



SPLIT UMBILICAL HOSE INSTRUCTIONS

Product Number: TX0208

This instructions for use (IFU) is an integral part of the product, describing how to safely use it as intended. Read this IFU prior to using this product and keep the IFU with product so it is accessible at all times.

INTENDED USE

Therm-X AT is intended to administer cold, heat, contrast, and compression therapy to patients for which these therapies are indicated.

INDICATIONS FOR USE

The Split Umbilical Hose is an optional component of the Therm-X system. Therm-X AT combines cold, heat, contrast, and compression therapy. Therm-X is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to treat post traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated. Therm-X AT is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.

INTENDED POPULATION

The Therm-X AT is indicated for patients 12 years of age and older.

INTENDED USERS

Therm-X AT is intended to be used by, or on the order of, licensed health care professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.
















CLINICAL BENEFITS

Therm-X AT reduces edema, swelling, and pain by providing heat, cold, contrast and/or compression therapy to patients with acute musculoskeletal injuries, post traumatic injuries, or in medical recovery (Post-Surgical). Where appropriate, the Therm-X AT device can be used in place of ice, heating pads, compressions stocking or similar treatments to provide more consistent and continuous thermal and compression control.

DESCRIPTION

The Split Umbilical Hose is an umbilical hose intended to facilitate simultaneous use of two Therm-X multi-patient use thermal garments with the Therm-X device. One end of the hose connects to the front of the Therm-X unit, and the other end of the hose connects to two Therm-X multi-patient use thermal garments (e.g. knee, back, shoulder, ankle, elbow, or hip).

SYMBOLS AND ABBREVIATIONS ON THE PRODUCT AND PACKAGING

Symbol/Term	Significance	Symbol/Term	Significance	Symbol/Term	Significance
	Identification label		Caution! Consult the Instructions for Use for important cautionary information.		EU Rep (Authorized Representative in the European Union)
	CE Mark - European Conformity		Follow instructions for use		Caution: Federal law restricts this device to sale by or on the order of a physician
	Product number		Manufacturer		Lot number
	Unique Device Identifier		Date of Manufacture		Medical Device
	Temperature Limitation		Humidity Limitation		Pressure Limitation

OPERATING INSTRUCTIONS

Please see the Therm-X AT Instructions for Use for specific instructions on how to connect the Therm-X Split Umbilical Hose with the Therm-X system.

CONTRAINDICATIONS

Therm-X compression therapy should not be used by any patient with any of the following pre-existing conditions:

- Presumptive evidence of congestive heart failure
- Pre-existing DVT conditions
- Deep acute venal thrombosis (Phlebothrombosis)
- Inflammatory phlebitis process
- Episodes of pulmonary embolism or other signs of embolism
- Pulmonary edema
- Acute inflammation of the veins (Thrombophlebitis)
- Decompensated cardiac insufficiency
- Arterial dysregulation
- Erysipelas
- Carcinoma and carcinoma metastasis in the affected extremity
- Decompensated hypertonia
- Acute inflammatory skin diseases or infection
- Venous or arterial occlusive disease
- Venous or lymphatic return is undesirable
- Poor peripheral circulation
- Severe arteriosclerosis or active infection
- Decompensated hypertonia in the affected region
- Vascular impairment that is significant in the affected area
- Hematological dyscrasias which affect thrombosis

Therm-X thermal therapy should not be used by any patient with any of the following pre-existing conditions:

- Raynaud's phenomenon or other vasospastic conditions
- Cold allergy
- Cold agglutinin disorders
- Hypersensitivity to cold or heat
- History of cold injury
- Severe cardiovascular disease
- Anesthetic skin, hypercoagulation disorders
- Poor circulation
- Extremities sensitive to pain
- Extremely low blood pressure that are incapacitated
- Decreased skin sensitivity
- Vein ligation or recent skin grafts
- Pheochromocytoma

WARNINGS/CAUTIONS

- ⚠ Do not use the device without a physician's prescription.
- ⚠ If using a Therm-X Split Umbilical Hose, ensure that two Therm-X thermal garments are attached to the hose and to the patient.
- ⚠ Follow the prescribed instructions of your professional treatment regimen(s), area, frequency, and duration.
- ⚠ A licensed healthcare practitioner must select the correct regimen for use.
- ⚠ Patients vary in cold sensitivity. Check regularly on patient's comfort.
- ⚠ Immediately stop compression therapy if you experience any sense of discomfort, numbness, or tingling of the limb.
- ⚠ Exercise special precautions for children under 12 or patients with any of the following: hypercoagulation disorders, diabetes, neuropathies, arthritic conditions, diabetes peripheral vascular disease, and decreased skin sensitivity.
- ⚠ Patients with any of following conditions must use Therm-X for temperature therapy under the supervision of a physician:
 - Extremities not sensitive to pain
 - Extremely low blood pressure
 - Raynaud's disease
 - Hypersensitivity to cold
 - Children under 12
 - Diabetics
 - Incapacitated patients
 - Decreased skin sensitivity
 - Poor circulation
 - Vein ligation or recent skin grafts
- ⚠ Do not use garments near open flame.
- ⚠ Do not smoke while therapy garments are in use.
- ⚠ Observe all warning and caution labels. Never remove the labels.
- ⚠ Do not allow the therapy garment or umbilical hose to contact sharp objects that could puncture them.
- ⚠ **WARNING:** Use carefully. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of Therm-X by children or incapacitated persons may be dangerous.

RECOMMENDED USE AND STORAGE

- Use between 15.6°C-26.7°C and below 60% humidity.
- Store between 0.6°C – 50.0°C and below 60% humidity.
- Use and Store in atmospheric pressure between 700 hPa – 1060 hPa (corresponds to a max. elevation of 3000 m).



WARRANTY

This Split Umbilical Hose carries a one year limited warranty. You can find the terms, conditions and limitations of this garment Warranty in the Therm-X Unit instruction manual. **THERE ARE NO OTHER WARRANTIES, EXPRESS OR IMPLIED.** A copy of such Warranty may also be obtained online at thermxttherapy.com or by emailing customerservice@thermxttherapy.com.

SERVICE AND CUSTOMER SUPPORT

To obtain service for this Split Umbilical Hose, contact your distributor.

When reporting problems, provide the Unique Device Identification number (e.g. Serial Number) of the Split Umbilical Hose to the manufacturer or its authorized representative and your National Authority.

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