

This form may be electronically duplicated for use on other applications within the Documentation department

INSPECTION REQUIREMENTS													
The inspection requirements specified herein are for use by St. Jude Medical, Implantable Electronic Systems Division (IESD) only. The manufacturer of the device(s) is responsible for meeting all the electrical, physical and general requirements of this specification. This IR and the resultant performance record may be depicted and captured electronically.													
RIR/W.O./SR./LOT#:													
INSPECTION AIDS/TOOLS													
A. OMIS/EQUIV													
INSPECTOR'S NOTES													
1. IR TO BE USED IN CONJUNCTION WITH 60026091 (FOR USE IN SYLMAR), DWI-4.3.1.3AZ (FOR USE IN SCOTTSDALE), 20009251 (FOR USE IN LIBERTY), 60033093 (FOR USE IN MALAYSIA), OR 602675 (FOR USE IN PUERTO RICO).													
PART NUMBER LEGEND													
A=100159631													
NO.	TOOL	T/M #	PARAMETER	PART #	AOQL (%)	AQL (%)	S.S.	ACC.	REJ.	INSP.	DATE		
			DOCUMENTATION										
			N/A										
			PROCESS VERIFICATION TEST										
			N/A										
			MECHANICAL INSPECTION										
			N/A										
DRAWING NO.			60084597									REV	01

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INSPECTION REQUIREMENTS												(continued)	
NO.	TOOL	T/M #	PARAMETER	PART #	AOQL (%)	AQL (%)	S.S.	ACC.	REJ.	INSP.	DATE		
			ELECTRICAL INSPECTION										
			N/A										
			VISUAL INSPECTION										
10	A		GENERAL WORKMANSHIP	A	5	N/A							

VERIFY REVISION PRIOR TO USE

DRAWING NO.	60084597	REV	01	RELEASE STATUS	In Work	ECO	GD78272	INCorp. BY	S. LEE	TITLE:	SUTURE PIN																																																		
EQUIPMENT/TOOL(PER PROCEDURE 86125): <input type="checkbox"/> TYPE 0 <input type="checkbox"/> TYPE MI <input type="checkbox"/> TYPE I <input checked="" type="checkbox"/> TYPE II <input type="checkbox"/> TYPE III <input type="checkbox"/> TYPE IV										TOOL SPECIFICATION FORM																																																			
TOOL DESCRIPTION: (PROVIDE A BRIEF DESCRIPTION OF THE TOOL AND A PURPOSE)					TOOL CALIBRATION: CALIBRATION REQUIRED YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> <table><tr><td colspan="2">DIMENSION/PARAMETER</td></tr><tr><td colspan="2"></td></tr><tr><td colspan="2"></td></tr><tr><td colspan="2"></td></tr><tr><td colspan="2"></td></tr><tr><td colspan="2"></td></tr><tr><td colspan="2"></td></tr><tr><td colspan="2"></td></tr><tr><td colspan="2"></td></tr><tr><td colspan="2"></td></tr></table>							DIMENSION/PARAMETER																																																	
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CONSUMABLE TOOL USED TO PLUG SUTURE HOLE.																																																													
INSTALLATION CONDITIONS: (LIST ANY PREREQUISITES FOR INITIALIZING THE TOOL)					<table><tr><td colspan="2">MAINTENANCE CODE LEGEND</td><td>C</td><td>CLEAN</td><td>R</td><td>REPLACE</td><td>FI</td><td>FUNCTIONAL INSPECTION</td><td>T</td><td>TORQUE</td><td>L</td><td>LUBRICATE</td></tr><tr><td colspan="2"></td><td>VI</td><td>VISUAL INSPECTION</td><td>M</td><td>MEASURE</td><td>FC</td><td>FITCHECK</td><td>O</td><td>OTHER</td><td></td><td></td></tr><tr><td>CODE</td><td colspan="8">PREVENTIVE MAINTENANCE: (IDENTIFY PREVENTIVE MAINTENANCE PROCEDURE)</td><td colspan="2">FREQUENCY</td><td colspan="2">RESULT</td></tr><tr><td>N/A</td><td colspan="8">FIXTURE/TOOL WILL BE EVALUATED PRIOR TO EACH USE. NO PM REQUIRED.</td><td colspan="2">N/A</td><td>PASS <input type="checkbox"/></td><td>FAIL <input type="checkbox"/></td></tr></table>							MAINTENANCE CODE LEGEND		C	CLEAN	R	REPLACE	FI	FUNCTIONAL INSPECTION	T	TORQUE	L	LUBRICATE			VI	VISUAL INSPECTION	M	MEASURE	FC	FITCHECK	O	OTHER			CODE	PREVENTIVE MAINTENANCE: (IDENTIFY PREVENTIVE MAINTENANCE PROCEDURE)								FREQUENCY		RESULT		N/A	FIXTURE/TOOL WILL BE EVALUATED PRIOR TO EACH USE. NO PM REQUIRED.								N/A		PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>
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INSTALLATION INSTRUCTIONS/START AND STOP:					<table><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>PASS <input type="checkbox"/></td><td>FAIL <input type="checkbox"/></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>PASS <input type="checkbox"/></td><td>FAIL <input type="checkbox"/></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>PASS <input type="checkbox"/></td><td>FAIL <input type="checkbox"/></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>PASS <input type="checkbox"/></td><td>FAIL <input type="checkbox"/></td></tr></table>																	PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>											PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>											PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>											PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>		
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SAFETY FEATURES:					<table><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>PASS <input type="checkbox"/></td><td>FAIL <input type="checkbox"/></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>PASS <input type="checkbox"/></td><td>FAIL <input type="checkbox"/></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>PASS <input type="checkbox"/></td><td>FAIL <input type="checkbox"/></td></tr></table>																	PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>											PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>											PASS <input type="checkbox"/>	FAIL <input type="checkbox"/>														
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N/A																																																													

SHEET 3 OF 3

PERFORMED BY: _____

SIGNATURE: _____

DATE: _____

VERIFIED BY: _____

SIGNATURE: _____

DATE: _____

TEMPLATE NO. 60047787 G