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

SECTION 1: REQUIRED: REPORTER INFORMATION:		
NAME:	**TODAY'S DATE:**	**DATE MADE AWARE OF THE EVENT:**
IS THE REPORTER A HEALTHCARE PROVIDER? ☐ **YES** ☐ **NO**	**REPORTERS 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** ☐ **EPICEL** ☐ **CARTICEL**	☐ **CARTILAGE BIOPSY TRANSPORT KIT** ☐ **SKIN BIOPSY TRANSPORT KIT** ☐ **MACI SURIGICAL IMPLANTATION KIT**	☐ **BLOOD COLLECTION KIT** ☐ **NEXOBRID** ☐ **OTHER:**

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):	
DESCRIPTION OF EVENT:	
PATIENT OUTCOME:	☐ **EVENT RESOLVED** ☐ **HOSPITALIZATION** ☐ **DEATH** **DATE OF DEATH:** **CAUSE OF DEATH:** ☐ **OTHER:**

To be completed by Customer Care, Quality Assurance, and Pharmacovigilance	
Select *all* that apply:	☐ Product Complaint ☐ Adverse Event
Product Event Number:	
Pharmacovigilance Case ID:	