

## **CONFORM CLAAS Implant**

□ Source □ Data Transfer Tool

Site Number:

Subject ID:

Note: Please keep the Investigational Product Sticker of any device opened/used. If more than 2 devices were used, please complete another form if using as source.

CLAAS Device Size	□ Regular (27 MM) □ Large (35 MM)	CLAAS Device Size	□ Regular (27 MM) □ Large (35 MM)
Lot #	Place product sticker here	Lot #	Place product sticker here
Device Outcome	<ul> <li>Used</li> <li>Opened, Not Used</li> <li>Opened, Used, Disposed</li> <li>Opened, Used, Returned</li> <li>Opened, Not Used, Returned</li> </ul>	Device Outcome	<ul> <li>Used</li> <li>Opened, Not Used</li> <li>Opened, Used, Disposed</li> <li>Opened, Used, Returned</li> <li>Opened, Not Used, Returned</li> </ul>
Did device meet position criteria?	□ Yes □ No	Did device meet position criteria?	□ Yes □ No
Did device meet anchor criteria?	□ Yes □ No	Did device meet anchor criteria?	□ Yes □ No
Did device meet seal criteria?	□ Yes □ No	Did device meet seal criteria?	□ Yes □ No
Was partial resheath attempted?	□ Yes, number of partial attempts: □ No	Was partial resheath attempted?	<ul> <li>Yes, number of partial attempts:</li> <li>No</li> </ul>
Was a full resheath attempted?	□ Yes □ No	Was a full resheath attempted?	□ Yes □ No
Did device deficiency or device malfunction occur?	<ul> <li>Yes If yes, complete a Device Deficiency</li> <li>Form</li> <li>No</li> </ul>	Did device deficiency or device malfunction occur?	□ Yes If yes, complete a Device Deficiency Form □ No

Site Personnel Signature

Date (DD/MMM/YYYY)