

FJ 2000™

POWER CONSOLE SYSTEM

PRODUCT MANUAL

Paragon 28® FJ 2000™ Power Console Product Manual



PRODUCT DESCRIPTION

The Paragon 28® FJ 2000™ Power Console is an electronic control system for operating MIS and Traditional Open Procedure handpieces. These handpieces operate drills, K-wires, burrs, and saws through the control of a foot pedal. It generates the signals necessary to run the motor and compatible equipment at the desired speed and direction as controlled by the operator. The speed is adjusted by a rotary knob on the equipment. The Foot Pedal can be used to manage the safety lock, forward or reverse direction, and turn irrigation on or off.

The Paragon 28® FJ 2000™ range of Single-Use surgical power tools are designed for use in orthopedic osteotomies in a variety of precision small bone cutting and drilling procedures. The Paragon 28® FJ 2000™ Console and Foot Pedal are provided non-sterile. Hand Pieces, Modules, and Burrs are supplied in a sterile package ready to use and for Single-Use only.

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FEATURED INSTRUMENTATION



FJ 2000™, Power Console with Irrigation Pump (P65-002-0001)

FJ 2000™, Foot Hook (P65-002-0007)



FJ 2000™, Foot Pedal w/ Foot Hook



FJ 2000™, Foot Pedal (P65-002-0002)

FEATURED INSTRUMENTATION



MIS Handpiece



High Speed (Traditional Open) Handpiece

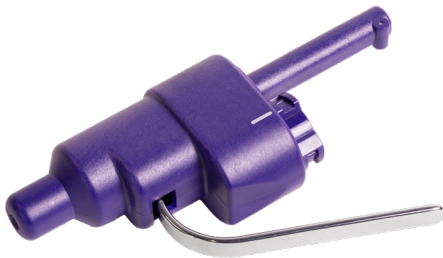


MIS Handpiece Module with Round Shank Connection & Irrigation

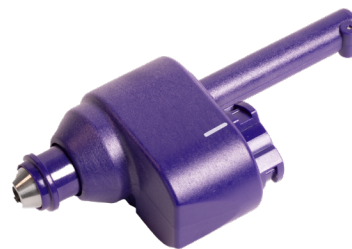


Sagittal Saw Handpiece Module + Driver

COMPATIBLE WITH BOTH HAND PIECES



K-wire Handpiece Module
(Compatible with 0.9-2.3 diameter K-wire)

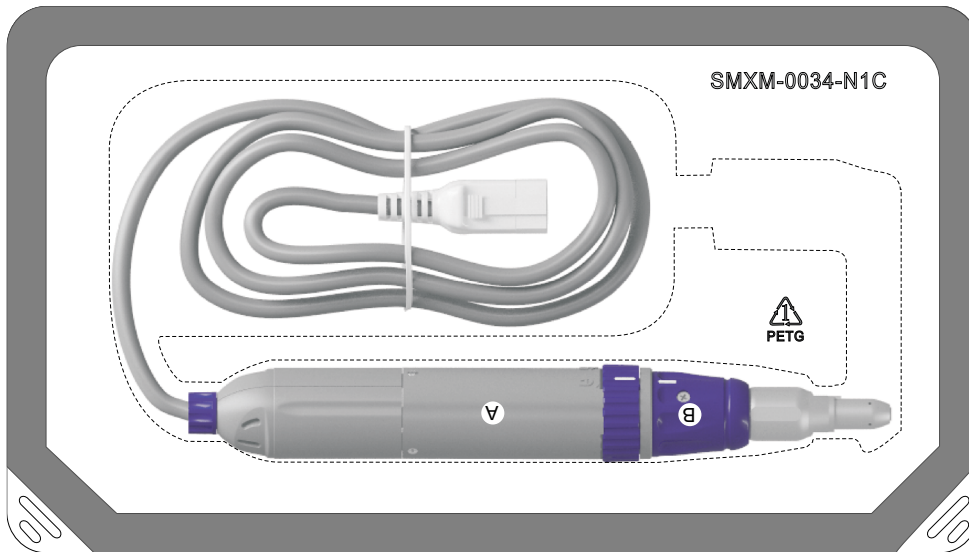


Cannulated AO Handpiece Module

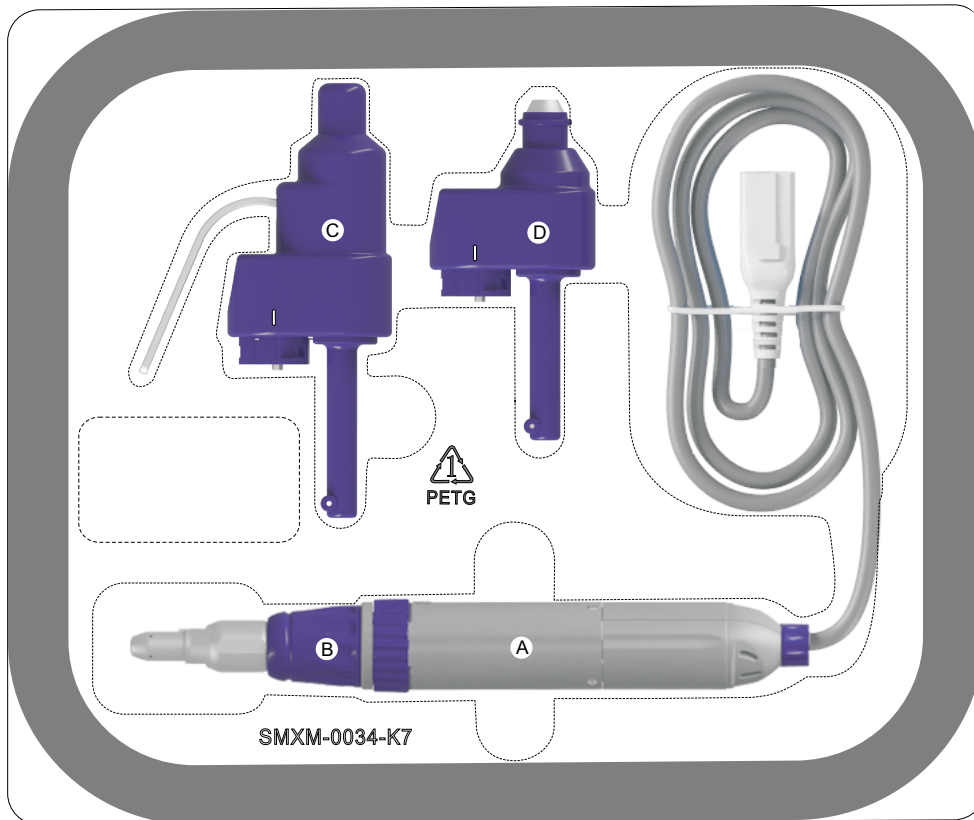
NOTE: Use the cannulated AO module for drilling and placing a screw under power.

FEATURED INSTRUMENTATION

STERILE PACKED KITS



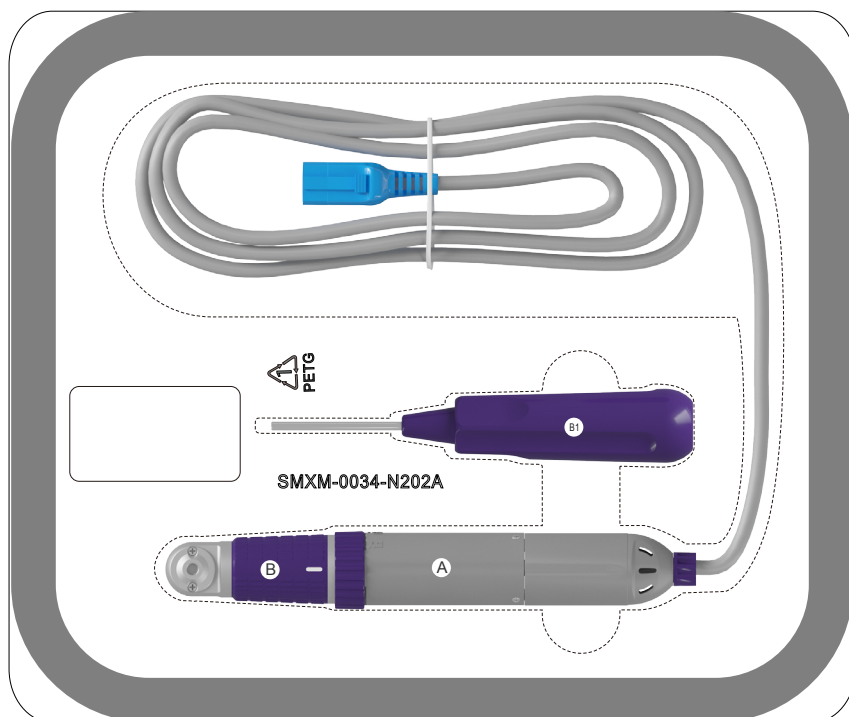
MIS Handpiece Round Shank Connection Kit (Sterile)
(P65-001-0009-SK)



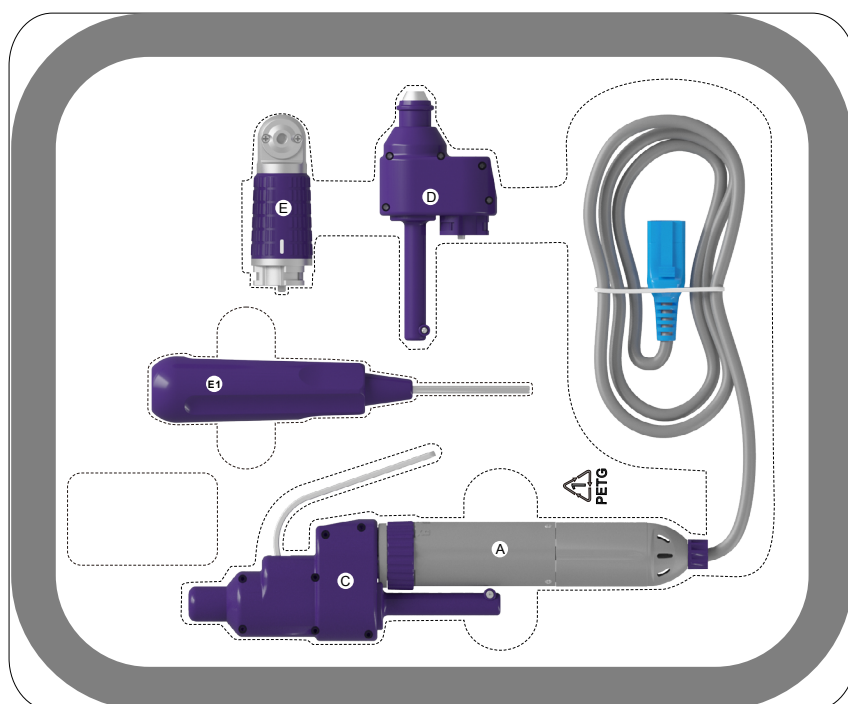
Minimally Invasive Procedure Kit for Hardware (Sterile)
(P65-001-0011-SK)

FEATURED INSTRUMENTATION

STERILE PACKED KITS



High Speed Handpiece with Sagittal Saw Kit (Sterile)
(P65-001-0003-SK)



Open Procedure with Sagittal Saw Kit (Sterile)
(P65-001-0004-SK)

FEATURED INSTRUMENTATION



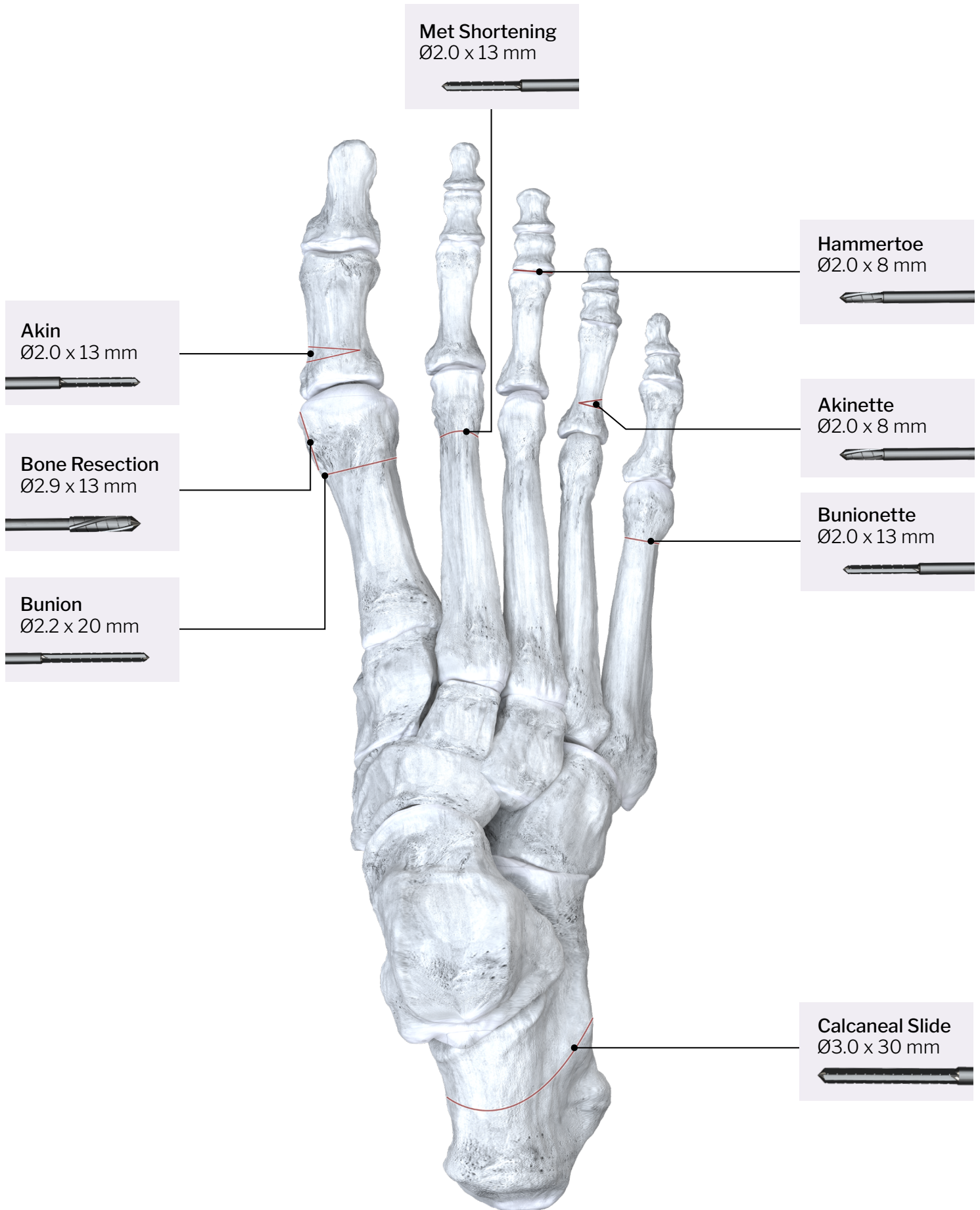
PORT IN WHITE				PORT IN BLUE		
MIS HANDPIECE				HIGH SPEED HANDPIECE		
SPEED	MIS Module	K-wire Module	Cannulated AO Module	Saw Module	K-wire Module	Cannulated AO Module
						
HIGH	10,000 RPM	1,500 RPM	1,500 RPM	20,000 RPM	3,000 RPM	3,000 RPM
MEDIUM	8,000 RPM	1,200 RPM	1,200 RPM	15,000 RPM	2,250 RPM	2,250 RPM
LOW	6,000 RPM	900 RPM	900 RPM	10,000 RPM	1,500 RPM	1,500 RPM

NOTE: Highlighted speeds represent the recommended speed for each respective handpiece and module. Bone quality or indication may require use of a different speed setting.

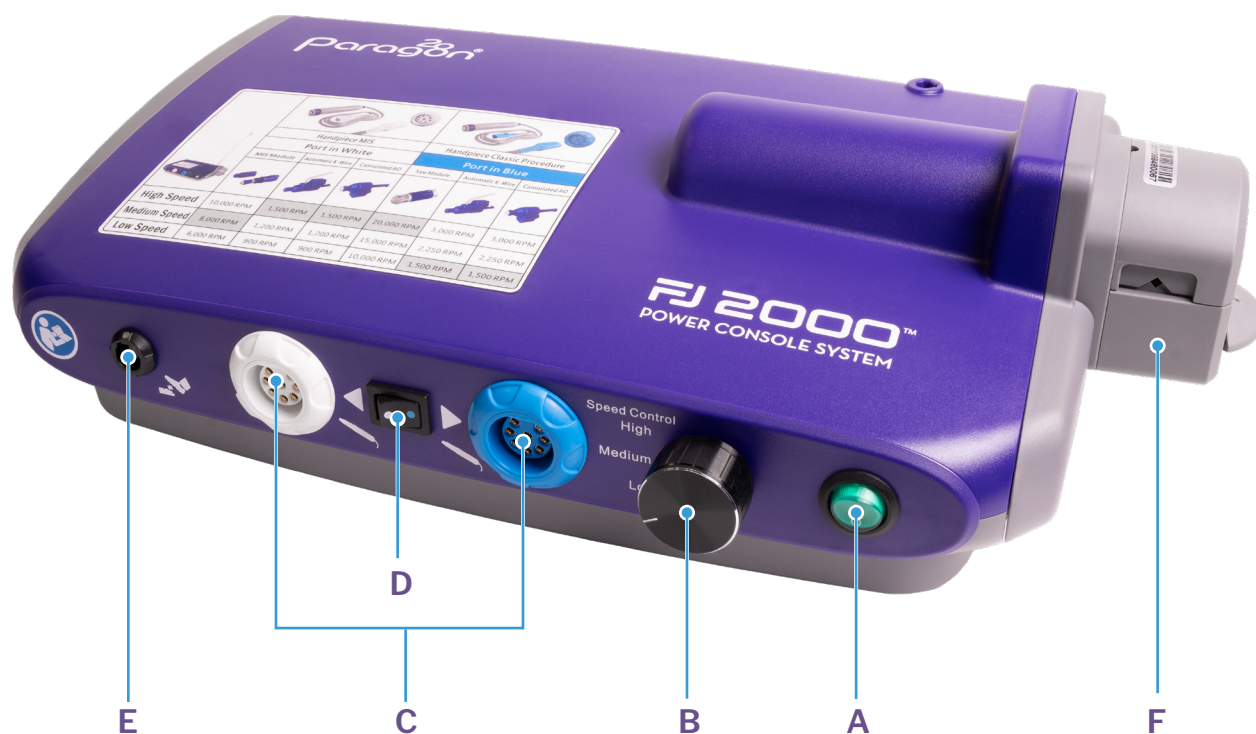
FEATURED INSTRUMENTATION

BURR	BURR STYLE	DIAMETER X CUTTING LENGTH X BURR LENGTH	INDICATION	PART NUMBER
	Corta	Ø2.0 x 8 x 65	Hammertoe Akinette	P65-106-2008-S
	Recta	Ø2.0 x 13 x 65 Ø2.0 x 20 x 65	Akin Bunionette	P65-106-2013-S P65-106-2221-S
	Corta	Ø2.0 x 20 x 65	Akin Bunion	P65-106-2021-S
	Recta	Ø2.2 x 20 x 65	Bunion	P65-106-2221-S
	Recta	Ø3.0 x 20 x 100 Ø3.0 x 30 x 82 Ø3.0 x 30 x 100	Calcaneal Osteotomy	P65-106-3020-S P65-106-3030-S P65-106-3031-S
	Wedge	Ø2.9 x 13 x 65 Ø4.3 x 13 x 65	Cheilectomy Osteophyte Bone Resection	P65-106-2913-S P65-106-4313-S
				

FEATURED INSTRUMENTATION



CONSOLE SET-UP



SYSTEM COMPONENTS

- A – ON/OFF POWER SWITCH
- B – SPEED CONTROL (LOW/MEDIUM/HIGH)
- C – HANDPIECE PORTS
- D – PORT SWITCH
- E – FOOT PEDAL PORT
- F – PUMP

CAUTION: DO NOT twist or force any plugs into outlets or their ports. Doing so could bend the pins in the cable and damage the cable and/or the console.

CONSOLE ASSEMBLY

- Open the pack and remove all the items
- Ensure Power Switch (A) is at OFF “O” position
- Plug the power cord to the back of the Console and plug into an outlet
- Plug the foot pedal to the foot pedal port (E).
- Plug the handpiece into the handpiece port (C) with the same color as the plug (white or blue)
- Turn the port switch (D) to the selected port side
- Turn ON the power console with the ON/OFF Power Switch (A)
- Choose the speed on the speed control (B) per surgeon preference

FOOT PEDAL SET-UP



SYSTEM COMPONENTS

- A – IRRIGATION ON/OFF
- B – SAFETY UNLOCK/LOCK
- C – CHANGE DIRECTION REVERSE/FORWARD
- D – FOOT HOOK
- E – PEDAL

FOOT PEDAL ASSEMBLY

- Insert the Foot Hook (D) on the back of the foot pedal
- Tighten the screw for the Foot Hook (not shown)
- Press GREEN BUTTON (B) to UNLOCK foot pedal (Green light ON)
- Press the pedal to operate handpiece
- Press PURPLE button to change motor direction.
 - Purple light ON: Reverse (counterclockwise)
 - Purple light OFF: forward (clockwise/default)
- Press BLUE Button (A) to turn ON/OFF irrigation function
 - Blue light ON: ON
 - Blue light OFF: OFF

NOTE: Press the GREEN button once to LOCK the foot pedal, preventing unintentional activation.

NOTE: Use the foot hook to reposition the foot pedal.

HAND PIECE SET-UP



MIS Handpiece



High Speed (Traditional Open) Handpiece

MIS MODULE ASSEMBLY

- Attach the MIS module to the handpiece by aligning the white lines and rotating until secure in the locked position (white line of the handpiece aligned with closed lock symbol).
- Rotate the locking collar counterclockwise to open.
- Fully insert the 2.35 mm round-shank burr into the burr adapter.
- Rotate the locking collar clockwise to secure the burr into the handpiece.
- Verify the burr is securely seated before use.



HANDPIECE ASSEMBLY

- Choose the appropriate module, twist the lock on the handpiece until secure in the open position (white line aligned with open lock symbol)
- Attach the module to handpiece by aligning the white lines
- Rotate the lock on the handpiece until secure in the closed position (white line of the handpiece aligned with closed lock symbol)
- Plug the handpiece into the appropriate port on the console and use the foot pedal to operate the handpiece



MIS IRRIGATION KIT

- Open the pump by turning it counterclockwise



- Insert the tube into the V aperture and close the pump by turning clockwise



Fluid Bag Bar



Pump

- Hang the irrigation solution to the fluid bag bar.
- Insert the spike into the irrigation solution
- Utilize the MIS Handpiece connection with irrigation and the white plug handpiece and white port on the console.
- When finished with the console, dismantle it by unplugging everything and dispose any sterile packed items that were used.

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

FLOW RATE = 85 ML/MINUTE



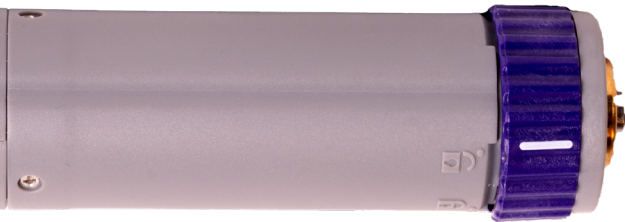
REDUCED
FLOW RATE = 50 ML/MINUTE



HIGH SPEED HANDPIECE WITH SAGITTAL SAW



- Plug the handpiece into the blue port on the console and turn the port switch to the blue side.



- Assemble the Handpiece by twisting the lock on the handpiece until secure in the open position (white line aligned with open lock symbol).
- Attach the module to handpiece by aligning the white lines.



- Rotate the lock on the handpiece until secure in the closed position (white line of the handpiece aligned with closed lock symbol).
- Insert the saw blade by loosening the saw blade locking screw counterclockwise and insert the saw blade to the desired position.
- Lock the saw blade in place by turning the key clockwise until secure. Ensure the blade is firmly tightened. To remove the blade, loosen the screw and remove.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
POWER CONSOLE HAS NO POWER	Fuse is damaged	Please contact Customer Service
	Power supply is damaged	Please contact Customer Service
	Console power cable is not properly inserted	Re-insert the cable into the console
HANDPIECE DOES NOT WORK	Power console is not powered ON	Turn ON the power
	Handpiece is not connected or poor contact with power console	Remove and reconnect the handpiece. If this does not correct the problem, please contact Customer Service
	Foot pedal is not connected or poor contact with power console	Remove and reconnect the foot pedal. If this does not correct the problem, please contact Customer Service
	Safety button on the foot pedal is in LOCK mode (Green light OFF)	Press the safety button (Green) to unlock the foot pedal.
	Port switch on the power console is not switched to the corresponding port color or the switch is damaged	Turn the port switch to the corresponding port color. If this does not correct the problem, please contact Customer Service
	PCB fault	Please contact Customer Service
HANDPIECE WORKS WITH THE FOOT PEDAL IN LOCK MODE	PCB fault	Please contact Customer Service
HANDPIECE STOPS SUDDENLY	Overload protection is activated	Wait until the handpiece has cooled down
NO IRRIGATION FLUID COMING OUT FROM THE TUBE	Tube is jammed in the pump	Open the pump and readjust the tube, make sure the tube is within the V shape aperture
	The pump is damaged	Please contact Customer Service

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
CAN NOT INSERT THE MODULE ON THE HANDPIECE	Handpiece twist lock is locked	Turn the handpiece twist lock to UNLOCK
MODULE IS LOOSE	Handpiece twist lock is locked	Turn the handpiece twist lock to UNLOCK
IRRIGATION BUTTON'S LIGHT IS ON, BUT THE PUMP DOES NOT WORK	PCB fault	Please contact Customer Service
IRRIGATION BUTTON'S LIGHT IS OFF, BUT THE PUMP WORKS	PCB fault	Please contact Customer Service
SAFETY BUTTON'S LIGHT IS ON, BUT THE HANDPIECE DOES NOT WORK	PCB fault	Please contact Customer Service
SAFETY BUTTON'S LIGHT IS OFF, BUT THE HANDPIECE WORKS	PCB fault	Please contact Customer Service
FORWARD/REVERSE BUTTON'S LIGHT IS ON, BUT THE HANDPIECE WORKS CLOCKWISE (FORWARD)	PCB fault	Please contact Customer Service

NOTES

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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Refer to www.paragon28.com/ifus for the complete
and most current instructions for use document

DISCLAIMER

The purpose of the FJ 2000™ Product Manual is to demonstrate the optionality and functionality of the FJ 2000™. Although variations in the use of the FJ 2000™ can be performed, the options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the FJ 2000™ can be employed, appropriate for the use of the device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.

Paragon 28 does not practice medicine. This product was developed in conjunction with healthcare professionals. This document is intended for healthcare professionals and is not intended for laypersons. Each healthcare professional should exercise his or her own judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training healthcare professionals have received. Results will vary based on health, weight, activity and other variables.

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