

<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><b><u>Dimensions:</u></b> 6 inch (width) x 6 inch Booklet</p>	<p><b><u>Color/Material/Finish:</u></b> Color Graphics on White Background 20# Bond or Equivalent</p>	<p><b><u>Label Stock:</u></b> N/A</p>	
	<p><b><u>Print Location:</u></b> Print Center</p>	<p><b><u>Suppliers/Services:</u></b> N/A</p>	<p><b><u>Description/Type:</u></b> Instructions For Use</p>	
			<p><b><u>Part Number:</u></b> 6209-001-708</p>	<p><b><u>Rev.</u></b> E</p>

**stryker**<sup>®</sup>

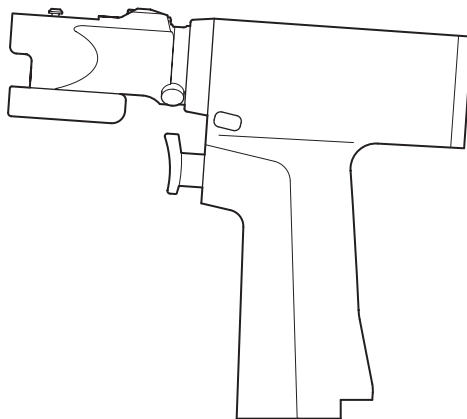
# System 6 Stryker Precision<sup>®</sup> Oscillating Tip Saw

REF 6209-000-000

Instructions For Use

**R<sub>x</sub> 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 Precision System is intended for use in the cutting and shaping of bone and other bone related tissue. The intended surgical applications are orthopedic surgeries involving the shoulder, hip, knee, and ankle.

## 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.
- Upon initial receipt and before each use, clean and sterilize the equipment as indicated. See the care instructions manual supplied with the equipment.
- 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.
  - DO NOT reuse, reprocess, or repackaged 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:

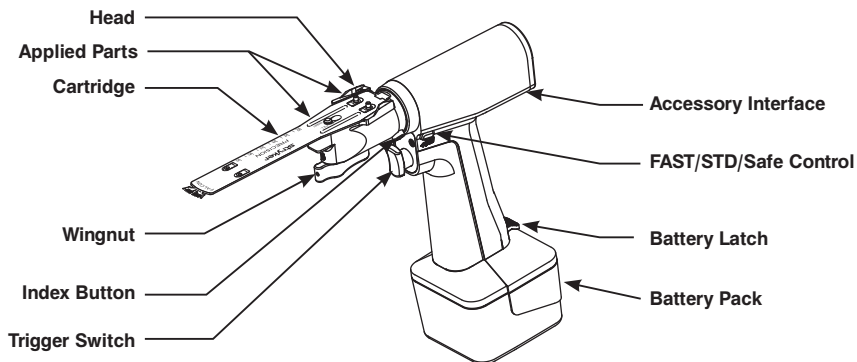
- Use only Stryker-approved system components and accessories, unless otherwise specified. Using other accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system. DO NOT modify any system component or accessory.
- ALWAYS use a Stryker Precision Oscillating Tip Saw Cartridge with this handpiece.

DESCRIPTION	REF
System 6 Aseptic Battery Kit, Large	6126-000-000
System 6 Battery Pack, Large	6215-000-000
Precision Oscillating Tip Saw Cartridges	6425-XXX-XXX series
	6525-XXX-XXX series
Precision Falcon® Oscillating Tip Saw Cartridges	6625-XXX-XXX series
	6720-XXX-XXX series
	6725-XXX-XXX series

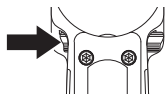
## Features

### Handpiece

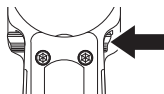
- **Battery Latch** - Depress the latch to release the battery pack from the handpiece.
- **Battery Pack** - Contains a rechargeable battery that provides power to the handpiece.
- **Head** - The head may be indexed in 45-degree increments and can turn in a complete 360-degree rotation to achieve the desired cutting angle.
- **Cartridge** - Single use, disposable cutting accessory with a stationary bar component and oscillating cutting tip.
- **Index Button** - Press to rotate and orient the position of the head as desired.
- **Wingnut** - Used to secure the cartridge to the handpiece.
- **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 and the cartridge (as defined by the standards listed in the *Specifications* section under *Product Safety Certification*).



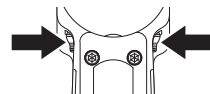
## FAST/STD/Safe Control



**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.





## Cartridge



**NOTE:** The incremental marks on the length of the cartridge are for reference only.

## 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
<b>Fast</b> ▶▶	FAST Mode
◀ <b>Std</b>	STD Mode
	CARTRIDGE LOCK
	CARTRIDGE UNLOCK
	General warning sign
	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



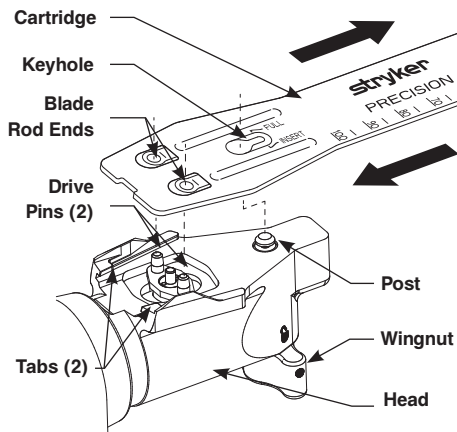
**WARNING:** ALWAYS place the FAST/STD/Safe control in the safe mode position while the handpiece is idle, before installing or removing any accessory or battery pack, or when passing the handpiece to another person.

### To Install the Cartridge



**WARNING:** ALWAYS install the cartridge with the FULL INSERT marking visibly facing up. Failure to comply may result in product damage and patient and/or healthcare staff injury.

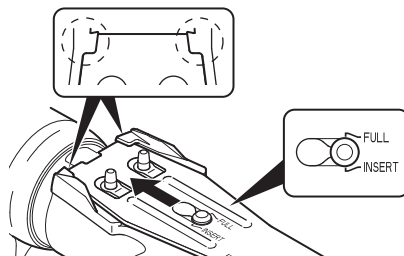
1. Slide the FAST/STD/Safe control to the safe mode position.
2. Rotate the wingnut to the UNLOCK position.
3. With the FULL INSERT marking visibly facing up, install the cartridge onto the head by aligning the blade rod ends with the drive pins on the head (see figure 1).



**Figure 1 – To Install Cartridge**

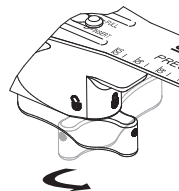
4. With the drive pins engaged in the rod ends, pull the cartridge away from the handpiece until the cartridge drops down onto the surface of the head. The post will pass through the large opening in the cartridge keyhole.

5. Guide the cartridge as it springs back toward the handpiece. Make sure the post is aligned with the FULL INSERT mark (see figure 2). The cartridge should be fully seated under the tabs on the head.



**Figure 2 – Align Post with FULL INSERT mark**

6. Rotate and align the wingnut dot with the LOCK symbol to secure the cartridge (see figure 3).



**Figure 3 – Rotate Wingnut to Lock**

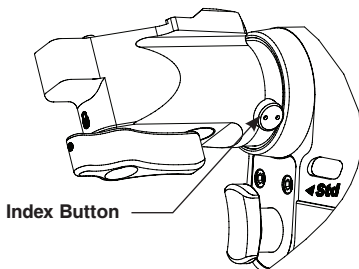


## To Index Sagittal Head

**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 4).



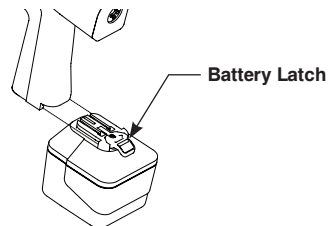
**Figure 4 – Push Button To Allow Head Rotation**

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) only. This battery pack 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 pack is secure (see figure 5).



**Figure 5 – Install Battery Pack**

2. Test the operation of the handpiece by sliding the FAST/STD/Safe control to either the FAST or STD mode position and squeezing the trigger.
3. Slide the FAST/STD/Safe control to the safe mode position until you are ready to use the handpiece.

## To Operate Handpiece



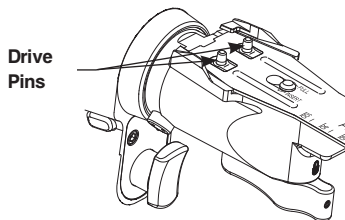
### WARNINGS:

- 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 place a hand on the drive pins located on the blade mount of the handpiece. Friction between the drive pins and hand may create heat.
- DO NOT apply excessive pressure, such as bending or prying, with a cutting accessory to prevent fracturing and/or excessively heating the accessory.

### CAUTIONS:

- 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.

1. Ensure the drive pins are free from all obstructions during operation (see figure 6).



**Figure 6 – Drive Pin Clearance**

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

## To Remove/Dispose of Cartridge



**WARNING:** ALWAYS place the FAST/STD/Safe control in the safe mode position before attaching or removing any accessory to prevent inadvertent running of the handpiece.

1. Slide the FAST/STD/Safe control to the safe mode position.
2. To unlock the cartridge, rotate the wingnut to the UNLOCK position. Pull the cartridge away from the head and lift the cartridge away from the handpiece (see figure 1).
3. Properly dispose of the single use cartridge.

## Battery Pack Removal

Depress the battery latch and pull the battery pack out of the handpiece.

## Care Instructions

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

## 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.
	Battery pack is expended.	Replace the battery pack.
	FAST/STD/Safe control is in the safe mode position.	Slide the FAST/STD/Safe control to the FAST or STD mode position.
	Cartridge is malfunctioning.	Replace the cartridge.
	Drivetrain is malfunctioning.	Return the handpiece for repair.
Motor runs but cartridge does not move.	Drivetrain is malfunctioning.	Return the handpiece for repair.
	Cartridge is malfunctioning.	Replace the cartridge.
Battery pack becomes unusually hot during use.	Circuitry is malfunctioning.	Check the battery pack on the Stryker charger and replace the battery pack if required. See the instructions for use supplied with the battery charger.
Handpiece has become noisy and vibrates.	Cartridge is not fully seated.	Reseat the cartridge.
	Cartridge is malfunctioning.	Replace the cartridge.
	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.

## 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.

<b>Model:</b>	System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000)
<b>Dimensions:</b>	8.9 inch [226 mm] height (with large battery pack) 1.6 inch [41 mm] width 7.2 inch [183 mm] length
<b>Mass:</b>	3.6 lb [1.63 kg] (with large battery pack)
<b>Speed:</b>	10,000 cycles per minute (STD mode); 12,000 cycles per minute (FAST mode)
<b>Excursion:</b>	12-degree arc
<b>Mode of Operation:</b>	Non-Continuous Operation
Duty Cycle:	1 minute on/4 minutes off, 5 times
Rest Between Cycles:	3 hours
<b>Equipment Type:</b>	 Type BF Applied Part
<b>Maximum Temperature of Applied Parts:</b>	Less than 124 °F [51 °C] (Maximum surface temperature as tested to the standards listed under <i>Product Safety Certification</i> .)
<b>Power Supply:</b>	Internally Powered 9.6 V --- (Direct current)
<b>Ingress Protection:</b>	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)**

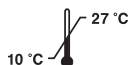
EN 60601-1:2006, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance*; IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010)

## Specifications (continued)

### Environmental Conditions:

Temperature Limitation:

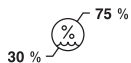
### Operation



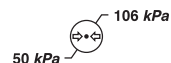
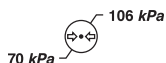
### Storage and Transportation



Humidity Limitation:



Atmospheric Pressure Limitation:



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


The System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) 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 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) 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 Harmonic emissions IEC 61000-3-2	Class B N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

<b>Guidance and manufacturer's declaration - electromagnetic immunity</b>			
The System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) 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 Stryker Precision Oscillating Tip Saw (REF 6209-000-000), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:  <math>d = 1.2\sqrt{P}</math> 80 MHz to 800 MHz  <math>d = 2.3\sqrt{P}</math> 800 MHz to 2,5 GHz</p> <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  <p>(Non-ionizing electromagnetic radiation)</p>
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.

<sup>a</sup> 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 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) is used exceeds the applicable RF compliance level above, the System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) 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 Stryker Precision Oscillating Tip Saw (REF 6209-000-000).

<sup>b</sup> 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 Stryker Precision Oscillating Tip Saw (REF 6209-000-000)**

The System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System 6 Stryker Precision Oscillating Tip Saw (REF 6209-000-000) 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	6209-001-710
JA/ZH/KO	6209-001-720
SV/DA/FI/PT/NO	6209-001-730
PL/EL/TR	6209-001-750



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