

Cervico 2000

User Manual



TABLE OF CONTENTS:

1.	Introduction	3
2.	Parts of the Cervico 2000	5
3.	Instruction for Use of the Cervico 2000	7
4.	Care and Maintenance of your Cervico 2000	11
5.	Labels	12
6.	Contact Information	13

1. INTRODUCTION

Congratulations on purchasing the latest concept in cervical spine treatment – the Cervico 2000. Offering safe, simple, compact, and effective treatment of cervical spine disorders, the Cervico 2000 brings to both the patient and physician a means of powerful, dynamic traction with simultaneous, three-dimensional action without the need for traction beds or restrictive braces. Thus, the Cervico 2000 allows the patient maximum mobility with minimal restrictions or discomfort during treatment. Designed with the patient in mind, the Cervico 2000 facilitates the treatment of the patient by the health service professional while also allowing chronic sufferers to administer self-treatment under qualified medical supervision.

We wish you good luck and good health with your Cervico 2000.

FOR YOUR OWN HEALTH AND SAFETY

Please read the following and familiarize yourself with all of the instructions before using your Cervico 2000.

Indications for use of the Cervico 2000:

- Neck pain as a result of discogenic disorders, osteoarthritis, or degenerative changes in the cervical spine
- Whiplash injuries, usually as a result of traffic accident (injuries which do not involve breakage or dislocation of the bones)
- Torticollis as a result of rheumatic or muscular pain or spastic torticollis with a neurological basis
- Job-related neck pain (i.e. clerks, secretaries), prolonged computer use, sewing, etc.
- Sports injuries (without breakage or dislocation)

Contra-indications for use of the Cervico 2000:

- Do not allow contact between the device and open wounds.
- Irritation of the skin on the jaw, neck, or shoulders
- Tumors or protrudences on the mandibula, cervical spine, or claviculae
- Breakage of the mandibula, cervical spine vertebrae, or claviculae, and following recent surgery
- Infections of the mandibula, cervical spine vertebrae, or teeth
- Temporo-mandibula joint disorders, including pains, infections, or subluxation
- Vascular disorders of the neck, partial clogging, or any kind of fusion, and following recent surgery
- Following dental surgery or implants (false teeth should be taken out).
- Neoplasms.

Adverse Reactions, Warnings and Precautions:

Although extremely uncommon, if any of the reactions listed below are experienced, immediately discontinue use of the Cervico 2000 and contact the administering medical professional.

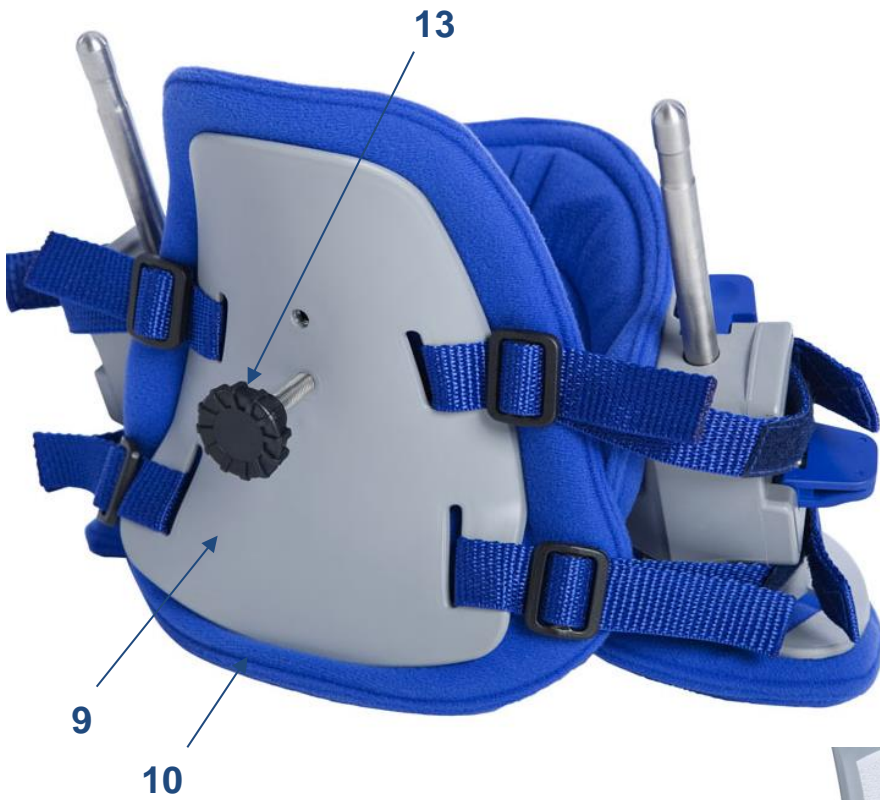
- Dizziness
- Breathing difficulties
- Headaches
- Abnormal fatigue
- Aggravation of symptoms

WARNING: The sale of this device is restricted to individuals by or on the order of a physician. The instructions provided by your health care provider should be followed precisely. Do not exceed the recommendations of your health care provider. Exceeding these recommendations may aggravate an existing condition or cause additional injury. Traction should never cause pain. A stretching sensation or some slight discomfort may be felt during treatment. If pain is increased in the neck, back, arms or legs, or if you experience dizziness, nausea or any other type of pain or discomfort during or after treatment, discontinue use immediately and consult your health care provider before further use.

2. PARTS OF THE CERVICO 2000



1. Collar
2. Pad for collar
3. Chin support
4. Pad for chin support
5. Release handle
6. Traction lever
7. Straps
8. Traction rod



- 9. Brace
- 10. Pad for brace
- 11. Location for horizontal pressure screw
- 12. Horizontal pressure pad
- 13. Horizontal screw

3. INSTRUCTION FOR USE OF THE CERVICO 2000

Step 1: Remove all jewelry such as earrings, necklaces, and hair accessories. Wash and dry the jaw and neck areas which will be in contact with the Cervico 2000. The patient should wear a comfortable shirt with no zippers, buttons, or protruding decorations which may cause discomfort during treatment. Cover the blue cushions under the chin support and the back pad of brace with a paper disposable tissue for each treatment.

Step 2: Make sure that the jack mechanism is at the lowest position and fits snugly into the traction rod housing of the collar. This is the “Zero Position”.

Step 3: To fit the horizontal pressure screw, remove the pad from the brace, then fit the horizontal screw through the upper or lower location, as appropriate, so that the pressure pad is on the inside and the screw thread is outside the device (**Fig. 1**). Refit the pad and fit the screw head.

Step 4: While holding the device so that the patient can read the words "Cervico 2000", make sure that the upper strap and the lower strap on one side are open and that the straps on the other side are attached by folding them back and securing them against the Velcro fastening strips on the surfaces of the straps (**Fig. 2**).



Fig. 1



Fig. 2

Step 5: While the device is still in the “Zero Position”, place the collar on the collarbones and shoulders so that the front of the jaw rests gently on the chin support (**Fig. 3**). The collar has two channels through which the straps should be threaded, folded back, and secured by the Velcro fastenings located on the surfaces of the straps. The collar and chin support should fit snugly, without pain or discomfort. During self-treatment, it is recommended that the patient fit the device in front of a mirror.



Fig. 3

Step 6: With the device resting comfortably, it may be necessary to adjust the placement of the collar, the brace, or the tightness of the straps in order to ensure the patient's comfort (**Fig. 4**). For larger or smaller patients, it is possible to move the traction rods forward or backward in the traction rod housing for a secure, comfortable fit. Only after the device is properly positioned is it possible to apply traction as necessary.



Fig. 4

Step 7: When the patient is ready, begin applying traction by gently lifting both traction levers simultaneously (**Fig. 5**). In cases of self-treatment it is recommended to use the index and middle fingers to grasp the top of the traction housing and then to apply firm pressure with the thumb to lift the traction levers. Repeat until the skin of the neck is taut and there is resistance to the traction of the device. The patient should feel gentle traction, but little or no discomfort. Always apply traction slowly, so as to prevent discomfort.



Fig. 5

Step 8: When the desired amount of decompression has been achieved, additional horizontal pressure can be applied to restore the lordosis. Apply the required horizontal pressure by turning the screw head gently in a clockwise direction until the patient feels gentle pressure, but little or no discomfort (**Fig. 6**). Always apply pressure slowly, so as to prevent discomfort.



Fig. 6

Step 9: It is possible to apply asymmetrical traction when needed (such as to the left or to the right) by jacking one side more than the other (**Fig. 7 and Fig. 8**). Again, traction should be applied slowly to avoid discomfort.

Step 10: Traction should be performed for approximately 15-20 minutes per day. Treatment of acute cases with the Cervico 2000 is recommended daily for approximately one week, but not more than ten days. In chronic or severe cases, it is recommended to undergo treatment twice daily for approximately two weeks, but only under qualified medical supervision. It is suggested that the patient walks or participates in active exercises during the treatment session (i.e. on a treadmill or using elastic bands).



Fig. 7



Fig. 8

Step 11: Upon finishing the treatment session, release the traction by pressing down on the release handles located on the jack mechanisms on both sides of the device (**Fig. 9**). Release traction slowly and simultaneously on both sides in order to avoid causing discomfort to the patient or damage to the device.

Step 12: Once the device has been returned to the “Zero Position”, release the upper and lower straps and remove it while the patient is sitting. It is recommended that the straps be released on one side of the device only so that the brace does not disconnect from the device and fall off the patient. The device is now ready for the next treatment.











Fig. 9

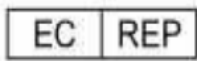


4. CARE AND MAINTENANCE OF YOUR CERVICO 2000

While the Cervico 2000 applies powerful treatment forces to the cervical spine, it is a precision device that needs proper care. Make sure to follow these simple steps:

-  Be sure to handle the device gently.
-  Keep the device properly stored in the “Zero Position” in its original carrying bag when not in use.
-  Avoid exposing the device to water, excess humidity, or direct sunlight for extended periods of time.
-  Wash and dry the neck area of the patient before use.
-  Before treatment, place a layer of tissue or sanitary paper on the device so that there is minimal contact between the patient's body and the pads which may become excessively soiled.
-  Clean the device by wiping the plastic and polyurethane with a cloth dampened with alcohol.
-  Wipe the foam and polyurethane pads with alcohol after each use whether the unit is being used for one patient, two patients, or twenty patients.
-  In a clinic environment, it is recommended that spare sets of pads be kept on hand for convenience and comfort of the patient. You can order them from your Cervico 2000 representative or directly from Meditrac.

5. LABELS



Authorized Representative in the EU



CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician



Manufacturer



Consult instructions for use



No Direct Sunlight

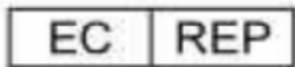


Medical Device



Keep Dry

6.



Meditrac's authorized representative:

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo n18
C.P 29006 Málaga
Spain
RPS/5269/2022

Meditrac's products carry the **FDA** and **ISO:13485**

and are registered with the United States Food and Drug Administration.

United States Federal Law permits the sale of these devices (within the US) by a doctor's prescription only



FDA: B-067324

UDI: 07290015711203

UDI-DI: 7290015711cervico20009S

Model No. : CERV8

Rev 02 - 12/21 IFU-08, CERV8

