

## 1 User and Indications for Use

User: Qualified Professionals

Indications for Use:

The General Cutting Contra Handpiece is powered by either an air-motor or electronic micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials and removal of crowns and filling materials.

### ⚠ CAUTION

- Connect ONLY to E type motors (ISO 3964 (EN ISO 3964)).

#### Forza M1 / Forza M5

- This handpiece can ONLY be connected to E type motors in accordance with ISO 3964 (EN ISO 3964) with a motor insert length of 23mm or less.



## 2 Precautions for Handling and Operation

- Please read these precautions carefully and use only as intended or instructed.
- Safety instructions are intended to avoid potential hazards that could result in personal injury or damage to the device. Safety instructions are classified as follows in accordance with the seriousness of the risk.

Class	Degree of Risk
⚠ WARNING	Hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.
⚠ CAUTION	Hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.

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## NOTICE

General product specification information highlighted to avoid product malfunction and performance reduction.

## ⚠ WARNING

- Clean and lubricate the handpiece immediately (within 1 hour) after each treatment to remove residue. Failure to properly maintain the handpiece may cause infection, product failure, overheating leading to burn injuries. (Refer to “7 Post-use Maintenance”)
- If blood infiltrates inside a handpiece, clean and lubricate the handpiece immediately using the PANA SPRAY Plus or clean the handpiece using a thermo-disinfector.

## ⚠ WARNING

- Depressing the Push Button while the handpiece is in rotation may lead to overheating, causing burn injuries or product failure. Avoid the push button to contact with any oral tissue.
- Supply coolant water and coolant air while using the handpiece. No supplying the coolant water and coolant air may lead to overheating, causing burn injuries or product failure.
- Do not use the handpiece for polishing purposes. Polishing paste could enter the handpiece, causing the failure of the Push Button or burn injuries due to the overheating of the handpiece head.

### WARNING

- Keep any debris or other foreign materials away from inside the gear or the handpiece. Foreign materials remaining inside may lead to overheating, causing burn injuries or other accidents.
- Ball bearings are wear items and may require replacement. Be sure to inspect the handpiece before use (Refer to “6 Checking the Handpiece Before Each Use”). If abnormal vibration or noise are found, the bearings or other internal parts may be worn out or damaged. Damaged parts may lead to handpiece overheating causing burn injuries. If overheating is suspected, stop using the handpiece immediately and contact Brasseler USA.

### CAUTION

- When operating the product always consider the safety of the patient.
- Users are responsible for the operational control, maintenance and continual inspection of this product.
- Prior to clinical use, inspect the handpiece. Check for vibration, noise and overheating. If any abnormalities are found, stop using the handpiece immediately and contact Brasseler USA. (Refer to “6 Checking the Handpiece Before Each Use”)
- Do not disassemble or alter the handpiece except as recommended by Brasseler in this Operation Manual.
- Do not allow any impact on to the product. Do not drop the product. Deformation may cause the handpiece to fail during use.
- Operators and all others in the area must wear eye protection and a mask when operating this handpiece.

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**⚠ CAUTION**

- Do not use burs with problems listed below as the bur may break, seize up or disengage from the chuck.
  - Bent, deformed, worn, rusted, broken, deficient bur.
  - Bur which is cracked on the edge or axis.
  - Non-ISO(EN ISO) standard, or tampered bur.
- Do not use burs other than specified in "10 Specifications" as such burs may be accidentally released or break during rotation.
- Always keep the bur shank clean. Dirt or debris in the chuck could cause poor bur concentricity or low chuck retention force.
- Always insert the bur all the way into the chuck. If insertion is insufficient, premature failure of the bearings or accidental release of the bur may occur.
- Do not exceed Max. Bur Length shown in "10 Specifications".

**⚠ CAUTION**

- Always follow the instructions provided by the bur manufacturer.
- Do not exceed the bur speed recommended by the bur manufacturer.
- Should the handpiece function abnormally during use, stop using the handpiece immediately and contact Brasseler USA.
- Do not use the following fluids to wipe, immerse or clean the product; strong/super acid water, strong acid/alkaline chemicals, chlorine containing solutions, solvents such as benzene or thinner.
- The handpiece is delivered in a non-sterile condition and must be autoclaved prior to use.
- Perform regular function and maintenance checks. (Refer to "9 Periodical Maintenance Checks")

### CAUTION

- If the handpiece has not been used for a long period, rotate the handpiece and check for noise, vibration and overheating before use.
- To avoid clinical downtime it is recommended that a spare be kept on hand in case of a breakdown during treatment.
- The operation of the handpiece is permitted only on dental units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

#### **Forza F5 / Forza M5**

- Do not use a surgical bur with its maximum length of 25mm or longer. Using such bur with this handpiece may lead to premature abrasion of the bearings. In addition, sudden release, bend or breakage of the bur may occur.

### NOTICE

- Repairs of this product are only to be performed by authorized service technicians according to Brasseler requirements. Contact Brasseler USA if repairs are necessary.

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### 3 Accessory List

No.	Part Name	Quantity
1	E-Type Spray Nozzle	1

### 4 Connecting and Disconnecting the Handpiece from the Motor

#### 4-1 Connecting

- 1) Insert the handpiece direct to the motor (Fig. 1). When connecting an optic handpiece, screw the handpiece until it clicks and locks into position.
- 2) Confirm that the handpiece is firmly connected to the motor.

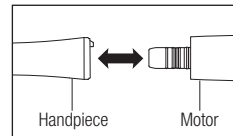


Fig. 1

## 4-2 Disconnecting

Hold the motor and the Handpiece, then pull apart.

### ⚠ CAUTION

- Do not connect or disconnect the handpiece until the motor has completely stopped.
- Do not exceed the Max. Rotation Speed (Motor) shown in "10 Specifications".
- Connect ONLY to E type motors (ISO 3964 (EN ISO 3964)).

### Forza M1 / Forza M5

- This handpiece can ONLY be connected to E type motors in accordance with ISO 3964 (EN ISO 3964) with a motor insert length of 23mm or less.

≤23mm



## 5 Mounting and Removing the Bur

### 5-1 Mounting the Bur

Forza F1 / Forza M1 (Fig. 2)

- 1) Insert the bur until it is correctly seated in place.
- 2) Depress the Push Button and insert the bur into the chuck until the bur "notch" mechanism engages. Release the button.
- 3) Confirm that the bur is not removed by gently pulling and pushing the bur without depressing the Push Button.

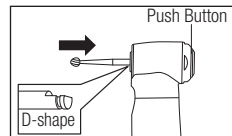


Fig. 2

### Forza F5 / Forza M5 (Fig. 3)

- 1) Insert the bur into the chuck.
- 2) Depress the Push Button to open the chuck (1).
- 3) Insert the bur fully into the chuck until it stops (2) then release the Push Button.
- 4) Confirm that the bur is not removed by gently pulling and pushing the bur without depressing the Push Button.

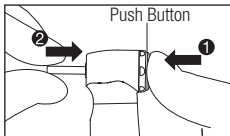


Fig. 3

### 5-2 Removing the Bur

Depress the Push Button to open the chuck (1) and remove the bur (2).

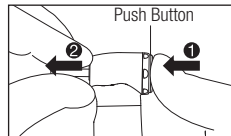


Fig. 4

#### NOTICE

- Grip the handpiece while placing your thumb tip on the Push button which makes it easier to depress the button.



**⚠ WARNING**

- Always use a clean sterile bur. Be sure to wear sterile gloves before mounting the bur.
- When changing burs during treatment, remove the bur and wipe around the bur insertion hole and gloves with a dry lint free cloth until the insertion hole is visually clean, then mount a clean, sterile bur. Residual blood or debris may enter the handpiece while changing burs, which could lead to higher risk of cross-contamination.

**⚠ CAUTION**

- Do not use burs with problems listed below as the bur may break, seize up or disengage from the chuck.
  - Bent, deformed, worn, rusted, broken, deficient bur.
  - Bur which is cracked on the edge or axis.
  - Non-ISO (EN ISO) standard, or tampered bur.
- Do not use burs other than specified in "10 Specifications" as such burs may be accidentally released or break during rotation.
- Insert a sterilized bur and always keep the bur shank clean. When changing burs, make sure that there is no dirt or debris in and around the bur insertion hole of the handpiece. Debris in the chuck could cause infection, heating, poor bur concentricity or low chuck retention force.

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### **⚠ CAUTION**

- Always insert the bur all the way into the chuck. If insertion is insufficient, premature failure of the bearings or accidental release of the bur may occur.
- Do not exceed Max. Bur Length shown in “10 Specifications”.
- Always follow the instructions provided by the bur manufacturer.
- Do not exceed the bur speed recommended by the bur manufacturer.
- Do not mount or remove the bur until the motor has completely stopped.
- Do not apply excess pressure to the bur as it may break or bend or become difficult to remove.

## **6 Checking the Handpiece Before Each Use**

Follow the check below before use. If any abnormalities are found, stop using the handpiece immediately and contact Brasseler USA.

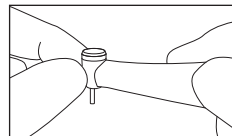


Fig. 5

- 1) Check the Head Cap is firmly tightened.
- 2) Check the coolant water is flowing properly.
- 3) Mount the bur. (Refer to “5 Mounting and Removing the Bur”)
- 4) Rotate the handpiece for about one minute with coolant water at the Max. rotation speed of the attached motor. During rotation, check for abnormalities such as abnormal rotation, vibration, noise.
- 5) After the handpiece rotation has completely stopped, touch the handpiece head to confirm the head is NOT heating abnormally (Fig. 5).

### CAUTION

- To avoid injury, keep your hands away from the bur during rotation.

## 7 Post-use Maintenance

After each patient maintain the product as follows.

### WARNING

- To ensure cleaning and sterilization efficacy, use only the following procedures for reprocessing.
- Follow any additional local directives, standards, and guidelines for cleaning and sterilization.
- Clean and lubricate the handpiece immediately (within 1 hour) after each treatment to remove residue. Failure to properly maintain the handpiece may cause infection, product failure, overheating leading to burn injuries.

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## 7-1 Cleaning at point-of use

### ⚠ CAUTION

- Do not use the following liquids to wipe, immerse, or clean the product: strong/super acid water, strong acid/alkaline chemicals, chlorine-containing solutions, solvents such as benzine or thinner.
- Do not immerse Brasseler instruments in disinfectant solution or clean in ultrasonic devices.

- 1) Always wear protective gloves, a mask, and protective goggles for safety purposes and to minimize the risk of infection. (Fig. 6)

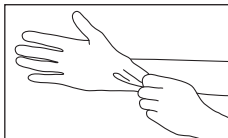


Fig. 6

- 2) Remove the bur. (Fig. 7)

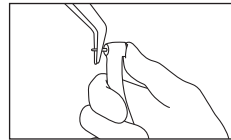


Fig. 7

- 3) Wipe the exterior of the handpiece clean using a cloth moistened with disinfectant or ethanol with a concentration of 60-90%. (Fig. 8)

When using disinfectant, follow the instructions given by the manufacturer of the disinfectant.

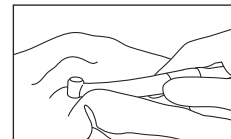


Fig. 8

Use a state-sanctioned disinfectant with proven bactericidal, fungicidal, and virucidal properties. The following disinfectants can be used in the United States and Canada.

CaviCide®, CaviWipes® (manufactured by Metrex)

- 4) Operate the handpiece at the chair-side for at least 20 seconds to purge fluids in the handpiece (Fig. 9). After the handpiece rotation has completely stopped, touch the handpiece head to confirm the head is NO heating abnormally.

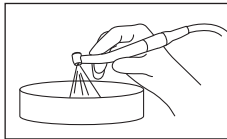


Fig. 9

#### ⚠ CAUTION

- If the head is heating abnormally, stop using the handpiece immediately and contact Brasseler USA.

- 5) Remove the handpiece from the motor. (Fig. 10)  
6) Carry the handpiece to the decontamination area.

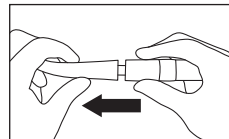


Fig. 10

## 7-2 Cleaning and Drying

Perform cleaning and drying using either the manual or automatic method.

### Manual Method (Cleaning and Drying the Exterior)

Wash the handpiece and irrigation nozzle under running water following the procedures below.

(Water condition:  $\leq 38^{\circ}\text{C}$ ,  $\geq 3.5\text{L/min}$ ; water should be of the same quality as drinking water)

- 1) Clean the external surfaces of the handpiece with a soft bristled toothbrush for 15 seconds or more. (Fig. 11)

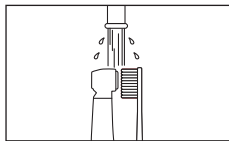


Fig. 11

- 2) Clean around the bur insertion hole for 15 seconds or more, using an interdental brush (wire thickness 0.7mm) that conforms to size 4 in ISO 16409. (Fig. 12)

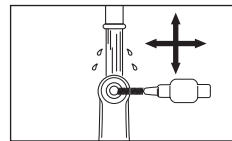


Fig. 12

Under appropriate lighting (natural office lighting, 500 lx or higher), inspect the handpiece for blood or other debris. If any visible debris remains, repeat the process until the handpiece is visually clean.

- 3) Wipe the exterior of the handpiece clean using a cloth moistened with disinfectant or ethanol with a concentration of 60-90%. (Fig. 13)

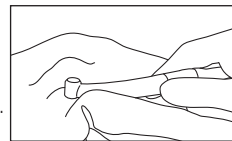


Fig. 13

When using disinfectant, follow the instructions given by the manufacturer of the disinfectant.

Use a state-sanctioned disinfectant with proven bactericidal, fungicidal, and virucidal properties.

The following disinfectants can be used in the United States and Canada.

CaviCide®, CaviWipes® (manufactured by Metrex)

After cleaning, if the residual moisture is present, wipe off with dry cloth or blow it off with compressed air ( $\leq 0.35\text{MPa}$ ) until there is no moisture in the interior and exterior.

When blowing off with compressed air, cover the handpiece with cloth to prevent scattering of water. Proceed to “7-3 Cleaning and Lubrication”.

## Automatic Method (Cleaning and Drying the Exterior and Interior)



Brasseler handpieces with this symbol are compatible with medical thermo-disinfectors.

Due to the variation in cleaning/disinfection cycles and cleaning agents available from the various manufacturers, Brasseler has validated the Getinge 46 Series Washer Disinfector Cycle P7-Anesthesia for automatic processing/reprocessing of the product.

Only validated procedures must be used for cleaning and sterilization. When using reprocessing procedures that are different from those described in this manual, those procedures must be validated by the respective practice or hospital using a thermo-disinfector that conforms to ISO 15883-1.

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### NOTICE

- All water is “building supply” (at least drinking water quality) unless otherwise indicated.

- 1) Prepare and pre-cleaning the device as described above in step “7-1 Cleaning at point-of use”.
- 2) Wipe off a dirt on a part held by a handpiece holder using the cloth moistened with 60-90% ethanol or disinfectant. When using disinfectant, follow the instructions given by the manufacturer of the disinfectant. Use a state-sanctioned disinfectant with proven bactericidal, fungicidal, and virucidal properties. The following disinfectants can be used in the United States and Canada.  
CaviCide®, CaviWipes® (manufactured by Metrex)

- 3) Perform main wash under the following conditions. Use a Getinge 46 Series thermo-disinfector (or equivalent device):  
Pre-Wash 1: Cold water (<110°F (43°C)) for 2 min  
Pre-Wash 2: None - Not Applicable  
Enzyme Wash: Hot tap water and 60ml of heated (95°F (35°C)) detergent (Getinge Clean Renuzyme) for 3 min at 120°F (49°C)  
Detergent Wash: None - Not Applicable  
Rinse 1: Hot tap water for 2 min  
Rinse 2: Hot tap water for 2 min  
RO Final Rinse: Hot tap water for 32 min at 167°F (75°C)  
Drying: 20 min  
Upon removal from the thermo-disinfector, if the residual moisture is present, wipe off with dry cloth or blow it off with compressed air ( $\leq 0.35\text{MPa}$ ) until there is no moisture in the interior and exterior.



- 4) After cleaning and drying the handpiece, confirm that it is clean under appropriate lighting (500 lx or higher).  
If dirt still remains, repeat the procedures.
- 5) Proceed to “7-3 Cleaning and Lubrication”.

**⚠ CAUTION**

- Handpieces must be removed from the thermo-disinfector immediately (within 1 hour) after the cleaning and drying cycle is complete to prevent corrosion.
- After washing with thermo-disinfector, prior to lubrication, dry the product until all internal moisture is completely removed. Thermo-disinfector moisture remaining inside the product could reduce the effect of lubrication and could cause corrosion inside of the product.

**7-3 Cleaning and Lubrication**

Perform cleaning and lubrication using the manual method, or lubrication using the automatic method.

**Manual Method (Lubricating the Chuck) (Only in the case of handpiece for FG bur)**

- 1) Attach the tip nozzle to the nozzle of the PANA SPRAY Plus.
- 2) Shake the can three or four times, then gently press in the push button to directly spray into the bur insertion hole (Fig. 14).

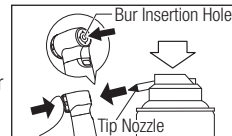


Fig. 14

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### Automatic Method (Lubricating the Chuck) (Only in the case of handpiece for FG bur)

Use a Brasseler automatic lubrication system to perform lubrication.

For information on using an automatic lubrication system, see the instruction manual for the automatic lubrication system. The Care3 Plus cannot be used to lubricate the chuck. Lubricate it manually.

#### ⚠ CAUTION

- If the chuck is not regularly lubricated the chuck grip may be weakened and the bur may be accidentally released during use.

### Manual Method (Cleaning and Lubricating the Interior)

- 1) Attach an E-Type Spray Nozzle to the nozzle of the PANA SPRAY Plus.
- 2) Shake the can 3 or 4 times, and insert the E-Type spray nozzle into the rear of the handpiece while holding

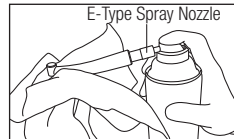


Fig. 15

- the head of the handpiece with a cloth etc.
- 3) Hold the handpiece, and spray for 2 or 3 seconds until oil comes out of the handpiece head (Fig. 15). Repeat lubrication until foreign material stops coming out of the tip.

### ⚠ CAUTION

- Do not use sprays other than Brasseler PANA SPRAY Plus. Using sprays other than PANA SPRAY Plus may cause the handpiece to overheat.
- Hold the spray can upright.
- Firmly hold the handpiece to prevent it slipping when spray pressure is applied.
- Spray lubricant until it expels from the handpiece head.
- If you wish to purge excessive oil from inside the handpiece, rotate the handpiece for approx 15 seconds without a bur. During the rotation, do not depress the push button, especially when using absorbent cloth to prevent oil from scattering. Depressing the push button during rotation may damage the chuck mechanism (Fig.16, Fig.17).

### ⚠ CAUTION

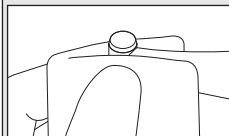


Fig. 16

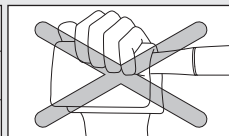


Fig. 17

### NOTICE

- Brasseler recommends the use of "Spray Mist Absorber" (Y900084) to prevent oil mist expelling out of the handpiece head.

### Automatic Method (Lubricating the Interior)

Use a Brasseler automatic lubrication system to perform lubrication.

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For information on using an automatic lubrication system, see the instruction manual for the automatic lubrication system.

**⚠ WARNING**

- If blood infiltrates inside a handpiece, clean and lubricate the handpiece immediately using the PANA SPRAY Plus or clean the handpiece using a thermo-disinfector.

**7-4 Packaging, Sterilizing, and Drying**

- 1) Insert the handpiece into an FDA-approved sterilization pouch that conforms to ISO 11607-1, and seal the pouch.
- 2) Perform steam sterilization with the following conditions.

Type	Gravity Displacement	Pre-Vacuum (Dynamic Air Removal)
Temperature	132°C	132°C
Full Cycle Time	15 min	4 min
Drying Time	30 min	30 min

**⚠ CAUTION**

- Use an FDA-approved steam sterilizer to perform sterilization.
- Follow local rules, regulations, and guidelines regarding the reprocessing of devices.
- Do not touch the product immediately after steam sterilization as it will be very hot and must remain in a sterile condition.
- Do not perform steam sterilization on the product with other instruments even when it is in a pouch. This is to prevent possible discoloration and damage to the product from chemical residue on other instruments.
- Clean and lubricate the handpiece prior to sterilization. If blood remains on the internal surface it can become clotted and cause product failure.
- Do not heat or cool the product too quickly. Rapid change in temperature could cause damage to the product.

**⚠ CAUTION**

- Be sure to use sterilizers that can perform sterilization up to 135°C. In some sterilizers, the chamber temperature may exceed 135°C. Do not use these sterilizers as failure of the handpiece could occur. Contact the sterilizer manufacturer for detailed information about cycle temperatures.
- Steam sterilization is recommended for the product. The validity of other sterilization methods (such as plasma sterilization or EOG sterilization) is not confirmed.

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## 7-5 Storage

Store the product in a dry, clean location.

### ⚠ CAUTION

- After the sterilization and drying cycles are complete, remove the handpiece immediately from the sterilizer to store it.
- Store the product in a well ventilated place out of direct sunlight and within the range of temperature, humidity and pressure specified in “10 Specifications”.
- Sterilization is not guaranteed after the sterilization retention period specified by the manufacturer and seller of the sterilization pouch has elapsed.  
If the sterilization retention period has elapsed, perform sterilization again with a new sterilization pouch.

## 8 Cleaning of Optic Illumination Points

When debris is attached to optic illumination points (Glass Rod), wipe clean all the optic illumination points using an alcohol-immersed cotton swab. Remove all debris. (Fig. 18)

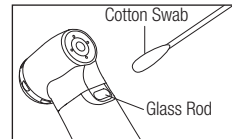


Fig. 18

### ⚠ CAUTION

- Do not use a sharp tool to clean the Glass Rod. It could damage the glass and reduce the light transmission.

## 9 Periodical Maintenance Checks

Perform periodical maintenance checks every three months, referring to the check sheet below. If any abnormalities are found, contact Brasser USA.

Points to check	Details
Head cap is loose	Check that the Head Cap is firmly tightened.
Rotation	Rotate the handpiece and check for abnormalities such as abnormal rotation, vibration, noise, and overheating.
Coolant Water	Operate the handpiece and check that the coolant water is flowing through all spray ports.

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## 10 Specifications

Model	Forza F1	Forza F5
Max. Rotation Speed (Motor)	40,000min <sup>-1</sup>	
Max. Rotation Speed (Handpiece)	40,000min <sup>-1</sup>	200,000min <sup>-1</sup>
Gear Ratio	1:1 Direct Drive	1:5 Increasing
Bur Type	ISO 1797-1 (EN ISO 1797-1) Type1 Ø2.35mm CA Bur	ISO 1797-1 (EN ISO 1797-1) Type3 Ø1.59-1.60mm Standard FG Bur
Chuck Length	11.6mm	
Max. Bur Length	22.5mm	25 mm (Recommended 19mm)
Max. Working Part Diameter	Ø4.0mm	Ø2.0mm
Optic	Glass Rod	Glass Rod
Water Spray Type	Single	Quattro



Model	Forza F1	Forza F5
Water Consumption	≥46mL/min (0.1MPa)	≥37mL/min (0.1MPa)
Chip Air Consumption	≥1.6L/min (0.15MPa)	≥2L/min (0.15MPa)

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Model	Forza M1	Forza M5
Max. Rotation Speed (Motor)	40,000min <sup>-1</sup>	
Max. Rotation Speed (Handpiece)	40,000min <sup>-1</sup>	200,000min <sup>-1</sup>
Gear Ratio	1:1 Direct Drive	1:5 Increasing
Bur Type	ISO 1797-1 (EN ISO 1797-1) Type1 Ø2.35mm CA Bur	ISO 1797-1 (EN ISO 1797-1) Type3 Ø1.59-1.60mm Standard FG Bur
Chuck Length	12.7mm	10.9mm
Max. Bur Length	22.5mm	25mm
Max. Working Part Diameter	Ø4.0mm	Ø2.0mm
Optic	Glass Rod	
Water Spray Type	Single	Quattro
Water Consumption	≥46mL/min (0.1MPa)	≥37mL/min (0.1MPa)
Chip Air Consumption	≥1.5L/min (0.15MPa)	≥2L/min (0.15MPa)

Use Environment	Temperature: 10 - 35°C, Humidity: 30 - 75% (No Condensation)
Transportation and Store Environment	Temperature: -10 - 50°C, Humidity: 10 - 85%, Pressure: 500 - 1,060hPa

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## 11 Symbol



This product can be sterilized in a steam sterilizer up to Max. 135°C.



This product can be washed via Thermo Disinfectant.



Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.



GS1 DataMatrix for Unique Device Identifier.

## 12 Warranty

Brasseler products are warranted against manufacturing errors and defects in materials. Brasseler reserves the right to analyze and determine the cause of any problem. Warranty is voided should the product be not used correctly or for the intended purpose or has been tampered with by unqualified personnel or has had non Brasseler parts installed. Replacement parts are available for seven years beyond discontinuation of the model. Contact Brasseler USA if repairs are necessary.

## 13 Spare Parts List

Model	Order Code
E-Type Spray Nozzle	5010055U0

## 14 Disposing product

In order to avoid the health risks of operators handling the disposal of medical equipment, as well as the risks of environmental contamination caused thereof, a surgeon or a dentist is required to confirm the equipment is sterile. Ask specialist firms who are licensed to dispose of specially controlled industrial wastes, to dispose the product for you.

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