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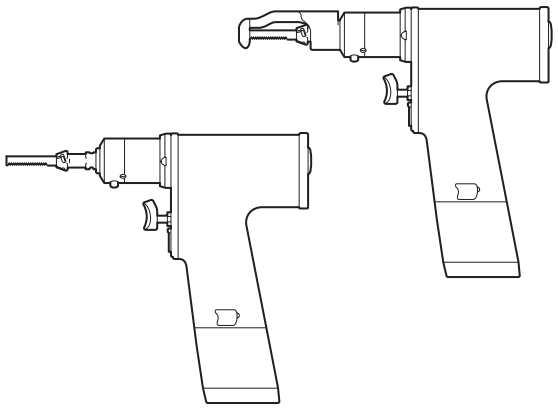
Orig.	Date	Approvals	Date	Mktg.	Date	Title	
	10/20/05	S/ P. Welch	8/26/05	S/ J. Lauria	9/14/05	Instructions For Use	
Q.A.	Date	Eng.	Date	Reg. Affairs	Date	Part No.	Rev-
S/ K. Cannan	9/12/05	S/ T. O'Keefe	9/1/05	S/ V. Franck	9/7//05	4207-001-703	C

IMPORTANT INFORMATION: File in your records

stryker SYSTEM 5

Recip/Sternum Saw

INSTRUCTIONS FOR USE **REF 4207**



stryker®

US Patents: 5,747,953;
6,001,115; 6,013,991

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10/05

4207-001-703 Rev-C

Important Information

WARNING - CAUTION - NOTE

Please read this manual and follow its instructions carefully. The words WARNING, CAUTION and NOTE carry special meanings and should be carefully reviewed.

WARNING: The personal safety of the patient and user may be involved. Disregarding this information could result in injury to the patient and/or user.

CAUTION: These instructions point out special service procedures or precautions that must be followed to avoid damaging the instrument.

NOTE: This provides special information to make maintenance easier or important instructions clearer.

An exclamation point within a triangle displayed on the product is intended to alert the user to the presence of important operating and maintenance instructions in this manual.

Intended Use

The Stryker System 5 Battery Powered Heavy Duty Recip/Sternum Saw is a linear cutting device used for cutting away bone and bone related tissue including the sternum.

Accessories

DESCRIPTION	REF
Battery Pack	4112, 4212, 4215, 4222, 4226
Sternum Blade Guard.....	4107-8

A list of cutting accessories is available from your Stryker Instruments sales representative.

*User/Patient Safety**

WARNINGS:

- Read and understand the information in this manual. Familiarization with the Stryker System 5 Battery Powered Instruments prior to use is important.
- Prior to each use, operate system components and inspect for damage. DO NOT use if damage is apparent. Take special precaution regarding electromagnetic compatibility (EMC) when using medical electrical equipment like the System 5 handpiece. Install and place the handpiece into service according to the EMC information in this manual. Portable and mobile RF communications equipment, such as wireless phones, can affect the function of the handpiece.
- Use only Stryker approved accessories. Other accessories may result in increased emissions or decreased immunity of the system. Contact your Stryker sales representative for a complete list of accessories. DO NOT modify any accessory. Failure to comply may result in patient and/or operating room staff injury.
- Prior to each use, system components should be operated and inspected for any loose components or damage. DO NOT use if these conditions exist. Loose components could fall off the handpiece into the wound site causing potential patient injury.
- Clean and sterilize instruments before first and every use.
- This equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Avoid unintentional operation of the handpiece. A handpiece that contains a battery should always be placed in the SAFE mode while it is either sitting idle or an accessory is being attached or removed. Remove the battery pack from the handpiece when the instrument is not in use.
- DO NOT pry or use excessive force on the blade as the blade may bend and/or break causing potential patient injury.
- Use only Stryker approved accessories. Only Stryker saw blades can be used with the Recip/Sternum Saw. A list of accessories is available from your Stryker Instruments sales representative.
- DO NOT service handpieces or battery packs. These products contain no parts that the user can service.
- If you are using a Stryker Reciprocating Double Sided Blade (REF 277-96-275) or a Reciprocating Heavy Duty Blade (REF 277-96-325), be alert to blade whip when the handpiece is operated below the maximum speed. Blade whip increases the chance of blade fracture and user/patient injury.
- DO NOT operate the handpiece until the blade is in contact with bone or tissue. Operating the handpiece before the blade is in contact with bone or tissue may cause the blade to break or eject from the handpiece and endanger persons nearby.
- Reuse of single use blades can cause blade breakage and possible injury to the patient and/or user.

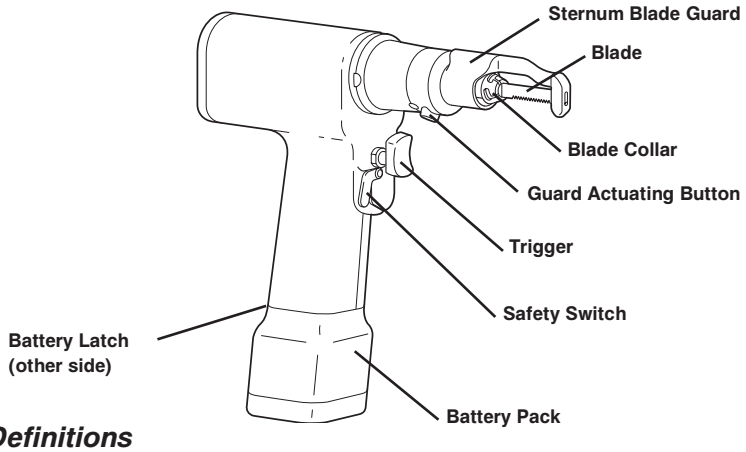
CAUTIONS:

- DO NOT stall the handpiece to prevent damaging the electric motor and/or battery pack. If the handpiece jams, release the trigger immediately. Remove any obstructions before continuing the procedure.
- DO NOT immerse the handpiece or battery pack. Water may enter the casing and damage the electrical components.

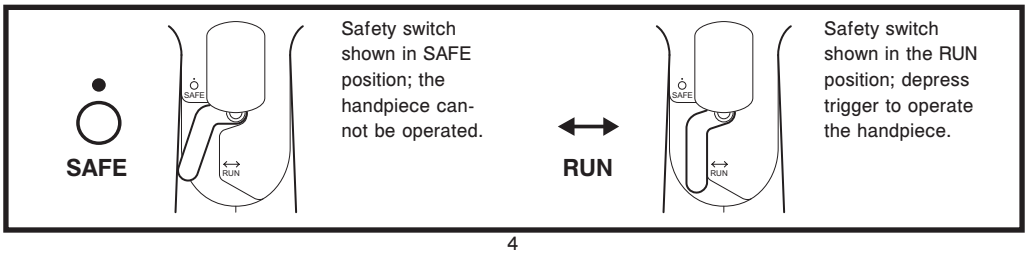
*For further information, contact your Stryker Instruments sales representative or Customer Service at 1-800-253-3210. Outside the USA, contact your nearest Stryker subsidiary.

Features and Functions

- **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.
- **Safety Switch** - The switch allows the cutting tool to operate in RUN or SAFE mode. The switch prevents inadvertent operation of the handpiece.
- **Blade Collar** - The spring-loaded blade collar allows the insertion and release of the blade.
- **Blade** - The blade teeth may be directed in any of four positions.
- **Sternum Blade Guard** - Protects soft tissue from coming into contact with the blade.
- **Guard Actuating Button** - Depress button to release the sternum blade guard.
- **Trigger** - The trigger is pressure sensitive for variable speed operation.



Symbol Definitions



Instructions

Blade Installation

WARNING:

Always place the safety switch in the SAFE position before attaching or removing any accessory to prevent inadvertent running of the handpiece.

1. Rotate the safety switch clockwise to the SAFE position.

2. Rotate the spring-loaded blade collar clockwise aligning the slots. Insert the blade (see figure 1).

NOTE: The blade teeth may be directed in any of four positions. However, if using the sternum blade guard, the teeth must point away from the sternum blade guard.

3. Release the blade collar. Ensure the blade collar springs back to its original position indicating the blade is properly seated.

4. Gently tug the blade back and forth to ensure it is secure.

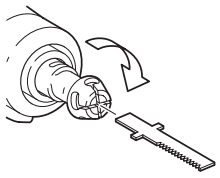


Figure 1 Blade Insertion

Sternum Blade Guard Installation

NOTE: When the sternum blade guard is used, it can be installed in the orientation shown or rotated 180˚ (see figure 2). The blade teeth must point away from the sternum blade guard.

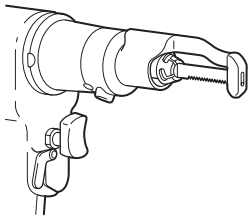


Figure 2 Guard Installation

1. Slide the guard actuating button and position the sternum blade guard over the blade so that the blade's teeth are pointing away from the guard. Release the guard actuating button to secure the sternum blade guard.

2. Gently tug the sternum blade guard to ensure it is secure.

3. Visually inspect the blade and sternum blade guard to ensure the blade neither retracts nor extends from the sternum blade guard.

Instructions (cont'd)

WARNINGS:

- If the blade retracts or extends from the end of the sternum blade guard, the blade may cause tissue damage.
- Do not grasp the handpiece near the guard actuating button or handle the handpiece in a way that may displace the guard actuating button during use. Displacing the guard actuating button causes the sternum blade guard to disengage and may cause loss of tactile control and patient injury.

Battery Pack Installation

NOTES:

- The Recip/Sternum Saw is designed to accept REF 4112, REF 4212, REF 4215, REF 4222 or REF 4226 batteries (or kit). These batteries may be charged in the System 4 Battery Charger configured with Charger Module REF 4110-412, REF 4110-422, or REF 4110-426 respectively. The REF 4112 battery may also be charged in the System 2000 Charger with Battery Adaptor (REF 4110-112).
- Refer to the instructions supplied with the battery charger and/or battery 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 3).

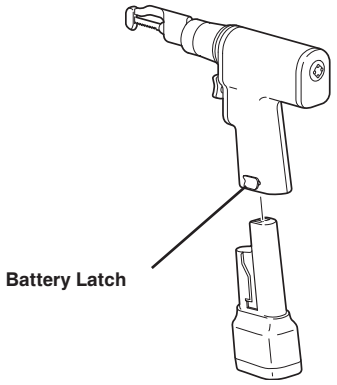


Figure 3 Battery Pack Installation

2. Test the operation of the handpiece by setting the safety switch to the RUN position and squeezing the trigger.

3. Set the safety switch to the SAFE position until you are ready to use the handpiece.

Saw Operation

NOTE: The handpiece has a variable speed motor that is controlled by slight pressure variations on the trigger.

CAUTION:

When operating the saw, let the blade do the cutting. Applying too much pressure will bend the blade and reduce the cutting quality.

Instructions (cont'd)

Battery Pack Removal
Depress the battery latch and pull the battery pack out.

Sternum Guard Removal
Rotate the guard actuating button to disengage the sternum blade guard and withdraw it from the handpiece.

Blade Removal
Rotate the spring-loaded blade collar clockwise to realign the slots and remove the blade.

*Troubleshooting Guidelines**

PROBLEM	CAUSE	ACTION
Instrument does not run or reciprocates at a reduced speed making cutting difficult.	Battery pack is discharged.	Recharge the battery in Stryker charger.
	Battery pack is expended.	Replace the battery pack.
	Safety switch is in the SAFE position.	Set the safety switch to the RUN position.
	Drivetrain is malfunctioning.	Return the handpiece for repair.
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 Stryker charger and replace if indicated. See *Charger Instructions*.
Blade will not fit into the blade collar.	Debris is inside the end of the blade collar.	Clean with a small brush.
	Blade collar is damaged.	Return the handpiece for repair.
Blade collar does not spring back to retain the blade.	Debris is inside of blade collar.	Clean with small brush, then actuate blade collar several times to obtain smooth operation.
Sternum blade guard will not fit into the handpiece.	Debris is inside of the blade guard retainer.	Clean with a small brush.
	Sternum blade guard is damaged.	Replace the sternum blade guard.
Handpiece has become noisy and vibrates.	Drivetrain is malfunctioning.	Return the handpiece for repair.

*This product is not field repairable. In case of operating difficulties, all Stryker products must be returned to Stryker Instruments for repair. For more information, contact your Stryker Instruments sales representative or call Stryker Customer Service at 1-800-253-3210. Outside the USA, contact your nearest Stryker subsidiary.

Troubleshooting Guidelines (cont'd)

PROBLEM	CAUSE	ACTION
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.

Storage and Handling

To ensure the longevity, performance and safety of this equipment, package in original packaging materials when storing or transporting.

Periodic Maintenance

INTERVAL	ACTIVITY
Prior to each use.	Inspect, operate and test the handpiece to ensure that it is working properly. Ensure there are no loose or missing components. Check all moving parts for free movement. Be alert for unusual sounds or vibrations and note the operating speed.

Cleaning Recommendations

WARNINGS:

- Handpieces, accessories and batteries must be cleaned and sterilized before first and every use.
- DO NOT use solvents, lubricants, or other chemicals unless otherwise specified.

CAUTION:

DO NOT immerse the handpiece or battery pack.

Battery Packs and Accessories

Refer to the *Cleaning Recommendations* for the battery packs, battery pack adaptors and chargers provided with those products.

Handpiece and Sternum Blade Guard

1. Remove the battery pack, sternum blade guard and blade from the handpiece.

2. Using a stiff bristle brush and mild detergent (hospital enzymatic cleaner), scrub the debris from the handpiece and sternum blade guard. Pay special attention to crevices and other hard to reach areas such as seams, joints, and details around the blade collar and trigger areas. Rotate the safety switch and guard actuating button to clean around and under them.

CAUTION:

DO NOT allow water to run directly into the battery chamber. Minimize the amount of water running into the guard slot.

3. Rinse all external surfaces of the handpiece and sternum blade guard under running water.

4. Actuate the guard actuating button to flush water from the small holes in the handpiece.

5. Visually inspect the handpiece for any remaining debris; if any is present, repeat the cleaning and rinsing procedure using fresh hospital enzymatic cleaner.

6. Dry the handpiece and sternum blade guard with a lint-free towel.

7. After cleaning, sterilize as directed. See *Sterilization Recommendations*.

Sterilization Recommendations

WARNINGS:

- Handpieces and batteries must be cleaned and sterilized before first and every use.
- Remove the sternum blade guard, blade and battery from the handpiece prior to sterilization.

Battery Packs

Refer to the *Sterilization Recommendations* provided with the battery packs.

Handpiece and Sternum Blade Guard

To obtain optimum performance from the instruments and help prevent damage to the instruments, it is essential that one of the following sterilization procedures be performed.

"Flash" Autoclave:
- Gravity displacement sterilizer
- 270-272˚F (132-134˚C)
- Unwrapped in an instrument tray
- 10-minute minimum exposure time

Hi Vac:
- Pre-vacuumed sterilizer
- 270-272˚F (132-134˚C)
- Wrapped or unwrapped
- 4-minute minimum exposure time
- 8-minute minimum dry time

ETO:
- 100% ETO
- 120-135˚F (49-57˚C)
- Wrapped in an instrument tray or fully perforated sterilization box
- 2-hour 30-minute exposure time, 8-hour minimum aeration time

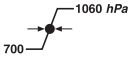
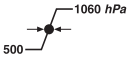
250˚F Gravity:
- Gravity displacement sterilizer
- 250-254˚F (121-123˚C)
- Wrapped in an instrument tray or fully perforated sterilization box
- 50-minute exposure time
- 8-minute minimum drying time

270˚F Gravity:
- Gravity displacement sterilizer
- 270-272˚F (132-134˚C)
- Wrapped in an instrument tray or fully perforated sterilization box
- 35-minute minimum exposure time
- 8-minute minimum dry time

Sterilization Recommendations
Validation based on AAMI protocol.

*Specifications**

Model:	REF 4207 Recip/Sternum Saw
Size:	7.4 in. [188mm] height (with battery) 1.5 in. [38.1mm] width 7 in. [178mm] length (without sternum blade guard)
Weight:	2.5 lbs. [1.13kg] (with battery, but without sternum blade guard)
Speed:	11,000 CPM
Excursion:	0.152 in. [3.9mm]
Duty Cycle:	 Intermittent Operation - 1 minute on / 4 minutes off 5 times with a 3 hour rest
Approvals:	 CSA International CAN/CSA-C22.2 No. 601.1-M90 UL 60601-1 IEC 60601-1
Equipment Type:	 **Type BF Applied Part**
Power Supply:	**Internally Powered**
Enclosure Protection:	IPX0 Ordinary Equipment

Environmental Conditions:	**Operation**	**Storage and Transportation**
Temperature:		
Relative Humidity:		
Atmospheric Pressure:		

*Specifications listed are approximate and may vary slightly from unit to unit or by power supply fluctuations.

Guidance and manufacturer's declaration - electromagnetic emissions		
The System 5 handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the System 5 handpiece should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The System 5 handpiece 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 B	
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 5 handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the System 5 handpiece should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the System 5 handpiece, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.67\sqrt{P}$
Conducted RF	3 Vrms	n/a	
IEC 61000-4-6	150 kHz to 80 MHz	n/a	$d=1.67\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF	3 V/m	3 V/m	$d=2.33\sqrt{P}$ 800 MHz to 2.5 GHz
IEC 61000-4-3	80 MHz to 2.5 GHz	80 MHz to 2.5 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 meters (m) Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800MHz 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.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The System 5 handpiece is intended for use in the electromagnetic environment specified below. The customer or the user of the System 5 handpiece 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	±2, 4, 6 kV contact ±2, 4, 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 differential mode ±2 kV common mode	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 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 characteristics of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the System 5 handpiece

The System 5 handpiece is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System 5 handpiece can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System 5 handpiece 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 $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	n/a	0.12	0.23
0.1	n/a	0.37	0.74
1	n/a	1.17	2.33
10	n/a	3.70	7.37
100	n/a	11.70	23.30

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 800MHz, 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.

Repair and Loaner Program

This service is available in the United States only. Outside the USA, contact your Stryker sales representative or nearest Stryker subsidiary.

On request, Stryker Instruments will provide a loaner unit for your use while repairs are being made. Please clean and sterilize all potentially contaminated products being sent in for repair, credit, or return of a loaner unit. The policy of Stryker Instruments is not to accept or process potentially contaminated products that do not meet this requirement.

Also, please be aware that it is unlawful to transport bio-contaminated products through interstate commerce that are not properly packaged and labeled as such.

1. Contact Stryker Customer Service at 1-800-253-3210 to request a loaner. Provide a name and address for shipping. Every effort will be made to send a loaner unit immediately.
2. Send the inoperative unit to Stryker with a purchase order number of authorization for repair. The order should explain the nature of the difficulty. Also, provide a name and address for shipping the repaired instruments.

   Return the inoperative unit to: **Stryker Instruments**
   Repair Department
   4100 E. Milham
   Kalamazoo, Michigan, 49001

3. The repaired unit will be shipped back and the repair invoice will follow under separate cover. Under most conditions, repair turnaround time will be approximately 2 to 3 weeks.
4. As soon as your repaired unit is returned, return the loaner to Stryker Instruments.

Limited Warranty

In the U.S.A. only, products of Stryker Instruments are warranted to the original purchaser for a period of one year from the date of purchase, with exceptions noted below. Products are warranted to be free from defects in material and workmanship. Abnormal wear and tear or damage caused by misuse or by failure to perform normal and routine maintenance as set out in these instructions, or as demonstrated by an authorized Stryker Instruments representative, is not covered by the warranty. Any effort at field repair or adjustment may invalidate your warranty.

The warranty extends to all purchasers and is limited to the repair or replacement of the product without charge when returned prepaid to Stryker Instruments. There are no other expressed warranties. This warranty gives you specific legal rights and you may have other rights which vary by state and municipality.

For selected products: Battery Packs are warranted for a period of 90 days from the date of invoice.

European Equiv.	*4207-001-713*
N. European Equiv.	*4207-001-731*
Japanese Equiv.	*4207-001-720*
Polish Equiv.	*4207-001-750*

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