ORTHOSENSOR Verasense Arthroplasty Force Sensor Instructions

Contents

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DESCRIPTION

VERASENSE provides a means for orthopedic surgeons to dynamically balance the knee during primary or revision Total Knee Arthroplasty (TKA). The VERASENSE device is an intelligent disposable tibial insert that measures dynamic loads in the medial and lateral compartments of the knee and wirelessly transmits the measured load data to the LinkStation MINI or LinkStation MINI Evaluation Kit with VERASENSE Software Application (VSA) installed for surgeon visualization. Individual VERASENSE devices are packaged sterile, for single patient use with a Shim Set for thickness adjustments. NOTE: The following accessories are necessary for the operation of the VERASENSE device:

• LinkStation MINI or LinkStation MINI Evaluation Kit
VERASENSE Software Application (VSA)

The LinkStation MINI and LinkStation MINI Evaluation Kit displays the measured load data by providing a graphical and numerical presentation of the loads in both the medial and lateral compartments of the knee. VERASENSE devices are implant system-specific due to variations in implant design. VERASENSE is compatible with the following implant systems:

- VERASENSE for Biomet Vanguard
- VERASENSE for Stryker Triathlon
- VERASENSE for Zimmer NexGen
- VERASENSE for Smith & Nephew Legion
- VERASENSE for Smith & Nephew Journey II
- VERASENSE for Zimmer Biomet Persona

Please see Table 3 for the listing of Catalog Numbers for each compatible implant system and sizes.

INDICATIONS

VERASENSE is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated. For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion

gap asymmetry. VERASENSE is sterile, for single patient use.

CONTRAINDICATIONS

- Any active or suspected latent infection in or about the knee joint.
- Refer to Implant Knee System IFU for additional contraindications.

WARNINGS

- The internal components of the VERASENSE devices have not been shown to be sterile. Immediately discontinue use of device if any cracks, damage, or internal fluid is observed. Failure to observe these warnings may expose patient to non-sterile material.
- The VERASENSE device consists of sophisticated calibrated internal microelectronics. Do NOT utilize excessive force or impact VERASENSE devices directly with a mallet. Excessive impaction force may damage or negatively impact function of the VERASENSE.
- Handle VERASENSE device with care when inserting, adjusting shim size or removing from tibial tray.
- Do not forcibly impact femoral implant trial onto the VERASENSE device placed in tibial tray.
- Do not attempt to use the VERASENSE device without selection and use of proper shim and appropriately sized tibial tray.
- If VERASENSE device or shim set packaging is open or damaged, do not use and immediately return to OrthoSensor.
- Maximum allowable load for the VERASENSE device is 70 lbf per compartment. If the physician perceives a difference between the loads displayed on the screen and the physical feel, the physician should either replace the device or continue the procedure using their standard instrumented trial technique and best clinical judgment.
- Note: Load values between 41-70 lbf are displayed for reference only.
- Note: If maximum allowable load of 70 lbf is reached in either compartment, the VERASENSE device must be removed from the knee joint and “re-zeroed” by holding VERASENSE with superior side (articulating surface) facing the floor for three (3) seconds, Re-Zero enabled will appear on the VERASENSE Software Application, followed by Re-Zero Complete indicating that VERASENSE has been reset to zero; or Re-Zero button from the VERASENSE Software Application by Pressing the Re-Zero button.
- Compartment Re-Zero allows for a re-zero of the device without removing it from the joint. With VERASENSE in the joint, apply a varus or valgus thrust to the knee to off-load the desired medial or lateral compartment.
- When the VERASENSE surface is visually unloaded, select the laterality indicator of the unloaded side to initiate the Re-Zero. Wait for Re-Zero Enabled and Re-Zero Completed messages to display. Repeat the steps on the opposite compartment to complete the Re-Zero. Note: Compartment Re-Zero is only available with VERASENSE devices that communicate with the LinkStation MINI via Bluetooth. Check label on the front of the sensor box for the Bluetooth symbol. 
- Do not use a prying device during surgical procedure while the VERASENSE device is in place as this may result in damage to the exterior of the device.
- Perform load measurements without the patella everted to avoid altered compartmental loads.
- It is recommended to evaluate compartment loads and joint balance with the patella reduced and the capsule closed.

- Verify ligament balancing after final cementation to avoid altered joint balance.
- Clinician learning curve for the use of VERASENSE and accessories during surgery is estimated to possibly cause the following complications to the patient.
- Prosthetic instability caused from incorrect reference of ligament tension, implant positioning and varus/valgus angles.
- Patient infection caused from the delay in surgery.
- Only use the necessary accessories for the operation of the VERASENSE.
- Do not power the transceiver from any device other than the provided LinkStation MINI or LinkStation MINI Evaluation Kit.
- Do not connect any other devices to the display unit input/output ports other than those supplied with the VERASENSE.
- Do not modify this equipment.
- Observe all warnings generated by the VERASENSE Software Application.
- VERASENSE for Zimmer Biomet Persona contains lithium batteries, thus special disposal instructions should be taken in the state of California, USA. The device cannot be incinerated.
- Modification of this device may void the user's authority to operate the equipment under the FCC rules.
- Federal law restricts this device to sale by or on the order of a licensed physician.

PRECAUTIONS

- Read and follow instructions for proper use and interpretation of force data displayed.
- Refer to appropriate implant knee system IFU for additional precautions.
- The VERASENSE device and shim sets are supplied as single-use sterile. Do not reuse or re-sterilize
- Do not use VERASENSE device after the expiration date printed next to  symbol on the package labeling.
- Do not use the VERASENSE device without a shim attached in the tibial tray for the VERASENSE for Stryker Triathlon Sizes 3-6, VERASENSE for Biomet Vanguard, or VERASENSE for Zimmer Biomet Persona devices.
- When detaching a shim from the VERASENSE device, detach anterior lip first, do not pry off posterior edge. Note: For the VERASENSE for Zimmer Biomet Persona, detach shim by prying on the posterior edge.
- Locate the version of the VERASENSE Software Application (VSA) in the bottom right corner of the LinkStation MINI or LinkStation MINI display unit. Confirm the version number of the VSA is greater than 5.1.0.17 for use with VERASENSE for Zimmer Biomet Persona and greater than 5.3.0.64 for use with VERASENSE for Stryker Triathlon with Bluetooth. Check label on the front of the sensor box for the Bluetooth symbol  .
- Do not use VERASENSE device if it appears to be functioning improperly.
  • Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the VERASENSE and accessories, including cables specified by the manufacturer. Otherwise, degradation of performance of this equipment could result.

INSTRUCTIONS

- Confirm the LinkStation MINI or LinkStation MINI Evaluation Kit is setup appropriately outside of the sterile field. Refer to the VERASENSE User Guide. The LinkStation MINI or LinkStation MINI Evaluation Kit is located

outside of the sterile field and the VERASENSE device and shims are used within the sterile field.

- Determine the specific implant type and size VERASENSE device required. Remove pouched Shims and device from the box. DO NOT OPEN POUCH SEALS.
    - Do not use if device or shim set packaging has been opened or damaged.
- Record VERASENSE device serial number ( ) onto patient and hospital records as required.
- To activate the VERASENSE device:
    - With the product still in the sealed pouches, place the device directly over the magnet on LinkStation MINI or LinkStation MINI Evaluation Kit. An LED light will illuminate on the device. Do not move the device until you observe the following:
        - LED turns off after approximately four (4) seconds.
        - VERASENSE Software Application launches. iii. Locate the version of the VERASENSE Software Application (VSA) in the bottom right corner of the LinkStation MINI or LinkStation MINI display unit. Confirm the version number of the VSA is greater than 5.1.0.17 for use with VERASENSE for Zimmer Biomet Persona and greater than 5.3.0.64 for use with VERASENSE for Stryker Triathlon with Bluetooth. Check label on the front of the sensor box for the Bluetooth symbol .
        - Initialization progress bar appears and completes.
        - Prompt to select left or right leg appears.
    - Device may now be removed from magnet.
- The VERASENSE Software Application will automatically prompt selection of left or right leg. Select the appropriate operative leg.
- Upon completion of the device initiation process as prompted on the VERASENSE Software Application, pass the sealed pouches to the nurses within the sterile field of the operating room.
- Open double sealed pouches per hospital protocol (VERASENSE device and shim set).
- With the VERASENSE device and shims removed from the pouches, apply designated shim to underside of VERASENSE device. Note: The VERASENSE for Zimmer Biomet Persona device shim attaches to the top of the device. Attach by inserting the devices anterior tab into the anterior loop on the shim, engage the posterior snapping mechanism by squeezing the assembly together. Input the selected shim thickness within the VERASENSE Software Application. Note: Once the product is removed from the pouch, the application of the initial shim, if applicable, relates to devices without mounted shims (VERASENSE for Stryker Triathlon Sizes 2 & 7, VERASENSE for Zimmer NexGen, VERASENSE for Smith & Nephew Journey II, and VERASENSE for Smith & Nephew Legion). Apply desired shim to all VERASENSE for Stryker Triathlon 3-6, VERASENSE for Biomet Vanguard, and VERASENSE for Zimmer Biomet Persona devices prior to use.
- To remove the shim, or exchange for another size, simply unsnap the anterior lip of the attached shim and replace. Note: VERASENSE for Zimmer Biomet Persona shim is removed by distracting the posterior aspect of the device from shim. This releases the posterior snapping mechanism.
- With the VERASENSE device and shim attached, physician should manually compress / apply load to the device and verify the response on the User Interface prior to placing VERASENSE device into the tibial tray.
- Place VERASENSE within tibial tray.
- Confirm that the VERASENSE device with shim is fully seated when placed in the tibial tray.
- Flex the joint throughout its full range of motion to ensure appropriate response on the User Interface.
- Proceed with TKA process per physician / hospital protocol. Note: If maximum allowable load of 70 lbf is reached in either compartment, the VERASENSE device must be removed from the knee joint and “re-zeroed” by holding VERASENSE with superior side (articulating surface) facing the floor for three (3) seconds, Re-Zero enabled will appear on the VERASENSE Software Application, followed by Re-Zero Complete indicating that

VERASENSE has been reset to zero; or Re-Zero button from the VERASENSE Software Application by Pressing the Re-Zero button.

- Compartment Re-Zero allows for a re-zero of the device without removing it from the joint. With VERASENSE in the joint, apply a varus or valgus thrust to the knee to off-load the desired medial or lateral compartment. When the VERASENSE surface is visually unloaded, select the laterality indicator of the unloaded side to initiate the Re-Zero. Wait for Re-Zero Enabled and Re-Zero Completed messages to display. Repeat the steps on the opposite compartment to complete the Re-Zero. Note: Compartment Re-Zero is only available with VERASENSE devices that communicate with the LinkStation MINI via Bluetooth. Check label on the front of the sensor box for the Bluetooth symbol .

- In VSA 5.3.0.64 or greater, when a VERASENSE for Zimmer Biomet Persona device is activated with the magnet, the user must acknowledge a description of the recommended workflow to handle temperature conditioning of the device prior to use.
  - After device is inserted into the knee, pressing the CONDITION or  button on the VSA.
  - After conditioning is complete, follow the instructions to unload and immediately re-zero sensor.
  - Repeat this Step 15 if the VERASENSE for Zimmer Biomet Persona device is removed from the knee.
- Upon completion of the procedure, deactivate the VERASENSE Software Application by pressing the Exit Button on the User Interface.
- Dispose of the VERASENSE device per institutional guidelines for biohazardous medical waste. Note: VERASENSE for Zimmer Biomet Persona contains lithium batteries, thus special disposal instructions should be taken in the state of California, USA. The device cannot be incinerated.

Model	Measurement Load Range	Load Accuracy
VERASENSE for Biomet Vanguard	5-40 lbf per compartment	≤3.5 lbf
VERASENSE for Stryker Triathlon		
VERASENSE for Zimmer NexGen		
VERASENSE for Smith & Nephew Legion		
VERASENSE for Smith & Nephew Journey I I		
VERASENSE for Zimmer Biomet Persona		

VERASENSE TROUBLESHOOTING

Table 1		
Issue	**Cause**	**Solution**
VERASENSE device LED does not li ght up	VERASENSE device batteries are dead	Discard VERASENSE device and replace
VERASENSE Device not transmitting data to LinkStation MINI or LinkStatio n MINI Evaluation Kit	VERASENSE device is out of wirel ess range	Move LinkStation MINI or LinkStat ion MINI Evaluation Kit closer to VERASENSE device
		Move LinkStation MINI or LinkStat ion MINI Evaluation Kit to achieve an unobstructed line-of-sight to th e VERASENSE device field of use
	VERASENSE device is powered o ff	Activate with LinkStation MINI or L inkStation MINI Evaluation Kit magnet
	VERASENSE device batteries are low	Discard VERASENSE device and replace
VERASENSE device breakage	VERASENSE device applied load i s beyond limit	VERASENSE device internal com ponents are potentially non- steril e and non-medical grade. Ensure patient safety. Discard device and replace.
Lag in reported data	Software latency	Maintain knee position until data settles (approximately 5 seconds)

DECONTAMINATION OF PRODUCT RETURNED FOR COMPLAINT INVESTIGATION

This section applies to all VERASENSE devices intended to be returned for complaint investigations. Any device that has been opened/removed from sterile packaging and exposed to biohazardous material must be sent to central processing within the hospital for decontamination according to this procedure prior to transport to OrthoSensor. The following guidelines have been proven effective for cleaning VERASENSE devices but are not guaranteed to result in a safe handling environment or sterilized devices. Note: Should a device be clearly marked as having been used on a patient with HIV or infectious disease of equivalent risk, the device must not be decontaminated but rather documented and destroyed.

Decontamination Procedure:

- Create cleaning solution in labeled cleaning container by combining 2 ounces (59 mL) of ENZOL Enzymatic detergent (or equivalent*) per gallon (3.8 L) of warm water.

- Soak device(s) for 5 minutes. If necessary, use brush to clean any dried-on material.
- Thoroughly rinse device(s) with clean running water. Dry device(s) and place on clean absorbent pad.
- Fill labeled disinfection container with enough Cidex OPA solution (or equivalent*) to cover device(s) completely.
- Immerse device(s) in solution and soak for 15 minutes. Ensure that all devices are 100% covered by the solution.
- Remove device(s) and rinse for at least one minute with a large volume of clean water. Dry device(s) and place decontaminated parts on clean absorbent pad.
- If the equivalent agent is used, it is recommended to follow the manufacturer's instructions for creating cleaning and disinfectant solutions.
- Once this procedure has been carried out, devices may be packaged in the enclosed return envelope and transported per instructions on return envelope.

VERASENSE DEVICE SPECIFICATIONS

The VERASENSE for Biomet Vanguard, VERASENSE for Stryker Triathlon, VERASENSE for Zimmer NexGen, VERASENSE for Smith & Nephew Legion, and VERASENSE for Smith & Nephew Journey II comply with Part 95 of the FCC rules. These devices may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation. The VERASENSE for Zimmer Biomet Persona and VERASENSE for Stryker Triathlon with Bluetooth (check label on the front of the sensor box for the Bluetooth symbol) comply with Part 15(c) of the FCC rules. Operation is subject to the following two conditions:

- this device may not cause harmful interference, and
- this device must accept any interference received, including interference that may cause undesired operation.

This device does not interfere with stations operating in the 2402-2480 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation. Modification of this device may void the user's authority to operate the equipment under the FCC rules above. This equipment has been tested and found to comply with IEC 60601-1 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 60601-1-2). No essential performance was identified and tested. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates and uses radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult OrthoSensor for help.

For additional safety information, see Table 4 which document the intended use environment and EMC compliance levels of VERASENSE. VERASENSE is intended for use in the electromagnetic environment specified in this IFU. Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is

normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

IEC 60601-1 Medical Electrical Equipment Classification for Protection Against Electrical Shock

Sensor: Internally powered (3.1 V dc)

- VERASENSE for Stryker Triathlon, VERASENSE for Zimmer NexGen,
- VERASENSE for Biomet Vanguard, VERASENSE for Smith & Nephew Journey II, and VERASENSE for Smith & Nephew Legion Devices: Internally Powered by Energizer 362/361 battery.
- VERASENSE for Zimmer Biomet Persona Devices: Internally powered by Renata CR1216 MFR FH battery.

LinkStation MINI / LinkStation MINI Evaluation Kit

Transceiver:

Class II USB powered and intended to be connected to the USB port of the LinkStation MINI display unit (5 V dc).

Display Unit:

Class I (65W universal 3-pin jack, 100-240V, 1.5A, 50-60Hz).

Table 2 – Symbols

Table 2 – Symbols		
Type:	Do not re-sterilize	
	Single Procedure use / Do not re-use	
Prescription:	By Prescription Only	
Sterility:	Sterilized using ethylene oxide	
Manufacturer:	 OrthoSensor, Inc. 1855 Griffin Road Suite A-310 Dania Beach, FL 33004-2200 USA	
Date of Manufacture:		
Device Type:	Type BF (sensor only)	
Caution:		
Use:	Do not use if package is damaged	
	Non-pyrogenic	
	Non-ionizing Radiation	
	Ingress Protection Rating	IPX4
	Consult User Guide	
	Bluetooth® Symbol	
	Temperature Conditioning	
Shelf Life:	Use-by date	
Identification:	Batch Code	LOT
	Serial number	SN
	Quantity	QTY
	Catalog number	REF
Authorized Representative in the European Community	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	EC REP

Australia Sponsor	PharmaDev Consulting Pty Ltd. Level 12 95 Pitt Street Sydney NSW 2000 Australia					
New Zealand Sponsor	PharmaDev Consulting Pty Ltd. Level 10 21 Queen Street Auckland 1010 New Zealand					
CE Mark and Notified Body Number	CE 0297					
	Model	FCC ID	Frequency band	Modulation	EIRP	Conducted Power
FCC ID:	VERASENSE for Stryker Triathlon	XNL-ORTHOSNSR1	402.0 - 405.0 MHz	GFSK	1.83 nW	
	VERASENSE for Biomet Vanguard	XNL-ORTHOSNSR2	404.3 - 404.3 MHz	GFSK	3.314 nW	
	Transceiver	XNL-ORTHOSNSR3	401.05 - 405.55 MHz	GFSK	N/A	
	VERASENSE for Zimmer NexGen	XNL-ORTHOSNSR5	404.3 - 404.3 MHz	GFSK	1.31 µW	
	VERASENSE for Smith & Nephew Journey II					
	VERASENSE for Smith & Nephew Legion					
	VERASENSE for Zimmer Biomet Persona	XNL-ORTHOSNSR7	2402 - 2480 MHz	GFSK	6 µW	2.1 mW
	VERASENSE for Stryker Triathlon (with Bluetooth)	XNL-ORTHOSNSR10	2402 - 2480 MHz	GFSK	0.77 mW	
	Model	Giteki Symbol	Certification Number			
Japanese Radio Law Certification	VERASENSE for Zimmer Biomet Persona	R	209-J00365			
Operating Range:	6.5 ft [2m] Unobstructed					
Power Supply:	Internally powered at less than 3.3 VDC					
Battery Life:	40 minutes (approximate)					
Temperature Limit:	**Operation**	37°C / 15°C	**Storage**	50°C / 0°C		
Relative Humidity:		100%, submersion / 30%		80%, non-condensing / 10%		
Atmospheric Pressure:		106 kPa / 47 kPa		106 kPa / 36 kPa		

Table 3 – Catalog Numbers

Table 3 – Catalog Numbers			
VERASENSE Device Model	**VERASENSE Catalog Number**	**Size**	**Compatible Implant System Catalog Number**
	BMT-VGCR63	63/67	32-483720, 32-483722, 32-483724, 32-483726, 32-483728
	BMT-VGCR71	71/75	32-483740, 32-483742, 32-483744, 32-483746, 32-483748
	BMT-VGCR79	79/83	32-483760, 32-483762, 32-483764, 32-483766, 32-483768

VERASENSE for Biomet Vanguard	BMT-VGPS63	63/67	32-483820, 32-483822, 32-483824, 32-483826, 32-483828
	BMT-VGPS71	71/75	32-483840, 32-483842, 32-483844, 32-483846, 32-483848
	BMT-VGPS79	79/83	32-483860, 32-483862, 32-483864, 32-483866, 32-483868
	SYK-TRCR02	2	5530-T-209, 5530-T-211, , 5530-T-213,
			5530-T-216
	SYK-TRCR03	3	5530-T-309, 5530-T-311, 5530-T-313,
			5530-T-316
	SYK-TRCR04	4	5530-T-409, 5530-T-411, 5530-T-413,
VERASENSE for Stryker Triathlon			5530-T-416
	SYK-TRCR05	5	5530-T-509, 5530-T-511, 5530-T-513,
			5530-T-516
	SYK-TRCR06	6	5530-T-609, 5530-T-611, 5530-T-613,
			5530-T-616
	SYK-TRCR07	7	5530-T-709, 5530-T-711, 5530-T-713,
			5530-T-716
VERASENSE for Zimmer NexGen	ZMR-NGCRCH34	C-H/3-4	00-5971-030-10, 00-5971-030-12, 00-5971-030-14, 00-5971-030-17
	ZMR-NGCRCH56	C-H/5-6	00-5971-040-10, 00-5971-040-12, 00-5971-040-14, 00-5971-040-17
	ZMR-NGCRCH70	C-H/7-10	00-5971-050-10, 00-5971-050-12, 00-5971-050-14, 00-5971-050-17
	ZMR-NGPSCD34	C-D/3-4	00-5961-030-10, 00-5961-030-12, 00-5961-030-14, 00-5961-030-17
	ZMR-NGPSEF34	E-F/3-4	00-5961-032-10, 00-5961-032-12, 00-5961-032-14, 00-5961-032-17
	ZMR-NGPSEF56	E-F/5-6	00-5961-040-10, 00-5961-040-12, 00-5961-040-14, 00-5961-040-17
	SNN-JRNYBCS12-L	1-2 Left	74027221, 74027222, 74027223, 74027224, 74027225
	SNN-JRNYBCS12-R	1-2 Right	74027211, 74027212, 74027213, 74027214, 74027215
	SNN-JRNYBCS34-L	3-4 Left	74027241, 74027242, 74027243, 74027244, 74027245
	SNN-JRNYBCS34-R	3-4 Right	74027231, 74027232, 74027233, 74027234, 74027235

VERASENSE for Smith & Nephew Journey II	SNN-JRNYBCS56-L	5-6 Left	74027261, 74027262, 74027263, 74027264, 74027265
	SNN-JRNYBCS56-R	5-6 Right	74027251, 74027252, 74027253, 74027254, 74027255
	SNN-JRNYBCS78-L	7-8 Left	74027281, 74027282, 74027283, 74027284, 74027285
	SNN-JRNYBCS78-R	7-8 Right	74027271, 74027272, 74027273, 74027274, 74027275
	SNN-JRNYCR12-L	1-2 Left	74025621, 74025622, 74025623, 74025624, 74025625

Table 3 – Catalog Numbers			
	SNN-JRNYCR12-R	1-2 Right	74025611, 74025612, 74025613, 74025614, 74025615
	SNN-JRNYCR34-L	3-4 Left	74025641, 74025642, 74025643, 74025644, 74025645
	SNN-JRNYCR34-R	3-4 Right	74025631, 74025632, 74025633, 74025634, 74025635
	SNN-JRNYCR56-L	5-6 Left	74025661, 74025662, 74025663, 74025664, 74025665
	SNN-JRNYCR56-R	5-6 Right	74025651, 74025652, 74025653, 74025654, 74025655
	SNN-JRNYCR78-L	7-8 Left	74025681, 74025682, 74025683, 74025684, 74025685
	SNN-JRNYCR78-R	7-8 Right	74025671, 74025672, 74025673, 74025674, 74025675
VERASENSE for Smith & Nephew Legion	SNN-LGNPS12	1-2	71453201, 71453171, 71453202, 71453172, 71453203
	SNN-LGNPS34	3-4	71453211, 71453173, 71453212, 71453174, 71453213
	SNN-LGNPS56	5-6	71453221, 71453175, 71453222, 71453176, 71453223
	SNN-LGNPS78	7-8	71453231, 71453177, 71453232, 71453178, 71453233
	SNN-LGNCR12	1-2	71453101, 71453181, 71453102, 71453182, 71453103
	SNN-LGNCR34	3-4	71453111, 71453183, 71453112, 71453184, 71453113
	SNN-LGNCR56	5-6	71453121, 71453185, 71453122, 71453186, 71453123

	SNN-LGNCR78	7-8	71453131, 71453187, 71453132, 7145318 8, 71453133
	ZBH-PSNCRCD39-L	C-D/3-9 Le ft	42-5170-004-10, 42-5170-003-03, 42-5170-003-13, 42-5279-003-00,
			42-5279-003-01, 42-5279-003-02, 42-5279-003-03, 42-5279-003-04
	ZBH-PSNCRCD39-R	C-D/3-9 Ri ght	42-5270-004-10, 42-5270-003-03, 42-5270-003-13, 42-5279-003-00,
			42-5279-003-01, 42-5279-003-02, 42-5279-003-03, 42-5279-003-04
	ZBH-PSNCREF311-L	E-F/3-11 L eft	42-5170-005-10, 42-5170-005-05, 42-5170-005-15, 42-5279-005-00,
VERASENSE for Zimmer Biomet			42-5279-005-01, 42-5279-005-02, 42-5279-005-03, 42-5279-005-04
Persona	ZBH-PSNCREF311-R	E-F/ 3-11 Right	42-5270-005-10, 42-5270-005-05, 42-5270-005-15, 42-5279-005-00,
			42-5279-005-01, 42-5279-005-02, 42-5279-005-03, 42-5279-005-04
	ZBH-PSNCRGH712-L	G-H/7-12 L eft	42-5170-006-10, 42-5170-007-07, 42-5170-007-17, 42-5279-007-00,
			42-5279-007-01, 42-5279-007-02, 42-5279-007-03, 42-5279-007-04
	ZBH-PSNCRGH712-R	G-H/7-12 Right	42-5270-006-10, 42-5270-007-07, 42-5270-007-17, 42-5279-007-00,
			42-5279-007-01, 42-5279-007-02, 42-5279-007-03, 42-5279-007-04

Table 4 – Guidance and manufacturer's declaration – electromagnetic emissions

Table 3 – Catalog Numbers			
	SNN-JRNYCR12-R	1-2 Right	74025611, 74025612, 74025613, 7402561 4, 74025615
	SNN-JRNYCR34-L	3-4 Left	74025641, 74025642, 74025643, 7402564 4, 74025645
	SNN-JRNYCR34-R	3-4 Right	74025631, 74025632, 74025633, 7402563 4, 74025635
	SNN-JRNYCR56-L	5-6 Left	74025661, 74025662, 74025663, 7402566 4, 74025665
	SNN-JRNYCR56-R	5-6 Right	74025651, 74025652, 74025653, 7402565 4, 74025655
	SNN-JRNYCR78-L	7-8 Left	74025681, 74025682, 74025683, 7402568 4, 74025685

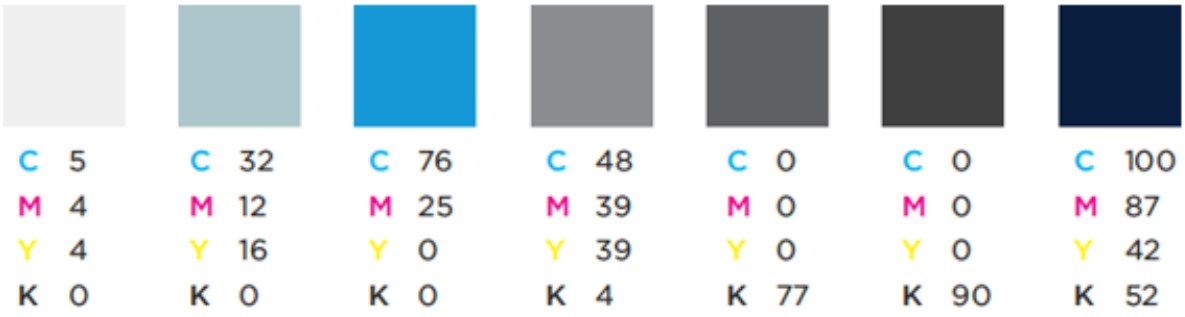
	SNN-JRNYCR78-R	7-8 Right	74025671, 74025672, 74025673, 74025674, 74025675
VERASENSE for Smith & Nephew Legion	SNN-LGNPS12	1-2	71453201, 71453171, 71453202, 71453172, 71453203
	SNN-LGNPS34	3-4	71453211, 71453173, 71453212, 71453174, 71453213
	SNN-LGNPS56	5-6	71453221, 71453175, 71453222, 71453176, 71453223
	SNN-LGNPS78	7-8	71453231, 71453177, 71453232, 71453178, 71453233
	SNN-LGNCR12	1-2	71453101, 71453181, 71453102, 71453182, 71453103
	SNN-LGNCR34	3-4	71453111, 71453183, 71453112, 71453184, 71453113
	SNN-LGNCR56	5-6	71453121, 71453185, 71453122, 71453186, 71453123
	SNN-LGNCR78	7-8	71453131, 71453187, 71453132, 71453188, 71453133
	ZBH-PSNCRCD39-L	C-D/3-9 Left	42-5170-004-10, 42-5170-003-03, 42-5170-003-13, 42-5279-003-00,
			42-5279-003-01, 42-5279-003-02, 42-5279-003-03, 42-5279-003-04
	ZBH-PSNCRCD39-R	C-D/3-9 Right	42-5270-004-10, 42-5270-003-03, 42-5270-003-13, 42-5279-003-00,
			42-5279-003-01, 42-5279-003-02, 42-5279-003-03, 42-5279-003-04
	ZBH-PSNCREF311-L	E-F/3-11 Left	42-5170-005-10, 42-5170-005-05, 42-5170-005-15, 42-5279-005-00,
VERASENSE for Zimmer Biomet			42-5279-005-01, 42-5279-005-02, 42-5279-005-03, 42-5279-005-04
Persona	ZBH-PSNCREF311-R	E-F/ 3-11 Right	42-5270-005-10, 42-5270-005-05, 42-5270-005-15, 42-5279-005-00,
			42-5279-005-01, 42-5279-005-02, 42-5279-005-03, 42-5279-005-04
	ZBH-PSNCRGH712-L	G-H/7-12 Left	42-5170-006-10, 42-5170-007-07, 42-5170-007-17, 42-5279-007-00,
			42-5279-007-01, 42-5279-007-02, 42-5279-007-03, 42-5279-007-04
	ZBH-PSNCRGH712-R	G-H/7-12 Right	42-5270-006-10, 42-5270-007-07, 42-5270-007-17, 42-5279-007-00,
			42-5279-007-01, 42-5279-007-02, 42-5279-007-03, 42-5279-007-04

Material: White, 24# Paper, 97 Brightness
Measurements: 8.5” x 11”

Specs:

- 4/4 CMYK
- Double sided print; letters out
- Trim, staple upper left corner and fold to 5.5” x 8.5”

Process Colors:



Documents / Resources

	ORTHOSENSOR Verasense Arthroplasty Force Sensor [pdf] Instructions ORTHOSNSR10, XNL-ORTHOSNSR10, XNLORTHOSNSR10, Verasense Arthroplasty Force Sensor, Arthroplasty Force Sensor, Force Sensor, Verasense

References

- Orthosensor Inc.