








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

Residual Limb – The part of the limb that remains after amputation

Amputee – A person who has had part of a limb removed

Description of Product

Royal Flush and Royal Double Fleece **Prosthetic & Orthotic Socks** are designed as standalone medical textiles to serve as an interface between the residual limb or braced limb and the prosthetic socket or orthotic device. These socks enhance comfort and maintain optimal fit throughout the day by managing volume changes and reducing friction.

Key Functions:

- 1. Comfort:** Acts as a cushioning layer, preventing direct contact between the prosthesis or orthotic brace and the skin, reducing pressure points and irritation.
- 2. Volume Management:** Adjusts for daily residual limb volume fluctuations (for prosthetic users) or provides enhanced skin protection from rigid orthotic braces.

Materials Used:

- **White Socks:** Coolmax® tetra-channel/polyester blend and Lycra® yarn.

- **Black Socks:** Polyester yarn and Lycra®.
- **Wool Socks:** 100% Virgin Wool with a Coolmax® tetra-channel/polyester blend and Lycra® yarn.
- All materials are **moisture-wicking**, ensuring a dry and comfortable fit throughout the day.

Intended User Group & Contraindications

- **Intended Users:** Prosthetic & orthotic socks are designed for **amputees and individuals using orthotic braces** and should be prescribed and fitted by a licensed Prosthetist or Orthotist.
- **Contraindications:** The product is **not suitable** for individuals without an amputation or orthotic requirement.

Care Instructions

- **Wear Clean Socks 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 Prosthetic & Orthotic Sock:

- a) The licensed Prosthetist or Orthotist must measure the patient's limb using three key dimensions:
 - **Distal circumference** (end of the limb or braced area)
 - **Proximal circumference** (top of the residual limb or braced area)
 - **Limb length** (from distal end to proximal end, adding 2" for the correct sock length)
- b) Use these measurements to **reference the sizing chart** and select the proper sock size.

How to Put on the Prosthetic & Orthotic Sock:

- a) Take the opened end of the sock and place it over the residual limb or braced limb.
- b) Pull the sock up, ensuring a **snug fit** against the skin or liner. **Do not overstretch the sock.**
- c) Check that there are **no loose areas**, and the sock fits smoothly against the limb or brace.
- d) If the sock is **too loose**, switch to a **smaller size**.
- e) If the sock is **too tight**, choose a **larger size**.
- f) The sock should fit comfortably without excessive tightness.

Replacing the Prosthetic & Orthotic Sock:

- a) If the sock becomes **too loose** or **too tight** over time, visit a **licensed Prosthetist or Orthotist for a refitting**.
- b) If the sock **shows signs of wear** or **fails to provide the intended support**, consult a **licensed Prosthetist or Orthotist for replacement**.

Warnings & Precautions

- a) **Do not wear damp or wet socks** for prolonged periods, as this can cause skin irritation.
- b) **Regularly inspect** for signs of wear, such as thinning or holes.
- c) **Discontinue use** if irritation, excessive

tightness, or discomfort occurs, and consult a Prosthetist or Orthotist.

Regulatory Compliance & Risk Management

This product complies with **MDR (EU) 2017/745** and has been evaluated under ISO standards for safety and performance.

Risk Management:

- .Pressure ulcers are minimized through appropriate fabric selection and moisture-wicking properties.
- .Proper sizing reduces the risk of poor prosthetic or orthotic fit.
- .Material testing ensures **hypoallergenic** options for sensitive users.

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

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

