Customer Feedback

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

1. Incident and Device Information:					
Date of Incident:		Date Apyx Personnel Became Aware:			
Nature of Problem:					
Procedure Being Performed:	☐ Cosmetic Surgery ☐ Dermal Resurfacing ☐ General / Open Surgery	☐ Liposuction / Body Contouring ☐ Subdermal Coagulation ☐ Other:			
Product Part Number:		Lot or Serial Number:			
Did death or serious injury occur?	☐ Yes ☐ No	***If "Yes", also complete Section 5 on Page 2***			
Did the device malfunction?	☐ Yes ☐ No	Will the device be returned?	☐ Yes ☐ No		
Characterization of Device Problem:	☐ Device Does Not Work ☐ Device is Damaged ☐ Device is Broken ☐ Loose Component	Output / Flow (Gas, Liquid, or Energy):	☐ None ☐ Low ☐ High ☐ Intermittent ☐ Inaccurate		
		Display Problem:	☐ Difficult to Read ☐ Incorrect Information ☐ Inaccurate Controls ☐ No Display		
Generator Error or Fault Code	E	F	FA	FI	FU
Other (Describe):					
When was the problem noted?	☐ During Prep (no patient contact) ☐ At the start of the procedure ☐ 10 - 20 minutes into procedure ☐ 20 minutes + into procedure ☐ Post Operatively				
Request results of investigation?	☐ Customer ☐ Representative ☐ Distributor				

2. Reporter Information:			
First & Last Name:		Occupation:	
Phone Number:		Email:	
Distributor/Sponsor (if applicable):		Principal Contact:	
		Email:	

3. Health Provider Information:					
Practice / Facility Name:					
Address:			City:		
State:		Country:		Post Code:	
Office Contact (First & Last Name):					
Phone:		Email:			
Physician First & Last Name:		Physician Experience with this Technology	☐ Less than 10 Procedures ☐ 10 – 20 Procedures ☐ 21 – 50 Procedures ☐ 51+ Procedures		
Physician Email:					
Training or Inservice performed?	☐ Yes ☐ No				

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4. Procedure Details:							
List Any Other Treatments Performed (Including Settings and Treatment Parameters):							
Sequence of Events Step by Step:							
For Renuvion / J-Plasma:							
Generator Settings	Power:		Flow:		Joules:		
Location of Insertion Sites:		Infiltration Amount:		Aspiration Amount:			
Type of Passes (Antegrade / Retrograde, or Retrograde):		Treatment Planes / Depths (Superficial, Intermediate, Deep):					
Number of Passes:		Speed and Spacing Between Strokes:					
For AYON:							
Ultrasound Settings	Power:	☐ Low ☐ Medium ☐ High	Mode:	☐ Standard ☐ Continuous			
	Skin Port:	☐ Small (3mm ID) ☐ Large (5mm ID) ☐ Corkscrew (5mm ID)					
	Probe:	Diameter		Length		Rings	
Infiltration Settings	Infiltration amount (Current Area Volumes):						
	Infiltration amount (Total Case Volume):		Infiltration Flow Rate:				
Aspiration Settings	Set Pressure Setting:		Actual Pressure Setting:		☐ mmHg (millimeters of mercury)		
	ASP1		ASP1		☐ inHg (inches of mercury)		
	ASP2		ASP2		☐ hPa (hectopascals)		
Cannula type and size							
5. Incident Information – Complete only if a Death or Serious injury occurred:							
Patient Gender:		Age at Time of Event:		Fitzpatrick Type (if Applicable):			
List previous procedures to treatment area: (e.g. type of liposuction, fillers, sutures, surgical lifting, energy-based procedures, etc.)							
Patient Medical History available?	☐ Yes ☐ No	Treatment Records available?	☐ Yes ☐ No				
When were the injuries first identified (during the start of procedure, after)?							
Immediate Treatment plan:		Current Patient Condition:					
Are there any long-term health effects as outcome?							

6. Return Instructions:

Patient Contacting Devices:

1) Place the device in a leakproof sealed/zipped plastic bag.
2) Apply orange biohazard label to the 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. Apply orange biohazard label to the outside of the box
4) Place the box in an outer shipping box. Do not apply biohazard label to outer shipping box.
5) Place Return Call Tag and write CMPT# on the outside of the box and schedule delivery for the return to be provided by the shipping service provider (E.g., UPS, FedEx).

Non-Patient Contacting Devices:

1) Place Return Call Tag and write CMPT# & RMA# on the outside of the box and schedule delivery for the return to be provided by the shipping service provider (E.g., UPS, FedEx).