Back Pro Smart Wrap™

User Guide

Model: KLV20002

For use with:
Kelvi Pro™ Series

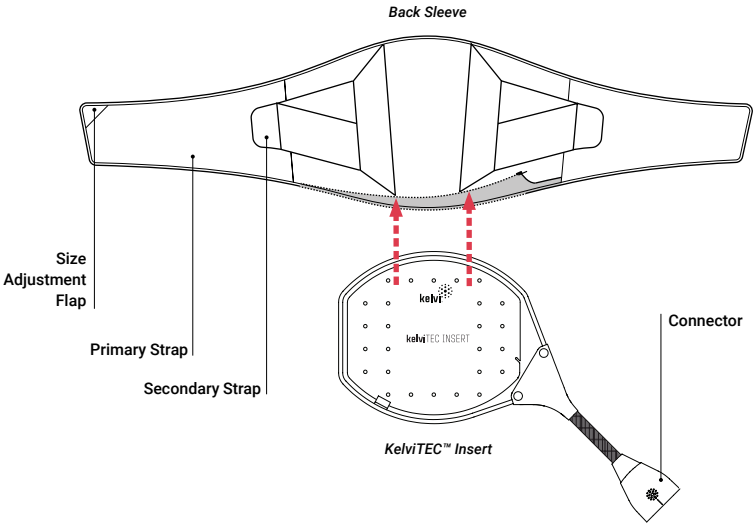
Smart Wrap™ Assembly

Back Pro Smart Wrap™ consists of a KelviTEC™ Insert and a Sleeve.

1. Place Back Sleeve on a flat surface as shown.

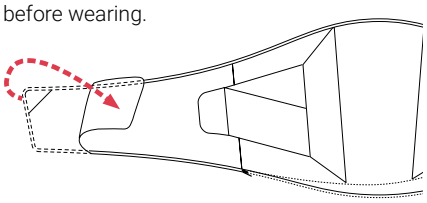
2. Insert Back KelviTEC™ Insert into Back Sleeve with tiles facing down.

3. Ensure Back KelviTEC™ Insert is flat inside Back Sleeve and close zipper.

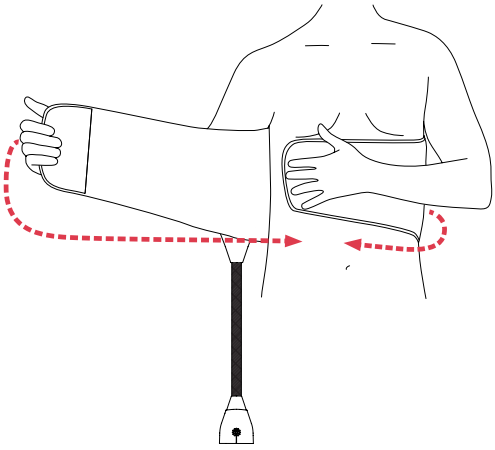


How to Wear

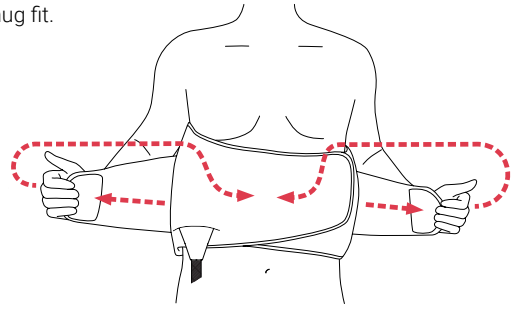
1.
Ensure that Secondary Straps are loose before moving on. For smaller sizes, fold in Primary Strap on left side before wearing.



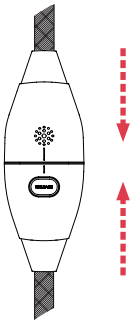
2.
Center Smart Wrap™ on lower back and tighten Primary Straps around the waist securely.



3.
Adjust Secondary Straps for comfort and snug fit.



4.
Attach the Smart Wrap™ to the Umbilical of the Kelvi Pro™ Series Console. An audible "click" will occur when the connectors engage. Use Air Control buttons to adjust fit.
To disconnect, depress Release Button and pull.



WARNING: Deflate air bladder after every use. Deflate air bladder by hitting Decrease Air Pressure button, (-) or disconnecting Smart Wrap™.

Removal of KelviTEC™ Insert

1. Disconnect Umbilical from Smart Wrap™.
2. Place Smart Wrap™ on a flat surface.
3. Unzip Smart Wrap™ and gently remove KelviTEC™ Insert.

Cleaning & Storage

Care of KelviTEC™ Insert

Remove KelviTEC™ Insert from Smart Wrap™ Sleeve. Wipe away any condensation with a dry towel. It is recommended that you wipe the KelviTEC™ Insert clean periodically with a soft cloth and either a mild detergent or 70% isopropyl alcohol. Dry KelviTEC™ insert after wiping down.

WARNING: Do not excessively dampen or wet KelviTEC™ Insert or submerge in any way. Do not hand wash or machine wash KelviTEC™ Insert. Doing so will damage the device and void its warranty.

Care of Sleeve

Sleeve should be cleaned after each use, especially for multi-patient use. Hand wash or machine wash cold with mild detergent and hang dry. Always remove KelviTEC™ Insert before washing.

IMPORTANT: Do not tumble dry, dry clean, iron, or use bleach on Sleeves.

Storage

Ensure that Smart Wraps™ are not sharply bent or creased during storage, which may cause damage and void the warranty. Smart Cases are designed to protect Smart Wraps™ from excessive stress, and are recommended for stacked storage.
Store Smart Wrap™ in appropriate storage case in a cool, dry place. For a list of Kelvi™cases and accessories please visit Kelvi.com.

WARNING: Fully read and understand all User Guides before using Kelvi Pro™ System. Failure to follow operating instructions could result in serious injury and voided warranty.

IMPORTANT: Read complete indications, contraindications, cautions, and warning before using this product. This product is intended to be used by, or on the order of, a licensed healthcare professional. Keep this document for future reference.

IMPORTANT: Ensure that Smart Wrap™ is applied with a snug fit and there are no tight bends that may impede water flow. Ensure the connector is positioned to prevent Smart Wrap™ from folding or kinking. Impeding water flow may prevent Smart Wrap™ from functioning properly.

Contraindications

The Kelvi Pro™ System should be used only under the direct supervision of a licensed healthcare practitioner in patients who:

- Experience or have been diagnosed with hypertension or extreme low blood pressure.
- Experience or have been diagnosed with rheumatoid arthritis in or around the treatment area.
- Experience or have been diagnosed with known and uncontrolled peptic ulcer (if the affected region is the abdominal region).
- Have been diagnosed with type I or type II diabetes.
- Have compromised local circulation or neurologic impairment (including paralysis or localized compromise due to multiple surgical procedures) in or around the treatment area.
- Have been diagnosed with a localized unstable skin condition (e.g., dermatitis, vein ligation, gangrene, or recent skin graft) in the affected region.
- Have recently had surgery in or around the treatment area.
- Are under 18 years old.

The Kelvi Pro™ System should NOT be used in patients who:

- Experience or have been diagnosed with any vascular impairment in or around the treatment region. This includes, but is not limited to, tissue that has experienced frostbite, arteriosclerosis, type II diabetes, or ischemic tissue of any type or cause.
- Have current clinical indications of deep vein thrombosis and/or significant peripheral edema in or around the treatment region.
- Have areas of skin deterioration or damage that may produce uneven heat conduction across the skin.
- Have impaired sensitivity to pain or temperature.
- Have cognitive or communicative impairments that prevent them from giving accurate and/or timely feedback.
- Have poor circulation, or over sensitive skin areas.

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- Have compromised local circulation or neurologic impairment (including paralysis or localized compromise due to multiple surgical procedures) in or around the treatment area.
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- Have poor circulation, or over sensitive skin areas.

The cryotherapy (cold) and contrast settings should NOT be used in patients who:

- Experience or have been diagnosed with hematological dyscrasias which affect or modify thrombogenic processes. This includes, but is not limited to, sickle-cell disease, paroxysmal cold hemoglobinuria, serum cold agglutinins, and cryoglobulinemia.
- Have current clinical indications of cellulitis, inflammatory phlebitis, or venous ulcers.
- Have current clinical indications or any risk factors suggestive of embolism. This includes, but is not limited to, pulmonary embolism, cerebral infarction, atrial fibrillation, endocarditis, myocardial infarction, and atheroma.
- Have any condition in which modified venous or lymphatic return may have adverse effect in or around the treated extremity. This includes, but is not limited to, carcinoma.
- Experience or have been diagnosed with Raynaud's disease or cold hypersensitivity (cold urticaria).
- Have been diagnosed with decompensated hypertonia in or around the treatment area.

The thermotherapy (hot) and contrast settings should NOT be used in patients who:

- Have inflamed tissue as a result of recent injury or exacerbation of chronic inflammatory condition.
- Have an acute, untreated fracture in the treatment region.
- Have local malignancy.
- Have actively bleeding tissue or hemorrhagic conditions.
- Have recently radiated tissue or areas affected by heat-sensitive skin diseases (e.g., eczema, psoriasis, vasculitis, dermatitis).
- Have any active local or systemic infection.
- Are pregnant.

The Kelvi Pro™System includes air pressure functionality for enhanced fit. The air pressure settings should NOT be used in patients who:

- Have hypertension, extreme low blood pressure, cardiac failure, or decompensated cardiac insufficiency.
- Have any active local or systemic infection.
- Have current clinical indications of cellulitis, inflammatory phlebitis, deep vein thrombosis, or venous ulcers.
- Have current clinical indications or any risk factors suggestive of embolism. This includes, but is not limited to, pulmonary embolus, cerebral infarction, atrial fibrillation, endocarditis, myocardial infarction, and atheroma.
- Have any condition in which modified venous or lymphatic return may have adverse effect in or around the treated extremity. This includes, but is not limited to, carcinoma.
- Have diabetes mellitus, multiple sclerosis, rheumatoid arthritis, poor circulation, or spinal cord injuries.

General Warnings and Cautions

Cautions

- Do not attempt to operate the Kelvi Pro™ System if there is any mechanical damage to the Console, cord or accessories.
- Be careful not to trip over power cord or Umbilical. Always position the device such that the power cord or Umbilical cannot pose a hazard to you or others in the surrounding area. Never wrap any Umbilical or power cord around anyone's body, as this may pose a risk of strangulation. Keep power cord and Umbilical out of the reach of children.
- During use, always place Kelvi Pro™ Series Console such that the device is quickly and easily accessible to the user. In the event of emergency, it may be necessary to disconnect power cord from the wall outlet to terminate functions of the System.
- Smart Wraps™ are designed for use on unbroken skin for time periods set by your healthcare practitioner. If the skin is broken or appears otherwise damaged, contact your healthcare practitioner before use. Your healthcare practitioner may determine that your Smart Wrap™ may be used with a layer of gauze or insulation between the skin and Smart Wrap™.
- The Kelvi Pro™ System should not be used in or near pooled bodies of liquid such as swimming pools or bathtubs. Do not spill liquids on the Kelvi Pro™ System or accessories.
- The Kelvi Pro™ System is not to be disassembled or serviced by the user, except as expressly directed in this manual. If service or repairs are needed, contact Kelvi™ customer service.
- When using a Smart Wrap™, KelviTEC™ Insert should not be removed from its sleeve. Do not use KelviTEC™ Insert directly against the skin under any circumstances. If the Sleeve becomes torn or damaged, replacement Sleeves are available.
- Do not puncture or otherwise damage Smart Wraps™. Damage may cause the system to operate incorrectly. If a Smart Wrap™ begins leaking for any reason, discontinue use of that Smart Wrap™ and contact customer service.
- Do not step on, stack, or compress Smart Wrap™. Doing so may damage Smart Wrap™ and may cause system to operate incorectly.
- Kelvi Pro™ Series Console is designed to be carried by its handle or transported using a Kelvi™ carry case. Do not use Smart Wrap™ or Umbilical to carry or transport Console.
- Always check Smart Wrap™ connector and the connector pocket on Console for debris before connecting. Do not apply undue force when connecting Umbilical to any part of the Kelvi Pro™ System or accessories. Application of undue force will void the warranty.
- Kelvi Pro™ Series Console should be handled with care. Damage sustained by inappropriate handling or impact may result in reduced Kelvi Pro™ System performance and will void all Kelvi™ warranties.
- Smart Wraps™ are meant to be used by one stationary person at a time. Do not transport the device or move Kelvi Pro™ Series Console while the device is attached to the body. Kelvi Pro™ Series Console and Smart Wraps™ contain hard components which can cause injury upon bodily impact.
- Keep Kelvi Pro™ System out of reach of small children or pets.
- In addition to the precautions listed above, additional warnings and safety precautions are posted throughout this manual. Read and carefully follow these instructions prior to operating the Kelvi Pro™ System.
- Operating Kelvi Pro™ Series Console while connected to a Wi-Fi network that includes other electronic equipment may result in previously unidentified risks to patients, operators, or third parties. These risks should be evaluated by the operator or responsible organization before use. Changes to the IT network during or after usage may introduce additional risks. Examples of changes to the IT network include changes in network configuration, update or upgrade of equipment, connection or removal of other items on the network.
- The use of a Mobile Device connected to an unsecured network is a security vulnerability and can result in a breach of Personal Health Information (PHI).
- The Kelvi Pro™ System should only be used under the care and/or direction of a licensed healthcare professional.

Warnings

- Smart Wraps™ are not sterile; do not place directly against open wounds, sores, rashes, infections, or stitches. The Kelvi Pro™ System is not intended for use in a sterile environment.
- Smart Wraps™ are rated for sufficient biocompatibility with healthy human skin. If patient develops any signs of allergic reaction during normal use, discontinue use of the device immediately. Consult the Care and Storage section of this manual and ensure that the device has been properly cleaned and maintained. Replace the Smart Wrap™ sleeve as necessary.
- During the course of Kelvi Pro™ treatment, the skin surrounding the treated region or the digits of the extremities of the treated limb should be monitored for uncomfortable burning or itching sensations, increased swelling or pain. For longer treatments, Smart Wrap™ should be removed every 90 minutes or less to inspect the skin. If any of these, or other signs, are or become present, or any changes in skin appearance occur (such as blisters, increased redness, discoloration, or other noticeable skin changes), immediately discontinue use of the device and consult a physician.
- Each Smart Wrap™ is designed to fit the unique contours of specific anatomical regions. Only use Kelvi Pro™ System on the area indicated for each Smart Wrap™ (i.e. the Knee Pro should only be used on the left or right knee). Do not use Kelvi Pro™ System outside of these anatomical guidelines.
- Do not use the Kelvi Pro™ System in conjunction with any treatment outside of the intended use.
- To avoid electrical shock or risk thereof, do not remove any panels from the device or otherwise open the device except as directed in this manual.
- Do not use any power cord other than those provided directly by Kelvi™. Use of any other power cords presents the risk of electrical shock and will void the Kelvi™ warranty.
- Do not use the Kelvi Pro™ System with any components or accessories other than those described in this manual. The Kelvi Pro™ System is not compatible with accessories from any other manufacturer.
- If damage occurs resulting in small parts or components becoming dislodged from the device or accessories, these parts may pose a risk of inhalation or swallowing. If damage occurs, discontinue use of the device and contact a Kelvi representative.
- Rough handling or transport conditions may result in loosened connections which can impair or degrade system performance. In the event of any unexpected or irregular performance, discontinue use of the device immediately and contact Kelvi support for further guidance.
- No modifications to this equipment may be made. Modifications without the authorization of the manufacturer may result in unsafe usage conditions and will void the product warranty.

WARNING: This product can expose you to chemicals including Antimony oxide (Antimony trioxide), Lead, Nickel (Metallic) which are known to the State of California to cause cancer or birth defects or other reproductive harm. For more information, visit www.P65Warnings.ca.gov.

Warranty Information

To obtain warranty support, please visit Kelvi.com

Kelvi™ warrants that the KelviTEC™ Insert, if properly used, will be free from defects in material and workmanship for a period of one (1) year after the date of purchase. If the KelviTEC™ Insert which is the subject of this limited warranty, fails during the warranty period for reasons covered by this Limited Warranty, Kelvi will, at its sole discretion, repair or replace the KelviTEC™ Insert with a separate KelviTEC™ Insert. This limited warranty and any implied warranties that may exist under state law apply only to the original purchaser of the device and are non-transferable.
This limited warranty does not cover damage due to external causes, including, but not limited to, storage, usage or handling not in accordance with product instructions, accident, misuse, neglect alteration, and/or unauthorized repair. Kelvi™ may elect, at its sole discretion, to replace or repair the KelviTEC™ Insert with a new or reconditioned product. Any product returned to Kelvi™ that is the subject of replacement or repair becomes the property of Kelvi™. Any replacement KelviTEC™ Insert provided to the original purchaser is warranted under the same warranty as the original KelviTEC™ Insert, and only for the remaining period of the original warranty.

ITEM	STANDARD WARRANTY
KelviTEC™ Insert	1 Year
Sleeve	If defective, report within 14 days from receipt for return or repair
Hard Case	If defective, report within 90 days from receipt for return or repair
Soft Case	If defective, report within 90 days from receipt for return or repair

Expected Service Life for the KelviTEC™ Insert is 3 Years.

How to obtain warranty service:

To obtain warranty service, contact Kelvi™ Support at kelvi.com. If Kelvi™ authorizes the return of the KelviTEC™ Insert, you will be issued a Return Merchandise Authorization (RMA) number. Customers are not to return any product without prior written authorization from Kelvi™. Instructions on how to pack and send the KelviTEC™ Insert will be provided in writing once the return is approved. You should keep this RMA number for your records. Kelvi™ will cover the cost of the return if the KelviTEC™ Insert is under warranty. If the KelviTEC™ Insert is outside the time frame of the warranty, the customer is responsible for all associated costs. If the KelviTEC™ Insert is not packaged per the given instructions, Kelvi™ is not responsible for any warranty work or damage which occurs during shipping.

Warranty disclaimers:

All Kelvi™ warranties are in lieu of any and all other warranties, express or implied including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Kelvi™ makes no express warranties beyond those stated here. Kelvi™ disclaims all other warranties, express or implied including, without limitation, implied warranties of merchantability and fitness for a particular purpose. Some jurisdictions do not allow the exclusion of implied warranties so this limitation may not apply to you. All express and implied warranties are limited in duration to the limited warranty period. Unless required, no warranties apply after that period. Some jurisdictions do not allow limitations on how long an implied warranty lasts, so this limitation may not apply to you. Kelvi™ warranties are non-transferrable.

Limitations of liability:

The responsibility of Kelvi™ under this, or any other warranty, implied or express, is limited to repair or replacement, as set forth above. These remedies are the sole and exclusive remedies for any breach of warranty. In no event shall Kelvi™ be liable to any person for any incidental, special, punitive or consequential damages, including lost profits, cost of procurement of substitute goods, downtime, goodwill, damage to or replacement of equipment or property or any indirect damages even if Kelvi™ has been informed of the possibility thereof and notwithstanding the failure of essential purpose of any limited remedy stated herein. Some jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to you. This limited warranty gives you specific rights, and you may also have other rights that vary from jurisdiction to jurisdiction.

Accessories and replacement parts:

Accessories and Replacement Parts can be purchased by contacting Kelvi™ Customer Service. Smart Wraps™ are available for various parts of the body including ankle, back, knee, and shoulder Kelvi™ also offers a line of travel cases for Smart Wraps™

Intellectual Property:

The Kelvi Pro™ System and all accessories are covered by intellectual property rights including, but not limited to, patents, trademarks, trade names, and copyrights, owned and/or licensed by Hypothermia Devices, Inc., dba Kelvi™. No license under such intellectual property rights are granted to users, and all such rights are hereby expressly reserved by Kelvi™. Without the express, written consent of Kelvi™, user shall not (i) modify any Kelvi™ product or documentation Kelvi™ provides to user or (ii) reverse engineer, decompile, or disassemble any Kelvi™ product, or encourage or assist any third party in doing so.

Software license:

Kelvi™ products use software code owned and/or licensed by Kelvi™ from third parties. Each sale of a Kelvi™ product is not a sale of the software contained therein but rather is a license to use the software in the Kelvi™ product in which the software was initially installed. Any license granted by Kelvi™ to use the software contained in its Kelvi™ products does not give the user/licensee the right to copy, alter, disassemble, reverse engineer, create derivative works of such software or to use such software in either original or modified form in any product other than the Kelvi™ product in which the software was initially installed by Kelvi™.

This manual may be updated periodically. The most current manual can be found at kelvi.com

kelvi™

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