Abbott

PRODUCT EXPERIENCE REPORT (PER) FORM

FRM649-E
Rev: C

Product Performance Group, PO Box 9018 Ynez Road, Temecula, CA 92591-4628, Phone 800-227-9902, Fax 951-914-3995, Email: qahotline@abbott.com

Event Details

Full Evaluation	Physician/ Customer Letter	Special Requests (Other)	Clinical Trial?	◯ Yes ◯ No
			Trial Name:	
Reported Event Details:				

Reporting Information

Reporting Abbott employee	Abbott Aware Date:	Method Reported to Abbott:	Method Reported to Abbott (Other)	Is this to report a Failure to Advance?
		6		◯ Yes ◯ No

Account Information

Account Number:		Physician Name:	
Hospital Name (if different from Account)		Account Contact 1:	
Country		Account Contact 2:	
SAP Replacement Transaction #		Account Contact Other	
		Initial Non-Abbott Reporter:	

Patient Information

Patient Involved? ◯ Yes ◯ No

☐ Patient information cannot be provided due to personal data privacy legislation/policy

Patient DOB:	Patient Age:	Age, Unit of Measure	Weight	Weight, Unit of Measure	Gender	Ethnicity	Race	Relevant Medical History	Reset This Section
		Years		LBS					Reset

Procedure Information

Procedure Date:	Abbott Employee Present During Procedure?	Relevant Test/Lab Data	Medication to Treat Device Issue

Product Experience Device Information

Product ID (part number)	Lot #	Product Name	Size	Serial #	Implant Date	Explant Date	Was the device requested for Return?	Is the Device Returning?	Device Return Status	Add Remove Row
										+ -

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Accessory Devices Used during Procedure

Product Type	Product Name & Size	Implant Date	Product ID (part number)	Lot #	Add Remove Row
					+ -

Were all devices reported to PPG? ◯ Yes ◯ No

Lesion Information

Vessel Treated	Vessel Calcification	Vessel Tortuosity	Stenosis Pre(%)	Stenosis Post (%)	Lesion History:	CTO	Additional Vessels Treated (Click +)	Add Remove Row
								+ -

Final Outcome

Clinically Significant Delay?		Replacement Device Used	
Death Date			

Print Form

Submit for Processing