# Customer Feedback

**Please complete the form and email as an attachment to: complaints.coordinator@boviemed.com**

## 1. Reporter (Your) Information

First and Last Name: _____ Today's Date: _____

Phone: _____ Email: _____

## 2. Health Provider Information

First and Last Name: _____

Medical/Surgical Specialty: _____

Practice Name: _____

City: _____ State: _____

Zip Code: _____ Country: _____

Phone: _____ Fax: _____

Email: _____

## 3. Device Information (list all products associated with the event)

☐ **Electrosurgical Unit**

Catalog #: _____ Device Name: _____

Serial Number: _____ Settings: _____

☐ Solid Pad ☐ Split Pad

Where was the grounding pad placed? _____

☐ **Handpiece**

Catalog #: _____ Device Name: _____

Lot Number: _____

☐ **Accessories**

Catalog #: _____ Device Name: _____

Lot Number: _____

- **Was device used on the patient?** ☐ Y ☐ N
- **Is device available for evaluation?** ☐ Y ☐ N
- **Was this the first time this device was used?** ☐ Y ☐ N
- **If a sterile device, had it been reprocessed and/or re-sterilized?** ☐ Y ☐ N

**Physician Provider Experience with Renuvion® and/or J-Plasma® Technology (select one):**

☐ Less than 10 procedures ☐ 11-20 procedures ☐ 20-50 procedures ☐ 50+ procedures

☐ **Other Medical Devices Used (e.g. Vaser)**

Catalog #: _____ Device Name: _____

Lot Number: _____ Description: _____

## 4. Incident Information

**Date of Incident:** _____

**Nature of Problem Encountered:** _____

_____

_____

☐ **Photos** (attach photos) ☐ **Video** (attach video)

**Was there patient injury?** ☐ Y ☐ N – **If yes, describe:**

_____

_____

**Approximate size of complication (e.g. lesion or burn):** _____

**When did complication first appear?** _____

**Was there user injury?** ☐ Y ☐ N – **If yes, describe:**

_____

_____

**Did the Device Function as Intended?** ☐ Y ☐ N – **If no, answer the following questions:**

- **When did issue/malfunction/injury occur?**

  ☐ Straight out of the box ☐ 0-10 min into the case ☐ 10-30 min into the case ☐ 30-60 min into the case

- **Characterization of device problem (select all that apply):**

  ☐ Packaging damage

  ☐ Device visual damage or breakage

  ☐ Moving part jammed (blade extension/retraction activation button, other buttons),

  Explain: _____

  ☐ Generator Error or Fault Code ( F _____ or E _____ )

  ☐ Unusual plasma flow (no flow, low flow, intermittent flow) _____

**Measures Taken to Correct Problem:**

_____

_____

**In the opinion of the health care professional, did the device(s) cause or contribute to the incident?** ☐ Y ☐ N

**Was MedWatch Form filed with FDA by facility?** ☐ Y ☐ N

## 5. Patient Information

**Operative Notes/Treatment Records available?** ☐ Y ☐ N

**Patient ID # and/or Initials:** _____ **Patient Gender:**_____

**Age at Time of Event:** _____

**Patient Medical History:**

_____

_____

_____

_____

_____

**Current Patient Condition (Status):**

_____

_____

_____

_____

_____

**Patient Treatment:**

_____

_____

_____

_____

_____

**Date(s) of Post Op Evaluation:**

_____

_____

_____

_____

_____

## 6. Procedure Information

**Type of Procedure Being Performed on Patient:**

☐ Laparoscopic

☐ General Surgery

☐ Cosmetic Surgery

☐ Subdermal Coagulation

☐ Other, Specify: _____

**Generator Settings Used:_____%, _____Flow**

**Complete the section below only for Subdermal Coagulation Procedures:**

**List other previous procedures done in the treatment area:** (e.g. type of liposuction, fillers, sutures, energy based procedures, surgical lifting, etc.)

_____

_____

**Location of insertion sites:** _____

**Infiltration amount infused:** _____ **And at what temperature:** _____

**Undermining performed with:** _____ **Instrument**

**Additional treatment with details:** (e.g.: VASER settings (continuous or pulsed), minutes delivered, cannula size)

_____

_____

**Aspiration performed:** _____

**Aspiration amount:** _____ **Length of aspiration time:** _____

**Treatment plane (depths):** (e.g.: One intermediate or two, one superficial one deep.)

_____

**Number of passes:** _____

**Were temperatures monitored?** ☐ Y ☐ N – **If yes, with what device?**

_____

**Was compression applied?** ☐ Y ☐ N – **If yes, when and how long?**

_____

**Immediate treatment plan:** (e.g.: Creams or ointments, RX Silvadene, continued compression, injections, masks etc.)

_____

## 7. Bovie® Medical Personnel Only

**Awareness Date (date event was first reported to you):** _____

**Did health care professional state device(s) caused or contributed to the incident?** ☐ Y ☐ N – **If yes, provide details:**

_____

_____

_____

_____

**Please complete the form and email along with any pictures or videos as an attachment to:**
**complaints.coordinator@boviemed.com**