

Instructions for Use

REF Unit of Sale Descriptions Instrapac[®] McIndoe Forceps - 1:2 Toothed 15cm 7989 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 Robinson Healthcare Instrapac® 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:

- **\$** 01909 735000
- enquiries@robinsonhealthcare.com
- www.robinsonhealthcare.com

COMPLIANCE STATEMENT

The CE 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 (For further information, visit robinsonhealthcare.com/symbols)

(E 2797
MD
REF

Indicates compliance with the Medical Devices Directive EC 93/42/EEC
Indicates that the device is a medical device as defined in the MDR 2017/745
Indicates the manufacturer's part number

SYMBOL GLOSSARY (continued)

LOT	Indicates the manufacturer's batch number
\bigotimes	Product is for single use only and must not be re-used or re-processed
EC REP	Indicates the authorised representative within the European Community
STERILE EO	Product is supplied sterilised by ethylene oxide
STERILE R	Product is supplied sterilised by gamma radiation
\triangle	Indicates a warning notice in the text
NON	Product is supplied non sterile
	Manufacturer (the person placing the device on the market)
\otimes	Do not use product if packaging is damaged
类	Keep product out of direct sunlight
Ť	Store product in a dry environment
X	Indicates the upper and lower temperature limits which the medical device can be safely exposed to
<u>%</u>	Indicates the range of humidity which the medical device can be safely exposed to
STERNIZE	Do not re-sterilise
ĺĺ	Consult instructions for use
M	Indicates the date of manufacture
	Indicates the product expiry date
Ronly	Caution: USA Federal law restricts this device to sale by, or on the order of, a physician

Robinson Healthcare Ltd Lawn Road, Worksop Nottinghamshire, S81 9LB United Kingdom www.robinsonhealthcare.com

EC REP Advena Ltd Tower Business Centre 2nd Floor, Tower Street Swatar, BKR 4013, Malta

IFU Code: C03386 (For 7989 Only) Version: Rev01 Text Prepared: 09/20





EO

STERILE

Instructions for Use - McIndoe Tissue Forceps

IMPORTANT WARNINGS

- FOR PROFESSIONAL USE ONLY •
- Robinson Healthcare Instrapac® single use McIndoe 1:2 Toothed Tissue Forceps 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 Robinson Healthcare Instrapac® single use instrument is entirely responsible for determining the suitability of its use for any intended clinical application
- Instrapac® single use instruments must be handled with meticulous care when in use to avoid needle-stick injuries to clinicians and their patients
- Robinson Healthcare Instrapac® single use McIndoe 1:2 Toothed Tissue Forceps 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 Robinson Healthcare 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

Robinson Healthcare Instrapac® single use 1:2 Toothed McIndoe Tissue Forceps are intended for use by appropriately qualified healthcare professionals only, and they are:

- Sterile single use medical devices, indicated for handling and manipulating tissues during surgical procedures
- Instrapac[®] single use McIndoe 1:2 Toothed Tissue Forceps are designed to perform in a specific manner - the operating clinician is entirely responsible for the selection of this instrument, based on their clinical training and experience, and which they deem to be most appropriate to complete the surgical procedure in hand
- Instrapac[®] single use McIndoe Toothed 15cm, 1:2 Tooth: Indicated for use as fine dissecting forceps during delicate surgical procedures, specifically designed to grasp or hold soft tissues during procedures, and for the application of surgical dressings, typically during plastic or dermatological surgical procedures

CONTRAINDICATIONS

- Contraindicated where the use of Instrapac® single use McIndoe 1:2 Toothed Tissue Forceps are not deemed to be clinically appropriate
- Robinson Healthcare Instrapac® single use McIndoe 1:2 Toothed Tissue Forceps are not intended for non-professional, domestic or recreational use

INSTRUCTIONS FOR USE

- 1 Before commencing the procedure ensure that Robinson Healthcare Instrapac® single use McIndoe 1:2 Toothed Tissue Forceps selected are appropriate for the safe and effective completion of the procedure
- Examine the pack before use. The pack must not be used 2 if the wrapper or seal is broken
- Open the sterile pack by peeling back the overwrap, 3 and observe the appropriate surgical techniques described in local policies and procedures
- Take care not to inadvertently traumatise tissues nor cause a sharps injury to either the patient or operator
- After use, Instrapac[®] single use McIndoe 1:2 Toothed Tissue Forceps 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 Instrapac[®] single use McIndoe 1:2 Toothed Tissue Forceps must be managed strictly in accordance with local healthcare waste management policies and procedures



Robinson Healthcare Ltd Lawn Road, Worksop Nottinghamshire, S81 9LB United Kingdom www.robinsonhealthcare.com

EC REP Advena Ltd Tower Business Centre 2nd Floor, Tower Street Swatar, BKR 4013, Malta

IFU Code: C03386 (For 7989 Only) Version: Rev01 Text Prepared: 09/20







EO



