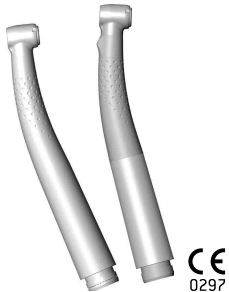


Instructions for use



PEOPLE HAVE PRIORITY



primea

RK-97 L, RG-97 L

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Symbols in the Instructions for use



WARNING!
(risk of injury)



ATTENTION!
(to prevent damage
occurring)




General explanations,
without risk to
persons or objects



**Do not dispose of
with domestic waste**

Symbols on the medical device / packaging

 CE marking with identification number of the Notified Body



DataMatrix Code for product information including UDI (Unique Device Identification)



Data structure in accordance with Health Industry Bar Code



Catalogue number



Thermo washer disinfectable



Sterilizable up to the stated temperature



Serial number



UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements



Date of manufacture

1. Introduction

Customer satisfaction has absolute priority in the W&H quality policy. This medical device has been developed, manufactured and subjected to final inspection according to legal regulations, quality and industry standards.

For your safety and the safety of your patients

Prior to initial use please read the Instructions for use. These explain how to use your W&H product and guarantee a smooth and efficient operation.

Intended use

The dental turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces.



Misuse may damage the medical device and hence cause risks and hazards for patient, user and third parties.

Qualifications of the user

We have based our development and design of the medical device on the dentists, dental hygienists, dental employees (prophylaxis) and dental assistants target group.



Production according to EU directive

The medical device meets the requirements of Directive 93/42/EEC.



Responsibility of the manufacturer

The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when it is used in compliance with the following directions:

- > The medical device must be used in accordance with these Instructions for use.
- > The medical device has no components that can be repaired by the user.
- > Assembly, modifications or repairs must only be undertaken by an authorized W&H service partner (see page 37).

Skilled application

The medical device is intended only for skilled application according to the intended use as well as in compliance with the valid health and safety at work regulations, the valid accident prevention regulations and in compliance with these Instructions for use.

The medical device should be prepared for use and maintained by staff who have been trained in procedures for infection control, personal safety and patient safety. Improper use, (e.g., through poor hygiene and maintenance), non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.

Service

In the event of operating malfunctions immediately contact an authorized W&H service partner (see page 37). Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

2. Safety notes



- > The operation of the medical device with light is permitted only on dental units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).

The power supply unit for the dental unit must satisfy the following requirements to be guaranteed by the system assembler:

- > Double insulation for the highest expected supply voltage must be provided between the primary and secondary power circuits.
- > Double insulation for the highest expected secondary voltage must be provided between the secondary voltage and protective earth (PE).
- > The secondary circuits must be galvanically isolated from each other.
- > The secondary circuits must be protected against short-circuiting and overloading.
- > The leakage currents of the applied part must be kept.
- > The secondary voltage must be limited to a maximum of 5 V AC / DC.



- > Operate the medical device with the W&H control unit and Roto Quick coupling with light.
- > Always ensure the correct operating conditions and cooling function.
- > Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction.
- > In case of coolant supply failure, the medical device must be stopped immediately.
- > Use only non-contaminated, filtered, oil-free and dry compressed drive air to operate the medical device.
- > Check the medical device for damage and loose parts each time before using [e.g, push-button chuck].
- > Do not operate the medical device if it is damaged.
- > Perform a test run each time before using.
- > Do not use the medical device at soft tissue wounds in the mouth (the air pressure can cause septic substances to enter the tissue or trigger embolisms).
- > Avoid contact between the instrument head and soft tissue (risk of burning due to the push-button chuck heating up).
- > Run the rinse function for the dental unit once per day.
- > Do not use the medical device as a light sensor.
- > Do not look directly into the LED.



Danger zones M and G

In accordance with IEC 60601-1 / ANSI/AAMI ES 60601-1, the medical device is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.



The medical device is not suitable for use in oxygen enriched atmospheres.



Zone M, is defined as a »medical environment« and constitutes the part of a room in which potentially explosive atmospheres may form due to the use of anaesthetics or medical antiseptics and antibacterial soaps; such atmospheres are typically localized and temporary.

Zone M comprises a truncated pyramid below the operating table which is tilted outwards at a 30° angle.



Zone G, also known as an »enclosed medical gas system«, does not necessarily include areas enclosed around all sides, in which explosive mixtures are continuously or temporarily generated, directed or used in small quantities.



Risks due to electromagnetic fields

The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillator (ICD) can be affected by electric, magnetic and electromagnetic fields.

- > Find out if patient and user have implanted systems before using the medical device and consider the application.
- > Weigh the risks and benefits.
- > Keep the product away from implanted systems.
- > Make appropriate emergency provisions and take immediate action on any signs of ill-health.
- > Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD.

Hygiene and maintenance prior to initial use

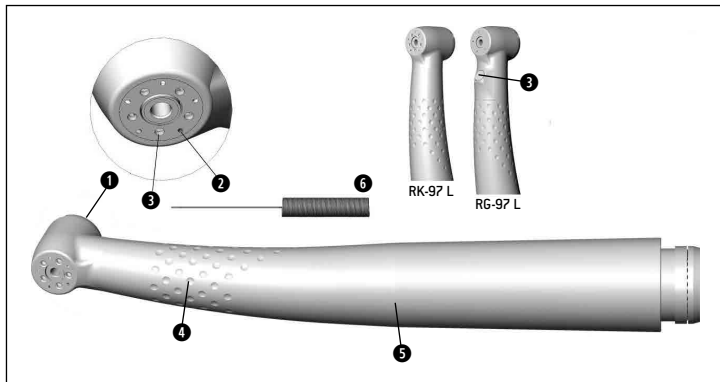


The medical device is in a clean condition and sealed in PE-film when delivered.

- > Lubricate the medical device.
- > Sterilize the medical device and the nozzle cleaner.

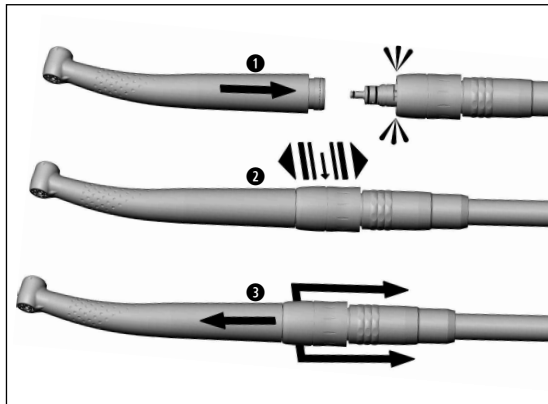
- > Oil service page 24
- > Sterilization page 28

3. Product description for RK-97 L, RG-97 L with Roto Quick coupling



- ① Push-button
- ② Spray nozzles
- ③ LEDs
- ④ Grip profile
- ⑤ Sheath
- ⑥ Nozzle cleaner

4. Operation – assembly / removal: Roto Quick coupling



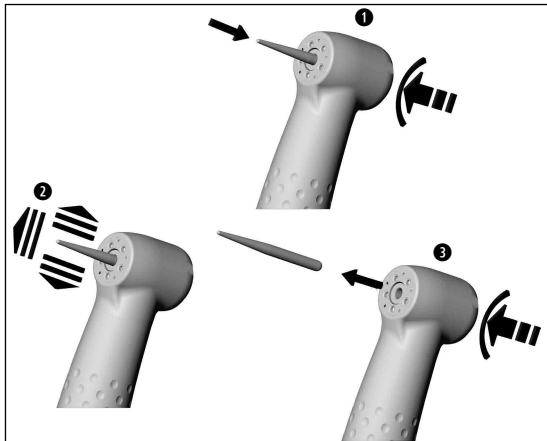
Do not assemble / remove during operation!

- 1** Push the medical device onto the Roto Quick coupling.
- 2** Check the secure hold on the Roto Quick coupling.
- 3** Pull the retention sleeve of the Roto Quick coupling back and remove the medical device by pulling in an axial direction.

Rotary instruments



- > Use only rotary instruments which are in perfect condition and which have shanks that meet the requirements of the ISO 1797-1 standard. Follow the operating instructions of the manufacturer.
- > Insert the rotary instrument only when the medical device is stationary.
- > Do not interfere with the running or slowing down of the rotary instrument.
- > Do not activate the push-button of the medical device during operation or slowing down. This leads to detachment of the rotary instrument resp. heating of the push-button (risk of injury).
- > Only use rotary instruments up to the maximum operating speed stipulated by the manufacturer.
- > Only use rotary instruments for which the maximum approved operating speed is more than the minimum adjustable speed of the control unit.



To change rotary instrument

- 1** Insert the rotary instrument.
Activate push-button, at the same time insert the rotary instrument until back stop.
- 2** Check secure location by applying slight axial tension.
- 3** Activate the push-button and remove the rotary instrument.

Test run



Do not hold the medical device at eye level.

- > Insert the rotary instrument.
- > Start the medical device.

- > In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating, coolant failure or leakage) or discoloration of the LED, stop the medical device immediately and contact an authorized W&H service partner [see page 37].

5. Hygiene and maintenance



Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.

> You can process the medical device manually or mechanically.



> Wear protective clothing.

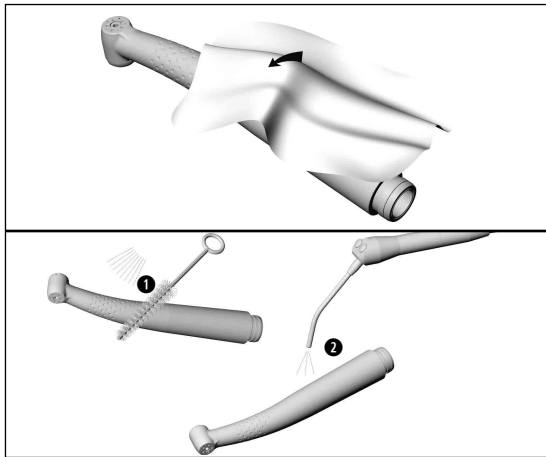
> Remove the medical device from the Roto Quick coupling.

> Remove the rotary instrument.

> Clean and disinfect the medical device **immediately after every treatment**, to flush out any liquid (e.g., blood, saliva etc.) and to prevent settling on the internal parts.


> Sterilize the medical device following manual or mechanical cleaning, disinfection and lubrication.

> Sterilize the nozzle cleaner following manual cleaning and disinfection.



Pre-disinfection

- > If heavily soiled, clean first with disinfectant cloths.

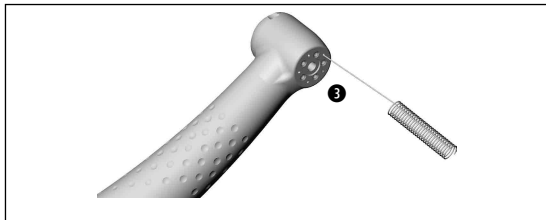
 Only use disinfectants that have no protein-fixing effects.

Manual cleaning internal and external

- ① Rinse and brush off under demineralized water (< 38 °C / < 100 °F).
- ② Remove any liquid residues (absorbent cloth, blow dry with compressed air).




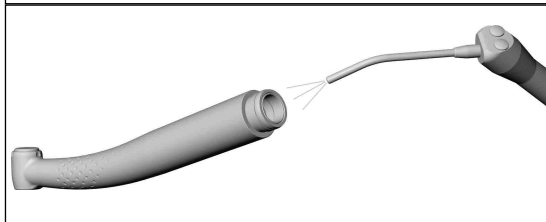
Do not place the medical device in liquid disinfectant or in an ultrasonic bath.



Cleaning of the spray nozzles


- ③ Clean spray nozzles carefully with the nozzle cleaner to remove dirt and deposits.

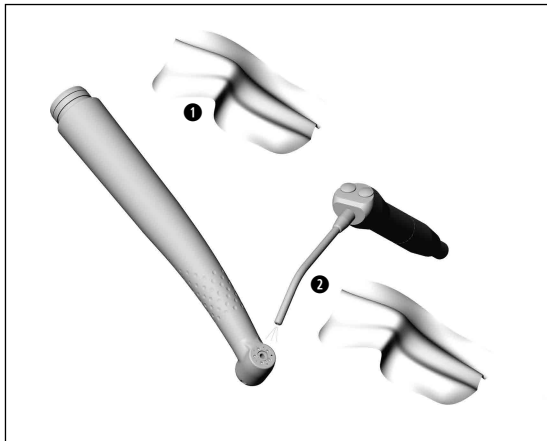
 Clean and disinfect the nozzle cleaner in an ultrasonic bath or disinfection bath.



Cleaning of the coolant channel

- > Blow through the coolant channel with the air syringe.

 In the case of clogged up spray nozzles or coolant channels contact an authorized W&H service partner [see page 37].



Cleaning of the LED

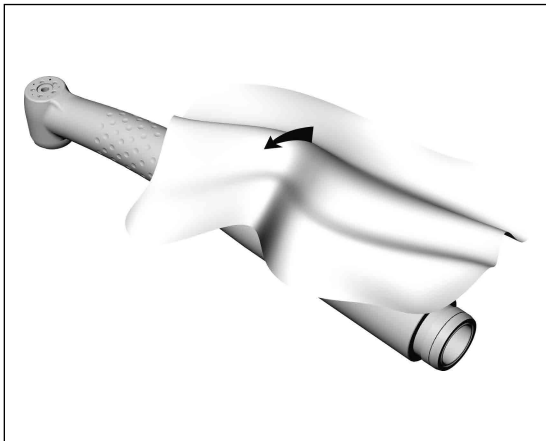


Avoid scratching of the LED!

- 1** Wash the the LED with cleaning fluid and a soft cloth.
- 2** Blow the LED dry with compressed air or dry it carefully with a soft cloth.



Carry out a visual inspection after each cleaning process. Do not use the medical device if the LED is damaged and contact an authorized W&H service partner (see page 37).



Manual disinfection



W&H recommends wiping down with disinfectant.

- > Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes.
- > Note the manufacturer's specifications for the use of the disinfectants.



After manual cleaning, disinfection and lubrication you must carry out a final thermal disinfection (unwrapped) or sterilization (wrapped) in a class B or S steam sterilizer (according to EN 13060).

Mechanical cleaning internal and external and lubrication



- W&H recommends mechanical cleaning and lubrication with W&H Assistina 3x3.
- > Follow the instructions in the Assistina Instructions for use.

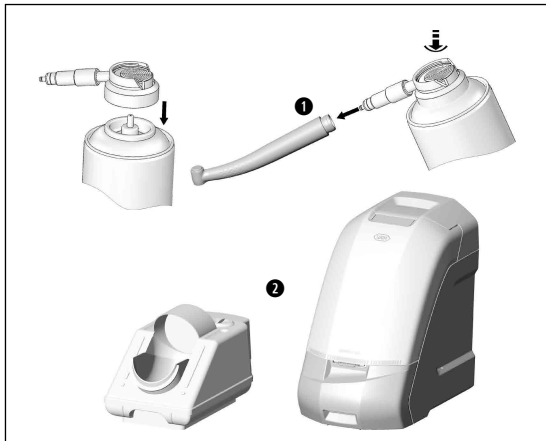
Mechanical cleaning and disinfection internal and external



- The medical device can be cleaned and disinfected in a thermo washer disinfectant.
- > Note the manufacturer's specifications on equipment, cleaning agents and detergents.



- > Make sure the medical device is completely dry internally and externally after thermo washer disinfection. Remove any liquid residues with compressed air.
- > Lubricate the dry medical device immediately after thermo washer disinfection.
- > Sterilize the medical device.



Lubrication

Recommended lubrication cycles

- > After 30 minutes of use
- > Essential after every internal cleaning
- > Before each sterilization
- > at least twice daily

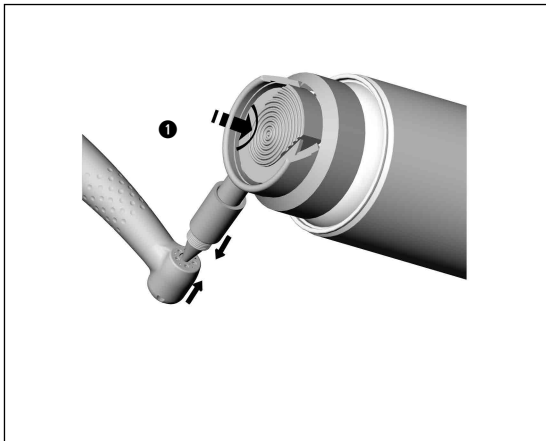
❶ With W&H Service Oil F1, MD-400

- > Follow the instructions on the oil spray can and on the packaging.

or

❷ With W&H Assistina 301 plus

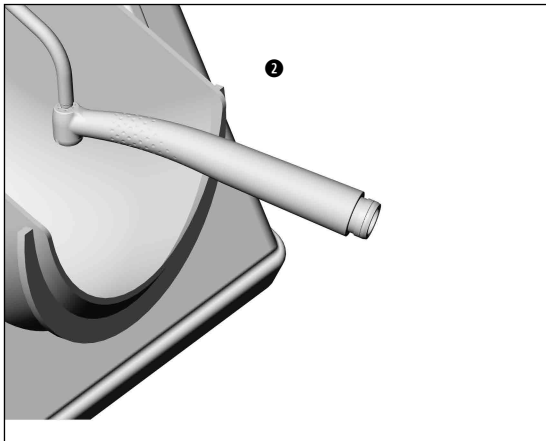
- > See Instructions for use of Assistina.



Weekly lubrication of the chucking system

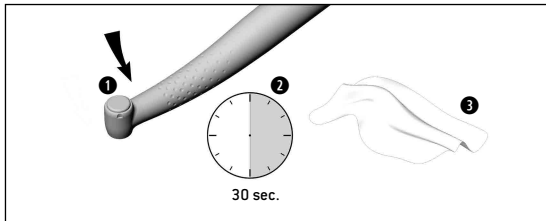
- ① **With W&H Service Oil F1, MD-400**
 - > Fit the spray cap REF 02036100 onto the oil spray can.
 - > Hold the medical device firmly.
 - > Press the tip of the spray nozzle firmly into the chucking system.
 - > Spray for approx. 1 second.

or



2 Only with W&H Assistina 301 plus


- > Fit the adaptor REF 02693000 onto the maintenance attachment.
Direct exit nozzle downwards.
- > Press the bur side of the medical device onto the adaptor from below.
- > Start the Assistina.
- > Press the medical device onto the adaptor for approx. 10 seconds.
- > Remove the medical device from the adaptor.
- > Close the cover of the Assistina and allow it to run for the remainder of the maintenance cycle [approx. 25 seconds].




Test run following oil service

- ❶ Place the medical device with the head positioned downwards.
- ❷ Start the medical device for 30 seconds to remove excess oil.
 - > Repeat the complete hygiene and maintenance process at any sign of dirt re-emerging.
- ❸ Wipe the medical device with gauze or soft cloth.
 - > Sterilize the medical device.

Sterilization and storage

 W&H recommends sterilization according to EN 13060, class B.

- > Note the instructions of the unit manufacturer.
- > Clean, disinfect and lubricate the medical device before sterilizing.
- > Wrap the medical device and the accessory in sterile goods packing according to EN 868-5.
- > Make sure, that you only remove dry sterile goods.
- > Store sterile goods dust-free and dry.

 The standard ISO 14457 stipulates a durability of at least 250 sterilization cycles.
In the case of W&H RK-97 L and RG-97 L, we recommend you to have a regular service carried out after 1,000 sterilization cycles or one year.

Approved sterilization procedures



Follow your local and national laws, directives, standards and guidelines.

- > Steam sterilization class B with sterilizers in accordance with EN 13060.
Sterilization holding time a minimum of 3 minutes at 134 °C (273 °F)

or

- > Steam sterilization class S with sterilizers in accordance with EN 13060.
The sterilizer manufacturer must give its express approval for the sterilization of the medical device.
Sterilization holding time a minimum of 3 minutes at 134 °C (273 °F)

6. W&H accessories and spare parts

Use only original W&H accessories and spare parts or accessories approved by W&H.

Suppliers: W&H partners

301	Assistina
02690400	Assistina adaptor for all W&H products with Roto-Quick system
02693000	Assistina adaptor for chuck system
10940021	W&H Service Oil F1, MD-400 (6 pcs)
02036100	Spray cap with nozzle for chucking system
02229200	Spray cap with spray nozzle for all W&H products with Roto-Quick system
02015101	Nozzle cleaner

7. Technical data with W&H control unit

RK-97 L, RG-97 L		RK-97 L	RG-97 L
Coupling according to standard	hose-side	W&H Roto Quick	W&H Roto Quick
Instrument shaft diameter	ISO 1797-1 (Ø mm)	1.6 – 0.01	1.6 – 0.01
Maximum length approved by W&H *	(mm)	21	21
Maximum operating part diameter	(mm)	2	2
Minimum chuck length		until limit stop	until limit stop
Speed range	(rpm)	60,000 – 320,000	60,000 – 320,000
Operating pressure	(bar)	variable	variable
Exhaust air pressure	(bar)	< 0.8	< 0.8
Air consumption at an operating pressure of 5.5 bar:	(NI/min)	75	75
Water setting range (recommended water pressure) **	(bar)	0.7 – 2 (1.5)	0.7 – 2 (1.5)
Chip air setting range (recommended chip air pressure) **	(bar)	3 ± 0.3	3 ± 0.3
Coolant supply volume	ISO 14457 (ml/min)	> 50	> 50
Chip air consumption at 2 bar	(NI/min)	> 1.5	> 1.5
Supply voltage	(V DC or V AC)	variable	variable
Current consumption	(A)	variable	variable

* see page 33

7. Technical data without W&H control unit

RK-97 L, RG-97 L		RK-97 L	RG-97 L
Coupling according to standard	hose-side	W&H Roto Quick	W&H Roto Quick
Instrument shaft diameter	ISO 1797-1 (\varnothing mm)	1.6 – 0.01	1.6 – 0.01
Maximum length approved by W&H *	(mm)	21	21
Maximum operating part diameter	(mm)	2	2
Minimum chuck length		until limit stop	until limit stop
Idle mode speed (\pm 30.000)	(rpm)	400,000	400,000
Operating pressure	(bar)	3 \pm 0.3	3 \pm 0.3
Exhaust air pressure	(bar)	< 0.5	< 0.5
Air consumption	(NI/min)	45	45
Water setting range (recommended water pressure) **	(bar)	0.7 – 2 (1.5)	0.7 – 2 (1.5)
Chip air setting range (recommended chip air pressure) **	(bar)	3 \pm 0.3	3 \pm 0.3
Coolant supply volume	ISO 14457 (ml/min)	> 50	> 50
Chip air consumption at 2 bar	(NI/min)	> 1.5	> 1.5
Supply voltage	(V DC or V AC)	3.2	3.2
Current consumption	(A)	0.4	0.4

* see page 33



* When using longer rotary instruments the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.

** Chip air pressure / water pressure must be set at the same time
Chip air pressure must be higher than water pressure

Power and speed data of medical devices are largely dependent on the quality of the tubings used and may therefore differ from the specified values.

rpm = min⁻¹ (Revolutions per minute)

Temperature information

Temperature of the medical device on the operator side:

max. 55 °C

Temperature of the medical device on the patient side:

max. 50 °C

Temperature of the working part (rotary instrument):

max. 41 °C

Ambient conditions

Temperature during storage and transport:

-40 °C to +70 °C

Humidity during storage and transport:

8% to 80% (relative), non-condensing

Temperature during operation:

+10 °C bis +35 °C

Humidity during operation:

5% to 80% (relative), non-condensing

8. Disposal



Ensure that the parts are not contaminated on disposal.



Follow your local and national laws, directives, standards and guidelines for disposal.

> Waste electrical equipment



> Packaging

Explanation of warranty terms

This medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for use have been followed.

As manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase.

12 months for: RG-97 L

24 months for: RK-97 L

Accessories and consumables are excluded from the warranty

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H!

Claims under warranty – accompanied by proof of purchase – must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

12/24 months warranty

Authorized W&H service partners

Find your nearest W&H service partner at <http://wh.com>

Simply go to the menu option »Service« for full details. Alternatively please contact:

W&H (UK) Limited, Unit 6, Stroud Wood Business Centre, Park Street, St Albans, AL2 2NJ Hertfordshire
t + 44 1727 874990, f + 44 1727 872254, E-Mail: technical.uk@wh.com

W&H IMPEX INC., 6490 Hawthorne Drive, Windsor, Ontario, N8T 1J9, Canada
t + 1 519 9446739, f + 1 519 9746121, E-Mail: service.ca@wh.com

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W&H Austria GmbH, Ignaz-Glaser-Straße 53, 5111 Bürmoos, Austria
t + 43 6274 6236-239, f + 43 6274 6236-890, E-Mail: office.at@wh.com

A-DEC Australia, *Office and showroom*, Unit 8, 5-9 Ricketty Street, 2020 Mascot NSW
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