

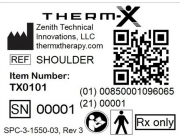









## Shoulder Garment Instructions:

Model Number: TX0101

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.

### 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
	Type BF applied part
	Caution: Federal law restricts this device to sale by or on the order of a physician

### Indications for Use for the Shoulder Garment:

The shoulder garment 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 Shoulder Garment:

The shoulder garment is a multi-patient use inflatable wrap intended for the thermal treatment of the shoulder. The shoulder thermal garment is a flexible coolant circulating garment that gets applied to the body to deliver cold, heat, or contrast therapy in combination with pneumatic compression.

## 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.
- ⚠ 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.
- ⚠ Therapy garments are to be selected by a healthcare professional.
- ⚠ Do not apply therapy garment so tightly as to restrict blood or fluid flow.
- ⚠ Use only Zenith Technical Innovations approved therapy garments.
- ⚠ Therapy garments are not sterile. Do not place directly on open wounds, sores, rashes, infections, or stitches.
- ⚠ Multi-patient use garments must be cleaned and disinfected as outlined in the cleaning section of each IFU-006, Rev. 8

garment IFU. Use of a garment with multiple patients without proper cleaning and disinfection may lead to risks of infection.

- ⚠ Garments should be inspected for cleanliness and damage for each treatment. Do not use garment if there are signs of damage as the garment may leak. If the garment is dirty, clean as indicated in the cleaning section of each garment IFU.
- ⚠ Do not attempt to sterilize therapy garment by any means.
- ⚠ Dressings used under the therapy garment should be applied lightly.
- ⚠ Do not allow the therapy garment to contact sharp objects that could puncture them.
- ⚠ Immediately stop compression therapy if you experience any sense of discomfort, numbness, or tingling of the limb.
- ⚠ 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.
- ⚠ Check for moisture on the therapy garment before placing on skin. Remove any moisture before use.
- ⚠ 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.
- ⚠ 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:

- Fold the garments up so that the fluid bladder is internal
- 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))

**Cleaning:**

Garments should be cleaned after each use when used with a single patient. Garments should never be used by multiple patients without proper cleaning and disinfection.

To clean the garment for **single patient use**, the following steps must be taken:

1. The internal surfaces (side that comes into contact with patient) of the Therm-X garment must be wiped with a lint-free cloth wetted with a solution of warm water and mild-detergent to remove all visible soil.
2. A second lint-free cloth wetted with cool tap water must be used to wipe the garment to remove all detergent residues.
3. Garments must be air dried before next use, not machine washed or placed in a dryer.

To clean and disinfect the garment for **multiple patient use**, the following steps must be taken:

1. Cavicide Spray should be used to spray the internal surfaces (side that comes in contact with patient) of the Therm-X garment so they are thoroughly wet for 1 minute.
2. After 1 minute of contact time, the garment should be wiped with a clean lint-free cloth to remove all visible soil.
3. Cavicide Spray should be used to spray the internal surfaces of the Therm-X garment so they are thoroughly wet for 5 minutes.
4. After 5 minutes of contact time, the garment should be wiped with a clean lint-free cloth wetted with warm water to remove disinfectant residue (Note: lint-free cloth should be wet, but not dripping).
5. Garments should be air dried before next use, not machine washed or placed in a dryer.

**Garment Preparation:**

- 1) Remove the product from the packaging
- 2) Check the product for damage before use
- 3) Check the product for cleanliness before use and clean as indicated in cleaning section, if dirty.

**Garment Priming:**

- 1) Connect the shoulder garment to the umbilical hose using the one-step quick connect fittings.
- 2) Fill the tank with the approved Therm-X coolant.
- 3) Attach the umbilical hose to the Therm-X device.
- 4) Plug the Therm-X device into an outlet allowing the pre-chill cycle to begin filling the empty garment.
- 5) Repeat step 4 by disconnecting and reconnecting the power supply until the garment has minimal to no air in the coolant bladder.

**Removing and Changing Garments:**

Press the red button to disconnect the garment from the hose. Undo the Velcro straps and remove the garment from the shoulder. Connect the new garment as specified by the garment specific IFU.

**Garment Sizing:**

The shoulder garment fits a chest size of 33"-55".

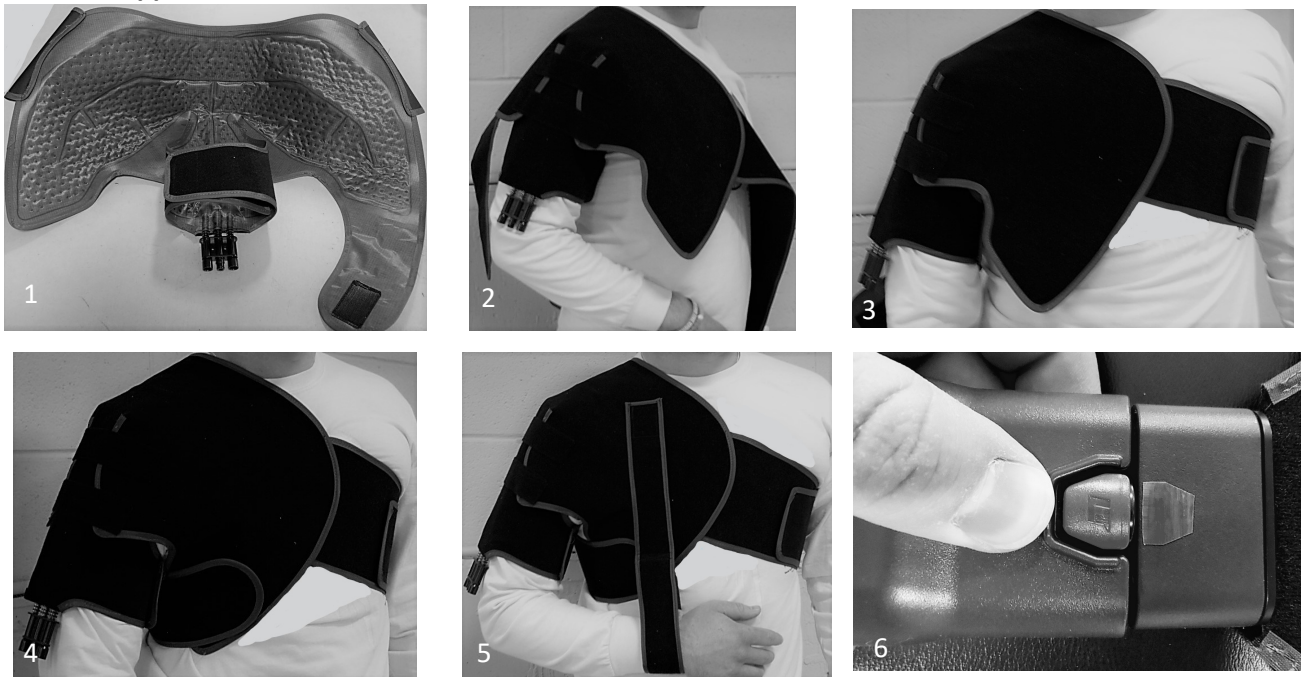
**Biocompatibility:**

The material that contacts the skin has been tested to meet biocompatibility requirements per ISO10993.

**Disposal:**

Dispose of product after use according to local regulations

## Garment Application:



- 1) Fasten the Velcro bicep strap in a circle, creating a hole for your biceps to fit through.
- 2) Slide arm into looped fabric. Adjust the Velcro strap to make sure it is snugly fit around the biceps.
- 3) Fasten the two straps underneath your opposite arm and around your chest. Make sure that the straps have a snug fit.
- 4) Attach the connector strap underneath the arm. Make sure that it is a snug fit and the strap isn't pinching around the armpit.
- 5) Readjust the two connecting straps over the deltoid to get desired fit. If desired, place wrist into the optional wrist sling and attach the loose end to the Velcro over the chest.
- 6) Connect the garment to the umbilical hose by inserting the three garment prongs into the hose. Push until a "click" is heard.
- 7) Recommended Max Pressure Setting: Low

## Warranty:

This garment carries a six month 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 [thermxtherapy.com](http://thermxtherapy.com) or by emailing [customerservice@thermxtherapy.com](mailto:customerservice@thermxtherapy.com).

## Service and Customer Support:

When reporting problems, provide the Unique Device Identification number (e.g. S/N) of the garment (as identified on the label on the 3-in-1 connector) in addition to the corresponding alert information, if any.

## Contact Information:

847-672-7481  
Zenith Technical Innovations  
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Gurnee, IL 60031