precisionplus™

DENTAL LOW SPEED HANDPIECE

L10-1

L10 Straight Handpiece

USER MANUAL

For your safety and the safety of your patients please read this user manual carefully before use and file for future reference.
This manual is published by Precision Plus.
Precision Plus does not guarantee its contents and reserves the right to amend without prior notice. Amendments will be published in new editions of this manual.

1. Indication for Use

- This low speed straight handpiece is intended for the purposes of dental treatment and prophylaxis.
- It is to be used for dental treatment by trained dental professionals.

2. Precautions for Handling and Operation

- All precautions should be read and understood before use.
- Devices are only to be used for its specified intended use.
- Safety instructions are provided in order to prevent the risk of personal injury or damage to the dental handpiece.

⚠ **WARNING:** Indicates a hazard that may result in serious injury/device damage if instructions are not correctly followed.

⚠ **CAUTION:** Indicates a hazard that may result in mild to moderate injury/device damage if instructions are not correctly followed.

3. Contraindications

Should be used with caution on infants, pregnant women, hemophiliacs and patients with heart problems.

4. Adverse Reactions

- Patients may feel tense, uncomfortable or experience pain during use of the device.
- Patients hearing may be affected during use of the device.

⚠ **WARNING**

- Immediately after each and every treatment, the handpiece should be inspected, cleaned, lubricated and sterilized. Failure to correctly maintain the handpiece may lead to overheating, injury to user/patient or damage to handpiece.
- Debris inside the gear mechanism can lead to overheating and burn injuries. Do not allow foreign materials into the gear mechanism or chuck.

⚠ **CAUTION**

- Users are required to protect themselves, the patient and third parties from danger.
- Users are responsible for correct and intended use, regular maintenance and continual inspection of the handpiece.
- Avoid impact or contamination of handpiece.
- Do not disassemble or alter the handpiece except as recommended in our user instructions.
- Correct eye, face and personal protection must be used by operator, assisting staff and patient whilst handpiece is being used.
- If the handpiece begins operating abnormally, immediately stop use and contact your authorized Precision Plus dealer.
- Handpiece is supplied in a non-sterile state and must be autoclaved before use.
- Handpiece should be carefully tested for vibration, noise or overheating prior to use, if it has not been used for a long time.

- Always inspect bur to confirm it is free of debris before inserting into handpiece. Debris inside chuck may cause rotation slip or allow the bur to become disengaged during use.
- Do not exceed the maximum length or speed of bur for the handpiece as recommend by Precision Plus. See “5. Specifications” of this manual for information on correct bur choice.
- Do not apply excess pressure to the bur during use, this can lead to bur bending or breaking causing injury to user/patient or the handpiece.
- Do not use burs that are bent, rusted, worn, cracked, deformed or have non ISO standard conforming shanks, Burs with these issues may disengage or break during use.
- Always engage bur correctly into handpiece head. Failure to correctly insert burs may cause damage to bearings leading to injury or premature failure of handpiece.
- Before use always inspect handpiece for excessive vibration, noise or overheating. If there are abnormalities stop use and contact authorized Precision Plus Dealer. (refer to 8 . Test prior to use)

5. Specifications

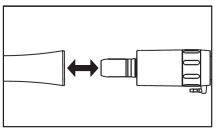
Model	L10-1
Gear Reduction Ratio	1:1
Maximum Speed	24,000 r.p.m. ±10%
Applicable Bur	Φ2.35(+0,-0.016) mm
Maximum Overall Length of Applicable Bur	44.6 mm (type 2 of ISO 14457)
Max. Working Dia of the Rotary Instruments	Φ4 mm
Minimum Fitting Length of Shank	Type 2: 15 mm
Type of Connector	ISO 3964

6. Connection & Disconnection of Handpieces to Motor

6.1 Connection

1. Connect handpiece to motor until it locks into place. (Fig.1)
2. Pull on handpiece to make sure it is securely attached to motor.

Fig. 1



6.2 Disconnection

1. Hold motor and handpiece separately and pull the handpiece off in an axial direction using a slight rotation (Fig.1).

CAUTION: Motor must have completely stopped rotating before connecting/disconnecting. Connect only to E type motors [ISO 3964]. Do not exceed the Max Rotational Speed as shown in '5. Specifications'.

7. Inserting & Removing the Bur

7.1 Inserting the Bur

1. Turn the Bur Locking Ring towards the mark until a “click” is heard.(Fig. 2)
2. Insert the bur fully into the chuck and then turn the Bur Locking Ring towards the mark until a “click” is heard (Fig. 2).

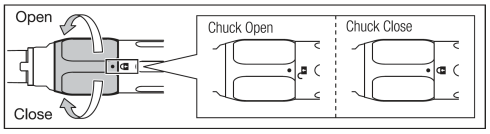


Fig. 2

3. The bur should now be engaged in the chuck. Test the Bur is secured by holding the handpiece and gently pulling the bur outwards.

7.2 Removing the Bur

1. Turn the Bur Locking Ring towards the mark until a “click” is heard.(Fig. 2) Gently pull the bur outwards to remove from chuck.

WARNING

- After engaging bur in chuck, check the ● mark is correctly aligned with the mark. If the marks are not correctly aligned, the bur will not be securely or safely engaged and overheating may occur. This may lead to handpiece damage or patient burn injuries.
- Remove the bur only after the handpiece has completely stopped rotating.

8. Test prior to Use

Once handpiece is correctly connected to motor, check for unusual vibration, noise or overheating. If there are any abnormalities, stop using and contact your authorized Precision Plus dealer.

CAUTION

- Always keep hands clear of bur during rotation to avoid injury.
- Do not run the handpiece without a bur inserted or when a bur is inserted but the Bur Locking Ring is in an open position.

9. Post-use Maintenance

CAUTION: Do not use the following fluids to wipe, immerse or clean the handpiece: strong/highly acidic water, strong acid/alkaline chemicals, chlorine containing solutions or solvents such as benzine or thinner.
Do not use ultrasonic bath during the cleaning process.

9.1 Preparation

1. Use correct eye, face and personal protection to avoid possible infection.
2. Remove the bur.
3. Disconnect handpiece from the Motor.

9.2 Cleaning

9.2.1 Preparation at the Point of Use:

Disconnect the handpiece from the air motor. Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don’t use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.
Store the instruments in a humid surrounding.
Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.

9.2.2 Pre-cleaning

Do a manual pre-cleaning, until the handpiece is visually clean. Submerge the handpiece in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristle brush.

9.2.3 Automated Cleaning:

Use a washer-disinfector meeting the requirements of the ISO 15883 series.
Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program:

- 4 min pre-washing with cold water (<40°C);
- emptying
- 5 min washing with a mild alkaline cleaner at 55°C
- emptying
- 3 min neutralising with warm water (>40°C);
- emptying
- 5 min intermediate rinsing with warm water (>40°C)
- Emptying

The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).
Note: Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.

9.2.4 Disinfection:

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for this device to achieve an A0 value of 3000.

9.2.5 Drying:
Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.

⚠ **CAUTION:** Visual inspection for cleanliness of the handpiece. If necessary, perform reprocessing process again until the handpiece is visibly clean. Before packaging and autoclaving, make sure that the handpiece has been maintained acc. to this instruction.

9.3 Lubricating
Lubricant must be applied after use and before autoclaving.

1. Attach the Spray Nozzle onto the Spray Port of the can. (not included with this device)
2. Insert the Spray Nozzle into the rear of the handpiece. Hold the handpiece firmly and spray lubricant for 2-3 seconds. Apply lubricant until it has been expelled from handpiece head for 2 seconds (Fig. 3).

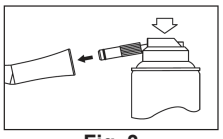


Fig. 3

⚠ **CAUTION**

- Always follow lubricant manufacturers instructions.
- Always hold lubricant can in an upright position.
- Hold handpiece firmly to avoid it being dislodged due to lubricant spray pressure.

9.4 Sterilization
Handpiece should be sterilized after each and every treatment.

1. Handpiece should be lubricated as per user manual.
2. Insert the handpiece into an autoclave pouch and seal pouch correctly. The autoclave pouch should comply with the requirements of EN ISO 11607.
3. Sterilize at 134 °C for 5 mins. Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Flash sterilization is not allowed on lumen instruments!
4. Handpiece should be stored in a sealed pouch in a dry, clean and dust free place out of direct sunlight until required for use.

⚠ **CAUTION**

- Do not use an ultrasonic bath during the cleaning process.
- Always follow the instructions provided by lubricant manufacturer. Be aware of all precautions and warnings.
- Handpiece must be cleaned and lubricated before sterilization.
- Any remaining blood on outer surface may become clotted and cause operational failure.
- Do not overheat or cool Handpiece too quickly. Rapid change in temperature may cause damage to the product.
- Do not use autoclaves exceeding 137°C during sterilization.
- Precision Plus recommends sterilization according to EN 13060/EN 285. Always follow autoclave manufacturer's instructions for use.
- Reprocessed products should be stored, protected from dust in a dry, dark and cool place with minimum exposure to germs.
- Autoclave sterilization is the only agreed method to correctly sterilize this handpiece.The validity of other sterilization methods is not confirmed or guaranteed.
- Resistance to reprocessing: 250 cycles (reprocessing cycles include cleaning and sterilization

10. Symbol

134°C	Sterilizable in a steam sterilizer (autoclave) at the temperature 134°C(273°F)
NON STERILE	The device has not been subjected to a sterilization process
MD	Medical Device
	Consult instructions for use
	Washer-disinfector for thermal disinfection

SN	Serial number
CE 0197	Conforms to CE European Directive of “Medical device directive 93/42/EEC”
EC REP	Authorized representative in the European Community.
LOT	Batch code
	Date of manufacture
	Manufacturer

11. Troubleshooting

Malfunction	Cause	Solution
High pitched or unusual noise, reduced cutting power or failure to rotate	Debris in handpiece or gear mechanism	Clean and lubricate handpiece
Reduction in speed	Motor problem	Check motor speed
Handpiece will not engage bur or hold bur in chuck	Damaged chuck	Send device to Precision Plus authorized repairer
Abnormal bur rotation or failure to cut	Bearing damage	Replace damaged components

If the handpiece will not work correctly after following above troubleshooting solutions, please contact Precision Plus or an authorized maintenance centre.

12. Warranty

Precision Plus products are warranted against manufacturing and material defects. Precision Plus reserves the right to analyze and determine the cause of any problem. The warranty is voided should the product not be used in accordance to the user manual, not for its intended purpose, has not been repaired by Precision Plus or an authorized Precision Plus repairer, or has non genuine Precision Plus parts installed. Replacement parts will be made available for seven years after the date of discontinuation of the model.

13. Disposal of Product

In order to avoid the health risks to operators handling the disposal of medical equipment, as well as the risks of environment contamination caused thereof, a surgeon or a dentist is required to confirm the equipment is sterile. Ask specialist firms who are licensed to dispose of specially controlled industrial wastes, to dispose of the product for you. Always follow your country specific laws, directives, standards and guidelines for disposal of medical devices.

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