INSTRUCTIONS FOR USE (EN)

LAPAROSCOPY INSTRUMENTS ‘‘SCREW-IN’’ – MONOPOLAR

“SCREW-IN“

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PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

PRODUCT

This instructions for use is valid for the RUDOLF Medical laparoscopy instruments ‘‘Screw-in’’.

The laparoscopy instruments ‘‘Screw-in’’ are connected to appropriate monopolar high frequency (HF) cables for endoscopic procedures.

The proper handling and use of these high-quality products are described below.

The instruments are intended to be used by professional users (surgeons, operating room nurses, medical device reprocessing technicians). The user must be trained on the proper handling of HF instruments.

There are no restrictions concerning the patient population. The instruments should not be used if in the opinion of the attending physician, the risks outweigh the benefit for the patient.

NON STERILE RUDOLF Medical instruments are delivered non-sterile and must be cleaned, disinfected, and sterilized before first use and immediately after each use. Make sure that the packaging is not damaged upon delivery. Protective caps and transport packaging must be removed before reprocessing.

INTENDED PURPOSE

Monopolar instruments are intended to dissect, grasp, cut and coagulate tissue during minimally invasive surgical procedures.

INDICATION

“Screw-in” instruments are intended for use in the medical fields of laparoscopy and endo-gynecology.

CONTRAINDICATIONS

- The instrument is not intended for use on the central nervous and circulatory system.
- Do not use the instrument when at least one of the following situations is given:
  - Patients with a pacemaker or other active implants. Please consult the corresponding expert before using the instrument on the patient.
  - Acute inflammation of the abdominal area
  - Vaginal infection
  - Pregnancy

⚠ WARNINGS AND PRECAUTIONS

General Notes

- Do not use the instrument if the insulation is damaged.
- Only coagulate if the contact surfaces of the instrument are visible. Do not touch any other metallic objects during coagulation.
- Improper use and excessive strain due to twisting / levering can lead to breaks and permanent deformation.
- Do not keep highly flammable or explosive substances nearby.
- Be careful when handling sharp tips and cutting edges because there is a risk of injury.
- Do not use metal brushes, sponges or abrasive cleaners as they can damage the surface, which in turn can lead to corrosion. The insulation can be damaged, which can lead to uncontrolled burning.
- Before clinical use, safe combination of instruments with each other or with implants must be checked by the user.
- Do not use monopolar laparoscopic instruments for MRI or X-Ray imaging applications.
- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.

Handling notes for HF surgery:

- Use the instrument only with a recovery peak voltage of **2000 Vp** max. in combination with original accessories.
- When using laparoscopic scissors with a monopolar connection, it is important to ensure that HF current is only activated when the jaws are closed. If HF current is activated during a cutting procedure, this can lead to a loss of cutting quality and permanent functional impairment of the instrument.
- Set the output power of the HF surgical device only to the value that is absolutely necessary for the procedure. If normal coagulation is not achieved in spite of using the standard setting of the HF surgical device, never increase the output capacity of the device without prior checking the output power. Do not exceed the maximum permissible peak voltage of the instrument in the respective modes.
- The surfaces of the contact points at the working end (jaw) must be free of residues. To achieve optimal coagulation results, it is vital that the working ends of the instruments are always clean. Dried blood and residual tissue impair the functionality. When the coagulation performance decreases, do not increase the power but clean the working ends of the instruments with a damp sterile swab.
- Unintentional activation or electrode movement outside the field of view can result in injury to the patient.
- Only activate the HF current if the electrode is in your field of view and in contact with the tissue. Otherwise, excessive heating of the irrigation fluid may result and cause patient injury.

Risk of infection:

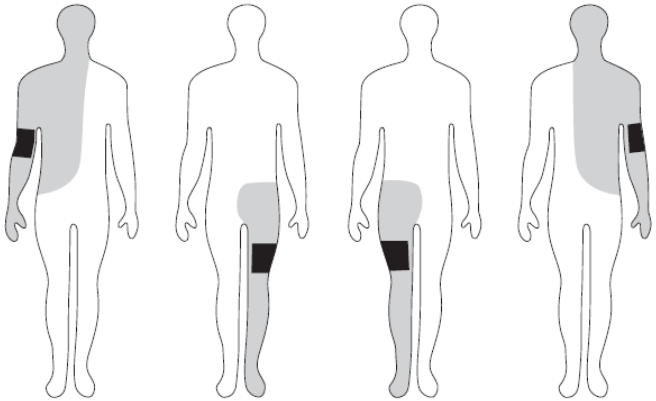
- In the case of patients with Creutzfeldt-Jakob disease (CJD), possible variants of this disease or suspected CJD, the applicable national regulations regarding the disposal and reprocessing of instruments must be applied.
- Inadequate cleaning and sterilization can also lead to a risk of infection.

POSITIONING THE PATIENT

- Ensure correct positioning of the return electrode, otherwise there is risk of burns.
- Make sure the patient never comes into contact with other metal parts (e.g., operating table) and is insulated against all electrically conductive parts.
- Lay the patient on a dry, electrically insulated pad.
- Avoid skin-to-skin contact (arms, legs). Place dry gauze between the body, arms and legs to prevent skin contact.
- The operating table must be earthed.

CURRENT FLOW IN THE BODY DURING MONOPOLAR HF SURGERY

- The path of the current in the patient's body should be short and must not flow across the thorax.
- There is a risk of burns if body hair in the affected area is not removed and moisture, e.g., disinfectant, is still present at the point of contact.
- The following illustration shows the position of the return electrode (black rectangle) and the permissible areas of use (grey) for the electrically conductive working ends of the instrument (jaws).
- Make sure that you select a monitoring-capable return electrode that is compatible with the contact quality monitoring system.



PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

Check for:

- External damage (e.g., deformed shaft, dents, burrs, cracks or sharp edges)
- Correct functioning
- Detergent or disinfectant residues
- Clear passage through the working channels
- Note the following in particular:
  - Proper contact of all HF connectors and cables
  - Functioning of the foot switch
  - Damage of the insulation of the HF cable and the instrument
  - Cleanliness of the distal end of the instrument (contact surfaces)

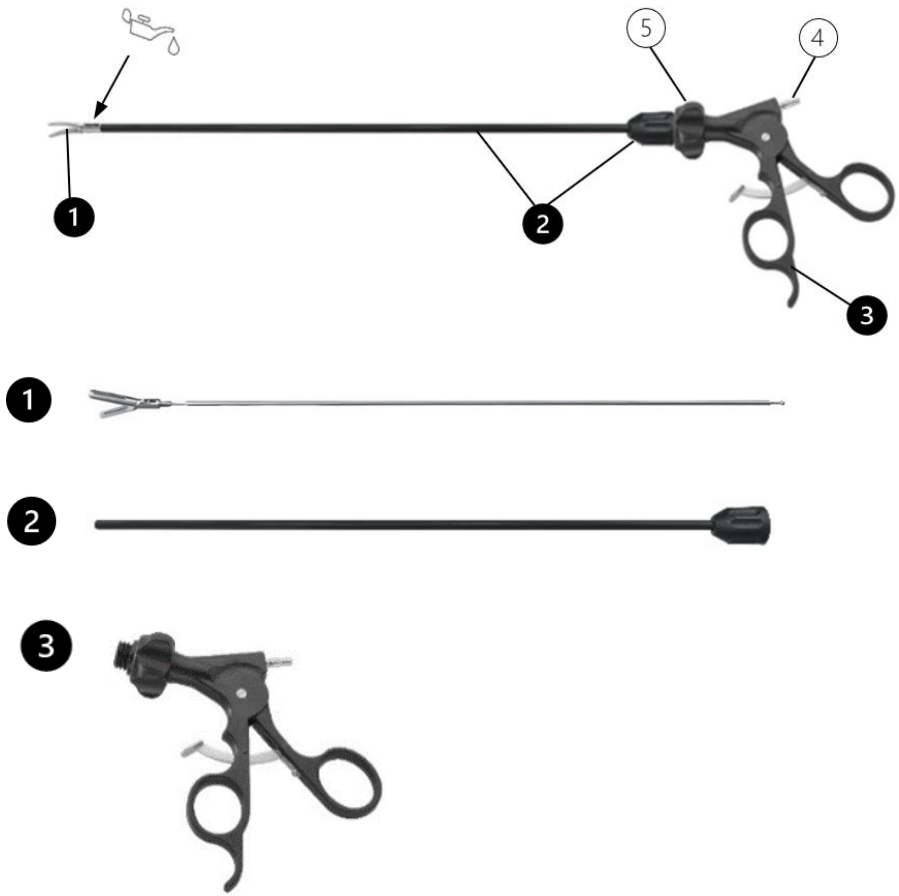
Please see also:

- See also section "Maintenance, control and inspection".
- Defective products: See section "Repairs and returns".

PRODUCT DESCRIPTION

- The RUDOLF Medical laparoscopic "Screw-in" system consists of three-part interchangeable, dismountable instruments with monopolar HF connection. The instruments come in various models (jaw inserts, handles, tubes) and designs (tube diameter, working length). Compatible cables for use with electrosurgical units can be found in the RUDOLF Medical laparoscopy catalog.
- The RUDOLF Medical "Screw-in" system makes it possible that tubes (with compatible jaw inserts) can be combined with all handles of the system. The handles are compatible with both Ø5mm tubes and Ø10mm tubes. The jaw inserts, on the other hand, are only compatible with tubes of an identical diameter.

Example: Grasping forceps with a tube diameter of 5mm, working length 330mm, handle with a ratchet.



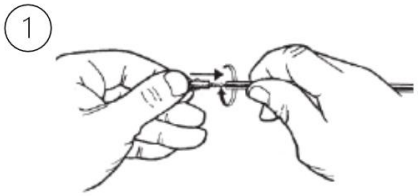
Combination parts and components:

(1) Jaw insert − example above with grasping forceps
(2) Tube with fastening screw nut. The fastening screw nuts come in various colors.
(3) Handle − example above shows a model with a ratchet
(4) HF connection, monopolar
(5) Rotatable adapter, 360° rotatable, with 10 latches (comfort handle: 12 latches)

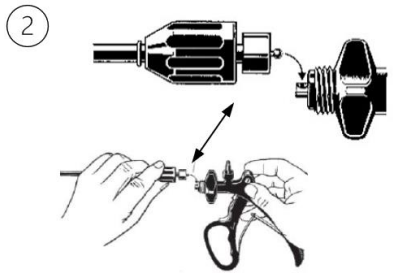
ASSEMBLY / DISASSEMBLY

⚠ Jaw inserts can be combined only with tubes of the same system diameter and working length.

Assembly

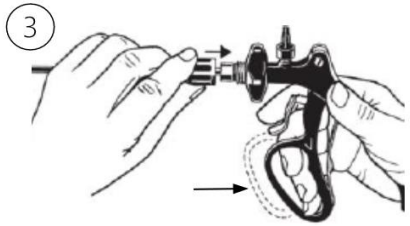


1. Slide the jaw insert into the tube and screw the tube onto the jaw insert by rotating it clockwise.
2. Fasten the tube only that much that the jaw insert cannot come loose during usage.



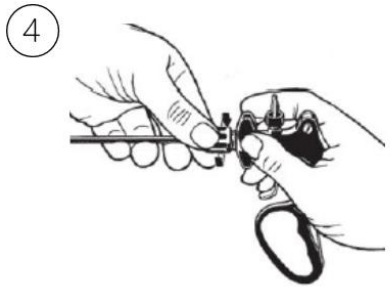
1. With its ball end first, insert the tube with the screwed-in jaw insert into the ball socket of the handle.
2. Make sure that the jaw is completely closed.

   The handle must be open. Do not operate it.



1. Operate the handle only so far until the metal cylinder of the tube rests against the threaded socket of the handle.
2. Then, slide the fastening screw nut over the metal cylinder of the tube towards the threaded socket of the handle.

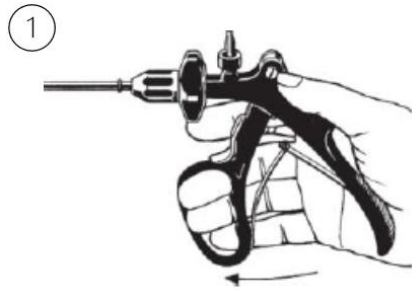
   This makes it easy and safe to screw the fastening screw nut to the handle.



1. Screw the fastening screw nut clockwise onto the threaded socket of the handle and tighten it while holding the rotatable adapter by the handle.
2. After the assembly, perform a functional check.

   For more information, see the “Prior to each use: visual and functional inspection” section.

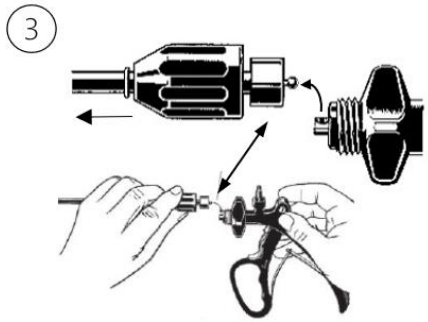
Disassembly



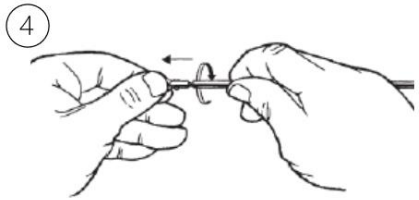
To unscrew the tube, open the instrument or the handle.

Built-in springs (see figure) in handles support automatic opening.

1. Hold firmly the rotatable adapter by the handle.
2. Loosen the fastening screw nut of the tube by rotating it counterclockwise.



1. Pull back the fastening screw nut over the metal cylinder of the tube.
2. Remove the tube including the jaw insert out of the ball socket of the handle.



1. Unscrew the tube from the jaw insert by rotating it counterclockwise.
2. Pull the jaw insert out of the tube.

REPROCESSING INSTRUCTIONS

- Wear personal protective equipment during reprocessing.
- The instruments must be reprocessed within an hour after use to prevent drying of contamination on the instruments.
- Use only the specified cleaning agents. Should other cleaning agents be used, they must be validated by you.
- When choosing a different cleaning agent, consider the material and properties of the instrument, the cleaning agents recommended by the WD manufacturer for the respective application, and the relevant lists and recommendations of the Robert Koch Institute (RKI) and of the German Society for Hygiene and Microbiology (DGHM) or the national recommendations.
- Do not use fixing agents.
- Use disinfectants with corrosion protection.
- Do not rinse under hot water.
- Do not use metal brushes, sponges or abrasive cleaners as they can damage the surface, which in turn can lead to corrosion. The insulation can be damaged, which can lead to uncontrolled burning.
- Do not expose plastic components to hydrogen peroxide (H2O2).

Restrictions

- The instruments are not intended to be manually reprocessed.
- The product lifetime depends on the following:
  - Number of applications and the reprocessing cycle
  - Maintenance and care
- Do not pre-clean the instruments with fixing agents or hot water (> 40°C), as this causes hardening of residues which can impair the cleaning process.
- Do not leave the instruments too long in the disinfectant solution. Follow the instructions of the manufacturer of the disinfectant solution.

⚠ Plastic handles must not come into contact with hydrogen peroxide (H2O2) because the handles could be damaged.

Initial treatment at the place of use

- Heavy contamination on the instruments must be removed with a disposable cloth immediately after use.
- To avoid blockages, working channels and lumens must be flushed at least 3 times immediately after use.
- The instruments must be reprocessed within 1 hour after use to prevent the drying of contamination on the instruments.
- Defective instruments must be clearly marked as such. They have to be reprocessed before being disposed of or returned.

Transportation

- Safe storage and transport of the instruments to the reprocessing site should be carried out in a closed receptacle / container system to avoid damage to the instruments and contamination of the environment.
- The instruments must not touch each other during transportation.

Preparation before cleaning

- The instruments must be disassembled or opened for reprocessing as far as possible without using tools.

Manual pre-cleaning

1. Instruments with difficult-to-access areas such as lumens, cavities, bores, threads, and slots must be soaked in cold water for at least 5 minutes and rinsed under water with a water jet pistol for at least 10 seconds (pulsed procedure).
2. Brush the inside of the tubes with a correspondingly large and soft brush.
3. Rinse the tubes again with a water jet pistol for 10 seconds (1.8 bar).
4. Brush the outer surfaces of the instruments with a soft brush until no visible residue remains.
5. Then place the instruments in an ultrasonic bath at room temperature: 0.5% neodisher MediClean cleaning agent, temperature of the cleaning agent must be below 40°C; duration 5 minutes, frequency 35 kHz.
6. Remove the instruments from the ultrasonic bath and rinse them thoroughly to remove the cleaning agent.
7. Observe the instructions of the manufacturer of the cleaning agent (concentration, temperature, and sonication time).
8. Vibrations can loosen small parts such as screws and nuts. After the ultrasonic treatment, ensure that the instruments are complete and check for loosened small parts.

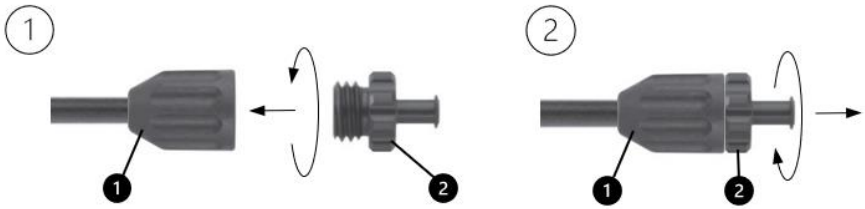
Automated cleaning and disinfection

- Clean and disinfect the instrument only in suitable washers and disinfectors (WD) with a procedure / program validated for the WD and this type of instrument (EN ISO 15883).
- Observe the operating and loading instructions of the washer-disinfector manufacturer.
- Open the jaw inserts for cleaning.
- The tubes must be connected to an appropriate rinsing device to ensure that these cavities are rinsed. The RUDOLF Medical rinsing adapter with Luer lock (see figures 1 + 2 below) can be used for this purpose.
- When choosing the cleaning agent, consider the material and properties of the instrument, the cleaning agents recommended by the WD manufacturer for the respective application, and the relevant lists and recommendations of the Robert Koch Institute (RKI) and of the German society for hygiene and microbiology (Deutsche Gesellschaft für Hygiene und Mikrobiologie, DGHM).

Tip: Use of the RUDOLF Medical rinsing adapter (REF: RS000-010) for tubes with a diameter of 5 and 10 mm for automated cleaning of tubes (Figures 1 + 2).

Assembly (Figure 1): Screw the rinsing adapter (2) clockwise into the fastening screw nut of the tubes. Hold the fastening screw nut (1) firmly.

Disassembly (Figure 2): Unscrew the rinsing adapter (2) counterclockwise from the fastening screw nut of the tube. Hold the fastening screw nut (1) firmly while doing so.



(1) Tubes with fastening screw nut
(2) Rinsing adapter with Luer lock

Automated cleaning and thermal disinfection

Process type	Alkaline
Cleaning agent	Dr. Weigert neodisher MediClean
pH value	10.2 - 10.5
Washer and disinfector (WD)	Miele G 7836 CD

Automated cleaning program with thermal disinfection in the WD using an alkaline process

Process	Reagents	Time / Min	Temp / °C
Pre-cleaning	Drinkable tap water	4	Cold
Draining	---	---	---
Cleaning	Deionized water, 0.5% neodisher MediClean	5	55
Draining	---	---	---
Rinsing and Neutralization	Deionized water	3	Cold
Draining	---	---	---
Rinsing	Deionized water	2	> 40 °C
Draining	---	---	---
Disinfection *	Demineralized water	10	> 90
Drying **	---	> 20	Max. 93

* For automated thermal disinfection, observe the national requirements for the A0 value from ISO 15883-1 (A0 = 3000).
** If necessary, manual drying with a lint-free cloth can also be carried out. When necessary, use medical compressed air to dry the instrument. Only use filtered compressed air (free of oil, germs and particles).

MAINTENANCE, CONTROL AND INSPECTION

- After cleaning and disinfection, the instruments must be subjected to a visual and functional inspection. The instruments must be macroscopically clean (free of visible residues). Particular attention should be paid to slots, ratchets, locks, and other areas that are difficult to access.
- If dirt residues/liquids are still visible, cleaning and disinfection must be repeated.
- After each cleaning and before sterilization, the moving parts must be oiled and maintained with a silicone-free biocompatible medical white oil.
- Before sterilization, the instrument must be assembled and checked for function, wear and damages (cracks, rust) and, if necessary, replaced.
- Ensure that the instruments are sterilized when open. When using handles with locks, ensure that they are not locked in place.
- Defective products must undergo the entire reprocessing process before being returned for repair or complaint.

PACKAGING

- The packaging of the instruments for sterilization must be according to standards DIN EN ISO 11607 and DIN EN 868.
- In case of individual packaging, ensure that the packaging is large enough to hold the product without putting tension on the sealing seam or without tearing the packaging. Pointed tips and sharp cutting edges must not perforate the sterilization packaging.

STERILISATION

- The sterilizers are validated in accordance with DIN EN 13060 and DIN EN 285.
- The steam sterilization process (fractionated vacuum process) is validated in accordance with DIN EN ISO 17665-1.
- Pre-vacuum: three times
- Sterilizer: Lautenschläger ZentraCert

Sterilization temperature	Minimum holding time	Drying time
134 °C – 137 °C	5 minutes	Minimum 20 minutes

The manufacturer's instructions for the sterilizer must be observed.

STORAGE

- Store the sterilized instruments in a low-germ, dry, clean and dust-free environment at 5 - 40°C.
- The packaging must ensure optimum protection of the sterile instruments during storage. The requirements of the relevant standard DIN EN ISO 11607 must always be complied with.

INFORMATION REGARDING THE VALIDATION OF THE REPROCESSING PROCEDURE

The following materials and machines were used in the validation:

Manual pre-cleaning in ultrasonic bath	• Cleaning agent: 0.5% Dr. Weigert neodisher® MediClean, alkaline • The temperature of the cleaning agent must be below 40°C. • Duration: 5 minutes • Frequency: 35 kHz
Automated cleaning and disinfection	• Cleaning agent: Dr. Weigert neodisher® MediClean, alkaline • pH value: 10.2-10.5 • Thermal disinfection • Washer-disinfector: Miele G 7836 CD
Sterilization	Steam sterilization, triple pre-vacuum
Sterilizer	Lautenschläger ZentraCert

ADDITIONAL NOTES

– If the specified chemical agents and machines are not available, the user needs to validate their process.

DISPOSAL

– Only after the products have been cleaned and disinfected properly, they should be disposed of accordingly.
– Comply with national regulations and applicable hospital guidelines when discarding or recycling the product / components.
– Be careful with sharp tips and cutting edges. Use suitable protective caps or containers to prevent third parties from being injured.

REPAIRS / RETURNS

– Never carry out repairs yourself. Service and repairs should only be carried out by appropriately trained and qualified persons. If you have any questions, contact RUDOLF Medical, your distributor or your medical technology department.
– Due to the risk of infection, defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.

PROBLEMS / EVENTS

– The user should report any problems with RUDOLF medical products to the respective distributor.
– In the event of serious incidents with the products, the user must report this to RUDOLF Medical as the manufacturer and to the competent authority of the member state in which the user resides.

WARRANTY

– The instruments are made of high-quality materials and are subjected to a strict quality control before delivery. If there are any discrepancies, please contact RUDOLF Medical or your distributor.

REPROCESSING - APPLIED STANDARDS

– DIN EN 285 Sterilization – Steam sterilizers – Large sterilizers
– DIN EN 868-8: Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
– DIN EN ISO 11607 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
– DIN EN 13060: Small steam sterilizers
– DIN EN ISO 15883: Washer-disinfectors – Part 1: General requirements, terms and definitions and tests
– DIN EN ISO 17664: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices

SYMBOLS

	Consult instructions for use
LOT	Batch code
REF	Catalog number
QTY	Quantity
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
CE 0297	CE marking according to Regulation (EU) 2017/745 for medical devices with notified body identification number.
	Keep dry
	Keep away from sunlight
	Lubricate with silicone-free, biocompatible white oil approved for medical devices and steam sterilization.
MD	Medical Device