

Instructions, Washing, Decontamination & Sterilising instructions

Frankenman International Limited

ENGLISH

These Instructions cover the following instruments
Frankenman re-usable Anvil Grasping Forceps

Product Name	Product Code
Frankenman Round Tipped Anvil Grasping Forceps	F-RT1
Frankenman Trocar -Tipped Anvil Grasping Forceps	F-TT1



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

All stainless steel re-usable instruments from Frankenman have been inspected for functionality before shipment to customers. Should you experience any problems when using them, please inform Frankenman or your local Frankenman/Chex distributor.

INDICATIONS

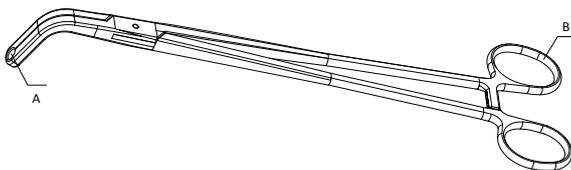
The Frankenman Round Tipped and Trocar Tipped Anvil Grasping Forceps are designed solely for the purpose of grasping appropriate Circular Stapler anvil shafts of the Frankenman/Chex CS circular stapler product range.

CONTRAINDICATIONS AND WARNINGS

- Care must be taken when handling the Trocar Tipped instrument range to avoid damage to surrounding tissue or the operator.
- If the Frankenman F-TT1 is used to puncture tissue to gain access to appropriate anvil care must be taken to ensure anvil lock is in the fully closed position, with handle fully compressed, to avoid surrounding tissue damage. (as shown in Fig 1.)
- When using either instrument care must be taking to avoid damage to surrounding tissue when jaws are closed. Closing of jaws should ideally be done under direct vision.
- These instruments are not designed, nor have they been tested, to be used in any other manufacturer's product where incorrect placement of the devices could cause damage to the anvil shaft itself. Frankenman accepts no liability for the products use with any other manufacturers Circular Stapling devices.
- When using the Frankenman F-RT1 Grasping Forceps do not grasp the anvil shaft other than in the grooves provided in the anvil shaft. If the anvil is grasped around the Anvil Locking Spring this could inhibit docking of the anvil shaft to the Circular Staplers trocar and create misfiring of the instrument.

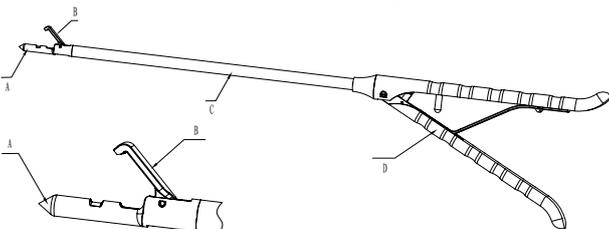
SCHEMATIC DRAWINGS

- Frankenman F-RT1 Round Tipped Anvil Grasping Forceps



- A. Round Tip
B. Handle (supplied with ratchet lock)

- Frankenman F-TT1 Trocar Tipped Anvil Grasping Forceps



- A. Trocar Tip
B. Anvil Lock
C. Instrument Shaft
D. Handle (supplied with ratchet lock)
E. Anvil Locking Spring

STERILIZATION

The surgical instruments must be sterilised prior to use using high temperature steam. Frankenman has no control over equipment and practice in your hospital: the sterility of any instrument is the responsibility of the customers.

To sterilise wrap the instruments individually or wrap the complete kit trays and use a steam autoclave. The standard parameters of 134-137 degrees centigrade for 3 – 3 ½ minutes are appropriate.

Note: individual autoclaves (even those of the same model) may vary in performance characteristics and must be validated; accordingly these aforementioned parameters were achieved during the validation of multi-layer instrument trays. The autoclave used was a vacuum assisted air removal phase prior to steam admission for sterilisation.

For further information related to the use of these instruments, please contact your Frankenman distributor or representative.

WASHING AND DECONTAMINATION

The Decontamination Process is dependant on effective cleaning and washing of instruments. Severe soiling should be removed under running water in a sink draining continually, using brushes and rigid nylon bristles. Attention should be paid to any cannulated instruments and any screw holes where debris may enter. Staff carrying out decontamination and washing process should operate according to local policy and procedures.

For automated washing machines a typical cycle should include the following cool/warm detergent below coagulation temp (<60 degree C), rinse to remove detergent. Hot wash Disinfection (>71 degrees C for 3mins), final rinse in purified water. Heat around drying cycle.

Damaged Instruments

If any instruments have been damaged or are found to be below your standard of expectation, please supply details so that we may investigate and rectify the situation.

Before returning any instrument to Frankenman, please ensure that washing and sterilising has been carried out. All equipment used must have a validated cycle. The reference numbers should be entered onto the decontamination certificates and included in any shipping documents and technical incident report forms supplied by Frankenman or its distributor if appropriate.



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