

Customer Clinical Complaint Questionnaire



I N M O D E

Rev. F

Form No.: 1009

Complaint No.		Received by:	
Date:	Time:	Ref:	
<u>Medical Director Info (if applicable)</u>			
Physician name:		Specialty:	
Operator/Treatment Provider Name:			
Title:			
Usage duration of system:			
Clinic:		Address:	
Telephone:		Mobile:	
Fax:		Email:	
Contact Person (if different from operator):			
<u>Device Info:</u>			
System Name:		System S/N:	
Hand piece Type:		Hand Piece S/N:	
Software number:			
<u>Patient Info:</u>			
Code name:			
Gender: FEMALE		Age:	
Body Areas:		Skin Type:	
Treatment indication:			
Medications:			
Significant Diseases (Current and History):			
Any Tanning before or after Treatment?			
Was sunscreen applied on the treatment area during the entire treatment period?			
Was the treatment area shaved and cleaned?			
If YES, what was the area cleaned with? (e.g. cleanser, alcohol, soap):			
Were Test Spots performed?			
If YES, where were the Test Spots performed?			
How much time passed after test spot till the treatment?			
Did the patient complain of pain, tingling, discomfort, hot spots during the treatment?			
If Yes, please describe:			

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Number of previous sessions:

Number of Days/Weeks post last Treatment Sessions:

List any combined treatment regimen if used:

Patient signed ICF? Yes No

Were before and after photos taken? (note on photo and attach):

Describe the treatment given to the patient immediately post incident:

Patient's current clinical status and date:

Other Medical Info:

Incident Info:

Description:

Incident timing post treatment:

Incident recording date (e.g. photos) post treatment:

Minimally Invasive: BodyTite/FaceTite/NeckTite/AccuTite/Aviva/InMode RF:

Applicator Name:

Treatment depth (1-5 levels or mm):

Protocol (according to IFU or other):

End Points:

Tumescent infiltration used & amount:

Prep Solution:

Post Op Care:

Total Energy (kJ):

RF Power (W):

Total/Fat Aspirate (cc):

Cut-Off Temperature (C°) (external and internal when applicable):

Was the handpiece operational:

Was the handpiece saved:

Access Sites:

Operating distance from access port:

Was Conductive Gel used? Yes No Sterile? Yes No Which brand?

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Fractora/FractoraV

Sedative/Anesthesia (Ingredients %,duration):	End Points:
Energy (levels per pin):	
Number of pins: Number of stacks: Number of passes:	Post Op Care:
Tip Overlap (%):	
Protocol (according to IFU or other):	
Post Op Care:	

Forma/Plus

Applicator:	Treatment Time per zone (min):
Treatment zone size:	
Energy (levels):	Cut-Off Temperature (C°):
Total Energy (kJ if applicable):	End Points:
Was Conductive Gel used? <input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, which brand?
Protocol (according to IFU or other):	
Post Op Care:	

BodyFX/MiniFX

Applicator:	Treatment zone size:
Protocol (according to IFU or other):	
Power:	End Points:
Pulse Width (s):	Cut-Off Temperature (C°):
Post Op Care:	
Was any cream/gel used during the procedure? <input type="checkbox"/> Yes <input type="checkbox"/> No	

LUMECCA/DIOLAZE/DIOLAZE XL/TRITON

Hand piece:	Wavelength:
Protocol (according to IFU or other):	
Fluence:	Pulse width:
Mode (pulses per second):	Cooling:
End points:	Number of passes:
Post Op Care:	
Was Conductive Gel used? <input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, which brand?

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FORMA V /Plus90

Was pelvic exam performed: <input type="checkbox"/> Yes <input type="checkbox"/> No			If Yes, any abnormal findings?
Hand piece:		Cut-Off Temperature (C°):	
Energy (levels):	External:	Internal: :	
Treatment Time (min):	External:	Internal: :	
Total Energy (kJ if applicable):	External:	Internal: :	
Depth of internal treatment:			
Protocol (according to IFU or other):			
Was Conductive Gel used? <input type="checkbox"/> Yes <input type="checkbox"/> No			If Yes, which brand?
Post Op Care:			

EVOLVE

Applicator:	Units used for treatment (1-8):
Energy (levels):	Treatment Time (min):
Cut-Off Temperature (C°):	Patient Call Button tested:
Protocol (according to IFU or other):	
Were Conductive Gel Pads used? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If Yes, which brand?	
Was Conductive Gel used? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If Yes, which brand?	
Were belts used? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Post Op Care:	

EVOKE

Applicator:	Units used for treatment (1-8):
Energy (levels):	Treatment Time (min):
Cut-Off Temperature (C°):	Patient Call Button tested:
Protocol (according to IFU or other):	
Were Conductive Gel Pads used? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If Yes, which brand?	
Was Conductive Gel used? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If Yes, which brand?	
Were belts used? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Post Op Care:	

MORPHEUS8

Number of pins:	Sedative/Anesthesia (Ingredients %,duration):
Number of stacks:	
Number of passes:	
Depth:	
Energy (levels per pin):	Tip Overlap %:
Protocol (according to IFU or other):	
Post Op Care:	

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Please send high resolution photos (with dates) and any supporting documents such as charts, summaries, etc.

Please send responses to:

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Comments: