



COMPLAINTS AND ADVERSE EFFECTS

No serious adverse events were observed during the clinical study evaluation of the miraDrySystem. Should an adverse event be suspected or reported, contact miraDry, Inc. at 855-647-2379; for those outside the U.S., contact your local miraDry representative.

CONTRAINDICATIONS

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

POTENTIAL RISKS

As with any medical device, there are possible risks associated with the use of the miraDry System. Patients should be monitored closely for symptoms to allow for early intervention. The most common side effects observed within or near the treatment area follow below.

- Swelling/tightness in the treated area
- Discomfort, tenderness or pain in the underarm when touched, usually treatable with nonprescription medications such as ibuprofen
- Redness from the device suction
- Bruising at the numbing injection sites
- Bumps under the treated area
- Temporary altered sensation or tingling in the treated skin and/or upper arm

Other less common side effects include:

- Swelling in the adjacent arm or torso
- Hyperpigmentation (darkening of skin) in the treatment area
- Soreness in the shoulders or arms due to positioning of the arms during the procedure
- Numbness or tingling in the arm due to the anesthesia
- Shaking due to epinephrine in the anesthesia
- Tight banding in the underarm

There have been rare reports of:

- Altered sweating elsewhere on the body
- Small blisters/ulcerations or rashes in the treatment area
- Temporary altered sensation or tingling in the forearm or finger
- Weakness in the arm or fingers that gradually goes away
- Pain in the arm or fingers that gradually goes away
- Pain in the underarm requiring prescription medications
- Infection/abscess
- Nerve damage
- Burns

1. International Hyperhidrosis Society, sweathelp.org
2. Clinical Evaluation of a Microwave Device for Treating Axillary Hyperhidrosis. Hong et al; Dermatologic Surgery 2012.
3. Long-term Efficacy and Quality of Life Assessment for Treatment of Axillary Hyperhidrosis With a Microwave Device. Mark Lupin, MD et al; Dermatol Surg 2014; 40: 805-807.
4. Retrospective Multistudy Analysis of Axillary Odor Reduction After Microwave Treatment, Sarah Yagerman, MD et al; American Society for Dermatologic Surgery, Inc.; 2018.
5. Taylor NAS, Machado-Moreira CA. Regional variations in transepidermal water loss, eccrine sweat gland density, sweat secretion rates and electrolyte composition in resting and exercising humans. Extrem Physiol Med. 2013;2:4
6. Data on file. miraDry, Inc.
7. A Prospective Study of Axillary Hair Reduction in Patients Treated With Microwave Technology. Jeremy A. Brauer, MD et al; American Society for Dermatologic Surgery, Inc. 2016.