

D0678 / Rev.C / DCR00855

# Safety Trocar



### Item numbers:

RU 0361-08/06	RU 0361-08/21	RU 0361-08/22
RU 0361-08/23	RU 0361-08/24	RU 0361-09/06
RU 0361-09/21	RU 0361-09/22	RU 0361-09/23
RU 0361-09/24	RU 0361-11/01	RU 0361-99/22
TR350-035	TR350-050	TR350-054
TR350-055	TR350-100	TR350-110
TR350-125		

# Intended use

- The decision on the suitability of the instrument for the intended application lies with the user. We assume no liability for the consequences of improper application and preparation.
- As the blind insertion of the first trocar is, without doubt, the most dangerous step during a laparoscopic procedure. By using the security trocar, the risk is minimized.
- The security mechanism is unlocked by activating the locking ratchet. The security obturator slides back and the sharp sleeve becomes free during insertion. The security obturator is activated again after penetrating the abdominal wall and is locked automatically. After that the trocar tip is secured again.

#### Function test

 After delivery and before each use each new instrument must undergo a thorough visual examination and must be tested for functionality. If the instrument exhibits any external faults (scratches, breakages, cracks, notches, damaged insulation, bent parts or stiffness) or if it does not function in the way described, please inform us as manufacturer or our sales partners immediately.



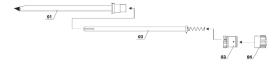
Do not use any damaged instruments.

## First use of new instruments

 The brand-new instrument must be taken out of its polyethylene bag to avoid condensation and must be

- stored in a clean, dry (max. atmospheric humidity of 75% RH) and aired protective container at room ambient temperature until first preparation.
- Security trocar is delivered non-sterile. The instrument must be cleaned and sterilized before the first use.

# Instructions for disassembly



- 01 Sharp Sleeve
- 02 Security Obturator for the sharp Sleeve
- 03 Locking Ratchet
- 04 Knurled Cap
- Please only dissemble instruments that have been prewashed.
- With one hand, hold the security trocar at the locking ratchet 03 and, with the other hand, unscrew the knurled cap 04. Remove the locking ratchet 03. Slightly tilt back the sharp sleeve 01 until the security obturator for the sharp sleeve 02 (including the spring) glides out.
- The security trocar is now completely disassembled.

#### Instructions for assembly

- Make sure when inserting the security obturator 02 into sharp shaft 01 that the setting-pin rotates smoothly in the guidance of the sharp sleeve 01.
- Make sure when sliding the locking ratchet 03 onto the spring and onto the sharp sleeve 01 that the setting-pin rotates smoothly into the guidance and that the locking-wheel of the locking ratchet 03 points to the sharp sleeve.
- Close the locking ratchet 03 by taking the sharp sleeve 01 into one hand and turning the locking ratchet 03 clockwise with the other hand. The locking ratchet 03 is closed when a clicking noise can be heard. Both marks have to be placed in the same line. Screw the serrated cap 04 on the locking ratchet 03.
- Check the instrument for proper function.
- The Security Trocar is now completely assembled.

### Handling and warning

## References for activating the safety mechanism:

For activating the safety mechanism, turn the locking ratchet marked with the white mark (positioned above

the arrow) clockwise until reaching the notch of the sharp sleeve 01. A clicking noise can be heard. The safety mechanism and the trocar tip are activated when the mark is located in such a position. After inserting the trocar tip into the abdominal wall, the safety mechanism is activated again. The risk of injury in the abdomen can be extremely minimized.



Please observe our instructions for preparation A0462 for reusable instruments (thermo resistant). In case you do not have them please ask for them.

### Product-specific instructions for preparation:

- · Restriction of preparation:
- There are not limitations or restrictions concerning the number of reprocessing cycles.
- Usage site:
- To avoid the drying of surgery residues on the trocar and cross-contamination in the operating room, the security trocar must be immersed immediately after use in a combination of cleaning agents and disinfectants. The manufacturer's instructions for cleaning agents and disinfectants must be observed.
- · Preparation for decontamination:
- The safety trocar is to be disassembled for cleaning and disinfection. The instructions for disassembly are to be followed.
- · Cleaning and disinfection: automatic / manual
- Take the cleaning efficiently for removing blood, pus and protein residues.
- · Maintenance, control and testing:
- Moving components must be oiled and revolving stop cocks and pistons lubricated before sterilization. We recommend using our special oil spray RU 8880-00.
- All plastic parts have to be checked of porosity, cracks and abrasion. All damaged parts have to be replaced by original components.
- Before each sterilization procedure the security trocar has to be assembled and tested for function, wear and damage and replaced, if necessary.

#### Repairs

 Even when used as intended surgical instruments are subject to more or less severe wear, depending on how intensely they are used. This wear cannot be avoided due to technical reasons.  Please do not carry out any repairs yourself. Servicing and repairs may only be carried out by ourselves - the manufacturer - or by other persons we authorized.

**Safety Trocar** 

Surgical instruments that are to be sent back for repair have to be cleaned, disinfected and sterilized.

### Symbols and explanations

i	Follow the instructions for use
REF	Order number
NON STERILE	Non-sterile
4	Manufacturer
Â	Potential danger for persons or material assets
LOT	Lot-Number
C€	CE-marking



RUDOLF Medical GmbH + Co. KG Zollerstr. 1, 78567 Fridingen, Germany Tel. +49 7463 9956-0 Fax +49 7463 9956-56 mail@rudolf-med.com www.rudolf-med.com