Informed Consent: Exosome / PDRN Treatment

Regenerative skin treatment (often combined with microneedling)

Client name: _____ DOB: _____ Date: _____

ABOUT THE PROCEDURE

Exosome and polynucleotide (PDRN) treatments use regenerative signaling compounds applied to the skin, most often immediately after microneedling to aid absorption, with the goal of supporting skin rejuvenation, tone, and texture. The specific product used will be recorded in my file. Initials ___

Regulatory status: I understand that the exosome product used is a **topical cosmetic solution, not a drug**; it is not intended to prevent, treat, or cure any disease or medical condition, and is **not intended to be injected or delivered intravenously**. Exosome products are **not approved by the FDA for aesthetic or therapeutic use**, their safety and long-term efficacy are not FDA-established, and the FDA has issued public safety warnings about unapproved exosome products. This treatment is elective and outside FDA-approved indications. I have had the opportunity to ask questions and choose to proceed. Initials ___

REALISTIC EXPECTATIONS

Results vary and are not guaranteed. Any improvement typically develops gradually over weeks and usually requires a series. Initials ___

WHAT TO EXPECT AFTER

When combined with microneedling, skin is typically red and flushed like a moderate sunburn, with tightness and possible light flaking, usually settling within 24 to 72 hours. Initials ___

RISKS & POSSIBLE SIDE EFFECTS

Not limited to: redness, swelling, itching, and (from microneedling) pinpoint bleeding; and less commonly **allergic or immune reaction to the product**, infection, prolonged redness, pigmentation change, and **unknown or long-term effects** given the investigational nature of these products. Initials ___

CONTRAINDICATIONS: PLEASE DISCLOSE. TREATMENT MAY BE DECLINED IF ANY APPLY

- ☐ Pregnant or nursing
- ☐ Active infection, cold sore, or open/irritated skin in the area
- ☐ Known allergy or sensitivity to the product or its ingredients
- ☐ Active cancer, or radiotherapy/chemotherapy (remission commonly advised)
- ☐ Autoimmune disorder or immunosuppressive therapy
- ☐ History of keloid or hypertrophic scarring
- ☐ Bleeding/clotting disorder or blood thinners (if combined with microneedling)
- ☐ Isotretinoin (Accutane) within the past 6 to 12 months

I confirm the above are accurate and have disclosed all relevant conditions and allergies. Initials ___

CONSENT