	Lifeline Ductus Arteriosus Stent System Final Assembly Traveler		LHR-DA2-0004, REV. 1
	P/N: STR-DA2-FS-00001. __ __ Rev: __		CO 25-0050
	Size: Ø ____ X ____ mm		EFFECTIVE DATE: TBD
	Build Lot No.: _____		

Build Start Date:	Target QTY:	Final QTY Built:	Date of Close-Out:
Initiated By:		Build Purpose: <input type="checkbox"/> Engineering <input type="checkbox"/> Clinical Trial <input type="checkbox"/> Production	

PRE-BUILD CHECKLIST		
<input type="checkbox"/>	Verify current released MPI on production line or include within LHR folder. (If redlined, attach a copy to the LHR)	
<input type="checkbox"/>	Verify training records to most current revisions/redlines for all operators.	
<input type="checkbox"/>	Confirm whether there are any active deviations that impact this build. If so, record below:	
	Deviation #:	<input type="checkbox"/> N/A
Signature: _____ Date: _____		



Lifeline Ductus Arteriosus Stent System Final Assembly Traveler

P/N: STR-DA2-FS-00001. ____ Rev: ____

Size: Ø ____ X ____ mm

Build Lot No.: _____

LHR-DA2-0004, REV. 1

CO 25-0050

EFFECTIVE DATE: **TBD****10 - STENT CRIMPING**

DESCRIPTION		REV	OPERATOR	DATE
MPI-00-0001	Manufacturing Line Clearance			
MPI-DA2-0010	Stent Crimping			
EQUIPMENT#				
ES-0053-____	Stent Crimper			
MFG. AIDS				
STR-DA2-DS-40021	Transfer Sheath	LOT #		
MATERIALS	REV	DESCRIPTION	LOT#	QTY
STR-DA2-PT-10012.____		Coated Pushertube DDPC32		
STR-DA2-IM-10009.____		Stent Assembly Ø ____ x ____ mm (Note: only one stent lot may be used per top-level lot)		



Lifeline Ductus Arteriosus Stent System Final Assembly Traveler

P/N: STR-DA2-FS-00001. ____ Rev: ____

Size: Ø ____ X ____ mm

Build Lot No.: _____

LHR-DA2-0004, REV. 1

CO 25-0050

EFFECTIVE DATE: **TBD**

15 - STENT CRIMPING INSPECTION

QUALITY INSPECTION		REV	INSPECTED BY	DATE
MPI-00-0001	Manufacturing Line Clearance			
QI-0002	Stent Crimping Inspection			
EQUIPMENT				
129-05229, or equivalent	Microscope		Equipment ID:	



Lifeline Ductus Arteriosus Stent System Final Assembly Traveler

P/N: STR-DA2-FS-00001. ____ Rev: ____

Size: Ø ____ X ____ mm

Build Lot No.: _____


LHR-DA2-0004, REV. 1

CO 25-0050

EFFECTIVE DATE: **TBD**


20 - STENT LOADING

DESCRIPTION		REV	OPERATOR	DATE
MPI-00-0001	Manufacturing Line Clearance			
MPI-DA2-0011	Stent Loading			
MATERIALS	REV	DESCRIPTION	LOT#	QTY
STR-DA2-CA-10001		Catheter Assembly DDPC32		
MS-00-50002		Rotating Hemostasis Valve		

	Lifeline Ductus Arteriosus Stent System Final Assembly Traveler P/N: STR-DA2-FS-00001. ____ Rev: ____ Size: Ø ____ X ____ mm Build Lot No.: _____	LHR-DA2-0004, REV. 1 CO 25-0050 EFFECTIVE DATE: TBD
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30 – PUSHERTUBE HUBBING


DESCRIPTION				REV	OPERATOR			DATE
MPI-00-0001		Manufacturing Line Clearance						
MPI-DA2-0012		Pushertube Hubbing						
EQUIPMENT#								
129-01910 (or equivalent)		Dymax UV Light Source	Equipment ID		Cal ID		Cal Due	
129-02116 (or equivalent)		UV Intensity Meter	Equipment ID		Cal ID		Cal Due	
Process Parameter				Set Point:	Actual:			
Intensity [W/cm ²]:								
MATERIALS	REV	DESCRIPTION				LOT#	QTY	
MS-DA2-50002		Pushertube Hub Bushing DDPC32						
MS-DA2-50003		Pushertube Hub Housing DDPC32						
MS-00-50003		Hub Adhesive		EXP DATE:			A/R	

	Lifeline Ductus Arteriosus Stent System Final Assembly Traveler P/N: STR-DA2-FS-00001. ____ Rev: ____ Size: Ø ____ X ____ mm Build Lot No.: _____		LHR-DA2-0004, REV. 1 CO 25-0050 EFFECTIVE DATE: TBD	

STR-DA2-DS-30014		Strain Relief, DDPC32		
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35 – FINAL INSPECTION

QUALITY INSPECTION		REV		INSPECTED BY		DATE	
MPI-00-0001	Manufacturing Line Clearance						
QI-0003	Lifeline Full System Inspection						
EQUIPMENT							
129-05317 (or equivalent)	Ruler	Equipment ID:		Cal ID:		Cal Due:	
129-05782 (or equivalent)	Laser Micrometer	Equipment ID:		Cal ID:		Cal Due:	

	Lifeline Ductus Arteriosus Stent System Final Assembly Traveler		LHR-DA2-0004, REV. 1 CO 25-0050 EFFECTIVE DATE: TBD
	P/N: STR-DA2-FS-00001. ____ Rev: ____		
	Size: Ø ____ X ____ mm		
	Build Lot No.: _____		

40 – LABEL PRINTING

DESCRIPTION		REV	OPERATOR	DATE
MPI-00-0001	Manufacturing Line Clearance			
MPI-DA2-0009	Label Printing			
EQUIPMENT#				
ES-0059-__	Zebra Label Printer			
		Process Parameter:	Set Point:	
		Darkness [arb.]		
		Speed [in/s]		
MATERIALS	REV	DESCRIPTION	LOT#	QTY
MS-00-50014		Thermal Transfer Ribbon		
LBL-DA2-0001		Lifeline Stent Shelf Carton and Pouch Label Printed Static Artwork		
Total Qty Labels Printed:				

	Lifeline Ductus Arteriosus Stent System Final Assembly Traveler	
	P/N: STR-DA2-FS-00001. __ __ Rev: __	LHR-DA2-0004, REV. 1
	Size: Ø ____ X ____ mm	CO 25-0050
	Build Lot No.: _____	EFFECTIVE DATE: TBD

45 - LABEL INSPECTION

QUALITY INSPECTION		REV	INSPECTED BY	DATE
MPI-00-0001	Manufacturing Line Clearance			
QI-0001	Lifeline Label Printing Inspection			

AFFIX SAMPLE LABEL HERE



Lifeline Ductus Arteriosus Stent System Final Assembly Traveler

P/N: STR-DA2-FS-00001. ____ Rev: ____


Size: Ø ____ X ____ mm

Build Lot No.: _____

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	Lifeline Ductus Arteriosus Stent System Final Assembly Traveler P/N: STR-DA2-FS-00001. ____ Rev: ____ Size: Ø ____ X ____ mm Build Lot No.: _____	LHR-DA2-0004, REV. 1 CO 25-0050 EFFECTIVE DATE: TBD
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50 – FULL SYSTEM PACKAGING

DESCRIPTION					REV	OPERATOR		DATE
MPI-00-0001		Manufacturing Line Clearance						
MPI-DA2-0013		Full System Packaging						
STM-0008		Pouch Peel Tensile Strength						
EQUIPMENT#								
EQID-15386		Pouch Sealer		Cal ID			Cal Due	
5670 (or equivalent)		Instron		SN		Cal ID		Cal Due
129-05317 (or equivalent)		Ruler		SN		Cal ID		Cal Due
Peel Strength [lbf] : First Pouch							Last Pouch:	
MATERIALS		REV	DESCRIPTION				LOT#	QTY
STR-DA2-PK-30007			Hoop Support Card					
STR-DA2-PK-30006			Tyvek Pouch					
STR-DA2-PK-30004			Shelf Carton					
LBL-DA2-0005			Patient Card					
LBL-DA2-0004			Instructions for Use					
MS-00-50012			Tamper Seal					
MS-00-50013			Sterilization Indicator					



Lifeline Ductus Arteriosus Stent System Final Assembly Traveler

P/N: STR-DA2-FS-00001. ____ Rev: ____

Size: Ø ____ X ____ mm


Build Lot No.: _____

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CO 25-0050

EFFECTIVE DATE: **TBD**


Total Qty Labels Applied:

	Lifeline Ductus Arteriosus Stent System Final Assembly Traveler P/N: STR-DA2-FS-00001. ____ Rev: ____ Size: Ø ____ X ____ mm Build Lot No.: _____	LHR-DA2-0004, REV. 1 CO 25-0050 EFFECTIVE DATE: TBD
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55 - PACKAGING INSPECTION


QUALITY INSPECTION		REV	INSPECTED BY	DATE
MPI-00-0001	Manufacturing Line Clearance			
QI-0004	Packaging Inspection			
EQUIPMENT				
129-05317 (or equivalent)	Ruler	Equipment ID: _____	Cal ID: _____	Cal Due: _____

POST-BUILD REVIEW (Build Supervisor or designee)		
Verified	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	Verify all required information has been recorded correctly and all LHR fields are complete to this point.
<input type="checkbox"/>	<input type="checkbox"/>	Verify cross-outs are initialed and dated and any change(s) to the records are understandable.
<input type="checkbox"/>	<input type="checkbox"/>	Verify any redlines to the released documentation (LHR, MPI's etc) have been approved and all additional comments written on the LHR are clear and accurate.
<input type="checkbox"/>	<input type="checkbox"/>	Verify copies of all associated training records are attached or are on file (including any redlined procedures used in the build).
<input type="checkbox"/>	<input type="checkbox"/>	Verify all parts labeled with Part Number and Lot Number
Completed by:		Date:

	Lifeline Ductus Arteriosus Stent System Final Assembly Traveler		LHR-DA2-0004, REV. 1 CO 25-0050 EFFECTIVE DATE: TBD
	P/N: STR-DA2-FS-00001. ____ Rev: ____		
	Size: Ø ____ X ____ mm		
	Build Lot No.: _____		

60 – SHIP TO STERILE

DESCRIPTION		REV	OPERATOR	DATE
MPI-00-0001	Manufacturing Line Clearance			
MPI-DA2-0014	Shipping to Sterile			
DOC-0021	Bill of Lading			
			QTY SHIPPED:	
MATERIALS	REV	DESCRIPTION	LOT#	QTY
STR-DA2-PK-30003		Starlight Stent System Shipper Box		

	Lifeline Ductus Arteriosus Stent System Final Assembly Traveler		LHR-DA2-0004, REV. 1 CO 25-0050 EFFECTIVE DATE: TBD
	P/N: STR-DA2-FS-00001. ____ Rev: ____		
	Size: Ø ____ X ____ mm		
	Build Lot No.: _____		

70 – RECEIVE FROM STERILE

DESCRIPTION		REV	OPERATOR	DATE
MPI-00-0001	Manufacturing Line Clearance			
MPI-DA2-0015	Receiving from Sterile			
DOC-0021	Bill of Lading			
			QTY RECEIVED:	

QUALITY REVIEW AND WORK ORDER CLOSURE			
<input type="checkbox"/>	Verify completeness of package per requirements above.		
<input type="checkbox"/>	Verify that material transfer form has been completed and approved if appropriate.		
<input type="checkbox"/>	Verify that all reference documents (NCMRs or CAPAs) have been resolved and a copy is included in the build package. (Unit specific NCMR's may remain open and the lot can be closed. Ensure units are segregated.)		
	(Unit Specific <input type="checkbox"/> or Lot Specific <input type="checkbox"/>) NCMR#:	<input type="checkbox"/> N/A	
<input type="checkbox"/>	Label the parts with "Accepted" label if appropriate.		
<input type="checkbox"/>	Close Work Order in Lot number log.		
Completed by:			Date:
QUANTITY RELEASED:			



Lifeline Ductus Arteriosus Stent System Final Assembly Traveler

P/N: STR-DA2-FS-00001. ____ Rev: ____

Size: Ø ____ X ____ mm

Build Lot No.: _____

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CO 25-0050

EFFECTIVE DATE: **TBD**