smartIPR

ENG INSTRUCTIONS FOR USE

Rx Only

REF: 2100477-0000/2026.03

MEDICAL DEVICE (REF)

smartIPR
REF 1601415-001
Catalogue number: ES-HP-PRO-00A

Optional accessories (REF)

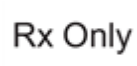
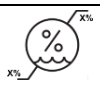
Spraynet®
REF 1600036-006

Lubrifluid®
REF 1600064-006

Table of content

1 Symbols

1.1 Description of symbols used

Symbol	Description	Symbol	Description
	Manufacturer.		Catalogue number.
	Medical device.		Serial number.
	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Water tap, open (To be cleaned under an open water tap).
	Wear protective gloves.		Consult instructions for use or consult electronic instructions for use.
	CAUTION! hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.		Thermo washer disinfectable.
	Data Matrix code for product information including UDI (Unique Device Identification).		WARNING! hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.
	General symbol for recovery/recyclable.		Sterilizable in a steam sterilizer (autoclave) at the specified temperature.
	Atmospheric pressure limitation.		Temperature limitation.
	Keep away from rain.		Humidity limitation.

2 Identification & Intended Use

2.1 Identification

Medical device manufactured by Bien-Air Dental SA.

Type

SmartIPR handpiece, without irrigation, without light, to be connected to a E type short micromotor (ISO 3964).

The device can only be used with IPR discs available on the market (EverSmile®*-smartIPR, smart DISK PRO 0.1 mm (ES-SMDISK-PRO-001), smart DISK PRO 0.2 mm (ES-SMDISK-PRO-002), smart DISK PRO 0.3 mm (ES-SMDISK-PRO-003), smart DISK PRO 0.4 mm (ES-SMDISK-PRO-004).

Note: EverSmile® is a registered trademark of EverBrands, Inc.*

2.2 Intended use

Device is intended to be used in orthodontics for interproximal reduction (IPR).

2.3 Intended patient population

The intended patient population includes any person visiting a dental or medical practitioners' office to receive treatment in line with the device's intended use. There is no restriction concerning subject age, race, or cultural background. The intended user is responsible to select the adequate device for the patient according to the specific clinical application.

2.4 Intended User

Device intended for professional use only. Used by dentists and dental professionals.

2.5 Use environment

Professional healthcare facility environment.

2.6 Intended Medical conditions

Orthodontic treatment to create access and open contacts between teeth during interproximal reduction (IPR).

2.7 Patient contra-indications and side effects

No specific patient contra-indication, side effects nor warnings exist when the device is used as intended.

2.8 In case of accident

If an accident occurs, the device must not be used until its repairs have been completed by a qualified, authorized and trained technician in a repair center.

If any serious incident occurs in relation to the device, report it to a competent authority of your country, as well as the manufacturer through your regional distributor. Observe relevant national regulations for detailed procedures.

⚠ **WARNING**

Any use other than that for which this device is intended is prohibited and may be dangerous.

3 User and Patient Safety: Warnings & Precautions for use

⚠ **WARNING**

The device must be used by qualified dental professionals in compliance with the current legal provisions concerning occupational safety, health and accident prevention measures, and these instructions for use. In accordance with such requirements, the operators:

- must only use devices that are in perfect working order; in the event of irregular functioning, coolant failure, excessive vibration, abnormal heating, unusual noise or other signs that may indicate malfunction of the device, the work must be stopped immediately; in this case, contact a repair centre that is approved by Bien-Air Dental SA and have the service personnel carry out repair work.
- must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger.
- Any modification of the medical device is strictly forbidden.
- Any use other than that for which this device is intended is prohibited and may prove dangerous.

To prevent any risk of infection, the warnings below must be observed:

⚠ **WARNING**

- The device is supplied not sterile. Respect the cleaning, sterilization and maintenance procedure detailed in section 6. Sterilization before first use is mandatory.
- Rest the device on a cleanable support to avoid risks of infection for yourself, the patient or third parties.
- Medical personnel using or performing maintenance on medical devices that are contaminated or potentially contaminated must comply with universal precautions, in particular the wearing of personal protective equipment (gloves, goggles, etc.). Pointed and sharp instruments should be handled with great care.
- When disposing of the device, the user must return it sterilized to their dealer or contact an authorized body for the treatment and recovery of this type of equipment.

To prevent any risk of device overheating, the cautions below must be observed:

⚠ **CAUTION**

- Respect the cleaning, sterilization and maintenance procedure detailed in section 6.
- Do not operate the device until a tool has been inserted.

To prevent any risk of injury and/or material damage the warnings below must be observed:

⚠ **WARNING**

- Never insert or remove a device while the micromotor is rotating.
- Always follow the IPR disc manufacturer's instructions. Never use a disc if the shaft is not compliant, as there is a risk it can become detached during the procedure and injure the practitioner, the patient or third parties.
- Each time a disc is inserted, check that the disc is fully inserted to the stop. If it is blocked, contact your usual supplier or Bien-Air Dental SA for repair.
- Always check that the disc is locked by gently pushing and pulling the disc.
- Do not touch the dental disc while it is in motion.
- Check the device for damage and loose parts before each use. Never use the device with damaged component.

- In the event of excessive vibrations, abnormal heating, unusual noise or other signs suggesting that the device is malfunctioning, work must be suspended immediately. In this case, contact a repair centre approved by Bien-Air Dental SA.
- These medical devices are intended to be used at a maximum height of 1.5 m, to avoid damage in the event of a fall.

To prevent any risk of device malfunction the caution below must be observed:

⚠ **CAUTION**

- Before performing any clinical application, always activate your device to ensure its proper operation.
- Only use original Bien-Air Dental SA devices and accessories or those recommended by Bien-Air Dental SA.

FIG. 1

4 Description

4.1 Overview

FIG. 1

(1) IPR disc (consumable, not part of the device)
(2) Clamping ring
(3) Oscillating IPR disc movement identification ring

Note: *the technical specifications, illustrations and dimensions contained in these instructions are given merely as an indication. They may not give rise to any claim.*
The original language of those instructions for use is English.
For any further information, please contact Bien-Air Dental SA at the address given on the back cover.

4.2 Technical data

Technical data	smartIPR
Motor coupling compatibility	Coupling according to ISO 3964
Motor max speed	40’000 rpm
Recommended motor speed range	20’000 – 30’000 rpm

4.3 Classification

Class I according to FDA Code of Federal Regulations 21 CFR 872.4200 relating to medical devices. This medical device complies with the legislation in force.

4.4 Performances

Performances	smartIPR
Speed transmission ratio	2.6:1
Tool max frequency	15’200 cpm*
Stroke	12° – 40°

*cpm: cycle per minute

4.5 Operating Conditions

Operating conditions		
	Temperature range:	+10°C – +35°C (+50°F – +95°F)
	Relative humidity range:	30% – 80%
	Air pressure range:	700 hPa – 1060 hPa

5 Operation

Pictograms used

	Back-and-forth movement.		Move in the direction indicated.
			Move fully to the stop, in direction indicated.

5.1 Changing the IPR disc

1. Pull the clamping ring to the rear and gently insert the IPR disc into the handpiece until it reaches the thrust stop. If necessary, apply a slight twist to ensure the disc shaft indexes correctly into the corresponding indexing recess. Then release the clamping ring, which should freely return to its initial position (**FIG. 2** step 1).
2. Gently push and pull the IPR disc to check it is correctly attached (**FIG. 2** step 2).
3. If the IPR disc is not correctly in place, pull the clamping ring to the rear, remove it and start the operation again (**FIG. 3**).

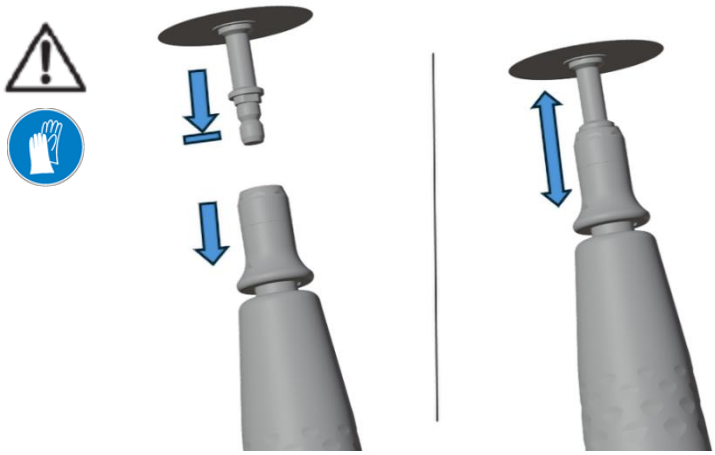


FIG. 2

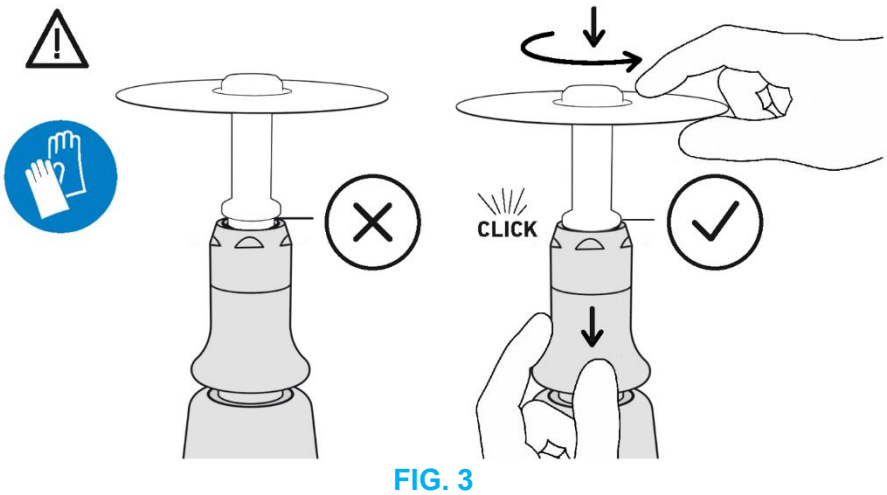


FIG. 3

5.2 Operating conditions and procedure

Before operating the device, follow this procedure:

1) Check that the ambient temperature ranges between +10°C to +35°C (+50°F to +95°F) and that it is under standard humidity conditions (relative humidity below 80%, without condensation).
2) Fix a suitable IPR disc to the handpiece.
3) Connect the handpiece with the disc to a micro-motor compatible with ISO 3964.
4) Operate without load for at least 5 seconds and check that it performs properly.

6 Maintenance and servicing

WARNING

- The device supplied is "non sterile". Clean, dry and sterilize the devices prior to first use.
- Follow your national directives, standards and guidelines for cleaning and sterilization recommendations.

6.1 Maintenance – General information

6.1.1 Precautions for maintenance

- Within a maximum of one hour after each treatment, clean and disinfect the instrument. Observing this procedure eliminates any blood, saliva or residues and prevents the transmission system from being blocked.
- Only use original Bien-Air Dental SA maintenance products and parts or those recommended by Bien-Air Dental SA. For suitable maintenance products refer to section 6.1.2 Suitable maintenance products. Using other products or parts may cause faults during operation and/or void the warranty.

CAUTION

- Carry out the cleaning-disinfection-sterilization processes of the device with the chuck mechanism open, without an IPR disc fitted.
- Use detergents that are pH 8-11, are neither corrosive nor contain chlorine or acetone and/or aldehydes.
- Do not submerge in physiological liquid (NaCl) nor use saline solution to keep the device moist until it can be cleaned.
- Clean using manual cleaning or automated washer/disinfector only (do not use ultrasonic cleaner).
- As with all instruments, following each sterilization cycle, including drying, remove the device from the sterilizer to avoid excess exposure to heat which can result in corrosion.
- Use only dynamic sterilizers: do not use a steam sterilizer with a gravity displacement system.

6.1.2 Suitable maintenance products

Manual pre-cleaning:

- Use tap water if the local tap water has pH within the range 6.5-8.5 and chloride content below 100 mg/l. If the local tap water does not meet these requirements, use demineralized (deionized) water instead.
- Spraynet®.

Manual cleaning:

- Alkaline detergent (pH 8-11) recommended for cleaning of dental or surgical instruments (e.g. Neodisher® mediclean Forte).

Manual disinfection:

- Alkaline detergent-disinfectant recommended for cleaning-disinfection of dental or surgical instruments (e.g. products containing quaternary ammonium like Neodisher® Septo Plus).

Automatic cleaning-disinfection:

- Use an alkaline product recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8-11).

FIG.4

6.2 Pre-Cleaning

Preparation

- Disconnect the handpiece from the motor.
- Remove the disc.

6.2.1 Internal and external cleaning

Remove dirt / deposits

- Clean the exterior and interior of the device under tap water at 40°C-60°C (104°F-140°F) during at least 30 seconds, the handpiece oriented vertically with the head down, provided that the local tap water has a pH within the range of 6.5-8.5 and a chloride content below 100 mg/l. If the local tap water does not meet those requirements, use demineralized (deionized) water instead.
- After selecting the appropriate nozzle, spray twice inside the device with Spraynet® (**FIG. 4**).

6.3 Manual cleaning and disinfection

6.3.1 Manual cleaning

1. Dip the device in a bath containing a detergent.
   The use of an alkaline product at low concentration and at room temperature for a duration of 5-10 minutes is recommended (for example, Neodisher® Mediclean Forte at 0.5% for 5-6 minutes). Follow the concentration recommended by the manufacturer of the chemical agents.

2. Brush the external surfaces and the opening of the clamping mechanism with a smooth, flexible brush (e.g. soft-bristled toothbrush) for 2 minutes minimum until all visible soil is no longer visible.

3. Rinse the device for at least 20 seconds. It is recommended to use purified water (20°C- 38°C) (68°F-100°F) obtained via reverse osmosis (RO) treatment or equivalent procedures (the bacteria should be <10 CFU/mL and endotoxin <10 EU/mL).

6.3.2 Manual disinfection

1. Dip the device in a bath containing a detergent-disinfectant product (e.g. chemical agents containing quaternary ammonium or equivalent detergent-disinfectants).
   The use of detergent-disinfectant products at low concentration and at room temperature 20°C-25°C (68°F-77°F) for a duration of 5-10 minutes is recommended (for example, Neodisher® Septo Plus at 1% for 5-6 minutes). Follow the concentration recommended by the fabricant of the chemical agent.

2. Brush the external surfaces and the opening of the clamping mechanism with a smooth, flexible brush (e.g. soft-bristled toothbrush) for 2 minutes minimum.

3. Rinse the device for at least 20 seconds. It is recommended to use purified water (20°C- 38°C) (68°F-100°F) obtained via reverse osmosis (RO) treatment or equivalent procedures (the bacteria should be <10 CFU/mL and endotoxin <10 EU/mL).

6.3.3 Manual drying

1. After selecting the appropriate nozzle, spray inside the device with Spraynet® **FIG.4**
2. Dry the external surfaces with sterile non-woven compresses (low linting textiles).

6.4 Automatic cleaning and disinfection

The automatic cleaning and disinfection procedure is in alternative to the manual cleaning and disinfection procedure 6.3.
Carry out automatic cleaning- disinfection using an approved washer disinfector which complies with ISO 15883-1 standard.

6.4.1 Loading the washer disinfector

Place the devices into the washing racks without overloading them. Then place the racks on the wash supports of the washer-disinfector.
Avoid any contact between the devices, which may cause damage during washing.

6.4.2 Specifications and parameters for washing disinfector program

Detergent and washing cycle

Use an alkaline or enzymatic detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 8 - 11), e.g. Neodisher® Mediclean Forte with concentration 0.5-0.6%.

Recommended specifications of the thermo-disinfection cycle:

Phase	Parameters
Pre-cleaning	<45°C (113°F); ≥ 2 minutes
Cleaning	45-55°C/ (113-131°F) for enzymatic detergents and 45-65°C (113-140°F) for alkaline detergents ≥ 5 minutes
Neutralization	≥2 minutes
Rinsing	Reverse osmosis (RO) water, ≤30°C (86°F), ≥ 2 minutes cold water
Thermal Disinfection	Reverse osmosis (RO) water, 90°C-95°C (194°F-203°F), 10 minutes
Drying	22 minutes

WARNING

- Never cool devices by rinsing them.

CAUTION

If an automatic washer is used at the place of the washer/thermo-disinfector, respect the previous program for the Pre-cleaning, Cleaning, Neutralization and Rinsing phases. If the local tap water has a pH outside the range of 6.5-8.5 or if it contains more than 100 mg/l chloride (Cl-ion), do not dry the device inside the automatic washer but dry it manually with low linting textiles. For disinfection and drying, follow the manual procedure defined in sections 6.3.2 and 6.3.3.

FIG.5

6.5 Lubrication

6.5.1 Verifying cleanliness

Before lubrication, visually inspect the device to ensure it is clean. Repeat the cleaning and disinfection procedure if necessary.

Before each sterilization lubricate with Lubrifluid® **FIG.5**. If the local directives impose sterilization never lubricate after the sterilization.

6.5.2 Lubrication with Lubrifluid®

1. Place the device in a sterile, non-woven cloth to collect the excess of lubricant.
2. Select the appropriate nozzle.
3. Insert the nozzle of the can Lubrifluid® in the rear of the device.
4. Activate the spray for about 1 second.
5. Clean the excess oil on the exterior with a sterile, non-woven compress.

6.6 Sterilization

WARNING

- The quality of the sterilization is highly dependent on how clean the instrument is. Only perfectly clean instruments may be sterilized. To improve the effectiveness of the sterilization, make sure the handpiece and the attachment are completely dry before and after the sterilization.
- Loading procedure must allow for free circulation of steam around each item. Therefore, perforated trays should be placed so the tray is parallel to the shelf; nonperforated containers should be placed on their edge.

CAUTION

- Do not use a sterilization procedure other than the one described below.

6.6.1 Procedure

1. Before sterilization, package each single device in an independent single legally marketed (i.e. "FDA-cleared" or compliant to ISO 11607) sterilization pouch.
2. Sterilize using steam, following dynamic air removal cycle (ANSI/AAMI ST79, Section 2.19), i.e. air removal via forced evacuation (ISO 17665) at 135°C (275°F), for 3 minutes, at 134°C (273.2°F), for 3-5 minutes or 132°C (269.6°F) for 4 minutes. In jurisdictions where sterilization for prions is required, sterilize at 135°C (275°F) for 18 minutes.

The recommended parameters for the sterilization cycle are:

- The maximum temperature in the autoclave chamber does not exceed 137°C (278°F), i.e. the nominal temperature of the autoclave is set between 132°C – 135.5°C (269.6°F – 275.9°F) taking into account the uncertainty of the sterilizer as regards temperature.
- The maximum duration of the interval at the maximum temperature of 137°C (278°F) is in accordance with national requirements for moist heat sterilization and does not exceed 30 minutes.
- The absolute pressure in the chamber of the sterilizer is 0.07 bar to 3.17 bar (1 PSIA to 46 PSIA/28''hg to 31 PSIG)
- The rate of change of temperature does not exceed 15°C/min (27°F/min) for increasing temperature and -35°C/min (-63°F/min) for decreasing temperature.
- The rate of change of pressure does not exceed 0.45 bar/min (6.6 psia/min) for increasing pressure and -1.7 bar/min (-25 psia/min) for decreasing pressure.
- No chemical or physical reagents are added to the boiler feedwater.
- Recommended dry time is 30 minutes. During the drying phase, the temperature should be in the range: 60°C – 135°C (140°F – 275°F).

WARNING

- Never rinse the devices to cool them.

CAUTION

- Only use dynamic air removal cycles: pre-vacuum or steam flush pressure pulse (SFPP) cycles.

After cleaning, disinfecting and sterilizing the device, and before using it, start it up at moderate speed with an IPR disc in the locking mechanism for 10 to 15 seconds to distribute and remove the excess lubricant.

6.7 Packing and storage

The device must be stored inside the sterilization pouch in a dry and dust free environment. The temperature must not exceed 55°C (131°F). If the device will not be used for 7 days or more after the sterilization, extract the device from the sterilization pouch and store it in the original package. If the device is not stored in a sterilization pouch or if the pouch is no longer sterile, clean, lubricate and sterilize the device before using it.

Storage conditions		
	Temperature range:	0°C – +40°C (+32°F – +104°F)
	Relative humidity range:	10% – 80%
	Air pressure range:	650 hPa – 1060 hPa
	Keep away from rain.	

WARNING

- Comply with the expiration date of the sterilization pouch which depends on the storage conditions and the type of packaging.

CAUTION

- If the medical device has been stored refrigerated, allow it to warm up to room temperature prior to its use.

6.8 Servicing

Never dismantle the device. For all servicing or repair operations, you are advised to contact your usual supplier or Bien-Air Dental directly.

In order to avoid any risk of contamination, the user must return the device sterilized to their distributor or service center.

Regular service is recommended for the device after 4'000 processing cycles or two years.

7 Transport & disposal

7.1 Transport

Transport conditions		
	Temperature range:	-20°C – +50°C (-4°F – +122°F)
	Relative humidity range:	5% - 80%
	Air pressure range:	650 hPa -1060 hPa
	Keep away from rain.	

7.2 Disposal

The disposal and/or recycling of materials must be performed in accordance with the legislation in force.

The device must be recycled. In order to avoid any risk of contamination, the user must return the device sterilized to their dealer or contact an authorized body for the treatment and recovery of this type of equipment.

8 General information

8.1 Terms of warranty

Bien-Air Dental SA grants the user a warranty covering all functional defects, or material or manufacturing faults.

The warranty period for this medical device is 18 months from the date of invoice.

In the event of a justified claim, Bien-Air Dental SA or its authorized representative will repair or replace the product free of charge.

All other claims of any kind whatsoever, particularly claims for damages, are excluded.

Bien-Air Dental SA cannot be held liable for damage or injury and the consequences thereof, resulting from:

- Excessive wear and tear.
- Infrequent or improper use.
- Failure to observe the servicing, assembly or maintenance instructions.
- Damage caused by unusual chemical, electrical or electrolytic influences.
- Faulty air, water or electrical connections.

⚠ **CAUTION**

- The warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorized by Bien-Air Dental SA.
- Warranty requests will only be taken into consideration if the product is accompanied by a copy of the invoice or delivery note. The following information must be clearly indicated: purchase date, product reference and serial number.

8.2 References

8.2.1 Medical devices (see cover)

REF	Legend
1601415-001	smartIPR

8.2.2 Optional accessories (see cover)

REF	Legend
1600036-006	Spraynet®, 500ml cleaning spray, box of 6 cans
1600064-006	Lubrifluid®, 500ml spray lubricant oil, box of 6 cans

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