SOLVE TRIAL: PRODUCT DEFECT FORM (DILAPAN-S)

Please report immediately any Dilapan-S product defects by completing this form and faxing to the SOLVE Trial office 0121 415 9136

Part A: Product information (DILAPAN-S)	
Product LOT number:	Product Serial number:
Date Used or Implanted: DD /MMM /YYYY	Date Explanted: DD /MMM /YYYY

Part B: Product return information:	**Yes**	**No**
Is the product being returned?	☐	☐
Is the product used, contaminated or non-sterile?	☐	☐
What is the number of pieces being returned?	☐	

Part C: Event details:

Date of event	**The event occurred (please tick one)**	**Did this result in SAE (please tick)**
DD /MMM /YYYY	1 Before patient preparation ☐ 2 During application of device ☐ 3 After application of device ☐ 4 During removal of device ☐	Yes ☐ No ☐ **If Yes has the SAE form been returned to BCTU?** Yes ☐ No ☐ **If NO why?**

Please give full details of the event:

Part D: Other information relevant to event:	**Yes**	**No**
Did the event result in a clinically relevant increase in duration of proceedure (defined by clinician)?	☐	☐
Was a report made by the clinician to the local regulatory bodies?	☐	☐
Is there video or picture evidence of the device/proceedure?	☐	☐
Other, please specify:		

Part E: Patient information (if applicable):

SOLVE Trial Number	☐☐☐☐	Patient's date of birth	DD /MMM /YYYY
Relevant medical history & medications used with procedure?	Yes ☐	No ☐	
If YES please specify:			
Was the patient injured as a result of the event?	Yes ☐	No ☐	

If YES, describe the actions taken relevant to the care of the patient, and the patient outcome:

Part F: Complainant information:

Signature of Person Reporting: _____ **Date of Reporting:** DD / MMM / YYYY

You must have signed the Site Delegation Log

Print Name:	Position:	Tel No:
Email:	Hospital:	

BCTU USE ONLY

Complaint reference number:

Corresponding SAE reference number (if applicable)

Date reported to BCTU? DD/MMM/YYYY

Date reported to Medicem? DD/MMM/YYYY

Date:_____ Signature: _____PRINT Name: _____