CAPER
Cutaneous Procedures Adverse Event Reporting
Physician Form

Only VOLUNTARY reporting of adverse events, drug/product/device/biologic/surgical treatment problems. Please fill out 1 form per AE.

CAPER STAFF USE ONLY
Staff Received Date:
Staff Follow-Up Date:
Date of Report:

A. PATIENT INFORMATION

1. Internal ID (for staff completion)	2. Age *(yrs)*:	
3. Sex:[1] ☐ Male ☐ Female ☐ Prefer not to say ☐ Other _____ 4. Gender Identity: _____	5. Weight: _____ ☐ lbs ☐ kg 6. Height: _____ ☐ in ☐ cm	7. Ethnicity *(check single best answer)*: ☐ Hispanic/Latino ☐ Not Hispanic/Latino

8. Race *(Check all that apply)*: ☐ Asian ☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Black or African American ☐ White ☐ Unknown or Not Reported

9. Fitzpatrick skin type: ☐ I ☐ II ☐ III ☐ IV ☐ V ☐ VI

10. Relevant tests/laboratory data, including dates:

Use continuation page if needed

11. Relevant medical history:

Use continuation page if needed

12. Prescriptions, over-the-counter medications (topical and systemic), dietary supplements, or herbal remedies taken at time of procedure:

Use continuation page if needed

[1]Clayton JA, Tannenbaum C. Reporting Sex, Gender, or Both in Clinical Research? JAMA. 2016;316(18):1863–1864. doi:10.1001/jama.2016.16405

B. PROVIDER INFORMATION

1. Original product/procedure/device /surgery was administered/operated/performed by:
☐ Dermatologist
☐ Non-Dermatologist Physician
☐ Nurse or Nurse Practitioner
☐ Physician Assistant
☐ Aesthetician
☐ Medical assistant
☐ Medi-spa staff (if so, explain) _____
☐ Other (specify job title)_____
☐ Patient/self-administered
☐ Unknown

2. Original procedure/treatment setting location:
☐ Academic-based Dermatologist Office
☐ Private Practice Dermatologist Office
☐ Medi-spa
☐ Non-Dermatologist Academic Physician Office
☐ Non-Dermatologist Private Practice Physician Office
☐ Other (specify)_____

3. Years performing provider has been practicing:

4. Was performing provider made aware of AE? ☐ Yes ☐ No ☐ Unknown

5. Was performing provider made aware of outcome? ☐ Yes ☐ No ☐ Unknown

6. Has performing provider been involved in management of AE? ☐ Yes ☐ No ☐ Unknown

7. If no, was this due to patient preference? ☐ Yes ☐ No ☐ Unknown

8. AE treatment/correction was administered/performed by:
☐ Dermatologist
☐ Non-Dermatologist Physician
☐ Nurse or Nurse Practitioner
☐ Physician Assistant
☐ Aesthetician
☐ Medical assistant
☐ Medi-spa staff (if so, explain) _____
☐ Other (specify job title)_____
☐ Unknown

9. AE treatment/correction setting location:
☐ Academic-based Dermatologist Office
☐ Private Practice Dermatologist Office
☐ Medi-spa
☐ Non-Dermatologist Academic Physician Office
☐ Non-Dermatologist Private Practice Physician Office
☐ Other (specify)_____

C. ADVERSE EVENT

1. *Check **all** that apply*:
☐ Adverse event ☐ Drug/Product/Device problem *(defects/malfunctions)* ☐ Product/Device use error ☐ Surgical treatment

2. Date of AE onset per patient recollection *(mm/dd/yyyy)*:	3. Date patient reported AE to provider *(mm/dd/yyyy):*	4. Severity of AE ☐ Mild ☐ Moderate ☐ Severe 5. Duration of AE ☐ Resolved with treatment ☐ Resolved spontaneously ☐ Persistent/Permanent ☐ Lost to follow-up 6. If resolved, date of resolution: _____

7. Type of AE (check all that apply):

☐ Visual disturbances	☐ Doctor or other healthcare office/clinic visit	☐ Nodules/induration
☐ Blindness	☐ Nerve injury	☐ Contour irregularity
☐ Congenital anomaly/birth defects	☐ Compression phenomenon	☐ Scar
☐ Permanent injury	☐ Cerebrovascular compromise	☐ Keloid
☐ Permanent disability	☐ Vascular compromise	☐ Hyperpigmentation
	☐ Swelling	☐ Hypopigmentation
	☐ Erythema	☐ Infection
	☐ Pain	☐ Skin necrosis
	☐ Blistering	
	☐ Skin texture alteration	
☐ None of the above	☐ Other (please describe):	

8. Outcome of AE (check all that apply):
☐ Hospitalization
☐ Emergency room/dept or urgent care
☐ Death (mm/dd/yyyy):
☐ Life-threatening event
☐ Other
☐ None

9. Has the AE been reported anywhere else? ☐ Yes (*date if Yes mm/dd/yyyy*): _____ ☐ No
If Yes, where has it been reported? *Check all that apply*: ☐ FDA ☐ Manufacturer ☐ Other: _____
If No, do you plan to report to the FDA MAUDE Database? ☐ Yes ☐ No

10. Describe the original procedure/treatment, desired outcome/indication, drug/device/biologic. Include all products/devices used, along with volume/units, lot numbers, treatment parameters, location, and other information you think is relevant.

Use continuation page if needed

11. Describe the AE, including timeline from initial detection, and response offered for the AE. Who performed treatment response and what was the course of action?

D. DRUG/PRODUCT INFORMATION (Only fill out if suspected drug/product)			
1. Name of drug/product:		2. Manufacturer/Compounder:	
3. ID or Lot #:	4. Dose:	5. Frequency:	6. Route administered (topical, injectable, needle/cannula, etc.)
7. Anatomic location(s) of administration:			
8. Date used (*from mm/dd/yyyy)*:			
9. Reason for use:			
10. Expiration date *(mm/dd/yyyy)*:			
11. Was product mixed or diluted? ☐ Yes ☐ No ☐ Unknown 12. If Yes, why? (please explain) 13. If Yes, with what product? (please explain)			

E. DEVICE INFORMATION (Only fill out if suspected device)		
1. Device name:	2. Manufacturer:	
3. Common name:	4. Model #:	5. Serial #:
6. Date used (*from mm/dd/yyyy)*:		
7. Reason for use:		
8. Anatomic area(s) treated		
9. Anatomic area(s) of the reported AE		
10. Was regular device maintenance performed?		
11. Device errors reported during treatment		
12. Years of device experience of operator:		

F. CELLULAR THERAPY/GENE THERAPY/VACCINE THERAPY/BIOLOGIC INFORMATION (Only fill out if suspected cellular therapy/gene therapy/vaccine therapy/biologic)		
1. Brand name:	2. Manufacturer:	
3. Common name:	4. Model #:	5. Serial #:
6. Date used (*from mm/dd/yyyy)*:		
7. Reason for use:		
8. Anatomic location(s)		
9. Expiration date if applicable *(mm/dd/yyyy)*:		

G. SURGICAL TREATMENT (Only fill out if suspected surgical treatment)
1. Treatment procedure name:
2. Date treatment was performed (*from mm/dd/yyyy)*:
3. Reason for treatment:

H. REPORTER			
1. First and Last Name:			
2. Title of Reporter: ☐ Dermatologist ☐ Non-Dermatologist Physician ☐ Nurse or Nurse Practitioner ☐ Physician Assistant ☐ Aesthetician ☐ Medical assistant ☐ Medi-spa staff (if so, explain) _____ ☐ Other (specify job title)_____			
3. Address:		4. City:	5. State:
6. Zip code:	7. Phone:	8. Email:	
9. Occupation:		10. Is provider an ASDS Member: ☐ Yes ☐ No	
11. Are you reporting your own AE or reporting an AE caused by someone else? ☐ Own AE ☐ AE caused by other			
12. Best physician/healthcare professional to contact about this AE (optional): Name: _____ Phone: _____ Email: _____			

I. ATTESTATION
I have received written permission from the patient to report their case to the CAPER registry and have proper HIPAA forms on file. _____ _____ Signature (First and Last Name) Date

CAPER **Continuation Page (use only if you need more space)**

A.8. Relevant tests/laboratory data, including dates:
A.9. Relevant medical history:
A.10. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies taken at time of procedure:

C 10. Describe the original procedure/treatment, desired outcome/indication, drug/device/biologic. Include all products/devices used, along with volume/units, lot numbers, treatment parameters, location, and other information you think is relevant.

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C 11. Describe the AE, including timeline from initial detection, and response offered for the AE. Who performed treatment response and what was the course of action?