

EverSmile®

smartIPR™

smartIPR System Reprocessing Guide



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smartDISKS

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smartIPR Air Motor

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smartIPA Gauge and smartIPR Disk Block Organizer

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smartIPR Handpiece & Accessories

MEDICAL DEVICE (REF)



smartIPR Handpiece
REF 1601403-001

Optional accessories (REF)



Spraynet®
REF 1600036-006



Lubrifiuid®
REF 1600064-006

ENG INSTRUCTIONS FOR USE

1 Symbols

1.1 Description of symbols used

Symbol	Description	Symbol	Description
	Manufacturer.		Catalogue number.
	Medical device.		Serial number.
Rx Only	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 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-PRO004).

*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

Orthodontics for gaining access and opening 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.

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 the 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 Handpiece
Weight [g]	<150
Overall length [mm]	110±10
Diameter [mm]	Ø19.6
Coupling type	ISO 3964
Maximum motor speed [rpm]	40'000
Recommended motor speed range [rpm]	20'000 - 30'000
Oscillating angle [°]	>12

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 Handpiece
Speed transmission ratio	2.6:1

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**).

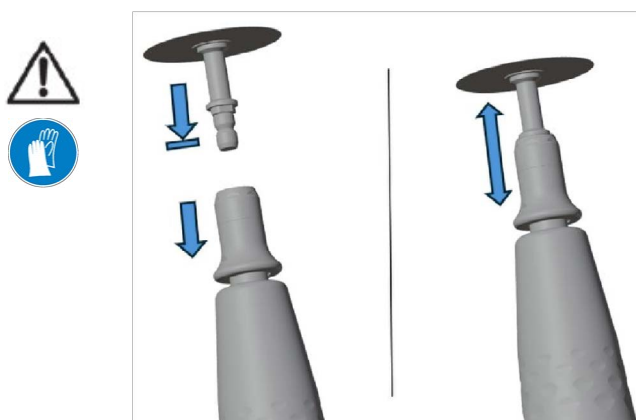


FIG. 2

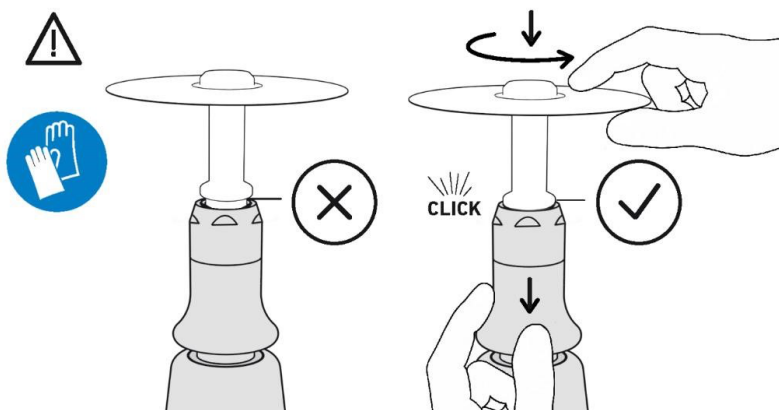


FIG. 3

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).

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 15°C-38°C (59°F-100°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).



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 (15°C-38°C) (59°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 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 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.

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®



FIG.5

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 17665-1, ISO/TS 17665-2) 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.



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 guarantee

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

The warranty period for this medical device is 12 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
1601403-001	smartIPR Handpiece

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

Länggasse 60 Case postale 2500 Bienne 6 Switzerland
Tel. +41 (0)32 344 64 64 Fax +41 (0)32 344 64 91 dental@bienair.com
Other addresses available at www.bienair.com

INSTRUCTIONS FOR USE FOR STERILE AND NON-STERILE-DIAMOND COATED DENTAL BURS, TUNGSTEN CARBIDE DENTAL BURS AND DENTAL DISCS

SCOPE

These Instructions For Use (IFU) provide general instructions for MDT's rotary devices and specific reprocessing instructions that are applicable to the cleaning and steam sterilization of the multi-use Diamond Dental Burs/Discs and Tungsten Carbide (from herein after "TC") burs prior to initial use, and there after every subsequent re-use. The multi-use Diamond Dental Burs/Discs and TC burs are supplied mechanically clean, but NOT sterile.

MDT Diamond Dental Burs are manufactured from stainless steel coated with Diamond.

Tungsten Carbide Burs – are manufactured from a single piece of TC or from a TC tip brazed onto a surgical grade stainless-steel stem.

Diamond coated dental discs are manufactured from stainless steel coated with diamond particles on the working part.

The Diamond Burs/Discs and TC dental burs are part of MDT's Dental Rotary instruments portfolio available to its customers including diamond coated burs, TC dental burs, discs and dental polishers.

The rotary instrument can be supplied as Single use Sterile  using Gamma Irradiation or non-sterile for multi-use as follow:

	 Multi-Use*	 Single Use
Diamond burs	+	+
Tungsten-Carbide burs	+	+
Diamond Discs	+	-

* Following reprocessing instructions

DENTAL ROTARY INSTRUMENT INDICATION FOR USE

These rotary instruments are intended for a wide variety of restorative procedures including but not limited to removal of caries or old restorations, preparation of cavities for restoration, finishing of restorations, interproximal reduction (IPR), removal of crowns, orthodontic device procedure and any other dental operation. It can be used to cut, grind or polish a wide variety of dental materials, including tooth material such as enamel, dentine, as well as dental materials such as amalgam, composite, zirconia, Lithium di silicate, glass cements, polymer and ceramic veneers and various alloys.

INTENDED PURPOSE

The dental rotary instrument is intended for laboratory and dental applications in clinics and hospitals both chair side and within the dental oral orifice.

INTENDED USERS

Professional use - Dental Rotary Instruments are intended for dentistry and must only be used by dentists and other qualified professionals who are familiar with use of these instruments based on their training and experience. Therefore, user training is not needed to ensure specified performance and safe use of the medical device. For laboratory applications, the use of these instruments must be by a licensed technician.

INTENDED POPULATION

All patients in need for dental care.

CONTRAINDICATIONS AND WARNINGS

- For the use of MDT Diamond burs, TC bur or Diamond discs is contraindicated on any patient with known allergy to Nickel.
- The use of Tungsten Carbide burs in patients with known sensitivity to cobalt is not recommended; In these cases, the use of alternative devices should be considered.

PRODUCTS IN COMBINATION WITH MDT'S DENTAL BURS/DISCS:

The diamond and TC dental burs/discs are compatible with any approved medical device handpiece that can be operated with FG, RA or HP bur shanks. MDT's rotary instruments can be supplied in any of the following shanks:

MDT Rotary Instrument	FG	RA	HP
Diamond burs	+	+	+
Tungsten-Carbide burs	+	+	+
Diamond discs	-	+	+

Maintain handpieces in good working conditions to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to procedural delays or injury of the patient or user, aspiration or swallowing of the device or damage to the preparation site due to vibration of a worn chuck or turbine.

STORAGE (PRE-USE):

Store in a dry and clean environment at ambient temperature.

The bur pattern selected will be chosen to cut a specific material in a specific application.

The following table gives guidance and provides **recommended RPM** for the user.

For FG diamond burs:

Instrument head diameter 1/10 mm	Maximum permissible speed (RPM)	Recommended operational speed (RPM)
007 - 010	450,000	100,000 - 220,000
011 - 014	450,000	70,000 - 220,000
015 - 018	450,000	55,000 - 160,000
019 - 023	300,000	40,000 - 120,000
024 - 027	160,000	35,000 - 110,000
028 - 031	140,000	30,000 - 95,000
032 - 040	120,000	25,000 - 75,000
041 - 054	95,000	15,000 - 60,000
055 - 070	60,000	12,000 - 40,000
071 - 100	45,000	10,000 - 20,000

For HP burs and HP diamond discs, the following table applies:

Process	Gross reduction	Contouring	Finishing	Polishing
Standard color Code	blue	green	yellow	white
Speed, rpm	7,000-10,000	7,000-10,000	2,000-3,000	2,000-3,000

For Tungsten-Carbide burs, the recommendations are listed below:

Application	TC Bur Type	Material	Size (mm)	MDT's ID Number	Recommended operational speed (RPM)
Cavity preparation	Standard	Enamel/Dentine	010-023	FG.TC0002-0008 / 0057 / 0556-0557	<450,000
Removal of fillings	Standard	Amalgam/Composite	010-018	FG.TC0330-0331	60,000-120,000
Excavation	Standard	Enamel/Dentine	010-023	FG.TC0002-0008 / 0035	<2,000
Finishing margins	Finishing	Enamel	010-016	FG.TC0057	10,000-20,000
Finishing restorations	Finishing	Amalgam	012-023	FG.TC0245	18,000-30,000
Finishing restorations	Finishing	Composite	012-023	FG.TC 557 / 057	10,000-20,000
Finishing restorations	Finishing	Glass ionomer	012-023	FG.TC 557 / 057	10,000-20,000
Crown & bridge finishing	Finishing	C&B polymer	010-016	FG.TC 557 / 057	40,000-80,000
C&B metal trimming	Standard	Metals	018-027	FG.TC1157-1158 / 1557-1558	<30,000
Prosthetic polymer trimming	Standard	Polymer	018-027	FG.TC 1157 / 1158 / 330	<20,000

CLINICAL PRECAUTIONS AND WARNINGS:

Read carefully:

- a) The device is to be used as per the following instructions by physician or licensed practitioner.
- b) Carefully read package labels to ensure appropriate use of the device. Failure to do so may cause procedural delays or patient or user injury. Before use check sterile packaging integrity for damage and tears that may impair the sterility of the product.
- c) Failure to follow this IFU may cause the following: possible damage to the tooth/restoration, injury to the patient or user, or possible aspiration or swallowing of the instrument.
- d) Clean and sterilize the instruments supplied in a non-sterile condition in accordance with the directions below before first use and before each reuse to avoid any risk of contamination.
- e) Always wear gloves when handling contaminated instruments.
- f) Sterile devices' pouch must be opened right next to use. The pouch should be kept until the end of treatment in order to allow proper identification.
- g) Protect patient's eyes and vulnerable tissues when using these instruments.
- h) Clinicians should wear eye protection and facemask when using these instruments.
- i) Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- j) Ensure the instrument is fully seated and gripped in the handpiece collet to. Failure to follow these instructions may cause possible damage to the tooth, injury to the patient or user, or possible aspiration or swallowing of the instrument.
- k) Prior to use inspect the instrument for rust, broken and/or damaged flutes, discard any potentially defective burs/discs. Do not use worn- out or dull instruments.
- l) Do not apply excessive pressure on the instrument as this could cause undesirable heat and/or may cause the device to fail.
- m) Move the device continuously when in use to avoid localized heating and/or damage to the instrument. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- n) Avoid removing the instrument at too sharp angle to avoid leverage and breakage which could cause patient or user injury.
- o) Never force an instrument into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- p) Do not exceed the maximum speeds as shown on the label as this may generate undesirable heat or lack of application.
- q) Pediatric Diamonds Burs should be used with mini handpiece intended for use with short shank burs and normal burs up to 20 mm in length.
- r) Do not use after the expiry date indicated on the package of the device.

The dental instrument pattern and shape shall be selected by physician discretions and will be chosen according to the needed application.

REPROCESSING INSTRUCTIONS FOR DIAMOND DENTAL BURS/DISCS AND TC BURS (MULTI-USE)

SCOPE

The reprocessing instructions detailed below apply only to reusable burs/discs. Burs shall be reprocessed upon initial use and prior to being reused.

LIMITATIONS OF RE-USE

Reprocessing will have little effect on MDT's dental burs/discs. The end of bur/disc's life is determined by wear and damage in use and the burs should be inspected for defects during the preliminary cleaning process. Delay between use and reprocessing must be kept to a minimum to avoid contaminants drying, thereby making cleaning more difficult. Therefore, keep the unclean dental instruments immersed in the cleaning/disinfecting agent in accordance with manufacturer instructions, but in any event, do not exceed 12 hours. Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided. Caution: Do not leave burs/discs immersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the burs/discs have been thoroughly cleaned first.

WARNINGS

Used instrument should be considered as being contaminated and appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient. Used burs are also considered as biohazard and need to be discarded as bio-hazard waste unless reprocessing procedures has been done according to the instructions.

PREPARATION FOR CLEANING	There are no special requirements for pre-cleaning unless local infection controls require the use of a disinfectant immediately after use, in which case the selected disinfectant must be validated by the user for cleaning dental burs/TC/Discs shall be used and the manufacturer's instructions followed. Due to limited reproducibility of manual cleaning, automated cleaning and steam sterilization are the preferred processes for the cleaning stage.
MANUAL CLEANING, DRYING AND INSPECTION PROCEDURE	If manual cleaning is implemented, the instruments should be cleaned in a sink reserved for this purpose. Pre-clean under running water with a brush directly after use, particularly at the difficult to access points (grooves, bristles, holes, rough surfaces). 1) Rinse the instrument under running cold water at least 1 minute. 2) Soak in a 0.1-0.3% enzymatic neutral cleaning or cleaning/disinfecting detergent labeled for use on dental rotary instruments or other types of reusable medical instruments, following the agent manufacturer's instructions. Soak for at least 2 minutes. 3) Then, keeping them immersed, brush thoroughly away from the body in a slow controlled way to avoid spreading contaminants by spraying or splashing during the brushing process. 4) In all cases soft nylon brush is recommended in order to avoid possible device damage. 5) Take the instruments out of the bath and rinse them under warm running water for at least 2 minutes and until visibly clean. 6) After cleaning, inspect the cleanliness of the instruments with the aid of magnifying glass, to ensure that all contamination has been removed. Repeat the cleaning process if necessary. 7) Dry the instruments using a non-shedding wipe or clean compressed air. 8) Inspect the instruments, with the aid of magnifying glass if necessary for any signs of damage and/or deterioration such as corrosion. Pay particular attention to the flute, teeth and shanks for any chips/cracks, chatter marks, distortion, and general wear & tear. Any instrument found in condition which causes concern, must be discarded. Note: Surface contamination on the instruments must be removed prior to automatic reprocessing.
AUTOMATED CLEANING	PRE-CLEANING – 1) Prepare a 0.1-0.3% neutral/mild pH enzymatic detergent, according to manufacturer's instructions. 2) Rinse the instruments under running tap water for at least one (1) min. 3) Soak instruments immediately into detergent solution, for at least two (2) minutes. 4) Scrub under running water with soft nylon brush to remove any remaining blood or debris for at least one (1) minute (for discs- one minute for each side). 5) Place the instruments on a clean cloth to avoid any contact between them during the next cleaning procedure.

	AUTOMATED CLEANING PROCEDURE Place the instruments in the washer in a suitable small parts tray or on the load carrier such that all surfaces of the instruments will be cleaned and disinfected. 1. Run the automatic wash cycle – Short cycle parameters. 2. Two (2) Minutes prewash at 30±5°C (86±9°F) with tap water. 3. Ten (10) Minutes main wash with neutral pH detergent and tap water at 45±5°C (113±9°F). 4. One (1) Minute rinse with tap water at 30°C (86°F). 5. Ten (10) Minutes distilled water rinse at 30°C (86°F). 6. Twenty (20) Minutes air drying phase at high temperature of 80°C (176°F). 7. Five (5) minutes air drying phase at high temperature of 110°C (230°F). Note: For the purpose of MDT instruments automated reprocessing validation, a Miele PROFESSIONAL washer (model PG8593) and the cleaning agent Power Zyme (Deconex) were used. Other equivalent reprocessing cleaning agents can be used upon local validation by the user. Any cleaning and disinfecting agents used must be compatible with dental burs/discs; otherwise, accelerated corrosion or other damage may occur. The washer disinfectant and the cleaning agent manufacturers' instructions must be followed. POST AUTOMATED CLEANING PROCEDURE – 1) Remove the instruments at the end of the washer program . 2) Check that the instruments are dry, if necessary, dry with medical grade compressed air . 3) Visually inspect the burs for cleanliness. If contamination is still visible, reclean the instruments again manually. 4) Subsequently, the recleaned instruments must be reprocessed again automatically before sterilization. 5) All instruments must be inspected visually for cleanliness, integrity, and functionality, if necessary, by using an illuminated magnifying glass. 6) All instruments are to be checked for damage and wear. Damaged medical devices may no longer be used and must be sorted out.
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STERILIZATION - USING STEAM

SCOPE

These sterilization instructions applicable to burs and discs initially provided non-sterile and to non-sterile burs that are being reused. No sterilization before first use is required for burs labeled 'Sterile'.

PACKAGING FOR STERILIZATION	When using either an autoclave with a pre-vacuum cycle or gravity displacement, place the instruments in appropriate instrument trays or pack them in pouches validated for steam sterilization. <i>NOTE: Local legislation for sterilization may require that dental instruments are wrapped in pouches for processing in either type of autoclave.</i>						
STERILIZATION	Follow the autoclave manufacturer’s instructions to sterilize the instruments. In particular, care must be taken not to exceed the maximum recommended load for the autoclave. MDT has validated steam sterilization in an autoclave for both pre vacuum as well as in a gravity displacement type for a holding time of 4 minutes at a temperature of 134 °C and drying time of 15 Min. The holding time is the minimum time for which the minimum temperature is sustained. Note: For the purpose of MDT dental instruments, steam sterilization validation a Yipak self-sealing sterilization pouches were used. 1) Place the packaged instruments in the sterilization chamber. 2) Start the program (The validated time was four (4) minutes as a minimum, longer time is also possible). <table><tr><td>Cycle duration minutes minimum (Min.)</td><td>Cycle temperature (°C)</td><td>Drying time (Min.)</td></tr><tr><td>4</td><td>134 °C</td><td>15</td></tr></table> 3) Remove the instruments at the end of the program and allow them to cool down. 4) Check the packaging for possible damage and screening effects. 5) Faulted packaging must be inspected as being non-sterile. The instruments must be repacked and re-sterilized. NOTE: Instrument blocks (stand) can be used for sterilization purposes for immediate use only.	Cycle duration minutes minimum (Min.)	Cycle temperature (°C)	Drying time (Min.)	4	134 °C	15
Cycle duration minutes minimum (Min.)	Cycle temperature (°C)	Drying time (Min.)					
4	134 °C	15					
STORAGE	The device should be stored in the sterilization pouch until required. Storage should be in dry, clean conditions and at ambient temperature.						

VALIDATION OF CLEANING AND STEAM STERILIZATION

The above detailed processes have been validated as being capable of preparing MDT's dental burs and discs for reuse. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed, using the equipment, materials and personnel in the reprocessing facility, achieve the required results. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

DISPOSAL

Used burs are considered as biohazard and need to be discarded as bio-hazard waste in accordance with local regulations.

TRACEABILITY

Each package includes Lot number  on its label. This number must be quoted in any correspondence regarding to the product.

CONTACTING MDT:

Any serious incident that has occurred in conjunction to our device, must be reported to MDT (at the address listed below) and to the competent authority of the Member State in which the user/patient is established.

In the event of burs being returned to MDT, please ensure any contaminated and/or potentially contaminated burs have been effectively cleaned and are appropriately packaged for return.

GLOSSARY OF SYMBOLS:

	CE Compliance
	Indicate the authorized representative
	Medical Device
	Manufacturer
	Date of manufacture
	Expiry date <i>Note: for sterile products only</i>
	Catalogue number / Part Number (P/N)
	Batch code/number
	Unique Device Identifier
	Wear mask and eye protection gear while operating
	Sterilized using irradiation <i>Note: for sterile products only</i>
	Do not re-use <i>Note: for sterile products only</i>
	Do not Re-sterilize. <i>Note: for sterile products only</i>
	Indicate a single sterile barrier system <i>Note: for sterile products only</i>

	Non-Sterile Product <i>Note: for non-sterile products only</i>
	Importer
	Needs to be sterilizable in a steam sterilizer <i>Note: for non-sterile products only</i>
	Consult Instruction for use
	Do not use if package is damaged and consult instructions for use
	Keep Dry
	Keep away from sunlight.
	Temperature limit- from 5°C to 40°C.
	Maximum speed (RPM)
RxOnly	(ref US FDA CDRH) DEVICE for professional use only

CONTACT INFORMATION:

 Manufacturer	MDT, MICRO DIAMOND TECHNOLOGIES LTD. HA'AMAL 2 ST., AFULA 1857107, ISRAEL PHONE: +972-4-6094422 FAX: +972-4-6597812 EMAIL: INFO@MDTDENTAL.COM WEB: WWW.MDTDENTAL.COM
 European Community Authorized Representative	OBELIS S.A BD. GÉNÉRAL WAHIS 53 1030 BRUSSELS, BELGIUM TEL: + (32) 2. 732.59.54 FAX: +(32) 2.732.60.03 E-MAIL : MAIL@OBELIS.NET
 Translation	AbroadLink Translations Castellana Business Center C/Paseo de la Castellana 40, 8th Floor 28046, Madrid.

**CONTROLLED
DOCUMENT**

Rini Lahav, M.Sc.
CTO QA RA
Director P&RC
MDT Micro Diamond Technologies Ltd.

Aquilon Fixed 4-Hole

Air Motor

Instructions For Use



TABLE OF CONTENTS

- Before You Begin
- Safety Information
- Technical Specifications
- Attachments Installation
- Cleaning & Lubrication
- Sterilization
- Warranty



WARNING!
(Risk of injury)



ATTENTION!
(To prevent damage)



Thermal Washer
Disinfectable



Sterilizable up to the
stated temperature

BEFORE YOU BEGIN

Please read this instruction prior to using your slow speed attachments. The use of this product is intended for use by trained dental personnel. We recommend that you retain this manual for future reference.

SAFETY INFORMATION

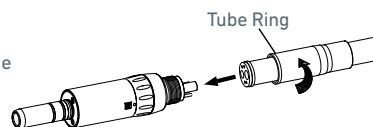
- Handpieces and attachments should be sterilized after each patient to prevent any transmission of infective organisms.
- Suitable hygienic measures must be taken to prevent cross contamination among patients, operators, and other personnel.
- The handpiece must only be operated when the attachment is properly seated.

TECHNICAL SPECIFICATIONS

Reference	1602000-001
Attachments	ISO E-type attachments (Standard Size)
Maximum Speed	20,000 RPM
Air Pressure Range	0.2 - 0.3 MPa
Recommended Exhaust Pressures	0.07 MPa, max. *0.25 MPa
Recommended Air Pressure Range	0.25 MPa
Water Pressure Range	0.05 - 0.2 MPa
Usage Speed Range	5,000 - 20,000 RPM
Air Flow (at 0.25 MPa)	46 NL/min.
Stop Torque (at 0.25 MPa)	3.5 Ncm

MOUNTING AIR MOTOR

Line up the pipes on the motor with the holes in the tube connector, and put the motor on the tube. Tighten up the tube ring. FIG. 1



MOUNTING ATTACHMENTS

Place the handpiece or shank attachment on the motor until it clicks into place. The attachment is free-turning. FIG. 2

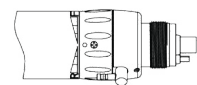


DISCONNECT THE ATTACHMENT

Pull the attachment off the motor.

SPEED AND DIRECTION ADJUSTMENT

Turn the Speed Adjustment Ring to set the speed and rotation direction. FIG. 3



Speed Adjustment Ring

WARNING

- Before each use, always operate the handpiece outside the oral cavity to ensure it runs smoothly in the intended direction and at the intended speed. Ensure that the bur does not wobble. Patient injury could occur.
- Never touch the connection buttons while the motor is running. Instruments could disconnect and injure the patient.
- Wait for the instrument to stop rotating before withdrawing from the patient's oral cavity to avoid injuring the patient.
- Remove attachments when not in use to avoid risk of accidental injury.



FIG. 3

DISINFECTION & LUBRICATION

Clean and lubricate the motor with Spraynet[®] & Lubrifluid[®] once a day or before autoclaving. Remove the motor from its tube. Set the speed adjustment ring on the Forward direction.

- Carefully clean all motor surfaces with a cloth soaked in Spraynet[®] (FIG. 4).
- Mount the spray nozzle into the appropriate spray port on the Spraynet[®] can.
- Shake the can well to mix solution and propellant.
- Insert the spray nozzle in the rear of the attachment and spray for approximately 1 second or until liquid is visible from attachment end points.
- Repeat previous step with Lubrifluid[®] for lubricating the interior of the motor.

⚠ CAUTION

- Hold spray can upright. FIG. 5
- Firmly hold the motor to prevent slippage from spray pressure.
- Supply lubricant until liquid is visible from attachment end points.
- Always dry the exterior of the motor with a cloth soaked in Spraynet[®].



FIG. 4

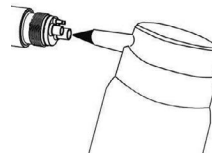


FIG. 5

STERILIZATION

Bien-Air recommends cleaning and sterilizing this motor before treatment of each patient. Sterilize wrapped attachments at 132°C for a minimum of 10 minutes or at 121°C for a minimum of 50 minutes. Do not exceed 135°C.

An unwrapped attachment should be steam sterilized at 132°C for a minimum of 8 minutes or at 121°C for a minimum of 30 minutes. Do not exceed 135°C.

⚠ Note: an unwrapped motor must be used immediately or sterility cannot be reasonably maintained.

 Do not exceed the sterilizer manufacturer's guidelines for load capacity.

⚠ CAUTION

Use steam sterilization exclusively for complete sterility. Do not use dry heat sterilizations, ultrasonic cleaning, chemical disinfection, or cold sterilization. Examples include:

- Immersion techniques or surgical milk
- Surface wipes, handsoaps, or detergents
- Surface sprays
- Sterilization bags containing disinfectants

LIMITED WARRANTY

Bien-Air USA hereby grants the user a warranty covering any operating fault, or material or manufacturing defect. The warranty period is 12 months from the date of invoicing.

In the event of a justified claim, Bien-Air USA 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 USA 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 or water connection.



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 states in which they practice to use or order the use of this device. Bien-Air USA is not responsible for any typographical errors. Subject to technical change without notice.

 **Bien-Air USA**

8861 Research Drive Irvine CA 92618

(800) 433-2436

sales-us@bienair.com

Other addresses available at

www.bienair.com

Sterilization Instructions

smartIPR Gauge and smartIPR Disk Block

Clean promptly after use, keep devices separated from dissimilar metals, and ensure they are completely dry before sterilization or storage.

1. Cleaning-Agent Restrictions

Use cleaning agents and disinfectants that are compatible with the device materials. Select products with a pH between 5 and 9. Do not use products containing:

- Strong acids or strong alkalis
- Organic solvents
- Hydrogen peroxide or other oxidizing agents
- Chlorine, iodine, or bromine
- Aromatic or halogenated hydrocarbons
- Heavy-metal salts
- Aldehydes or other fixatives

2. General Precautions

- Clean the smartIPR Gauge and smartIPR Disk Block immediately after use.
- Do not allow blood, saliva, tissue, or debris to dry on the devices.
- Use only a soft-bristled brush. Do not use steel wool or metal brushes.
- Keep devices made from different materials separated during cleaning, disinfection, ultrasonic cleaning, and sterilization.
- Rinse away all cleaning and disinfecting agents thoroughly.
- Dry devices completely before packaging, sterilization, or storage.
- Do not use any device that is corroded, cracked, damaged, or excessively worn.

3. Pretreatment

Begin pretreatment as soon as possible and no later than one hour after use.

1. Separate the smartIPR Gauge and smartIPR Disk Block from other instruments.
2. Place the devices in a water bath for at least 10 minutes.
3. Remove visible contamination under running water using a soft-bristled brush.
4. Thoroughly rinse all surfaces and openings.
5. Inspect each device for cleanliness and damage.

4. Water and Cleaning Solutions

- Use distilled or deionized water whenever possible; potable water is the minimum acceptable quality.
- Use fully demineralized, endotoxin-free water for the final rinse when available.
- Use freshly prepared cleaning and disinfecting solutions.
- Do not combine cleaning agents with disinfectants.
- Follow the chemical manufacturer's instructions for concentration, temperature, and contact time.

5. Automated Cleaning and Disinfection

1. Position the devices in the washer-disinfector so water can reach and drain from all surfaces.
2. Prevent the devices from touching each other or other instruments.
3. Run an approved instrument-cleaning cycle using a compatible cleaning agent.
4. Thermally disinfect at 90 °C (194 °F) for 5 minutes.
5. Remove the devices promptly after the cycle.
6. Inspect and dry completely before packaging.

6. Manual Ultrasonic Cleaning

1. Place the devices in an appropriate ultrasonic cleaning basket or cassette.
2. Prevent the devices from touching each other or other instruments.
3. Clean at 35 kHz for 10 minutes at approximately 20 °C (68 °F), using deionized water and a compatible ultrasonic cleaning solution.
4. Remove the devices from the ultrasonic bath.
5. Rinse all surfaces at least three times under running deionized water for at least 10 seconds, or until visibly clean.

7. Manual Disinfection

1. Fully immerse the cleaned devices in a compatible disinfecting solution.
2. Follow the disinfectant manufacturer's required contact time.
3. Ensure all surfaces are covered and no air pockets remain.
4. Prevent the devices from touching each other.
5. Remove the devices after the required contact time.

Final Rinsing and Drying

1. Completely immerse the devices in a large volume of fresh water for at least 1 minute.
2. Thoroughly rinse all surfaces at least five times.
3. Discard the rinse water after each rinse.
4. Repeat the complete rinse procedure two additional times using fresh water, for a total of three rinse cycles.
5. Dry all surfaces using filtered compressed air.
6. Package only after the devices are completely dry.

8. Steam Sterilization

Use a validated fractionated-vacuum steam autoclave. Do not expose either device to temperatures above 134 °C (273 °F).

Region	Sterilization Cycle	Drying Time
United States	132 °C (270 °F) for 4 minutes	30 minutes
Europe	134 °C (273 °F) for 3 minutes	Validated local practice
Other Countries	132–134 °C (270–273 °F) for at least 3 minutes	Validated local practice

Do Not Use

- Radiation
- Plasma sterilization
- Formaldehyde sterilization
- Ethylene oxide sterilization

9. Dry Heat

- Do not use dry heat.

10. After Sterilization

- Confirm that the devices and sterilization packaging are completely dry.
- If moisture is visible, repackage and repeat sterilization using a longer drying cycle.
- Store sterile devices according to the sterilization-pouch or container manufacturer's instructions.
- Follow the autoclave manufacturer's instructions for loading, maintenance, cycle operation, and performance testing.
- Do not sterilize corroded or damaged devices with intact instruments.