Label and Packaging, Product, VERASENSE for Zimmer Biomet Persona Family

DESCRIPTION

1. This document specifies the information that is printed on to the Product Label and packaging assembly requirements for the following family.

    VERASENSE for Zimmer Biomet Persona

PRODUCT LABEL NOTES

- Create label from: LB-1029 "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:

   **01**00816818021234**11**YYMMDD**17**YYMMDD**10**1234567**21**9876543210

    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

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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:
  a. Print the symbol with the size requirements shown below, including the required white space around the figure.
  b. Use the highest possible resolution, not going below 16x16 pixels
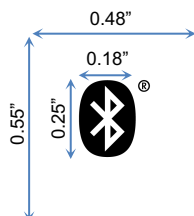
Label and Packaging, Product, VERASENSE for Zimmer Biomet Persona Family

Product Label field Descriptions:
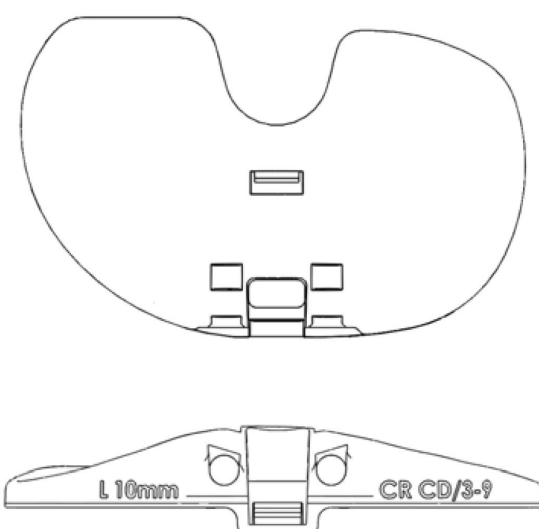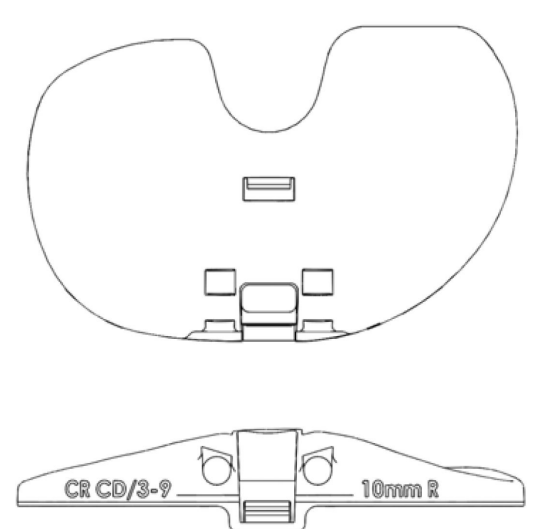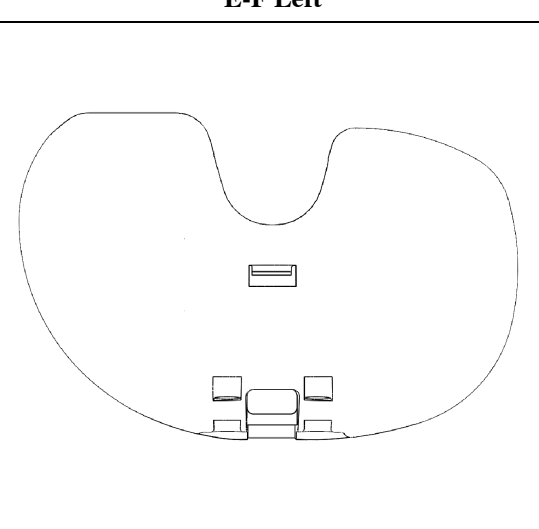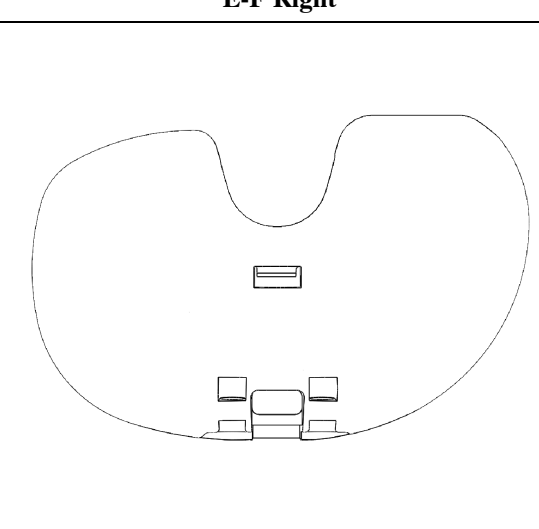
Item #	Field	Description	Font Size pts (Arial)	Print
1		**Print image.** See Table 1- Select image based on work order	NA	Fill all available space
2		**Sizes accommodated.** Table 2.	**BOLD 9**	Text
3	SN	Programmed Device Model ID Number	**BOLD 10**	Text
4	LOT	Manufacturing Lot Number	**BOLD 10**	Info
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 fourteen months in YYYY-MM-DD format.	**BOLD 10**	Info
7	ᴍ	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	LOT	Manufacturing Lot Number	**BOLD 7**	Info
11, 33, 38	SN	Programmed Device Model ID Number	**BOLD 7**	Info
12, 31, 37	REF	**See table 2. Select the appropriate description per work order**	**BOLD 7**	Info
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	SN	Programmed Device Model ID Number	**BOLD 9**	Text
18, 30, 47, 48		Contract Manufacturer's Internal Tracking Identifier (Optional)	NA	Bar Code
19	REF	**See table 2. Select the appropriate description per work order.**	**BOLD 10**	Text
23	LOT	Manufacturing Lot Number	**BOLD 9**	Text
24	REF	**See table 2. Select the appropriate description per work order.**	**BOLD 9**	Text
20		FCC ID XNL-ORTHOSNSR7	7	Text
25	⧗	Device Expiration Date = Manufactured date plus fourteen months in YYYY-MM-DD format.	**BOLD 9**	Text
26		**See table 2. Select the appropriate description per work order.**	**BOLD 9**	Text
40, 45	⧗	Device Expiration Date = Manufactured date plus fourteen months in YYYY-MM-DD format.	**BOLD 7**	Text
42	REF	Shim assembly drawing number as defined per the applicable BOM for the build.	**BOLD 7**	Text
46		**Print Bluetooth® symbol as specified in the product label notes.**	NA	Symbol

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Table 1 DEVICE Images

Item # 1	
C-D Left	**C-D Right**
E-F Left	**E-F Right**

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G-H Left	G-H Right

Label and Packaging, Product, VERASENSE for Zimmer Biomet Persona Family

Table #2

Item 5 GTIN	Item 2	Items 8, 16, 26	Items 12, 19, 24	Items 15 & 27	Items 9 & 28	Items 14 & 29
00816818021416	10, 11, 12, 13, 14, 16mm	VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Left	ZBH-PSNCRCD39-L	C-D/3-9	Left	CR
00816818021423	10, 11, 12, 13, 14, 16mm	VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Right	ZBH-PSNCRCD39-R	C-D/3-9	Right	CR
00816818021430	10, 11, 12, 13, 14, 16mm	VERASENSE for Zimmer Biomet Persona CR E-F/3-11 Left	ZBH-PSNCREF311-L	E-F/3-11	Left	CR
00816818021447	10, 11, 12, 13, 14, 16mm	VERASENSE for Zimmer Biomet Persona CR E-F/3-11 Right	ZBH-PSNCREF311-R	E-F/3-11	Right	CR
00816818021454	10, 11, 12, 13, 14, 16mm	VERASENSE for Zimmer Biomet Persona CR G-H/7-12 Left	ZBH-PSNCRGH712-L	G-H/7-12	Left	CR
00816818021461	10, 11, 12, 13, 14, 16mm	VERASENSE for Zimmer Biomet Persona CR G-H/7-12 Right	ZBH-PSNCRGH712-R	G-H/7-12	Right	CR

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

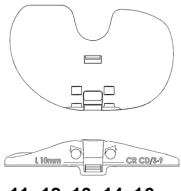**Label and Packaging, Product, VERASENSE for Zimmer Biomet Persona Family**

PRODUCT LABEL REFERENCE FIGURES

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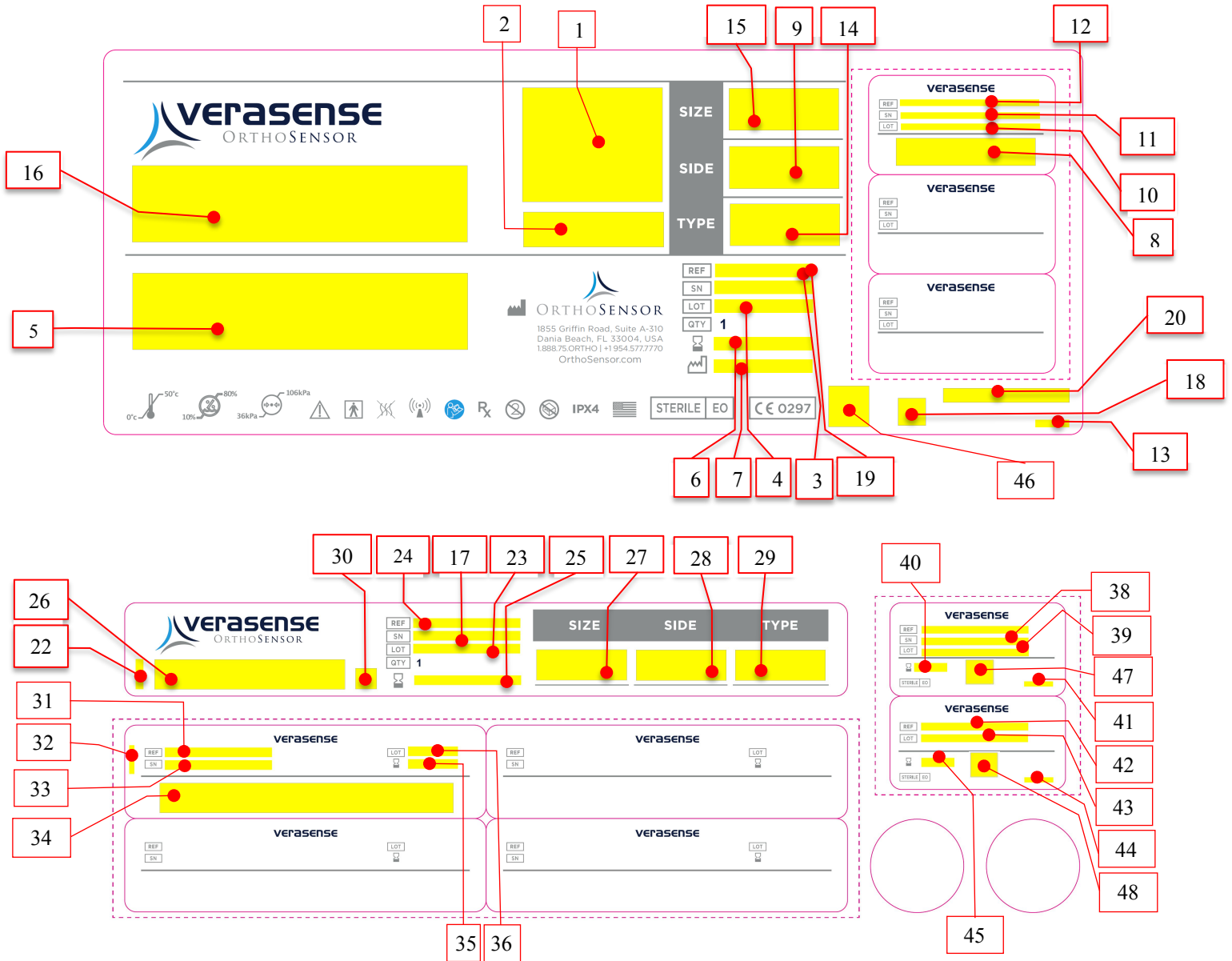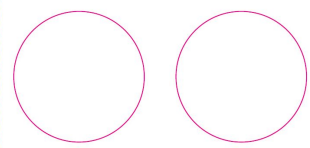
OrthoSensor®

2. Below is an example of the completed Label with all fields filled and the barcodes with encoded information:

verasense
ORTHOSENSOR

VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Left

10, 11, 12, 13, 14, 16mm

SIZE	C-D/3-9
SIDE	Left
TYPE	CR

OrthoSensor
1855 Griffin Road, Suite A-310
Dania Beach, FL 33004, USA
1.888.75.ORTHO | +1 954.577.7770
OrthoSensor.com

REF	ZBH-PSNCRCD39-L
SN	510845011
LOT	011314V10694
QTY	1
	2018-02-18
	2017-01-18

(01) 00816818021416 (11) 170118 (17) 180218 (10) 011314V10694 (21) 510845011

50°C / 0°C   80% / 10%   106kPa / 36kPa   IPX4   STERILE EO   CE 0297

FCC ID XNL-ORTHOSNSR7
LB-5044-5

verasense
REF ZBH-PSNCRCD39-L
SN 510845011
LOT 011314V10694
VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Left

verasense
REF ZBH-PSNCRCD39-L
SN 510845011
LOT 011314V10694
VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Left

verasense
REF ZBH-PSNCRCD39-L
SN 510845011
LOT 011314V10694
VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Left

verasense
ORTHOSENSOR
VERASENSE for Zimmer Biomet Persona CR C-D/3-9

REF	ZBH-PSNCRCD39-L
SN	510845011
LOT	011314V10694
QTY	1
	2018-02-18

SIZE	SIDE	TYPE
C-D/3-9	Left	CR

verasense
REF ZBH-PSNCRCD39-L
SN 510845011
LOT 011314V10694
2018-02-18
STERILE EO
LB-5044-5

verasense
REF DWG-03006-206
LOT 011314V10694
2018-02-18
STERILE EO
LB-5044-5

REF ZBH-PSNCRCD39-L
SN 510845011
LOT 011314V10694
2018-02-18
(01) 00816818021416 (11) 170118 (17) 180218 (10) 011314V10694 (21) 510845011

REF ZBH-PSNCRCD39-L
SN 510845011
LOT 011314V10694
2018-02-18
(01) 00816818021416 (11) 170118 (17) 180218 (10) 011314V10694 (21) 510845011

REF ZBH-PSNCRCD39-L
SN 510845011
LOT 011314V10694
2018-02-18
(01) 00816818021416 (11) 170118 (17) 180218 (10) 011314V10694 (21) 510845011

REF ZBH-PSNCRCD39-L
SN 510845011
LOT 011314V10694
2018-02-18
(01) 00816818021416 (11) 170118 (17) 180218 (10) 011314V10694 (21) 510845011

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PACKAGING ASSEMBLY NOTES

- See separate Bill of Materials, VERASENSE for Zimmer Biomet Persona BOM-1014 for Item description.
- Refer to Contract Manufacturer's Quality System for:
    - Part Inspection requirements
    - Functional testing requirements
    - Part handling and cleanliness
    - Packaging and Labeling
    - Traceability and Documentation requirements
- Contract Manufacturer's Quality System shall meet or exceed the requirements per the Quality Agreement established with the Contract Manufacturer.
- Contract Manufacturer's internal Tracking & Identification labels are permissible on all components per the following:
    - Labels are permitted on: Box, Envelope, Bags, IFU and Addendum, Product Label, and on the outer Pouch of the Pouched Sensor and Pouched Shim-Set.
    - Labels are not permitted on any Inner Pouch, or on any VERASENSE or Shim surfaces.
    - Labels must be permanent, and printed with indelible ink. Maximum label size is 1.0" x 0.5".
    - Labels should be located near a corner, or in an innocuous location, and not obscure any other marking or lettering.

PACKAGING ASSEMBLY PROCEDURES

1. Assemble per the following instructions. Refer to the figures below.
2. Separate the In-Carton labels and the Pouch Labels from the Box Labels.
3. Place the top Pouch Labels from $\boxed{\text{SN}}$ symbol on the Pouched Sensor and the bottom Pouch Label on the Pouched Shim-Set.
4. With the box oriented as shown below, place contents into box in the order shown below: Return Envelope on bottom, followed by Instructions-for-Use, Translation Addendum, In-Carton Labels, Pouched Shim-Set, and the Pouched Sensor on top.
    1. Insert Pouched Shim-Set and Pouched Sensor clear side up, and the factory sealed end going into the box first.
    2. Do not bend, wrinkle or distort pouches when inserting into product box.
5. Affix Product and End Flap Labels as shown below. Label Barcode IDs shall be traceable to the Device Model ID number.
6. Affix other stickers as shown.

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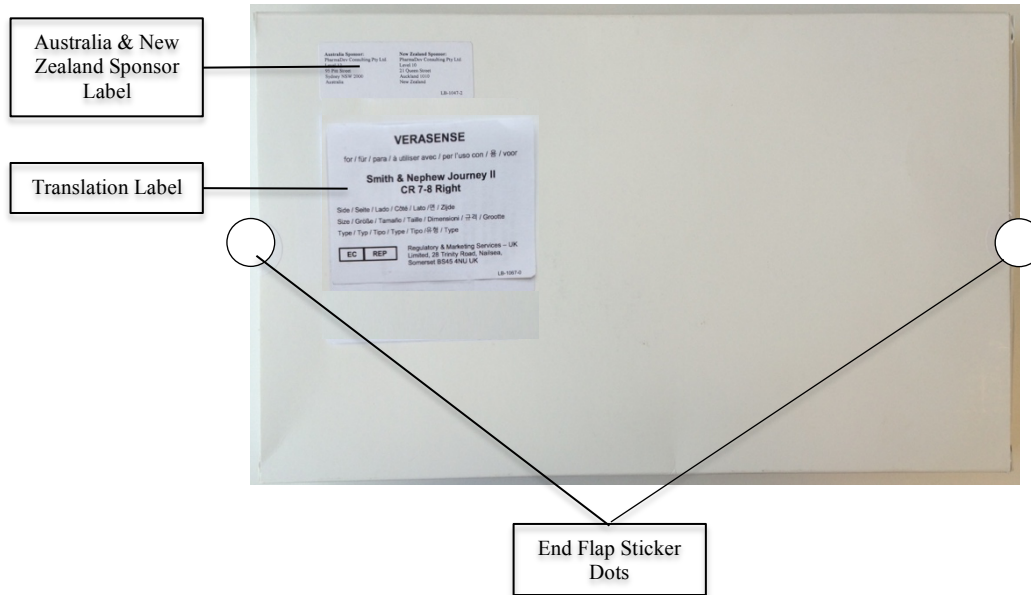## PACKAGING ASSEMBLY REFERENCE FIGURES
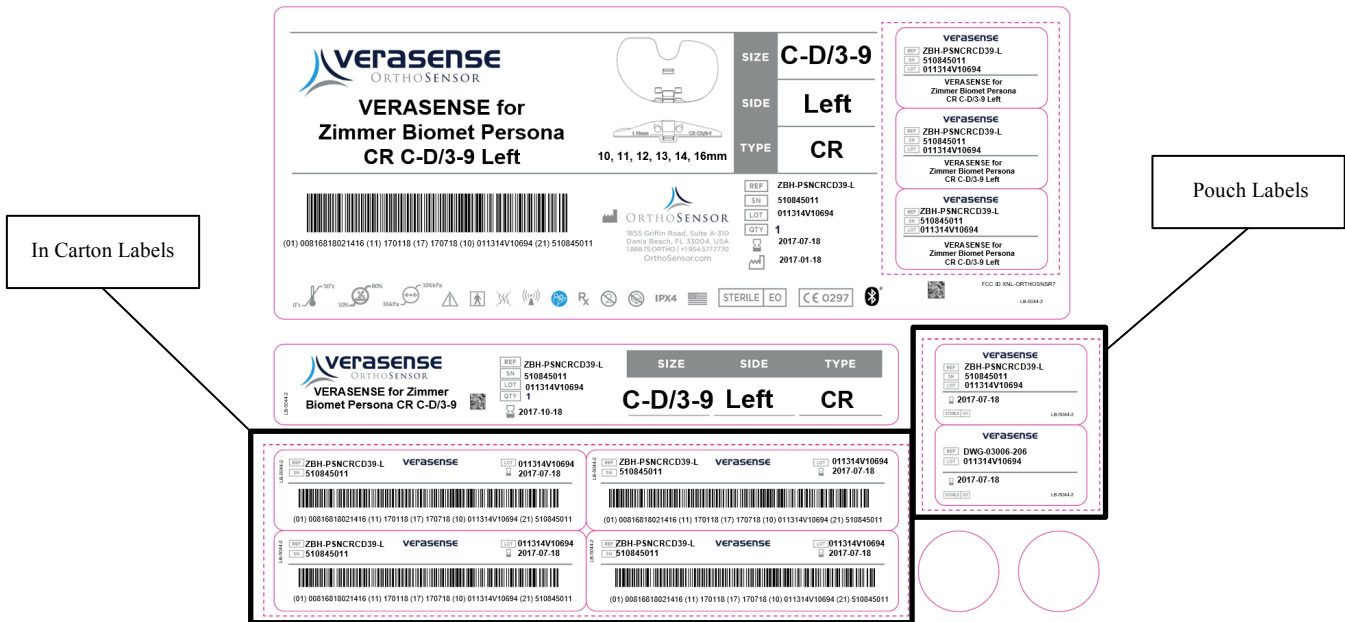
1. Build per Bill of Materials, VERASENSE for Zimmer Biomet Persona BOM-1014 and Router/Work Instruction. Generic image used below for illustration.
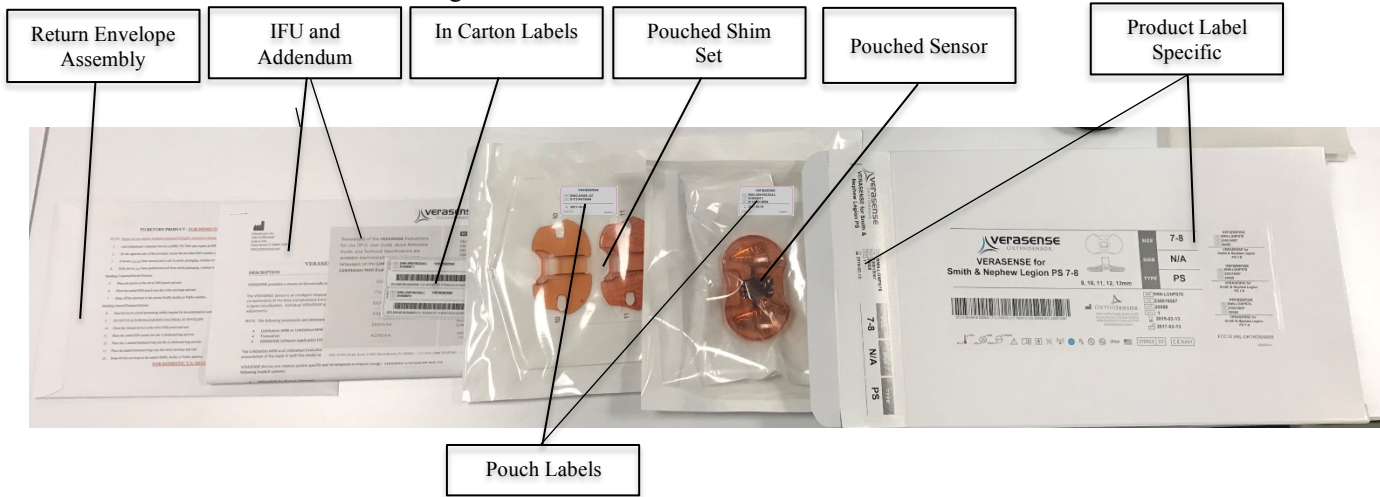
Front of Box

Label and Packaging, Product, VERASENSE for Zimmer Biomet Persona Family

Back of Box

Label and Packaging, Product, VERASENSE for Zimmer Biomet Persona Family

REVISION HISTORY

Rev	Description	Date
0	Initial Release for engineering build.	12/09/16
1	Barcodes symbol sizes table updated. Updated example figure to include current revision.	2/3/2017
2	Addition of size E/F and device images to Table 1. Removed instructions for addition of "Caution Not Sterile" and "Not for Human Use" stickers. Product label template updated, including addition of Pouch and In-Carton labels. Changed expiration date to three months from manufacturing date.	11/6/17
3	Optional manufacturing tracking identifier was added to inner pouch labels. Added description for manufacturing date Item 7, Prodict Label Field Descriptions.	12/20/17
4	Font size in row 2 and 26 were updated in the Product Label Field Descriptions table.	2/5/2018
5	Expiration date updated to fourteen months from manufacturing date.	02/22/18