Reprocessed by

Sustainability Solutions

Instructions for Use
Reprocessed Blood Pressure Cuffs

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

Blood Pressure Cuffs are sold as Non-sterile.

Explanation of Icons

 Date of Processing

REF Product Code

 See Instructions For Use

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Reprocessed Blood Pressure Cuffs

Blood Pressure Cuff Description
Blood Pressure Cuffs are specifically designed cuffs with a bladder and tubing to be connected to a manual or automatic non-invasive blood pressure measurement system. The cuffs are inflated after they have been wrapped around a patient's upper arm above the brachial artery or in rare cases above the femoral artery and then deflated while listening to the Korotkoff sounds with a stethoscope and recording the readings with a manometer. Since the proper cuff size is an important factor for a successful and accurate reading, blood pressure cuffs are available in a wide range of color-coded cuff sizes to properly and comfortably fit a wide range of patients from infant to large adult. In general, the bladder inside the cuff should encircle 80 % of an adult's arm and 100 % of a child less than 13 years old.

Indications for Use
Reprocessed Blood Pressure Cuffs are indicated for use in manual measurement and automatic non-invasive blood pressure monitoring.

Contraindications for Use
- Any uses other than the measurement of blood pressure.

Warnings – None.

Precautions
- Do not connect to other than blood pressure measurement device.
- Do not use the cuffs on limbs used for intravenous infusion.
- Do not connect cuff to Intravascular fluid systems that may allow air to be pumped into a blood vessel, which could lead to serious patient injury.
- Do not use the cuffs on limbs used for other monitoring.
- Do not place the cuff to areas with lacerated skin or tissue.
- Minimize limb movement/cuff motion to ensure accuracy.
- Avoid contact with the blood pressure cuff while monitoring as this may cause inaccurate blood pressure values.
- When taking repetitive measurements over a period of time, check the limb for signs of obstructed blood flow to prevent certain conditions caused by the pressure applied on a patient's tissue, e.g. purpura, compartmental syndrome, skin avulsion, ischemia and/or neuropathy.
- Do not obtain determinations more frequently than clinically indicated. Weighing the benefits of frequent measurement against the risk.
- Ensure the use of the appropriate cuff size. A too narrow cuff will result in too high blood pressure readings whereas a too large cuff could lead to too low readings.
- Do not apply the cuff to the upper arm if the width of the cuff is greater than the length from the armpit to the elbow of the patient.
- Ensure the cuff is not wrapped too loosely which will result in too high readings or applied over clothing that will result in inaccurate readings.
- Remove cuff from patient when monitoring has been suspended.

Adverse Reactions – None.

Directions for Use
1. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted. Return the device and packaging to Stryker Sustainability Solutions if it is not in acceptable condition for the procedure.
2. Remove the blood pressure cuff from the package.
3. Inspect the cuff for overall condition and physical integrity, e.g. tear and wear of cuff, the bladder and the tubing.
4. Check for the presence of air. If any air is present, squeeze all air out of the cuff. Do not inflate cuff when not on patient.
5. Wrap the cuff around the upper arm and ensure that the INDEX LINE falls between the RANGE marks on the cuff. If it does not, replace cuff with either a larger or smaller cuff. Make sure to align arrow marked 'artery' over the patient's brachial artery. Press the rough and soft sides of the closure together.
6. Ensure there is enough space left between arm and cuff. Allow two finger's space in between arm and cuff.
7. Support the patient's arm for accurate readings. If the patient is in a seated position, ensure the arm is rested at heart level. When the patient is lying down, position the arm slightly raised at the side of the body.
8. Check connection to blood pressure measurement device for overall integrity.
9. Follow a suitable blood pressure measurement protocol.

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.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE 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 processing and may contain the trademarks of unrelated third parties that do not sponsor this device.

This product and its packaging have been exposed to ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been exposed to ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

BPC Rev. F 6-2012 RM702002