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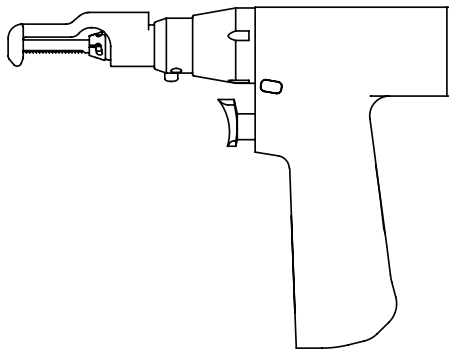
# Electric System 6™ Sternum Saw

REF 6297-000-000

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.

**NOTE:** The user and/or patient should report any serious product-related incident to both the manufacturer and the Competent Authority of the European Member State where the user and/or patient is established.

## Indications For Use

The Stryker Electric System 6 Heavy Duty Sternum Saw is used with the Consolidated Operating Room Equipment (CORE™) System. The saw is a linear cutting device used for cutting bone and bone related tissue including the sternum.

## 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.
- Upon initial receipt and before each use, clean and sterilize the equipment as indicated. See the care instructions manual supplied with the equipment.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen, or nitrous oxide.
- ALWAYS place the handpiece in the safe mode position while the handpiece is idle, before installing or removing any accessory, and when passing the handpiece to another person.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.

## Accessories



**WARNING:** 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.

**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:

DESCRIPTION	REF
Handpiece Cord	6292-004-000

## Blades



### WARNINGS:

- 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.
- Upon initial receipt and before use, visually inspect the package for damage to confirm the integrity of the sterile barrier. Do not use the product if damage is apparent, the sterile barrier is compromised, or the package is unintentionally opened.

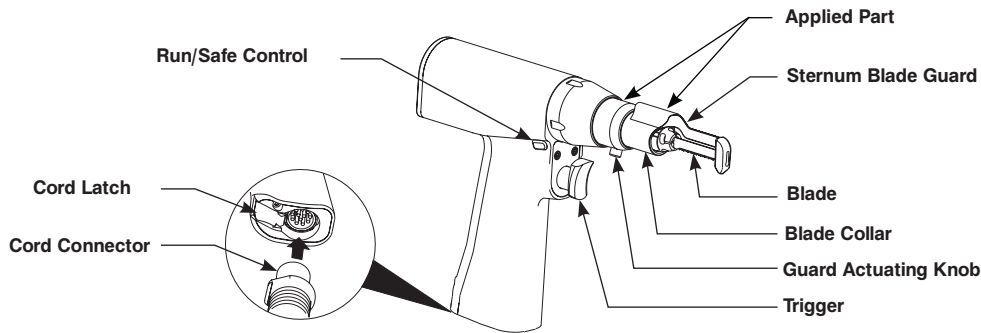
**NOTE:** Sterile cutting accessories are sterilized by irradiation.

DESCRIPTION	REF
Sternum Blade, Offset	0296-097-102
	0298-097-100
	0298-097-101
	0298-097-104
Stryker Performance Series® Sternum Blade	6207-097-101
Sternum Blade Guard	4107-008-000
	7207-002-000
	7207-003-000

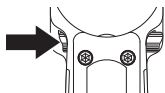
## Features

### Handpiece

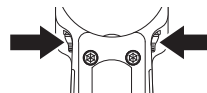
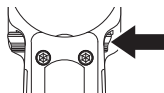
- **Cord Latch** - To release the handpiece cord from the handpiece, press the latch.
- **Cord Connector** - Install the handpiece cord into this connector.
- **Run/Safe Control** - The run mode position allows the handpiece to operate. The safe mode position prevents inadvertent operation of the handpiece.
- **Blade Collar** - The spring-loaded blade collar allows the insertion and release of the blade.
- **Blade** - The blade teeth may be directed in one of two positions. The teeth must always be directed away from the sternum blade guard.
- **Sternum Blade Guard** - Protects soft tissue from coming into contact with the blade.
- **Guard Actuating Knob** - To release the sternum blade guard, push on knob with a circular motion.
- **Trigger** - The trigger is pressure sensitive for variable speed operation.
- **Applied Part** - The distal end of the handpiece and the sternum blade guard (as defined by the *Product Safety Certification* standards listed in the *Specifications* section of the instructions for use supplied with the console).



## Run/Safe Control






**Run Mode** – Slide the run/safe control to either run mode position (two available) to allow the handpiece to operate while the trigger is depressed.



**Safe Mode** – Slide the run/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
	Run Mode/Safe Mode
	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

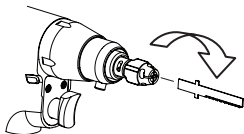
### To Install Cutting Accessory



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

1. Slide the run/safe control to the safe mode 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 one of two positions. When using the sternum blade guard, the teeth must point away from the sternum blade guard.



**Figure 1 – To Install Blade**

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 cutting accessory to ensure it is secure.

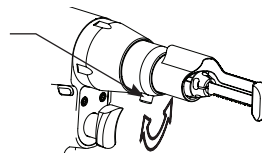
### To Install Sternum Blade Guard



**WARNING:** DO NOT allow the blade to retract or extend from the end of the sternum blade guard.

**NOTE:** The sternum blade guard may be installed in the orientation shown in figure 2 or rotated 180 degrees. ALWAYS orient the sternum guard such that the blade teeth point away from the guard as illustrated.

**Knob on Collar**



**Figure 2 – To Install Sternum Blade Guard**

1. Push against the guard actuating knob to rotate the collar. Install the sternum blade guard over the blade ensuring the blade's teeth are pointed away from the guard. Release the guard actuating knob to allow the spring-loaded collar to snap back and lock sternum blade guard in place.
2. Gently tug the sternum blade guard to ensure that 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.

## To Operate Handpiece



### WARNINGS:

- ALWAYS place the run/safe control in the safe mode position while the handpiece is idle, before installing or removing an accessory, and when passing the handpiece to another person.
- DO NOT operate the handpiece until the blade is in contact with bone or tissue. Failure to comply may cause the blade to break or eject from the handpiece.
- While operating the handpiece, DO NOT grasp the handpiece near the guard actuating knob or cause the knob to move. Moving the knob during operation may cause the sternum blade guard to disengage. Failure to comply may cause the loss of tactile control.
- DO NOT apply excessive pressure, such as bending or prying, with a cutting accessory to prevent fracturing the accessory. Applying excessive pressure, especially during high operating speeds, may cause the cutting accessory to bend significantly and result in tissue damage, loss of tactile control and the ejection of cutting accessory pieces at a high velocity.
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.

### 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. If the handpiece jams, release the trigger immediately. Remove any obstructions before continuing the procedure.
1. Slide the run/safe control to the safe mode position.
  2. Insert the handpiece cord into cord connector of the handpiece until the connector latch engages. An audible click should be heard. Gently tug on the cord to ensure that the cord is secure.
  3. Connect the other end of the handpiece cord to the console.
  4. At the console, program the operational settings of the handpiece as required. See the instructions for use supplied with the console.
  5. Slide the run/safe control to either run position to allow the handpiece to operate.
  6. Squeeze the pressure-sensitive trigger for variable speed operation.
  7. Slide the run/safe control to the safe mode position when you are finished operating the handpiece.



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## To Remove Handpiece Cord

Press the cord latch and pull the handpiece cord out of the handpiece.

## To Remove Sternum Blade Guard

1. Slide the run/safe control to the safe mode position.
2. Push against the guard actuating knob to rotate the collar. Remove the sternum blade guard from the handpiece. Release the guard actuating knob to allow the spring-loaded collar to snap back to its original position.

## To Remove Cutting Accessory

1. Slide the run/safe control to the safe mode position.
2. Rotate the spring-loaded blade collar clockwise to realign the slots and remove the blade.

## 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 reciprocates at a reduced speed making cutting difficult.	Handpiece cord is not properly connected.	Reconnect the handpiece cord between the handpiece and console.
	Handpiece cord is damaged.	Return the handpiece cord for repair.
	Run/safe control is in the safe mode position.	Slide the run/safe control to the run mode position.
	Handpiece is damaged.	Return the handpiece for repair.
Motor runs but blade does not move.	Handpiece is damaged.	Return the handpiece for repair.
Blade will not fit into the blade collar.	Debris is inside the end of the blade collar.	Clean the handpiece 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 the handpiece with small brush. Actuate the 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 the handpiece with a small brush.
	Sternum blade guard is damaged.	Replace the sternum blade guard.
Handpiece has become noisy and vibrates.	Handpiece is damaged.	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>	Electric System 6 Sternum Saw (REF 6297-000-000)
<b>Dimensions:</b>	5.6 inch [142 mm] height 1.49 inch [38 mm] width 7 inch [178 mm] length (without sternum blade guard)
<b>Mass:</b>	2.20 lb [1.00 kg] (without sternum blade guard)
<b>Speed:</b>	14,000 cycles per minute
<b>Excursion:</b>	0.152 inch [3.9 mm]
<b>Mode of Operation:</b>	Non-continuous Operation
Duty Cycle:	1 minute on/4 minutes off, 5 times
Rest Between Cycles:	3 hours
<b>Power Supply:</b>	Externally supplied (CORE console REF 5400-050-000) (CORE 2 console REF 5400-052-000)
<b>Ingress Protection:</b>	IPX0 Ordinary Equipment
<b>Maximum Temperature of Applied Part:</b>	Less than 124 °F [51 °C] (Maximum surface temperature as tested to the standards listed under <i>Product Safety Certification</i> in the instructions for use supplied with the console.)

### Environmental Conditions:

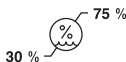
Temperature Limitation:



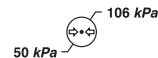
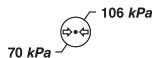
### Storage and Transportation



Humidity Limitation:



Atmospheric Pressure Limitation:



ES/DE/FR/IT/NL	6297-001-710
JA/ZH/KO	6297-001-720
SV/DA/FI/PT/NO	6297-001-730
PL/EL	6297-001-750



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