BD GLOBAL PRODUCT INCIDENT REPORT (PIR) FORM
1501-092-011-R

1. BD Contact Information

Employee Name (For Internal Use Only)		Email
		Phone

2. Customer Information

Reporter Name/Title			
Facility name			
Address			
City/Region/State/Post Code/ Country			
Country Event Occurred			
Phone/Email			
Report received by (For Internal Use Only)	Phone ☐	Email ☐	Other ☐ *Specify:*

3. Product Details

Product name				
Lot number(s) and/or Serial number(s)				
Material/Catalog Number				
Quantity Involved			Contaminated? Yes ☐ No ☐	
Used product available to be returned for evaluation	No ☐	Yes ☐ *How many units?*		
Unused devices from the same lot number available for evaluation (representative samples)	N/A ☐	No ☐	Yes ☐ *How many units?*	
Current location of device(s)	End user ☐	Distributor ☐	Other location ☐ *Specify:*	Destroyed ☐

Replacement or Credits for affected devices? (For Internal Use Only)	**Replacement** ☐	**4. Incident Date** *(DD/MM/YYYY)*	
	Credit ☐	**5. BD Awareness Date** *(DD/MM/YYYY)* (For Internal Use Only)	

Once completed, this document is considered a record that must be stored in accordance with company procedures.

6. Description

***INFORMATION**: Give specific and objective details of feedback or event. Include copies of all relevant correspondence, photographs etc.*
Where/When does the problem occur? Physical location of defect on the device, Step in the Process/Procedure, What Happened vs Expected? Was there any patient/end user involvement? Was the intent of the process/procedure changed?)
I.e. The needle was clogged and the user was unable to administer insulin. However, the patient was able to administer the insulin with a second needle.

How often has the defect occurred?	Once ☐	Several times ☐ *How many times?*	Whole batch ☐

7. Adverse Event Questions

When did the incident occur?	Before Use ☐	During Use ☐	After Use ☐	Unknown ☐
Death?	No ☐ Unknown ☐	Yes ☐ *Date:* *Time:* *Detailed Death Description:*		
Serious Injury	Unknown ☐	No ☐	Yes ☐	*Description:*
Erroneous Results	Unknown ☐	No ☐	Yes ☐	*Description:*
Course of treatment changed due to event *Include any alternate testing provided relative to the change in treatment*	Unknown ☐	No ☐	Yes ☐	*Description:*
Exposure to Blood/Bodily Fluid *Include exposure of toxic medication to skin and list the specific medication that leaked. Indicate if exposure to mucosal membrane occurred*	Unknown ☐	No ☐	Yes ☐	*Description:*
Medical int. other than first aid *X-ray, CT Scan, MRI, Ultrasound, delay or change in treatment/diagnosis, administration of antibiotics, surgical removal of a cannula, and etc.*	Unknown ☐	No ☐	Yes ☐	*Description:*
Needle/Probe Stick	Unknown ☐	No ☐	Yes ☐	*Description:*
Safety Issue *Retraction failures, shielding failures, safety feature failed to cover the needle properly. Indicate whether the feature failed prior to use*	Unknown ☐	No ☐	Yes ☐	*Description:*
Other actions taken *Test or admin of medication (drugs/solutions) due to over or under dosage, imaging studies, admin of prophylactic/antibiotics, blood transfusion ,admin of antivirals due to needle stick, post lab testing, hospitalization*	Unknown ☐	No ☐	Yes ☐	*Description:*

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