English

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1. Introduction

1.1 Important information to be read before use

You have purchased a high-quality Riester device, which was manufactured in compliance with Regulation (EU) 2017/745 and is subject to the strictest quality controls at all times. Read through these instructions for use carefully before using the device and keep them in a safe place. If you have any questions, we are available at any time, and our contact information is provided at the end of this IFU. Contact information for Riester sales and dsitribution partners can be provided upon request. Please note all instruments described in these instructions for use may only be used by appropriately trained personnel. The safe functioning of this device is only guaranteed if Riester original parts and accessories are used.

1.2 Safety symbols

Symbol	Note on symbol
	Meaning of the symbol on the outer packaging/scale: Caution, please observe the operating instructions
MD	Medical device
	The operator is obliged to read the instructions of the operating manual
	Warnings The general warning symbol indicates a potentially dangerous situation that can lead to serious injuries.
	Caution! The caution symbol indicates a potentially dangerous situation that can lead to minor or moderate injuries. The symbol may also indicate unsafe practices.
	Date of manufacture YYYY-MM-DD / (Year-Month-Day)
	Manufacturer
LOT	Manufacturer's batch number
	Temperature requirements for transport and storage
	Relative humidity for transport and storage
CE	CE Mark

1.3 Packaging symbols

Symbol	Note on symbol
	Fragile. The package should be handled with care.
	Keep the package from getting wet.
	This way up. The symbol indicates the correct positioning for transporting the package.
	Keep away from sunlight
	"Green Dot" (country-specific)

1.4 Purpose

The Riester salpingograph is used for sterility diagnostics and hysterosalpingography, after Prof. Dr. Günther K.F. Schultze, for X-ray contrast imaging of the cavum uteri (uterine cavity) and the Fallopian tubes (oviducts) as well as for tube patency testing (pertubation) with a holding device for two uterine grasping forceps. For this, sterile utilisation of the salpingograph is mandatory, as contact will occur with both internal tissues as well as sterile medicinal products.

1.4.1 Indications

Hysterosalpingography - pertubation
Hysterosalpingography is used for x-ray contrast imaging of the cervix, the uterine cavity and the tube lumen.

1.4.2 Contraindications

⚠
An allergy to X-ray contrast media is a contraindication to hysterosalpingography. No pertubation and hysterosalpingography in the presence of:
- Florid cervical or pelvic infections.
- Pregnancy
- The examination should ideally take place in the first half of the cycle and not during menstruation.

1.4.2.1 Side effects

⚠
- The distension of the uterine cavity and the passage of X-ray contrast medium through the tubes can lead to pain and peritoneal irritation.
- Occasionally, vasovagal reactions are seen.

1.4.3 Intended patient population

The salpingograph is intended for use on female patients.

1.4.4 Intended operator/user

The salpingograph is for use by doctors in hospitals, medical institutions, clinics and doctor's offices.

1.4.5 Required skills/operator training

The user must have the qualifications of a doctor.
The salpingograph is an instrument commonly used in gynaecology.

1.4.6 Environmental conditions

The device is intended for use in rooms with a controlled environment.
The device must not be exposed to adverse/harsh environmental conditions.

1.5 Warnings/caution

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An allergy to X-ray contrast media is a contraindication to hysterosalpingography. No pertubation and hysterosalpingography in the presence of:
- Florid cervical or pelvic infections.
- Pregnancy
- The examination should ideally take place in the first half of the cycle and not during menstruation.

⚠
Use only cleaned, reprocessed instruments to limit cross-contamination.
Observe the cleaning, disinfection and sterilisation specifications in the instructions for use!
⚠
The product is only suitable for use by appropriately trained doctors.
⚠
Never place the manometer (pressure gauge) in liquid. Make sure that no liquids penetrate the housing interior.
⚠
All serious incidents related to the product must be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is resident.

2. First use

2.1 Scope of delivery

No. 5250
1 x 20 ml glass syringe with Luer Lock connector
1 x manometer with pressure scale in mm Hg
1 x middle piece
1 x uterine probe
Three portio adapters (uterine occlusion cones) in the following sizes:
1 x small (base Ø 16 mm),
1 x medium (base Ø 24 mm),
1 x large (base Ø 30 mm),
Height 25 mm each
1 x user manual
1 x case

2.2 Device function

1. 20 ml glass syringe with Luer Lock connector
2. Manometer with pressure scale in mm Hg
3. Middle piece
4. Uterine probe
5. Three portio adapters (uterine occlusion cones) in the following sizes:
small (base Ø 16 mm),
medium (base Ø 24 mm),
large (base Ø 30 mm), height 25 mm each

3. Operation and function

3.1 Symbol identification

	Meaning of the symbol on the outer packaging/scale: Caution, please observe the operating instructions
mm Hg	Millimetres of mercury
ml	Millilitres

3.2 Startup

3.2.1 Introduction

The salpingograph after Prof. Dr. Günther K.F. Schultze is just as suitable for hysterosalpingography as for pertubation. Its gear system for securing the cervical grasping forceps, and the differently sized metal cones, permit a complete sealing of the cervix in each case and thus fulfil the most important requirements for successful diagnostics.

3.2.2 Special advantages

The gear system integrated in the uterine probe (4) is used to lock the cervical grasping forceps. Due to the infinitely variable adjustability, the tension on the grasping forceps and thus the contact pressure of the metal cone on the portio can be precisely regulated.

3.2.3

Three metal cones (5) of different sizes serve as portio adapters. They are screwed onto the tip of the uterine probe (4), which protrudes from the cone by 1-2 cm. The thread of the cone ensures a complete seal for contrast medium and air.

3.2.4

The manometer (2) can be inserted between the uterine probe (4) and the glass syringe (1) so that the pressure required for pertubation can be recorded precisely in mm Hg. The device can also be used for hysterosalpingography without an intermediate manometer.

3.2.5

The scale display of the manometer is coated with luminous material so that the pressure values can also be read in the dark.

3.3 Hysterosalpingography - pertubation

Hysterosalpingography is used for x-ray contrast imaging of the cervix, the uterine cavity and the tube lumen. After injection of X-ray contrast medium into the cervical canal, fluoroscopy is used to follow how the contrast medium first fills the cervical canal and uterine cavity and then empties retrogradely via the patent tubes into the free abdominal cavity. Contrast medium recesses in the cervical canal or the uterine cavity indicate intracavitary masses (e.g. polyps, fibroids). Congenital malformations of the uterus (e.g. a subseptate uterus) can be demonstrated in a particularly impressive manner. The filling of the Fallopian tubes allows their patency to be assessed, for one thing, and also permits detection of changes important for the assessment of tubal function, such as calibre variations, stenoses or sactosalpinx formation.
The pertubation is used to check tubal patency. By interposing the manometer, the pressure required for pertubation can be determined. Usually the uterine cavity expands at a pressure of 40-60 mm Hg. From a pressure of 70 mm Hg, the distension medium (liquid and gaseous) passes physiologically into the tubal lumen and retrogradely into the abdominal cavity.
During pertubation, care must be taken that the distension pressure does not exceed 200 mm Hg. If the pertubation is carried out with air or gas, the passage into the free abdominal cavity can be recognized by a typical "bubble sound" during auscultation of the abdomen. Hysterosalpingography and pertubation both have a therapeutic effect in sterility therapy. In about a quarter to a third of the cases, one finds that conception occurs within 4 months of the procedure.

Gebrauchsanweisung
Salpingograph

Instructions
Salpingograph

Rudolf Riester GmbH
P.O. Box 35 | Bruckstraße 31
DE - 72417Jungingen | Germany
Tel.: +49 (0) 7477 / 9270-0
Fax.: +49 (0) 7477 / 9270-70
E-Mail: info@riester.de | www.riester.de

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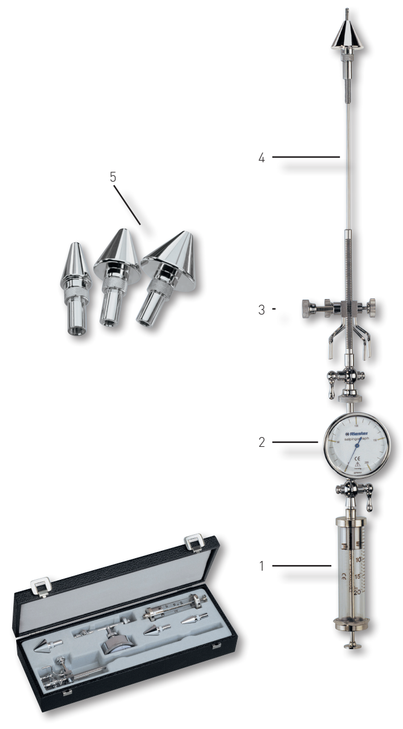
CE

Riester



3.4 Implementation

⚠
The patient is positioned on the X-ray table of the fluoroscopy station. Tables with attachable leg holders at the caudal end, into which the patient's legs are placed, have proven to be best. Then follows the speculum examination with adjustment of the portio. The injection of some local anaesthetic into the anterior lip of the cervix makes clasping the portio painless. After disinfection, the anterior lip of the cervix is gripped crosswise with the ball forceps. Introduce the salpingograph of your choice and screw on the appropriate cone. Insert the ball forceps into the hooks of the gear system and slowly build up the tension by turning back the gear drive. Connect the filled glass syringe. Now correctly position the patient on the X-ray table with her legs outstretched. The instruments can be placed on ⚠ small sandbag between the legs. Carefully but rapidly inject the contrast medium while fluoroscopy is in progress.
After completing the X-rays, remove the instruments.

4. Care instructions

4.1 General information

The cleaning and disinfecting of medical devices serves to protect the patient, the user and third parties and to maintain the value of the medical devices. The product design and materials used make it impossible to define an upper limit on max. feasible treatment cycles. The service life of medical devices is determined by their function and careful handling. Before return for repair, defective products must have undergone the prescribed reprocessing procedure.
⚠
If a reusable device shows signs of material deterioration, it should no longer be reused and should be disposed of/claimed according to the procedures described in the disposal/warranty sections.

4.1.1 Preparation on site:

⚠
Remove gross detritus immediately after using the instruments. Do not use any fixation agents or hot water (→ 40°C / 104°F) to do this, as this can lead to fixation of residues and impact the effectiveness of cleaning.

4.1 ⚠ ansport:

⚠
To avoid damage to the instruments and environmental contamination, securely store them in a closed container during transport to the reprocessing site.

4.1 ⚠ eparation for decontamination:

⚠
Disassemble the instrument into 5 parts. The manometer must only be cleaned manually.

4.2 Cleaning and disinfection

4.2.1 Pre-cleaning:

⚠⚠
- Remove all visible impurities from the manometer using a lint-free, moist cloth, and then dry using a lint-free cloth or sterile compressed air.
- Completely immerse all the other parts of the dismantled instrument in cold tap water for at least 5 minutes.
- Brush areas that are difficult to access, such as lumina, with a soft brush / bottle brush u ⚠ cold running tap water.

4.2.2 Cleaning

⚠
Use a cleaning regimen analogous to the one below:
- Preclean for 2 min. with cold tap water
- E ⚠ /
- Clean for 5 min with tap water at 55°C / 131°F and 0.5% cleaning solution
- Empty
- Rinse for 3 min with cold demineralised water
- Empty
- Rinse for a further 2 min with cold demineralised water
- Empty
- If applicable, consider any contrary recommendations provided by the manufacturer of the cleaning chemicals.

4.2.3 Disinfection:

⚠
Carry out mechanical-thermal disinfection in compliance with national requirements with regard to the A0 value (see ISO 15883) by: e.g. 5 minutes rinsing with demineralised water at 90°C / 194°F for an A0 value of 3000.

4.2.4 Drying:

⚠
Dry the instrument using the drying cycle of the washing/disinfecting device.
If necessary, manual drying can be carried out in addition, using a lint-free cloth and/or sterile compressed air.

4.2.6 Functional testing, maintenance:

⚠
Visual inspection for cleanliness; then care, assembly and functional test as per the operating instructions.
If necessary, repeat the reprocessing procedure until the instrument is optically clean.

4.3 Sterilisation

4.3.1 Packaging:

⚠
Standardised packaging for instruments to be sterilised according to ISO 11607 and EN 868.

4.3.2 Sterilisation:

⚠
Steam sterilise the products via the fractional pre-vacuum procedure (according to ISO 13060 / ISO 17665) in compliance with the relevant national requirements. The minimum requirements for the sterilisation process are:
- 3 pre-vacuum phases
- Temperature 132°C / 269.6°F

- Holding time 3 minutes
- Drying time 20 minutes

4.3.3 Storage:

⚠
Store the sterilised instruments in a dry, clean and dust-free environment at moderate temperatures of 5°C / 41°F to 40°C / 104°F.

4.3.4 Information regarding validation of the processing:

The following test instructions, materials and machines were used for the validation by SMP GmbH:

Detergents:	Neodisher MediClean, (Dr. Weigert; Hamburg)
Cleaning/disinfection device:	Miele G 7836 CD, (Miele & Cie. GmbH & Co.)
Rack trolleys:	Miele E429, (Miele & Cie. GmbH & Co.)
Steriliser:	Selectomat HP 666-1HR, (Münchner Medizin Mechanik GmbH)
For details see report	SMP report 26816
Cleaning:	SMP report 00917
Sterilisation:	SMP GmbH accreditation according to DIN EN ISO IEC17025 and in accordance with Directives 93/42/EEC and 90/385/EEC confirmed by certificate number:
	D-PL-17769-01-01

⚠
Additional instructions: If the chemicals and machines described above are not available, it is the user's responsibility to validate their process accordingly.
⚠
It is the user's obligation to ensure that the reprocessing procedure, including resources, materials and personnel, is suitable to achieve the required results.
Current best practice and national laws require following validated processes.
⚠
Never place the manometer (pressure gauge) in liquid. Make sure that no liquids penetrate the housing interior.

5. Technical specifications

Ambient temperature:	10°C / 50°F to 40°C / 104°F with a relative humidity of 85% (non-condensing)
Storage conditions:	-20°C / -4°F to 70°C / 158°F with a relative humidity of 85% (non-condensing)
Manometer:	Scale: Display range 0 to 200 mm Hg in steps of 10 mm Hg. No zero point fixation
Pressure generation:	Via syringe with Luer Lock closure

6. Spare parts and accessories

Item no. 11210 Syringe 20 ml with Luer Lock closure
Item no. 11212 Uterine probe
Item no. 11213 Closing cone, small
Item no. 11214 Closing cone, small
Item no. 11215 Closing cone, small

7. Maintenance/accuracy check/calibration/applied standards

Riester salpingographs and their accessories do not require special maintenance. If the salpingograph needs to be checked for any reason, please send it to us or an authorized Riester dealer in your area, the details of which we will provide upon request.

8. Disposal

⚠ **Caution!**
The used medical device must be disposed of in accordance with current medical practices or local regulations on the disposal of infectious biological medical waste.
⚠
Batteries and electrical/electronic devices may not be treated as domestic waste and must be disposed of in accordance with local regulations.
⚠
If you have any questions about the disposal of products, please contact the manufacturer or their representative.

9. Warranty

This product has been manufactured under the strictest quality standards and has undergone a thorough final quality check before leaving our factory.
We are therefore pleased to be able to provide a warranty of **2 years from the date of purchase** on all defects, which can verifiably be shown to be due to material or manufacturing faults. A warranty claim does not apply in the case of improper handling.
All defective parts of the product will be replaced or repaired free of charge within the warranty period. This does not apply to wearing parts.
For r1 shock-proof, we grant an additional warranty of 5 years for the calibration, which is required by CE-certification.
A warranty claim can only be granted if this Warranty Card has been completed and stamped by the dealer and is enclosed with the product.
Please remember that all warranty claims have to be made during the warranty period. We will, of course, be pleased to carry out checks or repairs after expiry of the warranty period at a charge. You are also welcome to request a provisional cost estimate from us free of charge.
In case of a warranty claim or repair, please return the Riester product with the completed Warranty Card to the following address:

Rudolf Riester GmbH
Dept. Repairs RR
Bruckstr. 31
72417 Jungingen
Germany

Serial number or batch number, date,
stamp and signature of the specialist dealer