RESET FORM

VERICEL

Product Event Report Form

Options to report this Safety Event within 1 Business Day of Receipt include:
1) Email this Report to PatientSafety@vcel.com
2) Call Customer Care: 1-800-453-6948 option #2

PART 1: SAFETY EVENT SECTION

ARGUS NUMBER (Pharmacovigilance Only)	PRODUCT EVENT NUMBER (Customer Care Only)

SECTION 1: REPORTER			
Your Name		Today's Date	
Date you learned of Event			
Product(s) (Select all that apply)	☐ MACI ☐ Epicel ☐ Carticel ☐ MACI Biopsy Kit ☐ Epicel Biopsy Kit ☐ Surgical Instrument ☐ Other:		
Lot Number(s)			

SECTION 2: PATIENT IDENTIFIERS	
Patient Initials	☐ Unknown
Description of Patient	Sex: ☐ Male ☐ Female ☐ Unk | DOB: ☐ Unk | Age: ☐ Unk ☐ Fetus ☐ Neonate ☐ Infant ☐ Child ☐ Adult ☐ Elderly ☐ Unknown

SECTION 3: EVENTS	
Report Term(s) and Brief Description	
Event Start Date:	
Outcome	☐ Ongoing ☐ Resolving ☐ Recovered, if so when: ☐ Unk
Check all that apply	☐ Death, if so, date of death: Cause of Death: ☐ Hospitalization (initial or prolonged). Dates of hospitalization: ☐ Life-threatening ☐ Congenital Anomaly/Birth Defect ☐ Disability or Permanent Damage ☐ Other Series (Important Medical Event): ☐ Unknown

SECTION 4: HEALTH CARE PROVIDERS ONLY - RELATEDNESS	
If the initial reporter is a HCP, do they consider the event to be related to the product?	☐ 1) Definitely Related ☐ 2) Probably Related ☐ 3) Possibly Related ☐ 4) Unlikely Related ☐ 5) Not Related
If Unlikely or Not Related, what is the most likely cause, per the reporting HCP?	

SECTION 5: INITIAL REPORTER (person who initially reported the event to you, if applicable)	
Name	
Phone Number	
Email Address	
Institution Address	
Credentials	

INTERNAL USE ONLY

PART 2: PRODUCT EVENT INTAKE

ARGUS NUMBER (Pharmacovigilance Only)	**PRODUCT EVENT NUMBER** (Customer Care Only)

SECTION 1: INTAKE POINT INFORMATION	
Customer Care Representative	
Date of Notification	
Date Opened	

SECTION 2: PRODUCT EVENT INFORMATION			
Product Part Number		Product Name	
Treatment Date(s)			
Quantity Affected		Sales Order Number	
Lot Number		Product Expiration Date	
Product being returned from Customer?	☐ YES ☐ NO	Associated RGA Number (if applicable)	
Product Event Description:			
Treating Physician (and contact information)			
Institution Address			
Email Address			
Phone Number			

SECTION 3: INTERNAL APPROVALS	
Name, Signature, and Date (eSignature Acceptable)	
Quality Assurance Approval	**Customer Care Approval**