

REF P65-001-0009-SK

General Description

The Paragon FJ2000 range of disposable surgical power tools are designed for use in orthopedic osteotomies and a variety of precision small bone cutting and drilling procedures. The Paragon range is supplied in a sterile package "Ready to Use" and for Single-Use only.

The Handpiece with RS module attached offers a maximum speed of 10,000 rpm.



Read the operating instruction carefully before use. Failure to follow may cause damage or injuries.

Indications

Orthopedic osteotomies and a variety of precision small bone cutting and drilling procedures.

Contraindications

Must not be used for cranial surgery.

Warnings

Failure to follow may cause possible harm to persons.

- The device must be used solely by orthopedic surgeons and healthcare professionals trained to conduct orthopedic osteotomies and a variety of precision small bone cutting and drilling procedures.
- Wear protective equipment to avoid infectious splash backs.
- Sterile only if package is unopened and undamaged. Single use only! **DO NOT Re-sterilize!**
- **DO NOT** operate damaged or malfunctioning instruments.
- One P65-001-0009-SK device per operation.
- Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Caution

Failure to follow may cause damage to product.

- **DO NOT** use this product in any other manner other than the purpose or the operation method described in this instruction manual.
- **DO NOT** submerge instrument in liquid.
- **DO NOT** drop or hit the instrument.
- Store in a cool dry place.
- No modification of this equipment is allowed.
- Personnel should familiarize themselves with the power equipment before it is set-up for use in any procedure. Trained personnel includes but is not limited to, central processing personnel, members of the surgical team, and the bioengineering department.
- Ensure the port switch is turned to the white port side

NOTE: The user/patient should report any serious incident relating to the device to the manufacturer and competent authority of its Member State.

Instructions for Use

Plug into the Power Console Non-sterile Person:

Plug the handpiece white plug to the white port and make sure to turn the port switch to the white port side.

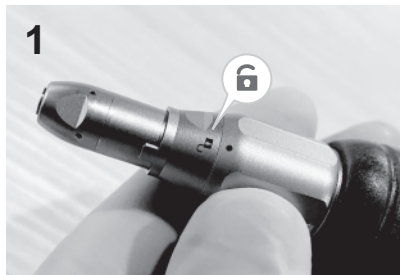


Instruction for use

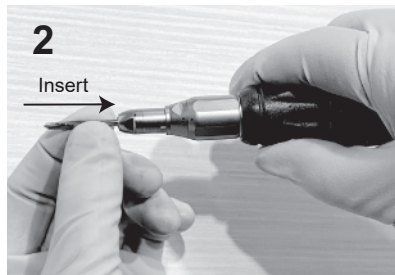


- MIS RS module
- MIS Handpiece
- Burr NOT included

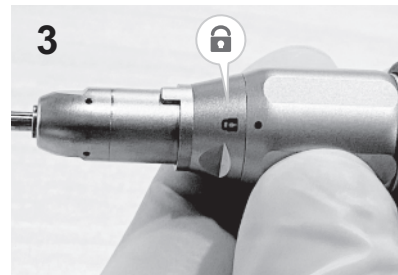
Installation Sterile Person:



Turn to unlock the chuck mechanism

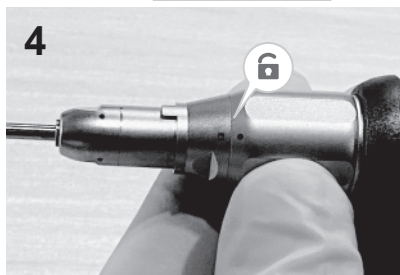


Insert the burr.

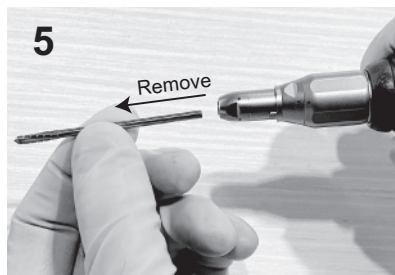


Turn to lock the chuck mechanism.

Removal Sterile Person:



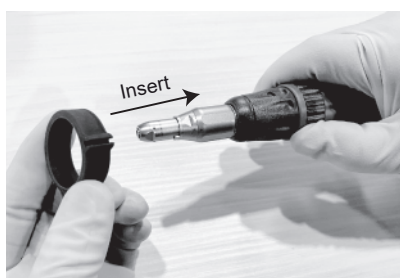
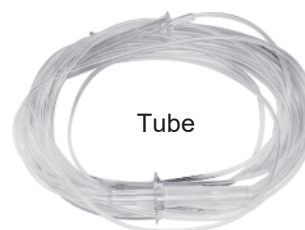
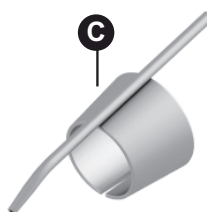
Turn to unlock the chuck mechanism.



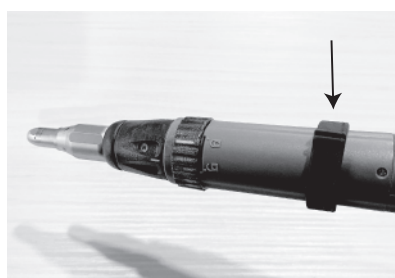
Remove the burr.

P65-001-0008-SK MIS Irrigation Kit RS (Optional)

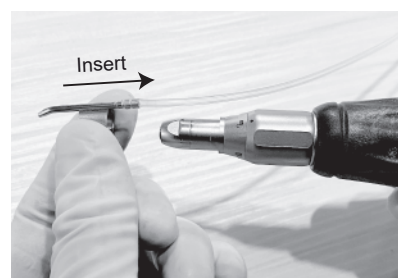
Installation Sterile Person:



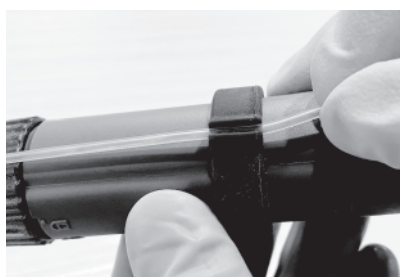
Insert the ring. **B**



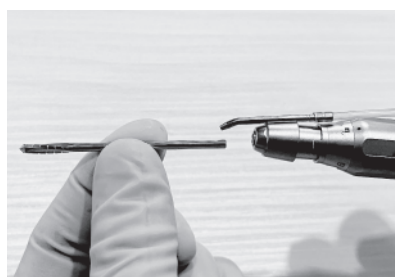
Adjust the ring position.



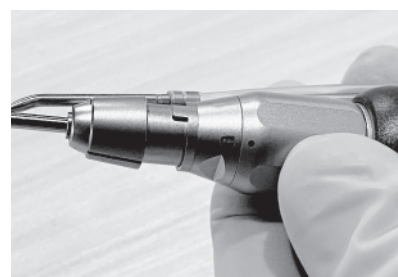
Insert the irrigation clip. **C**



Align the tube and fix it to the ring.



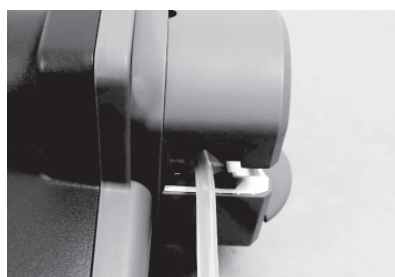
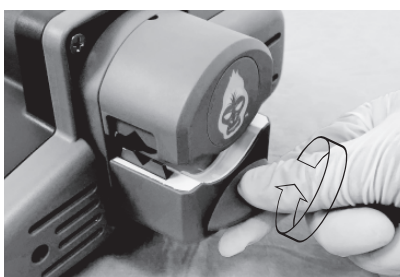
Turn to unlock the chuck mechanism and insert the burr.



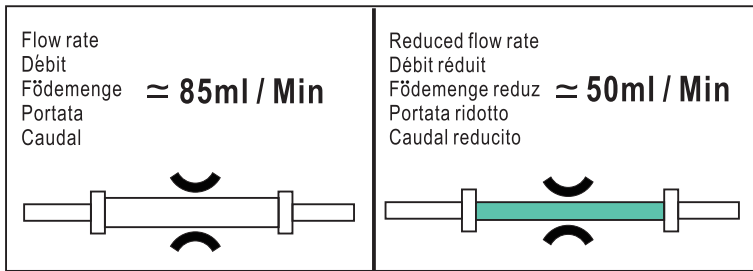
Turn to lock the chuck mechanism.

Non-sterile Person:

Open the pump by turning counter clockwise, make sure to insert the tube into the V aperture, and close the pump by turning clockwise.



NOTE: Irrigation flow differs according to which section of the tube is inserted to the pump.



Insert the spike into the irrigation solution.



Specifications

- Speed : 10,000 RPM (High)
8,000 RPM (Medium)
6,000 RPM (Low)
- Torque: 0.237 Nm (High)
0.189 Nm (Medium)
0.142 Nm (Low)
- Round shank bit module connector
- 24V DC Brushless Motor

Operation

- Temperature: 10°C~25°C
- Relative Humidity: 30%~75%RH
- Atmospheric Pressure: 80kPa ~106kPa
- Altitude limit: 2,000 meters

Transportation and Storage

- Temperature: -10°C~+40°C
- Relative Humidity: 15%~75%RH
- Atmospheric Pressure: 80kPa ~106kPa

Duty Cycle

Continuous operation with intermittent loading.
T_{on}:30s/ Min.T_{off}:30s for Max. 5 consecutive cycles

Shelf Life

3 years

Disposal

- Detach all power sources before disposal.
- Dispose of all single use components, as appropriate, immediately after use.
- Ensure that the device is disposed of safely and in accordance with all current national and international waste disposal directives. Please contact the local authorities responsible for waste disposal if questions arise.

Labeling Symbols

 Refer to instruction manual/booklet	 Distributor	 Use by date
 General warning sign / Caution	 Importer	 BF Type
 Do not reuse	 Complies with EU directives	 Date of manufacture
 Do not use if package is damaged	 Manufacturer	 Medical Device
 Keep Dry	 Authorized representative in the European Community	 Single sterile barrier system
 Sterilized using ethylene oxide	 Swiss Authorised Representative	 Single sterile barrier system with protective packaging outside
 Catalog number	 UK Responsible Person	 Single sterile barrier system with protective packaging outside, enclosed in a carton.
 Batch code	 Unique Device Identifier	 Humidity limitation
 Do not resterilize		 Atmospheric pressure limitation
		 Temperature limit

R Only Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner

 **Paragon 28 Inc.**
14445 Grasslands Drive
ENGLEWOOD CO
80112 USA

 **Paragon 28**
Block 7, Beckett Way
Park West Business Park
Dublin 12, D12 X884
IRELAND

 **miCUTec AG**
Chamerstrasse 172,
6300 Zug, Switzerland

 **Paragon 28 UK Limited**
7 Meadway Court
Stevenage, Hertfordshire
SG1 2EF

 **MedNet EC-REP GmbH**
Borkstrasse 10, 48163
Muenster, Germany

 **Medimap Ltd**
2 The Drift, Suffolk,
Thurston, IP31 3RT,
United Kingdom

 **miCUTec AG**
Chamerstrasse 172,
6300 Zug, Switzerland
Tel. +41 41 740 24 66

 **Dongguan Kaiser Technology Co., Ltd.**
No.6, 2nd Road, Sanjiang Industrial Block,
Hengli Town, Dongguan City, 523462
Guangdong P.R.China