Instructions for use

BRASSELER USA®

FORZA LS

Low Speed Air Motors

LS-25WK, LS-25BR, LS-25MW, LS-5MW, LS-25ST, LS-5ST

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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

REF	Catalogue number
SN	Serial number
	Date of manufacture
R 0 F	Forward-/Reverse drive
	DataMatrix Code for product information including UDI (Unique Device Identification)
	Thermo washer disinfectable
135°C	Sterilizable up to the stated temperature

℞ only Caution! Federal law restricts this device to sale by or on the order of a dentist, physician, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

1. Introduction

Customer satisfaction has absolute priority in the Brasseler 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 medical device and guarantee a smooth and efficient operation.



Observe the safety notes.

Intended use
The air motor is intended for the following applications: Drive for dental transmission instruments for dental restoration and prophylaxis. Supply of dental transmission instruments with cooling air, chip air, spray water and light.



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.

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.
> Modifications or repairs must only be undertaken by an authorized Brasseler service partner (see page 39).

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 Brasseler, invalidates all claims under warranty and any other claims.



Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

2. Safety notes



> Before using the medical device for the first time, store it at room temperature for 24 hours.
> The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
> Never touch the patient and the electrical contacts on the medical device simultaneously.
> Use only the supply hoses as specified by EN ISO 9168:
> 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 the filtered, oil-free and cooled air supplied by dental compressors for drive air
> Replace faulty or leaky O-rings immediately.
> Check the medical device for damage and loose parts before each use (e.g. O-ring).
> Do not operate the medical device if it is damaged.
> Perform a test run before each use.
> It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the treatment water decontamination system, as well as its handling.
> Always follow recommendations made by the manufacturer of the transmission instrument and the rotary instrument.

Hygiene and maintenance prior to initial use

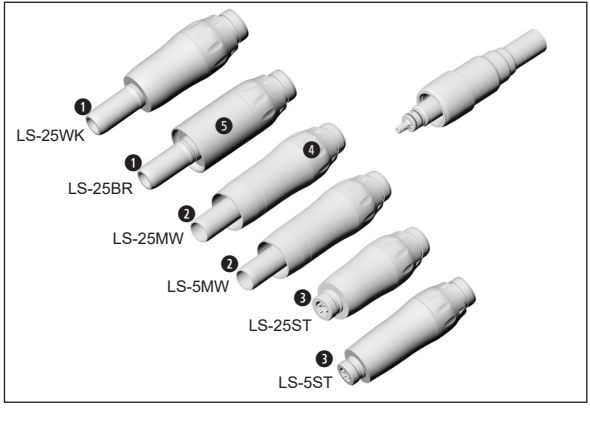


> The medical device is sealed in PE film and not sterilized when delivered.
> The PE film and the packaging are non-sterilizable.



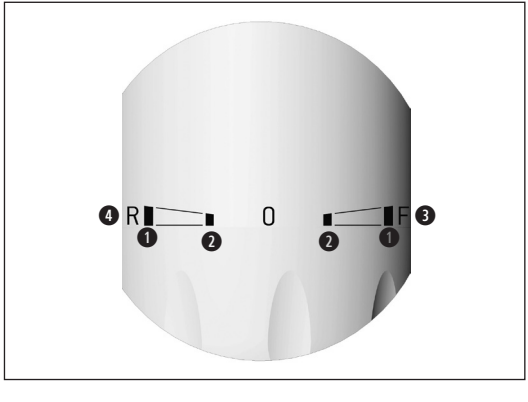
> Clean, disinfect and lubricate the medical device.
> Sterilize the medical device.

3. Product description



LS-25WK, LS-25BR, LS-25MW, LS-5MW, LS-25ST, LS-5ST

1. ISO 3964 connection
2. Midwest connection
3. Star Dental connection
4. Speed control ring
5. Motor sheath

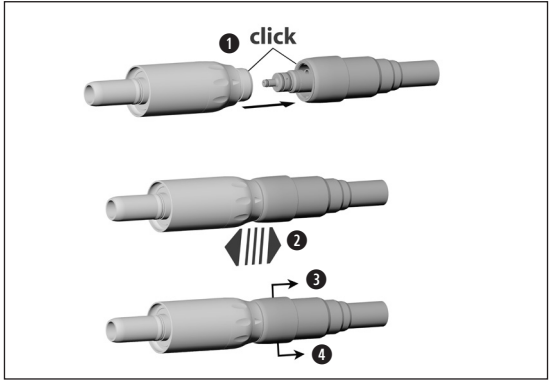


Speed control

❶ Maximum speed
❷ 50 % of the maximum speed
❸ Forward drive (F)
❹ Reverse drive (R)

The air motor is set to »F« (forward) when delivered.

Assembly/Removal - Roto Quick coupling



Do not assemble or remove the medical device during the operation!

❶ Push the medical device onto the Roto Quick coupling.

❷ Verify full engagement

or

❸ Pull back the sleeve of the Roto Quick coupling.

❹ Remove the air motor by pulling it axially.

Test run



Do not hold the air motor at eye level.

> Start the medical device idle for 5 seconds.
> Turn the speed control ring to »F« forward or »R« reverse.
> Vary the speed from minimum to maximum.



In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating, coolant failure or leakage) **stop the medical device immediately** and contact an authorized Brasseler service partner.

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

The information on the validated reprocessing methods serves as an example for an ISO 17664 compliant reprocessing of the medical device.

> Wear protective clothing, safety glasses, face mask and gloves.
> Remove the transmission instrument from the air motor.
> Set the speed control ring to F or R.
> Remove the air motor from the supply hose.

> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar (43.5psi) for manual drying.

Cleaning agents and disinfectants



> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
> Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
> It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
> Use disinfectants which have been tested and found effective by the Verbund für Angewandte Hygiene e.V. (VAH = Association for Applied Hygiene), the Österreichischen Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) or the U.S. Environmental Protection Agency (EPA).



The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.

The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

> Send worn or damaged medical devices and/or medical devices with material changes to an authorized Brasseler service partner.

Processing cycles

> The use of the medical device is guaranteed until at least 1,000 reprocessing cycles.
> If a washer-disinfector (WD) is not used
  > the use of the medical device is guaranteed until at least 4,000 reprocssing cycles.



Clean 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.

> Operate the medical device for at least 10 seconds at idle speed.
> Ensure that all coolant outlets are rinsed out.



> Wipe the entire surface of the medical device with disinfectant.
> Remove the motor from the supply hose.

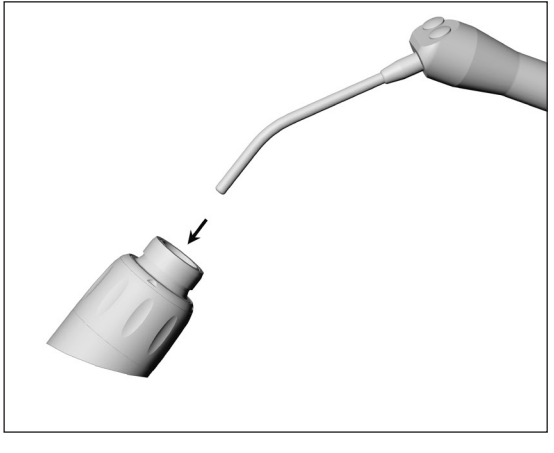


Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfectant step after cleaning.



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

> Clean the medical device under running tap water (< 35°C / < 95°F).
> Rinse and brush off all internal and external surfaces.
> Move moving parts back and forth several times.
> Remove any liquid residues using compressed air.



Cleaning the coolant tubes

Blow through the coolant tube with the air syringe.

If it proves impossible to correct the malfunction, please contact an authorized Brasseler service partner.

Brasseler recommends wiping down with disinfectant.

Evidence of the medical device's basic suitability for effective manual disinfection was provided by an independent test laboratory using the disinfectants “mikrozid® AF wipes” (Schülke & Mayr GmbH, Norderstedt).

Automated cleaning and disinfection for **LS-25BR** only.



Brasseler recommends automated cleaning and disinfection using a washer-disinfector (WD).
> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of washer-disinfectors, cleaning agents and/or disinfectants.



Evidence of the medical device's basic suitability for effective automated disinfection was provided by an independent test laboratory using the »Steelco DS 50« (Steelco) washer-disinfector and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg) according to ISO 15883.

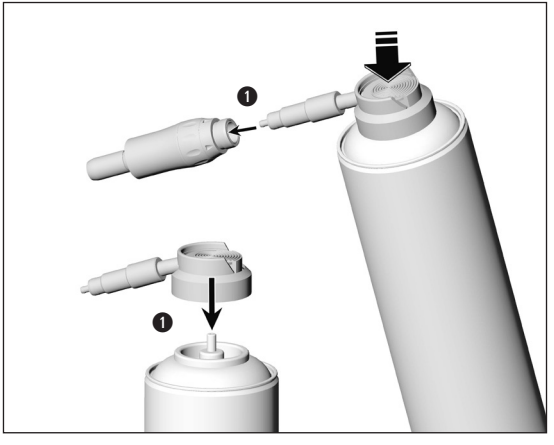
> Cleaning at 60 °C (140 °F) – 3 minutes
> Disinfection at 90 °C (194 °F) – 1 minutes

> Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
> Remove any liquid residues using compressed air.

Inspection



> Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
> Reprocess any medical devices that are still soiled.
> Sterilize the medical device following cleaning, disinfection and lubrication.



Lubrication

> Set the speed control ring to F or R. (if. available)

> Lubricate the dry medical device at least once a week or after 90 minutes of use or after every internal cleaning (WD).

> Direct the medical device downwards

❶ With Brasseler Handpiece Spray Lubricant

> Fit appropriate spray adapter onto universal cap nozzle of Brasseler Handpiece Spray Lubricant.

> Insert spray adapter completely into back of the air motor and hold it in place.

> Dispense spray for 1-2 seconds, then hold the air motor upside down, run air motor to purge cleaner/lubricant.

> Repeat the steps until cleaner/lubricant expelled from air motor is clear.

> Wipe excess cleaner/lubricant from air motor with dry, lint-free cloth.

Test after lubrication



> Set the speed control ring to F or R. (if available)
> Direct the medical device downwards.
> Operate the medical device so that excess oil can escape.

Pack the medical device and the accessories in sterilization packages that meet the following requirements:

> The sterilization package must meet the applicable standards in respect of quality and use and must be suitable for the sterilization method.
> The sterilization package must be large enough for the sterilization goods.
> The filled sterilization package must not be under tension.

Brasseler recommends sterilization according to EN 13060, EN 285 or ANSI/AAMI ST55.

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of steam sterilizers.
> The program selected must be suitable for the medical device.

Recommended sterilization procedures

> “Dynamic-air-removal prevacuum cycle” (type B) / “Steam-flush pressure-pulse cycle” (type S)*/**
  134°C (273°F) for at least 3 minutes, 132°C (270°F) for at least 4 minutes
> “Gravity-displacement cycle” (type N)**
  121°C (250°F) for at least 30 minutes
> Maximum sterilization temperature 135°C (275°F)

Evidence of the medical device's basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L* steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)), the Systec VE-150* steam sterilizer (Systec) and the CertoClav MultiControl MC2-S09S273** steam sterilizer (CertoClav GmbH, Traun).

"Dynamic-air-removal prevacuum cycle" (type B):	134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/**
"Steam-flush pressure-pulse cycle" (type S):	134°C (273°F) – 3 minutes*, 132°C (270°F) – 4 minutes*/**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

Drying times:

"Dynamic-air-removal prevacuum cycle" (type B):	132°C (270°F) – 30 minutes**
"Steam-flush pressure-pulse cycle" (type S):	132°C (270°F) – 30 minutes**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

* EN 13060, EN 285, ISO 17665
** ANSI/AAMI ST55, ANSI/AAMI ST79



> Store sterile goods dust-free and dry.
> The shelf life of the sterile goods depends on the storage conditions and type of packaging.

In the event of operating malfunctions immediately contact an authorized Brasseler service partner.
Repairs must only be undertaken by an authorized Brasseler service partner.



> Ensure that the medical device has been completely processed before returning it.

7. Brasseler Accessories and spare parts

Use only original Brasseler accessories and spare parts or accessories approved by Brasseler.
Supplier: Brasseler partners

5029555U0	Brasseler Quick Coupler Spray Cap
5029558U0	Brasseler Handpiece Spray or other approved handpiece lubricant

Everclean maintenance machine or other approved maintenance machine
Everclean maintenance adapters or other approved adapters

8. Technical data

	LS-25BR	LS-25WK	LS-25MW	LS-5MW	LS-25ST	LS-5ST
Coupling hose-side according to standard Motor/transmission instrument connection according to standard Outer diameter of the motor sheath (mm)	W&H RQ ISO 3964 20	W&H RQ ISO 3964 16	W&H RQ Midwest 16.9	W&H RQ Midwest 16.9	W&H RQ Star-Dental 16.5	W&H RQ Star-Dental 16.5
Operating pressure range (bar/psi)	2.2 – 3.5 bar 32 – 50.8psi					
Recommended operating pressure	3.2 bar 46.4psi					
Speed range (rpm) at an operating pressure up to (at resultant exhaust air pressure of maximum 0.25 bar/3.6psi)	25,000** +/–10%	25,000** +/–10%	25,000** +/–10%	5,600** +/–10%	25,000** +/–10%	5,600** +/–10%
Speed control	yes	yes	yes	yes	yes	yes
Maximum torque up to (Ncm)	4**	4**	4**	14.6**	4**	14.6**
Maximum power up to (W)	30**	30**	30**	25**	30**	25**
max. air consumption (Nl/min) at recommended operating pressure	< 60	< 60	< 60	< 60	< 60	< 60

* Chip air pressure / water pressure must be set at the same time. Chip air pressure must be higher than water pressure.
** Power and speed are dependent on the quality of the supply hoses used and may differ from the specified values.
rpm = min-1 (Revolutions per minute)

Temperature information
Temperature of the medical device on the operator side: maximum 55°C (131°F)

Ambient conditions

Temperature during storage and transport:	-40°C to +70°C (-40°F to +158°F)
Humidity during storage and transport:	8% to 80% (relative), non-condensing
Temperature during operation:	+10°C to +35°C (+50°F to +95°F)
Humidity during operation:	15% to 80% (relative), non-condensing

9. Disposal



Ensure that the parts are not contaminated on disposal.



Follow your local and national laws, directives, standards and guidelines for disposal
> Medical device
> Packaging

Explanation of warranty terms

This Brasseler 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, Brasseler is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase.

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

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

24 months warranty

Authorized Brasseler service partners

Brasseler U.S.A. Dental, LLC
One Brasseler Blvd.
Savannah, GA 31419, USA
800.841.4522



Brasseler U.S.A. Dental, LLC
One Brasseler Blvd.
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