

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Blood Pressure Cuffs
Manufactured by SterilMed, Inc.
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Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

These devices are reprocessed reusable blood pressure cuffs from various original equipment manufacturers (OEM). Blood pressure cuffs are designed to non-invasively measure and monitor systolic and diastolic blood pressure.

Each OEM provided an 'Instructions for Use' (IFU) document with the original device. The health institution that wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTIONS

Reprocessed reusable blood pressure cuffs are inflatable devices that are fitted to a patient's limb above an artery by a qualified healthcare professional. They are connected via one or more air hoses and connectors to a separate manual or automatic inflation system. When the cuff is inflated, it compresses the artery beneath it, totally occluding blood flow. The pressure in the cuff is then slowly released and the health care professional relies on auditory cues using a stethoscope or other means to determine the patient's systolic and diastolic blood pressure values.

These blood pressure cuffs contain single inflatable bladders with one or more inflation tubes and come in multiple sizes and configurations to fit upper or lower extremities. They are comprised of known biocompatible materials and are connected to a separate pneumatic compressor, which provides pressure to the cuffs.

These reusable blood pressure cuffs have been cleaned, evaluated for continued integrity, and packaged for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor the number of times reprocessed.

This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.

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CONTRAINDICATIONS

1. Welch Allyn® reusable blood pressure cuffs are contraindicated for neonatal use. Only clearly marked GE Neonatal reusable cuffs are intended for use on neonates.

WARNINGS AND PRECAUTIONS

1. Do not connect cuffs with luer lock connectors to intravenous fluid systems or air may enter the patient. Immediately consult a physician if this occurs.
2. Do not allow a blood pressure cuff to remain on patient for more than 10 minutes when inflated above 10mm Hg. This may cause patient distress, disturb blood circulation, and contribute to the injury of peripheral nerves.
3. Only use the cuff when visible artery index marker falls within the range markings indicated on the cuff, otherwise erroneous readings may result.
4. Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
5. Allow space for 1 to 2 fingers between patient and cuff.
6. Do not apply cuff to limbs used for IV infusion.
7. Minimize cuff movement and limb motion during readings.
8. Ensure an airtight seal at all connections point prior to use.
9. Avoid contact with the cuff while monitoring, since it may cause inaccurate blood pressure values.
10. Check cuff site and limb frequently for signs of impeded blood flow, especially when monitoring at frequent intervals and /or over extended periods of time. Rotate site if appropriate.
11. Do not press cuff with hot iron.
12. Do not inflate cuff unless the hook and loop is closed.
13. Do not allow foreign debris to ingress into tubes or port on cuff.
14. Do not use steam or heat to sterilize the cuff or tubing.
15. Do not exceed 250mm Hg with thigh size disposable cuffs at or above 30°C/96°F.

DIRECTIONS FOR USE

1. Select appropriate cuff size. Measure patient's limb and select appropriately sized cuff according to size marked on cuff or cuff packaging. When cuff sizes overlap for a specified circumference, choose the larger size. Accuracy depends on use of a properly sized cuff.
2. Before use, check that the cuff, cuff tubing and hose are clean and free of damage. Replace cuff when aging, tearing or weak closure is apparent.
3. Select the appropriate blood pressure measurement site. Inspect patient's limb prior to application.
4. Apply the cuff by wrapping it around the upper arm and make sure the INDEX LINE falls between the RANGE marks on the cuff. If it does not, either a larger or

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- a smaller cuff should be used. Make sure to align arrow marked ARTERY over the patient's artery. Press the rough and soft sides of the closure together.
5. The cuff should be snug and not too tight, allowing space for two fingers to fit between patient and cuff.

POTENTIAL ADVERSE EVENTS

The following potential risks may be associated with the use of blood pressure cuffs. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention.

1. Purpura
2. Skin avulsion
3. Compartmental syndrome
4. Ischemia
5. Neuropathy
6. Pain
7. Redness
6. Swelling
8. Itching

GENERAL INSTRUCTIONS AND INFORMATION

Inspect package and product for signs of damage. The manufacturer packaged an Instruction for Use document with the original device, and the health institution that wishes the device to be reprocessed should retain this original document.

Use of this reprocessed device should be limited to those physicians and/or staff trained in use of this device and associated equipment.

If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

METHODS TO TEST REPROCESSED DEVICES

Devices have been tested to demonstrate biocompatibility following reprocessing. Validated methods are used for cleaning and packaging. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

Instructions for Use can be found at www.sterilmed.com.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.

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