

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:

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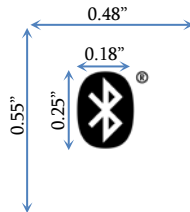
010081681802123411YYMMDD17YYMMDD101234567219876543210

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



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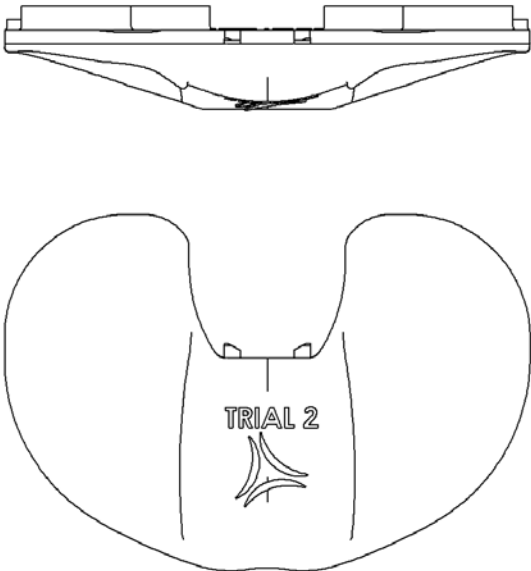
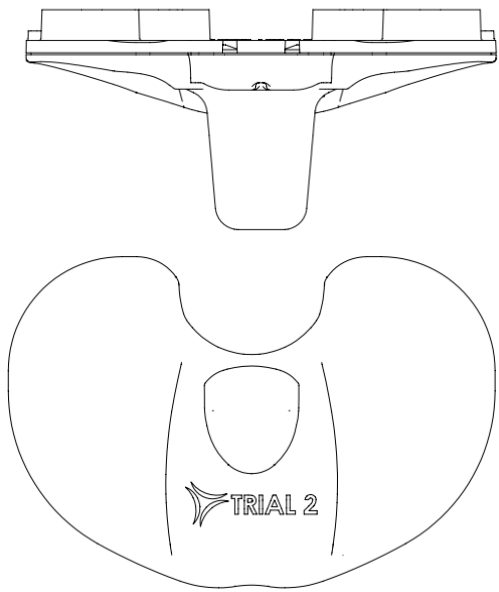
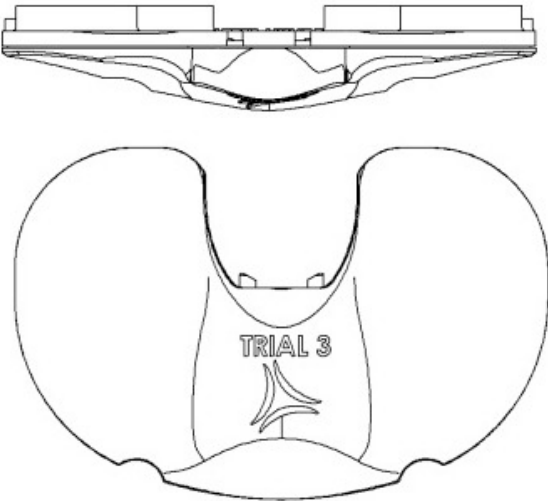
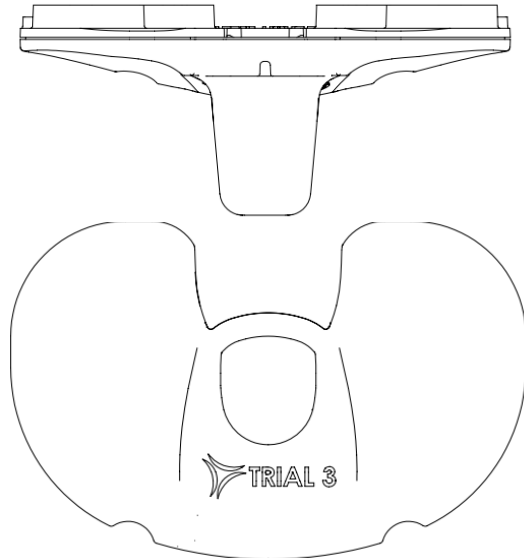
Product Label field Descriptions:

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

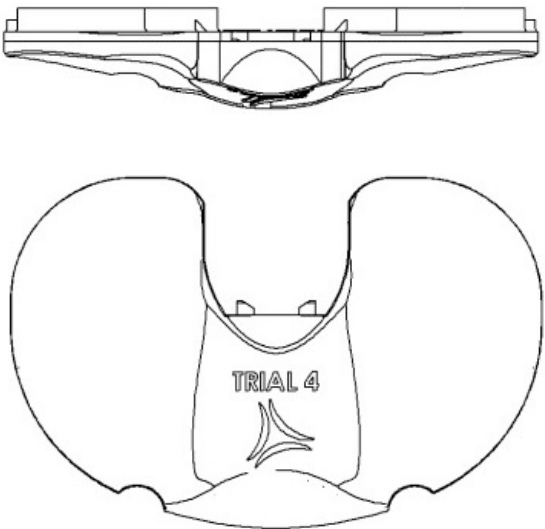
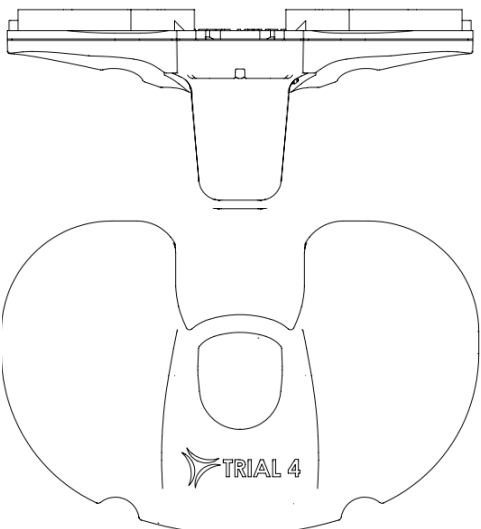
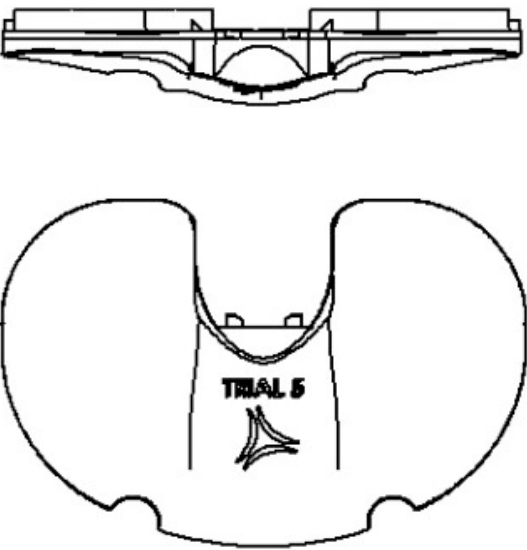
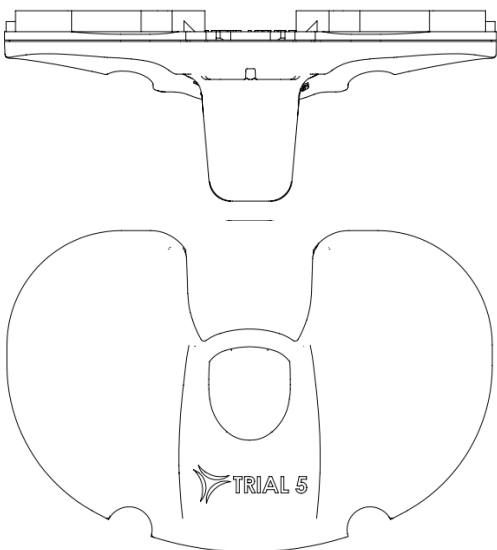
Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

46	Print Bluetooth® symbol as specified in the product label notes.	NA	Symbol
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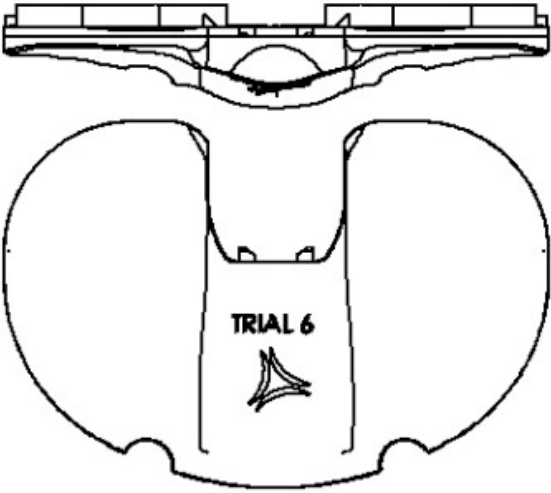
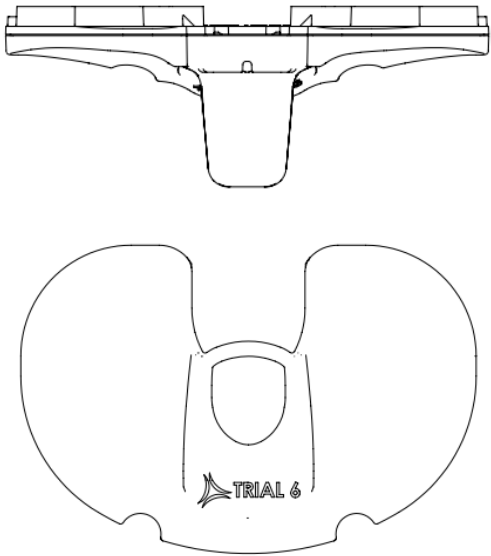
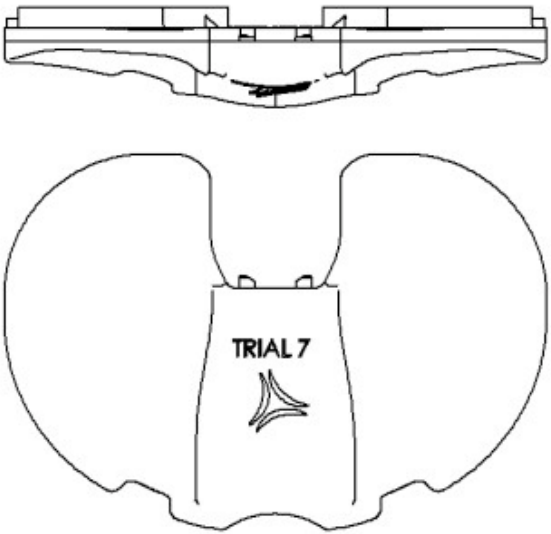
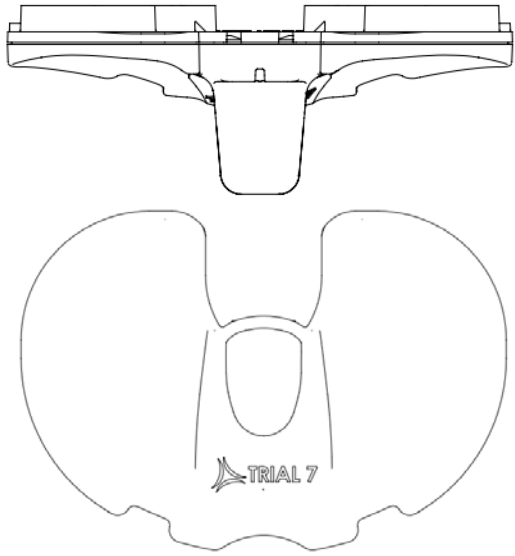
Table 1 DEVICE Images

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

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

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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

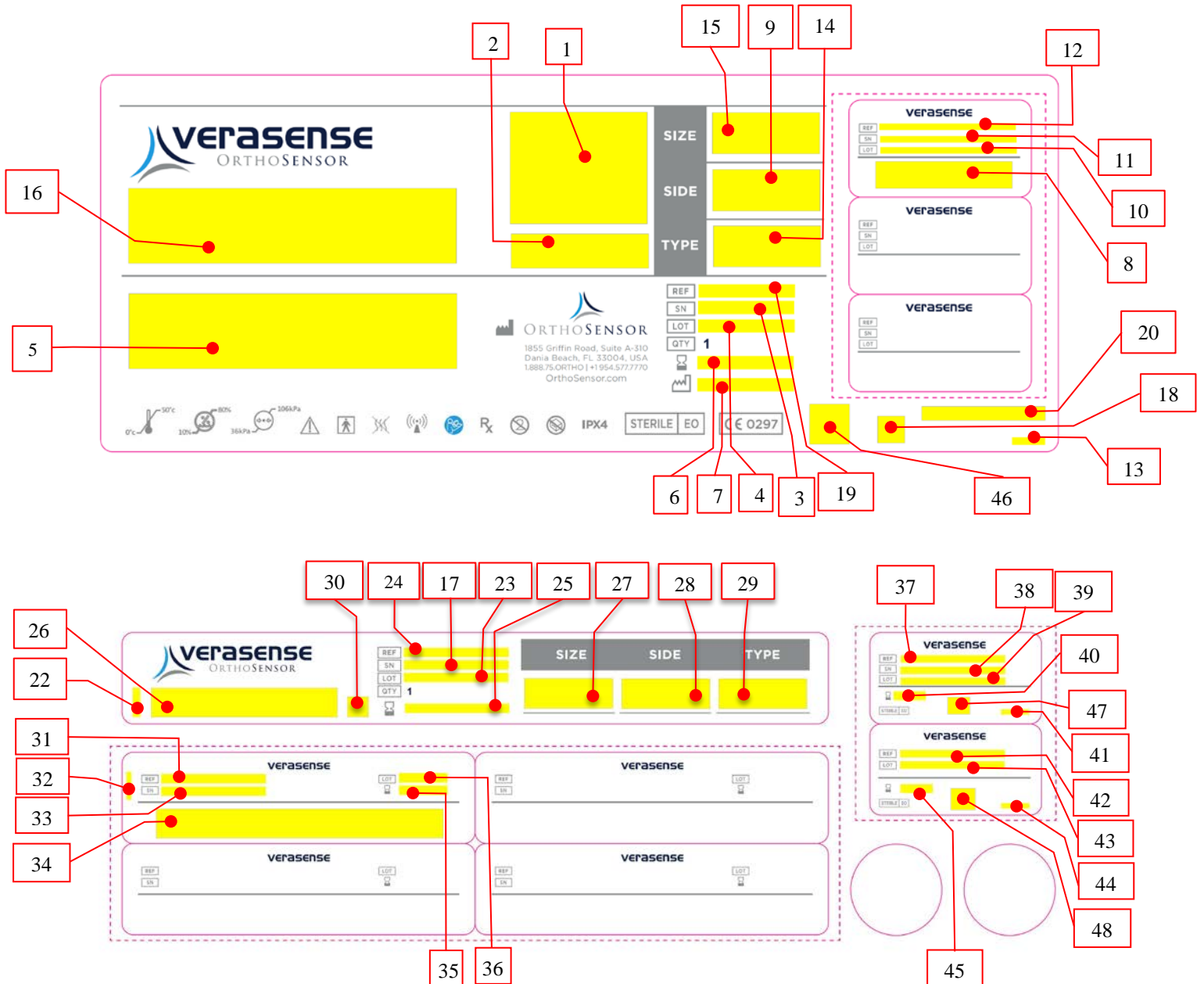
Item 5 GTIN	Item 2	Items 8, 16, 26	Items 42	Items 12, 19, 24, 31, 37	Items 15 & 27	Items 9 & 28	Items 14 & 29
00816818022253	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon CR Size 2	DWG-03000-003	SYK-TRCR02	2	N/A	CR
00816818022260	9, 10, 11, 12, 13, 16mm	VERASENSE for Stryker Triathlon CR Size 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.

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



PRODUCT LABEL REFERENCE FIGURES

1. Blank label is shown below with the required print fields highlight:



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

APPENDIX 1 - Example Labels

 <p>VERASENSE for Stryker Triathlon CR Size 2</p>	 <p>9, 10, 11, 12, 13, 16 mm</p>	SIZE	2
		SIDE	N/A
		TYPE	CR

REF	SYK-TRCR02
SN	431845011
LOT	80085
QTY	1
	2021-11-18
	2019-11-18

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

STERILE EO

FCC ID XNL-ORTHOSNSR10
LB-5110-2

 <p>VERASENSE for Stryker Triathlon CR Size 2</p>	REF	SYK-TRCR02	SIZE	2	SIDE	N/A	TYPE	CR
	SN	431845011						
	LOT	80085						
	QTY	1						
		2021-11-18						

REF	SYK-TRCR02	VERASENSE	LOT	80085	2021-11-18
SN	431845011				
 <p>(01) 0 0816818 022253 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>					

REF	SYK-TRCR02	VERASENSE	LOT	80085	2021-11-18
SN	431845011				
 <p>(01) 0 0816818 022253 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>					

REF	SYK-TRCR02	VERASENSE	LOT	80085	2021-11-18
SN	431845011				
 <p>(01) 0 0816818 022253 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>					

REF	SYK-TRCR02	VERASENSE	LOT	80085	2021-11-18
SN	431845011				
 <p>(01) 0 0816818 022253 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>					

REF	SYK-TRCR02
SN	431845011
LOT	80085
	2021-11-18

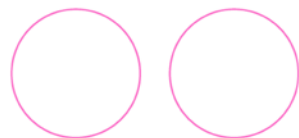
STERILE EO

LB-5110-2


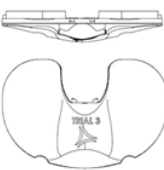
REF	DWG-03000-003
LOT	80085
	2021-11-18

STERILE EO

LB-5110-2



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

 <p>VERASENSE ORTHOSENSOR</p> <p>VERASENSE for Stryker Triathlon CR Size 3</p>	 <p>9, 10, 11, 12, 13, 16 mm</p>	SIZE	3
		SIDE	N/A
		TYPE	CR

REF	SYK-TRCR03
SN	431845011
LOT	80085
QTY	1
	2021-11-18
	2019-11-18

1855 Griffin Road, Suite A-310
Dania Beach, FL 33004, USA
1888.75.ORTHO | +1 954.377.7770
OrthoSensor.com

0°C, 50°C, 10%, 30%, 36kPa, 100kPa, IPX4, STERILE EO, CE 0297, FCC ID XNL-ORTHOSENSR10 LB-5110-2

VERASENSE
REF: SYK-TRCR03
SN: 431845011
LOT: 80085
VERASENSE for Stryker Triathlon CR Size 3

VERASENSE
REF: SYK-TRCR03
SN: 431845011
LOT: 80085
VERASENSE for Stryker Triathlon CR Size 3

VERASENSE
REF: SYK-TRCR03
SN: 431845011
LOT: 80085
VERASENSE for Stryker Triathlon CR Size 3

LB-5110-2

REF	SYK-TRCR03
SN	431845011
LOT	80085
QTY	1
	2021-11-18

SIZE	SIDE	TYPE
3	N/A	CR

VERASENSE
REF: SYK-TRCR03
SN: 431845011
LOT: 80085
2021-11-18
STERILE EO LB-5110-2

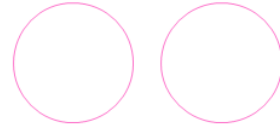
VERASENSE
REF: DWG-03000-167
LOT: 80085
2021-11-18
STERILE EO LB-5110-2

REF	SYK-TRCR03	VERASENSE	LOT	80085
SN	431845011			2021-11-18


(01) 0 0816818 022280 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

REF	SYK-TRCR03	VERASENSE	LOT	80085
SN	431845011			2021-11-18

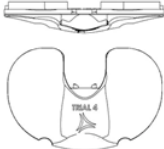
(01) 0 0816818 022280 (11) 191118 (17) 211118 (10) 80085 (21) 431845011



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




VERASENSE for Stryker Triathlon
CR Size 4




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

SIZE	4
SIDE	N/A
TYPE	CR

REF	SYK-TRCR04
SN	431845011
LOT	80085
QTY	1
EXP	2021-11-18
MFG	2019-11-18



(01) 0 0816818 022277 (11) 191118 (17) 211118 (10) 80085 (21) 431845011



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REF	SYK-TRCR04
SN	431845011
LOT	80085
QTY	1
EXP	2021-11-18
MFG	2019-11-18

REF	SYK-TRCR04
SN	431845011
LOT	80085

VERASENSE for Stryker Triathlon CR Size 4

REF	SYK-TRCR04
SN	431845011
LOT	80085

VERASENSE for Stryker Triathlon CR Size 4

REF	SYK-TRCR04
SN	431845011
LOT	80085

VERASENSE for Stryker Triathlon CR Size 4

0°C 50°C 100°C 100% 36kPa 100kPa

STERILE EO CE 0297

FCC ID XNL-ORTHOSENSOR10 LB-5110-2



VERASENSE for Stryker Triathlon CR Size 4

REF	SYK-TRCR04
SN	431845011
LOT	80085
QTY	1
EXP	2021-11-18

SIZE	SIDE	TYPE
4	N/A	CR

REF	SYK-TRCR04
SN	431845011
LOT	80085
EXP	2021-11-18
MFG	2019-11-18

REF	SYK-TRCR04
SN	431845011
LOT	80085
EXP	2021-11-18
MFG	2019-11-18

REF	SYK-TRCR04
SN	431845011
LOT	80085
EXP	2021-11-18
MFG	2019-11-18


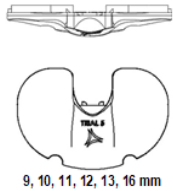
REF	SYK-TRCR04
SN	431845011
LOT	80085
EXP	2021-11-18
MFG	2019-11-18

REF	SYK-TRCR04
SN	431845011
LOT	80085
EXP	2021-11-18
MFG	2019-11-18

REF	DWG-03000-168
LOT	80085
EXP	2021-11-18
MFG	2019-11-18

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

 <p>VERASENSE for Stryker Triathlon CR Size 5</p>	 <p>9, 10, 11, 12, 13, 16 mm</p>	SIZE	5
		SIDE	N/A
		TYPE	CR

REF	SYK-TRCR05
SN	431845011
LOT	80085
QTY	1
EXP	2021-11-18
MAN	2019-11-18

1855 Griffin Road, Suite A-310
Dania Beach, FL 33004, USA
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STERILE EO C E 0297

FCC ID XNL-ORTHOSNSR10
LB-5110-2

VERASENSE

REF SYK-TRCR05
SN 431845011
LOT 80085

VERASENSE for Stryker Triathlon CR Size 5

VERASENSE

REF SYK-TRCR05
SN 431845011
LOT 80085

VERASENSE for Stryker Triathlon CR Size 5

VERASENSE

REF SYK-TRCR05
SN 431845011
LOT 80085

VERASENSE for Stryker Triathlon CR Size 5

LB-5110-2

REF	SYK-TRCR05	SIZE	5	SIDE	N/A	TYPE	CR
SN	431845011						
LOT	80085						
QTY	1						
EXP	2021-11-18						

VERASENSE

REF SYK-TRCR05
SN 431845011
LOT 80085

2021-11-18

STERILE EO

LB-5110-2

VERASENSE

REF DWG-03000-169
LOT 80085

2021-11-18

STERILE EO

LB-5110-2

LB-5110-2

REF SYK-TRCR05
SN 431845011

VERASENSE

LOT 80085
2021-11-18

(01) 0 0818518 022284 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

LB-5110-2

REF SYK-TRCR05
SN 431845011

VERASENSE

LOT 80085
2021-11-18

(01) 0 0818518 022284 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

LB-5110-2

REF SYK-TRCR05
SN 431845011

VERASENSE

LOT 80085
2021-11-18

(01) 0 0818518 022284 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

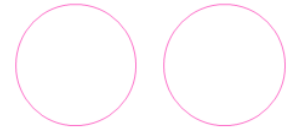
LB-5110-2

REF SYK-TRCR05
SN 431845011


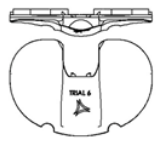
VERASENSE

LOT 80085
2021-11-18

(01) 0 0818518 022284 (11) 191118 (17) 211118 (10) 80085 (21) 431845011



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

 <p>VERASENSE ORTHOSENSOR</p> <p>VERASENSE for Stryker Triathlon CR Size 6</p>	 <p>9, 10, 11, 12, 13, 16 mm</p>	SIZE	6
		SIDE	N/A
		TYPE	CR

REF SYK-TRCR06
 SN 431845011
 LOT 80085
 QTY 1
 2021-11-18
 2019-11-18

ORTHOSENSOR
 1855 Griffin Road, Suite A-310
 Dania Beach, FL 33004, USA
 1888.75.ORTHO | +1.954.577.7770
 OrthoSensor.com

(01) 0 0818818 022291 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

50°C 100% 80% 36kPa 106kPa
 STERILE EO CE 0297

FCC ID: XNL-ORTHOSENSR10
 LB-5110-2

LB-5110-2

 <p>VERASENSE ORTHOSENSOR</p> <p>VERASENSE for Stryker Triathlon CR Size 6</p>	REF SYK-TRCR06 SN 431845011 LOT 80085 QTY 1 2021-11-18	<table border="1"> <tr> <th>SIZE</th> <th>SIDE</th> <th>TYPE</th> </tr> <tr> <td>6</td> <td>N/A</td> <td>CR</td> </tr> </table>	SIZE	SIDE	TYPE	6	N/A	CR
SIZE	SIDE	TYPE						
6	N/A	CR						

LB-5110-2

REF SYK-TRCR06	VERASENSE	LOT 80085
SN 431845011		2021-11-18

(01) 0 0818818 022291 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

LB-5110-2

REF SYK-TRCR06	VERASENSE	LOT 80085
SN 431845011		2021-11-18

(01) 0 0818818 022291 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

LB-5110-2

REF SYK-TRCR06	VERASENSE	LOT 80085
SN 431845011		2021-11-18

(01) 0 0818818 022291 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

LB-5110-2

REF SYK-TRCR06	VERASENSE	LOT 80085
SN 431845011		2021-11-18

(01) 0 0818818 022291 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

VERASENSE

REF SYK-TRCR06	
SN 431845011	
LOT 80085	

2021-11-18

STERILE EO LB-5110-2

VERASENSE


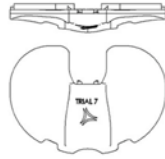
REF DWG-03000-170	
LOT 80085	


2021-11-18

STERILE EO LB-5110-2




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

 <p>VERASENSE ORTHOSENSOR</p> <p>VERASENSE for Stryker Triathlon CR Size 7</p>	 <p>9, 10, 11, 12, 13, 16 mm</p>	SIZE	7
		SIDE	N/A
		TYPE	CR




(01) 0 0816818 022307 (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-TRCR07
SN	431845011
LOT	80085
QTY	1
EXP	2021-11-18
EXP	2019-11-18



STERILE	EO
CE 0297	

REF	SYK-TRCR07
SN	431845011
LOT	80085


VERASENSE for Stryker Triathlon CR Size 7


REF	SYK-TRCR07
SN	431845011
LOT	80085


VERASENSE for Stryker Triathlon CR Size 7

REF	SYK-TRCR07
SN	431845011
LOT	80085

VERASENSE for Stryker Triathlon CR Size 7

LB-5110-2	 <p>VERASENSE ORTHOSENSOR</p> <p>VERASENSE for Stryker Triathlon CR Size 7</p>	<table border="1"> <tr><td>REF</td><td>SYK-TRCR07</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-TRCR07	SN	431845011	LOT	80085	QTY	1	EXP	2021-11-18	<table border="1"> <tr><th>SIZE</th><th>SIDE</th><th>TYPE</th></tr> <tr><td>7</td><td>N/A</td><td>CR</td></tr> </table>	SIZE	SIDE	TYPE	7	N/A	CR	<table border="1"> <tr><td>REF</td><td>SYK-TRCR07</td></tr> <tr><td>SN</td><td>431845011</td></tr> <tr><td>LOT</td><td>80085</td></tr> </table> <p>2021-11-18</p> <p>STERILE EO</p>	REF	SYK-TRCR07	SN	431845011	LOT	80085
REF	SYK-TRCR07																									
SN	431845011																									
LOT	80085																									
QTY	1																									
EXP	2021-11-18																									
SIZE	SIDE	TYPE																								
7	N/A	CR																								
REF	SYK-TRCR07																									
SN	431845011																									
LOT	80085																									

LB-5110-2	<table border="1"> <tr><td>REF</td><td>SYK-TRCR07</td></tr> <tr><td>SN</td><td>431845011</td></tr> </table> <p>VERASENSE</p> <p>LOT 80085</p> <p>2021-11-18</p>	REF	SYK-TRCR07	SN	431845011	 <p>(01) 0 0816818 022307 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>	<table border="1"> <tr><td>REF</td><td>SYK-TRCR07</td></tr> <tr><td>SN</td><td>431845011</td></tr> </table> <p>VERASENSE</p> <p>LOT 80085</p> <p>2021-11-18</p>	REF	SYK-TRCR07	SN	431845011
REF	SYK-TRCR07										
SN	431845011										
REF	SYK-TRCR07										
SN	431845011										

LB-5110-2	<table border="1"> <tr><td>REF</td><td>SYK-TRCR07</td></tr> <tr><td>SN</td><td>431845011</td></tr> </table> <p>VERASENSE</p> <p>LOT 80085</p> <p>2021-11-18</p>	REF	SYK-TRCR07	SN	431845011	 <p>(01) 0 0816818 022307 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>	<table border="1"> <tr><td>REF</td><td>SYK-TRCR07</td></tr> <tr><td>SN</td><td>431845011</td></tr> </table> <p>VERASENSE</p> <p>LOT 80085</p> <p>2021-11-18</p>	REF	SYK-TRCR07	SN	431845011
REF	SYK-TRCR07										
SN	431845011										
REF	SYK-TRCR07										
SN	431845011										

REF	SYK-TRCR07
SN	431845011
LOT	80085

2021-11-18

STERILE EO

LB-5110-2






REF	DWG-03000-004
LOT	80085

2021-11-18

STERILE EO

LB-5110-2

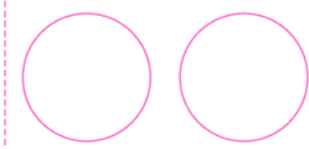
Label and Packaging, Product, VERASENSE for Stryker Triathlon (GEN 4) Family

 <p>VERASENSE for Stryker Triathlon PS Size 2</p>	 <p>9, 10, 11, 12, 13, 16 mm</p>	<table border="1"> <tr><th>SIZE</th><td>2</td></tr> <tr><th>SIDE</th><td>N/A</td></tr> <tr><th>TYPE</th><td>PS</td></tr> </table>	SIZE	2	SIDE	N/A	TYPE	PS	<table border="1"> <tr><th>REF</th><td>SYK-TRPS02</td></tr> <tr><th>SN</th><td>431845011</td></tr> <tr><th>LOT</th><td>80085</td></tr> </table> <p>VERASENSE for Stryker Triathlon PS Size 2</p> <table border="1"> <tr><th>REF</th><td>SYK-TRPS02</td></tr> <tr><th>SN</th><td>431845011</td></tr> <tr><th>LOT</th><td>80085</td></tr> </table> <p>VERASENSE for Stryker Triathlon PS Size 2</p> <table border="1"> <tr><th>REF</th><td>SYK-TRPS02</td></tr> <tr><th>SN</th><td>431845011</td></tr> <tr><th>LOT</th><td>80085</td></tr> </table> <p>VERASENSE for Stryker Triathlon PS Size 2</p>	REF	SYK-TRPS02	SN	431845011	LOT	80085	REF	SYK-TRPS02	SN	431845011	LOT	80085	REF	SYK-TRPS02	SN	431845011	LOT	80085
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		SIDE	N/A																								
TYPE	PS																										
REF	SYK-TRPS02																										
SN	431845011																										
LOT	80085																										
REF	SYK-TRPS02																										
SN	431845011																										
LOT	80085																										
REF	SYK-TRPS02																										
SN	431845011																										
LOT	80085																										
 <p>(01) 0 0816818 022314 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>	 <p>1855 Griffin Road, Suite A-310 Dania Beach, FL 33004, USA 1888.75.ORTHO +1954.577.7770 OrthoSensor.com</p>	<table border="1"> <tr><th>REF</th><td>SYK-TRPS02</td></tr> <tr><th>SN</th><td>431845011</td></tr> <tr><th>LOT</th><td>80085</td></tr> <tr><th>QTY</th><td>1</td></tr> </table> <p>2021-11-18 2019-11-18</p>	REF	SYK-TRPS02	SN	431845011	LOT	80085	QTY	1																	
REF	SYK-TRPS02																										
SN	431845011																										
LOT	80085																										
QTY	1																										
		<p>STERILE EO</p> <p>CE 0297</p> <p>FCC ID XNL-ORTHOSNR10 LB-5110-2</p>																									



LB-5110-2	 <p>VERASENSE for Stryker Triathlon PS Size 2</p>	<table border="1"> <tr><th>REF</th><td>SYK-TRPS02</td></tr> <tr><th>SN</th><td>431845011</td></tr> <tr><th>LOT</th><td>80085</td></tr> <tr><th>QTY</th><td>1</td></tr> </table> <p>2021-11-18</p>	REF	SYK-TRPS02	SN	431845011	LOT	80085	QTY	1	<table border="1"> <tr><th>SIZE</th><td>2</td></tr> <tr><th>SIDE</th><td>N/A</td></tr> <tr><th>TYPE</th><td>PS</td></tr> </table>	SIZE	2	SIDE	N/A	TYPE	PS
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LOT	80085																
QTY	1																
SIZE	2																
SIDE	N/A																
TYPE	PS																

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REF	SYK-TRPS02						
SN	431845011						
LOT	80085						
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REF	DWG-03000-003						
LOT	80085						

<table border="1"> <tr><th>REF</th><td>SYK-TRPS02</td></tr> <tr><th>SN</th><td>431845011</td></tr> </table> <p>VERASENSE</p> <p>LOT 80085</p> <p>2021-11-18</p>  <p>(01) 0 0816818 022314 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>	REF	SYK-TRPS02	SN	431845011	<table border="1"> <tr><th>REF</th><td>SYK-TRPS02</td></tr> <tr><th>SN</th><td>431845011</td></tr> </table> <p>VERASENSE</p> <p>LOT 80085</p> <p>2021-11-18</p>  <p>(01) 0 0816818 022314 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>	REF	SYK-TRPS02	SN	431845011
REF	SYK-TRPS02								
SN	431845011								
REF	SYK-TRPS02								
SN	431845011								
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REF	SYK-TRPS02								
SN	431845011								
REF	SYK-TRPS02								
SN	431845011								



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

 <p>VERASENSE ORTHOSENSOR</p> <p>VERASENSE for Stryker Triathlon PS Size 3</p>	 <p>9, 10, 11, 12, 13, 16 mm</p>	SIZE	3
		SIDE	N/A
		TYPE	PS

REF	SYK-TRPS03
SN	431845011
LOT	80085
QTY	1
	2021-11-18
	2019-11-18

01) 0 0816818 022321 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

ORTHOSENSOR
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Dania Beach, FL 33004, USA
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OrthoSensor.com

STERILE EO CC 0297

FCC ID: XNL-ORTHOSENSOR10 LB-5110-2

Verasense		
REF	SYK-TRPS03	
SN	431845011	
LOT	80085	
VERASENSE for Stryker Triathlon PS Size 3		

Verasense		
REF	SYK-TRPS03	
SN	431845011	
LOT	80085	
VERASENSE for Stryker Triathlon PS Size 3		

Verasense		
REF	SYK-TRPS03	
SN	431845011	
LOT	80085	
VERASENSE for Stryker Triathlon PS Size 3		

LB-5110-2

REF	SYK-TRPS03	
SN	431845011	
LOT	80085	
QTY	1	
	2021-11-18	

SIZE	SIDE	TYPE
3	N/A	PS

Verasense		
REF	SYK-TRPS03	
SN	431845011	
LOT	80085	
	2021-11-18	
STERILE EO LB-5110-2		

Verasense		
REF	DWG-03000-167	
LOT	80085	
	2021-11-18	
STERILE EO LB-5110-2		

LB-5110-2

REF	SYK-TRPS03	
SN	431845011	
LOT	80085	
	2021-11-18	

VERASENSE

01) 0 0816818 022321 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

LB-5110-2

REF	SYK-TRPS03	
SN	431845011	
LOT	80085	
	2021-11-18	

VERASENSE

01) 0 0816818 022321 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

LB-5110-2

REF	SYK-TRPS03	
SN	431845011	
LOT	80085	
	2021-11-18	

VERASENSE

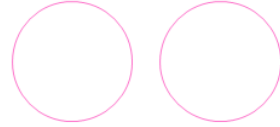
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LB-5110-2


REF	SYK-TRPS03	
SN	431845011	
LOT	80085	
	2021-11-18	

VERASENSE

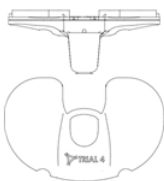
01) 0 0816818 022321 (11) 191118 (17) 211118 (10) 80085 (21) 431845011



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



VERASENSE for Stryker Triathlon PS Size 4




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

SIZE	4
SIDE	N/A
TYPE	PS


VERASENSE

REF	SYK-TRPS04
SN	431845011
LOT	80085

VERASENSE for Stryker Triathlon PS Size 4




(01) 0 0818818 022338 (11) 191118 (17) 211118 (10) 80085 (21) 431845011



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Dania Beach, FL 33004, USA
1888.75.ORTHO | +1 954.577.7770
OrthoSensor.com

REF	SYK-TRPS04
SN	431845011
LOT	80085
QTY	1
EXP	2021-11-18
MFG	2019-11-18



FCC ID XNL-ORTHSNSR10
LB-5110-2



VERASENSE for Stryker Triathlon PS Size 4

SIZE	4	SIDE	N/A	TYPE	PS
------	---	------	-----	------	----

REF	SYK-TRPS04
SN	431845011
LOT	80085
QTY	1
EXP	2021-11-18

VERASENSE

REF	SYK-TRPS04
SN	431845011
LOT	80085

2021-11-18

REF	SYK-TRPS04
SN	431845011
LOT	80085

2021-11-18



(01) 0 0818818 022338 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

REF	SYK-TRPS04
SN	431845011
LOT	80085

2021-11-18



(01) 0 0818818 022338 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

REF	SYK-TRPS04
SN	431845011
LOT	80085

2021-11-18



(01) 0 0818818 022338 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

REF	SYK-TRPS04
SN	431845011
LOT	80085

2021-11-18



(01) 0 0818818 022338 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

REF	DWG-03000-168
LOT	80085


2021-11-18




(01) 0 0818818 022338 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

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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 0818818 022345 (11) 1911118 (17) 2111118 (10) 80085 (21) 431845011



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Dania Beach, FL 33004, USA
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OrthoSensor.com

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

REF	SYK-TRPS05
SN	431845011
LOT	80085

VERASENSE for Stryker Triathlon PS Size 5

REF	SYK-TRPS05
SN	431845011
LOT	80085

VERASENSE for Stryker Triathlon PS Size 5


REF	SYK-TRPS05
SN	431845011
LOT	80085

VERASENSE for Stryker Triathlon PS Size 5

0°C 50°C 100°C 150°C 200°C 250°C 300°C 350°C 400°C 450°C 500°C 550°C 600°C 650°C 700°C 750°C 800°C 850°C 900°C 950°C 1000°C

IPX4 STERILE EO CE 0297

FCC ID XNL-ORTHOSENSR10 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

REF	SYK-TRPS05
SN	431845011
LOT	80085

VERASENSE for Stryker Triathlon PS Size 5

REF	DWG-03000-169
LOT	80085

2021-11-18

REF	SYK-TRPS05
SN	431845011

VERASENSE

LOT	80085
EXP	2021-11-18

REF	SYK-TRPS05
SN	431845011

VERASENSE


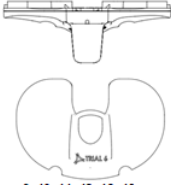



LOT	80085
EXP	2021-11-18

REF	SYK-TRPS05
SN	431845011

VERASENSE

LOT	80085
EXP	2021-11-18

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

 <p>VERASENSE for Stryker Triathlon PS Size 6</p>	 <p>9, 10, 11, 12, 13, 16 mm</p>	<p>SIZE 6</p>
		<p>SIDE N/A</p>
		<p>TYPE PS</p>
 <p>(01) 0 0816818 022352 (11) 191118 (17) 211118 (10) 80085 (21) 431845011</p>	 <p>1855 Griffin Road, Suite A-310 Dania Beach, FL 33004, USA 1888.75.ORTHO +1.954.577.7770 OrthoSensor.com</p>	<p>REF SYK-TRPS06 SN 431845011 LOT 80085 QTY 1 2021-11-18 2019-11-18</p>
	<p>STERILE EO CE 0297</p>	<p>FCC ID XNL-ORTHOSENSOR10 LB-5110.2</p>

<p>LB-5110.2</p>  <p>VERASENSE for Stryker Triathlon PS Size 6</p>	<p>REF SYK-TRPS06 SN 431845011 LOT 80085 QTY 1 2021-11-18</p>	<p>SIZE 6</p>	<p>SIDE N/A</p>	<p>TYPE PS</p>
	<p>REF SYK-TRPS06 SN 431845011 LOT 80085 2021-11-18</p>	<p>REF SYK-TRPS06 SN 431845011 LOT 80085 2021-11-18</p>	<p>REF SYK-TRPS06 SN 431845011 LOT 80085 2021-11-18</p>	<p>REF SYK-TRPS06 SN 431845011 LOT 80085 2021-11-18</p>

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

REF SYK-TRPS06
SN 431845011
LOT 80085
2021-11-18



LB-5110
Rev 2

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

VERASENSE
ORTHOSENSOR

VERASENSE for Stryker Triathlon PS Size 7

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

SIZE	7
SIDE	N/A
TYPE	PS

REF: SYK-TRPS07
SN: 431845011
LOT: 80085
QTY: 1
2021-11-18
2019-11-18

ORTHOSENSOR
1855 Griffin Road, Suite A-310
Dania Beach, FL 33004, USA
1388.75.ORTH01 | 1.954.577.7770
OrthoSensor.com

(01) 0 0816818 022369 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

FCC ID XNL-ORTHOSNR10
LB-5110-2

LB-5110-2

VERASENSE
ORTHOSENSOR

VERASENSE for Stryker Triathlon PS Size 7

SIZE	7	SIDE	N/A	TYPE	PS
------	---	------	-----	------	----

REF: SYK-TRPS07
SN: 431845011
LOT: 80085
QTY: 1
2021-11-18

LB-5110-2

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

(01) 0 0816818 022369 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

LB-5110-2

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

(01) 0 0816818 022369 (11) 191118 (17) 211118 (10) 80085 (21) 431845011

LB-5110-2

REF	SYK-TRPS07	VERASENSE	LOT	80085
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REF	SYK-TRPS07	VERASENSE	LOT	80085
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VERASENSE

REF	SYK-TRPS07	LOT	80085
SN	431845011	2021-11-18	

STERILE EO LB-5110-2

VERASENSE

REF	DWG-03000-004	LOT	80085
SN		2021-11-18	

STERILE EO LB-5110-2

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

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