| conformal THE SHAPE OF STROKE PREVENTION | **CONFORM Control Implant**<br>**☐ Source ☐ Data Transfer Tool** |
|---|---|
| | Site Number: _____ Subject ID: _____ |

| | | |
|---|---|---|
| Control Product Used | | |
| ☐ Amulet | ☐ 16 mm<br>☐ 18 mm<br>☐ 20 mm<br>☐ 22 mm | ☐ 25 mm<br>☐ 28 mm<br>☐ 31 mm<br>☐ 34 mm |
| ☐ Watchman FLX | ☐ 20 mm<br>☐ 24 mm<br>☐ 27 mm<br>☐ 31 mm<br>☐ 35 mm | |
| ☐ Watchman FLX PRO | ☐ 40 mm | |
| Please confirm the primary reason for selection of the commercially available device | ☐ Subject Anatomy<br>☐ Investigator Preference<br>☐ Other, specify: _____ | |
| Device Outcome | ☐ Used<br>☐ Opened, Not Used<br>☐ Opened, Used, Disposed<br>☐ Opened, Used, Returned<br>☐ Opened, Not Used, Returned | |
| Did device meet release criteria per Manufacturer DFU/IFU? | ☐ Yes<br>☐ No | |
| Was partial recapture attempted? | ☐ Yes, number of partial attempts: _____<br>☐ No | |
| Was full recapture attempted? | ☐ Yes<br>☐ No | |
| Did device deficiency or device malfunction occur? | ☐ Yes *If yes, provide a brief description below*<br>☐ No | |

| | |
|---|---|
| Device deficiency or malfunction description: | |
| Device Deficiency due to: | ☐ Device Malfunction<br>☐ User error<br>☐ Inadequate labeling<br>☐ Other |

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

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

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