



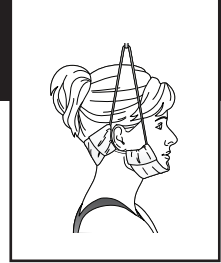


HEAD HALTER

	SINGLE PATIENT USE
	NON-STERILE
	MEDICAL DEVICE
	NOT MADE WITH NATURAL RUBBER LATEX
RX ONLY	FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO SALE OR USE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.




DELUXE HEAD HALTER:
6101 Series



DISPOSABLE HEAD HALTER:
6104-00/6105-00

IMPORTANT INFORMATION

 Please read all instructions, warnings and cautions before use. Correct application is essential for proper product function and to reduce the risk of injury or re-injury inherent with the use of any brace. Use only on the person it was provided to by a healthcare professional and only for the use it was intended.

INTENDED USE

The DeRoyal® Head Halter is used in conjunction with the standard over-door cervical traction unit to hold the head in the proper position for cervical traction as prescribed by a clinician.

CAUTIONS

- A physician or properly licensed practitioner (a "prescriber") who is familiar with the use and purpose of this brace must fit it to the user. The prescriber has a duty to provide wearing instructions and risks related to the use of this brace to other healthcare practitioners treating the users and the users themselves, including duration of use. The instructions provided in this sheet do not supersede hospital protocol or direct orders of the prescriber. Use only as directed.
- Inspect brace for damaged or missing components before use.
- Discontinue use and consult your prescriber if the brace or its components break or become damaged.
- Inspect the fit of the brace on the patient to ensure fit is proper. **DO NOT OVERTIGHTEN.** Check regularly to ensure circulation is not compromised.
- Consult your prescriber immediately if you experience sensation changes, unusual reactions, swelling or increased pain while using this brace. Discontinue use if pressure

injuries develop.

- Specific instructions for weight, frequency of use, time of use, and chair position should be described by the treating physician.
- This product should not be used by an unattended individual.
- If use of this product causes dizziness, vertigo, blurring of vision, black-out spells or undue discomfort, discontinue use until consulting the treating physician.

DIRECTIONS FOR USE

- Place halter over head. The back strap should fit over the base of the skull behind the ear. The front strap should fit over the chin and not the throat. Use in conjunction with the standard over-door traction unit.

NOTE: The instructions apply to product numbers listed above.

INSTRUCTIONS

Hand wash with mild soap and let air dry completely, prior to reapplication.

STORAGE AND TRANSPORT CONDITIONS

	KEEP DRY
	KEEP AWAY FROM SUNLIGHT

In addition to the competent authority in the country where the patient resides, serious incidents must be reported to DeRoyal Industries, Inc.



WARRANTY

DeRoyal® products are warranted for ninety (90) days from the date of shipment from deroyal as to product quality and workmanship. **DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**



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