

## INFORMED CONSENT

**QWO (Collagenase Clostridium Histolyticum-aes) for subcutaneous injection use only**

### GENERAL INFORMATION

**QWO** is a prescription medication used for the treatment of moderate to severe cellulite in the buttock of adult women. **QWO** treatment consists of 3 separate treatment sessions, 21 days apart. In some patients, additional treatment may be indicated. Results are not optimal with less than 3 treatments. **QWO** does not treat skin laxity, ONLY cellulite dimples. We cannot guarantee how each individuals' dimples will appear once injected. The results of **QWO** may or may not be permanent. For optimal results, it is recommended to continue lifestyle changes with a combination of diet and exercise. The development of cellulite is multifactorial and additional treatments may be necessary.

### Do Not Receive QWO if you:

- Are allergic collagenase or to any ingredients in **QWO**.
- Have an active infection or an open wound to the treatment area.

### Before Receiving QWO tell your healthcare provider about your medical conditions, including:

- Have had an allergic reaction to a **QWO** injection in the past.
- Have a bleeding disorder, or take blood-thinning medications.
- Are pregnant or plan to become pregnant. It is not known if **QWO** will harm the fetus.
- Are breastfeeding or plan to breastfeed. It is not known if **QWO** can be excreted through breast milk.

Tell your healthcare provider about all the medications you take, including prescription and over the counter medications, vitamins, and herbal supplements. Ensure you disclose to your healthcare provider if you take a medication that prevents the clotting of your blood (antiplatelet or anticoagulant medication).

### **QWO** may cause serious side effects including:

- Allergic (hypersensitivity) reactions, including anaphylaxis.  
Call your healthcare provider right away, if you have any of these symptoms of an allergic reaction after an injection of **QWO**:
  - Hives
  - Swollen Face
  - Trouble Breathing
  - Chest Pain
  - Dizziness or fainting
- The most common side effects were related to the injection site (**bruising, pain, nodules, pruritus, erythema, discoloration, swelling, and warmth of the treatment site.**)
- You will have injection site bruising that can last up to 4 weeks or more.
- The most common side effects of **QWO** include bruising, pain, areas of hardness, itching, redness, discoloration, swelling and warmth in the treatment area.
- Infection

- These are not all of the possible side effects of **QWO**. Report any Major side effects to the FDA at 1-800-FDA-1088.

There are many variable conditions that may influence the long-term result of **QWO** injections. Though risks and complications occur infrequently, the risks cited are particularly associated with **QWO** injections. Other complications and risks can occur but are uncommon. Should any complication occur differing treatments may be necessary.

Although desired results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

The long-term effects of **QWO** on tissue is unknown.

#### **FINANCIAL RESPONSIBILITIES**

The cost of **QWO** injection may involve several charges. This includes the professional fee for the injections, follow-up visits to monitor the effectiveness of the treatment, and the cost of the **QWO** material itself. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs of medical treatment would be your responsibility should complications develop from **QWO** injections. **In signing the consent for this procedure, you acknowledge that you have been informed about its risks and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

**Patient Name (Printed):**

**Patient Signature:**

**Date:**

**Provider Name (printed):**

**Provider signature:**

**Date:**