

Instructions for use




PATTERSON[®]
DENTAL

PD-44 M

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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



Date of manufacture



Thermo washer disinfectable



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



Data structure in accordance with Health Industry Bar Code



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



Caution! According to Federal law, this medical device may only be sold by or on the order of a dentist, physician or any other medical practitioner licensed by the law of the State in which he or she practices and who intends to use or order the use of this medical 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 used to clean and polish the surface of the teeth 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.

Device labeling statement

U.S. Federal law restricts this device to sale by or on the order of a dentist, physician, or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of this device.

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.

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).
- > Always ensure the correct operating conditions.
- > Use only the filtered, oil-free and cooled air supplied by dental compressors for drive air.
- > Check the medical device for damage and loose parts before each use (e.g. push-button).
- > Do not operate the medical device if it is damaged.
- > Perform a test run before each use.

Hygiene and maintenance prior to initial use



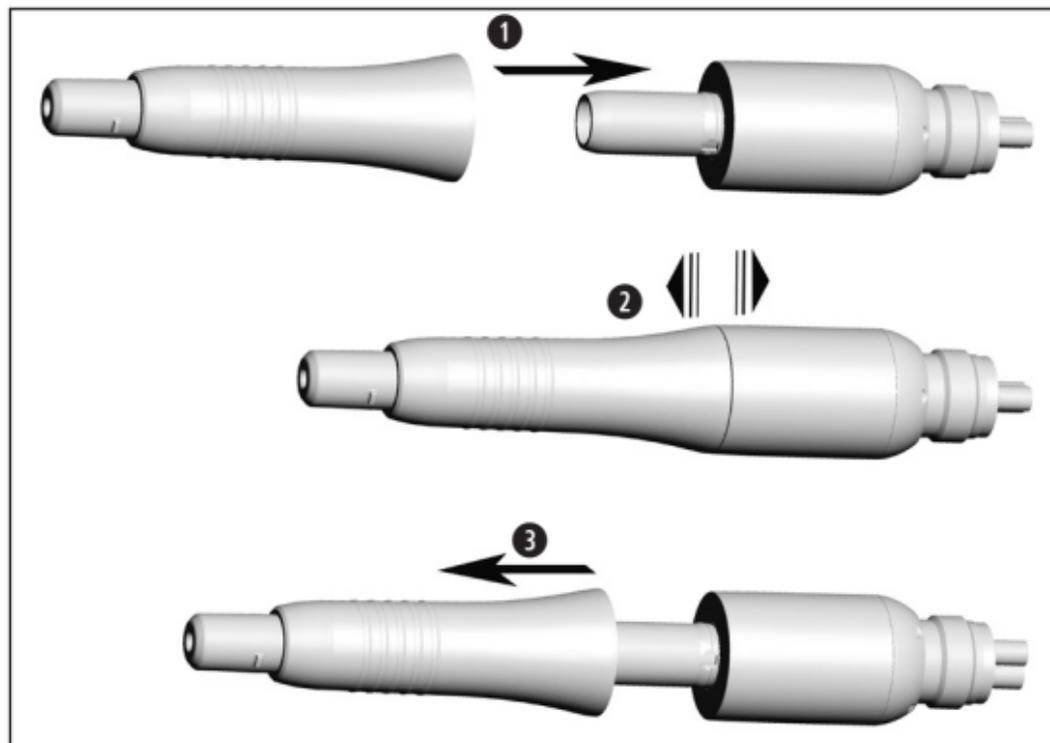
- > The medical device is sealed in PE film and not sterilized when delivered.
- > The PE film and the packaging are non-sterilizable.



- > 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!

- ① Push the medical device onto the motor.



② Verify full engagement.

- ③ Remove the medical device by pulling in an axial direction.

Rotary instruments



- > Prophy disposable contra-angle handpiece
- > Prophy Cup or Brush
- > Snap-on adaptor for Prophy Cup or Brush



- > 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.

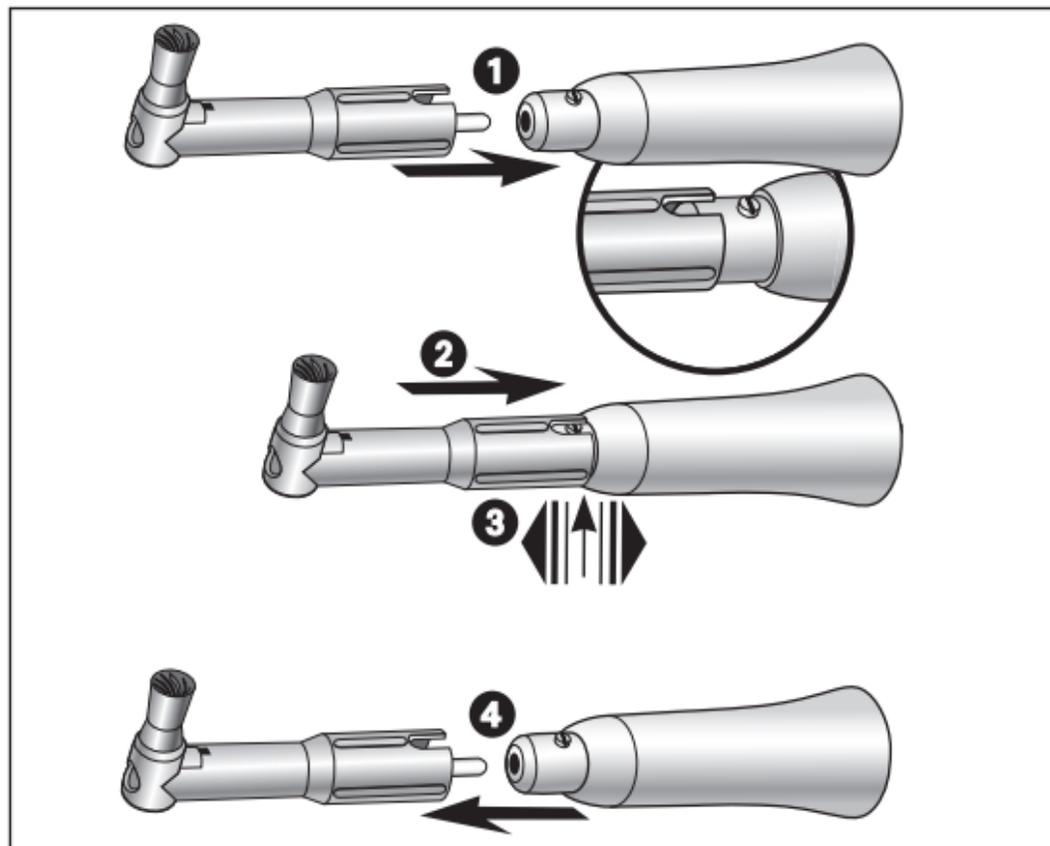
PD-44 M straight handpiece (Prophy Angle with plastic shank, Doriot system)



- > The straight handpiece has an automatic clamping chuck system.
- > Only use Prophy Angles with plastic shanks.
Prophy Angles with metal shanks damage the clamping chuck system.
- > Only use Prophy Angles with plastic shanks for the Doriot system.



- > Only use the medical device in forward operation. The rotary instrument can come loose in reverse operation (risk of injury).



PD-44 M straight handpiece

> Prophy Angle Cup or Brush

- 1** Position the groove on the Prophy Angle with the nose of the straight handpiece.
- 2** Push the Prophy Angle onto the straight handpiece until the limit stop.



3 Verify full engagement.

4 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.



> Wear protective clothing, safety glasses, face mask and gloves.



> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar 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, for example: 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 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 was provided by an independent test laboratory using the »mikrozid[®] AF wipes« disinfectant (Schülke & Mayr GmbH, Norderstedt).



Patterson 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 »Miele PG 8582 CD« washer-disinfector (Miele & Cie. KG, Gütersloh) and the »Dr. Weigert neodisher® MediClean forte« cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg).

- > Cleaning at 55°C (131°F) – 5 minutes
- > Disinfection at 93°C (200°F) – 5 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



- > 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 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.

 Patterson recommends sterilization according to EN 13060, EN 285 oder 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

- > Fractionated pre-vacuum process (type B)
- > Gravity displacement process (type N)
- > Sterilization time at least 3 minutes at 134 °C (273 °F), 4 minutes at 132°C (270°F), 30 minutes at 121 °C (250 °F)
- > 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)) and the CertoClav MultiControl MC2-S09S273 gravitation sterilizer (CertoClav GmbH, Traun).

- > Fractionated pre-vacuum process (type B): temperature 134°C (273°F) – 3 minutes*
- > Gravity displacement process (type N): temperature 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.

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]	5,000 – 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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St. Paul, MN 55120
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800-873-7683**

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