Instructions for use

BRASSELER USA®



HPX-S
HPX-D

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Symbols in the Instructions for use



WARNING!
(risk of injury)



ATTENTION!
(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

REF	Catalogue number
SN	Serial number
QTY	Quantity
	Date of manufacture
	DataMatrix Code for product information including UDI (Unique Device Identification)
135°C	Sterilizable up to the stated temperature
	Thermo washer disinfectable
c UL us	UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements
	Consult Instructions for use

℞ only Caution! According to Federal law restricts this device to sale by or on the order of a physician, dentist, 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

Customer satisfaction has absolute priority in the Brasseler quality policy. 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. These explain how to use your medical device and guarantee a smooth and efficient operation.


Observe the safety notes.

Indications for use
The Proxeo straight/contra-angle 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.
> Modifications or repairs must only be undertaken by an authorized Brasseler service partner (see page 43).

Skilled application
The medical device is intended only for skilled application according to the intended use as well as in compliance with the valid health and safety at work regulations, the valid accident prevention regulations and in compliance with these Instructions for use.

The medical device should be prepared for use and maintained by staff who have been 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 which are not approved by Brasseler, 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!

2. Safety notes

> Use only the medical device with the drive handpiece Hygiene Pro X Cordless.

> Before using the medical device for the first time, store it at room temperature for 24 hours.
> 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 each time before using.

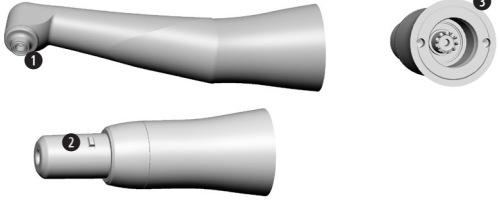
Hygiene and maintenance prior to initial use



> 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.

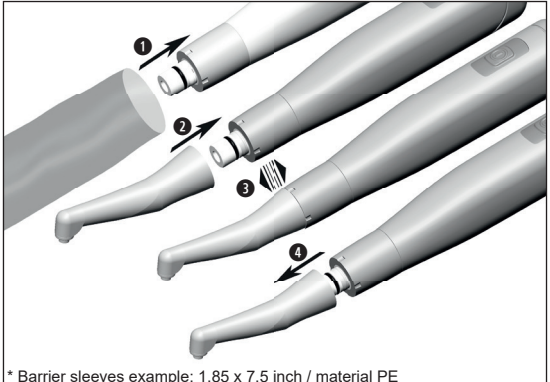


HPX-S
System Screw-in Young
❶ Thread

HPX-D
System Doriot
❷ Nose

❸ W&H connection

Assembly/Removal



* Barrier sleeves example: 1.85 x 7.5 inch / material PE

Do not assemble or remove the medical device during operation!

1. Place disposable barrier sleeve* over the internal shoulder of the handpiece drive.
2. Push the medical device onto the handpiece drive.
3. Verify full engagement.

or

4. Remove the medical device and barrier sleeve.

When choosing a barrier sleeve select one which is closest to the model listed below and works best for your particular use. Refer to the manufacturer's instructions for proper use of the sleeve.

Rotary instruments
> Prophy Cup or Brush System Screw-in Young
> Prophy Angle Cup or Brush System Doriot

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

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

Contra-angle head HPX-S (System Screw-in Young)



> Only use the straight/contra-angle handpiece in forward operation. The rotary instrument can come loose in reverse operation (risk of injury).



> The head of the contra-angle head is equipped with a Triple Seal from Young Dental.
> To ensure tightness and functionality, use only Young Dental Prophy Cups or Brushes for the Screw-in system.

Handpiece head HPX-D (System Doriot)



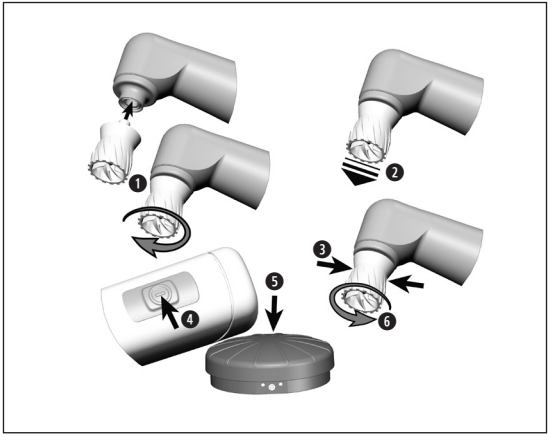
> Only use Prophy Angles with plastic shanks for the Doriot system. Prophy Angles with metal shanks damage the clamping chuck system.



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



> The handpiece head has an automatic clamping chuck system.



Contra-angle head HPX-S

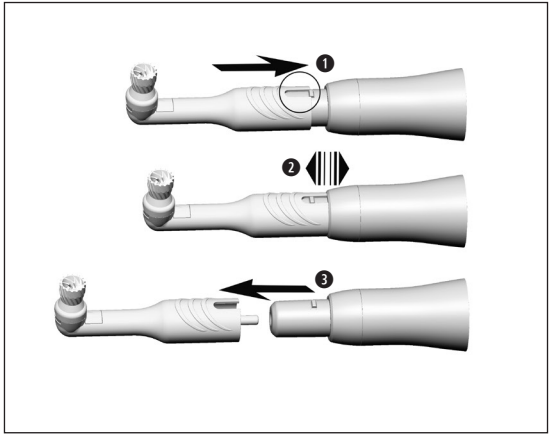
> Prophy Cup or Brush (System Screw-in Young)

❶ Screw the Cup or Brush in until the limit stop.

❷ Verify full engagement.

or

❸ Hold the Cup or Brush firmly.
❹ Keep pressed the ON/OFF button of the handpiece drive.
❺ And press the foot control.
❻ The Cup or Brush is unscrewed.



Handpiece head HPX-D

> Prophy Angle Cup or Brush (System Doriot)

❶ Position the groove on the Prophy Angle with the nose of the handpiece head and push it on until the limit stop.

❷ Verify full engagement.

or

❸ 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 (e.g. vibrations, unusual noises or overheating) **stop the medical device immediately** and contact an authorized Brasseler service partner.



Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.



The information on the validated reprocessing procedures serves as an example of an ISO 17664 compliant processing 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 3 bar 43.5 psi) 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 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 Brasseler service partner.

Processing cycles

> We recommend a regular service for the Brasseler 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 coolant outlets are rinsed out.

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

Brasseler recommends wiping down with disinfectant “CaviWipes™” (Metrex) (intermediate level).

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 liquid residues using compressed air.

> Brasseler 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).



Brasseler 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) according to ISO 15883.
> 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 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.
> Direct the medical device downwards.

Recommended lubrication cycles

> Essential after every internal cleaning
> Before each sterilization

or

> After 30 minutes of use or once a day

Test after lubrication



> Direct the medical device downwards.
> Operate the medical device 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.

Brasseler 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 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 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 an authorized Brasseler service partner.
Repairs and maintenance work must only be undertaken by an authorized Brasseler service partner.



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

7. Brasseler Accessories and spare parts



Use only original Brasseler accessories and spare parts or accessories approved by Brasseler!
Suppliers: Brasseler

5029558U0 Brasseler Handpiece Spray or other approved handpiece lubricant

Everclean maintenance machine or other approved maintenance machine
Everclean maintenance adapters or other approved adapters

8. Technical data

Medical device	**HPX-S**	**HPX-D**
Transmission ratio	4:1	
Maximum drive (min^{-1})	12,000	
Motor coupling	HygienePro X coupling	
Rotary instruments	System Screw-in Young Prophy Cups and Brushes	System Doriot Prophy Angle
Maximum speed on the rotating instrument (min^{-1})	3,000	

min^{-1} (revolutions per minute)

Temperature information

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

Ambient conditions

Temperature during storage and transport:	-40°C to +70°C (-40°F to +158°F)
Humidity during storage and transport:	8% to 80% (relative), non-condensing
Temperature during operation:	+10°C to +35°C (+50°F to +95°F)
Humidity during operation:	15% to 80% (relative), non-condensing

9. Disposal

Ensure that the parts are not contaminated on disposal.



Follow your local and national laws, directives, standards and guidelines for disposal.
> Medical device
> Packaging

Explanation of warranty terms

This Brasseler medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for Use have been followed.

As the manufacturer, Brasseler is liable for material or manufacturing defects within a warranty period of 24 months from the date of purchase.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by Brasseler.

Claims under warranty accompanied by proof of purchase must be sent to Brasseler or to an authorized service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

24 months warranty

Authorized Brasseler service partners

Brasseler U.S.A. Dental, LLC
One Brasseler Blvd.
Savannah, GA 31419, USA
800.841.4522

Manufactured For:
Brasseler U.S.A. Dental, LLC
One Brasseler Blvd.
Savannah, GA 31419, USA
800.841.4522

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