Instructions for use

PATTERSON® DENTAL

PD-25 RM

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

Symbols

on the medical device / packaging

REF — Catalog number

SN — Serial number

 Date of manufacture

 Sterilizable up to the stated temperature

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

HIBC — Data structure in accordance with Health Industry Bar Code

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

℞ only — 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 air motor is intended for the following applications: Drive for dental handpieces for dental restoration and prophylaxis. Supply of cooling air.

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), non-compliance 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

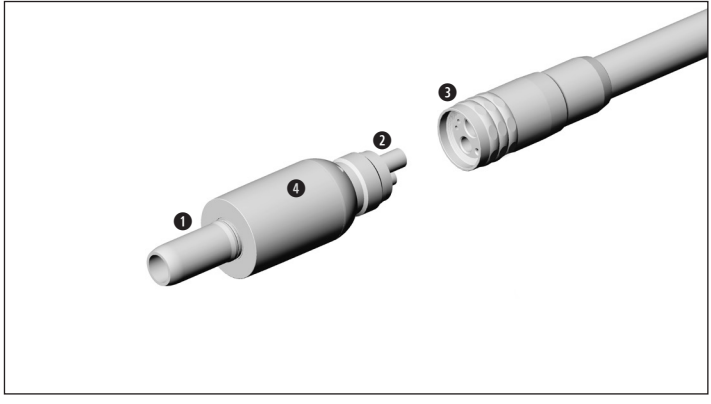
- The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- Before using the medical device for the first time, store it at room temperature for 24 hours.
- Use only the supply hoses as specified by EN ISO 9168.
- Always ensure the correct operating conditions.
- Use only 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.
- Do not operate the medical device if it is damaged.
- Perform a test run before each use.

Hygiene and maintenance prior to initial use

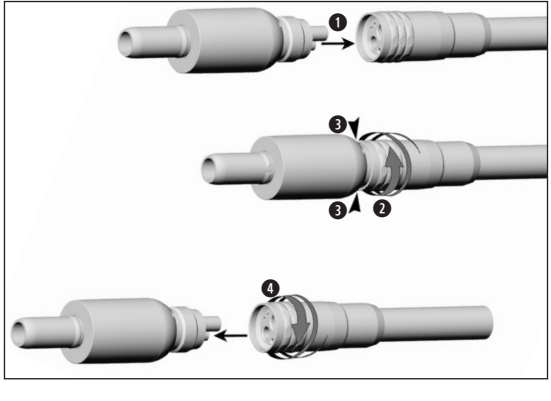
> The medical device is sealed in PE film and not sterilized when delivered.
> The PE film and the packaging are non-sterilizable.

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

3. Product description



1. ISO 3964 connection
2. Standard 6-hole
3. Coupling nut
4. Motor sheath



Do not assemble / remove during operation!

1. Push the medical device with RM connection into the apertures of the tubing.
2. Firmly screw the medical device and the coupling nut together.
3. Check for leakage.

4. Verify full engagement.

or

4. Unscrew the coupling nut.
5. Pull the medical device from the from the tubing.

Test run

Do not hold the medical device at eye level!

> Start the medical device.

In the event of operating malfunctions, such as vibrations, unusual noise, overheating, smell or leakage, **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 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 straight and contra-angle handpiece from the airmotor.
> Remove the airmotor from the tube.

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.
> Remove any liquid residues using compressed air.

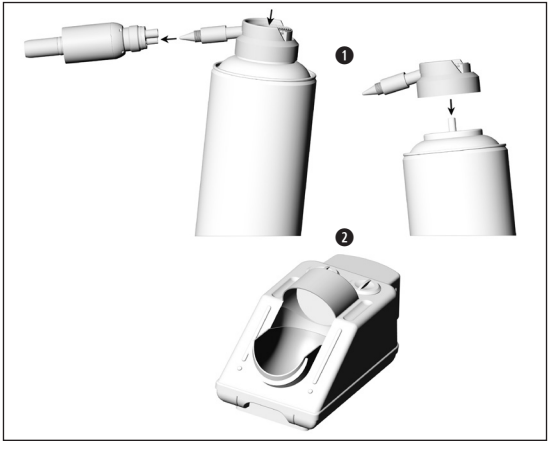
> Patterson recommends wiping down with disinfectant.

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).

> 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

Sterilize the medical device after each lubrication.

Recommended lubrication cycles

> After 30 minutes of use.
> Essential after every internal cleaning.
> Before each sterilization.
> at least twice daily.

❶ **With a high quality handpiece lubricant 085-2715**

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

or

❷ **With handpiece maintenance unit 035-4035**

> Follow Instructions for use of the handpiece maintenance unit.

Testing after lubrication

> 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.

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 522* steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)) and the Siroclav S3** gravitation sterilizer (Sirona).

> Fractionated pre-vacuum process (type B): temperature 134°C (273 °F) – 3 minutes*
> Gravity displacement process (type N): temperature121 °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
089-3123	Spray nozzle

8. Technical data

		PD-25 RM
Coupling	hose-side according to standard	ISO 9168
	Motor/transmission instrument connection according to standard	ISO 3964
	Outer diameter of the motor sheath (inch)	0.8
Speed range (rpm) at an operating pressure of:	32 psi	20,000*
(at resultant exhaust air pressure of maximum 3,6 psi)	43,5 psi	25,000*
Maximum torque	(Ncm)	4
Maximum power	(W)	20
Air consumption (Nl/min) at an operating pressure of:	32 psi	42
	43.5 psi	50
Operating pressure	(psi)	32 – 43.5

* Power and speed are dependent on the quality of the tubes 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 131°F (55°C)
Temperature of the medical device on the patient side:	maximum 122°F (50°C)
Temperature of the working part :	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:

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