conformal
THE SHAPE OF STROKE PREVENTION

CLAAS Device Deficiency

☐ Source ☐ Data Transfer Tool

Site Number: _____ Subject ID: _____

Note: This Device Deficiency form is for CLAAS only. To report a deficiency or malfunction for the CONTROL procedures, please follow the manufacturer's instructions.

Date of Device Deficiency	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)	
Component (select one)	☐ CLAAS Implant Regular 27mm ☐ CLAAS Implant Large 35mm ☐ Access Sheath Regular (27mm) Single Curve ☐ Access Sheath Regular (27mm) Double Curve ☐ Access Sheath Large (35mm) Single Curve ☐ Access Sheath Large (35mm) Double Curve ☐ Delivery Catheter Regular 27mm ☐ Delivery Catheter Large 35mm	
Lot #		
Deficiency occurred	☐ During procedure prep ☐ During procedure	☐ Other, specify: _____
Deficiency due to	☐ Device malfunction ☐ Use error	☐ Inadequate labeling ☐ Other, specify: _____
Did an adverse event occur due to the deficiency?	☐Yes (*Complete an Adverse Event Form and follow reporting guidelines per protocol)* ☐No	
Outcome of the device deficiency	☐ Used another CLAAS product ☐ CLAAS device embolized	☐ Procedure terminated ☐ Other, describe: _____
Will the device be returned to Sponsor/Manufacturer?	☐ Yes, *Please follow the device return instructions* ☐ No	
Summary of device deficiency		

Note: If utilizing as source (no other source exists)- form should be signed by device implanter.

_____ __ __ / __ __ __ / __ __ __ __

Site Personnel Signature **Date (DD/MMM/YYYY)**