Product Event Report Form - Medical Devices

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: REQUIRED: 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:

LOT NUMBER OF DEVICE		
VERICEL MEDICAL DEVICE	**ARTHROSCOPIC INSTRUMENTS INDIVIDUAL:** ☐15mm x 3cm Cannula Assembly ☐15mm x 4cm Cannula Assembly ☐18mm x 4cm Cannula Assembly ☐3.6mm Rake Curette ☐6.5mm Open-Ring Curette ☐4mm x 5mm Square Curette ☐MACI Arthroscopic Cutting Block	**ARTHROSCOPIC KITTED DEVICES:** ☐15mm V-Shuttle and Two-Pack MACI Applicator Kit ☐18mm V-Shuttle and Two-pack MACI Applicator Kit ☐12 mm x 21 mm Min Arthroscopic Cutter and 12 mm x 21 mm MACI Cutter Kit ☐ 14 mm x 26 mm Min Arthroscopic Cutter and 14 mm x 26 mm MACI Cutter Kit ☐14 mm x 26 mm **Max** Arthroscopic Cutter and 14 mm x 26 mm MACI Cutter Kit ☐17 mm x 28 mm **Max** Arthroscopic Cutter and 17 mm x 28 mm MACI Cutter Kit
	BIOPSY TRANSPORT KITS: ☐Cartilage Biopsy Transport Kit ☐Skin Biopsy Transport Kit	**MISCELLANEOUS:** ☐Blood Collection Kit ☐MACI Surgical Implantation Kit ☐Other:
WAS THE DEVICE(S) UTILIZED ON A PATIENT?	☐ **YES** ☐ **NO** **IF YES: COMPLETE SECTION 3** **IF NO: N/A SECTION 3**	
WHAT STEPS ARE BEING TAKEN WITH THE DEVICE(S)?	☐ **Return to Vericel/CMO: CONTACT CUSTOMER CARE** ☐ **DISCARDED INTO BIOHAZARD WASTE** ☐ **OTHER:**	

SECTION 3: PATIENT INFORMATION: ☐ N/A (if not associated with patient)

LOT NUMBER OF PRODUCT DEVICE WAS USED ON			
PATIENT NAME OR INITIALS			
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)			
PATIENT OUTCOME (CHECK ALL THAT APPLY)	☐**EVENT RESOLVED** ☐**HOSPITALIZATION** ☐**DEATH** ☐**DATE OF DEATH** ☐**CAUSE OF DEATH** ☐**OTHER**		

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SECTION 4: REQUIRED: DESCRIPTION AND DETAILS OF EVENT(S)	
EVENT DATE(S)	
DESCRIPTION OF EVENT	
DID THE EVENT RESULT IN A PROLONGATION OR CHANGE OF THE PROCEDURE? **IF YES, DESCRIBE IN THE "DESCRIPTION OF EVENT" SECTION.**	☐ **YES** ☐ **NO** ☐ **UNKNOWN** ☐ **N/A**

SECTION 5: INTERNAL VERICEL APPROVALS	
CUSTOMER CARE SIGNATURE/DATE:	**QUALITY ASSURANCE SIGNATURE/DATE:**