Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed RD SET® Pulse Oximeter Sensor

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- NOT MADE WITH NATURAL RUBBER LATEX
- EXPOSED TO VAPORIZED HYDROGEN PEROXIDE (VHP)

Explanation of Symbols

Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
Rx Only	21CFR801	N/A	Prescription only	Indicates Federal (USA) law restricting device to sale by or on order of a physician.
	ISO 15223-1 Clause 5.1.1	3082	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Clause 5.2.7	2609	Non-Sterile	Indicates a medical device has not been subjected to a sterilization process.
	ISO 15223-1 Clause 5.1.3	2497	Manufacturing Date (Reprocessing Date)	Indicates the date which the medical device is manufactured
	ISO 15223-1 Clause 5.1.4	2607	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Clause 5.1.5	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Clause 5.4.3	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.2	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1 Clause 5.2.8	2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	N/A	N/A	Not made with natural rubber latex	Notification that natural rubber latex was not used as a material in the finished product or packaging.
	F2503-20	N/A	MR Unsafe	Indicates a medical device poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

	ISO 15223-1 Clause 5.3.7	0632	Storage Temperature Range	Indicates the temperature limits for which the medical device can be safely exposed.
	ISO 15223-1 Clause 5.3.8	2620	Humidity Limitation	Storage Humidity Range.
	ISO 15223-1 Clause 5.3.1	0621	Fragile, Handle with care	Indicates a medical device that can be broken or damaged if not handled properly.
	ISO 15223-1 Clause 5.3.4	0626	Keep Dry	Indicates a medical device that needs protection from moisture.
	N/A	5665	Body weight	Indicates the intended patient body weight for a device.
	N/A	N/A	Light Emitting Diode (LED)	LED emits light when current flows through.

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Reprocessed RD SET Pulse Oximeter Sensor Description

This sensor is a previously used Masimo™ RD SET® adhesive pulse oximeter sensor which has been reworked, inspected, tested, packaged, and decontaminated by Stryker Sustainability Solutions.

This insert is intended for the following oxygen transducers:

Model	Device Description
4000	RD SET Adt Pulse Oximeter Sensor
4001	RD SET Pdt Pulse Oximeter Sensor
4002	RD SET Inf Pulse Oximeter Sensor
4003	RD SET Adt Pulse Oximeter Sensor

When used with Masimo SET® Radical™:

	4000 Adt	4001 Pdt	4002 Inf		4003 Adt
Body Weight	>30 kg	10-50 kg	3-10 kg	10-20 kg	>40 kg
Application Site	Finger or Toe	Finger or Toe	Thumb or Great Toe	Finger or Toe	Finger or Toe
SpO_2 Accuracy, No Motion	2.2%	2.2%	2.2%	2.2%	2.2%
SpO_2 Accuracy, Low perfusion	2.5%	2.5%	2.5%	2.5%	2.5%
Pulse Rate Accuracy, No Motion (30 – 200 bpm)	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm
Pulse Rate Accuracy, Low perfusion (30 – 200 bpm)	3 bpm	3 bpm	3 bpm	3 bpm	3 bpm

Indications for Use

Reprocessed RD SET Pulse Oximeter Sensors are indicated for use in continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for use with adult, pediatric, and infant patients during no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

Reprocessed RD SET Pulse Oximeter Sensors are not intended to be used as the sole basis for making diagnosis or treatment decisions; they are intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

Contraindications for Use

Reprocessed RD SET Pulse Oximeter Sensors should not be used in patients who exhibit allergic reactions to foam rubber product and/or adhesive tape.

Warnings

- All sensors and cables designed for use with specific monitors. Verify the compatibility of the monitor, cable and sensor before use, otherwise degraded performance and/or patient injury can result.
- The sensor should be free of visible defects, discoloration and damage. If the sensor is discolored or damaged, discontinue use. Never use a damaged sensor or one with exposed electrical circuitry.
- The site must be checked frequently or per clinical protocol to ensure adequate adhesion, circulation, skin integrity and correct optical alignment.
- Exercise caution with poorly perfused patients; skin erosion and pressure necrosis can be caused when the sensor is not frequently moved. Assess site as a frequently as every (1) hour with poorly perfused patients and move the sensor if there are signs of tissue ischemia.
- During low perfusion, the sensor site needs to be assessed frequently for signs of tissue ischemia, which can lead to pressure necrosis.
- With very low perfusion at the monitored site, the reading may be lower than the core arterial oxygen saturation.
- Do not use tape or secure the sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage, and/or pressure necrosis or damage the sensor.
- Sensors applied too tightly or that become tight due to edema will cause inaccurate readings and can cause pressure necrosis.
- Misapplied sensors or sensors that become partially dislodged may cause incorrect measurements.

- Misapplications due to wrong sensor types can cause inaccurate or no readings.
- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor).
- Venous pulsations may cause erroneous low SpO_2 readings (e.g. tricuspid valve regurgitation).
- The pulsations from intra-aortic balloon support can affect the pulse rate displayed on the oximeter. Verify patient's pulse rate against the ECG heart rate.
- Carefully route cable and patient cable to reduce the possibility of patient entanglement or strangulation.
- Avoid placing the sensor on any extremity with an arterial catheter or blood pressure cuff.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If sensor is exposed to the radiation, the reading might be inaccurate or not provided for the duration of the active radiation period.
- Do not use the sensor during MRI scanning or in a MRI environment.
- High ambient light sources such as surgical lights (especially those with a xenon light source, bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of the sensor.
- To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.
- High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 measurements.
- Elevated Total Bilirubin levels may lead to inaccurate SpO_2 measurements.
- Abnormal fingers, intravascular dyes such as indocyanine green or methylene blue or externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc. may lead to inaccurate SpO_2 measurements.
- Inaccurate SpO_2 readings may be caused by severe anemia, low arterial perfusion or motion artifact.
- To prevent damage, do not soak or immerse the sensor in any liquid solution. Immersion in liquid will compromise the device performance.
- Do not modify or alter the sensor in any way. Alteration or modification may affect performance and/or accuracy.
- Do not attempt to reuse on multiple patients, reprocess, recondition or recycle sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for the oxygen saturation must be carefully selected in accordance with accepted clinical standards.
- **Caution:** Replace the sensor when a replace sensor message is displayed, or when a low SIQ message is consistently displayed after completing the low SIQ troubleshooting steps identified in the monitoring device operator's manual.
- **Note:** The sensor is provided with X-Cal® technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. The sensor will provide up to 120 hours of patient monitoring time for the 4000, 4001, and 4002 models or up to 168 hours for the 4003 model. After single-patient use, discard sensor.

Environmental Conditions

	Operating	***Storage/Transport***
Temperature	+5°C to +40°C	-20°C to +50°C
Relative Humidity	15% to 95%	25% to 90%

Performance Specifications

The table below shows A_{rms} (Accuracy Root Mean Square) values measured using the RD SET Adhesive Sensor with Masimo SET Oximetry Technology in the clinical studies.

SpO_2 Decile	**4000**	**4003**
	A_{rms}	**A_{rms}**
70-80	2.50%	2.62%
80-90	2.33%	2.45%
90-100	1.42%	1.40%

No motion conditions

The pulse oximeter accuracy was tested in 12 healthy subjects, aged 25-45, with skin tones varying from Fitzpatrick Type I-VI. Three (3) subjects had dark skin with Fitzpatrick V or VI. Five (5) subjects were male and 7 subjects were female. The following tables shows the bias and accuracy by gender and skin pigmentation.

4000: 9 subjects, Skin Type I-IV, No-Motion				
SaO_2 Range	70-100	70-80	80-90	90-100
# Data Pairs	202	49	68	85
Bias (%)	-1.09	-2.13	-1.4	-0.23
A_{rms}	1.99	2.59	2.14	1.36

4000: 3 subjects, Skin Type V-VI, No-Motion				
SaO_2 Range	70-100	70-80	80-90	90-100
# Data Pairs	57	14	15	28
Bias (%)	-0.26	-0.55	-1.16	0.37
A_{rms}	2.2	2.15	3.05	1.59

4003: 9 subjects, Skin Type I-IV, No-Motion				
SaO_2 Range	70-100	70-80	80-90	90-100
# Data Pairs	199	49	67	83
Bias (%)	-1.02	-2.02	-1.39	-0.13
A_{rms}	1.88	2.53	2.21	0.87

4003: 3 subjects, Skin Type V-VI, No-Motion				
SaO_2 Range	70-100	70-80	80-90	90-100
# Data Pairs	57	14	15	28
Bias (%)	1.11	1.45	-0.09	1.59
A_{rms}	2.78	2.89	3.34	2.35

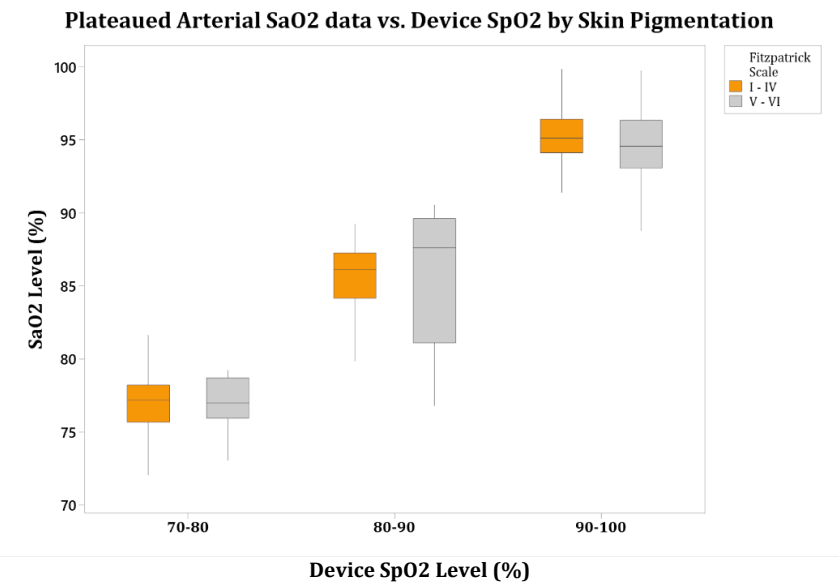
4000: 7 subjects, Female, No-Motion				
SaO_2 Range	70-100	70-80	80-90	90-100
# Data Pairs	153	38	50	65
Bias (%)	-1.08	-2.13	-1.38	-0.25
A_{rms}	1.75	2.38	2.11	0.69

4000: 5 subjects, Male, No-Motion				
SaO_2 Range	70-100	70-80	80-90	90-100
# Data Pairs	106	25	33	48
Bias (%)	-0.64	-1.25	-1.33	0.14
A_{rms}	2.52	2.94	2.86	1.98

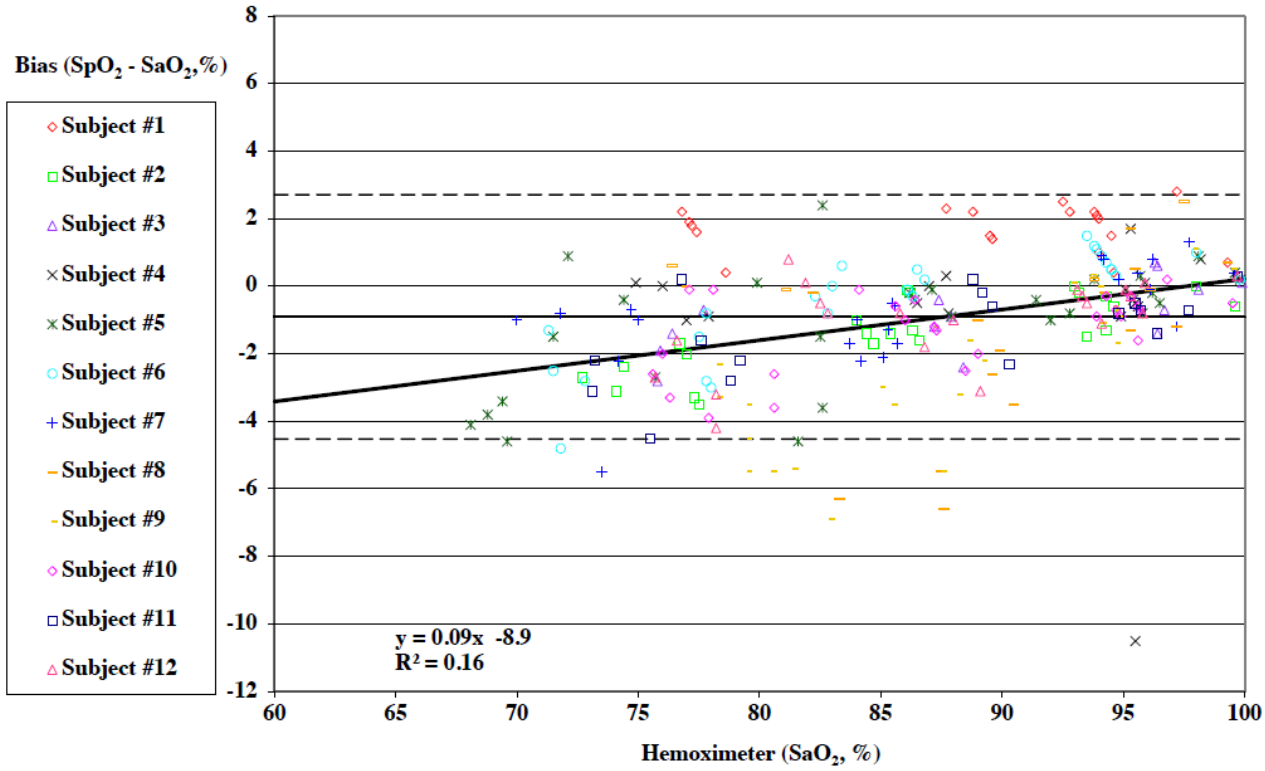
4003: 7 subjects, Female, No-Motion				
SaO_2 Range	70-100	70-80	80-90	90-100
# Data Pairs	150	38	49	63
Bias (%)	-0.78	-1.70	-1.13	0.07
A_{rms}	2.10	2.59	2.30	1.52

4003: 5 subjects, Male, No-Motion				
SaO_2 Range	70-100	70-80	80-90	90-100
# Data Pairs	106	25	33	48
Bias (%)	-0.23	-0.57	-1.18	0.60
A_{rms}	1.98	2.36	2.42	1.31

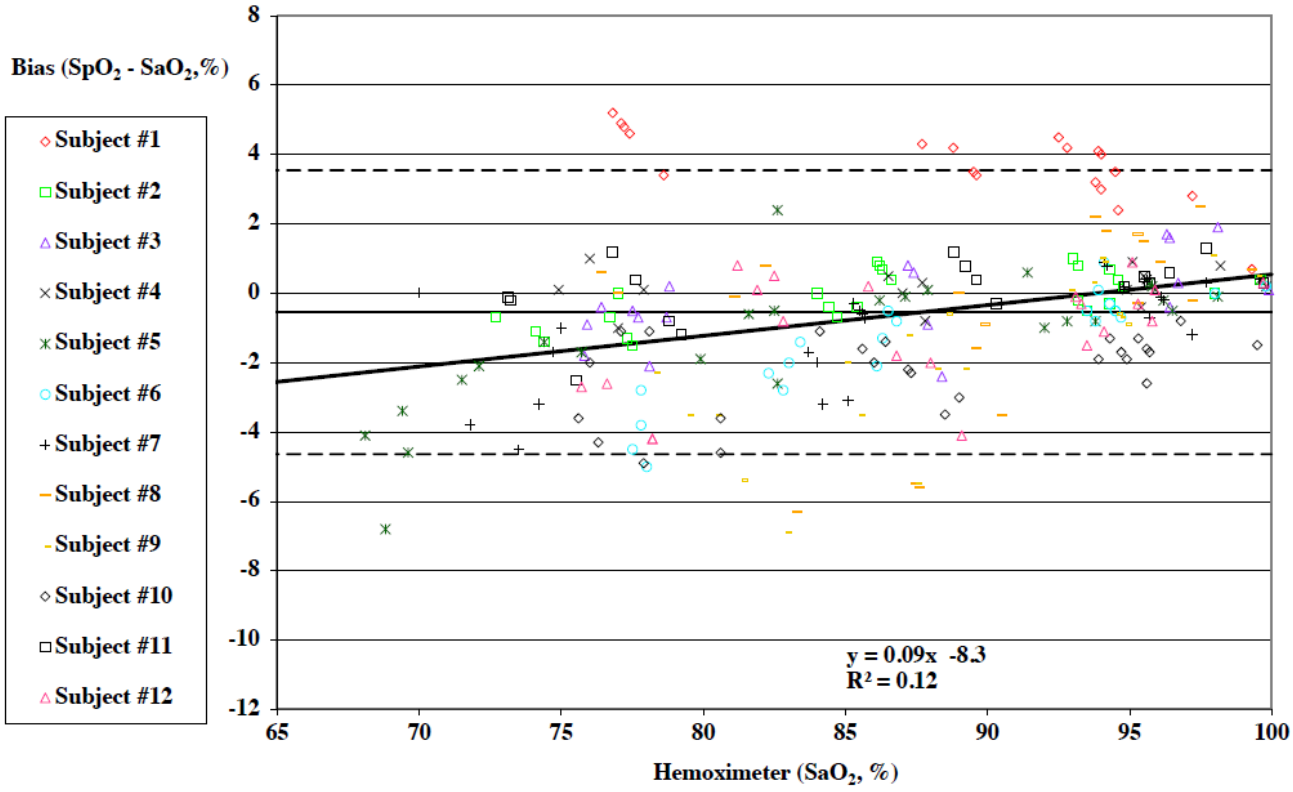
The boxplot graph below shows the oxygen saturation obtained from the pulse oximeter sensors versus the arterial oxygen saturation grouped by decile, with the oxygen saturation comparison for Fitzpatrick I-IV and V-VI skin types.



Bland-Altman Plot, 4000 no motion



Bland-Altman Plot, 4003 no motion



Directions for Use

When selecting a sensor, consider patient's weight and activity level, need for sterility, perfusion adequacy, sensor site availability, and expected monitoring duration. Site should be cleaned for debris and dry prior to sensor placement.

Inspect packaging before opening. If the package is damaged or if it was opened and the instrument was not used, return the sensor and the package to Stryker.

RD SET® Series:

1. **Site Selection**

4000 Adt: Adult Sensor

- >30 kg The middle or ring finger of the non-dominant hand is the preferred site.

4001 Pdt: Pediatric Sensor

- 10-50 kg The middle or ring finger of the non-dominant hand is the preferred site.

4002 Inf: Infant Sensor

- 3-10 kg The big toe or the thumb is the preferred site.
- 10-20 kg The middle or ring finger of the non-dominant hand is the preferred site.

4003 Adt: Adult Sensor

- >40 kg The middle or ring finger of the non-dominant hand is the preferred site.

2. **Attaching the sensor to the patient**

Peel the pouch and remove the sensor. Remove backing from the sensor.

4000 Adt (>30 kg) and 4001 Pdt (10-50 kg)

- Adjust the sensor tail so that the detector can be placed first. Press the detector onto the part of the finger near the tip of the finger. Press tip of finger on to dashed line with the fleshly part of the finger covering the finger outline and detector window.
- Wrap the sensor with the emitter over the fingernail and secure the wings down around the finger. The emitter and the detector should be vertically aligned when properly applied.
- Check sensor to confirm correct positioning and reposition if necessary. Entire coverage of the detector window is needed to ensure accurate data.

4002 Inf (10-20 kg) and 4003 Adt (>40 kg)

- Adjust the sensor tail so that the detector can be placed first. Press the detector onto the part of the finger near the tip of the finger and align with the (✻) symbol on the device.
- Wrap the sensor with the emitter around the finger over the fingernail. The emitter and the detector should be vertically aligned when properly applied.
- Check sensor to confirm correct positioning and reposition if necessary. Entire coverage of the detector window is needed to ensure accurate data.

4002 Inf (3-10 kg)

- Adjust the sensor tail so that it either points away from patient or runs along the bottom of the foot. Place the detector onto the flesh part of the toe so that the dashed line is at the tip of the finger/toe.
- Wrap the adhesive sensor around the toe. Ensure the emitter window aligns on the top of the toe directly opposite of the detector.
- Check sensor to confirm correct positioning and reposition if necessary. Entire coverage of the detector window is needed to ensure accurate data.

3. **Attaching the Sensor to the Patient Cable**

- Adjust the sensor's connector tab so that black PCB and copper contacts are facing up. Adjust the patient cable with the color bar and the finger grips facing up.
- Insert the sensor's connector tab into the patient cable until there is a tactile or audible click of connection.

4. **Reattachment**

- If the emitter and detector windows are clear and the adhesive still adheres to the skin, then the sensor may be reapplied to the same patient.
- Use a new sensor if the adhesive no longer adheres to the skin.

5. Disconnecting the Sensor from the Patient Cable

- To remove from the patient cable, pull firmly on the sensor connector.

Returning the Sensor to Stryker for Reprocessing

- Only sensors that functioned properly during clinical use should be placed in the collections container for reprocessing.
- Gently place in the Stryker provided collection container.
- Once the container is full, place it in the pre-addressed carton provided by Stryker, seal the carton and deliver it to the hospital shipping department.

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4)

products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

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