

Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

DESCRIPTION

This document specifies the information that is printed on to the Product Label and packaging assembly requirements for the following. This label is used for BOM-1071 VERASENSE for Stryker Triathlon GEN 4, manufactured at Dreamtech.

- VERASENSE for Stryker Triathlon CR (GEN 4)
- VERASENSE for Stryker Triathlon PS (GEN 4)

NOTE: VERASENSE for Stryker Triathlon CR (GEN 3) and VERASENSE for Stryker Triathlon CR (GEN 4) have the same product name and catalog number but are distinguished by the Global Trade Identification Number (GTIN) that is part of the Unique Device Identifier (UDI). The VERASENSE for Stryker PS is only available in GEN 4. This document only applies to VERASENSE for Stryker Triathlon GEN 4. Refer to LB-5027 for VERASENSE for Stryker Triathlon CR GEN 3.

PRODUCT LABEL NOTES

- Create label from: LB-5036 “VERASENSE Label Set Template”
- Record all required information on Device History Record (DHR).
- Print all required information directly onto Label Set blank using laser printer and black ink.
- Print each field per the Field-Description table below. Per the Print column, print either the exact text show, or the information as described.
- Items 8 and 10-12 are repeated on the three peel-off stickers.
- All printed text is to be legible with unaided eye. Printed text shall not overlap.
- Items 5 is GS1-128 single concatenated type one dimensional barcode and human readable printed below barcode as described below:
 - Generation of GS1-128 barcode may be accomplished by several validated software methods, such as specialized software, Excel add-in, or online software.
 - Information encoded into Barcode is particular to an individual sensor following programming and calibration.
 - Encode the following data per the example below (The values on the table for reference only. For the GTIN reference Table #2 and all other use the actual values from work order /route detailed in the table below in the order and formats shown.) Only the values are encoded, not the descriptor in the first column.

Descriptor	Value
GS1 Application Identifier (AI) for Global Trade Identification Number (GTIN)	01
GTIN (must be in a 14 digit format)	00816818021234
GS1 AI for Date of Manufacture	11
Date of Manufacture (six numeric characters)	YYMMDD
GS1 AI for Expiration Date	17
Use by Date (six numeric characters)	YYMMDD
GS1 AI for Lot number	10
Mfg Lot Number (maximum 20 alphanumeric characters)	1234567
GS1 AI for Serial Number	21
Serial Number (maximum 20 alphanumeric characters)	9876543210

- The data is encoded as a single text string of the format below:

Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

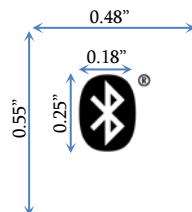
010081681802123411YYMMDD17YYMMDD101234567219876543210

NOTE: For clarity, the numbers representing the AI and numbers representing the date element are shown in bold in the example above.

Barcodes symbol sizes

Item	X-dimension			Minimum Symbol Height for Given X mm (inches)			Quiet Zone		Minimum Quality Specification
	Minimum	Target	Maximum	For Minimum X-dimension	For Target X-dimension	For Maximum X-dimension	Left, Right	Above, Below	
5	0.170 (0.0067")	0.495 (0.0195")	0.495 (0.0195")	12.70 (0.500")	12.70 (0.500")	12.70 (0.500")	10X	2X	1.5 /06/660
34	0.170 (0.0067")	0.495 (0.0195")	0.495 (0.0195")	4.76 (0.1875")	4.76 (0.1875")	4.76 (0.1875")	10X	2X	1.5 /06/660

- Human readable format is printed below the barcode in the following format:
(01) 00816818021234 (11) YYMMDD (17) YYMMDD (10) 1234567 (21) 9876543210
- Items 18 and 30 are undefined fields to be used by the Contract Manufacturer for internal tracking (e.g. alpha-numeric, 1D barcode, etc...). Print must fit within the specified space.
- Item 13, 22, 32, 41, and 44 contain the document number and revision.
- The specification for the Bluetooth® symbol is as described below:
 - Print the symbol with the size requirements shown below, including the required white space around the figure.
 - Use the highest possible resolution, not going below 16x16 pixels



Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

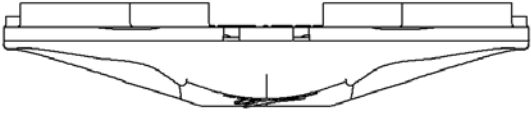
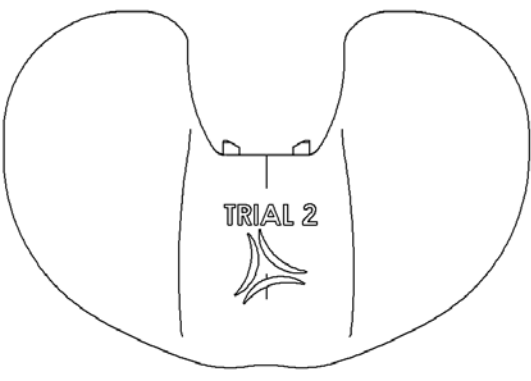
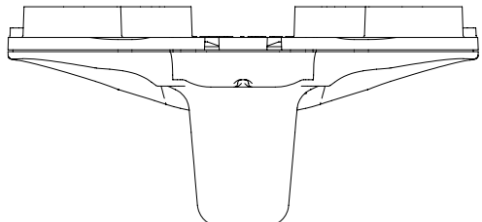
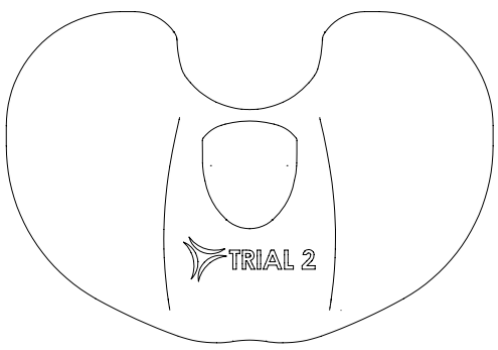
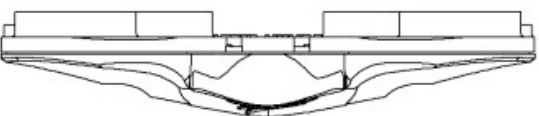
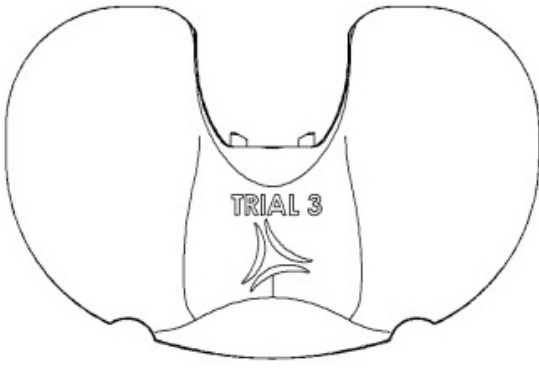
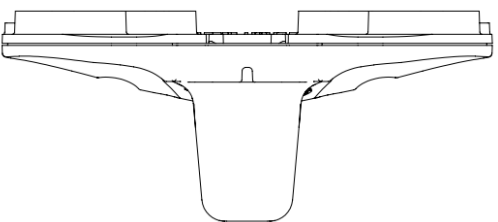
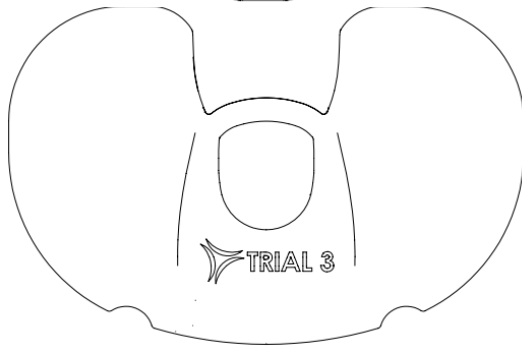
Product Label field Descriptions:

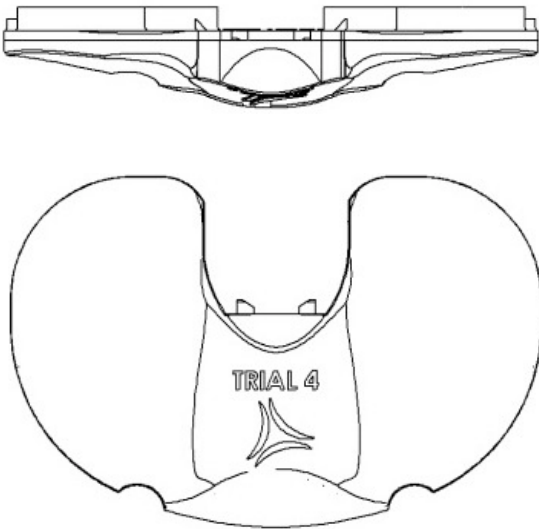
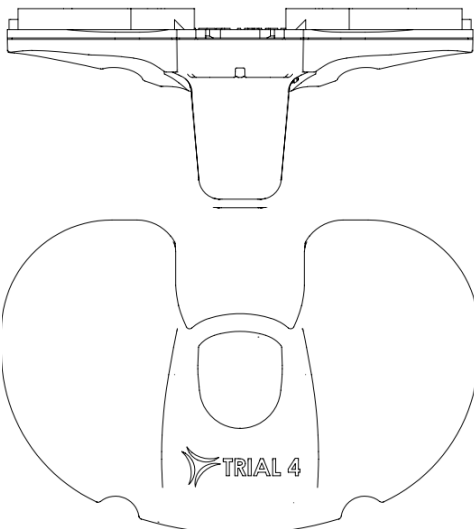
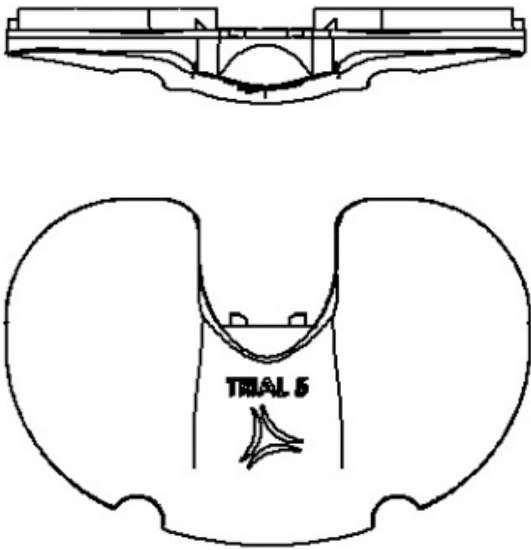
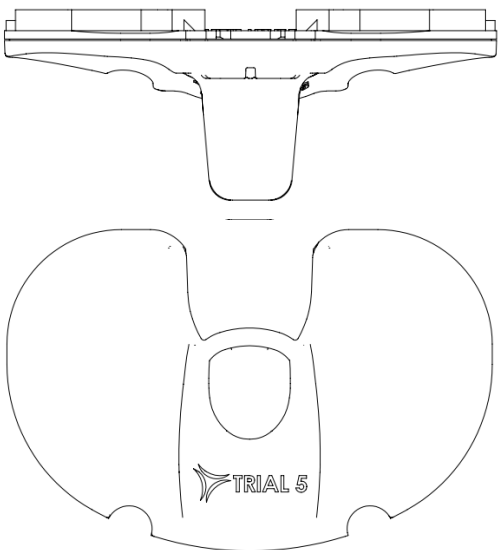
Item #	Field	Description	Font Size pts (Arial)	Print
1		Print image. See table 1- Select image based on work order	NA	Fill all available space
2		Sizes accommodated. Table 2.	BOLD 12	Text
3		Programmed Device Model ID Number	BOLD 10	Text
4		Manufacturing Lot Number	BOLD 10	Info
5, 34		1D Bar-Code and Human Readable Interpretation. Select appropriate GTIN per work order.	7	Bar Code and human readable
6		Device Expiration Date = Manufactured date plus two years in YYYY-MM-DD format.	BOLD 10	Info
7		Manufacturing Date (date that FTS is preformed, obtained from the DHR) in YYYY-MM-DD format.	BOLD 10	Info
8		See table 2. Select the appropriate description per work order.	BOLD 7	Text
9, 28	Side	See table 2. Select the appropriate side per work order.	BOLD 20	Text
10, 36, 39, 43		Manufacturing Lot Number	BOLD 7	Info
11, 33, 38		Programmed Device Model ID Number	BOLD 7	Info
12, 31, 37		See table 2. Select the appropriate description per work order	BOLD 7	Info
42		Refer table 2. – Pouch Drawing number from Bill of Materials	BOLD 7	Text
13, 22, 32, 41, 44		Document number and revision	6	Text
14, 29	Type	See table 2. Select the appropriate type per work order.	BOLD 20	
15, 27	Size	See table 2. Select the appropriate size per work order.	BOLD 20	Text
16		See table 2. Select the appropriate description per work order.	BOLD 19	Text
17		Programmed Device Model ID Number	BOLD 9	Text
18, 30, 47, 48		Contract Manufacturer's Internal Tracking Identifier (Optional)	NA	Bar Code
19		See table 2. Select the appropriate description per work order.	BOLD 10	Text
23		Manufacturing Lot Number	BOLD 9	Text
24		See table 2. Select the appropriate description per work order.	BOLD 9	Text
20		FCC ID XNL-ORTHOSNSR10	9	Text
25		Device Expiration Date = Manufactured date plus two years in YYYY-MM-DD format.	BOLD 9	Text
26		See table 2. Select the appropriate description per work order.	BOLD 12	Text
35, 40, 45		Device Expiration Date = Manufactured date plus two years in YYYY-MM-DD format	BOLD 7	Text
42		Shim assembly number as defined in Table 2	BOLD 7	Text

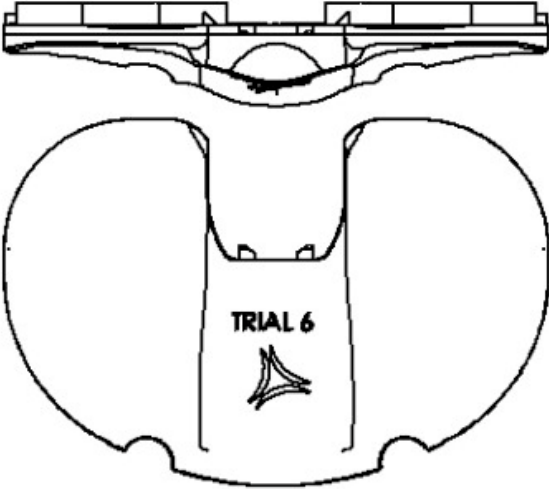
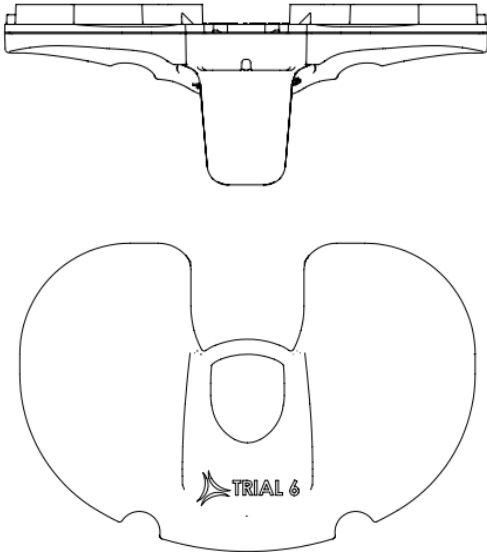
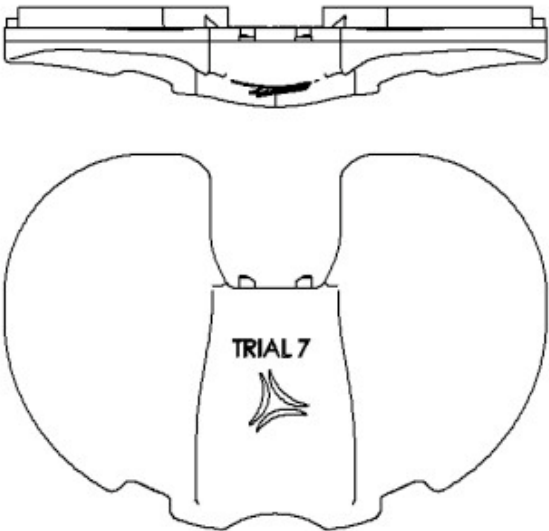
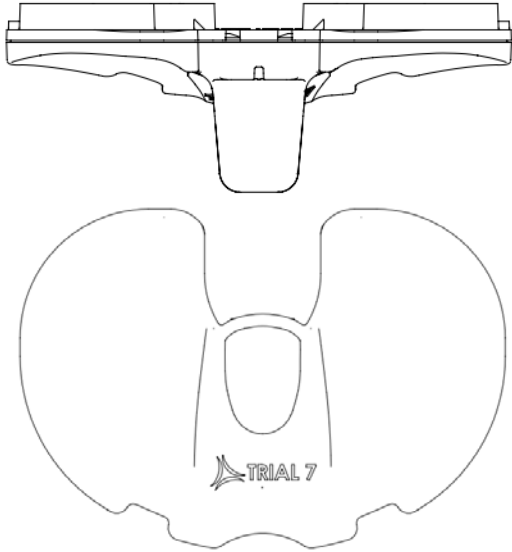
Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

46		Print Bluetooth® symbol as specified in the product label notes.	NA	Symbol
----	--	--	----	--------

Table 1 DEVICE Images

Item # 1	
CR Size 2	PS Size 2
 	 
CR Size 3	PS Size 3
 	 

Item # 1	
CR Size 4	PS Size 4
	
CR Size 5	PS Size 5
	

Item # 1	
CR Size 6	PS Size 6
	
CR Size 7	PS Size 7
	

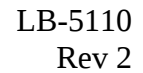
Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

Table #2

Item 5 GTIN	Item 2	Items 8, 16, 26	Items 42	Items 12, 19, 24, 31, 37	Items 15 & 27	Items 9 & 28	Items 14 & 29
00816818022253	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon CR Size 2	DWG-03000-003	SYK-TRCR02	2	N/A	CR
00816818022260	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon CR Size 3	DWG-03000-167	SYK-TRCR03	3	N/A	CR
00816818022277	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon CR Size 4	DWG-03000-168	SYK-TRCR04	4	N/A	CR
00816818022284	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon CR Size 5	DWG-03000-169	SYK-TRCR05	5	N/A	CR
00816818022291	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon CR Size 6	DWG-03000-170	SYK-TRCR06	6	N/A	CR
00816818022307	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon CR Size 7	DWG-03000-004	SYK-TRCR07	7	N/A	CR
00816818022314	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon PS Size 2	DWG-03000-003	SYK-TRPS02	2	N/A	PS
00816818022321	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon PS Size 3	DWG-03000-167	SYK-TRPS03	3	N/A	PS
00816818022338	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon PS Size 4	DWG-03000-168	SYK-TRPS04	4	N/A	PS
00816818022345	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon PS Size 5	DWG-03000-169	SYK-TRPS05	5	N/A	PS
00816818022352	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon PS Size 6	DWG-03000-170	SYK-TRPS06	6	N/A	PS
00816818022369	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon PS Size 7	DWG-03000-004	SYK-TRPS07	7	N/A	PS

NOTE: When selecting the appropriate item, please ensure is the correct side, size and type per the work order.

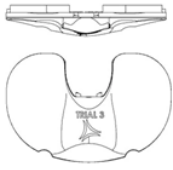
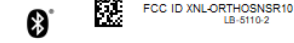
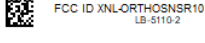
[illegible]



APPENDIX 1 - Example Labels

UNCONTROLLED COPY UNLESS MARKED "ORIGINAL" OR "CONTROLLED COPY" WITH A RED INK STAMP Page 9 of 21

Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

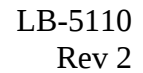
 VERASENSE for Stryker Triathlon CR Size 3		 9, 10, 11, 12, 13, 16 mm		<table border="1"> <tr> <td>SIZE</td> <td>3</td> </tr> <tr> <td>SIDE</td> <td>N/A</td> </tr> <tr> <td>TYPE</td> <td>CR</td> </tr> </table>	SIZE	3	SIDE	N/A	TYPE	CR	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>QTY</td> <td>1</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> <tr> <td>EXP</td> <td>2019-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	QTY	1	EXP	2021-11-18	EXP	2019-11-18	<table border="1"> <tr> <td colspan="2">VERASENSE</td> </tr> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td colspan="2">VERASENSE for Stryker Triathlon CR Size 3</td> </tr> </table>	VERASENSE		REF	SYK-TRCR03	SN	431845011	LOT	80085	VERASENSE for Stryker Triathlon CR Size 3	
SIZE	3																																	
SIDE	N/A																																	
TYPE	CR																																	
REF	SYK-TRCR03																																	
SN	431845011																																	
LOT	80085																																	
QTY	1																																	
EXP	2021-11-18																																	
EXP	2019-11-18																																	
VERASENSE																																		
REF	SYK-TRCR03																																	
SN	431845011																																	
LOT	80085																																	
VERASENSE for Stryker Triathlon CR Size 3																																		
 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011		 1855 Griffin Road, Suite A-310 Dania Beach, FL 33004, USA 1.888.75.ORTHO +1.954.577.7770 OrthoSensor.com		<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>QTY</td> <td>1</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> <tr> <td>EXP</td> <td>2019-11-18</td> </tr> </table>		REF	SYK-TRCR03	SN	431845011	LOT	80085	QTY	1	EXP	2021-11-18	EXP	2019-11-18	<table border="1"> <tr> <td colspan="2">VERASENSE</td> </tr> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td colspan="2">VERASENSE for Stryker Triathlon CR Size 3</td> </tr> </table>	VERASENSE		REF	SYK-TRCR03	SN	431845011	LOT	80085	VERASENSE for Stryker Triathlon CR Size 3							
REF	SYK-TRCR03																																	
SN	431845011																																	
LOT	80085																																	
QTY	1																																	
EXP	2021-11-18																																	
EXP	2019-11-18																																	
VERASENSE																																		
REF	SYK-TRCR03																																	
SN	431845011																																	
LOT	80085																																	
VERASENSE for Stryker Triathlon CR Size 3																																		
						 FCC ID XNL-ORTHOSENSOR10 LB-5110-2																												

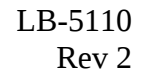
LB-5110-2	 VERASENSE for Stryker Triathlon CR Size 3	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>QTY</td> <td>1</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	QTY	1	EXP	2021-11-18	<table border="1"> <tr> <td>SIZE</td> <td>3</td> </tr> <tr> <td>SIDE</td> <td>N/A</td> </tr> <tr> <td>TYPE</td> <td>CR</td> </tr> </table>	SIZE	3	SIDE	N/A	TYPE	CR	<table border="1"> <tr> <td colspan="2">VERASENSE</td> </tr> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td colspan="2">VERASENSE for Stryker Triathlon CR Size 3</td> </tr> </table>	VERASENSE		REF	SYK-TRCR03	SN	431845011	LOT	80085	VERASENSE for Stryker Triathlon CR Size 3	
REF	SYK-TRCR03																													
SN	431845011																													
LOT	80085																													
QTY	1																													
EXP	2021-11-18																													
SIZE	3																													
SIDE	N/A																													
TYPE	CR																													
VERASENSE																														
REF	SYK-TRCR03																													
SN	431845011																													
LOT	80085																													
VERASENSE for Stryker Triathlon CR Size 3																														

LB-5110-2	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	EXP	2021-11-18	 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	LB-5110-2	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	EXP	2021-11-18	 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	LB-5110-2	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	EXP	2021-11-18	 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011
REF	SYK-TRCR03																															
SN	431845011																															
LOT	80085																															
EXP	2021-11-18																															
REF	SYK-TRCR03																															
SN	431845011																															
LOT	80085																															
EXP	2021-11-18																															
REF	SYK-TRCR03																															
SN	431845011																															
LOT	80085																															
EXP	2021-11-18																															

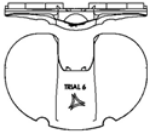
LB-5110-2	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	EXP	2021-11-18	 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	LB-5110-2	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	EXP	2021-11-18	 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	LB-5110-2	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	EXP	2021-11-18	 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011
REF	SYK-TRCR03																															
SN	431845011																															
LOT	80085																															
EXP	2021-11-18																															
REF	SYK-TRCR03																															
SN	431845011																															
LOT	80085																															
EXP	2021-11-18																															
REF	SYK-TRCR03																															
SN	431845011																															
LOT	80085																															
EXP	2021-11-18																															

LB-5110-2	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	EXP	2021-11-18	 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	LB-5110-2	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	EXP	2021-11-18	 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	LB-5110-2	<table border="1"> <tr> <td>REF</td> <td>SYK-TRCR03</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>EXP</td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR03	SN	431845011	LOT	80085	EXP	2021-11-18	 (01) 0 0816818 022260 (11) 191118 (17) 211118 (10) 80085 (21) 431845011
REF	SYK-TRCR03																															
SN	431845011																															
LOT	80085																															
EXP	2021-11-18																															
REF	SYK-TRCR03																															
SN	431845011																															
LOT	80085																															
EXP	2021-11-18																															
REF	SYK-TRCR03																															
SN	431845011																															
LOT	80085																															
EXP	2021-11-18																															



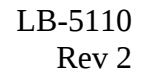


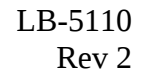
Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

 VERASENSE for Stryker Triathlon CR Size 6		 9, 10, 11, 12, 13, 16 mm	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="background-color: #cccccc;">SIZE</td> <td style="text-align: center;">6</td> </tr> <tr> <td style="background-color: #cccccc;">SIDE</td> <td style="text-align: center;">N/A</td> </tr> <tr> <td style="background-color: #cccccc;">TYPE</td> <td style="text-align: center;">CR</td> </tr> </table>	SIZE	6	SIDE	N/A	TYPE	CR	VERASENSE REF SYK-TRCR06 SN 431845011 LOT 80085 VERASENSE for Stryker Triathlon CR Size 6 VERASENSE REF SYK-TRCR06 SN 431845011 LOT 80085 VERASENSE for Stryker Triathlon CR Size 6 VERASENSE REF SYK-TRCR06 SN 431845011 LOT 80085 VERASENSE for Stryker Triathlon CR Size 6							
SIZE	6																
SIDE	N/A																
TYPE	CR																
 (01) 0 0816818 022291 (11) 191118 (17) 211118 (10) 80085 (21) 431845011		 1855 Griffin Road, Suite A-310 Dania Beach, FL 33004, USA 1888.75.ORTHO +1 954.577.7770 OrthoSensor.com		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="background-color: #cccccc;">REF</td> <td>SYK-TRCR06</td> </tr> <tr> <td style="background-color: #cccccc;">SN</td> <td>431845011</td> </tr> <tr> <td style="background-color: #cccccc;">LOT</td> <td>80085</td> </tr> <tr> <td style="background-color: #cccccc;">QTY</td> <td>1</td> </tr> <tr> <td style="background-color: #cccccc;"></td> <td>2021-11-18</td> </tr> <tr> <td style="background-color: #cccccc;"></td> <td>2019-11-18</td> </tr> </table>		REF	SYK-TRCR06	SN	431845011	LOT	80085	QTY	1		2021-11-18		2019-11-18
REF	SYK-TRCR06																
SN	431845011																
LOT	80085																
QTY	1																
	2021-11-18																
	2019-11-18																
 -50°C  80%  106kPa                      IPX4  STERILE  EO  CE 0297   FCC ID XNL-ORTHOSEN10  LB-5110-2																	

LB-5110-2	 VERASENSE for Stryker Triathlon CR Size 6	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="background-color: #cccccc;">REF</td> <td>SYK-TRCR06</td> </tr> <tr> <td style="background-color: #cccccc;">SN</td> <td>431845011</td> </tr> <tr> <td style="background-color: #cccccc;">LOT</td> <td>80085</td> </tr> <tr> <td style="background-color: #cccccc;">QTY</td> <td>1</td> </tr> <tr> <td style="background-color: #cccccc;"></td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR06	SN	431845011	LOT	80085	QTY	1		2021-11-18	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="background-color: #cccccc;">SIZE</td> <td style="background-color: #cccccc;">SIDE</td> <td style="background-color: #cccccc;">TYPE</td> </tr> <tr> <td style="text-align: center;">6</td> <td style="text-align: center;">N/A</td> <td style="text-align: center;">CR</td> </tr> </table>	SIZE	SIDE	TYPE	6	N/A	CR	VERASENSE REF SYK-TRCR06 SN 431845011 LOT 80085 2021-11-18 STERILE EO LB-5110-2 VERASENSE REF DWG-03000-170 LOT 80085 2021-11-18 STERILE EO LB-5110-2
REF	SYK-TRCR06																			
SN	431845011																			
LOT	80085																			
QTY	1																			
	2021-11-18																			
SIZE	SIDE	TYPE																		
6	N/A	CR																		

LB-5110-2	 VERASENSE for Stryker Triathlon CR Size 6	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="background-color: #cccccc;">REF</td> <td>SYK-TRCR06</td> </tr> <tr> <td style="background-color: #cccccc;">SN</td> <td>431845011</td> </tr> <tr> <td style="background-color: #cccccc;">LOT</td> <td>80085</td> </tr> <tr> <td style="background-color: #cccccc;">QTY</td> <td>1</td> </tr> <tr> <td style="background-color: #cccccc;"></td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRCR06	SN	431845011	LOT	80085	QTY	1		2021-11-18	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="background-color: #cccccc;">SIZE</td> <td style="background-color: #cccccc;">SIDE</td> <td style="background-color: #cccccc;">TYPE</td> </tr> <tr> <td style="text-align: center;">6</td> <td style="text-align: center;">N/A</td> <td style="text-align: center;">CR</td> </tr> </table>	SIZE	SIDE	TYPE	6	N/A	CR	VERASENSE REF SYK-TRCR06 SN 431845011 LOT 80085 2021-11-18 STERILE EO LB-5110-2 VERASENSE REF DWG-03000-170 LOT 80085 2021-11-18 STERILE EO LB-5110-2
REF	SYK-TRCR06																			
SN	431845011																			
LOT	80085																			
QTY	1																			
	2021-11-18																			
SIZE	SIDE	TYPE																		
6	N/A	CR																		

[illegible]



 VERASENSE for Stryker Triathlon PS Size 2		 9, 10, 11, 12, 13, 16 mm		SIZE	2							
		SIDE	N/A									
		TYPE	PS									
 (01) 0 0816818 022314 (11) 191118 (17) 211118 (10) 80085 (21) 431845011		 1855 Griffin Road, Suite A-310 Danis Beach, FL 33004, USA 1.888.75.ORTHO +1.954.577.7770 OrthoSensor.com		<table border="1" style="margin-bottom: 5px;"> <tr><td>REF</td><td>SYK-TRPS02</td></tr> <tr><td>SN</td><td>431845011</td></tr> <tr><td>LOT</td><td>80085</td></tr> <tr><td>QTY</td><td>1</td></tr> </table> 2021-11-18 2019-11-18	REF	SYK-TRPS02	SN	431845011	LOT	80085	QTY	1
REF	SYK-TRPS02											
SN	431845011											
LOT	80085											
QTY	1											
50°C 10% 36kPa 100% IPX4 STERILE EO CE 0297 LB-5110-2 												

VERASENSE

REF	SYK-TRPS02
SN	431845011
LOT	80085
QTY	1

2021-11-18

SIZE	2
SIDE	N/A
TYPE	PS

VERASENSE

REF	SYK-TRPS02
SN	431845011
LOT	80085
QTY	1

2021-11-18

VERASENSE

REF	SYK-TRPS02
SN	431845011
LOT	80085
QTY	1

2021-11-18

VERASENSE

REF	SYK-TRPS02
SN	431845011
LOT	80085
QTY	1

2021-11-18

VERASENSE

REF	SYK-TRPS02
SN	431845011
LOT	80085
QTY	1

2021-11-18

VERASENSE

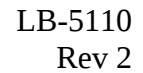
REF	SYK-TRPS02
SN	431845011
LOT	80085
QTY	1

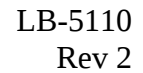
2021-11-18

VERASENSE

REF	SYK-TRPS02
SN	431845011
LOT	80085
QTY	1

2021-11-18





Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family



VERASENSE for Stryker Triathlon PS Size 5



9, 10, 11, 12, 13, 16 mm

SIZE	5
SIDE	N/A
TYPE	PS



(01) 0 0816818 022345 (11) 191118 (17) 211118 (10) 80085 (21) 431845011



1855 Griffin Road, Suite A-310
Dania Beach, FL 33004, USA
1.888.75.ORTHO | +1.954.577.7770
OrthoSensor.com

REF	SYK-TRPS05
SN	431845011
LOT	80085
QTY	1
EXP	2021-11-18
EXP	2019-11-18



FCC ID XN-ORTHOSNR10
LB-5110-2

LB-5110-2



VERASENSE for Stryker Triathlon PS Size 5

REF	SYK-TRPS05
SN	431845011
LOT	80085
QTY	1
EXP	2021-11-18

SIZE	SIDE	TYPE
5	N/A	PS

LB-5110-2

REF	SYK-TRPS05
SN	431845011
LOT	80085
EXP	2021-11-18

LB-5110-2

REF	SYK-TRPS05
SN	431845011
LOT	80085
EXP	2021-11-18

LB-5110-2

REF	DWG-03000-169
LOT	80085
EXP	2021-11-18

LB-5110-2

REF	SYK-TRPS05
SN	431845011
LOT	80085
EXP	2021-11-18

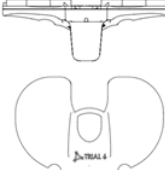
LB-5110-2

REF	SYK-TRPS05
SN	431845011
LOT	80085
EXP	2021-11-18

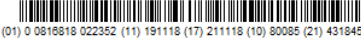
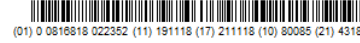
LB-5110-2

REF	SYK-TRPS05
SN	431845011
LOT	80085
EXP	2021-11-18

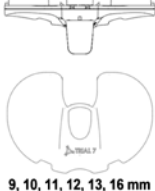
Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

 VERASENSE for Stryker Triathlon PS Size 6		 9, 10, 11, 12, 13, 16 mm	<table border="1"> <tr> <td>SIZE</td> <td>6</td> </tr> <tr> <td>SIDE</td> <td>N/A</td> </tr> <tr> <td>TYPE</td> <td>PS</td> </tr> </table>	SIZE	6	SIDE	N/A	TYPE	PS	VERASENSE REF SYK-TRPS06 SN 431845011 LOT 80085 VERASENSE for Stryker Triathlon PS Size 6						
SIZE	6															
SIDE	N/A															
TYPE	PS															
 (01) 0 0810818 022352 (11) 191118 (17) 211118 (10) 80085 (21) 431845011		 1855 Griffin Road, Suite A-310 Dania Beach, FL 33004, USA 1888.75.ORTHO +1 954.577.7770 OrthoSensor.com	<table border="1"> <tr> <td>REF</td> <td>SYK-TRPS06</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>QTY</td> <td>1</td> </tr> <tr> <td></td> <td>2021-11-18</td> </tr> <tr> <td></td> <td>2019-11-18</td> </tr> </table>	REF	SYK-TRPS06	SN	431845011	LOT	80085	QTY	1		2021-11-18		2019-11-18	VERASENSE REF SYK-TRPS06 SN 431845011 LOT 80085 VERASENSE for Stryker Triathlon PS Size 6
REF	SYK-TRPS06															
SN	431845011															
LOT	80085															
QTY	1															
	2021-11-18															
	2019-11-18															
0°C 50°C 10N 30N 106kPa 36kPa STERILE EO CE 0297		FCC ID XNL-ORTHOSENSOR10 LB-5110-2														

LB-5110-2  VERASENSE for Stryker Triathlon PS Size 6	<table border="1"> <tr> <td>REF</td> <td>SYK-TRPS06</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td>QTY</td> <td>1</td> </tr> <tr> <td></td> <td>2021-11-18</td> </tr> </table>	REF	SYK-TRPS06	SN	431845011	LOT	80085	QTY	1		2021-11-18	<table border="1"> <tr> <td>SIZE</td> <td>6</td> </tr> <tr> <td>SIDE</td> <td>N/A</td> </tr> <tr> <td>TYPE</td> <td>PS</td> </tr> </table>	SIZE	6	SIDE	N/A	TYPE	PS	VERASENSE REF SYK-TRPS06 SN 431845011 LOT 80085 2021-11-18 LB-5110-2
REF	SYK-TRPS06																		
SN	431845011																		
LOT	80085																		
QTY	1																		
	2021-11-18																		
SIZE	6																		
SIDE	N/A																		
TYPE	PS																		

LB-5110-2 <table border="1"> <tr> <td>REF</td> <td>SYK-TRPS06</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td></td> <td>2021-11-18</td> </tr> </table>  (01) 0 0810818 022352 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	REF	SYK-TRPS06	SN	431845011	LOT	80085		2021-11-18	LB-5110-2 <table border="1"> <tr> <td>REF</td> <td>SYK-TRPS06</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td></td> <td>2021-11-18</td> </tr> </table>  (01) 0 0810818 022352 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	REF	SYK-TRPS06	SN	431845011	LOT	80085		2021-11-18
REF	SYK-TRPS06																
SN	431845011																
LOT	80085																
	2021-11-18																
REF	SYK-TRPS06																
SN	431845011																
LOT	80085																
	2021-11-18																
LB-5110-2 <table border="1"> <tr> <td>REF</td> <td>SYK-TRPS06</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td></td> <td>2021-11-18</td> </tr> </table>  (01) 0 0810818 022352 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	REF	SYK-TRPS06	SN	431845011	LOT	80085		2021-11-18	LB-5110-2 <table border="1"> <tr> <td>REF</td> <td>SYK-TRPS06</td> </tr> <tr> <td>SN</td> <td>431845011</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td></td> <td>2021-11-18</td> </tr> </table>  (01) 0 0810818 022352 (11) 191118 (17) 211118 (10) 80085 (21) 431845011	REF	SYK-TRPS06	SN	431845011	LOT	80085		2021-11-18
REF	SYK-TRPS06																
SN	431845011																
LOT	80085																
	2021-11-18																
REF	SYK-TRPS06																
SN	431845011																
LOT	80085																
	2021-11-18																

LB-5110-2 <table border="1"> <tr> <td>REF</td> <td>DWG-03000-170</td> </tr> <tr> <td>LOT</td> <td>80085</td> </tr> <tr> <td></td> <td>2021-11-18</td> </tr> </table> STERILE EO LB-5110-2	REF	DWG-03000-170	LOT	80085		2021-11-18	 
REF	DWG-03000-170						
LOT	80085						
	2021-11-18						

 VERASENSE for Stryker Triathlon PS Size 7		 9, 10, 11, 12, 13, 16 mm	<table border="1"> <tr> <td>SIZE</td> <td>7</td> </tr> <tr> <td>SIDE</td> <td>N/A</td> </tr> <tr> <td>TYPE</td> <td>PS</td> </tr> </table>	SIZE	7	SIDE	N/A	TYPE	PS	VERASENSE REF SYK-TRPS07 SN 431845011 LOT 80085 VERASENSE for Stryker Triathlon PS Size 7
SIZE	7									
SIDE	N/A									
TYPE	PS									
 (01) 0 0816818 022369 (11) 191118 (17) 211118 (10) 80085 (21) 431845011		ORTHOSENSOR 1855 Griffin Road, Suite A-310 Dania Beach, FL 33004, USA 1.888.75.ORTHO 1.954.572.7770 OrthoSensor.com		REF SYK-TRPS07 SN 431845011 LOT 80085 QTY 1 2021-11-18 2019-11-18						
0°C - 50°C 10% 30% 100Pa 30Pa STERILE EO CE 0297 FCC ID XNL-ORTHOSNSR10 LB-5110-2										

LB-5110-2 VERASENSE REF SYK-TRPS07 SN 431845011 LOT 80085 QTY 1 2021-11-18	<table border="1"> <tr> <td>SIZE</td> <td>7</td> </tr> <tr> <td>SIDE</td> <td>N/A</td> </tr> <tr> <td>TYPE</td> <td>PS</td> </tr> </table>	SIZE	7	SIDE	N/A	TYPE	PS	VERASENSE REF SYK-TRPS07 SN 431845011 LOT 80085 2021-11-18 STERILE EO LB-5110-2
SIZE	7							
SIDE	N/A							
TYPE	PS							

LB-5110-2 VERASENSE REF SYK-TRPS07 SN 431845011 LOT 80085 2021-11-18	LB-5110-2 VERASENSE REF SYK-TRPS07 SN 431845011 LOT 80085 2021-11-18	LB-5110-2 VERASENSE REF DWG-03000-004 LOT 80085 2021-11-18 STERILE EO LB-5110-2
---	---	--

LB-5110-2 VERASENSE REF SYK-TRPS07 SN 431845011 LOT 80085 2021-11-18	LB-5110-2 VERASENSE REF SYK-TRPS07 SN 431845011 LOT 80085 2021-11-18	
---	---	--

REVISION HISTORY

Rev	Description	Date
0	Initial Release.	See QT9
1	Assigned new GTINs for addition of intermediate shims 10 and 12 mm to VERASENSE for Stryker Triathlon CR. Removed spaces in SYK CR catalog numbers and moved CR in name before Size. Removed packaging assembly instructions since this is located in the work instruction. Removed instructions for printing DVT labels. Added Appendix 1 with examples of all labels. Bom number was included in the description section. Item 42 column was included in table 2 In product Label field Descriptions table – Item 42 was included Samples labels were updated to include DWG number	See QT9
2	Added VERASENSE for Stryker Triathlon PS Gen 4. Corrected shim assembly numbers for CR sizes 3-6.	See QT9