

TOE-*niquet*TM

A simple, safe and cost effective
digital tourniquet solution



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Product Information

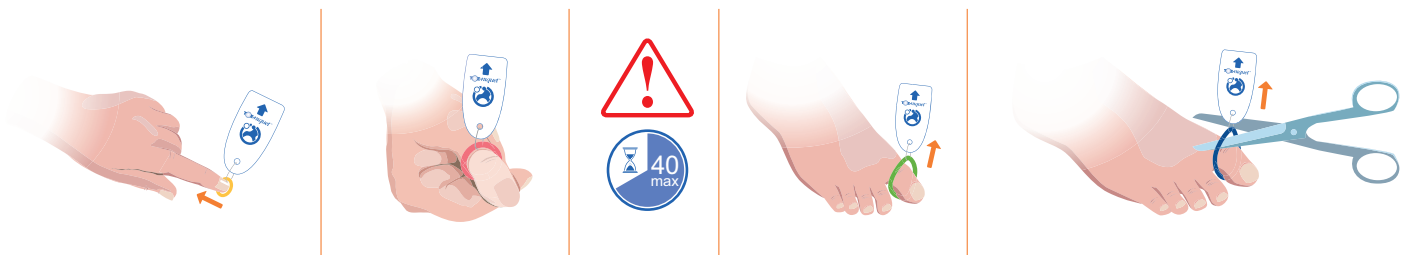
Toe-niquets™ are Single Use disposable 'elastic-ring' tourniquet devices designed to stop blood flow in digits of the hands and feet (fingers and toes) for use during surgery, trauma or first aid. Toe-niquets™ are easily applied by rolling over the tip of any digit.

Toe-niquets™ allow you to exanguinate (remove) blood from a digit and stop further blood flow at the point of application. Treatment may continue safely, quickly and easily without the risks of visual or physical obstructions associated with bleeding.

Toe-niquets™ are used during surgery, trauma or first aid by Medical Doctors, Surgeons, Surgical Theatres, Emergency Room Facilities and Podiatrists worldwide. They are supplied sterile ready for use in any clinical or surgical environment.

User Guide

Prepare the patient fully ready for treatment and select the correct size Toe-niquet™



1. Prepare the patient fully ready for treatment and select the correct size Toe-niquet™.

2. As the Toe-niquet™ is applied the blood is pushed out (exanguinated).

3. Apply an appropriate dressing or wound closure.

4. Pull on the Tag and nylon tie to lift the Toe-niquet™ and cut to remove.



Warning! – DO NOT exceed maximum length of tourniquet application or use on patients where ischaemia is contraindicated. Conform to local, national and international clinical protocols and guidelines.

Conformity to Approved Clinical Standards

Sterility

Toe-niquets™ are individually packed, sterilised by irradiation and offer a 5 year shelf life. The peel pouch is made from high quality Tyvek and conforms to BSEN-5 1999 Standard, providing full traceability with batch numbers for medical records.

Toe-niquets™ carry the 'Single Use' only symbol for improved patient safety.

Regulatory Standards

Toe-niquets™ conform to current EC Medical Devices Directive (93/42/EEC Annex V).

Toe-niquets™ conform to current FDA Directives.

Toe-niquets™ are CE Sterile and carry the CE Class 1 – Sterile Mark

Toe-niquets™ are FDA Sterile registered and carry a FDA Registered Mark.

Health Services Standards

Toe-niquets™ meet the criteria and recommendations set out in the UK NHS National Patient Safety Agency's, Rapid Response Report (NPSA/2007/RRR007 dated on 9th December, 2009) aimed at 'Reducing risks of tourniquets left on after finger and toe surgery'.

CE 0120

FDA



STERILE R



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Key Product Features

Hypoallergenic

4 sizes (S, M, L, XL)

2 sets (S&M, L&XL)

Colour Coding & Strong Pull Tag

Optimal Elasticity Vs Compression Ratio

- ✓ Latex free Medical Grade Silicone
- ✓ Increased intra operative options
- ✓ Less Stock for Distributors and Users
- ✓ Improved Safety & Easier to Removal
- ✓ Easy application, reduced tissue trauma

Product Range



Size 1

Small
8mm

Medium
11mm



Measurements are
internal diameter

Large
14mm

Extra Large
17mm

Size 2



Bag of 10 Units
Dimensions:
120mm x 180mm x 20mm
Weight: 55g
Code: **40660**



Bag of 10 Units
Dimensions:
120mm x 180mm x 20mm
Weight: 65g
Code: **40670**

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Toe-niquet™ Safety data Sheet:

Important Note: This data sheet relates to the material(s) in their final manufactured form as the product is supplied and not to their properties associated with other forms such as raw states. This product should only be used by suitably qualified individuals and in accordance with 'User Manual' - download the latest copy visit www.toe-niquet.com.

1. Manufacturer and Supplier Information:

- a. Company Name: Toe-niquet
- b. Address: 130 Llanover Road, Wembley, Middlesex. HA9 7LT
- c. Tel. No.: +44 20 8908 1425

2. Chemical Name and manufacturer's information:

- a. Product name: Toe-niquets™ (available in a variety of ring sizes)
- b. Chemical Composition: Silicone 100% (Toe-niquet™ ring)

3. Hazardous Identification:

Silicone is considered to be an inert substance. Therefore, when used in accordance with instruction as per intended use, it will be non irritant to skin or eye.

4. First-Aid Measures:

- a. Inhalation : Not applicable
- b. Skin Contact: None required
- c. Eye Contact : Not applicable
- d. Ingestion: Do not induce vomiting. Give 50-100ml of water to drink. Obtain medical attention and allow natural passage through bowels.
- e. Further medical treatment: Symptomatic treatment and supportive therapy as indicated.

5. Fire-fighting Measures:

- a. Combustible but not readily ignited. Combustion or thermal decomposition will evolve toxic, irritant.
- b. Extinguishing media: Water spray, Foam, Dry Powder or CO2.
- c. Fire fighting protective equipment: Self protective clothing should be worn in fire conditions.

6. Accidental release measures:

- a. Do not allow to enter drains, sewers or watercourse.

7. Handling and storage:

- a. Keep away from oxidizing agent, acids, alkalis, moisture, heat, direct sunlight and nitrogen oxide.

8. Exposure controls / Personal protection:

None required

9. Physical and Chemical properties:

- a. Water solubility: Insoluble
- b. Volatile: Non applicable
- c. Water/Oil coefficient index: None

10. Stability and Reactivity:

- a. Reactivity: Stable in room temperature.
- b. Oxidation: None
- c. Condition to avoid: The sources of ignition.

11. Toxicological information:

- a. Inhalation: Combustion or thermal decomposition will evolve toxic and irritant vapour.
- b. Skin Contact: Not Applicable
- c. Eye Contact: Not Applicable
- d. Ingestion: Low oral toxicity.
- e. Long term Exposure: No Data
- f. Other Toxicity: No Data

12. Ecological Information:

- a. Degradation: Non biodegradable
- b. Accumulation: No Data

13. Disposal Information:

Disposal should be in accordance with local, national and international legislation.

14. Transport Information:

No Classification

15. Regulatory Information:

It should be in accordance with local, national and international legislation.

16. Other Information:

- a. May deteriorated from prolonged exposure to sunlight
- b. Product control should be first in, first out.

Safety Features

The two main risks associated with digital tourniquets are damage to peripheral neurovascular structures resulting from excessive pressure or necrosis due to a forgotten digital tourniquet. In fact a study conducted by the UK National Health Service concluded this to be the case and recommended that 'only labelled and bright coloured digital tourniquets designed for purpose' should be used and other devices including surgical gloves should NOT BE USED as digital tourniquets.

Toe-niquets™ have been designed with optimal elastic vs compression ratio to minimise trauma to the tissues. Additionally the use of bright colours and a warning Safety Tag provides a means of identifying the device during use as well as assisting the safe removal the Toe-niquet™ at the end of the procedure. TAG ensures that the device remains visible throughout the procedure and offers a physical obstruction when applying a dressing so that the device is not accidentally left in place.



UK & EU Distribution by:

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Designed & Manufactured by:



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