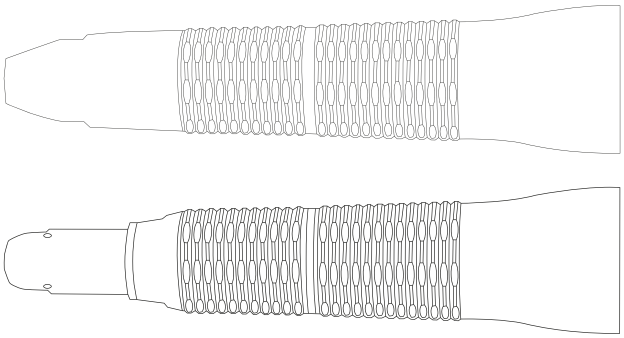


CE 0123

1 Explanation of symbols

	See chapter **2. Safety**
	Important information for the user
	Product can be sterilized in a steam sterilizer (Autoclave)
	Can be used in thermal disinfectors
CE	CE-mark – Confirms that this product fulfills all requirements for medical products
REF	Reference number
SN	Serial number

2 Safety

2.1 Description of danger levels

	**CAUTION**
	CAUTION is used if a deficiency in adequate care may result in an endangering of the patient, the user or others.

	**WARNING**
	WARNING is used if improper use may result in serious injuries.

2.2 Safety notes

	**WARNING**
	Risk of injury for the patient and the operator Concerning damages like irregular running noise, irregular vibrations, an unspecific rise in temperature and/or other defects. → Stop operating immediately and contact our service.

	**WARNING**
	Risk of infection In case of an injury of the tissue in the oral area, do not proceed to work with air-operated instruments because of a high risk of an infection.

WARNING	**WARNING**
	Burns due to an increased heat of the head of the instrument Burns in the oral area may occur due to an increased heat of the head of the instrument.

CAUTION	**CAUTION**
	Accelerated deterioration and dysfunctions due to long term non-usage → Before storage, clean, maintain and dry the instrument according to the norm. Store in the original packing, dry and dustproof.

We recommend an annual check-up and maintenance of the entire spindle system by MK-dent or by MK-dent authorized personnel.

3 Product description

This manual can be used for the following MK-dent products:

Handpieces of the Basic Line series
LB01, LB02

3.1 Intended purpose

This medical product may only be used in a dental surgery. Intended use is mostly outside the mouth to prepare better fit of prothesis and polishing tooth and restauration surfaces. Also caused by the straight shape it is nearly not possible to use this handpiece inside the mouth.

3.2 Use according to regulations

This product may only be used for the intended purposes, executed by professionally trained personnel.
The indications and warnings in this manual must be considered. This also includes the observing of the processing (see chapter **5 Processing according to ISO 17664**) and the valid national health and safety regulations. Any other use may result in an endangering of the patient, the operator or others and is strictly prohibited. Before each application, the perfect functionality of the instrument must be tested.

3.3 Technical specifications

	LB01	**LB02**
Transmission/reduction	1:1	1:1
Max. speed	20 000 min^{-1}	20 000 min^{-1}
Max. drive speed	20 000 min^{-1}	20 000 min^{-1}
Label	blue ring	blue ring
Motor connection according to ISO 3964/DIN 13940	yes	yes

Contra angle burs are usable. The handpiece can be adjusted to motors that fulfill the ISO 3964/DIN 13940 requirements.

3.4 Transport and storage requirements

CAUTION	**CAUTION**
	Dysfunction of the instrument after a overcooled storage → Heavily cooled instruments must be warmed to room temperature prior to operating.

For transportation and storage, please consider the following:

Temperature	-20 °C - +70 °C (-4 °F - +158 °F)
Relative humidity	5% - 95%, non-condensing
Air pressure	700 hPa - 1060 hPa (10 psi - 15 psi)

Protect this medical instrument from moisture!

4 Putting into service and operation

WARNING	**WARNING**
	Risk of infection for patients and operator due to non-sterile instruments → Before the first and after each further use the instrument must be processed and sterilized as defined in chapter **5 Processing according to ISO 17664.**

WARNING	**WARNING**
	Risk of infections for others at waste disposal → Before waste disposal, this medical product has to be processed according to instructions and must at least be sterilized.

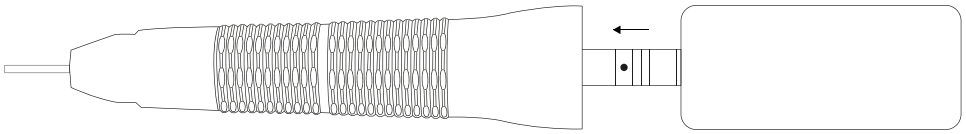
CAUTION	**CAUTION**
	Dysfunctions and/or risk of an infection caused by moist and contaminated compressed air and by contaminated cooling water → This product may only be operated with CE-certified dental units or with others certified by actual national guidelines and with a corresponding supply of water and compressed air according to the valid norms of dental care.

4.1 Attaching the instrument to the motor

WARNING	**WARNING**
	Dysfunctions due to a decoupling of the instrument while operating An instrument that is not correctly attached to the coupler may loosen while operating. → Prior to each use check if the instrument and the coupler are correctly attached by slightly pulling at the instrument.

CAUTION	**CAUTION**
	Damages due to an insertion or a removal of the instrument, while the motor is rotating Damages to the collector of the motor → Do not unplug or plug the instrument to the motor, when the motor is rotating!

CAUTION	**CAUTION**
	The handpiece stops, when the handpiece and the motor are connected while there is no tension on the spindle → Only use the handpiece with a tensioned spindle.



☞ Place the instrument exactly on the motor and press firmly until the connection clicks in place.
☞ Check the proper fitting of the instrument on the motor by slightly pulling at the instrument.
☞ For removal, hold the motor in one hand, while pulling the instrument upwards in a turning motion with the other hand.

4.2 Insertion of rotating instruments

WARNING	**WARNING**
	Risk of injury for the patient and possible damage of the instrument Use of instruments, other than mentioned above. → Only use rotating instruments that fulfill the requirements mentioned above. → Follow the manual for intended use of the rotating instrument.

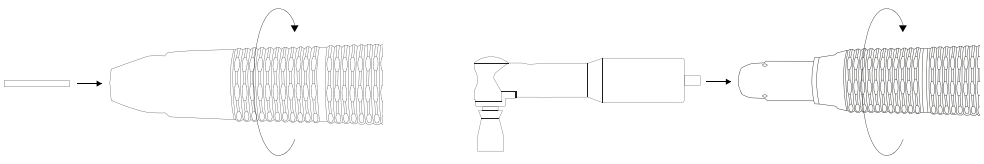
WARNING	**WARNING**
	Risk of injury due to the use of worn out rotating instruments Rotating instruments can fall out while operating and thus injure the patient. → Do not use any rotating instruments with a worn out shaft.

WARNING	**WARNING**
	Risk of injury for the user due to rotating instruments Cuts and resulting infections may occur due to incorrect use. → Always use gloves or a finger protection.

WARNING	**WARNING**
	Risk of injury for the user due to a defective spindle In case of a defective spindle, the bur may fall out and cause injuries. → Check the correct attaching of the spindle by slightly pulling at the bur. → Use gloves or finger protection for insertions and removals of the spindle to prevent injuries and infections.

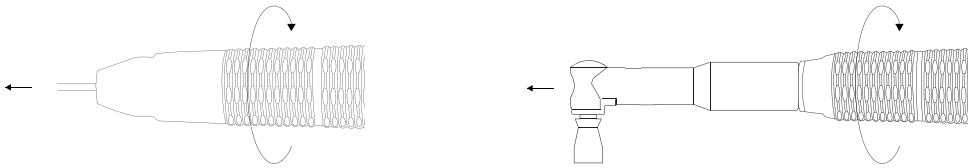
Only use rotating instruments made of steel or carbide metal that fulfill the EN ISO 1797-1 requirements and also the following criteria:

Diameter of the shaft	2.334 mm to 2.350 mm
Min. insert length of the shaft	30 mm
Max. insert length of the shaft	44.5 mm



☞ Untighten the tension ring by completely turning it in the direction of the arrow and insert the bur/prophy cup into the spindle.
☞ Tighten the tension ring by bringing it into the original position.
☞ Check the holding force of the rotating instrument by slightly pulling at the bur.

4.3 Removal of rotating instruments



☞ After the bur/prophy cup has come to a complete stop, turn the tension ring in the direction of the arrow as far as it will go and remove the bur.
☞ Never close the tension ring without having previously inserted a bur or a test pin.

5 Processing according to ISO 17664

5.1 Processing at the location of use

WARNING	**WARNING**
	Risk of infection due to non-sterile instruments. → Always wear gloves.

☞ Process the instrument within one hour after each treatment in order to prevent piling.
☞ Immediately remove any debris of cement, blood or composite.
☞ Ensure a dry transport of the instrument to the place of processing.
☞ Do not put the instrument in any kind of solution.

5.2 Cleaning

WARNING	**WARNING**
	Dysfunctions due to cleanings in an ultrasonic bath → Only clean the instrument as described below.

5.2.1 Manual pre-cleaning

CAUTION	**CAUTION**
	Risk of infection due to multiple uses of dental brushes → To prevent cross infections always use a new dental brush for each instrument.

CAUTION	**CAUTION**
	Insufficient cleaning of the surface and the water- and air pipes → In order to ensure a successful cleaning a thorough manual pre-cleaning, even with the small brush, must be done.

Tools:
- Drinkable water 30 °C ± 5 °C (86 °F ± 10 °F)
- Brush or soft tooth brush
- Dental brush
- 50 ml syringe without cannula

☞ To pre-clean the instrument place it under running water and carefully brush debris completely off the surface by using one of the tools mentioned above.
☞ To pre-clean the spindle, please insert the enclosed dental brush in the spindle opening. Carefully loosen and remove any residue and debris by circular motions with the brush.
☞ Repeat the process several times and each time clean the dental brush with water.
☞ To pre-clean the water- and air pipes place the syringe at the lower end of the handpiece and rinse the cavities at least 5 times.

5.3 Disinfection

CAUTION	**CAUTION**
	The use of disinfecting baths and/or of chlorinated disinfectants may lead to defects and dysfunctions of the instrument. → Only clean and disinfect the instrument in a thermal disinfector.

5.3.1 Manual disinfection of the surface
Only use disinfectants whose microbiological effectiveness is ensured by the manufacturer (e.g. VAH/DGHM-regis-tration and CE-mark).
Concerning the material compatibility, only disinfectants free of aldehyde and based on alcohol may be used.

☞ Apply the disinfectant to a cloth and wipe the instrument clean.
☞ Consider the reacting time that is set by the manufacturer of the disinfectant.
☞ Follow the manual for the disinfectant.

5.3.2 Mechanical cleaning and disinfection of the interior and the exterior

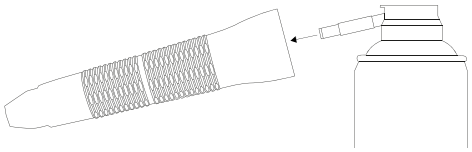
MK-dent recommends thermal disinfectors that fulfill the EN ISO 15883-1 requirements and are approved by the manufacturer for the straight- and contra angle, as well as for high speed handpieces. The cleaning should be carried out at a minimum of 55°C (131°F) and for at least 5 minutes, the disinfection at a minimum of 90°C (194°F) and for at least 5 minutes (for an A0-value > 3,000). For the cleaning a mild alkaline cleaning agent with a pH of 9 to 11 is recommended, like e.g. Neodisher® MediClean Forte. For the validation of the process see chapter **6.2 Validation of the processing.**

☞ For the internal cleaning the adaptors specified by the manufacturer must be used.
☞ Repeat the process, if visible contaminations still exist after the treatment in a thermal disinfector.
☞ Before use the instrument must be dry and free of residues.
☞ To prevent any kind of impairments of the instrument, make sure after every cycle that the instrument is dry on the inside and the outside.
☞ Directly afterwards use the MK-dent Premium Service Oil to lubricate the instrument.

5.4 Process of drying
5.4.1 Manual drying
☞ Blow on the instrument with compressed air from the inside and the outside until no visible drops are left.

5.4.2 Mechanical drying
The drying process normally is part of the cleaning process of your thermal disinfector. Please follow the instructions for your thermal disinfector**.**
☞ In case of moisture remaining on the instrument after the cleaning process, blow with compressed air until completely dry.

5.5 Maintenance with the MK-dent Premium Service Oil LU1011
MK-dent recommends lubricating and maintaining the instrument after each mechanical cleaning and before each sterilization process.



☞ For the maintenance of the cartridge screw the enclosed lubrication tool onto the lubrication can.
☞ Insert the lubrication tool into the lower end of the instrument and spray into the canal for drive air for approximately 2 seconds.
☞ Plug the instrument onto your treatment unit and let it run for 15 to 20 seconds so that the surplus lubricant can escape from the instrument.

6 Sterilization

The sterilization bag has to be big enough for the instrument so that the instrument fits without stretching the bag. Concerning quality and application, the bag has to fulfill all the valid norms and has to be suitable for the sterilization process.

☞ Shrink-wrap each instrument individually into a sterilization bag.

6.1 Sterilization with a steam sterilizer (Autoclave) according to EN 13060/ISO 17665-1

CAUTION	**CAUTION**
	Damages due to inappropriate maintenance or service may result in dysfunctions and/or deterioration. Reduced lifetime of the product → Lubricate the instrument with the MK-dent Premium Service Oil before each sterilization.

CAUTION	**CAUTION**
	Contact corrosion caused by moisture Damages of the product →After sterilization, immediately remove the instrument from the autoclave.

135°C This medical product has a temperature resistance of up to max. 135 °C (275 °F).

Only apply the following sterilization process:
- Autoclave with a triple pre-vacuum (recommended): minimum of 5 minutes at a minimum of 134°C (273°F)

☞ Pay close attention to the manufacturer´s instruction.

6.2 Validation of the processing

The validation of the cleaning and of the disinfection was carried out with the device Miele® G 7835 in the programme Vario TD with the cleanser Neodisher® MediClean Forte.

Adjustment:
- Pre-rinsing for 1 minute
- Cleaning at 55°C (131°F) for 5 minutes with a dosage of 0.5% Neodisher® MediClean Forte
- Neutralization
- Washing down
- Disinfection at 90°C (194°F) for 5 minutes

The sterilization was validated with the device Tuttnauer® EHS 3870 in a fractional pre-vacuum process at 134°C (273°F) for 5 minutes. Please note, that the reprocessing procedure performed in your dental office must be validated also.

For more information on the entire preparation process download our MK-dent Processing Guide for High- & Low Speed Handpieces from our website www.mk-dent.com/downloadcenter.

6.3 Maintenance & service

CAUTION	**CAUTION**
	Inappropriate maintenance or service may result in dysfunctions and/or deterioration. → Always perform proper maintenance and service.

7 Storage

☞ Store the cleaned and sterilized instrument in a dry, dark and cool place, sheltered from dust and germs.
☞ Please pay attention to the date of expiry of the sterilization liquid.

8 Tools & spare parts

	LB01	**LB02**
Handpiece of the Basic Line series	LB01	LB02
Lubrication tool	LT1013	
Premium Service Oil	LU1011	
Premium Service Oil for KaVo® QUATTROCARE	LU1022	

KaVo® is a registered trademark. MK-dent does not have any economical connection to the company mentioned above.

9 Warranties

MK-dent provides the end user a warranty for proper function, immaculate material and workmanship for a period of 12 months after purchasing. Relevant for this is the invoice date.

In case of justified complaints MK-dent carries out a free repair or a possible free replacement. This will be decided by MK-dent.
Other claims of any kind, in particular damage compensation are excluded. In the event of default, gross negligence or intent, this shall only apply nless there are compelling legal regulations.

MK-dent is not liable for defects and their consequences that have arisen whose arising may be due to natural wear, improper handling, improper cleaning, or maintenance, non-compliance with operating or manual instructions, calcination or corrosion, contaminated air and water supply or chemical or electrical influences that are unusual or not permitted according to MK-dent's instruction for use or to other manufacturer's instructions.

The warranty does usually not cover lamps, light conductors made of glass fibers, glassware, rubber parts and the color fastness of plastic parts. All liability is excluded if defects or their consequences arise because of interventions or modifications on the product by the end user or by a third party not authorized by MK-dent.

Warranty claims will only be accepted if the product is submitted with a proof of purchase in the form of an invoice or a copy of the delivery note. Dealer, purchase date, model and serial number must be clearly visible.

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