EXTENDER STRAPS INSTRUCTIONS

Product Number: TX0109

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 Extender Straps are optional components 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 Extender Straps are a multi-patient strapping system intended to increase the size of the patient population able to use the Therm-X garments.

SYMBOLS AND ABBREVIATIONS ON THE PRODUCT AND PACKAGING

Symbol/Term	Significance
	Identification label
CE	CE Mark - European Conformity
REF	Product number
UDI	Unique Device Identifier
	Consult the instructions for use
	Temperature Limitation

Symbol/Term	Significance
	Caution! Consult the Instructions for Use for important cautionary information.
	Follow instructions for use
	Manufacturer
	Date of Manufacture
	Type BF applied part
	Humidity Limitation

Symbol/Term	Significance
EU REP	EU Rep (Authorized Representative in the European Union)
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
LOT	Lot number
MD	Medical Device
	Pressure Limitation

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.

⚠ 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 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. 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).

CLEANING

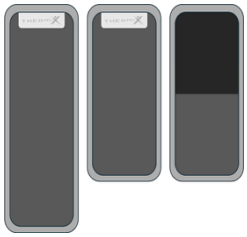
Garments should be cleaned after each use when used with a single patient. Garments should never be used by multiple patients without proper cleaning and disinfection.

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 into 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.

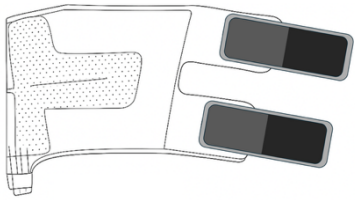


GARMENT PREPARATION

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 APPLICATION

1) Unpack and layout the Extender Straps.
2) Affix the loop side of the Extender Straps to the existing hook on the garment.
3) Apply the garment per the garment IFU.
4) Ensure that the hook and loop of the Extender Straps fully engages the existing garment.



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.

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 or by emailing customerservice@thermxtherapy.com.

SERVICE AND CUSTOMER SUPPORT

When reporting problems, provide the Unique Device Identification number (e.g. Lot Number) of the garment (as identified on the label found on the packaging) to the manufacturer or its authorized representative and your National Authority.

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