

Instructions For Use

For PrimePad Anti-Skid Operating Room Pads



<https://primemedicalllc.com/ifu/>

Description: PrimePad is an anti-skid patient positioning pad that offers pressure reduction and patient support in order to ensure the patient remains immobile during a medical procedure. These pads are available in a variety of sizes, shapes and kits.

Intended Use: PrimePad anti-skid pads are intended to support and stabilize a patient or their body parts in a desired position on a surgical table during a medical procedure. Some of the devices are intended to prevent patient sliding while in the Trendelenburg position or when applying traction.



Warnings & Precautions:

- The device should only be used by licensed healthcare professionals.
- Always follow your facility's protocols for patient positioning and monitoring frequency.
- Do not use if the package is damaged.
- No materials should be placed between the device and the surgical table.
- Prolonged exposure of polyurethane foam to temperatures in excess of 240°F (115°C) may cause loss of volatile components, therefore do not expose the foam to excessively high temperatures.

Limitations and Contraindications:

- The device is contraindicated for use in patients who may have a sensitivity to polyurethane foam.



Directions:

1. Before use of the device, ensure the surgical table mattress is clean, dry and securely affixed to the surgical table.
2. Place the pad on the table, aligning the pad and mattress perineal cutouts. Be sure nothing is placed between the surgical table mattress and the PrimePad.
3. Position the patient as required for the procedure. Maximum patient contact with the pad is important to clinical efficacy. Minimize the lift or draw sheet width to maximize patient contact with the pad. Ensure the patient's sacrum, torso and shoulders are in direct contact with the pad. For intraoperative positioning of the patient's head, preference is for a small foam or gel roll. If using a pillow, ensure the patient's shoulders are in contact with the pad as opposed to the pillow.
 - Pads with table rail straps only: The built-in table straps should be on the bottom side of the pad. Slide the straps downward between the rail and the table. Bring them back up and around the side of the rail, and affix the strap back on to itself securely.
4. Dispose of pads after use.

Contents: The product is provided nonsterile and is intended to be used on one patient. Do not reuse. The product is manufactured out of flexible polyurethane foam. The product is latex free.

Cleaning: PrimePads have not been validated for use with chemical cleaners or disinfectants.

Storage: When not in use, store in a cool, dry place out of direct sunlight.

Disposal: The pads should be disposed of in compliance with local, regional, national and/or international regulations.

Notice to User and/or Patient: In the event of an adverse incident related to the device, remove the device and report the incident to the manufacturer.

Label Symbols: The symbols used on the product label or product literature are defined in the Symbols Legend at this hyperlink: www.PM-eifu.com/symbols



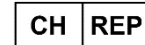
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This Instruction For Use (IFU) is applicable to the following PrimePad model numbers.

PrimePad/Plus-1: Anti-Skid Pad w/perineal cutout, 44"x23"x1".

PrimePad/Plus-1S: Anti-Skid Pad w/perineal cutout w/rail straps, 44"x23"x1".

PrimePad/Plus-2: 2" Anti-Skid Pad w/perineal cutout, 44"x23"x2".

PrimePad/Plus-2S: 2" Anti-Skid Pad w/perineal cutout w/rail straps, 44"x23"x2".

PrimePad/Plus-3: Ramped 1" to 2" Anti-Skid Pad w/perineal cutout, 44"x23"x2".

PrimePad/Plus-3S: Ramped 1" to 2" Anti-Skid Pad w/perineal cutout, rail straps, 44"x23"x2".

PrimePad/Plus-W1: Anti-Skid Pad w/integrated 24"x24" arm tucking/protection, perineal cutout, rail straps, 44"x23"x1".

PrimePad/Plus-W2: Anti-Skid Pad w/integrated 24"x16" arm tucking/protection, perineal cutout, rail straps, 44"x23"x1".

PrimePad/Plus-K1: Anti-Skid Pad w/perineal cutout w/rail straps, single body strap set, 44"x23"x1".

PrimePad/Plus-K2: Anti-Skid Pad w/perineal cutout w/rail straps, single body strap set, disposable draw sheet, 44"x23"x1".

PrimePad/Plus-K3: Anti-Skid Pad w/perineal cutout w/rail straps, single body strap set, arm tucking sleeve pair, 44"x23"x1".

PrimePad/Plus-K4: Anti-Skid Pad w/perineal cutout, head/ shoulder positioner, single body strap set, arm board pair, 44"x23"x1".

PrimePad/Plus-K5: 2" Anti-Skid Pad w/perineal cutout, head/shoulder positioner, single body strap set, arm tucking sleeve pair, 44"x23"x2".

PrimePad/Plus-K6: Anti-Skid Pad w/perineal cutout w/rail straps, single body strap set, disposable draw sheet, arm tucking sleeve pair, 44"x23"x1".

PrimePad/Plus-K7: Anti-Skid Pad w/perineal cutout w/rail straps, single body strap set, disposable draw sheet, arm tucking sleeve pair, head cradle, 44"x23"x1".

PrimePad/Plus-K8: Anti-Skid Pad w/integrated 24"x16" arm tucking/protection, perineal cutout, rail straps, single body strap set, disposable draw sheet, head cradle, 44"x23"x1".

PrimePad/Plus-K9: Anti-Skid Pad w/perineal cutout w/rail straps, disposable draw sheet, 44"x23"x1".

PrimePad/Plus-K10: 2" Anti-Skid Pad w/perineal cutout w/ rail straps, single body strap set, disposable draw sheet, 44"x23"x2".

PrimePad/Plus-PED: Pediatric Anti-Skid Pad, 24"x20"x1".

PrimePad/Plus-SQ1: Square positioning foam 12"x12"x1".

PrimePad/Plus-SQ2: 2" Square positioning foam 12"x12"x2".

PrimePad/Plus-BBO: Bean Bag Overlay, 40"x38"x1".

PrimePad/Plus-CVP: Cardiovascular Pad, 72"x23"x1".

