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## INFORMED CONSENT- EXOSOME FACIAL REJUVENATION MICRONEEDLING

**Informed Consent Instructions:** This is an informed consent document to provide written information about the above named procedure regarding risks, benefits, and alternatives. It is important that you understand the information provided to you prior to proceeding with this procedure; please ask your healthcare professional any/all questions prior to signing this consent form.

**I read, write, and understand English. Initials:** \_\_\_\_\_

I, \_\_\_\_\_, do understand that I will undergo **Exosome Facial Rejuvenation**, which uses exosomes derived from mesenchymal stem cells applied after a microneedling procedure in the agreed upon treatment area(s) by: \_\_\_\_\_ to promote cellular regeneration and boost collagen production. The goal of this aesthetic treatment may include: improved skin texture and thickness, reduction in appearance of photoaging and pigment changes, reduction in appearance of fine lines and wrinkles, increased volume via the production of new collagen and elastin, increased skin hydration, and the diminished appearance of scars.

*Provider Use:*

**Treatment Location(s):** \_\_\_\_\_

.....  
**Purpose of Treatment and General Information:**

*Exosome Therapy is not an FDA-approved medical treatment. Exosome Facial Rejuvenation is not intended to prevent, treat or cure diseases or medical conditions.*

**What Is Exosome Facial Rejuvenation:** Exosomes perform a variety of functions in our bodies, including communicating cell damage between cells and supplying regenerative molecules to target cells. When exosomes detect damaged cells, they signal the delivery of repair molecules and prompt damaged cells to perform regeneration. Exosomes used in this procedure are derived from human umbilical cord mesenchymal stem cells manufactured in the USA by DynaCord and distributed by Advanced Biologics. We use only the highest quality, safest, most pure, and most potent Exosomes available. Each batch is extensively tested and abides by the FDA's 351(a) regulations to meet purity, potency, consistency, and safety standards in addition to sterility testing. All of our saline exosome products come with a Certificate of Analysis (COA) showing the exact contents of the product as it relates to the exosome count, proteins, lipids, cytokines, growth factors... etc. It's important for us to know that we are treating our clients with the best product to ensure the best results. **Microneedling** is a procedure that uses very small needles to pierce tiny punctures into your skin at a depth determined by your treatment provider for your skin's unique and specific needs. Microneedling creates micro-injuries to your skin that initiate a healing cascade with collagen and elastin production. Topical exosomes enhance and amplify the healing process with natural growth factors and repair mechanisms that rejuvenate treated skin for an extended period of time. As a result of treatment, collagen production is boosted and skin quality and complexion are improved.

**What To Expect During Treatment:** Your treatment provider will begin by thoroughly cleansing your skin and will then apply a topical numbing medication 30-60 minutes prior to beginning treatment. During treatment, the microneedling device is gently pressed against the treatment area using a gliding agent to create numerous, tiny, micro-channels. The gliding agent will be wiped off and the exosomes applied to your skin; the microchannels deliver the exosomes into the dermal layers. The microneedling procedure and topically-applied exosomes promote a wound healing cascade and encourage collagen production. Microneedling can also help to mechanically break down any existing scar tissue. **The procedure may feel like** light sandpaper moving across your face during treatment and may cause some minor discomfort. **Duration of treatment** is dependent upon treatment location but the average treatment is around 1-2 hours. Minor redness, skin dryness, and skin tightness are common side effects after treatment. There is **no expected downtime** with Exosome Rejuvenation and *most* clients are able to resume normal activities immediately following treatment. Most people are satisfied with a single treatment but if you want further improvements, you can schedule multiple treatments to achieve your desired results. Should you choose to have another treatment, we recommend spacing them out 30 days apart for optimal results. **Maintenance treatments** may be necessary to maintain desired results.

*I understand Exosome Facial Rejuvenation is a cosmetic procedure and is not an FDA approved medical treatment intended to cure or treat medical conditions. I further understand the treatment goal is to increase skin firmness, skin appearance, scar reduction, and/or skin elasticity and that repeated treatments may be necessary in order to maintain desired results.*

### Alternative Treatments:

Alternative forms form of non-surgical and surgical treatment consist of: No treatment whatsoever, surgical facelift, PRP microneedling, dermaplaning, laser treatments, dermal fillers, local muscle relaxer (Botox, Dysport, Xeomin), prescription creams, and/or chemical peels. Every procedure will involve a certain amount of risk. An individual's choice to undergo a procedure is based on the comparison of the risk to the potential benefit. Although most patients do not experience adverse complications, you should discuss your concerns and potential risks with your treatment provider in order to make an informed decision.

*It has been explained to me that alternative treatments are available.* Initials: \_\_\_\_\_

### Possible Risks and Side Effects:

The possible side effects and risks of Exosome Facial Rejuvenation Microneedling include, but are not limited to:

**1. General Side Effects:** I understand there is a risk of swelling, discomfort, pinpoint bleeding, local numbness, pain at the treatment site, bruising, allergic reaction, damage to deeper structures, or irritation of the skin that may occur.

**2. Infection:** Although rare, if an infection occurs as a result of treatment, additional treatment including antibiotics or an additional procedure may be necessary.

**3. Bleeding/Bruising:** It is possible, though unusual, to have minor pinpoint bleeding during treatment. Bruising in soft tissues may occur. Should you develop post-treatment blood clot or bleeding, you may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, and other "herbs / homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take these for ten days before or after your Microneedle treatment.

**4. Skin Redness, Itchiness, Flaking/Crusting, and Tightness:** Redness of the treated area is common and may occur; redness may resemble a sun-burn and typically resolves within 1 week. Skin may also feel warm, tight, and itchy, but this will normally resolve within 12-48 hours. Skin flaking or minor dryness may occur with scab formation in rare instances. It is important that you not pick or scratch any scabbing or crusting areas, as this may lead to permanent scars or promote an infection. If scabbing occurs, please call your treatment provider for advisement.

**5. Damage to Deeper Structures:** Deeper body structures such as nerves, blood vessels, glands, and muscles may be inadvertently damaged during aesthetic treatments. The potential for this to occur varies according to where the treatment is being performed and the treatment type. Injury to deeper structures may be temporary or permanent.

**6. Scarring:** Scarring is a rare occurrence, but is a possibility when the skin surface is disrupted. To minimize the chances of scarring, it is IMPORTANT that you follow all post-treatment instructions provided by your healthcare staff

**7. Swelling:** Swelling of the treated area is not common but may occur; swelling typically resolves within a few days.

**8. Discomfort:** You may experience some discomfort during and after your treatment.

**9. Allergic Reactions and/or Contact Dermatitis:** Allergies to topical local anesthetic preparations and/or sensitivities to metals used in the Microneedle Device may occur. If you experience an allergic reaction, you may require additional treatment. Potential increased sensitivity, irritation/itching, or allergic reaction of the skin due to skin surface disruption.

**10. Skin Lightening/Darkening and Freckle Lightening:** There is a possibility of the treatment area becoming lighter or darker than the surrounding skin. This is usually temporary, but on rare occasions, may become permanent. Utilizing appropriate sun protection in the form of hats, SPF, and limiting exposure to tanning beds and direct sunlight can help minimize the risk of skin pigment changes. Existing freckles may become lighter in treatment area and *may* permanently disappear.

**11. Dilated Pores:** Although rare, widening of existing pores may occur due to collagen contraction that occurs as part of the resurfacing process which may become permanent.

**12. Milia and/or Acne:** Ointments that occlude hair follicles, sweat ducts, or sebaceous ducts may lead to milia/acne formation. This is more common in patients with a history of cystic acne or oily skin.

*This list is not meant to be inclusive of all possible risks associated with Exosome Facial Rejuvenation Microneedling treatments, as there are both known- and unknown- side effects associated with any medication or procedure.*

*I have read and understand possible risks, side effects, and complications.* Initials: \_\_\_\_\_

**Contraindications To Treatment:**

Exosome Facial Rejuvenation Microneedling is not recommended for those who:

- are pregnant or breastfeeding
- have active cancer or malignancies anywhere throughout body, including skin
  - it is recommended to be in remission from cancer for a period of 5 years prior to this treatment
- have used Accutane or similar medications within the last twelve months
- have an active sunburn or have open wounds or a skin infection or have active cold sores in treatment area
- have had radiation treatment in treatment area within the last year
- are taking anti-coagulants or have blood clotting disorders have a history of keloid scars
- have an autoimmune disease causing delayed wound healing, including: HIV/AIDs, Lupus, Scleroderma, etc.

*I have read and understand the contraindications to treatment and affirm that I do not have any of the aforementioned conditions and have disclosed pertinent medical history to my treatment provider: Initials: \_\_\_\_\_*

**Pre- Treatment Care Acknowledgement:**

I affirm that I have been provided Pre-Treatment advisement and have:

- discontinued use of any isotretinoin products like Accutane for the past 6 months.
- waited 1 week after anti-wrinkle injections and 2 weeks after filler injections to have Microneedling treatment.
- not used depilatory cream, wax, or shaved treatment area for 48 hours prior to treatment
- discontinued the use of anti-inflammatory drugs 3-7 days prior to your treatment. This includes steroidal and non-steroidal drugs including, but not limited to: Aspirin, Motrin, and Ibuprofen.
- discontinued the use of any other blood thinning agents such as: Vitamin E, Vitamin A, Ginkgo Biloba, Garlic, Flax Oil, Cod Liver Oil, Essential Fatty Acids (EFAs and DHAs) etc. at least 3 days to 1 week before and after treatment to minimize bruising and bleeding.
- not used systemic or corticosteroids within the last 2 weeks prior to treatment. Please consult your prescribing physician prior to discontinuing the use of these medications.
- taken prophylactic anti-viral medication 3 days prior to treatment if you are prone to herpes outbreaks more than 4 times per year in the area of treatment, including cold sores around the mouth.

*I have read and followed pre-treatment advisement and care instructions: Initials: \_\_\_\_\_*

**Multiple Treatments:**

Although most people are satisfied with a single treatment, if you want further improvements, you can schedule multiple treatments to achieve your desired results as determined by your treatment provider in conjunction with your personal treatment plan.

*I have read and understand I may require future treatments to maintain results. Initials: \_\_\_\_\_*

**Maintaining Results:**

Results are temporary. For continuing results, you may require additional Exosome Facial Rejuvenation Microneedling treatments at intervals as determined by your treatment provider in conjunction with your personal treatment plan.

*I have read and understand I may require future treatments to maintain results. Initials: \_\_\_\_\_*

**No Guarantee of Results:**

In some situations, it may not be possible to achieve optimal results. It is also possible that Exosome Facial Rejuvenation Microneedling treatments may fail to produce the desired results in the targeted areas. Should complications occur, additional or other treatments may be necessary.

*I have read and understand results are not guaranteed. Initials: \_\_\_\_\_*

**Financial Responsibility:**

I understand the regular charge applies to all subsequent treatments. I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment to bear the cost of collection, and/or Court cost and reasonable legal fees, if required.

*I have read and understand I am financially responsible for services rendered. Initials: \_\_\_\_\_*

**Aftercare:**

I have received, and will follow, all aftercare instructions provided. Initials: \_\_\_\_\_

**Exosome Facial Rejuvenation Microneedling Treatment Consent:**

**By signing below, I acknowledge and agree:**

- I have fully disclosed on my client intake form and during face-to-face consultation with treatment provider any and all medications, previous complications, planned or previous surgeries, sensitivities, allergies, or current conditions that may, or may not, affect my treatment.
- I have read the foregoing informed consent for Exosome Facial Rejuvenation Microneedling Treatment; I agree to the treatment and all known and unknown associated risks.
- I have received and will follow all aftercare instructions
- I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
- **I consent to the collection of photo(s) and video(s) of the treatment to be performed, including appropriate portions of my body for: medical documentation, insurance documentation, and/or educational and training purposes. I understand that efforts will be made to conceal my identity, but in some circumstances the photographs may portray features that will make my identity recognizable.**
- For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
- For women of childbearing age: by signing below I confirm that I am **not pregnant** and do not intend to become pregnant anytime during the course of this treatment and that I am not breastfeeding. Furthermore, I agree to keep my treatment provider informed should I become pregnant during the course of this treatment.
- It has been explained to me in a way that I understand:
  - The above cosmetic treatment to be undertaken and that it is not an FDA approved medical treatment.
  - There may be alternative procedures or methods or treatments.
  - There are risks, known and unknown, to the procedure or treatment proposed.
- I have had ample opportunity to ask any questions regarding Exosome Facial Rejuvenation Microneedling Treatment benefits, side effects and after care, and all of my questions have been answered to my satisfaction. I believe I have adequate knowledge to understand the nature and risk of the treatment to which I am consenting.
- By signing below, I am consenting to undergo this, and any subsequent Exosome Facial Rejuvenation Microneedling Treatments, with all aforementioned understood by me. I release the overseeing clinic physician, the person performing the Microneedling Treatment, and the clinic facility from liability associated with treatment.

<b>Patient Name (Print)</b>	<b>Patient Signature</b>	<b>Date</b>
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<b>Witness Name (Print)</b>	<b>Witness Signature</b>	<b>Date</b>
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**Authorization for Collection and Use of Photography and Video for Promotional Purposes:**

**A)** I hereby grant permission to **COMPANY NAME** to collect and distribute photo(s) and video(s) for the purposes of advertising or promotion including, but not limited to: emails, newsletters, promotional materials, brochures, pamphlets, flyers, social media posts, and internet websites. I release all rights, license, and authority to any copyright or publishing claim associated with all photograph(s) and/or video(s) related to use in publication as described above; this includes any claim for payment in connection with distribution or publication of the photograph(s) and/or video(s). I understand that efforts will be made to conceal my identity, but in some circumstances the photographs may portray features that will make my identity recognizable. I hereby waive the right to inspect or approve any photo(s) and/or video(s) collected and distributed as described above.

**Yes**, I consent to the collection, use, and distribution of my before/after photo(s) and/or video(s) as described above in paragraph (A).

**No**, please do not distribute my photo(s) or video(s) for any promotional or advertising purposes.

<b>Patient Name (Print)</b>	<b>Patient Signature</b>	<b>Date</b>
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Company: \_\_\_\_\_

Phone: \_\_\_\_\_

Address: \_\_\_\_\_

Email: \_\_\_\_\_

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Web: \_\_\_\_\_

## CLIENT ACKNOWLEDGEMENT AND LIABILITY RELEASE

### **Treatment Liability Waiver**

I acknowledge that aesthetic treatments and vein treatments including, but not limited to: endovenous vein treatment, sclerotherapy, microablation, microdermabrasion, waxing, electrolysis, facial toning, body treatments, laser treatments, brown spot removal, Botulinum Toxin (A) injections, Collagen, Dermal Fillers, Sclerotherapy, Mesotherapy, Dermaplaning, and various other beauty procedures is not an exact science and no specific guarantees can, or have been made, concerning the outcome.

I further understand that some clients experience more change and improvement than others. In nearly all cases, multiple treatments are required to achieve desired results or see a difference in appearance. I understand that response to treatment varies on an individual basis and that specific results are not guaranteed.

I also understand and agree to assume the following risks and hazards which may occur in connection with any particular treatment including but not limited to: unsatisfactory results, soreness, poor healing, discomfort, redness, blistering, nerve damage, scarring, infection, and change in skin pigmentation, allergic reaction, and bleeding. I understand that even though precautions may be taken in my treatment, not all risks can be known in advance.

Therefore, in consideration for any treatment received, I agree to unconditionally defend, hold harmless and release from any and all liability the company and the individual that provided my treatment, the insured, and any additional insured's, as well as any officers, directors, or employees of the above companies for any condition or result, known or unknown, that may arise as a consequence of any treatment that I receive.

I understand and agree that any legal action of any kind related to any treatment I receive will be limited to binding arbitration using a single arbitrator agreed to by both parties.

### **Covid-19 and Communicable Diseases**

Acceptance of Risk; Release; Indemnification. I am fully aware that there are a number of risks associated with me entering on the [YOUR COMPANY NAME] property during the COVID-19 pandemic under the circumstances of receiving treatments, including without limitation: (a) I could contract COVID-19 or other diseases such as the flu or legionnaires disease which could result in a serious medical condition requiring medical treatment in a hospital or could possibly lead to death; and (b) I will be subject to normal risks associated with general exposure to viruses and other communicable diseases.

By signing below, I acknowledge and agree:

I have carefully read the information on this page and understand that I may be giving up some important legal rights by signing.

\_\_\_\_\_  
**Patient Name (Print)**

\_\_\_\_\_  
**Patient Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Witness Name (Print)**

\_\_\_\_\_  
**Witness Signature**

\_\_\_\_\_  
**Date**

Company: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 \_\_\_\_\_

Phone: \_\_\_\_\_  
 Email: \_\_\_\_\_  
 Web: \_\_\_\_\_

## EXOSOME FACIAL REJUVENATION PRE-TREATMENT INSTRUCTIONS

**What To Expect During Treatment:** Your treatment provider will begin by thoroughly cleansing your skin and will then apply a topical numbing medication 30-60 minutes prior to beginning treatment. During treatment, the microneedling device is gently pressed against the treatment area using a gliding agent to create numerous, tiny, micro-channels. The gliding agent will be wiped off and the exosomes applied to your skin; the microchannels deliver the exosomes into the dermal layers. The microneedling procedure and topically-applied exosomes promote a wound healing cascade and encourages collagen production. **The procedure may feel like** light sandpaper moving across your face during treatment and may cause some minor discomfort. **Duration of treatment** is dependent upon treatment location but the average treatment is around 1-2 hours. Minor redness, skin dryness, and skin tightness are common side effects after treatment. There is **no expected downtime** with Exosome Rejuvenation and *most* clients are able to resume normal activities immediately following treatment. Most people are satisfied with a single treatment but if you want further improvements, you can schedule multiple treatments to achieve your desired results. Should you choose to have another treatment, we recommend spacing them out 30 days apart for optimal results. **Maintenance treatments** may be necessary to maintain desired results.

*Please review and follow these important instructions prior to your scheduled appointment*

### Stop Taking/Using/Doing Prior To Appointment:

6 Months	2 Weeks	5-7 Days	2-3 Days	Day Of
Accutane	IPL Laser Treatments Botox/Neurotoxin Dermal Fillers Sunbathing/Tanning Chemical Peels Microdermabrasion	Aspirin Steroids* Blood Thinners* Anti-Platelet Meds* Waxing/Electrolysis/ Depilatory Retin-A & Topical Meds	Ibuprofen Aleve/Advil/Anancin NSAIDS  <b>24 Hours</b> Alcohol Cigarettes Niacin	No shaving/waxing treatment area  Do not apply makeup, lotion, oil, perfume, or sunscreen to treatment area
*Consult prescribing physician for guidance on stopping these meds				

### Please DO:

1. Plan to avoid strenuous exercises that can cause sweating, jacuzzi, sauna or steam baths for 24 hours due to open pores, or up to 48 hours if inflammation/swelling is present. You can return to work 1 day after treatment.
2. Cleanse face/treatment area prior to your procedure and do not wear make-up, moisturizers, lotion, oil, perfume, or sunscreen to treatment area.
3. If you have a history of cold sores, take your prescribed antiviral treatment for 2 days prior to + day of treatment.
4. Wear a button down or zipper front shirt and comfortable, loose clothing if you will be having body treatments.
5. You will not be under general sedation during your treatment. You can take an anxiolytic to relax during the procedure, if needed. Please ask your provider to prescribe an anxiolytic for you prior to your appointment. If you will be taking medications that will sedate you, please arrange for someone to drive you home following the procedure.
6. Expect to experience tenderness, redness, warmth, skin flaking, and some swelling to treatment area for 1-7 days.
7. Understand that multiple treatments may be necessary to achieve desired results.
8. Reschedule if a rash, open sore/wound, sunburn, or blemish develops in treatment area.
9. **If you're planning to attend an event, please schedule treatment at least 1 week prior to ensure adequate time for redness to dissipate.**

Your Exosome Facial Appointment is: M T W T H F S S U \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 Day (circle one) Date Time

For questions or concerns during office hours, please call:000-000-0000

Company: \_\_\_\_\_

Phone: \_\_\_\_\_

Address: \_\_\_\_\_

Email: \_\_\_\_\_

\_\_\_\_\_

Web: \_\_\_\_\_

## EXOSOME FACIAL REJUVENATION AFTERCARE INSTRUCTIONS

### **Do NOT:**

- 1. Do NOT** take/use Arnica cream or capsules, anti-inflammatory medications, Ibuprofen, Advil, Motrin, etc. or other NSAIDs for **1 week** post-treatment, as it may interfere with the natural inflammatory process critical to your skin rejuvenation results.
- 2. Do NOT** have dermal fillers, botox/neurotoxin, laser, IPL, or waxing in treatment area for 2 weeks after treatment.
- 3. Do NOT** engage in strenuous exercise that can cause sweating, jacuzzi, sauna or steam baths for 24 hours due to open pores, or up to 48 hours if inflammation/swelling is present. You can return to work 1 day after treatment.
- 4. Do NOT** wash your face or apply makeup, lotions, or other topical products for *at least* the first 24 hours after treatment.

### **Please DO:**

1. Stay hydrated to promote the healing process.
2. Gently wash the treated area daily with cool water and gentle cleanser & pat to dry for 5-7 days.
3. Cold compresses may be used 20 minutes on 20 minutes off to reduce swelling 2-3x per day during the 1st 1-2 days if needed.
4. Understand it is not uncommon to experience the following for the next 1-5 days: redness, peeling, pinpoint bruising, mild inflammation, soreness, and mild swelling. If you experience an *increase* in these symptoms after the first 72 hours, please call the office for a follow-up. **You may apply cold compresses, take acetaminophen (Tylenol), and sleep elevated to help reduce swelling or discomfort.**
5. Avoid prolonged exposure to sunlight/heat/UV for the first 2 weeks; use sunscreen daily on face as soon as inflammation has subsided.
6. **Optional dietary recommendations:** Eat fresh pineapple, tart cherry juice, salmon, bone broth based soups, and consider taking a collagen 1 & 3 supplement for 2 weeks to optimize healing.

### **Important Info:**

- Please expect redness, peeling, warmth, pinpoint bruising, peeling, or swelling for one to three days after treatment. Redness for 3-5 days is a common side effect.
- Results: Elastin and collagen building takes place over 4-6 weeks after treatment, with optimal results seen at 3-6 months after the last treatment.
- Facial Treatments: Most are satisfied with a single treatment. Should you choose to get additional treatment, each should be 4-6 weeks apart for maximum benefit.
- Body Treatments: 6-10 treatments are recommended at 4-6 weeks apart to achieve desired or maximum results.
- Once desired results are achieved, a maintenance treatment should be done every 8 to 10 months to maintain results.

Your Next Appointment Is:

M T W T H F S S U

Day (circle one)

\_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Date

\_\_\_\_  
Time

.....  
For questions or concerns during office hours, please call: 000-000-0000

**In case of emergency, call 911**