

Please complete the form and email as an attachment to: Complaints.Coordinator@ApyxMedical.com

1. Reporter (Your) Information

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

IMPORTANT: If patient injury is reported, obtain and attach photos (before and after procedure)

2. Health Provider Information

First and Last Name: _____
Medical/Surgical Specialty: _____
Practice Name: _____
City: _____ State: _____
Postal Code: _____ Country: _____
Phone: _____ Fax: _____
Email: _____

Training Received? Y N

If yes: Date: _____ Trainer: _____ Location: _____

Inservice Performed? Y N

If yes: Date: _____ Trainer: _____ Location: _____

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? _____

Is device available for evaluation? Y N N/A

Handpiece

Catalog #: _____ Device Name: _____

Lot Number: _____

Is device available for evaluation? Y N N/A

Accessories

Catalog #: _____ Device Name: _____

Lot Number: _____

Is device available for evaluation? Y N N/A

• **Was device used on the patient?** 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:**

Any operative notes/treatment records available? Y N – **If yes, attach notes/records**

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):**

When the handpiece was activated during the issue/malfunction was an audible tone present? Y N

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) _____

Any support provided by Apyx™ Personnel? Y N – **If yes, who:** _____

Device visual damage or breakage

Packaging damage

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 (Not required for product malfunctions)

Operative Notes/Treatment Records available? Y N

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

Age at Time of Event: _____

Patient Medical History:

Previous Surgical/Cosmetic Procedures to the affected area?

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. Apyx[™] 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@ApyxMedical.com