

<p>NOTE: This portion of the document should not appear on produced Labels or IFUs.</p> <p>Stryker Instruments (269) 323-7700 (800) 253-3210</p>	<p><u>Dimensions:</u> 6 inch (width) x 6 inch Booklet</p>	<p><u>Color/Material/Finish:</u> Color Graphics on White Background 20# Bond or Equivalent</p>	<p><u>Label Stock:</u> N/A</p>	
	<p><u>Print Location:</u> Print Center</p>	<p><u>Suppliers/Services:</u> N/A</p>	<p><u>Description/Type:</u> Instructions For Use</p>	
			<p><u>Part Number:</u> 6208-001-701</p>	<p><u>Rev.</u> E</p>

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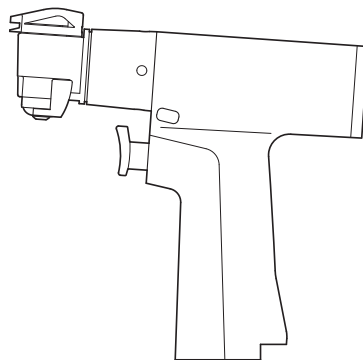
System 6 Sagittal Saw

REF 6208-000-000

Instructions For Use

R_x ONLY

CE 0197



ENGLISH (EN)

Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the safe and effective use of your product. This manual may be used by in-service trainers, physicians, nurses, surgical technologists, and biomedical equipment technicians. Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

For additional information, especially safety information, or in-service training, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

Indications For Use

The Stryker System 6 Battery Powered Heavy Duty Sagittal Saw is an oscillating cutting device used for cutting bone and bone related tissue.

Contraindications

None known.

User/Patient Safety



WARNINGS:

- Only trained and experienced healthcare professionals should use this equipment. Before using any system component or any component compatible with this system, read and understand the instructions. Pay particular attention to WARNING information. Become familiar with the system components prior to use.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique used for each patient. Stryker, as a manufacturer, does not recommend surgical procedure or technique.
- Upon initial receipt and before each use, operate the equipment and inspect each component for damage. DO NOT use any component if damage is apparent.
- Perform recommended maintenance as indicated. Only trained and experienced healthcare professionals should maintain this equipment. See the care instructions manual supplied with the equipment.

- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen, or nitrous oxide.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like the handpiece. Install and place the handpiece into service according to the EMC information in this manual. Portable and mobile RF communications equipment can affect the function of the handpiece.
- ALWAYS use Stryker sagittal saw blades with this handpiece.
- DO NOT reuse, reprocess, or repackage single use cutting accessories. All cutting accessories are intended for a single use only. Reuse may create a serious risk of contamination and lead to infection or cross-infection. Reprocessing may compromise the structural integrity of the cutting accessory and result in fragmentation during use. Critical product information may be lost if the cutting accessory is repackaged.

NOTE: For a complete list of accessories, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

The following Stryker-approved accessories are sold separately:

Accessories



WARNINGS:

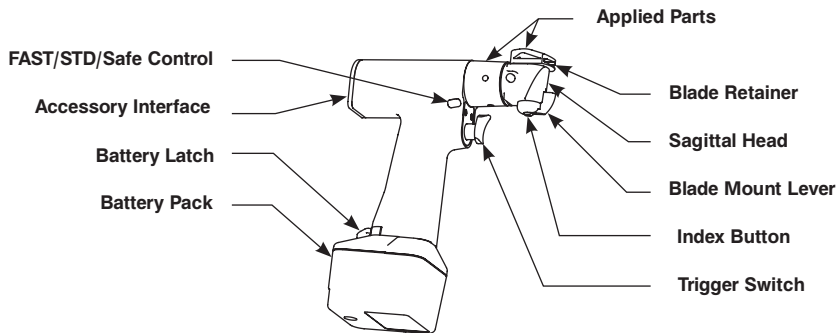
- Use only Stryker-approved system components and accessories, unless otherwise specified. Using other accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system. DO NOT modify any system component or accessory.

DESCRIPTION	REF
System 6 Aseptic Battery Kit, Large	6126-000-000
System 6 Battery Pack, Large	6215-000-000

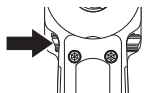
Features

Handpiece

- **Battery Latch** - To release the battery pack from the handpiece, depress the battery latch.
- **Battery Pack** - Rechargeable battery pack that provides power to the handpiece.
- **Index Button** - To allow the indexing of the sagittal head, push the index button.
- **Blade Mount Lever**- Rotate the lever to the LOAD or RUN position to install or lock the blade into place.
- **Blade Retainer** - The retainer holds the blade.
- **Sagittal Head** - The sagittal head may be indexed in 45-degree increments and can turn in a complete 360-degree rotation to achieve the desired cutting angle.
- **Trigger Switch** - The trigger is pressure sensitive for variable speed operation.
- **FAST/STD/Safe Control** - Based on its position, allows the handpiece to operate in the FAST or STD mode; the safe mode position prevents inadvertent operation of the handpiece.
- **Accessory Interface** - Connector provides power and communication for future accessories.
- **Applied Parts** - The distal end of the handpiece (as defined by the standards listed in the *Specifications* section under *Product Safety Certification*).



FAST/STD/Safe Control



FAST Mode – Slide the FAST/STD/ Safe control to the FAST mode position to allow the handpiece to operate at high torque and high speed when the trigger is depressed.




STD Mode – Slide the FAST/ STD/ Safe control to the STD (standard) mode position to allow the handpiece to operate at high torque and standard speed when the trigger switch is depressed.





Safe Mode – Slide the FAST/STD/ Safe control to the safe mode position to lock the trigger and prevent inadvertent operation of the handpiece; the handpiece cannot be operated.

Definitions

The symbols located on the equipment and/or labeling are defined in this section or in the Symbol Definition Chart. See the *Symbol Definition Chart* supplied with the equipment.

SYMBOL	DEFINITION
Fast ▶▶	FAST Mode
◀▶ Std	STD Mode
	General warning sign

SYMBOL	DEFINITION
LOAD	LOAD
RUN	RUN
	ARROW - Rotate the blade mount lever to the RUN position to lock the blade.
	Per European Union Directive 2012/19/EU, product must be collected separately. Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information.

Instructions

To Install Cutting Accessory



WARNING: To prevent the inadvertent running of the handpiece, ALWAYS place the FAST/STD/safe control in the safe mode position before installing or removing any accessory.

1. Slide the FAST/STD/Safe control to the safe mode position.
2. Rotate the blade mount lever to the LOAD position.
3. Hold the handpiece in a vertical orientation with the sagittal head and blade entry slot facing up. (See figure 1).
4. Insert the blade into the slot. Ensure the full insert line of the blade disappears in the blade retainer indicating the blade is positioned properly.

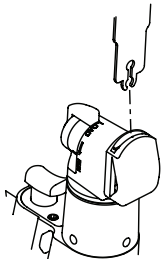


Figure 1 – To Install Blade Rotate the Lever

5. Rotate the blade mount lever to the RUN position while maintaining the vertical orientation of the handpiece to lock the blade.
6. Gently tug the blade to ensure it is secure.

To Index Sagittal Head

CAUTION: Before operating the handpiece, ensure the sagittal head is locked into position. Failure to comply may result in product damage.

NOTE: The sagittal head has eight possible cutting angle positions (45-degree increments).

1. Push and hold the index button; rotate the sagittal head to the desired cutting angle (see figure 2).

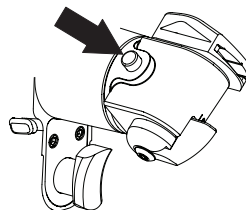


Figure 2 – To Index Head Push the Button

2. Once the sagittal head is positioned, release the index button, and gently turn the sagittal head to ensure it is locked into position.

To Install Battery Pack

NOTES:

- This handpiece is designed to accept the Stryker Large Battery Pack (REF 6215-000-000) or the Large Aseptic Battery (REF 6126-000-000). These battery packs can be charged in the Stryker System 6 Battery Charger (REF 6110-120-000) or the Universal Battery Charger (REF 7110-120-000) configured with the appropriate battery charger module.
 - See the instructions for use supplied with the battery charger and/or battery pack for charging details and specifications.
1. Slide a fully charged battery pack firmly into the handpiece until the battery latch snaps, indicating the battery pack is secure (see figure 3).

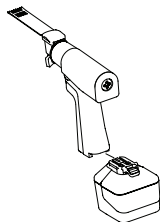


Figure 3 – Install Battery Pack

2. Test the operation of the handpiece by sliding the FAST/STD/Safe control to the FAST or STD mode position and squeezing the trigger.

3. Slide FAST/STD/Safe control to the safe mode position until you are ready to use the handpiece.

To Operate Handpiece



WARNINGS:

- ALWAYS place the FAST/STD/Safe control in the safe mode position while the handpiece is idle, before installing or removing any accessory, or when passing the handpiece to another person.
- DO NOT apply excessive pressure, such as bending or prying, with a cutting accessory to prevent fracturing the accessory.

CAUTIONS:

- When operating the handpiece, let the blade do the cutting. Applying too much pressure will bend the blade and reduce the cutting quality.
- DO NOT stall the handpiece. Failure to comply may damage the electric motor and/or battery pack. If the handpiece jams, release the trigger immediately. Remove any obstructions before continuing the procedure.
- If any power loss is experienced while using a handpiece, ALWAYS replace the battery pack with a fully charged battery pack. Failure to comply may result in a drained or damaged battery pack with a shortened life.

To Operate Handpiece (continued)

1. Slide the FAST/STD/Safe control to the FAST or STD mode position to allow the handpiece to operate.
2. Squeeze the pressure sensitive trigger for variable speed operation.
3. Slide the FAST/STD/Safe control to the safe mode position when you are finished operating the handpiece.

To Remove Battery Pack

Depress the battery latch and pull the battery pack out.

To Remove Cutting Accessory

Rotate the blade mount lever to the LOAD position and remove the blade.

Troubleshooting



WARNING: DO NOT disassemble or service this equipment.

NOTE: For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

PROBLEM	CAUSE	ACTION
Handpiece does not run or oscillates at a reduced speed making cutting difficult.	Battery pack is discharged.	Recharge the battery pack in Stryker charger.
	FAST/STD/Safe control is in STD mode position.	Set the FAST/STD/Safe control to the FAST mode position.
	Battery pack is expended.	Replace the battery pack.
	FAST/STD/Safe control is in the safe mode position.	Set the FAST/STD/Safe control to the FAST or STD mode position.
	Drivetrain is malfunctioning.	Return the handpiece for repair.

PROBLEM	CAUSE	ACTION
Motor runs but blade does not move.	Drivetrain is malfunctioning.	Return the handpiece for repair.
Battery pack becomes unusually hot during use.	Circuitry is malfunctioning.	Check the battery pack on the charger. Replace the battery pack if required. See the instructions for use supplied with the battery charger.
Blade will not fit into the blade retainer or cannot be secured.	Debris is inside the end of the blade retainer.	Clean the handpiece with a small brush.
	Blade is not a Stryker product.	Use a Stryker blade.
	Blade retainer is damaged.	Return the handpiece for repair.
Handpiece has become noisy and vibrates.	Blade is not a Stryker product.	Use a Stryker blade.
	Drivetrain is malfunctioning.	Return the handpiece for repair.
Sporadic electrical interference is experienced.	Electrical noise is present.	Turn off all electrical equipment not in use in the operating room.
		Relocate electrical equipment; increase spatial distance.
		Plug operating room equipment into different operating room outlets.

Care Instructions


For processing instructions and disposal/recycle information, see the care instructions manual supplied with the equipment.

Specifications



WARNING: ALWAYS check any documentation that accompanies attachments, burs, pins, and/or blades for special duty cycle and usage instructions.

NOTE: Specifications are approximate and may vary between devices or as a result of power supply fluctuations.

Model:	System 6 Sagittal Saw (REF 6208-000-000)
Dimensions:	8.5 inch [216 mm] height (with large battery pack) 1.5 inch [38 mm] width 6.4 inch [163 mm] length
Mass:	3.5 lb [1.58 kg] (with large battery pack)
Speed:	12,000 cycles per minute (FAST mode); 10,000 cycles per minute (STD mode)
Excursion:	5-degree arc
Mode of Operation:	Non-continuous Operation
Duty Cycle:	1 minute on/4 minutes off, 5 times
Rest Between Cycles:	3 hours
Equipment Type:	 Type BF Applied Part
Maximum Temperature of Applied Parts:	Less than 124 °F [51 °C] (Maximum surface temperature as tested to the standards listed under <i>Product Safety Certification</i> .)
Power Supply:	Internally Powered 9.6 V --- (Direct current)
Ingress Protection:	IPX0 Ordinary Equipment

**Product Safety
Certification:**

CSA International

International Electrotechnical Commission

IEC 60601-1:2005, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*; IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007)

IEC 60601-1:1988, *Medical Electrical Equipment – Part 1: General Requirements for Safety - Second Edition*; Amendment 1 (1991); Amendment 2 (1995); Corrigendum 1 (1995)

Canadian Standards Association

CAN/CSA-C22.2 No. 60601-1:08, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*

CAN/CSA-C22.2 No. 601.1-M90, *Medical Electrical Equipment – Part 1: General Requirements for Safety*

**American National Standards Institute / Association for the Advancement of
Medical Instrumentation**

ANSI/AAMI ES60601-1:2005, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*; Consolidated Reprint (2009); Amendment 2 (2010)

Underwriters Laboratories

UL 60601-1, *Medical Electrical Equipment, Part 1: General Requirements for Safety – First Edition*; Revisions through and including April 26, 2006

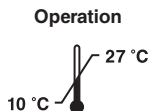
European Committee for Electrotechnical Standardization (CENELEC)

EN 60601-1:2006, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*; IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010)

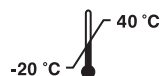
Specifications (continued)

Environmental Conditions:

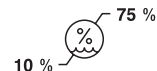
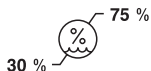
Temperature Limitation:



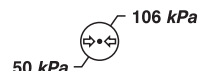
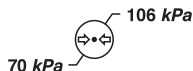
Storage and Transportation



Humidity Limitation:



Atmospheric Pressure Limitation:




Guidance and manufacturer's declaration - electromagnetic emissions

The System 6 Sagittal Saw (REF 6208-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 6 Sagittal Saw (REF 6208-000-000) should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The System 6 Sagittal Saw (REF 6208-000-000) 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	Class B	The System 6 Sagittal Saw (REF 6208-000-000) is suitable for use in all establishments other than domestic 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	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration - electromagnetic immunity			
The System 6 Sagittal Saw (REF 6208-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 6 Sagittal Saw (REF 6208-000-000) should assure that it is used in such an environment.			
Immunity test	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	N/A	N/A
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	N/A	N/A
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.

NOTE: U_T is the alternating current mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity			
The System 6 Sagittal Saw (REF 6208-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 6 Sagittal Saw (REF 6208-000-000) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	<p>Portable and mobile RF communications equipment should be used no closer to any part of the System 6 Sagittal Saw (REF 6208-000-000), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance: $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>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 meters (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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  (Non-ionizing electromagnetic radiation)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

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 System 6 Sagittal Saw (REF 6208-000-000) is used exceeds the applicable RF compliance level above, the System 6 Sagittal Saw (REF 6208-000-000) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System 6 Sagittal Saw (REF 6208-000-000).

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

Recommended separation distances between portable and mobile RF communications equipment and the System 6 Sagittal Saw (REF 6208-000-000)

The System 6 Sagittal Saw (REF 6208-000-000) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System 6 Sagittal Saw (REF 6208-000-000) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System 6 Sagittal Saw (REF 6208-000-000) as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	N/A	0.12	0.23
0,1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

ES/DE/FR/IT/NL	6208-001-711
JA/ZH/KO	6208-001-721
SV/DA/FI/PT/NO	6208-001-731
PL/EL/TR	6208-001-751



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