiving proper medical care.
- **Cosmetic Dermal Fillers/Implants.** This Handpiece has not been evaluated or tested on areas with cosmetic dermal fillers, neurotoxins, or implants.
- **Unprotected sun exposure or use of tanning beds or creams in areas to be treated.** Protected sun exposure means wearing protective clothing and the daily use of a SPF-45 or greater sunscreen. Those being treated should be advised to discontinue indoor and outdoor tanning at least four (4) weeks prior to treatment, during the treatment course, and four to six (4 to 6) weeks after treatment. This will reduce the chance of skin color changes and manifestation of new pigmented lesions.
- **Menstrual dysfunction/Polycystic Ovarian Syndrome (PCOS).** Those with menstrual dysfunction, such as PCOS and/or ovarian hyperandrogenism, may have unpredictable results. These subjects tend to have hirsutism secondary to their disease and should consult a primary care physician before a light-based treatment.
- **Mechanical epilation.** Advise hair removal clients to avoid any mechanical epilation such as waxing, tweezing, electrolysis, etc., during the treatment course.
- **Other Conditions.** History of vitiligo, eczema, psoriasis, allergic dermatitis, autoimmune diseases, any diseases affecting collagen including Ehlers-Danlos syndrome, and scleroderma may affect response to treatment.
- **Risk of paradoxical hair growth.** This can occur in people of Middle Eastern and Mediterranean descent and those who have an ill-defined hair line with no obvious transition of the hairline to the face. These clients are at a high risk for hair stimulation and should be advised of this phenomenon before treating.
- **Suitability.** A qualified practitioner is solely responsible for evaluating each subject's suitability to undergo laser or light-based treatment and for informing those being treated about any risks involved with the treatment, pre-and postoperative care, and any other relevant information.

1540 Fractional Non-Ablative Skin Resurfacing Pre-Treatment Cautions

Read all additional Cautions as they appear throughout the Clinical Reference Guide and Operator's Manual. Before any Icon Aesthetic System Fractional Non-Ablative Skin Resurfacing treatment, a pertinent medical history should be obtained to determine whether any Cautionary Criteria or Contraindications are met. Pre-treatment cautions for light-based treatment includes, but is not limited to:



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- **Allergies.** Ensure that those being treated are not allergic to medications, latex or other substances that may be used during treatment course.
- **Skin Type.** Evaluate and document the client's skin type. Verify that the client's skin type is appropriate for the handpiece you are using.
- **Test Spots** should always be administered before every treatment, on each client and at every visit. Doing so will help decrease side effects.
- **Medications.** Review both prescriptions and non-prescriptions. Be sure to include herbal and natural remedies as some of these may cause photosensitivity. For persons taking photosensitizing medication, perform test spots at least 24 hours before treatment.
- **Clients who are currently taking blood thinning medications** or anti-coagulants should be treated with caution. The client should discontinue the use of these medications if determined to be safe to do so by their prescribing physician. With the prescribing physician's approval, the client should stop taking the medication at least 2 weeks prior to and throughout the treatment course.
- **Blood Disorders.** Clients with conditions or taking medications that alters the ability of the blood to coagulate should be treated with caution after consultation with their managing physician.
- **Tretinoin and topical retinoids, e.g., Retin-A[®], Renova[®] and exfoliating products.** Although use in the area to be treated is not absolutely contraindicated, it is known to make skin more sensitive and prone to exfoliation. Candidates for Icon™ 1540 treatment should be advised to discontinue the use of exfoliating creams and other exfoliating products two (2) weeks prior to and during the entire treatment course.
- **Heat Urticaria.** Persons with a history of heat urticaria may develop hives with exposure to laser pulses.
- **Herpes I or II within the treatment area.** Before a treatment, candidates should consult their primary care physician for medical evaluation and possible prophylaxis to minimize the chance of a herpetic breakout. A small percentage of persons may experience an activation of oral herpes simplex virus infection within 5-10 days after the procedure, even with appropriate prophylaxis.

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- **Botulinums:** There is the possibility for increased diffusion of Botulinums, such as Botox[®], as a result of edema associated with facial laser treatment, which may result in facial asymmetry when these procedures are performed at the same visit. Many physicians recommend waiting for a minimum of two (2) weeks after a Botox injection before performing facial laser treatments. Cynosure has conducted no clinical trials and cannot recommend any specific waiting time.
- **Diabetes.** Have client get clearance from their primary care physician before laser treatment.
- **Pigmented Lesions.** If treating over a pigmented lesion, the lesion must be diagnosed as benign by a qualified practitioner prior to treatment. Inaccurate diagnosis and inadvertent treatment of a skin cancer may lead to a delay in the person receiving proper medical care.
- **Cosmetic Dermal Fillers/Implants.** This Handpiece has not been evaluated or tested on areas with cosmetic dermal fillers or implants.
- **Unprotected sun exposure or use of tanning beds or creams in areas to be treated.** Protected sun exposure means wearing protective clothing and the daily use of a SPF-45 or greater sunscreen. Those being treated should be advised to discontinue indoor and outdoor tanning at least four (4) weeks prior to treatment, during the treatment course, and four to six (4 to 6) weeks after treatment. This will reduce the chance of skin color changes and manifestation of new pigmented lesions.
- **Other Conditions.** History of vitiligo, eczema, psoriasis, allergic dermatitis, autoimmune diseases, any diseases affecting collagen including Ehlers-Danlos syndrome, scleroderma, and other skin conditions may affect a person's response to treatment.
- **Suitability.** A qualified practitioner is solely responsible for evaluating each subject's suitability to undergo laser or pulsed- light treatment and for informing those being treated about any risks involved with the treatment, pre-and postoperative care, and any other relevant information.

Pigmented and Vascular Lesion Pre-Treatment Cautions

Read all additional Cautions as they appear throughout the Clinical Reference Guide and Operator's Manual. Before any Icon Aesthetic System Pigmented or Vascular Lesion treatment, a pertinent medical history should be obtained to determine whether any Cautionary Criteria or Contraindications are met. Pre-treatment cautions for light-based treatment includes, but is not limited to:



- **Allergies.** Ensure that those being treated are not allergic to medications, latex or other substances that may be used during treatment course.
- **Skin Type.** Evaluate and document the client's skin type. Verify that the client's skin type is appropriate for the handpiece you are using.
- **Test Spots.** Should always be administered before every treatment, on each client and at every visit. Doing so will help decrease or eliminate side effects.
- **Medications.** Review both prescription and non-prescription medications. Be sure to include herbal and natural remedies as some of these may cause photosensitivity. For those taking photosensitizing medication, perform test spots 24 hours up to one week before considering treatment.
- **Clients who are currently taking blood thinning medications** or anti-coagulants should be treated with caution. The client should discontinue the use of these medications if determined to be safe to do so by their prescribing physician. With the prescribing physician's approval, the client should stop taking the medication at least 2 weeks prior to and throughout the treatment course.
- **Blood Disorders.** Clients with conditions or taking medications that alters the ability of the blood to coagulate should be treated with caution after consultation with their managing physician.
- **Tretinoin and topical retinoids, e.g., Retin-A[®], Renova[®] and exfoliating products.** Although use in the area to be treated is not absolutely contraindicated, it is known to make skin more sensitive and prone to exfoliation. Candidates for Icon[™] Aesthetic System light-based treatment should be advised to discontinue the use of exfoliating creams and other exfoliating products two (2) weeks prior to and during the entire treatment course.
- **Heat Urticaria.** Those with a history of heat urticaria may develop hives with exposure to light pulses.
- **Herpes I or II within the treatment area.** Before a treatment, candidates should consult their primary care physician for medical evaluation and possible prophylaxis to minimize the chance of a herpetic breakout. A small percentage of persons may experience an activation of oral herpes simplex virus infection within 5-10days after the procedure, even with appropriate prophylaxis.
- **Botulinums:** There is the possibility for increased diffusion of Botulinums, such as Botox[®], as a result of edema associated with facial light-based treatment, which may result in facial asymmetry when these procedures are performed at the same visit. Many physicians recommend waiting for a minimum of 2 weeks after a Botox injection before performing facial light-based treatments. Cynosure has conducted no clinical trials and cannot recommend any specific waiting time.

- **Diabetes.** Those to be treated should obtain clearance from their primary care physician.
- **Pigmented Lesions.** If treating over a pigmented lesion, the lesion must be diagnosed as benign by a qualified practitioner prior to treatment. Inaccurate diagnosis and inadvertent treatment of a skin cancer may lead to a delay in the person receiving proper medical care.
- **Cosmetic Dermal Fillers/Implants.** This Handpiece has not been evaluated or tested on areas with cosmetic dermal fillers, neurotoxins, or implants.
- **Unprotected sun exposure or use of tanning beds or creams in areas to be treated.** Protected sun exposure means wearing protective clothing and the daily use of a SPF-45 or greater sunscreen. Those being treated should be advised to discontinue indoor and outdoor tanning at least four (4) weeks prior to treatment, during the treatment course, and four to six (4 to 6) weeks after treatment. This will reduce the chance of skin color changes and manifestation of new pigmented lesions.
- **Menstrual dysfunction/ Polycystic Ovarian Syndrome (PCOS).** Those with menstrual dysfunction, such as PCOS and/or ovarian hyperandrogenism, may have unpredictable results. These subjects tend to have hirsutism secondary to their disease and should consult a primary care physician before a pulsed-light treatment.
- **Other Conditions.** History of vitiligo, eczema, psoriasis, allergic dermatitis, autoimmune diseases, any diseases affecting collagen including Ehlers-Danlos syndrome, and scleroderma may affect response to treatment.
- **Risk of paradoxical hair growth.** This can occur in people of Middle Eastern and Mediterranean descent and those who have an ill-defined hair line with no obvious transition of the hairline to the face. These clients are at a high risk for hair stimulation and should be advised of this phenomenon before treating.
- **Suitability.** A qualified practitioner is solely responsible for evaluating each subject's suitability to undergo laser or pulsed- light treatment and for informing those being treated about any risks involved with the treatment, pre-and postoperative care, and any other relevant information.



1540 NON-ABLATIVE LASER POST-TREATMENT INSTRUCTIONS

- Application of cool gel packs and appropriate topical creams immediately following treatment can help alleviate post treatment itchiness and stinging that may occur.
- Edema, and sometimes blanching, is expected immediately post-treatment and generally resolves within 24-48 hours. It may last up to 3-5 days in some clients.
- Those being treated may experience significant redness, broken capillaries and bronzing in the treatment area for approximately 1-3 days after treatment. This may persist in a mild form for several weeks particularly in areas other than the face.
- Following a more aggressive treatment, it may be helpful to use some occlusive ointment on the skin after treatment during the healing process to help minimize trans-epidermal water loss which may result in significant desquamation or crusting.
- To help remove debris and bronzing of skin that can appear 1 to 4 days after treatment, soak treated areas for 5 – 15 minutes with gauze or wash cloth wet with water, then gently remove debris. Do not pick at or scrub the treated areas.
- Gentle cleansing and use of non-irritating cosmetics are permitted after treatment. It is suggested that retinoids be discontinued 1-2 weeks prior to the initial treatment and throughout the course of treatment. The use of retinoids during the treatment course may result in undesirable side effects and prolonged healing.
- Those prone to acne outbreaks should avoid heavy make-up or moisturizers for 24 hours post treatment.
- As healing occurs, clients should avoid injury and sun exposure for at least two weeks following treatments. It is highly recommended that clients use a sunscreen with SPF 45 or higher containing UVA/UVB protection between treatments, along with a sun blocker such as zinc oxide or titanium dioxide.
- Those being treated should continue to use SPF 45 or higher up to 6 months following final treatment whenever they are outside.
- Once the treatment area has healed, some itching or dryness may occur. This will gradually clear. The use of non-irritating moisturizers may provide some relief.
- Advise the person being treated to contact the treatment provider if there are any issues or concerns following the treatment.
- **NOTE:** After treating striae (stretch marks) with the 1540 Laser Handpiece, it is recommended to avoid tight-fitting clothes around the treated areas for three (3) months after the last laser treatment.



HAIR REMOVAL POST TREATMENT INSTRUCTIONS

- A mild sunburn-like sensation is expected. This usually lasts two to twenty-four (2-24) hours but can persist up to seventy-two (72) hours. Mild swelling and redness may accompany this, but it usually resolves in two to three (2-3) days.
- Apply cooling to the treatment area for ten to fifteen (10-15) minutes every hour for the next four hours, as needed. An oral, over-the-counter anti-inflammatory (ibuprofen such as Advil®) or an analgesic (acetaminophen such as Tylenol®) may be taken to reduce discomfort. Use such medicine according to manufacturer's recommendations.
- Until redness has resolved, it is recommended to **AVOID THE FOLLOWING:**
 - Applying cosmetics to treated areas.
 - Swimming, especially in pools with chemicals.
 - Hot tubs, Jacuzzis, saunas.
 - Activities that cause excessive perspiration, or any activity that may raise core body temperature.
 - Sun exposure or tanning to treated areas. Apply a SPF 45 or greater sunscreen to prevent skin color changes.
 - Aggressive scrubbing and use of exfoliants on the treated area.
- Bathe or shower as usual. Treated areas may be temperature-sensitive.
- Appearance of hair growth or stubble will continue for seven to thirty (7-30) days post-treatment. This is not new hair growth, but treated hairs being expelled from the skin.
- Hairs that were in the resting phase (telogen) at the time of treatment may enter the active growing phase (anagen) in one to six (1-6) months, depending on the body area. Follow-up treatment may be needed.
- If any darkened lesions occur, advise persons being treated not to pick or pull at darkened lesions as scarring may occur.



Pigmented Lesion Treatment Clinical Endpoints

The lesion will eventually darken and crust. It will be naturally shed by the skin in an average of seven to twenty-one (7-21) days.

Schedule a follow-up appointment for evaluation in three to four (3-4) weeks and retreat the area if necessary.

Pigmented Lesion Post-Treatment Guidelines

The mechanism of pulsed-light pigmented lesion removal is based upon selective destruction of melanocytes and melanosome-containing epidermal keratinocytes. Their destruction is associated with some crusting and epidermal damage, which typically resolves within a one to four (1-4) week period.

- A mild sunburn-like sensation is expected. This usually lasts two to twenty-four (2-24) hours but can persist up to seventy-two (72) hours. Mild swelling and/or redness may accompany this, but it usually resolves in two to three (2-3) days. Apply wrapped ice or gel packs to the treatment area for ten to fifteen (10-15) minutes every hour for the next four hours, as needed. Never apply ice directly to skin. An oral, over-the-counter anti-inflammatory (ibuprofen such as Advil[®]) or an analgesic (acetaminophen such as Tylenol[®]) may be taken to reduce discomfort. Use medicine according to manufacturer's recommendations.
- Until redness has resolved, it is recommended to **avoid the following**:
 - Applying cosmetics to treated areas.
 - Swimming, especially in pools with chemicals, such as chlorine.
 - Hot tubs, Jacuzzis, and saunas.
 - Activities that cause excessive perspiration or any activity that may raise core body temperature.
 - Sun exposure and tanning in treated areas. Apply a SPF 45 or greater sunscreen to prevent skin color changes.
 - Aggressive scrubbing and use of exfoliants on the treated area.
- Bathe or shower as usual. Treated areas may be temperature-sensitive.
- The lesion may initially look raised and/or darker with a reddened perimeter.
- The lesion will gradually turn darker over the next twenty-four to forty-eight (24-48) hours. It may turn dark brown or even black.
- The lesion will progress to darkening and/or crusting and will start flaking off in an average of seven to twenty-one (7-21) days.
- The lesion is usually healed in twenty-one to thirty (21-30) days. It will continue to fade over the next six to eight (6-8) weeks.
- **Advise persons being treated not to pick or pull at darkened lesions as scarring may occur.**



VASCULAR LESION POST-TREATMENT INSTRUCTIONS

- A mild sunburn-like sensation is expected. This usually lasts two to twenty-four (2-24) hours but can persist up to seventy-two (72) hours. Mild swelling and/or redness may accompany this, but it usually resolves in two to three (2-3) days. Apply wrapped ice or gel packs to the treatment area for ten to fifteen (10-15) minutes every hour for the next four hours, as needed. Never apply ice directly to skin. An oral, over-the-counter anti-inflammatory (ibuprofen such as Advil®) or an analgesic (acetaminophen such as Tylenol®) may be taken to reduce discomfort. Use medicine according to manufacturer's recommendations.
- The vessels may undergo immediate graying or blanching, or they may exhibit a slight purple or red color change. The vessels will fully or partially fade in about ten to fourteen (10-14) days.
- Until redness has resolved, it is recommended to **AVOID THE FOLLOWING:**
 - Applying cosmetics to treated areas.
 - Swimming, especially in pools with chemicals.
 - Hot tubs and Jacuzzis.
 - Activities that cause excessive perspiration.
 - Sun exposure to treated areas. Apply an SPF 45 or greater sunscreen to prevent skin color changes.
 - Aggressive scrubbing and use of exfoliants on the treated area.
 - No exercising for 24-48 hours post-treatment.
- Bathe or shower as usual. Treated areas may be temperature-sensitive.
- Schedule a follow-up appointment for evaluation. Repeat treatments may be performed every seven to fourteen (7-14) days if skin has fully recovered. One to four (1-4) treatments may be necessary seven to fourteen (7-14) days apart.
- Do not to pick, remove, or pull at any darkened lesions as scarring may occur.