



INTENDED USE

Use of circulating water through a flexible body wrap to provide localized cryo-therapy to body surfaces for treatment of musculoskeletal conditions.

TREATMENT

Recommended cycle = 30 minutes

Wait at least 1 hour between treatments and inspect skin between sessions to prevent cold-related injuries.

INDICATIONS FOR USE

Intended to deliver thermal therapy to provide topical cooling for the purposes of:

- relief of pain
- relief of soreness or discomfort
- managing inflammation and swelling
- relaxation of muscles
- providing post-operative or post-injury recovery support
- reducing swelling associated with soft tissue injuries

PRODUCT INFO

Manufactured by Ultra Pain Products, Inc.

CONTRAINDICATIONS

- patients with Raynaud's disease
- acute, unstable fracture
- patients with rheumatoid arthritis to the limb or treatment area
- open wounds or skin conditions
- cold hypersensitivity
- poor or absent sensation in the treatment area
- patients that are pregnant
- severe hypertension
- severe low blood pressure
- circulation disorders
- vascular disease
- severe and uncontrolled diabetes
- arteriosclerosis
- ischemia
- hematological dyscrasias which affect thrombosis (paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle-cell disease, or serum cold agglutinins).
- inflammatory phlebitis in the treatment area

FDA REGISTRATION

Product code: ILO

Class: II

Regulation #: 890.5720

Water circulating cold pack
(510k exempt)

SHOULDER



Temperature of the treatment wrap

*using 4 parts water, 1 part ice.

Temperature after 15 minutes of use
12.3°C
54.14°F

Temperature after 30 minutes of use
12.9°C
55.22°F

Average Compression Exerted (mmHg) per Level

- Level 1: **111.25** mmHg
- Level 2: **159.5** mmHg
- Level 3: **207.75** mmHg
- Level 4: **245.25** mmHg
- Level 5: **303** mmHg

CERVICAL



Temperature of the treatment wrap

*using 4 parts water, 1 part ice.

Temperature after 15 minutes of use
12.3°C
54.14°F

Temperature after 30 minutes of use
12.9°C
55.22°F

Average Compression Exerted (mmHg) per Level

- Level 1: **284.5** mmHg
- Level 2: **357.75** mmHg
- Level 3: **366** mmHg
- Level 4: **369.25** mmHg
- Level 5: **370.25** mmHg

BACK



Temperature of the treatment wrap

*using 4 parts water, 1 part ice.

Temperature after 15 minutes of use
12.3°C
54.14°F

Temperature after 30 minutes of use
12.9°C
55.22°F

Average Compression Exerted (mmHg) per Level

- Level 1: **74.75** mmHg
- Level 2: **117.5** mmHg
- Level 3: **148.5** mmHg
- Level 4: **175** mmHg
- Level 5: **203.25** mmHg

KNEE



Temperature of the treatment wrap

*using 4 parts water, 1 part ice.

Temperature after 15 minutes of use
12.3°C
54.14°F

Temperature after 30 minutes of use
12.9°C
55.22°F

Average Compression Exerted (mmHg) per Level

- Level 1: **109.75** mmHg
- Level 2: **151.25** mmHg
- Level 3: **187.75** mmHg
- Level 4: **218.75** mmHg
- Level 5: **268.75** mmHg

ANKLE



Temperature of the treatment wrap

*using 4 parts water, 1 part ice.

Temperature after 15 minutes of use
12.3°C
54.14°F

Temperature after 30 minutes of use
12.9°C
55.22°F

Average Compression Exerted (mmHg) per Level

- Level 1: **127.25** mmHg
- Level 2: **180.75** mmHg
- Level 3: **242** mmHg
- Level 4: **270.5** mmHg
- Level 5: **309.5** mmHg