

# **INTRODUCTION**

The Pneu-Trac Traction Collar is a comfortable, lightweight and easily applied pneumatic controlled orthosis that goes a step beyond the traditional over door cervical traction device. Relief is provided by an inflatable collar that allows each patient to vary air pressure appropriate to the level of cervical distraction required. This unique feature provides mobility to help the patient progress in a continuing home treatment/exercise program.

A hand-held inflator bulb with an air release valve puts the patient in control. This allows for static or intermittent cervical stretch to provide effective management of cervical pain.

#### **Features**

- Provides mobile cervical traction
- Relieves discomfort in the neck and shoulders caused by cervical spine/disc abnormality
- Controlled pressure for distraction force
- Can be worn anywhere

Product Code	Size	Neck Circumference
A26700	Small	12¼"-14 ¼" (31 cm - 36 cm)
A26701	Medium	14 ½"-17" (37 cm - 43 cm)
A26702	Large	17"-20" (43 cm - 51 cm)

#### **INDICATIONS**

Cervical Radiculopathy, muscle spasms, pressure from compressed nerve roots, arthritis.

#### **CONTRAINDICATIONS**

Severe rheumatoid arthritis, fractures, inflammatory disease, spinal cord compression or disc-fragmentation.

# **INSTRUCTIONS FOR USE**

These are general guidelines to be followed in the absence of instructions from the prescribing physician. Specific instructions from the prescribing physician supersede the general guidelines found on these pages.

The Pneu-Trac Traction Collar is a prescriptive device and should be used only by the person for whom it was prescribed. Familiarization of its proper use and application should be understood before initial use. If you experience dizziness, nausea, pain or decreased sensation while using Pneu-Trac Traction Collar, discontinue use immediately.



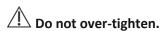




# **Donning Collar**

The Pneu-Trac Traction Collar is a two-part construction; an upper section secured with hook and pile overlapping a lower section. This allows for vertical adjustment if necessary. With few exceptions this device should be used in its lowest configuration (i.e. as received).

- 1. Place the front of the collar against the palm of the right hand. Close the hand to form a "U" shape. This will cause the thumb and forefinger to capture the two corners of the chin support.
- 2. With head slightly flexed (tilted forward) place the chin support under the chin. Squeeze thumb and forefinger slightly to feel the edge of the jawbone when properly placed. The rounded bottom pad should be felt against the chest.
- 3. While holding the collar in place, slide the left hand around to the left side of the brace until the fingers meet at the center of the back of the neck. Repeat the process with the right hand until the fingers of the right hand meet fingers of left hand.
- 4. Maintain pressure against the brace with the heel of the left hand and slide the closure flap toward the right hand. As the hook and pile contact is made, grab the closure flap with the right fingers to guide the closure evenly between the round padding at the top and bottom of the collar.



- 5. Observe yourself in a mirror. The chin support should be centered. The brace should feel comfortably snug, not tight. With head level you should be able to grasp the brace with both hands, thumbs under lower padding and fingers over upper padding with just enough freedom to rotate the collar.
- 6. Ensure that the air bladder is lying outwardly flat.
- 7. Familiarize yourself with the thumb screw valve control on the inflator bulb. Turn the screw valve counterclockwise to open and release air; clockwise to close and maintain pressure. The screw release valve puts you in control of the air flow and allows for static or intermittent cervical stretch. Close the valve (clockwise) to begin session.

# **Intermittent Traction (recommended for initial use)**

- 1. Assume a comfortable sitting position, head slightly flexed, shoulders and neck muscles relaxed. Take several slow deep breaths and "let go" with each exhale to facilitate relaxation.
- 2. Squeeze the inflator bulb four to six times. Relax. Notice if air is inflating the bladder evenly and check that the brace is not uncomfortably tight. Make adjustments if necessary. If there is no sensation of stretching in the neck region continue inflating the bladder with four or five full squeezes or until you feel a "mild to moderate" stretch. Breathe slowly with emphasis on relaxing while exhaling. Continue to relax by dropping shoulders and chin. Maintain for up to two minutes if no discomfort is encountered.

Never over-inflate. This may cause muscle strain or damage to the air bladder. If you feel discomfort or light-headed, deflate and remove immediately.

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- 3. Slowly release the air by turning the thumb screw valve counterclockwise.
- 4. Close the valve, rest for 15 20 seconds.
- 5. Repeat the process outlined in Intermittent Traction Step 1 thru 5.
- 6. To end your session (not to exceed 15–20 minutes intermittent use) slowly release the air. Relax for about 30 seconds before removing the cervical collar.

#### **Static Traction**

- 1. Assume a comfortable sitting position, head slightly flexed, shoulders and neck muscles relaxed. Take several slow deep breaths and "let go" with each exhale to facilitate relaxation.
- 2. Squeeze the inflator bulb four to six times. Relax. Notice if air is inflating the bladder evenly and check that the brace is not uncomfortably tight. Make adjustments if necessary.
- 3. If there is no sensation of stretching in the neck region, continue inflating the bladder with four or five full squeezes until you feel a "mild to moderate" stretch. Breathe slowly with emphasis on relaxing while exhaling. Continue to relax by dropping shoulders and chin. Maintain for up to 5–8 minutes if no discomfort is encountered.

Never over-inflate. This may cause muscle strain or damage to the air bladder. If you feel discomfort or light-headed, deflate and remove immediately.

4. To end your session (not to exceed 12–15 minutes static use) slowly release the air. Relax for about 30 seconds before removing the cervical collar.

CAUTION: It is important after each session to avoid any excessive or exaggerated stretching movements or motion which may cause muscle tension or stiffness to neck and shoulders.

After you have become familiar with the Pneu-Trac Traction Collar you may feel comfortable enough to move about during your session, however do not engage in activities that detract from your ability to keep shoulders and neck relaxed.

# **STORAGE AND USE**

There are no identified restrictions on the temperature of storage and use.

# **DISPOSAL**

There are no hazardous materials in the device. Comply with local and national laws and regulations.

#### **LEGAL INFORMATION**

The use of this class 1 medical device is subject to the respective national laws of the country of use and may vary accordingly. The user of this device should report any serious incident to Trulife and the competent authority of the country of use.









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#### **LIMITED WARRANTY**

Trulife warrants that the PRODUCT will be free from defects in material and workmanship from the date of installation for the warranty period stated on the PRODUCT warranty card.

This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repaired by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by a certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.

As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.



