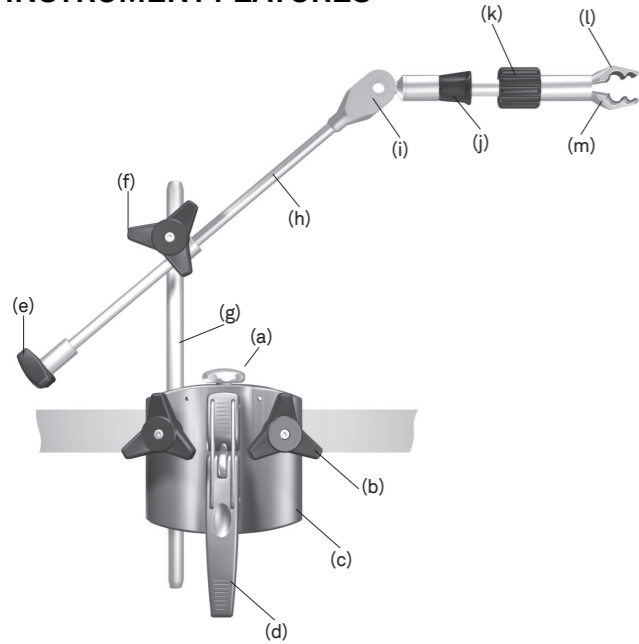


FastClamp™

ENDOSCOPIC CLAMPING SYSTEM

EN Instructions for use

INSTRUMENT FEATURES



Legend

- (a) Jaw Adjustment Knob
- (b) Vertical Bar Clamping Knob
- (c) Table Clamp
- (d) Clamping Handle
- (e) 280° Swivel Joint Locking Knob
- (f) Arm Positioning Knob
- (g) Vertical Bar
- (h) Instrument Clamp
- (i) 280° Swivel Joint
- (j) 360° Jaw Rotation Knob
- (k) Rotate to open and close jaws
- (l) Rubber lined to protect instruments
- (m) Jaws for accommodating 5 mm and 10 mm instruments

SYMBOLS USED ON PRODUCT AND PACKAGES

- Date of manufacture
- Manufacturer of device
- Consult instructions for use
- Non-sterile
- CAUTION:** Federal law in the U.S.A. restricts this device to sale by or on the order of a physician.

Surgical Innovations

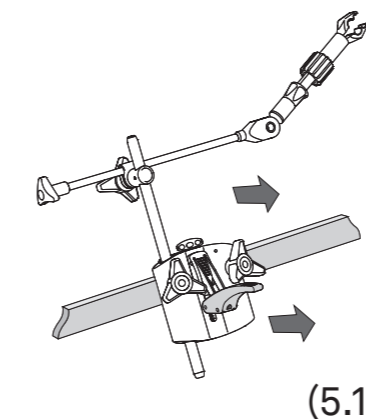
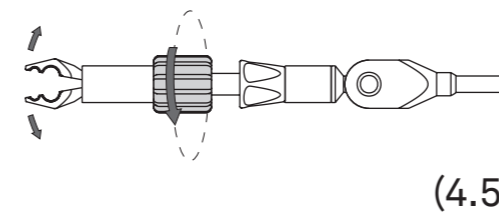
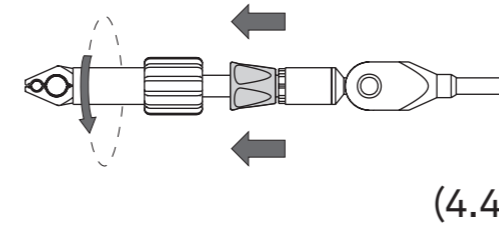
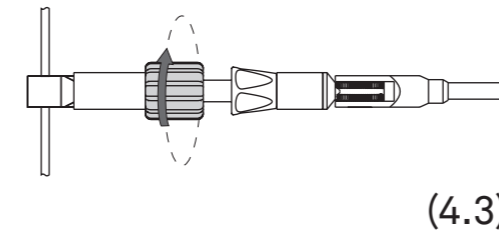
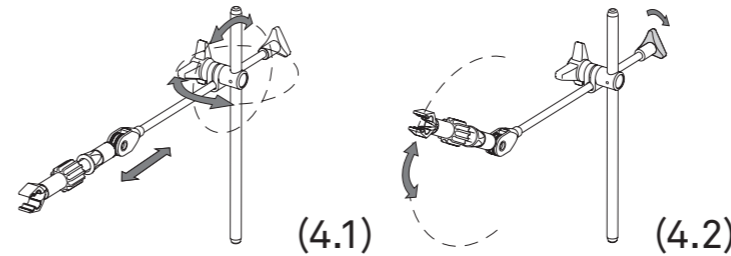
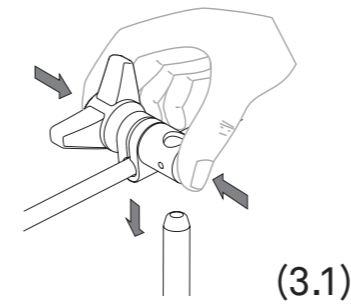
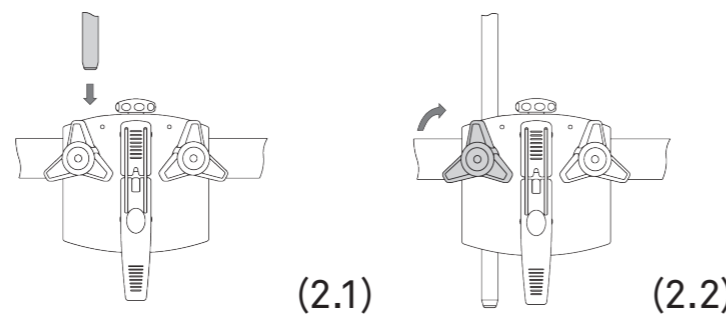
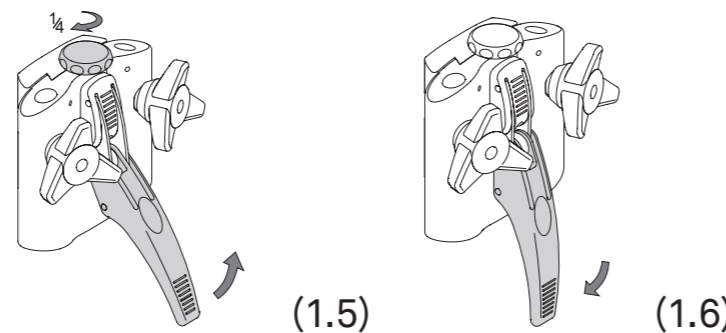
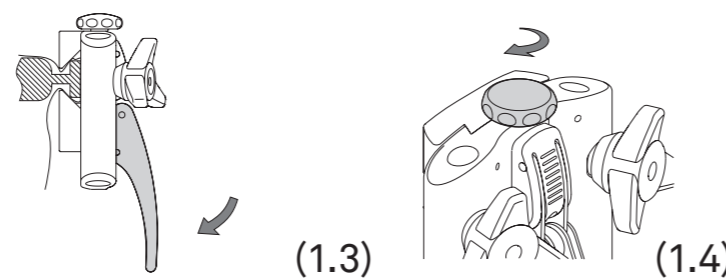
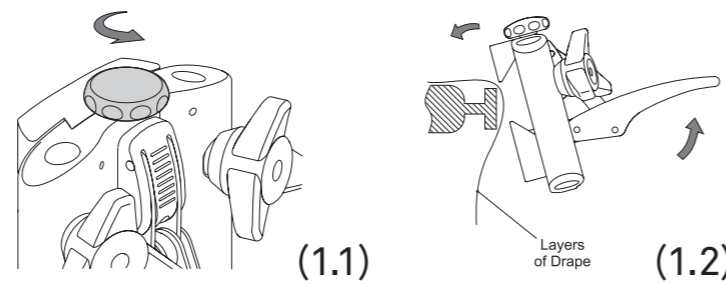
CE Rx Only

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SYSTEM PART NUMBERS

Description	Part number
FastClamp System Assembly	A-1000
Extended FastClamp System Assembly	A-1001
FastClamp Bar 300mm	BC-1030-01
FastClamp Bar 500mm	BC-1050-01
FastClamp Bar 700mm	BC-1070-01
Bariatric Bar	BC-1090-01
Instrument Clamp Assembly	IC-1000-01
Extended Instrument Clamp Assembly	IC-1001-01
Table Clamp	TC-1000-01

ASSEMBLY / DISASSEMBLY



EN INDICATIONS FOR USE

The FastClamp Endoscopic Clamping System is indicated for use in laparoscopic procedures for the surgeon to clamp endoscopic instruments in a fixed position for a period of time.

The FastClamp Endoscopic Clamping System is intended for use with a correctly positioned liver retractor, for holding a liver up to a maximum of 4kg.

CONTRAINDICATIONS

The FastClamp Endoscopic Clamping System is not indicated for use when minimally invasive surgical techniques are contraindicated.

DESCRIPTION

The FastClamp Endoscopic Clamping System comprises of an instrument clamp, vertical bars and table clamp to provide secure over the drape endoscopic instrument clamping.

WARNINGS

Devices shall be used in accordance with these instructions for use. Read all sections of this insert prior to use. Improper use of this device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and cause a serious injury to the patient or health care provider.

PRECAUTIONS

Use of device for a task other than that for which it is intended will usually result in a damaged or broken device. Prior to use, inspect device to ensure proper function and condition. Do not use devices if they do not satisfactorily perform their intended function or have physical damage. Only the cleaning and sterilisation processes which are defined within these instructions for use have been validated. Use only neutral pH (6-8) detergent solutions. The use of alkaline detergents may damage the surface coatings used on the table clamp. Handle with care. Do not use if surface coatings are cracked or damaged.

COMPATIBILITY

The FastClamp Endoscopic Clamping System is compatible with the Endoflex range of Surgical Retractors. The Instrument clamp will also attach to endoscopic instruments with a shaft diameter of 5mm or 10mm. The FastClamp Instrument Clamp, Table Clamp and Vertical Bars are only to be combined with devices from the FastClamp range. Do not combine with any other table clamp system.

SUPPLIED STATE

The FastClamp Endoscopic Clamping System is packed non-sterile and must be cleaned and sterilised prior to each use.

LIMITATIONS ON REPROCESSING

End of life is determined by wear and damage due to use, subject to inspection criteria outlined below.

RE-PROCESSING

POINT OF USE
Disassemble the device prior to cleaning. Remove Instrument Clamp from Vertical Bar. Remove Vertical Bar from Table Clamp. All knobs must be loosened. Thoroughly rinse the instruments under cool running tap water (<35°C/95°F) to remove gross soil.

CONTAINMENT AND TRANSPORTATION

It is recommended that instruments are reprocessed as soon as is reasonably practical following use. It is recommended to keep the instruments in moist conditions during transport for decontamination.

PREPARATION FOR CLEANING

Thoroughly rinse the instruments under cool running tap water (<35°C/95°F) to remove gross soil.

MANUAL CLEANING

1. Prepare a sink with a liquid enzymatic detergent (Viruzyme at 4ml per litre or equivalent neutral enzymatic detergent pH 6-8). If other enzymatic solutions are used, prepare in accordance with the detergent manufacturer's instructions.
2. Immerse the devices in the detergent and allow to soak for a minimum of 5 minutes or as per the detergent manufacturer's instructions. Actuate all movable parts during the initiation of the soak time.
3. Use a soft brush for 2-3 minutes to manually clean the soil from the devices. Actuate devices while brushing, paying particular attention to hinges, crevices and other difficult to clean areas.
4. Remove the devices from the detergent and rinse in running tap water.
5. Prepare an ultrasonic bath (compliant with HTM 01-05 or equivalent regional standard) with an enzymatic detergent (Viruzyme at 4ml per litre or equivalent neutral enzymatic detergent pH 6-8). If other enzymatic solutions are used, prepare in accordance with the detergent manufacturer's instructions.
6. Immerse the devices completely in the ultrasonic bath for a minimum of 10 minutes at 30 °C (86° F) (cycle frequency 37 kHz).
7. Remove the devices from the ultrasonic bath and rinse in running tap water.
8. Dry the devices with a clean, lint free cloth and HEPA filtered pressurised air.
9. Visually inspect each device for any remaining residual contamination. If the devices are not visually clean, repeat the full process as described above until they are clean.

AUTOMATED CLEANING

NOTES:

- A washer/disinfector with demonstrated efficacy (e.g. FDA approval, validated to ISO 15883, compliant with HTM 01-01) should be used.
 - Compatibility and cleaning efficacy was tested with neutral enzymatic detergents to achieve the required cleaning before disinfection.
 - Wash time, disinfection time and dry time are each shown as a minimum because it is dependent upon the load size placed into the washer/disinfector.
 - The thermal disinfection cycle should be performed to achieve a minimum value A0 = 600 (e.g. 90°C/194°F for 1 minute according to ISO 15883-1) and is compatible with FastClamp.
 - Enzyme solutions should be used in accordance with manufacturer's instructions, which include proper dilution of the enzymatic detergent and contact with equipment for the amount of time specified on the label.
1. Prepare a sink with a liquid enzymatic detergent (Viruzyme at 4ml per litre or equivalent neutral enzymatic detergent pH 6-8). If other enzymatic solutions are used, prepare in accordance with the detergent manufacturer's instructions.
 2. Immerse the devices in the detergent and allow to soak for a minimum of 5 minutes or as per the detergent manufacturer's instructions. Actuate all movable parts during the initiation of the soak time.
 3. Use a soft brush for 2-3 minutes to manually clean the soil from the devices.
 4. Remove the devices from the detergent and rinse in running tap water.
 5. Prepare an ultrasonic bath (compliant with HTM 01-05) with an enzymatic detergent (Viruzyme at 4ml per litre or equivalent neutral enzymatic detergent pH 6-8). If other enzymatic solutions are used, prepare in accordance with the detergent manufacturer's instructions.
 6. Immerse the devices completely in the ultrasonic bath for a minimum of 10 minutes at 30 °C (86° F) (cycle frequency 37 kHz).
 7. Remove the devices from the ultrasonic bath and rinse in running tap water.
 8. Transfer the devices to a validated automated washer disinfector for processing. The following cycle parameters are to be used as a guideline and indicate the minimum cycle times / temperatures to achieve the required level of device cleanliness (Longer times may be used if required):

Cycle Phase	Time (Minimum)	Temperature	Detergent
Pre –rinse	2 mins	Cold tap water	---
Main Wash Enzyme wash	4 mins	Hot water 55 °C (131 °F)	Neutral Enzymatic detergent (pH 6-8) as per manufacturer's recommended concentration
Rinse 1	2 mins	Hot tap water	---
De ionized water rinse 2	2 mins	65 °C (149 °F)	---
Hot thermal rinse	1 min	90 °C (194 °F)	Heated RO water
Drying	9 mins	90 °C (194 °F)	---

9. On completion of the cycle remove the cleaned device parts from the washer and perform a thorough visual inspection for any remaining residual contamination. If the devices are not visually clean, repeat the full process as described above until they are clean.

MAINTENANCE AND INSPECTION CRITERIA

Proper care and handling is essential for satisfactory performance of any surgical device. The previous cautions should be taken to ensure long and trouble-free service from all your surgical devices. Inspect devices before each use for broken, cracked, tarnished surfaces, movement of hinges, wand chipped or worn parts. If any of these conditions appear, do not use the device. Return devices to an authorized repair service centre for repair or replacement. Immediately proceed to recommended steam sterilisation. Do not store device prior to sterilisation.

STERILISATION

Sterilisation is accomplished by steam autoclave. The following are Surgical Innovations Ltd guidelines for instrument sterilisation.

Pre-vacuum (Dynamic air removal) Sterilisation 'Wrapped instruments'

Steriliser: Pre-vacuum Steam Steriliser

Sterilisation time: 4 minutes

Sterilisation temperature:132 °C (270°F)

Dry Time: 70 minutes (minimum)

Sample preparation: Individually wrapped in two layers of 1-ply polypropylene wrap (Using sequential wrapping techniques).

Gravity Displacement Sterilisation 'Wrapped instruments'

Steriliser: Gravity Displacement Steam Steriliser

Sterilisation time: 30 minutes

Sterilisation temperature:132 °C (270°F)

Dry Time: 90 minutes (minimum)

Sample preparation: Individually wrapped in two layers of 1-ply polypropylene wrap (Using sequential wrapping techniques).

PACKAGING

Wrap devices in accordance with local protocols and procedures.

STORAGE

After sterilisation, instruments should remain in sterilisation wrap and be stored in a clean, dry environment.

ASSEMBLY / DISASSEMBLY

1. Securing the Table Clamp

- 1.1 Fully unscrew Jaw Adjustment Knob by rotating counter-clockwise.
- 1.2 Offer Table Clamp to operating table – whilst holding the Clamping Handle in the 'open' position.
- 1.3 Push Clamping Handle closed.
- 1.4 Tighten Jaw Adjustment Knob in a clockwise direction until finger-tight.
- 1.5 Release Clamping Handle and turn Jaw Adjustment Knob an additional 1/4 turn in a clockwise direction.
- 1.6 Push Clamping Handle closed; a positive locking action should be felt. Ensure the Table Clamp is secure and ready for use.

2. Locating the Vertical Bar into the Table Clamp

- 2.1 Insert the Vertical Bar into one of the holes in the Table Clamp.
- 2.2 Tighten the Bar Clamping Knob by rotating clockwise.

3. Locating the Instrument Clamp onto Vertical Bar

- 3.1 Unscrew and push Arm Positioning Knob as shown to align holes and locate the Instrument Clamp onto the Vertical Bar.

4. Manipulating the Instrument Clamp

- 4.1 Unscrew the Arm Positioning Knob counter-clockwise to allow the Instrument. Clamp to be rotated about the horizontal or vertical axis and to be extended or retracted. Once the arm has been positioned screw the Arm Positioning Knob clockwise to lock.
- 4.2 Rotate Swivel Joint Locking Knob counter-clockwise to release 280° Swivel Joint. Reposition the Jaws and lock by rotating Swivel Joint Locking Knob fully clockwise until 'finger-tight'.
- 4.3 Push 360° Jaw Rotation Knob forward and rotate. Release knob to lock.
- 4.4 Rotate Jaw Locking Knob counter-clockwise to open Jaws.4.5 Release Clamping Handle and turn Jaw Adjustment Knob an additional 1/4 turn in a clockwise direction.
- 4.5 Insert instrument, rotate Jaw Locking Knob fully clockwise to lock.

5. FastClamp Removal

- 5.1 The FastClamp system can be removed as a complete system by releasing the Clamping Handle and lifting the system away from the operating table.

SURGICAL INNOVATIONS LTD GUARANTEE

All Surgical Innovations Ltd products are guaranteed to be free of defects in material and workmanship. Any product which proves to be defective in material or workmanship will be repaired or replaced at our discretion. This guarantee specifically does not cover damage to the product by overstress or mechanical shock.

Repair, alteration or modification of any instrument by persons other than Surgical Innovations Ltd, or instruments subjected to misuse or abuse will result in immediate loss of guarantee.

If Surgical Innovations Ltd instruments are damaged by accident or when used for a purpose other than originally intended, a repair charge will apply. Surgical Innovations Ltd offers a 2 year guarantee.

REPAIR SERVICE

If any Surgical Innovations Ltd instrument needs a service, return it to your authorised Surgical Innovations Ltd representative or the address stated. If the repair is covered under guarantee, it will be repaired or replaced at no charge when requested in writing. A nominal service charge will be made for repaired instruments outside the guarantee. Note: Guarantee is void if Surgical Innovations Ltd instruments are repaired by any other repair service, subjected to abuse, or improperly reprocessed. All instruments must be cleaned and sterilised prior to returning to Surgical Innovations Ltd. For repair services and/or advice for use concerning this instrument, please contact your local Surgical Innovations Ltd representative.