Instructions for use

PATTERSON®
DENTAL

PD-44 M

Contents

Symbols

in the Instructions for use

WARNING!
(risk of injury)

CAUTION!
(to prevent damage occurring)

General explanations, without risk to persons or objects

Do not dispose of with domestic waste

Not for re-use

Symbols

on the medical device / packaging

Sterilizable up to the stated temperature

Catalog number

Serial number

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

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

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 completely; they explain how to use your medical device and ensure proper, efficient and safe operation.

Observe the safety notes.

Intended use
The straight handpiece is intended for cleaning and polishing the tooth surface and fillings.

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.
> Repairs must only be undertaken by an authorized Patterson repair location.

Skilled application
The medical device is intended for use only by trained dental or medical practitioners for the purposes listed under the Indications for Use, in accordance with this document, the applicable health and safety regulations, and the valid accident prevention regulations.

The medical device should be prepared for use and maintained by staff who are trained in procedures for infection control, personal safety, and patient safety.

Improper use, (e.g., through poor hygiene and maintenance), noncompliance with our instructions, or the use of accessories, and spare parts that are not approved 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!

Service
In the event of operating malfunctions immediately contact your local Patterson Representative or call your local Patterson Branch at 800-873-7683.
Repairs and maintenance work must only be undertaken by authorized Patterson repair locations.

2. Safety notes

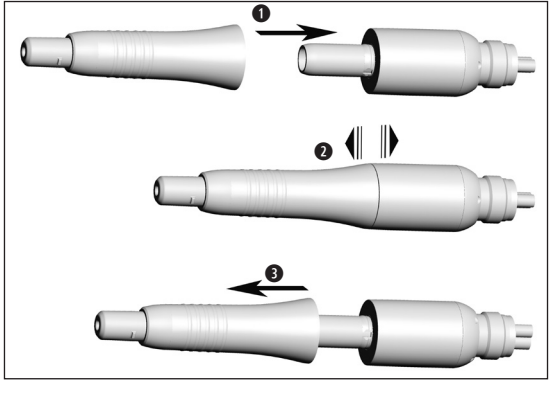
- Before using the medical device for the first time, store it at room temperature for 24 hours.
- The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- Use only the filtered, oil-free and cooled air supplied by dental compressors for drive air.
- Always ensure the correct operating conditions.
- Check the medical device for damage and loose parts each time before using.
- Do not operate the medical device if it is damaged.
- Perform a test run before each use.

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.

1. Nose
2. Sheath



Straight handpiece

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

❶ Push the medical device onto the motor.

❷ Verify full engagement.

❸ Remove the medical device by pulling in an axial direction.

Rotary instruments

> Prophy disposable contra-angle handpiece

> The rotary instruments are disposable articles and must be discarded after use.

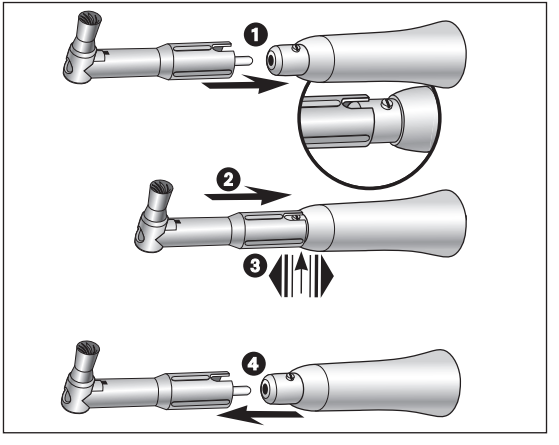
> Use only rotary instruments which are in perfect condition. Follow the operating instructions of the manufacturer.
> Insert the rotary instrument only when medical device is stationary.
> Never touch the rotary instrument while it is still rotating.

PD-44 M straight handpiece (Prophy Angle with plastic shank, Doriot system)

> Only use Prophy Angles with plastic shanks for the Doriot system.
Prophy Angles with metal shanks damage the clamping chuck system.

> Follow the recommendations of the disposable contra-angle handpiece manufacturers.

> The straight handpiece has an automatic clamping chuck system.



PD-44 M straight handpiece

> Prophy Angle Cup or Brush

❶ Position the groove on the Prophy Angle with the nose of the straight handpiece.

❷ Push the Prophy Angle onto the straight handpiece until the limit stop.

❸ Verify full engagement.

❹ Remove the Prophy Angle.

Test run

Do not hold the medical device at eye level!

> Insert the rotary instrument.
> Operate the medical device.

In the event of operating malfunctions such as vibrations, unusual noise, overheating or smell, **stop the medical device immediately** and contact an authorized Patterson repair location.

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.

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

> The product PD-44 M is not suitable for thermo disinfection.

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 Food and Drug Administration (FDA) and 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 service partner.

Processing cycles

> We recommend a regular service for the Patterson medical device after 1,000 processing cycles or one year.

Clean and disinfect the medical device immediately after every treatment, to flush out 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 outlets are rinsed out.

> Wipe the entire surface of the instrument with disinfectant.
> Remove the rotary instrument.
> Remove the medical device.

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.

> Patterson recommends wiping down with disinfectant.

Evidence of the medical device's basic suitability for effective manual disinfection (intermediate level) was provided by an independent test laboratory using the disinfectant "CaviWipes™" (Metrex).

> 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

> Lubricate the dry medical device immediately after cleaning and/or disinfection.

Recommended lubrication cycles

> Essential after every internal cleaning.
> Before each sterilization.

or

> After 30 minutes of use or at least twice daily.

With a high quality handpiece lubricant 085-2715

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

or

With a general handpiece maintenance unit

> Follow the instructions in the Instructions for use of the maintenance unit.

Testing after lubrication

> Direct the medical device downwards.
> Take the medical device into operation so that excess oil can escape.
> Excess oil may result in the medical device overheating.

Pack the medical device and the accessories in FDA cleared 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.

The manufacturer recommends sterilization according to ANSI/AAMI ST55, ANSI/AAMI ST79.

> 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”
  132°C (270°F) for at least 4 minutes
> “Steam-flush pressure-pulse cycle”
  132°C (270°F) for at least 4 minutes
> Maximum sterilization temperature 135°C (275°F)

Evidence of the basic suitability of the medical device 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)) and the Systec VE-150 steam sterilizer (Systec).

"Dynamic-air-removal prevacuum cycle":	temperature 132°C (270°F) – 4 minutes
"Steam-flush pressure-pulse cycle":	temperature 132°C (270°F) – 4 minutes

Minimum drying times:

"Dynamic-air-removal prevacuum cycle":	temperature 132°C (270°F) – 30 minutes
"Steam-flush pressure-pulse cycle":	temperature 132°C (270°F) – 30 minutes

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.

6. Servicing

Repairs and returns

In the event of operating malfunctions immediately contact your local Patterson representative or call your local Patterson branch at 800-873-7683.

Repairs must only be undertaken by an authorized Patterson service partner.

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

7. Accessories and spare parts

Use only original Patterson accessories and spare parts or accessories approved by Patterson.

035-4035	Maintenance unit
085-2715	Handpiece lubricant
089-3131	Spray cap E-Type

8. Technical data

Straight handpiece		**PD-44 M**
Transmission ratio		4:1
Outer diameter of the sheath	(mm)	20
Motor coupling acc. to		ISO 3964
Maximum drive speed	(rpm)	10,000

rpm = min^{-1} (Revolutions per minute)

Temperature information

Temperature of the medical device on the operator side:	maximum 131°F (55°C)
Temperature of the medical device on the patient side:	maximum 122°F (50°C)
Temperature of the working part (dental bur):	maximum 105.8°F (41°C)

Ambient conditions

Temperature during storage and transport:	-40°F to +158°F (-40°C to +70°C)
Humidity during storage and transport:	8% to 80% (relative), non-condensing
Temperature during operation:	+50°F to +95°F (+10°C to +35°C)
Humidity during operation:	5% to 80% (relative), non-condensing

9. Disposal

Ensure that the parts are not contaminated on disposal.

Instrument disposal

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

> Medical device
> Packaging

Warranty

Patterson warrants all products in this document against defects in material or workmanship for one year from time of delivery. Patterson's sole obligation under the warranty is to provide parts for the repair, or at its option, to provide the replacement product (excluding labor). The buyer shall have no other remedy. All special, incidental and coincidental damages are excluded.

Written notice of breach of warranty must be given to Patterson within the warranty period. The warranty does not cover damage resulting from improper installation or maintenance, accident or misuse. The warranty does not cover damage resulting from the use of cleaning, disinfecting or sterilization chemicals and processes. Failure to follow instructions provided in the Patterson owner's guide (operation and maintenance instructions) may void the warranty.

No other warranties as to merchantability or otherwise are made.

Manufactured for:

Patterson Dental Supply, Inc.
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Form-Nr. 50959 AEN
Rev. 001 / 05.08.2024
Subject to alterations