

Anspach Electric Systems. High speed performance and power in a variety of applications.

Instructions for Use



High Speed
Power Tools

Table of Contents

Introduction	Synthes Anspach	2
	High Speed Electric Systems	2
	Indications	3
	Warnings and Cautions	4
	Technical Specifications	5
	Glossary of Symbols	10

Operating Instructions	eMax 2 and eMax 2 Plus	12
	e12 Small Bone System	20

Attachments and Dissection Tool Assembly	Standard Attachments and Dissection Tool Assembly	21
	Minimal Access Attachment and Dissection Tool Assembly	27
	Micro Curved Attachment (MCA) and Curved Burr Support Sleeves (Curved Burr)	29
	microSaws and Small Attachments Assembly	30
	Sagittal Saw	33
	Compact SpeedReducer	34

Care and Maintenance	Inspection and Maintenance	35
	Manual Cleaning Procedure	39
	Sterilization	41
	Troubleshooting	42
	Ordering Information	44

Anspach Electric Systems. High speed performance and power in a variety of applications.

Synthes Anspach

Synthes Anspach 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 Synthes Anspach instruments are manufactured to conform to rigorous quality standards to provide dependable performance.

Warning: Before using any of the Synthes 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, please contact your local Sales Representative.

If you have any questions after reading this manual, please contact your local Sales Representative.

High Speed Electric Systems

The eMax 2 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, Neurotologists, Skull Base Surgeons, Spinal Surgeons, and Otolaryngologists.

The eMax 2 Plus incorporates all of the features of the eMax 2, but with a higher degree of torque. The additional torque is beneficial for power demanding procedures.

The e12 is designed specifically to meet the demands of surgical applications requiring a low speed instrument at a high performance level that is the hallmark of Anspach systems. It combines the advantages of an electric system with an optimum balance of power, smooth operation, and ergonomic comfort. The eMax 2 and eMax 2 Plus System Consoles provide power to the e12 for variable speed operation up to 12,000 rpm with your choice of either foot or hand control. The e12 quick disconnect mechanism provides simple exchange of Synthes Anspach microSaw attachments and small attachments (J-Latch and Jacobs Chuck) resulting in a complete range of attachments and tools for all of your small bone procedures.



eMax 2 Plus

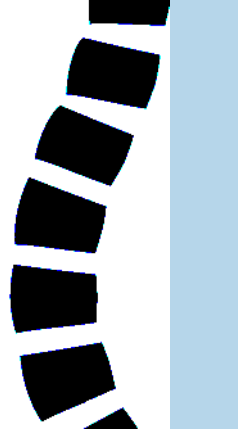


e12

Indications

The Synthes Anspach High Speed Electric Systems are intended for cutting and shaping bone including spine and cranium.

The Synthes Anspach High Speed Electric System is composed of Hand-piece models eMax2, eMax2 Plus, E12, and E-Sagittal; Electric Consoles models SC2000, SC2000U, SC2100, SC2101, and SC2102; Foot Control models E-FP, E-FP-DIR, E-FP-DIR/IRR, EPLUS-FP, EPLUS-FP-NS, EMAX2-FP, EMAX2-FP-NS; Hand Controls EMAX2-HC, E-HC and E12-HC.



Spine surgery



Neurosurgery and ENT

Warnings and Cautions

Warnings

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.

Irrigation is necessary for proper operation.

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 re-sterilize and/or re-use 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 Synthes Anspach, 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 in 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 Synthes Anspach 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 and eMax 2 Plus Handpiece Specifications

Speed:	10,000–80,000 rpm
Handpiece/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:	100–240 VAC, 50/60 Hz, 250 VA
Class I:	Protective Earth
Fluid Ingress Protection:	IPX0
Type B:	Applied Part Continuous Operation

Mechanical:

Size:	31.115 cm × 14.6 cm × 32.7 cm (12.25 in × 5.74 in × 12.87 in)
Weight:	6.25 kg (13.77 lbs)

The device complies with the following standards:
IEC 60601-1/IEC 60601-1-2



With regard to electrical shock, fire, mechanical hazards, this device is certified to UL 60601-1 and CAN/CSA C22.2 No. 601.1

This device complies with applicable EEC directives.



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

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

Environmental Conditions

Temperature	
Operating:	18°–30°C (65°–85°F)
Transportation and Storage:	–40°–70°C (–40°–158°F)

Relative Humidity	
Operating:	30–70 %
Transportation and Storage:	10–95 %

Atmospheric Pressure	
Operating:	70–106 kPa, 0.7–1.06 bar
Transportation and Storage:	Not applicable

Patent Information

Synthes Anspach products are manufactured under one or more of the following U.S. Patent Nos. RE 37,358; 5,405,348; 5,601,560; 5,630,818; 5,741,084; 5,904,687; 6,607,533; 6,733,218; 6,746,153; 6,749,341; 6,969,368; 7,128,544; 7,144,415; 7,217,090; 7,255,546; 7,261,526 and 7,458,979.

Additional U.S. and International patents pending.

Additional Information

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

Table 1: Emission

The Synthes Anspach High Speed Electric System is composed of Handpiece models eMax2, eMax2 Plus, E12, and E-Sagittal; Electric Consoles models SC2000, SC2000U, SC2100, SC2101, and SC2102; Foot Control models E-FP, E-FP-DIR, E-FP-DIR/IRR, EPLUS-FP, EPLUS-FP-NS, EMAX2-FP, EMAX2-FP-NS; Hand Controls EMAX2-HC and E12-HC.

Guidance and manufacturer's declaration – electromagnetic emissions

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

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

Table 2: Immunity (all devices)**Guidance and manufacturer's declaration – electromagnetic immunity**

The Synthes Anspach High Speed Electric System is intended for use in the electromagnetic environment specified below. The customer or the user of Synthes 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
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (0.5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5s	<5% U_T (0.5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5s	Mains power quality should be that of a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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.

Table 3: Immunity (not life-supporting devices)

Guidance and manufacturer’s declaration – electromagnetic immunity

The Synthes Anspach High Speed Electric System is intended for use in the electromagnetic environment specified below. The customer or the user of the Synthes 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 IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Synthes Anspach High Speed Electric System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Recommended separation distance


$$d = 1.2 \sqrt{P}$$

$$d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$$

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,^a should be less than the compliance level in each frequency range.^b

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.

^aField 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 Synthes Anspach High Speed Electric System is used exceeds the applicable RF compliance level above, the Synthes 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 Synthes Anspach High Speed Electric System.

^bOver 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 Synthes Anspach High Speed Electric System

The Synthes 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 Synthes 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 Synthes Anspach High Speed Electric System as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
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



Company Logo



Direction of rotation



Direction of rotation for lock position



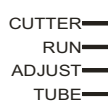
Indicates setting, position, or location



Indicates setting, position, or location



Indicates the drill tip exposure



Indicates the attachment setting, refer to MA-D20 and MA-DRIVER section in this document for further details



Indicates position or location



Indicates position or location



Indicates action of rotation and position for Secure (LOCK) and Release (UNLOCK)



Direction of rotation



Direction of rotation for lock position



Direction of rotation



Located on the Foot Pedal switch this indicates a change of rotational direction for the Handpiece



Located on the Foot Pedal switch this indicates a change state (on/off) for the Console Irrigation System



Located on the Foot Pedal switch this indicates a change state (on/off) for the Console Irrigation System



Located on the Foot Pedal switch this indicates a change of rotational direction for the Handpiece



Located on the Handpiece this indicates position of the knurled knob to the desired location



Symbol with yellow background: CAUTION: Refer to accompanying documentation



AC Power Source



Consult Operating Instructions



Located on the Console this indicates Motor or Handpiece unit



Located on the Console this indicates Foot Control activation



Located on the Console this indicates Hand Control activation



Located on the Console this indicates Forward (Clockwise rotation when looking at Handpiece from proximal end)



Located on the Console this indicates Reverse (Counterclockwise rotation when looking at Handpiece from proximal end)



RPM Revolution per Minute



Located on the Console this indicates a change state (on/off) for the Console Irrigation System



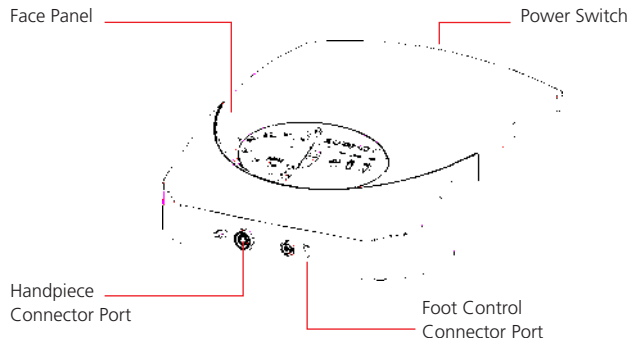
Located on the Console this indicates a change of irrigation rate for the Console Irrigation System

	Located on the Console this indicates a change of rotational speed rate for the Handpiece		Keep Dry (A.K.A. Protect from Moisture)
	Temperature Limits		Sterile unless damaged or open
	Equipotential post location		United States Federal law restricts this device to sale by or on the order of a physician or other licensed health-care provider
	Found on the Console ON/ OFF		CE Mark (A.K.A. CE Mark [notified body number], Conformité Européenne) Meaning: Device complies with applicable EEC Directives
	Located on the Console Irrigation Pump this indicates a possible finger pinch point		Lock (Run)
	Located on the Console Irrigation Pump these symbols are not used by the user since the pump is self adjusting to the Irrigation Tube diameter		Unlock (Load)
	Reference Number (A.K.A. Item Number, Catalog Number, Part Number)		Transmitter <i>Interference may occur in the vicinity of equipment marked with this symbol.</i>
	Lot (A.K.A. Lot Number, Batch Number, Batch Code)		Type B Electrical Equipment
	Serial Number		Product warranty is void if seal is damaged or removed.
	Use By Date (A.K.A. Expiration Date, Expiry)	Instrument System Key	
	Manufacturer		eMax 2 and eMax 2 Plus
	Authorized European Union Representative		e12
	Sterilized Using Irradiation	Latex-free Certification	
	Single Use Only (A.K.A. Do Not Reuse)	There is no latex material in Synthes Anspach products or packaging.	
	CAUTION: Refer to accompanying documentation		

eMax 2 and eMax 2 Plus Operating Instructions

The system console houses the electrical components that provide power, control, and cooling functions to the eMax 2 and eMax 2 Plus handpieces. 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 and eMax 2 Plus handpieces, foot controls, AC power inlet and the main power switch.

The eMax 2 and eMax 2 Plus High Speed Handpieces operate continuously at speeds up to 80,000 rpm.

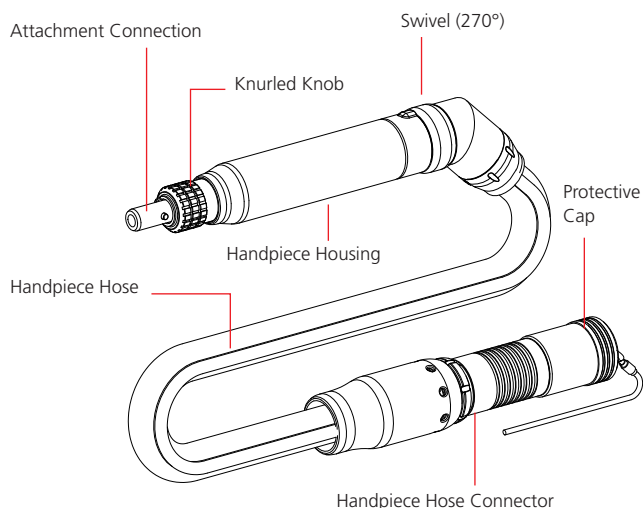
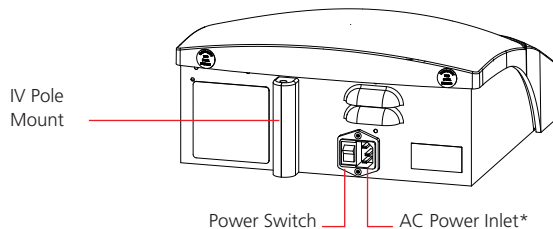


		Consoles					Foot Control Features		Hand Controls		
		SC2000	SC2000U	SC2100	SC2101	SC2102	Active Direction Control Switch	Active Irrigation Control Switch	EMAX2-HC	E12-HC	E-HC
Foot Controls	E-FP	•	•	•	•	•					
	E-FP-DIR	•	•	•	•	•	•				
	E-FP-DIR/IRR	•	•	•	•	•	•	•			
	EMAX2-FP	•	•	•	•	•	•	•			
	EPLUS-FP	•	•	•	•	•	•	•			
	EMAX2-FP-NS	•	•	•	•	•					
	EPLUS-FP-NS	•	•	•	•	•					
Accessories	E-SAGITTAL**	•	•	•	•	•					
	E12**	•	•	•	•	•				•	
Handpieces	EMAX2PLUS		•	•	•	•			•		•
	EMAX2	•	•	•	•	•			•		•
Console Features	Two Foot Control Ports*	•	•	•							
	Two Handpiece Ports*	•	•	•							
	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.
2. 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.

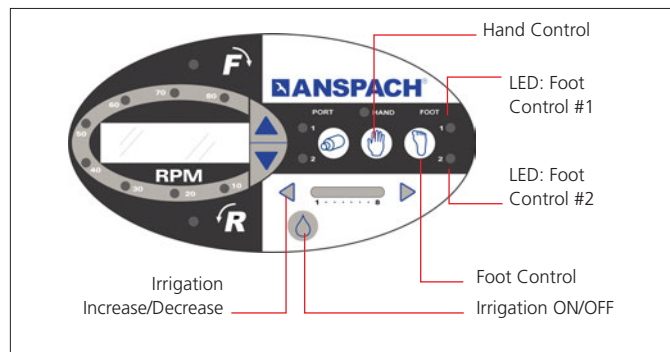
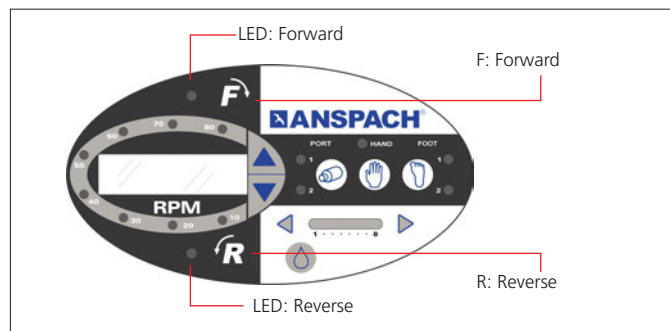
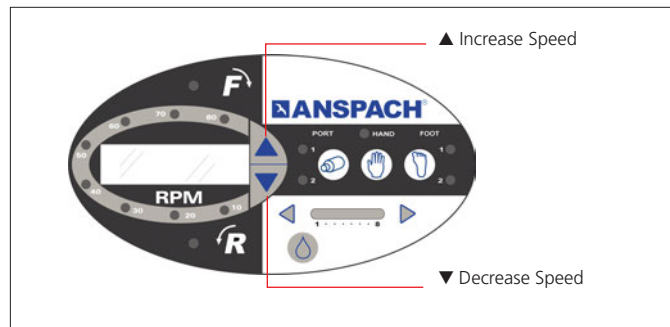
Note: Handpiece is fully functional at this time.

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

- 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
- 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.
- 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.

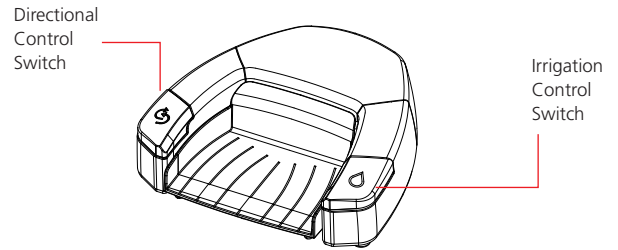
Foot Control Operation

Certain optional foot controls have direction and irrigation control switches.

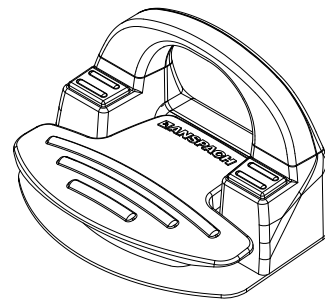
1. See Step 2 of Console Face Panel Operation to set operational direction of handpiece.
2. Optional: Depress "Foot" button on face panel to activate Foot Control 1, depress again to activate Foot Control 2. Only one foot control may be active at a time.

Note: Handpiece is fully functional at this time.

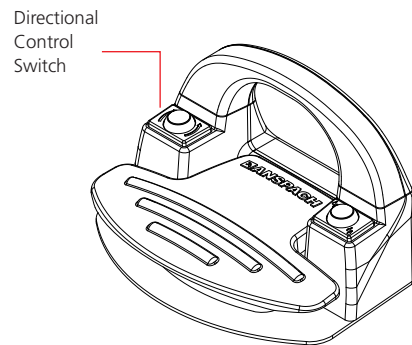
3. Press on foot control pedal to start handpiece. Increase pressure on pedal to increase speed of handpiece and release pressure on pedal to decrease speed of handpiece.
4. Optional: To change direction of handpiece, depress Directional Control Switch located on top left of foot control for a minimum 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.



EMAX2-FP or EMAX2PLUS-FP Foot Control



E-FP Foot Control



E-FP-DIR Foot Control

Hand Control Assembly and Operation

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

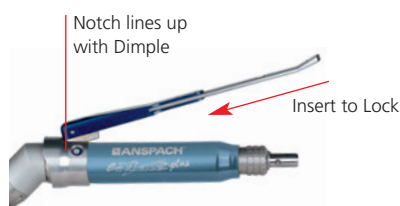
Warning: Do not expose handpiece to magnets (such as laying handpiece on magnetic drapes) when in hand control mode, as handpiece operation may occur.

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 startup 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.



eMax2-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

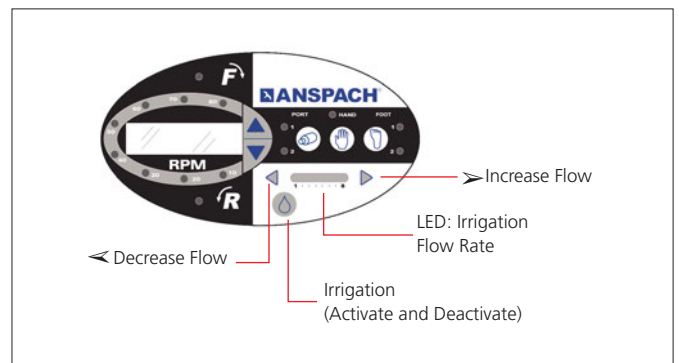
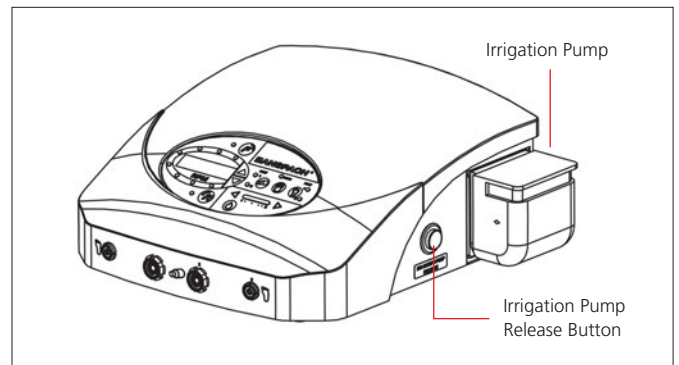
1. Lift top of pump head and insert large diameter tubing. Refer to diagram on irrigation pump housing to ensure tubing is routed properly (smaller diameter tubing flows towards Synthes Anspach handpiece housing).
2. Close lid on pump head.
3. Insert bayonet end of tubing into irrigation bag.

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 "Ordering Information" 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 Hose Clips, 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.

Caution:

- Do not sterilize, and do not allow liquid into pump.
- Do not operate with pumphead open.
- Do not use eMax 2 or eMax 2 Plus with MS-OSC or MS-SAG. Attempting to do so will result in damage to the saws and possible damage to the eMax 2 and eMax 2 Plus Motors.

Warning:

- Irrigation tubing, attachment clip, and hose clip are for SINGLE USE ONLY.
- Avoid stacking or placing the eMax 2 and eMax 2 Plus System consoles near other electrical equipment. If the eMax 2 or 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 and eMax 2 Plus Systems are 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 and eMax 2 Plus must be maintained at all times. Never force the dissection tool. Let the instrument do the cutting.
- Only Synthes Anspach XMax/microMax/eMax cutting burrs should be used with the eMax 2/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 2.5 A, 250 V. Item to be replaced by Synthes Anspach 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 Synthes Anspach 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 Synthes Anspach 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 Synthes Anspach 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.

e12 Small Bone System Operating Instructions

E12 e12 Electric Handpiece
E12-HC e12 Hand Control

The e12 Handpiece is compatible with the SC2000, SC2000U, SC2100, SC2101, and SC2102 consoles. Refer to “eMax 2 and eMax 2 Plus Operating Instructions” section of this manual.

Upon startup, console is set at maximum speed, and display reads 12,000 rpm.

The following instructions are written such that the handpiece and attachment are held with distal end pointed away from the user.

1. Hold e12 handpiece with red dot on cable connector pointed up and plug into either port 1 or port 2 located on console panel.
 2. Gently push cable connector into console until fully seated. Do not force into console port.
 3. Activate console by depressing power switch located on back of console to “I” position. Appropriate face panel lights illuminate and a beep will sound.
-

Note: Handpiece is now fully functional.

microSaws Saw and Small Bone Attachment Assembly

1. Insert attachment drive shaft into distal end of e12 handpiece. Rotate until three tabs on attachment engage three slots in e12 handpiece.
2. Continue to rotate counterclockwise while pushing attachment into e12 handpiece until attachment locks into position and release ring snaps into position.
3. When fully engaged, contours on e12 handpiece body, release ring, and small attachment will align.

For specific attachment assembly, refer to “microSaws and Small Bone Attachments Assembly” section in this manual.

Optional e12 Hand Control Assembly and Operation

Optional Hand Control attachment for e12 handpiece allows user to control operation of handpiece with a lever attached to e12.

1. To attach Hand Control, hold handpiece in one hand with the distal end pointed away.
 2. Hold Hand Control lever at U-shaped end with two fingers and snap onto notches at back of handpiece.
 3. Upon console startup Hand Control is OFF. LED is not illuminated.
 4. To activate Hand Control, depress “Hand” button on console face panel. This deactivates Foot Control; “Hand” LED on console face panel illuminates.
 5. Apply pressure on Hand Control to operate handpiece.
-

Note: Handpiece is now fully functional.

6. To deactivate Hand Control, depress “Foot” button on console face panel or flip lever backward 180°.
7. To remove Hand Control from handpiece, first deactivate Hand Control on console, then hold proximal end of Hand Control lever and pull off.

E12 Duty Cycle

30 Sec ON, 30 Sec OFF for 8 cycles.

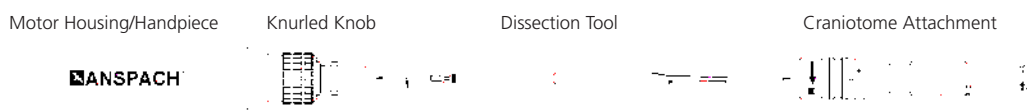
The recommendations for times of use for the E12 attachments have been determined under average load and worst case ambient air temperature of 85 °F (29 °C).

Standard Attachments and Dissection Tool Assembly

Straight Attachment Assembly



Craniotome Attachment 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

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" (☑), "LOAD" (☒) and "SAFE") refer to locking and unlocking the attachment and dissection tool onto the handpiece.

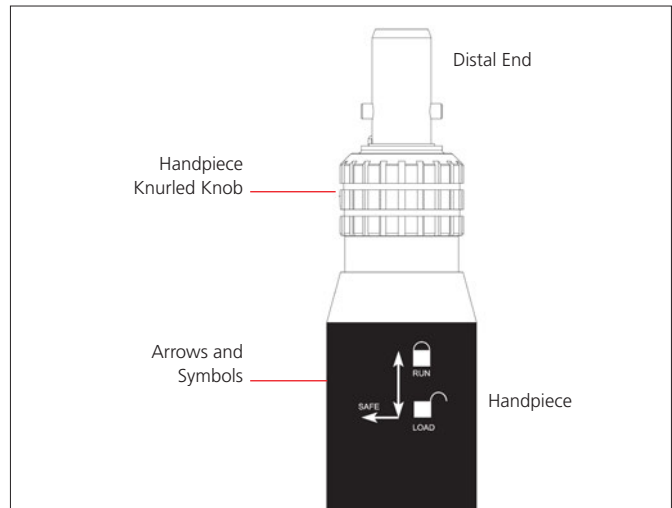
1. Move handpiece knurled knob to "RUN" (☑) position.
2. Slide attachment over distal end of handpiece. Pull attachment towards handpiece, and rotate attachment to right approximately one-quarter turn until fully seated. Handpiece knurled knob moves up to seat next to attachment.
3. Pull handpiece knurled 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" (☑) position.

Note: Handpiece is now fully functional.

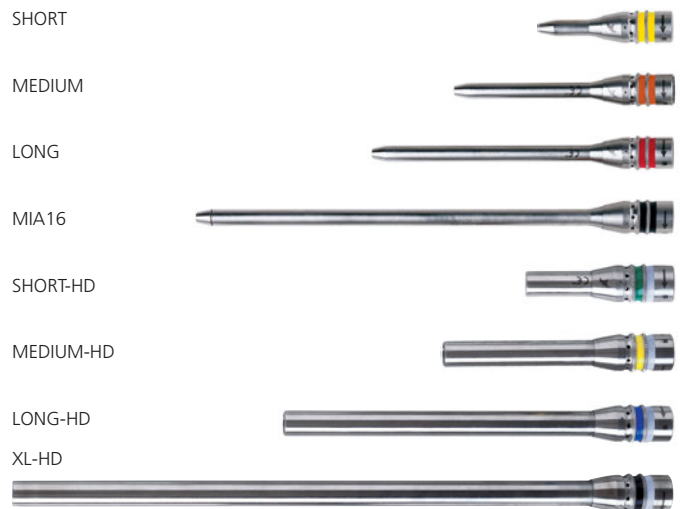
5. Pull dissection tool to ensure proper engagement.
6. Attachment and dissection tool are secure.

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° Contra 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.
4. 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-45



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" (☑) 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" (☑) 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.

CRANI-P



CRANI-A



CRANI-L



CRANI-A-R



ADG



CDA



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.

QD8



QD11



QD14



Micro Dissection Attachment

MDA Micro Dissection Attachment



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

1. Hold MDA by drive shaft. Insert dissection tool into MDA attachment until dissection tool seats in attachment. (Drops slightly proximally and stops rotating.) This is best accomplished by pushing slightly while rotating.
2. Pull dissection tool to ensure proper engagement.
3. Move handpiece knurled knob to "RUN" (■) position.
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.

Note: Handpiece is now fully functional.

Disassembly

1. Move handpiece knurled knob to "SAFE" position.
2. Slowly rotate dissection tool in alternating directions while removing distally.
3. Rotate attachment to left approximately one-quarter turn and remove from distal end of handpiece.

Warning: The Micro Dissection Attachment is 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.

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 and 15 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 hand-piece and attachment are pointed away from user.

eMax Driver Installation

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.

MA-D20



MA-DRIVER



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".
2. 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".

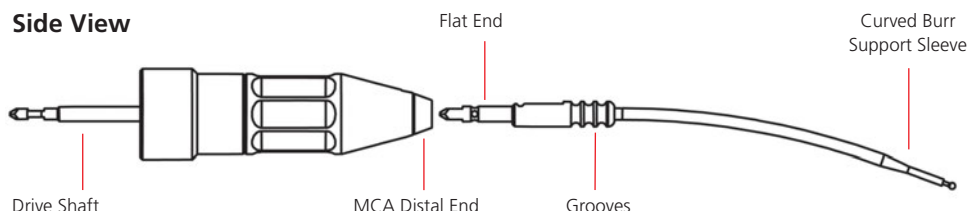
Bearing Sleeve Disassembly

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

Micro Curved Attachment (MCA) and Curved Burr Support Sleeves (Curved Burr)

Micro Curved Attachment Assembly

Side View



The Micro Curved Attachment (MCA) accepts Curved Burr Support Sleeves which are available in various dissection tool styles.

The Curved Burr Support Sleeve (Curved Burr) consists of the dissection tool and an outer sleeve that protects and supports the rotating shaft of the dissection tool.

The MCA and Curved Burrs are intended for surgical bone cutting and shaping procedures.

The MCA and Curved Burrs are recommended to be used primarily in otology procedures for delicate bone dissection such as a cochleostomy.

Warning: It is not intended for gross bone removal. Heavy loading and/or lack of irrigation while performing bone dissection may result in burr fracture.

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

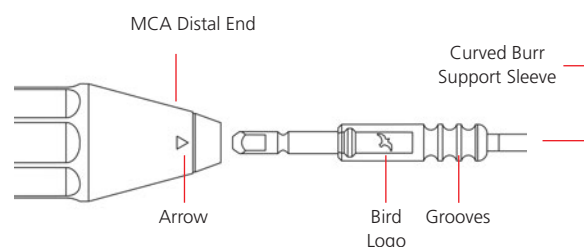
MCA Assembly

MCA Micro Curved Attachment

1. Ensure handpiece knurled knob is in "RUN" (■) position.
2. Insert MCA's drive shaft 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 MCA.
3. Gently twist back and forth to ensure MCA is locked into position.

Curved Burr Support Sleeve Assembly

Top View



1. Line up arrow located on the distal end of MCA with flat end (bird logo) of Curved Burr, push until fully seated. Listen for a click (see illustration).
2. Gently pull Curved Burr to ensure it is locked into position.

Curved Burr Support Sleeve Disassembly

1. Remove Curved Burr from distal end of MCA by grasping Curved Burr at grooves (see illustration).

MCA Disassembly

1. Move handpiece knurled knob to "SAFE" position.
2. Rotate MCA to left approximately one-quarter turn, and remove from distal end of handpiece housing.

microSaws and Small Attachments Assembly

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

DRIVER



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" (■) 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 or distal end of e12 handpiece. Rotate until three tabs on attachment engage three slots in keyless driver or e12 handpiece.
2. Continue to rotate counterclockwise while pushing attachment into keyless driver or e12 handpiece until attachment locks into position and release ring snaps into position. When fully engaged, contours on keyless driver body or e12 handpiece, release ring, and saw attachment will be in alignment.

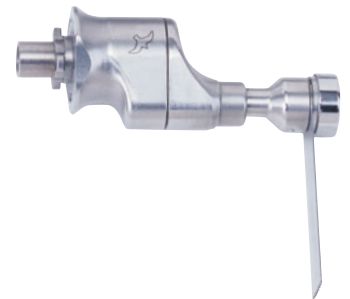
S-SAW



R-SAW



O-SAW



Oscillating Saw Blade Assembly

1. Press down on release button to open saw blade mounting plates.
2. 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.

J-Latch and Jacobs Chuck Small Attachments Assembly


E12	e12 Electric Handpiece
DRIVER	Keyless Driver
SA-JLATCH	Small Attachment, J-Latch
SA-JACOBS	Small Attachments, Jacobs Chuck

Note: Anspach 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 or distal end of e12 handpiece. Rotate until three tabs on attachment engage three slots in keyless driver or e12 handpiece.
2. Continue to rotate counterclockwise while pushing attachment into keyless driver or e12 handpiece until attachment locks into position and release ring snaps into position.
3. When fully engaged, contours on keyless driver body or e12 handpiece, 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.


SA-JLATCH



SA-JACOBS




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 or e12 handpiece with other hand counterclockwise until attachment is released.

Sagittal Saw

Electric High Power Sagittal Saw

E-SAGITTAL High Power e-Sagittal Saw

The Electric High Power Sagittal Saw is compatible with the SC2000, SC2000U, SC2101, and SC2102 consoles. Refer to eMax 2 and eMax 2 Plus Operating Instructions section of this manual.

1. Connect the Electric Sagittal Saw control cable to the proximal end of the saw attachment. Align the red dots on the connectors and gently push the cable connector into the saw connector until fully inserted.
2. The saw may be connected to either handpiece connector port on the console. Hold connector with red dot at the top of the connector. Gently push the cable connector into the handpiece connector port until fully inserted.
3. Depress the handpiece icon button on the console display until the desired handpiece port is indicated as active.
4. To remove the cable from the Sagittal Saw and console, grasp ridged portion of connector between thumb and forefinger of one hand. Gently pull the connector away from the console (or saw). 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 this will result in damage to the cable.

Note: The Foot Control must be connected to the System Console. See Foot Control Operating Instructions in the eMax 2 and eMax 2 Plus section of this manual.

Saw Blade Assembly

1. Raise and fully extend the extension handle on the saw blade attachment mechanism.
2. Rotate the extension handle counterclockwise to open the saw blade mounting plates.
3. Insert the saw blade into the opening and align the saw hub with the locking pins in the mounting plates. The blades can be aligned in 45° increments.
4. Rotate the extension handle clockwise to secure the saw blade and lower the handle into its closed position.

Note: Saw blades used must be Synthes Anspach blades.

Warning: All microSaw blades are for single use only.

Note: Electric High Power Sagittal Saw is now fully functional.



Compact SpeedReducer

Compact SpeedReducer

CSR60 Perforator Driver with Hudson End

This Perforator Driver attachment allows Hudson style cranial perforators to be used with the eMax 2 and eMax 2 Plus (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.
3. 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 Compact SpeedReducer is to prevent damage to the shaft.
 - The cap is removed for cleaning and washing but replaced for sterilization.
 - The device may be sterilized without the red storage cap.
-



Inspection and Maintenance

Perform these activities regularly as per institution policy.

Warning: Do not use any damaged equipment. Return to Synthes Anspach repair facility.

Attachments

Straight Attachments

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

Visually inspect for any damage to the tube.



Angle Attachments

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

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



Craniotomes

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

Visually inspect for bent or broken foot.



Specialty Attachments

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

Visually inspect for overall damage or missing components.



CSR60

Foot Controls

- E-FP
- E-FP-DIR
- E-FP-DIR/IRR
- EMAX2-FP
- EMAX2-FP-NS
- EPLUS-FP
- EPLUS-FP-NS

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



E-FP

Hand Controls

- E-HC
- EMAX2-HC

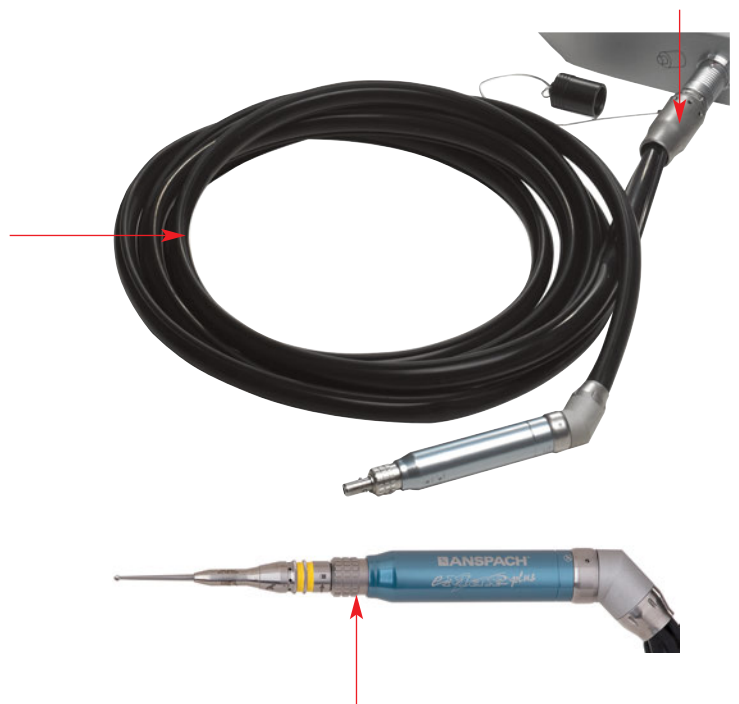
- **Visually inspect for damage to the levers.**
- **Visually inspect for presence of magnet on the lever mechanism.**



Handpiece

- E12
- EMAX2
- EMAX2PLUS

- **Ensure that the knurled 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.




Consoles

- SC2000
- SC2000U
- 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.**

If the irrigation flow LED display is not on, press the Drop button. 



Manual Cleaning Procedure

Operating Room (OR) Personnel Instructions

After completion of the procedure, remove external debris by wiping of the Attachments and Handpiece.

Cleaning and Processing Personnel Instruction

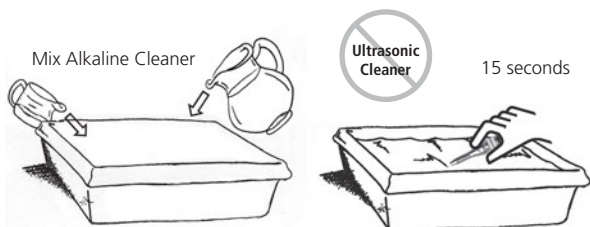
Attachments

Warning: Wear eye protection.

Note: "DO NOT IMMERSE" as marked on attachments is for OR personnel only. Please note that the use of an alkaline detergent can cause the handle color to fade. This does not impair function, however. The maximum pH value is 11.

Caution: Do not use ultrasonic equipment or corrosive or harsh chemical soaps. Do not rinse attachment with saline solution.

1. Remove the attachment and dissection tool from the handpiece.
2. 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.



Item Numbers 3 and 4 refer only to the Straight, Craniotome, Specialty, and QD Angle Attachments. For any other attachments, proceed to Item Number 5.

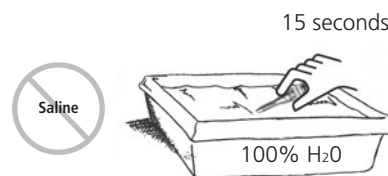
3. Gently insert and remove Synthes Anspach Attachment Cleaning Brush (ACB) wetted with cleaning solution through the distal or proximal opening of the attachment as many times as necessary to remove any foreign debris.

Caution: DO NOT insert anything into the attachment except the ACB as specified. Do not use with MA-D20 and MA-DRIVER.

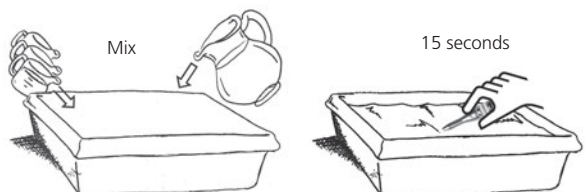
DO NOT FORCE the brush into or through the attachment. ACB is to be utilized once per system set and discard once the system cleaning is complete.



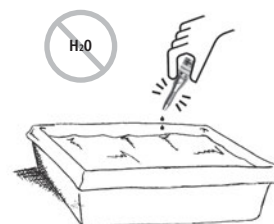
4. Remove the brush (ACB).
5. Rinse the attachment in a suitable container filled with deionized, distilled, or purified water and agitate for 15 seconds.



6. Repeat Step 2–3 if there is evidence of soils or residuals on the attachment surface or the ACB.
7. 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.



8. Remove the attachment and allow it to drain until no visible droplets are coming from it.
 - a. **DO NOT** rinse out instrument milk (lubricant).
 - b. **DO NOT** apply mineral oil or other lubricants, which may cause the attachment to overheat.



Minimal Access Attachment Bearing Sleeves

Follow the Attachment cleaning protocol for the bearing sleeves. The Minimal Access Attachment Bearing Sleeves are non-repairable. Reuse until bearing wear is detected and then replace. No bearing sleeve service or repair will be provided.

Dissection Tools

Warning: Disposable. Single use only.

Electric Console and Foot Control

Caution: DO NOT IMMERSE OR STERILIZE! DO NOT allow liquid to enter console or foot control.

1. Disconnect all power from console.
2. Clean console, foot control, and irrigation pump by wiping with non-abrasive cloth and disinfectant or mild detergent and water after each case.
3. Dry thoroughly with non-abrasive cloth.

Electric High Power Sagittal Saw

Caution: DO NOT IMMERSE! DO NOT allow liquid to enter Electric High Power Sagittal Saw.

1. Disconnect from console.
2. Wipe with non-abrasive cloth and disinfectant or mild detergent and deionized, distilled, or purified water.
3. Dry thoroughly with non-abrasive cloth.

Handpieces

Warning: Wear eye protection.

Caution: 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.

Prior to sterilization, wipe with a clean, water-dampened cloth and mild detergent (neutral pH) until no evidence of soil is found.

Silicone Spray or Instrument Milk may be added to lubricate the handpiece knurled knob.

Silicone spray may be used on the hose to prolong its flexibility and to facilitate foreign particle removal.

The handpiece should be tested by running it with an attachment and dissection tool prior to every use for one minute to ensure proper operation. If the distal tip and main body of the handpiece are uncomfortably hot to the touch, return the instrument to Synthes Anspach for servicing.

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

Sterilization Trays

Sterilization trays can be cleaned with deionized, distilled, or purified water and a mild detergent.

Mechanical Cleaning

For mechanical cleaning instructions, see information supplied with appropriate cleaning and sterilization basket for instruments being cleaned.

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

Contact your Sales Representative for replacement of product incinerated under this policy or for temporary equipment while original equipment is quarantined. Contact the Synthes Anspach Customer Service Department regarding TSE/CJD contamination for additional information.

Sterilization

Console and Foot Control

Caution: The eMax Console and Foot Control should not be sterilized.

Irrigation Pump

Caution: The Irrigation Pump should not be sterilized.

Handpieces and Attachments

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 Synthes Anspach's 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.

Caution: Place attached protective cap over electrical connector on Synthes Anspach handpiece prior to sterilization.

Before sterilizing: Ensure sterilization equipment is in proper working order as specified by the 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.

Synthes Anspach 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 the 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.

Recommended Sterilization Exposure Times

1. Steam Autoclave/Gravity Air Displacement
132 °C (270 °F)
15 minutes wrapped or unwrapped
30 minute dry time
2. Steam Autoclave/Prevacuum
132 °C (270 °F)
3 minutes wrapped or unwrapped
30 minutes dry time

Warranty. It is recommended a drying cycle be included to avoid possible adverse effects caused by exposure to condensation.

Process parameters which include higher temperatures up to 138 °C (280 °F) up to 15 minutes do not affect the performance of the product.

Electrical Systems (eMax 2, eMax 2 Plus and e12)

Problem	Possible Cause	Solution
Excessive handpiece noise	Faulty internal component	Return to Synthes Anspach for service
Lack of power to console	Plug is not fully inserted/power switch not turned on	Verify plugs to wall and back of console are pushed in completely and power switch is in "I" position.
	Outlet is not functional	Verify another piece of electrical equipment can receive power from outlet.
Handpiece vibration or extremely hot	Faulty internal component	Return to Synthes Anspach for service.
	Internal motor overheats due to continuous extreme cutting at near stalling conditions	Console will shut handpiece off. If it continues to shut off during normal cutting, return to Anspach for service.
	Hose may be kinked	Unkink hose (verify it is not being pinched or clamped to table).
	Handpiece out of balance	Return to Synthes Anspach for service.
	Handpiece hose damaged	Return to Synthes Anspach for service.
Excessive vibration of cutting burr	Cutting burr may be bent	Replace with new eMax 2/eMax 2 Plus cutting burr.
	Cutting burr may not be fully seated	Reassemble cutting burr and attachment.
	Improper attachment and cutting burr combination	Only use correct cutting burr with appropriate attachment.
	Possible attachment bearing damage	Return attachment to Synthes Anspach for service.
Attachment is hot	Debris lodged inside attachment	Clean attachment using Synthes Anspach Attachment Cleaning Instructions located in this manual.
	Possible bearing damage	Return attachment to Synthes Anspach for service.
Craniotome attachment is bent	Excessive force used in operation	Do not use, replace attachment.

Problem	Possible Cause	Solution
Inoperative Foot Control (LEDs are illuminated on face panel)	Selected foot control on face panel does not match foot control in use	Press Foot Control button on face panel to select other Foot Control.
	System is set in hand control mode (LED light is illuminated)	Press Foot Control button on face panel to set it for Foot Control 1 or 2, depending which one is in use.
	Plugs may not be fully inserted	Verify plugs for handpiece and foot control are fully inserted. Plug will latch in place once fully inserted.
	Handpiece is in "Safe" position or cutter is not rotating	Verify cutter is completely engaged and handpiece's knurled knob is in secure position.
	Defective attachment	Clean attachment or replace attachment.
Inoperative Hand Control	Defective internal component	Return to Synthes Anspach for service.
	Hand Control Attachment may not be fully installed	The circumferential groove on handpiece housing will be exposed when the Hand Control is fully installed.
	Selected Hand Control on face panel is not in use	Press Hand Control button on face panel to illuminate Hand Control LED.
	Internal handpiece switch activating Hand Control may be damaged	Return to Synthes Anspach for service.

Ordering Information

Anspach Attachments

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
MCA	Micro Curved Attachment
ORANGE-45	45° Contra Angle Attachment
ORANGE-90	90° Contra 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
EMAX2-HC	Hand Control
E12	e12 Electric Handpiece
E12-HC	e12 Hand Control

Electric Instrument System Accessories

EMAX2-TRAY	Sterilization Case and Tray
05.001.100	Cart
MERET	Equipment Tray

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. Please contact your local Sales Representative.



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All technique guides are available as PDF files at
www.synthes.com/lit

