Product Event Report Form

Must be reported within **1 Business Day** of Receipt by one of the following options:

1) Email this report to patientsafety@vcel.com 2) Call Customer Care: 1-800-453-6948 press option 2

VERICEL INTERNAL USE ONLY		
PRODUCT EVENT NUMBER: (COMPLETED BY CUSTOMER CARE)		Initials/Date
PV CASE ID: (COMPLETED BY CUSTOMER CARE OR QA INVESTIGATOR)		Initials/Date
RETURNED GOODS NUMBER: (COMPLETED BY CUSTOMER CARE)	☐ N/A	Initials/Date ☐ N/A

SECTION 1: REPORTER INFORMATION:

NAME:	**TODAY'S DATE:**	**DATE MADE AWARE OF THE EVENT:**
IS THE REPORTER A HEALTHCARE PROVIDER? ☐ **YES** ☐ **NO**	**REPORTER'S INSTITUTION:**	**PHONE NUMBER:** **EMAIL ADDRESS:**

SECTION 2: REQUIRED: PRODUCT INFORMATION: SEE PAGE 3 FOR WHERE TO OBTAIN INFORMATION

LOT NUMBER (or Serial Number for NexoBrid)				
PATIENT NAME OR INITIALS				
SELECT PRODUCT	☐ **MACI**	☐ **NEXOBRID**	☐ **EPICEL**	☐ **CARTICEL**

SECTION 3: ADDITIONAL PATIENT INFORMATION:

PATIENT DEMOGRAPHICS	**SEX:**	**DATE OF BIRTH:**	**AGE AT TIME OF THE EVENT:**
TREATMENT FACILITY			
TREATMENT DATE			
INDICATION (REASON PRODUCT WAS USED):			☐ **OFF-LABEL**
MEDICAL HISTORY (INCLUDING CONCOMITANT MEDICATIONS)			

SECTION 4: REQUIRED: DESCRIPTION AND DETAILS OF EVENT(S)

EVENT DATE(S)		**DID THE EVENT RESOLVE?** ☐ **YES** ☐ **NO** ☐ **UNKNOWN**	
DESCRIPTION OF EVENT			
PATIENT OUTCOME (CHECK ALL THAT APPLY)	☐ **HOSPITALIZATION** ☐ **DEATH**	☐ **OTHER** **DATE OF DEATH:**	**CAUSE OF DEATH:**

SECTION 5: INTERNAL VERICEL APPROVALS

CUSTOMER CARE SIGNATURE/DATE:	**QUALITY ASSURANCE SIGNATURE/DATE:**