Customer Feedback

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

1. Incident Information:			
Apyx Personnel Only – Awareness Date:			
Important: If patient injury is reported, obtain, and attach photos (before & after Procedure)			
Date of Incident:			
Nature of Problem Encountered:			
2. Reporter Information:			
First & Last Name:		Occupation:	
Phone Number:		Email:	
Distributor/Sponsor (if applicable):			
Principal Contact (if Distributor/Sponsor):		Principal Contact Email (if Distributor/Sponsor):	
☐ **Please check here to request result of investigation**		Investigation Results to go to:	☐ **Customer** ☐ **Distributor** ☐ **Rep**
3. Health Provider Information:			
Medical/Surgical Specialty:			
Practice Name:			
Office Contact First & Last Name:			
Address:		City:	
State:		Country:	Postal Code:
Phone:		Email:	
4. Training Information:			
Training Received	☐ **Yes** ☐ **No**	If Yes, Date:	
Trainer:		Location:	
Inservice Performed	☐ **Yes** ☐ **No**	If Yes, Date:	
Trainer:		Location:	
Physician Provider Experience with Renuvion® and/or J-Plasma® Technology (Select one):			
☐ **Less than 10 procedures** ☐ **11 – 20 procedures** ☐ **21 – 50 procedures** ☐ **51 + procedures**			
5. Device Information:			
☐ **Electrosurgical Unit** ☐ **Handpiece** ☐ **Accessories**			
Product Part #:		Lot Number:	

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Serial #:		Will the device be returned?	☐ Yes ☐ No
Generator Settings	_____%, _____Flow	Tracking Number:	**Email tracking and return info to: CustomerService@ApyxMedical.com**

6a. Incident Information:

Did death or serious injury occur?	☐ Yes ☐ No **If Yes, complete section 7**	**Who was injured?**	☐ Patient ☐ User

Did the device malfunction or have a deficient design or labeling?	☐ Yes ☐ No **If Yes, complete section 6b**
If the malfunction could recur could it cause death or serious injury?	☐ Yes ☐ No **If Yes, complete section 7**
Did the device cause or contribute to the death or serious injury?	☐ Yes ☐ No **If Yes, complete section 7**

6b. Incident Information (Specific device information):

Did the device malfunction?	☐ Yes ☐ No

Characterization of Device Problem (select all that apply)

Characterization of Device Problem (select all that apply):

☐ When the handpiece was activated during the issue/malfunction, was an audible tone present? ☐ Yes ☐ No

☐ A moving part was jammed (blade extension/retraction, activation button, other button) ☐ Yes ☐ No

Explain: _____

☐ Generator Error or Fault Code (E_____ or F_____)
☐ Unusual plasma flow? ☐ No Flow ☐ Low Flow ☐ Intermittent
☐ Worked for a while
☐ Never worked
☐ Device Damaged
☐ Packaging Damaged

When was the problem noted?	☐ During Prep (no patient contact) ☐ During start of the procedure ☐ 10 minutes – 20 minutes into the procedure ☐ 20 minutes + into the procedure
Measures taken to correct problem:	
Type of Procedure Being Performed:	☐ Laparoscopic ☐ General Surgery ☐ Cosmetic Surgery ☐ Subdermal Coagulation ☐ Other:

6c. Incident Information – Complete below ONLY for Subdermal Coagulation Procedures:

List previous procedures to treatment area: (e.g. type of liposuction, fillers, sutures, surgical lifting, energy based procedures, etc.)		Location of Insertion Sites:	
Infiltration amount infused:		And at what temperature:	
Undermining Performed with what instrument?		Additional treatment details: (e.g. VASER settings, minutes delivered, cannula size)	
Aspiration performed:		Aspiration amount and length of time:	

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Treatment plane (depths): (e.g. One intermediate or two, one superficial, one deep)		Number of passes:	
Were temperatures monitored?	☐ Yes ☐ No	Was compression applied?	☐ Yes ☐ No
Immediate Treatment plan: (e.g.: creams or ointments, Rx Silvadene, continued compression, injections, masks, etc.)			

7. Patient Information (Not required for product malfunctions):

Operative Notes/Treatment Records available?	☐ Yes ☐ No	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:			

8. Additional Information

Sequence of Events Step by Step:	
Are there any long-term health effects as outcome?	
Was the procedure completed with this device? Completed with a different device?	
How was the product stored at your facility? At hospital? Distribution center? Temperature, lighting, and or/humidity?	

Handpiece Return Instructions:	**Generator & Regulator Return Instructions:**
1) Place the device in a leakproof sealed/zipped plastic bag. 2) Apply orange biohazard label to outside of bag. 3) Place the bag in a box that will comfortably seat the device being returned so that the device is not cramped nor free to move freely in the box. 4) Apply orange biohazard label to outside of box. 5) Place box in a shipping box. 6) Write CMPT# on the shipping box. 7) Place Return Call Tag on the outside of the box and schedule delivery for the return to be provided by the shipping service provider (E.g., UPS, FedEx).	1) Write CMPT# & RMA# on the shipping box. 2) Place Return Call Tag on the outside of the box and schedule delivery for the return to be provided by the shipping service provider (E.g., UPS, FedEx)