



Split Umbilical Hose Instructions:

Model Number: TX0208

Symbols and Abbreviations on the Product and Packaging

Symbol/Term	Significance
	Identification label
	Product number
	Serial number
	Manufacturer
	Caution! There are specific warnings and precautions associated with this device.
	Follow instructions for use
	Caution: Federal law restricts this device to sale by or on the order of a physician

Indications for Use for the Split Umbilical Hose:

The split umbilical hose is a component of the Therm-X system. Therm-X (Therm-X Home and 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.

The Therm-X (Therm-X Home and Therm-X AT) is also intended for treatment of disorders associated with vascular or lymphatic insufficiency, such as lymphedema and chronic venous insufficiency (CVI).

Therm-X Home systems also provide DVT therapy. Therm-X Home systems with DVT therapy are intended to reduce the risk of the formation of deep venous thrombosis (DVT) by aiding blood flow back to the heart via lower extremity limb compression.

Therm-X (Therm-X Home and Therm-X AT) is intended to be used by, or on the order of, licensed health care

professionals in rehabilitation facilities, outpatient clinics, athletic training settings, and home settings.

Description for the Split Umbilical Hose:

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).

Specifications	
Length	1 ft. +/- 0.5 ft. section connected to two 4 ft. +/- 0.5 ft. sections
Type	Two 3-in-1 connectors for multi-patient use garments

Operating Instructions

Please see the Therm-X User Manual for specific instructions on how to use 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.
- ⚠ While using the device, you should check the skin condition every hour for increased redness, discoloration, itching, swelling, blisters, irritation and other changes. If any unusual conditions occur immediately discontinue using Therm-X and contact your physician.
- ⚠ 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 pull cords or hoses attached to Therm-X or otherwise put undue stress on Therm-X.
- ⚠ Do not allow the therapy garment or umbilical hose to contact sharp objects that could puncture them.
- ⚠ WARNING: Use carefully. May cause serious burns. 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 60°F - 80°F and below 60% humidity
- Store between 33°F - 122°F and below 60% humidity
- Use and Store in atmospheric pressure between 700 hPa – 1060 hPa (corresponds to a max. elevation of 9,842 ft 6 in (3000 m))

Warranty:

This split umbilical hose carries a 1 year limited warranty. You can find the terms, conditions and limitations of this 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 thermxtherapy.com or by emailing customerservice@thermxtherapy.com.

Service and Customer Support:

When reporting problems, provide the Unique Device Identification number (e.g. S/N) of the split umbilical hose in addition to the corresponding alert information, if any.

Contact Information:

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