

*Dear Physician,*

*Miramar Labs is providing the information below as background information only, based on information from clinical trials. It is up to you to seek appropriate advice from your own legal counsel or insurance carrier on your own requirements for a patient consent form for the miraDry procedure. Contact Miramar Labs Customer Service at 1-855-647-2379 (1-855-miradry) if you have any questions, or to request a copy of the miraDry Console User Manual that contains more information about the procedure.*

### **Procedure Consent Template: miraDry**

The miraDry procedure is a highly controlled delivery of energy designed to safely and effectively reduce sweating and hair in the underarm area. Patients may also experience a reduction in odor. Typically, patients may see a reduction in underarm sweat in as little as one treatment. In controlled clinical trials between 70% and 90% of subjects saw a significant reduction in their underarm sweat and virtually all the subjects achieved some reduction. Patients continued to show a dramatic reduction of sweat when tracked 12 months after the procedure. Like any other medical procedure, results can vary from patient-to-patient, so be advised that large reductions may not occur in every single case.

### **Procedure Description [optional section]**

The miraDry procedure is performed in a doctor's office, typically under the supervision of a specialist such as a dermatologist or plastic surgeon. You will be asked to shave both underarms prior to a procedure visit. This allows for ease of treatment. If you have not shaved, your clinic may reschedule your appointment.

You will be lying down on your back for the procedure, with your arms positioned above your head on a special support. At the start of each miraDry procedure, the staff will mark the skin of your underarm with markers or temporary ink. Injectable anesthetic will be used to numb the area prior to the procedure. When the anesthetic is injected, you may feel a pinch or stinging sensation with each injection. Numbing the underarms will make the procedure more comfortable.

Once your skin is numb, the staff will place the miraDry device on your underarm skin on the marked area. Once the device is positioned, the miraDry System will be turned on. You will feel suction of the skin and you will hear tones and beeps that indicate to the operator that the energy is being delivered. This will be repeated multiple times. If you begin to feel significant discomfort or pain during the procedure either in the treatment area or your arm, please alert the operator immediately.

After the procedure is complete, the staff will clean the treated area. You should apply an ice pack to the underarm area after the procedure to reduce potential swelling. You can then return to your normal activities, although we recommend avoiding any vigorous activity with your arms for several days.

The miraDry System is contraindicated in people:

- WITH HEART PACEMAKERS AND OTHER ELECTRONIC DEVICE IMPLANTS
- WHO NEED SUPPLEMENTAL OXYGEN
- WITH KNOWN RESISTANCE TO OR HISTORY OF INTOLERANCE OF LOCAL ANESTHESIA INCLUDING LIDOCAINE AND EPINEPHRINE.

Please inform the doctor if you are:

- PREGNANT
- HAVE ANY UNDERLYING SKIN CONDITIONS
- HAVE HAD PREVIOUS AXILLARY SURGERY

**Risks and discomforts:**

The following represent the more common side effects observed within or near the treatment area that can last between a **few days to few weeks** (unless otherwise noted):

- Swelling in the treated area
- Temporary altered sensation or tingling in the treated skin and/or upper arm (can last for several months)
- Discomfort, tenderness or pain in the underarm when touched (treatable with non-prescription medications such as ibuprofen)
- Redness from the device suction
- Bruising at the numbing injection sites
- Bumps under the treated skin (can last for several months)
- Partial underarm hair loss (may be long-lasting)

Less common reports of undesired effects include the following:

- Swelling in the adjacent arm or torso lasting several weeks
- Hyperpigmentation (darkening of skin) in the treatment area
- Soreness in the shoulders or arms due to procedure positioning
- Numbness or tingling in the arm due to the anesthesia, lasting less than 24 hours
- Shaking due to epinephrine in the anesthesia, lasting less than 24 hours
- Tight banding in the underarm (gradually resolves)

There have been rare reports of the following:

- Altered sweating elsewhere on the body
- Small blisters/ulcerations or rashes in the treatment area
- Temporary altered sensation or tingling in the forearm or fingers (can last for several months)
- Weakness in the arm or fingers that gradually goes away (can last for several months)
- Pain in the arm or fingers that gradually goes away (can last for several months)
- Pain in the underarm requiring prescription medications
- Infection/chronic infection/abscess
- Burns

*[insert standard payment and release paragraph/statement here]*

\_\_\_\_\_  
Patient Name

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

\_\_\_\_\_  
Date