



Instructions for Use



REF	Descriptions	Unit of Sale
EMP-2551-03	Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm Curved	1 Case of 20

INFORMATION

This instruction for use document is designed to provide a comprehensive source of information for the safe and effective use of Empire Medical SURGOPACK single use instruments. Please retain and consult this document before, during and after the use of this product.

The following conventions are used throughout this document:

- **WARNING** highlights a safety related issue:
Always comply with this information to prevent patient and/or healthcare staff injury
- **CAUTION** highlights product functionality information:
Always comply with this information to prevent product damage
- **NOTE** supplements and/or clarifies procedural information

In the event of a **serious product related incident**, or to request additional product information or a further copy of this IFU, contact us:

+44 2038731071

enquiries@empiremedical.co.uk - FOR USA/overseas Customers please

email at: sales@surgicalinstrumentscompany.com

www.empiremedical.co.uk

COMPLIANCE STATEMENT

The CE1639 mark displayed on the product and product packaging indicates compliance with the European Community Medical Devices Directive 93/42/EEC, as amended, and the standards associated with the device, including manufacture, packaging, risk assessment and quality management systems.

SYMBOL GLOSSARY



Indicates compliance with the Medical Devices Directive EC 93/42/EEC 1639 SGS Notified Body Belgium



Indicates that the device is a medical device as defined in the MDR 2017/745



Indicates the manufacturer's part number

SYMBOL GLOSSARY (continued)



Indicates the manufacturer's batch number



Product is for single use only and must not be re-used or re-processed



Indicates the authorised representative within the European Community



Product is supplied sterilised by ethylene oxide



Product is supplied sterilised by gamma radiation



Indicates a warning notice in the text



Product is supplied non sterile



Manufacturer (the person placing the device on the market)



Do not use product if packaging is damaged



Keep product out of direct sunlight



Store product in a dry environment



Indicates the upper and lower temperature limits which the medical device can be safely exposed to



Indicates the range of humidity which the medical device can be safely exposed to



Do not re-sterilise



Consult instructions for use



Indicates the date of manufacture



Indicates the product expiry date



Caution: USA Federal law restricts this device to sale by, or on the order of, a physician

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Text Prepared:



Instructions for Use - Nail Cutter Roller Spring 14cm Curved

IMPORTANT WARNINGS

• FOR PROFESSIONAL USE ONLY

- EMPIRE MEDICAL SURGOPACK ® Single Use Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm Curved are intended for use by , or under the instruction of , suitably qualified healthcare professionals only.
- Any healthcare professional performing any clinical procedure which involves the use of a EMPIRE MEDICAL SURGOPACK ® single use instrument is entirely responsible for determining the suitability of its use for any intended clinical application.
- SURGOPACK single use instruments must be handled with meticulous care when in use to avoid needle-stick injuries to clinicians and their patients.
- EMPIRE MEDICAL SURGOPACK ® Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm Curved are designed to be single use devices and **MUST NOT BE REUSED NOR REPROCESSED** under any circumstance , as this practice would be associated with the following attendant risks:
 - **Re-Use:** as with all types of surgical instruments, there is a significant risk of onward transmission of infection, including spongiform encephalopathies, should they be reused
 - **Re-Processing:** Single use instruments are not designed, nor manufactured to facilitate re-processing, and should this occur, their fitness for purpose will be severely compromised, with significant attendant clinical risk to both patients and operators
- If the product or product packaging is seen to be defective prior to use, **DO NOT USE** and contact your local representative or the EMPIRE MEDICAL Customer Support team, who will arrange for the return and replacement of the faulty product
- Before using this product, familiarise yourself with the product and its operational components
- Read and understand the instructions for use detailed in this document and on the product packaging - pay particular attention to **WARNING** information



INDICATIONS FOR USE

EMPIRE MEDICAL SURGOPACK ® Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm Curved Suitable for cutting normal or thickened toenails. Manufactured from medical grade surgical stainless steel.

- SURGOPACK® Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm help reduce user fatigue and RSI (repetitive strain injury).
- SURGOPACK® Single Use Nail Cutter with a high performance curved head and smooth action roller spring mechanism to help reduce user fatigue and RSI (repetitive strain injury). Suitable for cutting normal or thickened toenails. Manufactured from medical grade surgical stainless steel.

CONTRAINDICATIONS

- Contraindicated where the use of EMPIRE MEDICAL SURGOPACK ® Single Use Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm Curved are not deemed to be clinically appropriate.
- EMPIRE MEDICAL SURGOPACK ® Single Use Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm Curved are not intended for non-professional , domestic or recreational use.



INSTRUCTIONS FOR USE

- 1 Before commencing the procedure ensure that EMPIRE MEDICAL SURGOPACK ® Single Use Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm Curved selected are appropriate for the safe and effective completion of the procedure.
- 2 Examine the pack before use. **The pack must not be used if the wrapper or seal is broken**
- 3 Open the sterile pack by peeling back the overwrap, and observe the appropriate surgical techniques described in local policies and procedures.
- 4 Take care not to inadvertently traumatise tissues nor cause a sharps injury to either the patient or operator.
- 5 After use , SURGOPACK ® Single Use Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm Curved must be placed safely into an appropriate clinical sharps container , and disposed in accordance with local policies and procedures.



STORAGE AND HANDLING

- Store in a clean, dry environment out of direct sunlight
- Disposal of EMPIRE MEDICAL SURGOPACK ® Single Use Sterile Single Use Podiatry Nail Cutter Roller Spring 14cm Curved must be managed strictly in accordance with local healthcare waste management policies and procedures.



SURGOPACK? ECO-FRIENDLY? HOW? We are manufacturers the steel used to manufacture SURGOPACK is up to 99 % recyclable .
Causing no environmental considerations , as the steel is retrieved by a magnetic separator and can be used to produce new products .
Help us protect the Earth.

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