conformal THE SHAPE OF STROKE PREVENTION	**Device Deficiency** ☐ **Source** ☐ **Data Transfer Tool**
	Site Number: _____ Subject ID: _____

This Device Deficiency form is for both CLAAS and CONTROL devices.

Note: If an Adverse Event occurred related to a Device Deficiency, please complete an Adverse Event Form and follow reporting guidelines per protocol.

Date of Device Deficiency	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Date Sponsor was notified	__ __ / __ __ __ / __ __ __ __ (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 ☐ VizaraMed Multiflex Steerable Sheath ☐ Delivery Catheter Regular 27mm ☐ Delivery Catheter Large 35mm ☐ Watchman - Implant ☐ Watchman - Delivery Catheter ☐ Watchman - Access Sheath ☐ Amulet - Implant ☐ Amulet – Delivery Catheter ☐ Amulet – Access Sheath
Conformal Lot #	
Deficiency occurred	☐ During procedure prep ☐ During procedure ☐ Other, specify: _____
Deficiency due to	☐ Device malfunction ☐ Use error ☐ Inadequate labeling ☐ Other, specify: _____
Summary of device deficiency	
Did an adverse event occur due to the deficiency?	☐ Yes (*Complete an Adverse Event Form and follow reporting guidelines per protocol)* ☐ No If Yes, What is the AE#? : _____ If Yes, was it a Serious Adverse Event?: ☐Yes ☐No

	If No, could it have led to a Serious Adverse Device Effect (SADE)?: ☐Yes ☐No • if appropriate action had not been taken • if intervention had not occurred, or • if circumstances had been less fortunate
Location of Device	☐ Sponsor / Manufacturer ☐ Investigational /Study Site ☐ Remains Implanted ☐ Discarded ☐ Unknown ☐ Other *Specify:* _____
Action / Outcome of the device deficiency	☐ Used another CLAAS product ☐ Continued to use product ☐ CLAAS device embolized ☐ Procedure terminated ☐ Other, describe: _____
Will the device be returned to Sponsor/Manufacturer?	☐ Yes, *please follow the device return instructions* ☐ No

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

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