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

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

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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?	