



Tourniquet Instruction For Use (IFU)

Product Name: Tourniquet
Model: TNQ-T0C00, TNQ-T0A00
Sizes: One size
Classification: Class I, Non-Sterile, Single-Patient Use
Manufacturer: Rolseley Ltd, UK
EU Rep: Tikrola MB, Lithuania
Version & Date: v1.0 / 2025.06.25
Electronic Version: tourniquet.store/pages/IFU

ROLSELEY



Please carefully consider this instruction and read all the provisions prior to use. Follow the maintenance recommendations.

1. INTENDED USE & DESCRIPTION

Purpose: Temporary restriction of venous flow during blood draws or IV access.

Indications: Venipuncture, blood collection, IV insertion.

Contraindications: Circulatory disorders, known hypersensitivity to device materials, damaged skin, prolonged application.

Target Users: Trained healthcare professionals only.

Use Environment: Hospitals, clinics, labs, ambulances.

Functional Principle: The tourniquet works by applying controlled pressure to a limb using an elastic textile band and buckle mechanism to temporarily restrict venous blood flow.

Expected Clinical Benefits: Enhances vein visibility for safer venipuncture, reduces needlestick attempts, supports routine clinical use, minimizes skin reactions (latex-free), and maintains reliable performance with proper care.

Size: One size

Dimensions: 45 cm x 2,5 cm

Accessories & Spare Parts: None required.

Device Compatibility: Not to be used with automated or electronic compression devices.

2. APPLICATION & USE

Preparation for Use:

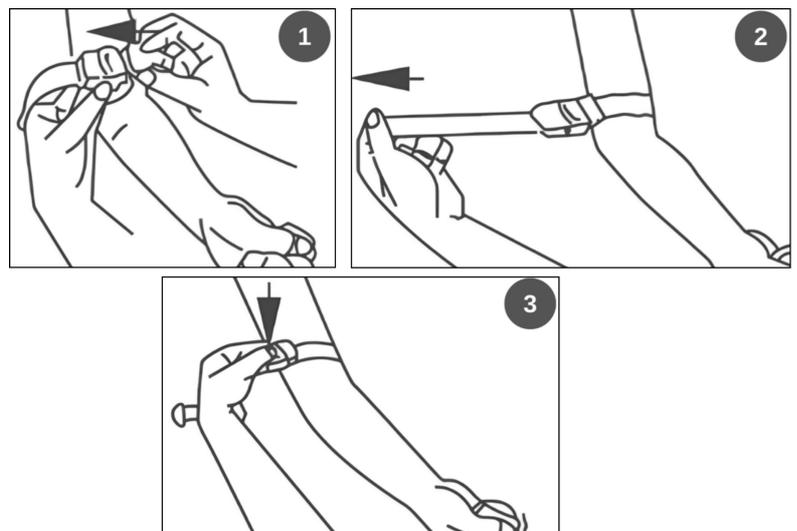
This device requires no installation, assembly, or calibration.

Before use, check for:

- visible damage
 - torn or frayed textile material
 - buckle malfunction
 - contamination or residues
- △ Discard if damaged.

Application

Place 5–7 cm above puncture site on clean, intact skin (fig. 1). Tighten to restrict venous, not arterial, flow (fig. 2). Avoid pinching or over-tightening. Remove immediately after use by pressing the release button (fig. 3).



Warning: Never apply on or near the neck — risk of suffocation. Any use beyond the stated intended purpose is improper and at the operator's own risk. The manufacturer is not liable for such misuse.

3. SINGLE-PATIENT USE

This device is intended for single-patient use only.

The tourniquet may be used multiple times on the same patient during a treatment episode if necessary.

To maintain hygiene:

- if visibly soiled, wipe with a alcohol disinfectant wipe
- allow the device to air dry before reuse on the same patient

△ Do not use on multiple patients.

Discard the device if:

- it becomes contaminated
- the textile band or buckle is damaged
- proper hygiene cannot be maintained

4. STORAGE & SHELF LIFE

Shelf life: 3 years.

Storage: Dry, cool place (10–30°C), away from sunlight, excessive humidity and chemical exposure.

5. RISK & SAFETY INFORMATION

Improper use may cause bruising, numbness, or nerve damage. Temporary skin marks or discomfort may occur; discontinue use if pain, redness, or swelling persists. Risks associated with the device are considered acceptable based on the manufacturer's risk management process.

△ Warnings & Precautions:

- Do not apply for over 1 minute. If unsuccessful, wait 2 minutes before retrying.
- Monitor skin color, temperature, and compression effect.
- Use only on limbs—not near or on the neck (risk of suffocation).
- Cut immediately if stuck and removal is unsafe.
- Do not use on damaged skin.
- Do not use if the device is damaged.
- Protect from heat, sunlight, and chemicals.
- Not for use by untrained persons, children, or impaired individuals.

6. DISPOSAL

Dispose of the device according to local waste regulations.

- General waste if not contaminated
- Medical waste if contaminated with biological material

Dispose of per local laws and EU Waste Directive 2008/98/EC.

7. PACKAGE & LABEL SYMBOLS

Contents: 1x Tourniquet.

Packaging: Sealed pouch.

Sterility: Non-sterile.

Storage: See Section 4.

UDI: The Unique Device Identifier (UDI) specific to this product variant (e.g., size and color) is printed on the product label and packaging.

Labeling Symbols (CE & UKCA marked; compliant with EN ISO 15223-1:2021):

	CE conformity mark		UKCA conformity mark
	Reference number		Medical device
	Manufacturer		Lot code

	Attention		Date of manufacture
	Keep away from moisture		Please follow Instruction for use
	EU representative		Keep out of sunlight
	Do not use if package is damaged		Use-by date
	Single-Patient Multiple Use		Non sterile product
	Temperature limit - 10°C / 30°C		Unique Device Identifier

8. CONTACT

Manufacturer information:

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Incident Reporting:

Report any serious incident or field safety corrective action to the Manufacturer (Rolseley Ltd) and, as applicable, to the MHRA (UK) or the national competent authority of the EU Member State where the incident occurred, in accordance with UK MDR 2002 and EU MDR 2017/745 Article 87.