

## EMAX 2 PLUS SYSTEM

High speed performance and power in a variety of applications



USER'S MANUAL

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### ANSPACH ELECTRIC SYSTEMS

### HIGH SPEED PERFORMANCE AND POWER IN A VARIETY OF APPLICATIONS

#### **DePuy Synthes Power Tools**

DePuy Synthes Power Tools manufactures pneumatic and electric high speed performance instruments and attachments to meet the specific needs of both surgeon and staff. While the advanced design of these instruments provides performance and reliability, they also allow for effortless assembly, meeting the needs of both surgeon and staff for the most demanding applications. No tools are required to assemble dissection tools or attachments.

All *DePuy Synthes Power Tools* instruments are manufactured to conform to rigorous quality standards to provide dependable performance.

Warning: Before using any of the Anspach High Speed Electric Systems, it is imperative that all individuals working with the system read this operating manual. The surgeon is responsible for learning the proper techniques in the use of this system, as improper use may cause injury.

To schedule a hands-on training course, either at *DePuy Synthes Power Tools* or from your local *DePuy Synthes Power Tools* Sales Representative, call (800) 327-6887 or (561) 627-1080.

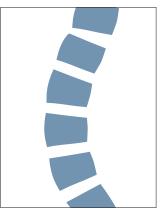
If you have any questions after reading this manual, please call the *DePuy Synthes Power Tools* Customer Service Department at (800) 327-6887 or (561) 627-1080.

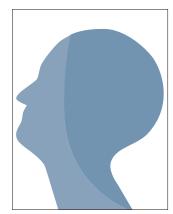


eMax 2 Plus

#### **High Speed Electric Systems**

The eMax 2 Plus operates up to 80,000 rpm. It offers variable speed, bi-directional operation, minimal noise levels, and an optional hand control. It is a high performance system that highlights minimal vibration performance, thermal energy management, and high reliability for Neurosurgeons, Otologist, Neurotologists, Skull Base Surgeons, and Spinal Surgeons.





Spine surgery

Neurosurgery and Otologic surgery

### INDICATIONS

The Anspach eMax 2 Plus High Speed Electric System is intended for cutting and shaping bone including spine and cranium.

The Anspach eMax 2 Plus High Speed Electric System is composed of the EMAX2PLUS Handpiece model; Electric Consoles models SC2100, SC2101, and SC2102; Foot Control models E-FP, E-FP-DIR, E-FP-DIR/IRR, EPLUS-FP, EPLUS-FP-NS; Hand Controls EMAX2-HC and E-HC.

### WARNINGS AND CAUTIONS

#### Warnings

#### Irrigation is necessary for proper operation.

Surgeon is responsible for learning proper techniques in use of equipment; improper use may cause serious injury to user or patient or damage to system.

Instrument operator and all operating room personnel must wear eye protection.

Visually inspect for damage before using; do not use if damage is evident.

Do not use if the product sterilization barrier or its packaging is compromised.

Do not use, or discontinue use of powered equipment exhibiting excessive temperatures that can cause patient injury (necrosis) and/or user discomfort.

Use of damaged or improperly maintained power equipment and/or misused powered equipment can result in excessive temperatures.

Use caution to avoid cutting or tearing gloves while handling dissection tools.

Dissection tools must be adequately retained within attachment to prevent distal migration, which may cause injury.

Confirm attachment is proper size for dissection tool and that it is secure.

Gently pull on dissection tool shaft to ensure it is fully seated and properly installed.

Only cut visible areas unless an image intensifier is utilized.

Delicate structures in proximity to dissection must be thoroughly protected to prevent injury.

Maintain firm control of instrument at all times.

Do not bend or use as a lever.

Use a gentle tapping motion or side-to-side motion and let instrument do cutting.

Do not use excessive force.

Forceful side loading of dissection tool may cause fracture of dissection tool, which may cause injury.

Dissection tools are disposable and intended for single patient use only. Do not resterilize and/or reuse dissection tools.

Use standard protocol for disposal of sharp instruments.

Continuous extreme cutting at or near stalling conditions will quickly overheat handpiece.

Do not operate in an explosive flammable environment.

Do not modify ground or power cord.

Do not allow liquid into console.

Portable and Mobile RF communications equipment can affect Medical Electrical Equipment.

Use of accessories or cable other than those provided by *DePuy Synthes Power Tools*, and specified for the electric system in use, may result in increased emissions or decreased immunity.

Do not use in oxygen rich environment.

Do not modify. Modifications could result is loss of electrical safety.

Dispose of items contaminated with body fluids with other biohazardous waste.

At end of life, recycle or dispose of device in accordance with local and national regulations. Irrigation Tubes contain DEHP a type of phthalate.

No modification of this equipment is allowed

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

#### Cautions

United States Federal law restricts this device to sale by or on order of a physician or other licensed healthcare provider.

Do not use accessories other than those provided by *DePuy Synthes Power Tools* and specified for use with Anspach systems.

Use care to protect hose when handling, cleaning, and during system use.

Damage to hose can cause leaking, rupture, or other related failures.

Do not step on, set equipment on, pinch, kink, clamp, or otherwise occlude handpiece hose during use.

To ensure equipment operates as designed, read and follow manufacturer's instructions.

Do not operate handpiece without an attachment and the corresponding dissection tool.

Do not engage safety mechanism while handpiece is running; doing so makes safety mechanism inoperable.

### TECHNICAL SPECIFICATIONS

#### eMax 2 Plus Handpiece Specifications

Speed:10,000-80,000 rpmHandpiece/hose Length:3.81 m (12.5 ft)Outside housing (diameter):18.8 mm (.74 in)Length of housing:127 mm (5 in)Handpiece weight:104 g (3.7 oz)Handpiece Hose Weight:0.59 kg (1.29 lbs)

#### Console (SC2000, SC2100, SC2101, SC2102) Specifications

Electrical:	
Primary:	100-240VAC, 50/60 Hz, 250 VA
Class I:	Protective Earth
Fluid Ingress Protection:	IPXO
Туре В:	Applied Part
	Continuous Operation
Mechanical:	
Size:	31.115 cm x 14.6 cm x 32.7 cm
	(12.25 in x 5.74 in x 12.87 in)
Weight:	6.25 kg (13.77 lbs)

The device complies with the following standards: IEC 60601-1:2005: + CORR. 1 (2006) + CORR. 2 (2007), EN 60601-1:2006 +A11:2011, ANSI/AAMI ES60601-1:2005, CAN/CSA-C22.2 No.60601-1:08, (3rd Edition) Medical electrical part 1: General requirements for basic safety and essential performance.

# ETL CLASSIFIED

With regard to electrical shock, fire, mechanical hazards, this ETL classified device conforms to AAMI STD ES60601-1 and is certified to CSA STD C22.2 No.60601-1

This device complies with applicable EEC directives.



#### Foot Pedal (E-FP, E-FP-DIR, E-FP-DIR/IRR) Specifications

Size: Weight: Cord: Fluid Ingress Protection: 26.7 cm x 16.5 cm x 14.7 cm (10.5 in x 6.5 in x 8.5 in) 2.0 kg (4.41 lbs) 3.66 m (12 ft) in length IPX8

#### **Environmental Conditions**

Temperature Operating: Transportation and Storage:	18°-30°C (65°-85°F) -40°-70°C (-40°–158°F)
Relative Humidity Operating: Transportation and Storage:	30-70% 10-95%
Atmospheric Pressure Operating: Transportation and Storage:	70-106 kpa, 0.7-1.06bar Not applicable

#### **Patent Information**

For patent information go to: www.DePuy.com/patentmarking

#### **Additional Information**

To isolate the device from the mains supply, remove the power cord. All specifications are subject to change.

#### Table 1: Emission

The Anspach eMax 2 Plus High Speed Electric System is composed of the eMax 2 Plus Handpiece model; Electric Consoles models SC2100, SC2101, and SC2102; Foot Control models E-FP, E-FP-DIR, E-FP-DIR/IRR, EPLUS-FP, EPLUS-FP-NS; Hand Controls EMAX2-HC and E-HC.

#### Guidance and manufacturer's declaration—electromagnetic emissions

The Anspach High Speed Electric System is intended for use in the electromagnetic environment specified below. The customer or the user of the Anspach High Speed Electric System should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment—guidance
RF emissions	Group 1	The Anspach High Speed Electric System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely
CISPR 11		to cause any interference in nearby electronic equipment.RF emissions.
RF emissions	Class A	The Anspach High Speed Electric System is suitable for use in all establishments, other than domestic establishments and those directly
CISPR 1		connected to the public low-voltage power supply network that supplies
Harmonic emissions	Class A	buildings used for domestic purposes.
IEC 61000-3-2		
Voltage fluctuations/ flicker emissions	Complies	
IEC 61000-3-3		

### Table 2: Immunity (all devices)

#### Guidance and manufacturer's declaration-electromagnetic immunity

The Anspach High Speed Electric System is intended for use in the electromagnetic environment specified below. The customer or the user of the Anspach High Speed Electric System should assure that it is used in such an environment.

Immunity test standardU <sub>T</sub> (25 cycles)	IEC 60601 test level	Compliance level	Electromagnetic environment— guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the
IEC 61000-4-2	±8 kV air	±8 kV air	relative humidity should be at least 30%.
Electrical fast transient/burst	±2 kV for power supply lines ±1 kV for	±2 kV for power supply lines ±1 kV for	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4	input/output lines	input/output lines	
Surge	$\pm 1$ kV line to line	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	±2 kV line to earth	±2 kV line to earth	
Voltage dips, short interruptions and	<5% U <sub>T</sub> (0,5 cycle)	<5% U <sub>T</sub> (0,5 cycle)	Mains power quality should be that of a typical commercial or hospital environment.
voltage variations on power supply lines	40% U <sub>T</sub> (5 cycles)	40% U <sub>T</sub> (5 cycles)	· ·
	70% U <sub>T</sub> (25 cycles)	70%	
IEC 61000-4-11	<5% U <sub>T</sub> for 5s		

#### Note: $\boldsymbol{U}_{T}$ is the a.c. mains voltage prior to application of the test level.

Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			

#### Table 3: Immunity (not life-supporting devices)

#### Guidance and manufacturer's declaration—electromagnetic immunity

The Anspach High Speed Electric System is intended for use in the electromagnetic environment specified below. The customer or the user of the Anspach High Speed Electric System should assure that it is used in such an environment.

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment— guidance
Conducted RF	3 Vrms	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Anspach High Speed Electric
IEC 61000-4-6	150 kHz to 80 MHz		System, including cables, than the recommended separation distance calculated from the equation applicable to the
Radiated RF	3 V/m	3 V/m	frequency of the transmitter.
IEC 61000-4-3	80 MHz to 2.5 GHz		Recommended separation distance
			$d = 1.2 \sqrt{P}$
			$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
			d = 2.3 $\sqrt{P}$ 800 MHz to 2.7 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>2</sup> a should be less than the compliance level in each frequency range. <sup>b</sup>
			Interference may occur in the vicinity of equipment marked with the following symbol: (

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Anspach High Speed Electric System is used exceeds the applicable RF compliance level above, the Anspach High Speed Electric System, or the device which contains it, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device containing the Anspach High Speed Electric System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

#### Table 4: Recommended separation distances (not life-supporting devices)

### Recommended separation distances between portable and mobile RF communications equipment and the Anspach High Speed Electric System

The Anspach High Speed Electric System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Anspach High Speed Electric System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Anspach High Speed Electric System as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output	Separation distance according to frequency of transmitter					
power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz			
W	d = 1.2 √P	d = 1.2 √P	d = 2.3 √P			
0.01	12 cm	12 cm	23 cm			
0.1	38 cm	38 cm	73 cm			
1	1.2 m	1.2 m	2.3 m			
10	3.8 m	3.8 m	7.3 m			
100	12 m	12 m	23 m			

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

### GLOSSARY OF SYMBOLS

30 Sec ON/ 30 Sec OFF	Duty Cycle of the e12 system and DRIVER	$\diamond$	Located on the Foot Pedal switch this indicates a change state (on/off) for the Console Irrigation System
X	Company Logo		
$\rightarrow$	Direction of rotation	G	Located on the Foot Pedal switch this indicates a change of rotational direction for the Handpiece
$\longrightarrow \hat{\blacksquare}$	Direction of rotation for lock position		Located on the Handpiece this indicates
∢	Indicates setting, position, or location		position of the knurl knob to the desired location
>	Indicates setting, position, or location		Symbol with yellow background: CAUTION:
CUTTER-	Indicates the drill tip exposure		Refer to accompanying documentation
ADJUST-		$\sim$	AC Power Source
3мм <b>&gt;</b> 4мм <b>&gt;</b>	Indicates the attachment setting, refer to MA-D20 and MA-DRIVER section in this	ī	Consult Operating Instructions
5мм> 6мм>	DMM>		Located on the Console this indicates Motor or Handpiece unit
	Indicates position or location		Located on the Console this indicates
	Indicates position or location	$\mathbf{V}$	Foot Control activation
SECURE	Indicates action of rotation and position for Secure (LOCK) and Release (UNLOCK)	c <sup>m</sup>	Located on the Console this indicates Hand Control activation
44	Direction of rotation	F	Located on the Console this indicates Forward (Clockwise rotation when looking at Handpiece from proximal end)
	Direction of rotation for lock position	Ŕ	Located on the Console this indicates Reverse (Counterclockwise rotation when
$\leftrightarrow$	Direction of rotation		looking at Handpiece from proximal end)
1	Located on the Foot Pedal switch this	RPM	Revolution per Minute
	indicates a change of rotational direction for the Handpiece		Located on the Console this indicates a change state (on/off) for the Console
Located on the Foot Pedal switch this indicates a change state (on/off) for the Console Irrigation System			Irrigation System
		Located on the Console this indicates a change of irrigation rate for the Console Irrigation System	

	Located on the Console this indicates a change of rotational speed rate for	Ĵ	Keep Dry (A.K.A. Protect from Moisture)
	the Handpiece	8	Sterile unless damaged or open
	Temperature Limits	RONLY	United States Federal law restricts this device to sale by or on the order of a physician or
$\bigtriangledown$	Equipotential post location	X	other licensed health-care provider
	Found on the Console ON/OFF	CE	CE Mark (A.K.A. CE Mark [notified body number], Conformité Européenne)
	Located on the Console Irrigation Pump this indicates a possible finger pinch point		Meaning: Device complies with applicable EEC Directives
•	Located on the Concele Irrigation		Lock (Run)
1.6	Located on the Console Irrigation Pump these symbols are not used by the user since the pump		Unlock (Load)
<b>0.5</b>	is self adjusting to the Irrigation Tube diameter	(((•)))	Transmitter
<b>32</b> 4.8 <b>4.9</b> 6.4 <b>6.4</b> 80 8.0			Interference may occur in the vicinity of equipment marked with this symbol.
REF	Reference Number (A.K.A. Item Number, Catalog Number, Part Number)	Ŕ	Type B Electrical Equipment
LOT	Lot (A.K.A. Lot Number, Batch Number, Batch Code)	S VOID 2 S VOID 2 S ROMEN	Product warranty is void if seal is damaged or removed.
SN	Serial Number	X	DO NOT DISPOSE OF IN HOUSEHOLD WASTE
00/0000	Use By Date (A.K.A. Expiration Date, Expiry)	<b>Instrument Sy</b> <b>EM</b> eMax 2 P	
	Manufacturer		
ECREP	Authorized European Union Representative	Latex-free Cer Products not m	<b>tification</b> ade with natural rubber latex.
STERILE R	Sterilized Using Irradiation		
2	Single Use Only (A.K.A. Do Not Reuse)		
$\triangle$	CAUTION: Refer to accompanying documentation		
PHT DEHP	CONTAINS or PRESENCE of PHTHALATES		

### EMAX 2 PLUS OPERATING INSTRUCTIONS

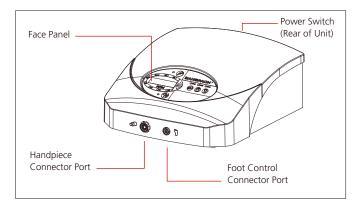
The system console houses the electrical components that provide power, control, and cooling functions to the eMax 2 Plus handpiece. It provides the user control for all system functions via an integral touch pad face panel. The system console has connections for the eMax 2 Plus handpiece, foot controls, AC power inlet and the main power switch.

The eMax 2 Plus High Speed Handpiece operates continuously at speeds up to 80,000 rpm.

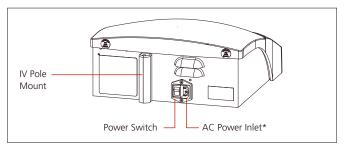
		Consoles			Control tues	На Сог	nd ntrols	
		SC2100	SC2101	SC2102	Active Direction Control Switch	Active Irrigation Control Switch	EMAX2-HC	E-HC
	E-FP	•	•	•				
slo	E-FP-DIR	•	•	•	•			
Foot Controls	E-FP-DIR/IRR	•	•	•	•	•		
Foot	EPLUS-FP	•	•	•	•	•		
	EPLUS-FP-NS	•	•	•				
Handpieces	EMAX2PLUS							
ures	Two Foot Control Ports*	•						
Console Features	Two Handpiece Ports*	•						
Cons	Console Irrigation	•	•					

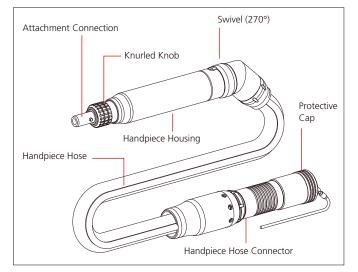
\* If two foot controls or two handpieces are connected upon startup of console it will default to Foot Control 1 and/or Handpiece 1.

\*\* "Port" LED on console face panel does not illuminate when this accessory is connected to console.



#### **Back of System Console**





#### Note: The hose length shown above is shorter than the actual length for easier viewing. Hose length is approximately 12 feet.

• Power cord provides means to disconnect from the mains.

 Position equipment in such a manner that provides access to the rear of the system in order to disconnect from mains.

#### System Assembly

- 1. Plug the hospital grade AC power cord into the AC power inlet on the back of the console. Plug the opposite end of the power cord into a standard, hospital grade grounded wall outlet. Connect to supply mains with protective earth only.
- Insert foot control cord connector into Foot Control 1 connector port. (A second foot control cord may be connected into Foot Control 2 connector port on applicable consoles.) Foot control cord connector is keyed. Align foot control cord connector with port on front of console. Do not push foot control cord connector into console connector port when out of alignment.
- 3. Plug handpiece hose connector into Handpiece 1 connector port located on front of console. (A second handpiece could be connected into Handpiece 2 connector port on applicable consoles.) Handpiece hose connector is keyed. Align handpiece hose connector with connector port on front of console. Do not push handpiece hose connector into console connector port when out of alignment.
- 4. Activate console by depressing power switch located on the back of the console to the "I" position. Appropriate Face Panel Light Emitting Diodes (LED) illuminate, and a beep sounds.
- 5. For operating instructions see Console Face Panel Operation and Foot Control Operation below.

#### Note: Handpiece is fully functional at this time.

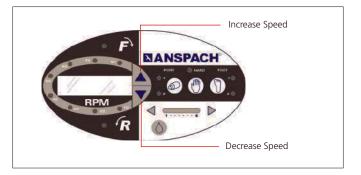
Warning: Before first use clean and sterilize as indicated.

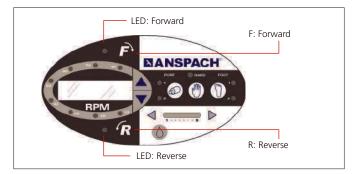
#### **Operating Instructions**

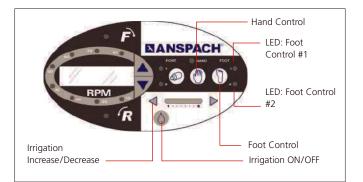
Upon startup, console is set to operate handpiece in forward (clockwise when viewed from the proximal end of the Handpiece) direction at maximum speed and display reads 80,000 RPM. System operation, including optional irrigation, can be controlled from console face panel. On applicable consoles LED's on face panel correspond to connector ports on connector panel. System operation can also be controlled by several available foot control options and an optional hand control.

#### **Console Face Panel Operation**

- 1. To increase or decrease speed of handpiece, depress blue arrows located on console face panel. Speed increases and decreases in 10,000 RPM increments. Each LED will indicate the max RPM:
  - 10 = 10,000 RPM
  - 20 = 20,000 RPM
  - 30 = 30,000 RPM
  - 40 = 40,000 RPM
  - 50 = 50,000 RPM
  - 60 = 60,000 RPM
  - 70 = 70,000 RPM
  - 80 = 80,000 RPM
- 2. To change direction, depress "R" or "F" arrow located on console face panel. Console beeps once, indicating handpiece direction has changed. Direction can only be changed when handpiece is not running. A series of three beeps indicates console is set to operate handpiece in reverse/counterclockwise direction. LED on console face panel located to left of "F" indicates forward direction. LED located to left of "R" indicates reverse direction.
- 3. Optional: To activate irrigation, depress "Irrigation" button on face panel. LED illuminates. To control flow of irrigation, depress arrows located to right of irrigation button on face panel.







Note: Depressing simultaneously the Irrigation Increase and Decrease buttons will display the Console Software version as a two digit number.

For example: XY this to be interpreted as Software Version X.Y.

On Consoles with no Irrigation (SC2102) the buttons are not marked but are located in the same location which are detectable by feel.

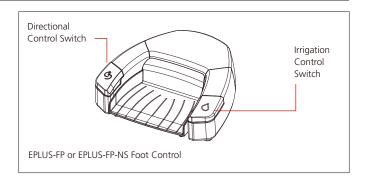
#### **Foot Control Operation**

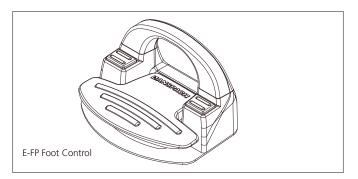
Certain optional foot controls have direction and irrigation control switches.

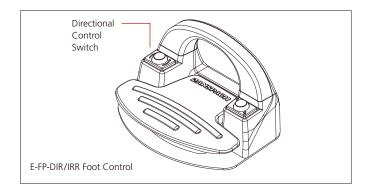
- 1. See Step 2 of Console Face Panel Operation to set operational direction of handpiece.
- 2. Optional: Depress "Foot" button on face panel to activate Foot Control 1, depress again to activate Foot Control 2. Only one foot control may be active at a time.

#### Note: Handpiece is fully functional at this time.

- 3. Press on foot control pedal to start handpiece. Increase pressure on pedal to increase speed of handpiece and release pressure on pedal to decrease speed of handpiece.
- 4. Optional: To change direction of handpiece, depress Directional Control Switch located on top left of foot control for a minimum of one second. When direction changes, a single beep will sound and LED on console face panel indicates direction of rotation. Direction can only be changed when handpiece is not running.
- 5. Optional: To activate irrigation, depress Irrigation Control Switch on top right of foot control for a minimum of one second and then step on center of foot control pedal. Upon activation, LED on face panel illuminates; irrigation pump and handpiece start.







#### Hand Control Assembly and Operation

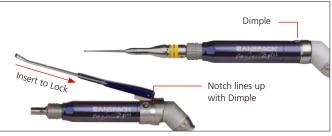
Optional hand control attachment for handpiece allows user to control operation with a lever attached to handpiece.

#### Warnings:

- Do not expose handpiece to magnets (such as laying handpiece on magnetic drapes) when in hand control mode, as handpiece operation may occur.
- It is recommended that a craniotome not be used in conjunction with Hand Control. Excessive rotational force on hand control may move it resulting in handpiece shutting down.
- 1. Upon console start-up Hand Control is OFF. LED is not illuminated.
- 2. Rotate handpiece until small dimple at proximal end (hose end) of handpiece faces up. Slide hand control over distal end of handpiece such that notch on hand control slides over dimple at proximal end (hose end) of handpiece. Slide Hand Control onto handpiece until secure.
- 3. To activate Hand Control, depress "Hand" button on console face panel. This deactivates Foot Control; Hand Control LED on face panel illuminates.
- 4. To prevent inadvertent operation, ensure silver lever on Hand Control is fully inserted in "Lock" position.
- 5. Extend silver lever from "Lock" position for operation.
- 6. Apply pressure on Hand Control to operate handpiece.

#### Note: Handpiece is fully functional at this time.

7. To deactivate Hand Control, depress "Foot" button on console face panel. To remove hand control from handpiece, slide towards distal end of handpiece and remove.



eMax 2-HC

### Optional Irrigation Assembly and Operation (Excludes SC2102)

- 1. Upon start-up Irrigation is OFF. LED is not illuminated.
- 2. Depress the button located on the right side of the console to eject pump head.
- 3. Insert IV pole into bracket on back of console.
- 4. Hang irrigation bag onto IV Pole.
- 5. To activate, depress the "Irrigation" button on the face panel. LED illuminates.
- 6. To control flow of irrigation, depress arrows located to right of irrigation button on face panel.
- 7. Irrigation can also be activated from certain optional Foot Controls (see Step 5 of Foot Control Operation). Depress Irrigation Control Switch on top right of the foot control. Upon activation, LED on face panel illuminates.

#### **Irrigation Tubing Set-up**

IRRIGATE-TUBE	Sterile Tubing and Hoseclips
	for Irrigation System
IRRIGATE-TUBE-HF	Sterile High Flow Tubing and
	Hoseclips for Irrigation System

#### Warning: These products may contain DEHP, a type of phthalate. DO NOT use product on children or pregnant or nursing mothers.

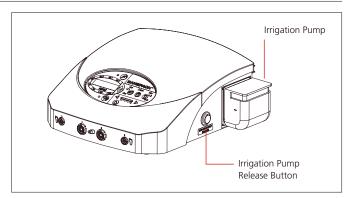
- 1. Lift top of pump head and insert large diameter tubing. Refer to diagram on irrigation pump housing to ensure tubing is routed properly (smaller diameter tubing flows towards the Anspach handpiece housing).
- 2. Close lid on pump head.
- 3. Insert bayonet end of tubing into irrigation bag.

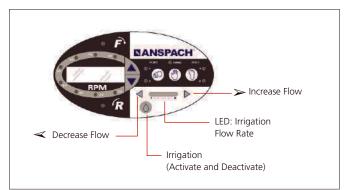
Caution: Tubing can disconnect from connectors without warning if occluded. DO NOT step on, set equipment on, pinch, kink, clamp, or otherwise occlude tubing during use.

#### **Irrigation Attachment Clip Assembly**

Refer to "Components" section for part numbers.

- 1. Slide irrigation tubing onto proximal end of irrigation attachment clip.
- 2. Attach irrigation attachment clip to handpiece.
- 3. Secure tubing to handpiece hose using Hoseclips, which are included with tubing.





#### System Shutdown

- 1. There are no special procedures for system shutdown.
- 2. To disconnect power cord from mains, grasp ridged portion of connector between thumb and forefinger of one hand. Gently pull the connector away from the console. The connector should remove easily. If not, ensure only the ridged portion of the connector is pulled. Do not pull on the smooth part of the connector, as the connector will not disengage from the console.

#### Cautions:

- Do not sterilize, and do not allow liquid into pump.
- Do not operate with pump head open.

#### Warnings:

- Irrigation tubing, attachment clip, and hose clip are for SINGLE USE ONLY.
- Avoid stacking or placing the eMax 2 Plus System consoles near other electrical equipment. If the eMax 2 Plus System consoles must be stacked or used adjacent to other electrical equipment, it should be observed to verify normal operation prior to use
- The eMax 2 Plus System is Medical Electrical. Equipment, requiring special precautions related to EMC, and for this reason must be put into service as described in this product manual.
- Firm control of the eMax 2 Plus must be maintained at all times. Never force the dissection tool. Let the instrument do the cutting.
- Only Anspach cutting burrs should be used with the eMax 2 Plus.
- Always use continuous irrigation to prevent heat build-up. Never use the attachments as a retractor to bend or pry.
- Power source should comply with applicable IEC, CEC, and NEC requirements. Grounding reliability can only be achieved when this equipment is connected to a receptacle marked "HOSPITAL GRADE."

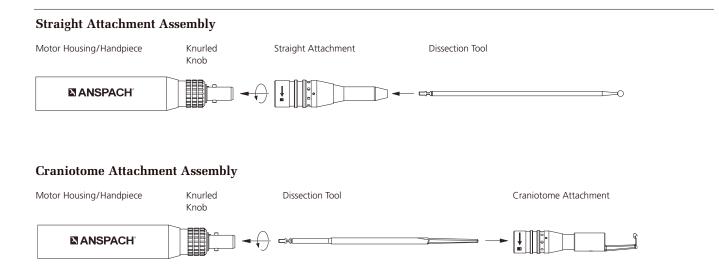
Note: If fuse replacement is necessary, use only Time Delay fuse rated 2.5A, 250V. Item to be replaced by a *DePuy Synthes Power Tools* repair facility ONLY.

### **Console Indicators**

Code	Description	Audible Signal*	Corrective Action
E1, E8	System Fault	None	Turn Power switch to off, and then back on. If fault does not clear, return console and handpiece to <i>DePuy Synthes Power Tools</i> for service.
E2	Handpiece Lock Engaged	10 slow beeps	Rotate the knurled knob on handpiece clockwise to ensure the handpiece is not locked.
E3	Handpiece Stall Warning	10 fast beeps	Remove pressure from foot control (or hand control), remove cutter from stalled location and restart handpiece.
E4, E5	Fault in Handpiece	None	Return console and handpiece to <i>DePuy Synthes Power Tools</i> for service.
E6, E7	Handpiece overheat warning, impending handpiece shutdown	5 second beep	Reduce or remove load from handpiece to allow handpiece to cool. If load is not reduced sufficiently, handpiece will shut down 30 seconds after tone is heard and/or code is displayed.
E9	Handpiece type not recognized	None	Disconnect connector and reconnect to console. If fault does not clear, return handpiece and console to <i>DePuy Synthes Power Tools</i> for service.
None	Handpiece set to reverse	3 beeps	

\* Note: Consoles with Software Version 3.0 and higher do not generate an Audible Signal for Codes E1-E9.

### STANDARD ATTACHMENTS AND DISSECTION TOOL ASSEMBLY



#### **Dissection Tool Identification**

All dissection tools are packaged sterile, unless otherwise indicated, and are manufactured for single use. Each dissection tool has a series of identification numbers and letters imprinted on the label and on the shaft. The first letter describes the type of attachment, and the following characters indicate the size and style of the dissection tool. An example follows:

#### Dissection Tool Part Number: S-2B

**Dissection Tool Description:** 2 mm Fluted Ball for Short attachment

Note: Each attachment is laser-marked with its corresponding part number.

#### Straight Attachments

SHORT	5 cm Short Attachment
MEDIUM	8 cm Medium Attachment
LONG	11 cm Long Attachment
MIA16	16 cm Minimally Invasive Attachment
SHORT-HD	5 cm Heavy Duty Short Attachment
MEDIUM-HD	8 cm Heavy Duty Medium Attachment
LONG-HD	12.4 cm Heavy Duty Long Attachment
XL-HD	20.2 cm Heavy Duty Extra Long Attachment

### Note: Instructions are written such that distal end of handpiece and attachment are pointed away from user.

The arrows, symbols, and printing on the distal end of the handpiece housing ("RUN" ( $\square$ ), "LOAD" ( $\_$ ) and "SAFE") refer to locking and unlocking the attachment and dissection tool onto the handpiece.

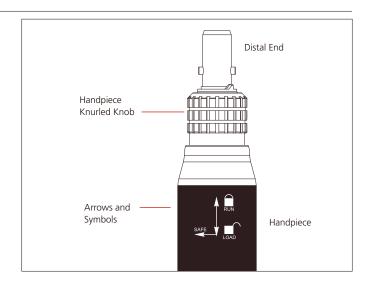
- 1. Move handpiece knurled knob to "RUN" ( $\square$ ) position.
- Slide attachment over distal end of handpiece. Pull attachment towards handpiece, and rotate attachment to right approximately one-quarter turn until fully seated. Handpiece knurled knob moves up to seat next to attachment.
- Pull handpiece knurled knob towards "LOAD" ( ) position and insert dissection tool into distal end of attachment. Rotate dissection tool slowly until fully seated.
- 4. Release handpiece knurled knob into "RUN" ( $\square$ ) position.

#### Note: Handpiece is now fully functional.

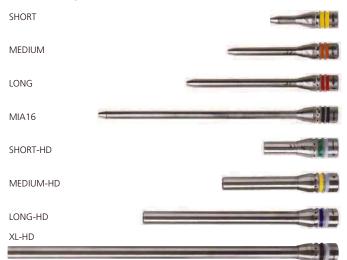
- 5. Pull dissection tool to ensure proper engagement.
- 6. Attachment and dissection tool are secure.

#### Disassembly

- 1. Move handpiece knurled knob to "SAFE" position.
- 2. Remove dissection tool from distal end of attachment.
- 3. Rotate attachment to left approximately one-quarter turn, and remove from distal end of handpiece.



#### eMax Straight Attachments



#### Orange 45° or 90° Contra Angle Attachments

ORANGE-45	45° Contra Angle Attachment
ORANGE-90	90° Right Angle Attachment

### Note: Instructions are written such that distal end of handpiece and attachment are pointed away from user.

- 1. Ensure knurled knob on handpiece is in "RUN"( ■) position.
- 2. Slide attachment over distal end of handpiece. Push attachment towards handpiece, and rotate attachment clockwise until fully seated. Handpiece knurled knob moves up to seat next to attachment.
- 3. Push latch on the distal end of the attachment up with your thumb.
- Insert dissection tool into the side of the distal end (opposite side of latch) while rotating slowly until dissection tool seats.
- 5. Release latch and check security of attachment by pulling it away from handpiece and check dissection tool by pulling on dissection tool head. Latch will be flush with attachment when dissection tool is secure.

#### Note: Handpiece is now fully functional.

#### Disassembly

- 1. Lift latch on the distal end of the attachment with your thumb. Remove dissection tool and release latch.
- 2. Move handpiece knurled knob to "SAFE" position.
- 3. Rotate attachment counterclockwise and remove from distal end of handpiece.



ORANGE-90



#### **Craniotome and Specialty Attachments**

CRANI-P	6.5 cm Pediatric Craniotome
CRANI-A	6.5 cm Adult Craniotome
CRANI-L	7.5 cm Large Craniotome
CRANI-A-R	6.5 cm Rotating Adult Craniotome
ADG	7.2 cm Adjustable Drill Guide
CDA	6.8 cm Controlled Depth Attachment

#### Warning: It is recommended that a craniotome not be used in conjunction with Hand Control. Excessive rotational force on hand control may move it resulting in handpiece shutting down.

### Note: Instructions are written such that distal end of handpiece and attachment are pointed away from user.

- 1. Pull handpiece knurled knob towards "LOAD" (■<sup>¬</sup>) position and insert dissection tool into distal end of handpiece. Rotate dissection tool slowly until dissection tool is fully seated.
- 2. Release handpiece knurled knob into "RUN" (  $\bigcirc$  ) position.

#### Note: Handpiece is now fully functional.

- 3. Pull dissection tool to ensure proper engagement.
- 4. Slide attachment over distal end of handpiece. Pull attachment towards handpiece, and rotate attachment to right approximately one-quarter turn until fully seated. Handpiece knurled knob moves up to seat next to attachment.
- 5. Attachment and dissection tool are secure.

#### Disassembly

- 1. Move handpiece knurled knob to "SAFE" position.
- 2. Rotate attachment to left approximately one-quarter turn, and remove from distal end of handpiece.
- 3. Remove dissection tool from distal end of attachment.



#### **QD** Angle Attachments

- QD8 8 cm Quick Disconnect Angle Attachment
- QD11 11 cm Quick Disconnect Angle Attachment
- QD14 14 cm Quick Disconnect Angle Attachment

### Note: Instructions are written such that distal end of handpiece and attachment are pointed away from user.

- 1. Move handpiece knurled knob to "RUN" ( ) position.
- 2. Slide attachment over distal end of handpiece. Pull attachment towards handpiece, and rotate attachment to right approximately one-quarter turn until fully seated. Handpiece knurled knob moves up to seat next to attachment.
- 3. Pull retaining sleeve on angle attachment towards handpiece and rotate to left to the "RELEASE" position.
- 4. Insert dissection tool into angle attachment. Rotate dissection tool slowly until it is fully seated. Release retaining sleeve on angle attachment by rotating retaining sleeve to right to the "SECURE" position.

#### Note: Handpiece is now fully functional.

- 5. Pull dissection tool to ensure proper engagement.
- 6. Attachment and dissection tool are secure.

#### Disassembly

- 1. Pull retaining sleeve on angle attachment towards handpiece and rotate to left.
- 2. Remove dissection tool from distal end of attachment.
- 3. Move handpiece knurled knob to "SAFE" position.
- 4. Rotate attachment to left approximately one-quarter turn, and remove from distal end of handpiece.



### MINIMAL ACCESS ATTACHMENT AND DISSECTION TOOL ASSEMBLY

Note: Instructions are the same for straight or angled drivers and for straight or curved bearing sleeves in both 10 cm, 15 cm, and 19 cm lengths. The four words labeled on the drivers mean the following:

CUTTER –	Insert or remove dissection tool.
RUN –	Attachment and dissection tool are
	now functional.
ADJUST –	Bearing Sleeve can be moved 3 mm
	forward or back.
TUBE –	Insert or remove bearing sleeve.



Warning: The Minimal Access Attachments are to be used only for bone dissection applications. Excessive force or side loads during use can cause rapid temperature increase at the distal end of the attachment. Always use copious irrigation with this attachment.

#### **Driver Installation**

MA-D20 20° Angle Driver MA-DRIVER Minimal Access Straight Driver

### Note: Instructions are written such that distal end of handpiece and attachment are pointed away from user.

- 1. Ensure handpiece knurled knob is in "Run" () position.
- 2. Insert drive shaft of driver into distal end of handpiece, push and rotate to right until it stops. Listen for a click as handpiece knurled knob moves up to seat next to driver.
- 3. Gently twist back and forth to ensure driver is locked into position.

#### Bearing Sleeve and Dissection Tool Assembly (20° Angle Driver or Straight Driver)

MA-10S	Bearing Sleeve, 10 cm Straight
MA-10C	Bearing Sleeve, 10 cm Curved
MA-15S	Bearing Sleeve, 15 cm Straight
MA-15C	Bearing Sleeve, 15 cm Curved
MA-15ST	Bearing Sleeve, 15 cm Straight Taper
MA-19ST	Bearing Sleeve, 19 cm Straight Taper

- 1. Rotate knurled knob on driver to line up arrow with "TUBE."
- Fully insert desired bearing sleeve into distal end of driver by lining up black line on bearing sleeve with black line on driver.
- 3. Rotate knurled knob to line up arrow with "CUTTER." Check security of bearing sleeve by pulling distally.
- 4. Insert dissection tool into distal tip of bearing sleeve. Rotate dissection tool slowly until it is fully seated. Rotate knurled knob on driver to line arrow with "RUN."

### Note: Additional force is required to seat dissection tool into curved bearing sleeve.

- 5. Check security of dissection tool by pulling distally on dissection tool head.
- 6. Bearing sleeve and dissection tool are secure.

#### **Dissection Tool Disassembly**

1. Rotate knurled knob on driver to line up arrow with "CUTTER." Remove dissection tool from distal end of attachment.

#### **Bearing Sleeve Adjustment**

- 1. Rotate knurled knob on driver to line up arrow with "ADJUST."
- 2. Pull bearing sleeve either 3 mm distally or proximally to desired exposure.
- 3. Rotate knurled knob on driver to line up arrow with "RUN."

#### **Bearing Sleeve Disassembly**

1. Rotate knurled knob on driver to line up arrow with "TUBE." Remove bearing sleeve from distal end of driver.

### MICROSAWS AND SMALL ATTACHMENTS ASSEMBLY

The microSaws were designed for small bone dissection. The microSaw Driver provides direct connection to all *DePuy Synthes Power Tools* electric handpiece systems. The Driver also enables rapid exchange of saw head styles through a unique quick-disconnect system.

DRIVER

MANSPACH

#### **Keyless Driver Installation**

DRIVER Keyless Driver

Note: Instructions are written such that distal end of handpiece and attachment are pointed away from user.

#### **Keyless Driver Installation**

- 1. Ensure knurled knob on handpiece is in "RUN" (a) position.
- 2. Insert drive shaft of keyless driver into handpiece and rotate clockwise until locked. Gently twist back and forth to ensure it is locked into position.

#### eMax Keyless Driver Removal (DRIVER)

- 1. Move handpiece knurled knob to "SAFE" position.
- 2. Rotate DRIVER counterclockwise and remove.

DRIVER Duty Cycle

30 Sec ON, 30 Sec OFF for 8 cycles. The recommendations for times of use for the DRIVER attachments have been determined under average load and worst case ambient air temperature of 85°F (29°C).

### Oscillating, Sagittal, and Reciprocating Saw Attachment Assembly

S-SAW	Sagittal microSaw Attachment
R-SAW	Reciprocating microSaw Attachment

- O-SAW Oscillating microSaw Attachment
- 1. Insert attachment drive shaft into distal end of keyless driver. Rotate until three tabs on attachment engage three slots in keyless driver.
- Continue to rotate counterclockwise while pushing attachment into keyless driver until attachment locks into position and release ring snaps into position. When fully engaged, contours on keyless driver body, release ring, and saw attachment will be in alignment.

#### **Oscillating Saw Blade Assembly**

- 1. Press down on release button to open saw blade mounting plates.
- Insert saw blade into opening and align saw blade hub with locking pins in mounting plates. Oscillating saw blades can be aligned in 45° increments.
- 3. Release button and ensure mounting plates are firmly seated on saw blade without gaps.

#### Sagittal Saw Blade Assembly

- 1. Press down on release button to open saw blade mounting plate.
- 2. Insert saw blade into opening through slot on mounting plate and align saw blade hub with locking pins in mounting plate.
- 3. Release button and ensure mounting plate is firmly seated on saw blade without gaps.

#### **Reciprocating Saw Blade Assembly**

- 1. Rotate chuck counterclockwise until chuck has opened sufficiently to accept a saw blade.
- 2. If blade has a shank with a shaft, insert shaft of blade in chuck jaws until it is fully inserted and tighten chuck knob clockwise until snug.
- 3. If blade has a flat shank, insert blade into slots in chuck until it is fully inserted and tighten chuck knob clockwise until snug.

#### Saw Blade Removal

1. Saw blade removal is reverse of installation.

#### S-SAW



R-SAW



O-SAW



#### J-Latch and Jacobs Chuck Small Attachments Assembly

DRIVERKeyless DriverSA-JLATCHSmall Attachment, J-LatchSA-JACOBSSmall Attachment, Jacobs Chuck

### Note: *DePuy Synthes Power Tools* does not supply dissection tools for SA-JLATCH or SA-JACOBS small attachments.

#### Keyless driver refers to DRIVER.

- 1. Insert attachment drive shaft into distal end of keyless driver. Rotate until three tabs on attachment engage three slots in keyless driver.
- 2. Continue to rotate counterclockwise while pushing attachment into keyless driver until attachment locks into position and release ring snaps into position.
- 3. When fully engaged, contours on keyless driver body, release ring, and small attachment will be in alignment.

#### J-Latch Dissection Tool Assembly

- 1. Pull back distal sleeve in direction of arrow on SA-JLATCH attachment and hold it down to insert dissection tool into distal end of attachment.
- 2. Rotate dissection tool slowly until fully seated.
- 3. Release distal sleeve and check security of dissection tool by pulling distally on dissection tool.
- 4. Dissection tool and attachment are secure.

#### J-Latch Dissection Tool Removal

- 1. Pull back distal sleeve in the direction of arrow ♥ on SA-JLATCH and hold it down while pulling dissection tool out distally for removal.
- 2. Release the distal sleeve.

#### **Keyless Jacobs Chuck Dissection Tool Assembly**

- 1. Press down on center > of release button located on SA-JACOBS attachment while rotating knurled knob on attachment clockwise until fully opened.
- 2. Insert dissection tool into distal end of attachment until it touches bottom.
- 3. Rotate knurled knob counterclockwise while centering dissection tool on attachment until tight; release button.
- 4. Check security of dissection tool by pulling distally on dissection tool.
- 5. Dissection tool and attachment are secure.

### Caution: Do not press down on release button while attachment is in use.



#### **Keyless Jacobs Chuck Dissection Tool Removal**

- 1. Press down on center > of release button located on SA-JACOBS attachment while rotating knurled knob on attachment clockwise until fully opened.
- 2. Pull dissection tool out distally for removal.
- 3. Release button.

#### Disassembly

#### microSaw and Small Attachment Removal

1. With one hand supporting attachment, rotate release ring on keyless driver with other hand counterclockwise until attachment is released.

### PERFORATOR DRIVER

#### **Perforator Driver**

CSR60 Perforator Driver with Hudson End

This perforator driver attachment allows hudson style cranial perforators to be used with the eMax 2 Plus Systems (60:1 Ratio, approximately 1,300 rpm.)

Refer to the cranial perforator manufacturer's operating instructions for rotational speed requirements.

### Note: Instructions are written such that distal end of handpiece and attachment are pointed away from user.

- 1. Remove red storage cover.
- 2. Move handpiece knurled knob to "RUN" (♥) position.
- Slide SpeedReducer over distal end of handpiece. Pull SpeedReducer towards handpiece and rotate to right approximately one-quarter turn until fully seated. Handpiece knurled knob will move up to seat next to SpeedReducer.
- 4. Pull SpeedReducer retaining sleeve towards handpiece. Insert Hudson-end of cranial perforator and release retaining sleeve.

#### Disassembly

- 1. Pull SpeedReducer retaining sleeve towards handpiece and remove cranial perforator from distal end of SpeedReducer.
- 2. Move handpiece knurled knob to "SAFE" position.
- 3. Rotate SpeedReducer to left approximately one-quarter turn and remove from distal end of handpiece.
- 4. Replace red storage cover.

Note: The red storage cap provided with the Perforator Driver is to prevent damage to the shaft. The cap is removed for cleaning, washing and sterilization. The cap is used for storage purposes only.



### INSPECTION AND MAINTENANCE

Perform these activities regularly as per institution policy.

Warning: Do not use any damaged equipment. Return to *DePuy Synthes Power Tools* repair facility.

#### Attachments

#### **Straight Attachments**

- LONG
- LONG-S
- LONG-01
- LONG-HD
- MEDIUM
- MEDIUM-HD
- MIA16
- SHORT
- SHORT-HD
- XL-HD

#### **Angle Attachments**

- MA-D20
- MA-DRIVER
- QD8
- QD8-S
- QD11
- QD11-S
- QD14
- QD14-S

#### Craniotomes

- CRANI-A
- CRANI-A-R
- CRANI-L
- CRANI-P
- CRANI-01
- CRANI-L-R

Visually inspect for any damage to the tube.



### Visually inspect for bent or broken drive shaft and for any damage to the tube.



Visually inspect for bent or broken foot.



#### **Other Attachments**

- ADG
- CDA
- CSR60
- DRIVER
- ORANGE-45
- ORANGE-90
- O-SAW
- R-SAW
- S-SAW
- SA-JACOBS
- SA-JLATCH

#### Foot Controls

- E-FP
- E-FP-DIR
- E-FP-DIR/IRR
- EPLUS-FP
- EPLUS-FP-NS

#### Visually inspect for overall damage or missing components.



- Visually inspect for damage electrical cord or connector.
- Visually inspect for damage or cracks to the housing or pedal.



#### Hand Controls

- E-HC
- EMAX2-HC

- Visually inspect for damage to the levers.
- Visually inspect for presence of magnet on the lever mechanism.



#### Ensure that the knurl knob operates properly.

- If the knob is hard to turn, it may be lubricated. Please refer to the instructions for use.
- Visually inspect for damage to the silicone hose or to the electrical connector.
- Connect to console and operate. The handpiece should operate smoothly.
- There is no requirement to operate with attachment or dissection tool.



#### Handpiece

• EMAX2PLUS

#### Consoles

- SC2100
- SC2101
- SC2102

- Visually inspect for damage or cracks to the housing.
- Visually inspect for damage to the electrical power cord.



- Power the system and inspect for illumination of the LEDs.
- If there is an irrigation pump present check for proper function.



### CLEANING INSTRUCTIONS

### ELECTRIC HIGH SPEED SYSTEMS

The following manual cleaning and mechanical/automated cleaning with manual pre-cleaning instructions have been validated by *DePuy Synthes Power Tools* for preparing a nonsterile medical device; this instruction is provided in accordance with ISO 17664:2004 and ANSI/AAMI ST81:2004.

Warning: Transmissible Spongiform Encephakopathies (TSE). *DePuy Synthes Power Tools* will not authorize or accept the return of products that directly contact patients or are contaminated with body fluids of a patient who is suspected or confirmed with a Transmissible Spongiform Encephalopathies/Creutzfeldt-Jakob Disease (TSE/CJD) diagnosis. *DePuy Synthes Power Tools* recommends that all *DePuy Synthes Power Tools* products used on a patient confirmed with a TSE/CJD diagnosis be incinerated. *DePuy Synthes Power Tools* dissecting tools used on a patient suspected of TSE/CJD diagnosis must be incinerated.

Note: At the point of use the equipment should be wiped of any gross soil and transferred to the cleaning and sterilization area for immediate processing. Contact your Sales Representative for replacement of product incinerated under this policy or for temporary equipment while the original equipment is quarantined. Contact the *DePuy Synthes Power Tools* Customer Service department regarding TSE/CJD contamination for additional information.

### MANUAL CLEANING

### HIGH SPEED HANDPIECES

#### Detergents

- Neutral PH enzymatic detergents are recommended for the manual washing of the high speed handpieces.
- Alkaline detergents with a maximum pH of 11 may be used but user must demonstrate their effectiveness.
- The process, detergent and any additives must be discussed with detergent manufacturer.

### Warning: Wear eye protection and any additional PPE required.

#### Cautions:

- Do not immerse! Do not insert brush into handpiece housing. Do not use saline solution for cleaning. Do not use cleaners containing chlorinated phenols of any concentration. Using cleaners/disinfecting agents containing chlorinated phenols will result in premature hose failure.
- Do not use alkaline detergent with a pH greater than 11. Alkaline detergents attack grease and seals which can increase wear and cause device malfunction. Please note: use of alkaline detergents can cause color to fade but this does not impair function of device.

#### 1

#### Preparation

Assemble all necessary supplies such as a lint-free cloth.

Remove the attachment and dissection tool from the handpiece (Figure 1).

Place the attached cap onto the console connector end of the handpiece (Figure 2).

#### 2

#### Clean

Wipe with a clean, deionized, distilled, or purified water-dampened cloth and mild detergent (neutral pH).

Caution: DO NOT IMMERSE. Handpiece must not be exposed to ingress of water or to severe physical trauma; degradation of unit function and/or performance may occur.

#### 3

#### Inspect

Visually inspect the handpiece and repeat step 2 until no visible soil remains.



Figure 1



### ATTACHMENTS

Caution: Manual Cleaning Instructions for all Attachments except the Minimal Access (MA) Attachments and bearing sleeves.

#### Detergents

- Alkaline detergents with a maximum pH of 11 are recommended for the manual washing of the attachments.
- The process, detergent and any additives must be discussed with detergent manufacturer.

### Warning: Wear eye protection and any additional PPE required.

Caution: Do not use alkaline detergent with a pH greater than 11. Alkaline detergents attack grease and seals which can increase wear and cause device malfunction. Please note use of alkaline detergents can cause color to fade but this does not impair function of device. Do not use ultrasonic equipment or corrosive or harsh chemical soaps. Do not rinse attachment with saline solution.

#### 1

#### Preparation

Assemble all necessary supplies including Attachment Cleaning Brush (ACB), sponge, lint-free cloth and soft bristle brush. Remove the attachment and dissection tool from the handpiece (Figure 1).

**CSR60 only:** The red storage cap provided with the Perforator Driver is to prevent damage to the shaft. The cap is removed for cleaning, washing and sterilization (Figure 2). The cap is used for storage purposes only.

#### 2

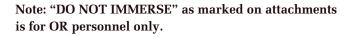
#### Immerse

Fully immerse the attachment in an alkaline cleaner (non-chlorinated detergent), prepared as described on the product label, at room temperature, in a suitable container and agitate for 15 seconds (Figure 3).

Figure 1



Figure 3



Please refer to cleaning instructions provided with the MA attachments for Minimal Access (MA) Attachments, Minimal Access Drivers (MA-D20, MA-DRIVER), Minimal Access Bearing Sleeves (MA-10S, MA-10C, MA-15S, MA-15C, MA-15ST, & MA-19ST).



#### **Clean Cannulations**

### Caution: This step refers ONLY to the following attachments (for other attachment proceed to step 4):

Type of Attachment	Names of Attachments
Straight Attachments	SHORT, MEDIUM, LONG, MIA16, SHORT-HD, MEDIUM-HD, LONG-HD, XL-HD, LONG-S, LONG-01
Craniotomes	CRANI-A, CRANI-A-R, CRANI-A-01, CRANI-P, CRANI-L, CRANI-L-R
Specialty Attachments	ADG, CDA
QD Attachments	QD8, QD8-S, QD11, QD11-S, QD14, QD14-S

Gently insert and remove Anspach Attachment Cleaning Brush (ACB) wetted with alkaline cleaner through either openings (distal or proximal) of the attachment as many times as necessary to remove any foreign debris (Figure 4).

Caution: Do not insert anything into the attachment except the ACB as specified. Do not force the brush into or though the attachment. Do not use ACB with MA-D20 and MA-DRIVER. ACB is to be utilized once per system set and discarded once the system cleaning is complete.



Figure 4

#### 4

#### Rinse

Rinse the attachment in a suitable container filled with deionized, distilled, or purified water and agitate for 15 seconds.

#### 5

#### Inspect

Repeat Steps 2–4 until there is no evidence of soils or residuals on the attachment surface or ACB.

## ELECTRIC CONSOLES, FOOT CONTROLS AND TRAYS

### Electric Console and Foot Control

Caution: Do not immerse or sterilize! Do not allow liquid to enter the console or foot control.

#### 1

#### Clean

Disconnect all power from console.

Clean console and foot control by wiping with nonabrasive cloth and disinfectant or mild detergent and deionized, distilled or purified water after each case.

#### 2

#### Dry

Dry thoroughly with non-abrasive cloth.





#### Trays

Trays can be cleaned with deionized, distilled, or purified water and a mild detergent (pH neutral).

### MANUAL PRE-CLEANING BEFORE MECHANICAL/ AUTOMATED CLEANING

### HIGH SPEED HANDPIECES

#### Detergents

- A neutral pH enzymatic detergent is recommended.
- Alkaline detergents with a maximum pH of 11 may be used but user must demonstrate their effectiveness.
- The process, detergent and any additives must be discussed with detergent manufacturer.

Caution: Do not use any alkaline detergent with a pH greater than 11. Alkaline detergents attack grease and seals which can increase wear and cause device to malfunction. Please note use of alkaline detergents can cause color to fade but this does not impair function of device.

#### 1

#### Preparation

Assemble all necessary supplies including Attachment Cleaning Brush (ACB), sponge, lint-free cloth and soft bristle brush. Remove the attachment and dissection tool from the handpiece (Figure 1).

**Electric systems only:** Place the attached cap onto the console connector end of the handpiece (Figure 2).







Figure 2

#### 2

#### Rinse

Rinse the handpiece with distal end pointing down under running cold tap water or drinking water for a minimum of two (2) minutes. Use a sponge, soft lint-free cloth or soft bristle brush to assist in removing gross soils (Figures 3 and 4).

Caution: Do not use high pressure water or air. Do not allow running water to enter distal end of handpiece.



Figure 4

Distal End



#### **Manipulate Moving Parts**

Manipulate the handpiece knurled knob under running cold tap water or drinking water to loosen or remove gross soil (Figure 5).



Figure 5

#### 4 Clean

Prepare a cleaning solution using neutral pH enzymatic detergent per the manufacturer's directions for correct temperature, water quality (i.e. pH, hardness) and product concentration/dilution.

Spray and wipe the handpiece with the cleaning solution for a minimum of two (2) minutes. Rinse the handpiece thoroughly under running cold tap water or drinking water for a minimum of two (2) minutes while manipulating the knurled knob (Figures 6 and 7).

Use a sponge, soft lint-free cloth or soft bristle brush to remove all visible soil.

Place locking mechanism in the "SAFE" position prior to performing the following step (Figure 8).

Hold the handpiece at a downward angle and insert the Anspach Cleaning Brush (ACB) wetted with cleaning solution into the distal end of the handpiece (Figure 9).

Warning: ACB is single use and should only be used to clean one handpiece and associated attachments.

Caution: Do not immerse. Do not allow running water to enter distal end of handpiece. Do not insert ACB beyond last bristle. Do not force ACB into handpiece.



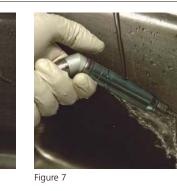


Figure 6





Figure 8





#### **Rinse Thoroughly**

Rinse the handpiece thoroughly under running hot tap water or drinking water for a minimum of two (2) minutes (Figure 10).

Place locking mechanism in "SAFE" position prior to performing the following step (Figure 11).

Hold the handpiece at a downward angle and flush inside of the distal end using a syringe or pipette filled with hot tap water or drinking water (Figure 12). Place the knurled knob in the "RUN" position (Figure 11).

Caution: Do not use high pressure water or air. Do not immerse. Do not allow running water to enter distal end of handpiece.





Figure 10

Figure 11



Figure 12

#### 6 Inci

#### Inspect

Visually inspect the handpiece and repeat Steps 2 thru 6 until no visible soil remains.

Warning: Manual pre-cleaning must be followed by mechanical/automated cleaning.

### ATTACHMENTS

#### Detergents

- A neutral pH enzymatic detergent is recommended.
- Alkaline detergents with a maximum pH of 11 may be used but user must demonstrate their effectiveness.
- The process, detergent and any additives must be discussed with detergent manufacturer.

Caution: Do not use any alkaline detergent with a pH greater than 11. Alkaline detergents attack grease and seals which can increase wear and cause device to malfunction. Please note use of alkaline detergents can cause color to fade but this does not impair function of device.

Warning: Do not clean the MA-19ST Minimal Access Bearing Sleeve in the EM/XM Cleaning and Sterilization Basket. Only indicated for the MA-10S, MA-10C, MA-15S, MA-15C, and MA-15ST.

#### 1

#### Preparation

Assemble all necessary supplies including Attachment Cleaning Brush (ACB), Small Diameter Cleaning Brush (SDCB), sponge, lint-free cloth and soft bristle brush. Remove the attachment and dissection tool from the handpiece (Figure 1).

Note: Red storage cap is provided with Perforator Driver to prevent damage to shaft. Cap is removed for cleaning, washing and sterilization (Figure 2). Cap should be used for nonsterile storage purposes only.



Figure 1



Figure 2

#### 2

#### Rinse

Rinse the attachment under running cold tap water or drinking water for a minimum of two (2) minutes. Use a sponge, soft lint-free cloth or soft bristle brush to assist in removing gross soil (Figures 3 and 4).

### Caution: Do not use high pressure water or air. Do not rinse attachment with saline solution.



Figure 3



#### **Manipulate Moving Parts**

Manipulate all moving parts such as release sleeves under running cold tap water or drinking water to loosen or remove gross soil (Figure 5).

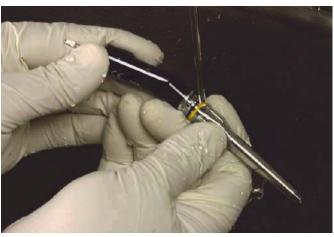


Figure 5

### **4**

Clean

Prepare a cleaning solution using neutral pH enzymatic detergent per the manufacturer's directions for correct temperature, water quality (i.e. pH, hardness) and product concentration/dilution.

Fully immerse the attachment in cleaning solution in a suitable container and manually agitate for 2 minutes (Figure 6). Use a sponge, soft lint-free cloth or soft bristle brush to remove all visible soil.

Gently use ACB or SDCB wetted in cleaning solution to clean cannulations of attachment. The brushes may be inserted from the distal or proximal end of the attachment (Figure 7).

### Warning: ACB and SDCB are single use and should only be used to clean one set of attachments.

Caution: Do not force ACB or SDCB into or through attachment. Do not use ACB or SDCB with MA-D20 and MA-DRIVER. For Minimal Access Attachment Bearing Sleeves use SDCB only. Do not use pipe cleaners.

Note: "DO NOT IMMERSE" as marked on the attachment is for Operating Room personnel only. SDCB may be inserted from distal or proximal end of bearing sleeve.





Figure 6

#### **Rinse Thoroughly**

Rinse the attachment thoroughly under running hot tap water or drinking water for a minimum of two (2) minutes (Figure 8). Use a syringe or pipette filled with hot tap water or drinking water to flush lumens or channels (Figure 9).

Caution: Do not use high pressure water or air. Do not rinse attachment with saline solution.



Figure 8

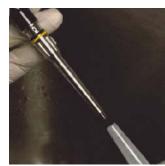


Figure 9

#### 6

#### Inspect

Visually inspect the attachment and repeat Steps 2 thru 6 until no visible soil remains.

### Warning: Manual pre-cleaning must be followed by mechanical/automated cleaning.

### MECHANICAL/AUTOMATED CLEANING FOLLOWING MANUAL PRE-CLEANING

### HIGH SPEED HANDPIECES AND ATTACHMENTS

#### Detergents

- A neutral pH enzymatic detergent is recommended.
- Alkaline detergents with a maximum pH of 11 may be used but user must demonstrate their effectiveness.
- The process, detergent and any additives must be discussed with detergent manufacturer.

Caution: Do not use any alkaline detergent with a pH greater than 11. Alkaline detergents attack grease and seals which can increase wear and cause device to malfunction. Please note use of alkaline detergents can cause color to fade but this does not impair function of device. Bearings and seals of all devices are exposed to greater stress during mechanical/automated cleaning than manual cleaning. If devices are mechanically cleaned they must be sent to a *DePuy Synthes Power Tools* Service Center at least once a year for maintenance.

Warning: Do not clean the MA-19ST Minimal Access Bearing Sleeve in the EM/XM Cleaning and Sterilization Basket. Only indicated for the MA-10S, MA-10C, MA-15S, MA-15C, and MA-15ST.

#### Mechanical/Automated Cleaning Guidelines

*DePuy Synthes Power Tools* can only be mechanically cleaned under the following conditions:

- Cannulations must be pre-cleaned with appropriate brushes as described in pre-cleaning instructions.
- Devices must not be cleaned using ultrasonic equipment.
- Handpieces must not be immersed in cleaning solution but may be sprayed with it.
- Fully demineralized (deionized) water must be used during final rinse to prevent corrosion and spots.
- Devices must be cleaned immediately after use to ensure blood and tissue never dry on them.
- National regulations must be observed.
- You must follow standard hospital procedures.
- You must follow manufacturer's recommendations for any detergents, disinfectants and washing equipment used.

#### Loading the Basket

EX-BSKT-BTM	EM/XM Cleaning and Sterilization Basket Bottom
EX-BSKT-INS	EM/XM Cleaning and Sterilization
	Basket Insert
EX-BSKT-LID	EM/XM Cleaning and Sterilization Basket Lid

Load the devices in the basket by securing them in the appropriate brackets as marked on the basket (Figure 1). Reference loading configuration pictures on Page 51 for proper placement and positioning of devices. Where applicable distal end of devices should be angled downward.

#### Warning: Red protective cap for Perforator Driver must be left off during mechanical/automated cleaning (Figure 2).

Note: Before putting on seal cap, turn black cap to wrap cable tight around it (Figure 3).

Caution: Connector ends of electric and pneumatic handpieces must be sealed with special seal caps provided (Figure 4).



Figure 1



Figure 3

Figure 4

#### 2

#### Mechanical/Automated Cleaning Cycle Process Parameters

Cycle	Duration (minimum)	Cleaning Instructions
Rinse	2 minutes	Cold tap water or drinking water
Pre-wash	1 minutes	Warm water (≥ 40°C); use detergent
Cleaning	2 minutes	Warm water (≥ 45°C); use detergent
Rinse	5 minutes	Rinse with deionized (DI) or purified water (PURW)
Thermal Processing	5 minutes	Hot DI water, ≥ 93°C
Dry	40 minutes	≥ 90°C

#### Caution: Do not use neutralizing agent.

#### 3

#### Inspect

Visually inspect the devices and repeat the manual pre-clean and mechanical/automated clean until no visible soil remains.

### LUBRICATION

### HANDPIECES

1

Do not lubricate the handpiece.

### ATTACHMENTS

#### Caution: This step is for attachments only.

#### 1

#### Immerse in Lubricant

After cleaning and rinsing, fully immerse the attachment in instrument milk (non-silicone based medical lubricant) prepared as described on the product label, at room temperature, in a suitable container and agitate for 15 seconds (Figure 2).

#### 2

#### Drain

Remove the attachment and allow it to drain until no visible droplets are coming from it.

Caution: Do not rinse out instrument milk. Do not apply mineral oil or other lubricants, which may cause the attachment to overheat.



### STERILIZATION

### HIGH SPEED HANDPIECES AND ATTACHMENTS

The following sterilization instruction has been validated by *DePuy Synthes Power Tools* in accordance with ISO 17665.

**Before sterilizing:** Ensure sterilization equipment is in proper working order as specified by manufacturer. Assure equipment manufacturer's instructions are properly employed by trained and qualified personnel. Assure actual cycle employed has been properly validated for the device(s)/load configuration being processed and appropriate sterilization indicator devices are included for each process and cycle.

Caution: Red protective cap for CSR60 must be removed prior to sterilization (Figure 1). In the case mechanical/ automated cleaning was done, in the EX-BSKT, seals cap from connector end of pneumatic handpiece must be removed prior to sterilization (Figure 2).

#### Preparation

Following mechanical cleaning and lubrication, load the basket and sterilize in accordance with the following guidelines.



Figure 1



#### If using the EMAX2-TRAY

Method/Cycle	Exposure Temperature	Exposure Time	Minimum Dry Time
Steam Autoclave/Pre-vacuum	Option 1: 132°C	4 minutes	30 minutes
(wrapped or unwrapped)	Option 2: 134°C–138°C	3–18 minutes	30 minutes
Steam Autoclave/Gravity	Option 1: 132°C	15 minutes	30 minutes
Air Displacement (wrapped or unwrapped)	Option 2: 132°C–138°C	15–18 minutes	30 minutes

# Warning: STERRAD<sup>®</sup> 100S—refer to the accompanying documentation of the individual products to determine compatibility.

#### If using the EX-BSKT Washing and Sterilization Basket

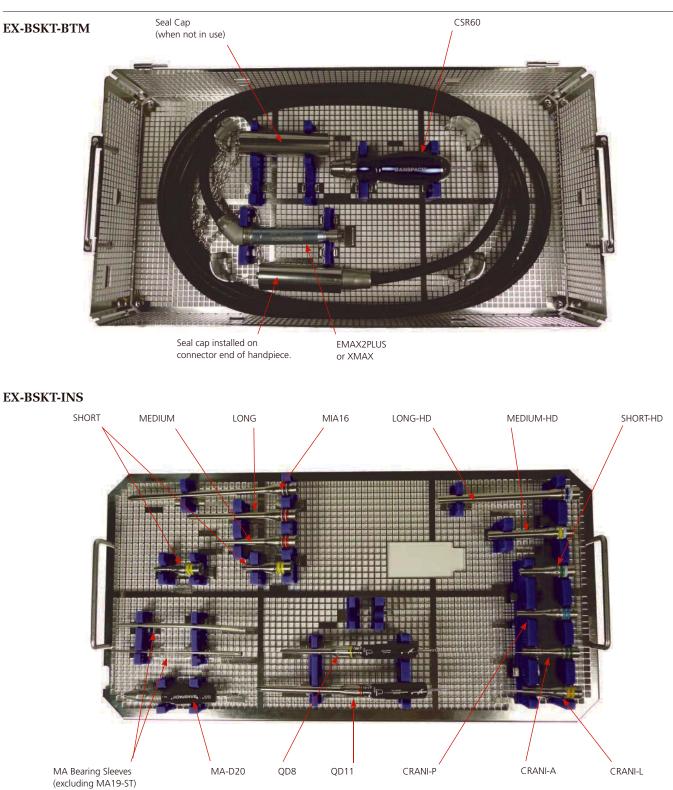
Method/Cycle	Exposure Temperature	Exposure Time	Minimum Dry Time
Steam Autoclave/Pre-vacuum	Option 1: 132°C	4 minutes	20 minutes
(wrapped or unwrapped)	Option 2: 134°C–138°C	3–18 minutes	20 minutes
Steam Autoclave/Gravity	Option 1: 132°C	15 minutes	15 minutes
Air Displacement (wrapped or unwrapped)	Option 2: 132°C–138°C	15–18 minutes	15 minutes

#### Notes:

- Foot Controls, consoles and irrigation pumps should not be sterilized.
- It is required to include the drying cycle to avoid possible adverse effects caused by exposure to condensation.
- Metal devices, tools and equipment are constructed of materials unaffected by normal environmental conditions of current standard sterilization means, when proper operational techniques are employed.
- Effectiveness of sterilization equipment or sterilization processes are directly dependent upon numerous factors beyond *DePuy Synthes Power Tools*' control including among other things; sterilization means, processes and wrapping techniques employed, brand, model and condition of sterilization equipment, care and maintenance techniques employed and operator knowledge and experience.
- DePuy Synthes Power Tools cannot anticipate all possible equipment, processes and/or conditions that may be encountered. The suggested operation conditions are to be considered as a starting point for determination of the overall process capability, without regard for type or condition of equipment used or methods, techniques or practices employed by user. Use of proper sterilization indicator devices is strongly recommended. It is recommended that a drying cycle be included to avoid possible adverse effects caused by exposure to condensation.

### LOADING CONFIGURATION

### HIGH SPEED HANDPIECES AND ATTACHMENTS



### TROUBLESHOOTING

### EMAX 2 PLUS

Problem	Possible Cause	Solution
Excessive handpiece noise	Faulty internal component	• Return to DePuy Synthes Power Tools for service.
Lack of power to console	<ul> <li>Plug is not fully inserted/power switch not turned on</li> <li>Outlet is not functional</li> </ul>	<ul> <li>Verify plugs to wall and back of console are pushed in completely and power switch is in "I" position.</li> <li>Verify another piece of electrical equipment can receive power from outlet.</li> </ul>
Handpiece vibration or	• Faulty internal component	• Return to DePuy Synthes Power Tools for service.
extremely hot	<ul> <li>Internal motor overheats due to continuous extreme cutting at near stalling conditions</li> <li>Hose may be kinked</li> <li>Handpiece out of balance</li> </ul>	<ul> <li>Console will shut handpiece off. If it continues to shut off during normal cutting, return to <i>DePuy Synthes Power Tools</i> for service.</li> <li>Unkink hose (verify it is not being pinched or clamped to table).</li> <li>Return to <i>DePuy Synthes Power Tools</i> for service.</li> </ul>
	Handpiece hose damaged	• Return to <i>DePuy Synthes Power Tools</i> for service.
Excessive vibration of cutting burr	<ul> <li>Cutting burr may be bent</li> <li>Cutting burr may not be fully seated</li> <li>Improper attachment and cutting burr combination</li> <li>Possible attachment bearing damage</li> </ul>	<ul> <li>Replace with new eMax 2 Plus cutting burr.</li> <li>Reassemble cutting burr and attachment.</li> <li>Only use correct cutting burr with appropriate attachment.</li> <li>Return attachment to <i>DePuy Synthes Power Tools</i> for service.</li> </ul>
Attachment is hot	<ul> <li>Debris lodged inside attachment</li> <li>Possible bearing damage</li> </ul>	<ul> <li>Clean attachment using <i>DePuy Synthes Power Tools</i> Attachment Cleaning Instructions located in this manual.</li> <li>Return attachment to <i>DePuy Synthes Power Tools</i> for service.</li> </ul>
Craniotome attachment is bent	• Excessive force used in operation	• Do not use, replace attachment.
Inoperative Foot Control (LEDs are illuminated on face panel)	<ul> <li>Selected foot control on face panel does not match foot control in use</li> <li>System is set in hand control mode (LED light is illuminated)</li> <li>Plugs may not be fully inserted</li> <li>Handpiece is in "Safe" position or cutter is not rotating</li> <li>Defective attachment</li> </ul>	<ul> <li>Press Foot Control button on face panel to select other Foot Control.</li> <li>Press Foot Control button on face panel to set it for Foot Control 1 or 2, depending which one is in use.</li> <li>Verify plugs for handpiece and foot control are fully inserted. Plug will latch in place once fully inserted.</li> <li>Verify cutting burr is completely engaged and handpiece's knurled knob is in secure position.</li> <li>Clean attachment or replace attachment.</li> </ul>
Inoperative Hand Control	<ul> <li>Defective internal component</li> <li>Hand Control Attachment may not be fully installed</li> <li>Selected Hand Control on face panel is not in use</li> <li>Internal handpiece switch activating Hand Control may be damaged</li> </ul>	<ul> <li>Return to <i>DePuy Synthes Power Tools</i> for service.</li> <li>The circumferential groove on handpiece housing wil be exposed when the Hand Control is fully installed</li> <li>Press Hand Control button on face panel to illuminate Hand Control LED.</li> <li>Return to <i>DePuy Synthes Power Tools</i> for service.</li> </ul>

### ORDERING INFORMATION

Anspach Atta	chments
SHORT	5 cm Short Attachment
MEDIUM	8 cm Medium Attachment
LONG	11 cm Long Attachment
LONG-S	10.5 cm Long Attachment
LONG-01	10.5 cm Long Attachment, Non-tapered End
MIA16	16 cm Minimally Invasive Attachment
SHORT-HD	5 cm Heavy Duty Short Attachment
MEDIUM-HD	8 cm Heavy Duty Medium Attachment
LONG-HD	12.4 cm Heavy Duty Long Attachment
XL-HD	20.2 cm Heavy Duty Extra Long Attachment
ADG	7.2 cm Adjustable Drill Guide
CDA	6.8 cm Controlled Depth Attachment
CRANI-A	6.5 cm Adult Craniotome
CRANI-A-01	6.5 cm Adult Craniotome, Thin
CRANI-P	6.5 cm Pediatric Craniotome
CRANI-L	7.5 cm Large Craniotome
CRANI-A-R	6.5 cm Rotating Adult Craniotome
CRANI-L-R	7.5 cm Large Rotating Craniotome
MA-D20	20° Angle Driver
MA-DRIVER	Minimal Access Straight Driver
MA-15S	Bearing Sleeve, 15 cm Straight
MA-15C	Bearing Sleeve, 15 cm Curved
MA-15ST	Bearing Sleeve, 15 cm Straight Taper
MA-19ST	Bearing Sleeve, 19 cm Straight Taper
MA-10S	Bearing Sleeve, 10 cm Straight
MA-10C	Bearing Sleeve, 10 cm Curved
ORANGE-45	45° Contra Angle Attachment
ORANGE-90	90° Right Angle Attachment
QD8	8 cm Quick Disconnect Angle Attachment
QD8-S	7.5 cm Quick Disconnect Angle Attachment
QD11	11 cm Quick Disconnect Angle Attachment
QD11-S	10.5 cm Quick Disconnect Angle Attachment
QD14	14 cm Quick Disconnect Angle Attachment
QD14-S	13.5 cm Quick Disconnect Angle Attachment
CSR60	Perforator Driver with Hudson End
DRIVER	Keyless Driver
O-SAW	Oscillating microSaw Attachment
R-SAW	Reciprocating microSaw Attachment
S-SAW	Sagittal microSaw Attachment
SA-JLATCH	Small Attachment, J-Latch
SA-JACOBS	Small Attachment, Jacobs Chuck

#### **Electric Instrument System**

EMAX2PLUS	eMax 2 Plus Handpiece
SC2101	System Console, with Irrigation
SC2102	System Console, without Irrigation
E-FP	Electric Systems Foot Control
E-FP-DIR	Electric Systems Foot Control with Direction
E-FP-DIR/IRR	Electric Systems Foot Control with Direction
	and Irrigation
E-HC	Hand Control
EMAX2-HC	Hand Control

#### **Electric Instrument System Accessories**

EMAX2-TRAY	Sterilization Case and Tray
05.001.100	Cart
EX-BSKT	EM/XM Cleaning and Sterilization Basket Set
EX-BSKT-BTM	EM/XM Cleaning and Sterilization Basket
	Bottom
EX-BSKT-INS	EM/XM Cleaning and Sterilization Basket Insert
EX-BSKT-LID	EM/XM Cleaning and Sterilization Basket Lid

#### **Irrigation System**

IRRIGATE-TUBE	Sterile Tubing and Hoseclips for Irrigation
	System
IRRIGATE-TUBE-HF	Sterile High Flow Tubing and Hoseclips for
	Irrigation System
IRR-CLIP-10	Irrigation Clip for SHORT
IRR-CLIP-20	Irrigation Clip for QD8, QD8-S, B-QD8
IRR-CLIP-30	Irrigation Clip for SHORT-HD, B-SILVER
IRR-CLIP-40	Irrigation Clip for MEDIUM-HD, LONG-HD,
	B-BLUE-S, B-VIOLET
IRR-CLIP-50	Irrigation Clip for MEDIUM, LONG, LONG-S,
	B-TURQ-L
IRR-CLIP-60	Irrigation Clip for QD11, QD11-S, QD14, QD14-S,
	B-QD11, B-QD11-S, B-QD14, B-QD14-S

Warranty and Return Policy is available upon request.

### **DANSPACH**

Limited Warranty and Disclaimer: The Anspach Effort, Inc. products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Please contact Customer Service for full Warranty statement.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician. To order in the US, call DePuy Synthes Power Tools Customer Service: (800) 327-6887. Not all products are currently available in all markets.



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