








ENG - Instructions for Use (IFU)

Symbols and Definitions

-  **Manufacturer** – Company that produces goods
-  **Non-Chlorine Bleach** – Bleach with no chlorine
-  **Dry Normal, Low Heat** – Dry on Normal cycle on low heat setting
-  **Machine Wash Warm** – Wash at 40°C (104°F)
-  **CE Marking** – Indicates conformity with health, safety, and environmental protection standards for products within the European Economic Area

Device Description

The TLSO Undershirt is a specialized textile interface designed for use with thoracolumbosacral orthoses (TLSOs) and other rigid spinal braces. It serves as a protective barrier between the skin and the orthotic device, preventing irritation, excessive moisture buildup, and pressure sores. The undershirt is made of **moisture-wicking, breathable, and hypoallergenic materials** to ensure maximum comfort and durability for extended wear.

Key Features:

- **Soft, stretchable material** for a snug, comfortable fit under a TLSO brace.
- **Seamless or flat-seam construction** to prevent pressure points.
- **Moisture-wicking properties** to keep the skin dry.
- **Hypoallergenic and breathable fabrics** for all-day wear.
- **Longer length design** to ensure full coverage and prevent rolling or bunching under the brace.

Materials Used:

- **Coolmax®** tetra-channel/polyester blend and Lycra® yarn.
- All materials are moisture-wicking, ensuring a dry and comfortable fit throughout the day.

Intended Use

The TLSO Undershirt is intended for individuals who wear a thoracolumbosacral orthosis (TLSO) or other rigid spinal braces. It is designed to:
- Provide a protective barrier between the skin and the brace to prevent irritation and pressure sores.
- Improve patient comfort and adherence to brace therapy.
- Regulate moisture and prevent excessive perspiration under the brace.

Intended Users:

- Individuals undergoing treatment for scoliosis, kyphosis, or post-operative spinal stabilization using a TLSO brace.

Contraindications:

- Not suitable for individuals who do not require an orthotic brace.
- Should not be used on broken or infested skin without medical consultation.

Care Instructions

- Wear Clean Brace Shirts Daily
- Machine wash warm (40°C / 104°F)
- Use non-chlorine bleach only when needed
- Do not use fabric softener sheets (liquid softener is acceptable)
- Do not hand wash
- Tumble dry low

Environmental Conditions

- **Usage:** Suitable for **indoor and outdoor** environments.
- **Limitations:** Not suitable for **prolonged exposure to water**.

Product Sterilization

- The product is **not sterilized** and **does not require sterilization**.

Electrical Components

- There are **no electrical components**; the material is **non-conductive**.

Hazardous Materials

- The device **contains no hazardous materials**.

Instructions for Use

Fitting the TLSO Undershirt:

- a) Ensure the skin is clean and dry before putting on the undershirt.
- b) Pull the undershirt over the head and adjust it so that it fits smoothly against the torso.
- c) Make sure the undershirt covers the entire area that will be in contact with the brace.
- d) Put on the TLSO brace over the undershirt and fasten it as instructed by your healthcare provider.
- e) Ensure the undershirt remains wrinkle-free and does not bunch under the brace..

Expected Performance & Safety

The TLSO undershirt is designed to:

- a) Maintain structural integrity after repeated washing and extended wear.
- b) Minimize the risk of skin irritation and pressure points.
- c) Provide a comfortable, breathable layer under a rigid spinal brace.

Warnings & Precautions

- a) Do not wear a **wet or damp undershirt** under your brace, as this can cause skin irritation.
- b) **Regularly** check the skin for signs of redness, irritation, or pressure sores: discontinue use and consult a healthcare provider if skin issues arise.
- c) **Ensure** the undershirt size is correct to prevent discomfort or bunching under the brace.

Regulatory Compliance & Risk Management

This product complies with MDR (EU) 2017/745 safety standards and has been tested under ISO guidelines for medical textile devices.

Risk Management:

- **Skin Irritation Prevention:** The undershirt is made from hypoallergenic materials that have been tested for biocompatibility under ISO 10993-1 to minimize the risk of allergic reactions and irritation.
- **Moisture Control:** Moisture-wicking fabrics help prevent excessive perspiration, reducing

the risk of fungal infections and skin breakdown.

- **Durability and Wear Testing:** The product has undergone extensive wear testing to ensure it maintains integrity after repeated washing and extended use.

- **Proper fit and Use:** Instructions emphasize the importance of proper sizing to avoid bunching, which could cause pressure sores or discomfort.

- **Post-Market Surveillance (PMS):** Ongoing PMS ensures continuous monitoring for any adverse effects or potential product improvements.

Post-Market Surveillance (PMS) & Clinical Feedback

- Post-market feedback and clinical evaluations indicate high user satisfaction with minimal reported side effects.

- The most common issue reported is **mild skin irritation**, usually resolved by switching to a different fabric.

- Ongoing monitoring ensures continued compliance with **safety, efficacy, and regulatory requirements**.

This IFU aligns with the **Clinical Evaluation Report (CER)**, ensuring that all **TLSO Body sock** specifications, usage recommendations, and risk management strategies are compliant with MDR regulations. For further details, consult the **Clinical Evaluation Report (CER) for TLSO Body Sock** or contact Royal Knit, Inc.

