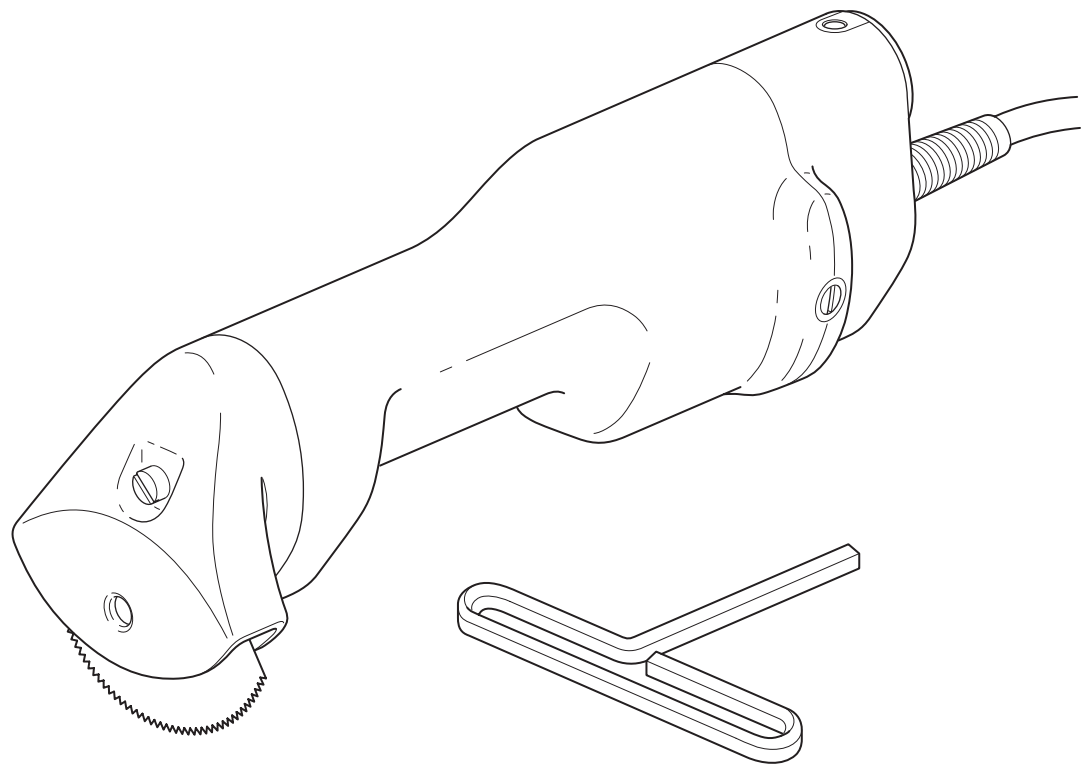


<p><i>Note: This portion of the document should not appear on produced Labels or IFUs.</i></p> <p>Stryker Instruments (269) 323-7700 (800) 253-3210</p>	<p>Dimensions: 8.5 inch (width) x 11 inch Booklet</p>	<p>Color/Material/Finish: Color Graphics on White Background 20# Bond or Equivalent</p>	<p>Label Stock: N/A</p>	
			<p>Description/Type: Instructions For Use</p>	
			<p>Part Number: 0940-001-025</p>	<p>Rev. L</p>

R_x ONLY



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, biomedical equipment technicians, and central supply/sterile processing 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 Cast Cutter is intended to section and remove synthetic and plaster casts.

Contraindications

None known.

For Use With

This section describes system components that must be used with the equipment described in this manual to create a safe and effective system.

DESCRIPTION	REF
Cast Cutter Blades	0940-XXX-XXX series



WARNING: ALWAYS select and install a blade that is appropriate for the cast material to be cut.

CAST MATERIAL	BLADE TYPE	BLADE REF
Plaster or Synthetic	Ion Nitrided	0940-023-000
Plaster	Stainless Steel	0940-025-000
Synthetic	Titanium Nitrided	0940-035-000

User/Patient Safety



WARNINGS:

- 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.
- Only trained and experienced healthcare professionals should use this equipment.
- 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 equipment if damage is apparent or the inspection criteria are not met. See the *Inspection, Testing, and Maintenance* section.
- Only individuals trained and experienced in the maintenance of reusable medical devices should install, inspect, service, and test this equipment as described in this manual.
- DO NOT modify any system component or accessory, including the power cord and power cord plug.
- ALWAYS position the equipment so that the power cord plug may be easily disconnected from the power supply.
- 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 this system. Install and place this system into service according to the EMC information contained in this manual. Portable and mobile RF communications equipment can affect the function of this system.

Accessories



WARNINGS:

- Use only Stryker-approved system components and accessories, unless otherwise specified. Failure to comply may result in fire, electric shock, or injury.
- Using other electronic components and accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.

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.

This section describes system components that may be ordered to replace original equipment that is damaged, worn, or must be replaced. This section may also contain optional components used with the system.

The following Stryker-approved accessories are sold separately:

DESCRIPTION	REF
Small Cast Spreader	0082-000-000
Large Cast Spreader	0083-000-000
Cast Cutter Blades	0940-XXX-XXX series
Blade Tool	0940-050-000
Vacuum Line Cap	0940-001-135
CastVac™	0986-000-000
	0987-000-000
	0996-000-000
Adaptor Hose with Cord (to connect Cast Cutter REF 0940-000-000 to Stryker PlasterVac™ REF 0886-000-000)	0940-886-000
Adaptor Hose with Cord (to connect Cast Cutter REF 0940-000-000 to Stryker PlasterVac REF 0846-000-000 or 0856-000-000)	0940-855-000
Adaptor Hose with Cord (to connect Cast Cutter REF 0940-000-000 to Stryker OrthoVac™ REF 0864-000-000)	0940-864-000
Cast Cutter Repair Kit	0940-001-140Q



WARNING: When using a Stryker CastVac, ALWAYS connect the Cast Cutter to a CastVac with an appropriate voltage. Failure to comply may result in fire, electric shock, or injury.

CAST CUTTER REF	VOLTAGE	CASTVAC REF
0940-000-000	100-120 V ~	0986-000-000 0987-000-000
0941-000-000	220-240 V ~	0996-000-000

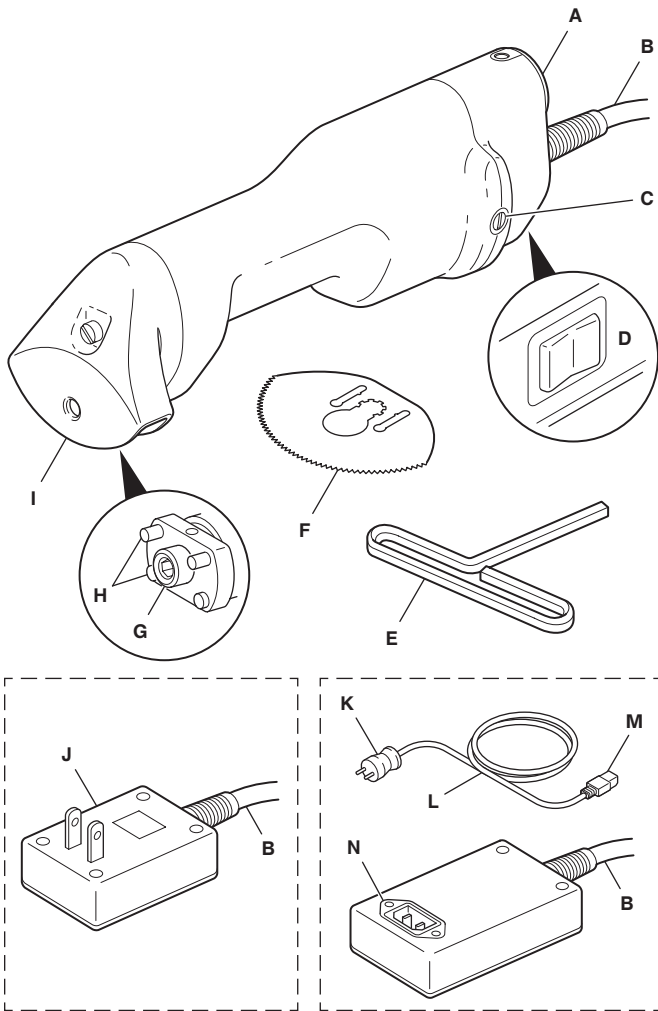
Definitions

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
	High Speed Mode
	Standby Mode
	Standard Speed Mode
	Class II equipment (Double Insulation)
	Type BF Applied Part
	Alternating current (AC)
	Non-ionizing electromagnetic radiation
	General warning sign
	Refer to instruction manual/booklet
	Consult instructions for use
	This symbol is intended to alert service personnel of the presence of voltage that may cause injury or fatal electric shock. Disconnect the device from the electrical supply before servicing.

Features

Cast Cutter



A	Vacuum Line Cap
B	Power Cord
C	Brush Cap
D	Function Switch
E	Blade Tool
F	Blade
G	Blade Retention Screw
H	Blade Guide Posts (4)
I	Vacuum Hood

Model REF 0940-000-000 Only:

J	Power Cord Plug
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Model REF 0941-000-000 Only:

K	Power Source Cord Plug
L	Power Source Cord
M	Appliance Inlet Connector Plug
N	Appliance Inlet Connector

Function Switch

	High Speed Mode – The Cast Cutter blade will oscillate at high speed.
	Standby Mode – The Cast Cutter blade will not oscillate. NOTE: When the Cast Cutter is not in use, set the function switch to the standby mode position.
	Standard Speed Mode – The Cast Cutter blade will oscillate at standard speed.

Instructions

To Install a Blade



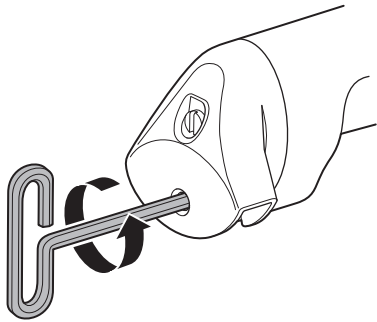
WARNINGS:

- ALWAYS disconnect the power cord plug from the facility power outlet or CastVac power outlet before installing a blade. Failure to comply may cause fire, electric shock, or injury.
- Before each use, inspect the blade for wear. DO NOT use a dull blade. Using a dull blade may cause a burn injury.

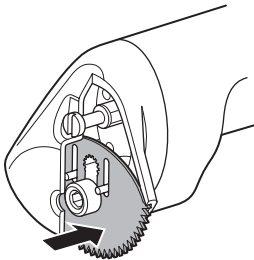
CAUTIONS:

- To ensure safe and efficient cutting and avoid damaging the equipment, ALWAYS install the blade as indicated in these instructions.
- The blade retention screw is captive and cannot be removed from the Cast Cutter. DO NOT attempt to remove the screw or loosen the screw beyond the point when it no longer turns.

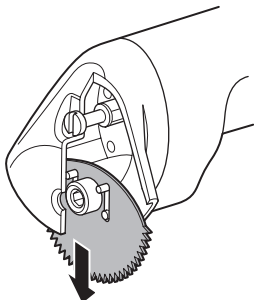
1. Use the blade tool supplied with the Cast Cutter to loosen the blade retention screw. Turn the screw counterclockwise until it no longer turns.



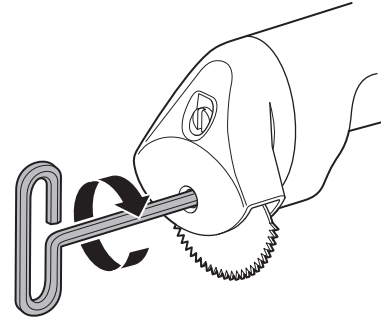
2. Slide a blade over the screw and the top two blade guide posts.



3. Pull the blade down behind the screw and over the bottom two blade guide posts. Make sure that all four posts are engaged with the blade.



4. Use the blade tool to tighten the blade retention screw against the blade.



WARNING: Before operating the equipment, ALWAYS make sure the blade is securely installed and the blade retention screw is tight. An improperly tightened screw may come loose and cause the blade to fracture.

5. Confirm that the blade is securely installed and the blade retention screw is tight against the blade.

To Connect the Cast Cutter to a Power Source



WARNING: ALWAYS set the function switch to the standby mode position before connecting the Cast Cutter to a facility power outlet or CastVac power outlet.

CAUTION: ALWAYS place the power cord where it will not be stepped on, tripped over, or otherwise subjected to damage or stress.

NOTE: The Cast Cutter may be connected to a facility power outlet or a CastVac with an appropriate voltage rating. For more information, see the *Accessories* section and the instructions for use supplied with the CastVac.

1. Set the function switch to the standby mode.
2. Connect the power cord plug to a facility power outlet or CastVac power outlet.

NOTE: To connect Cast Cutter REF 0941-000-000 to a facility power outlet, first connect the appliance inlet connector plug to the appliance inlet connector. See the *Features* section.

To Operate the Cast Cutter



WARNINGS:

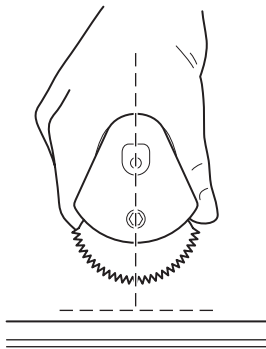
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- DO NOT use this equipment in the presence of fluids.
- ALWAYS set the function switch to the standby mode position before passing the Cast Cutter to another person.
- DO NOT apply excessive pressure, such as bending or prying, with the blade. Excessive pressure may cause the blade to fracture. If prying on the cast is required, use a cast spreader tool.

- ALWAYS use extreme caution when cutting synthetic cast material. The blade may overheat and cause a burn injury.
- DO NOT remove a non-padded cast with the Cast Cutter. Skin may adhere to the cast material and result in a cut or burn injury.
- DO NOT operate this equipment with a damaged power cord or power cord plug.
- DO NOT use Stainless Steel Cast Cutter Blade REF 0940-025-000 to cut synthetic cast material.

1. Set the function switch to the desired speed mode. The blade will begin to oscillate.

WARNING: To reduce the spray of cast debris, ALWAYS align the Cast Cutter blade in a vertical orientation, perpendicular to the cast when cutting.

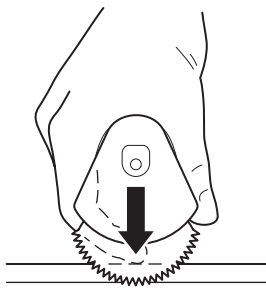
2. Grasp the Cast Cutter as shown, and align the blade in a vertical orientation, perpendicular to the cast.



3. Gently push the oscillating blade through the cast material.

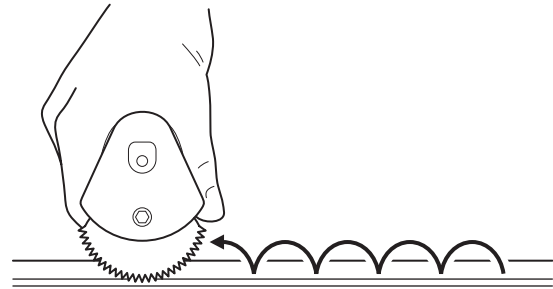
NOTES:

- Cutting action is achieved by high speed oscillation of the blade. The blade cuts on both the backward and forward strokes of the excursion. To engage more blade teeth and allow for more efficient cutting, the blade should be moved slightly up and down as the cut progresses.
- You should feel resistance as the blade cuts through the cast material. When the blade fully penetrates the cast, this resistance ends, and you should withdraw the blade.
- Use your index finger as a depth gauge to control the blade as it reaches the padding beneath the cast.



WARNING: DO NOT use a continuous, linear motion to cut the cast. Continuous contact of the blade against the skin or cast padding may cause a cut or burn injury.

4. Withdraw and advance the blade in the direction of the cut.



5. Repeat this motion of alternating pressure along the direction of the cut until the cut is complete.

NOTE: Use a cast spreader to remove the cast, if necessary.

6. Upon completion, set the function switch to the standby mode.

To Disconnect the Cast Cutter from the Power Source

WARNING:

- ALWAYS set the function switch to the standby mode position before disconnecting the Cast Cutter from the facility power outlet or CastVac power outlet.
- The function switch does not remove electrical power from the Cast Cutter. To remove the electrical power, you must disconnect the power cord plug from the facility power outlet or CastVac power outlet.

CAUTION: To reduce the risk of damage to the power cord, ALWAYS grasp the power cord plug, not the power cord, when disconnecting the Cast Cutter.

1. Verify the function switch is in the standby mode.
2. Disconnect the power cord plug from the facility power outlet or CastVac power outlet.

To Remove the Blade

WARNING: ALWAYS disconnect the power cord plug from the facility power outlet or CastVac power outlet before removing the blade. Failure to comply may cause fire, electric shock, or injury.

CAUTION: The blade retention screw is captive and cannot be removed from the Cast Cutter. DO NOT attempt to remove the screw or loosen the screw beyond the point when it no longer turns.

NOTE: It is not necessary to remove the blade after each use. Blade removal is required when installing a blade that is appropriate for the cast material or when replacing a worn blade.

1. Use the blade tool to loosen the blade retention screw. Turn the screw counterclockwise until it no longer turns.
2. Pull the blade off of the bottom two blade guide posts.
3. Slide the blade up behind the screw and remove the blade.
4. Save or dispose of the blade as required.

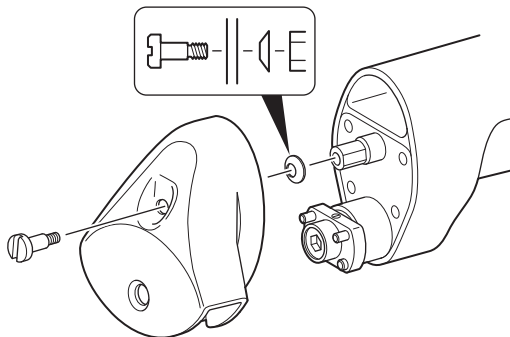
Cleaning

! WARNINGS:

- ALWAYS disconnect the power cord plug from the facility power outlet or CastVac power outlet before cleaning the equipment. Failure to comply may cause fire, electric shock, or injury.
- Upon initial receipt and before each use, clean and disinfect the equipment as indicated.
- DO NOT sterilize the equipment.
- DO NOT immerse or soak the equipment in liquid. DO NOT flush the internal vacuum line with liquid. DO NOT allow moisture or liquid to soak into electrical plugs, receptacles, or openings. Moisture or liquid inside the equipment may create an unsafe electrical condition, cause corrosion, and/or damage the electrical and/or mechanical components.
- Before each use, make sure the equipment is completely dry. DO NOT use any equipment if moisture is present.
- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.

To Clean the Equipment

1. Disconnect the power cord plug from the facility power outlet or CastVac power outlet.
2. If the vacuum hood is blocked with debris, perform the following steps:
 - 2.1. Use a standard slotted screwdriver to remove the captive screw, Belleville washer, and vacuum hood.



- 2.2. Remove any blockage and wipe away the debris.
- 2.3. Reinstall the vacuum hood and Belleville washer, and securely tighten the captive screw.

NOTE: Make sure the Belleville washer is oriented correctly during reassembly. See the illustration above.

3. Wipe the external surfaces of the equipment with a soft cloth moistened with a non-abrasive, mild detergent and water.
4. Thoroughly dry the equipment with a soft, absorbent cloth.

To Disinfect the Equipment

1. Wipe the external surfaces of the equipment with a soft cloth moistened with isopropyl alcohol. Blades can be disinfected with a standard disinfectant.
2. Thoroughly dry the equipment with a soft, absorbent cloth.

Inspection, Testing, and Maintenance

! WARNINGS:

- Only individuals trained and experienced in the maintenance of reusable medical devices should inspect, test, and maintain this equipment.
- DO NOT disassemble or service this equipment, unless otherwise specified. Failure to comply may cause fire, electric shock, or injury.
- ALWAYS disconnect the power cord plug from the facility power outlet or CastVac power outlet before performing maintenance procedures on the equipment. Failure to comply may cause fire, electric shock, or injury.
- Only the components listed in the *Inspection, Testing, and Maintenance* section are serviceable.
- When servicing or maintaining this equipment, use only Stryker-approved, identical replacement parts.
- DO NOT use the Cast Cutter if the leakage current exceeds the appropriate specification. See the *Specifications* section.

NOTES:

- The Cast Cutter has a lifetime lubrication system. No additional lubrication is required.
- Calibration adjustments for the Cast Cutter were made during manufacturing. No additional calibration is required.
- Maintenance documentation for this equipment is available upon request to Stryker-authorized service personnel only.
- For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

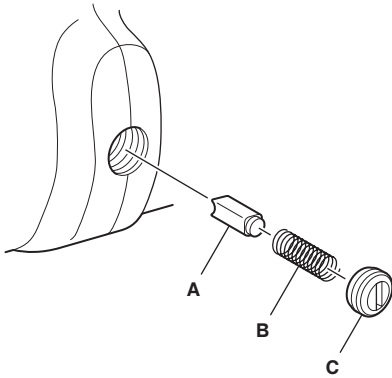
INTERVAL	ACTION	INSPECTION CRITERIA
Upon initial receipt and before each use.	Inspect the equipment.	If damage or excessive wear is apparent, contact Stryker for repair. If any components are loose or missing, contact Stryker for repair.
	Inspect the power cord and/or power source cord.	If cracks, cuts, or damage is apparent, contact Stryker for repair.
	Inspect the blade.	If the blade is dull, replace the blade. See the <i>Instructions</i> section.
	Operate the equipment.	If unusual sound, excessive noise, or vibration is apparent, contact Stryker for repair.
Annually.	Actuate the function switch five times.	If the equipment does not operate normally, contact Stryker for repair.
	Use a tachometer to determine the operating speed.	If the equipment does not operate at the proper speed, contact Stryker for repair. For speed information, see the <i>Specifications</i> section.

To Replace the Motor Brushes and Springs

! WARNINGS:

- ALWAYS disconnect the power cord plug from the facility power outlet or CastVac power outlet before performing maintenance procedures on the equipment. Failure to comply may cause fire, electric shock, or injury.
- DO NOT insert a metal tool or object into the Cast Cutter. To remove the spring and brush, turn the Cast Cutter upside down.

Required Parts



ITEM	DESCRIPTION	QUANTITY	REF
A	Brush	2	0940-001-113
B	Spring	2	0038-049-000
C	Brush Cap	2	0058-018-000

Required Tools

DESCRIPTION	QUANTITY
Standard Slot Screwdriver	1
Torque Wrench	1
Leakage Current Measuring Device	1

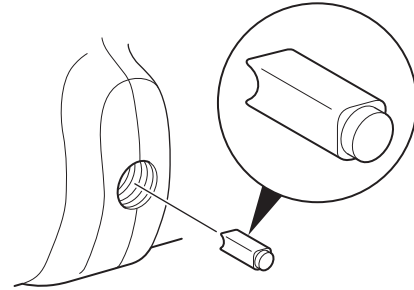
1. Disconnect the power cord plug from the facility power outlet or CastVac power outlet.

! WARNING: When installed, the brush cap is under pressure from the spring. Hold the brush cap to prevent the spring from ejecting the brush cap upon removal.

2. Loosen and remove the brush cap, spring and brush.
3. Dispose of the used spring and brush.

CAUTION: To ensure proper contact, install the brush so that the concave surface of the brush is oriented as shown.

4. Orient the concave surface of the brush as shown.



5. Insert the brush into the Cast Cutter.
 6. Place the spring onto the brush.
- CAUTION:** During installation, DO NOT overtighten the brush cap.
7. Install and carefully tighten the brush cap to 0.45-0.90 N-m [4-8 lb-in].
 8. Repeat the steps to replace the other motor brush and spring.

! WARNING: ALWAYS test the leakage current after replacing the motor brushes and springs.

9. Test the Cast Cutter to verify the leakage current is within the appropriate specification. See the *Product Safety Certification* standards in the *Specifications* section for leakage current test procedures and limits.

Storage and Handling

CAUTION: ALWAYS store the equipment within the specified environmental condition values throughout its useful life. See the *Specifications* section.

To ensure the longevity, performance and safety of this equipment, use of the original packaging material is recommended when storing or transporting this equipment.

Disposal/Recycle

! WARNING: ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.



To comply with European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, this device should be collected separately for recycling. Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information. Ensure infected equipment is decontaminated prior to recycling.

Troubleshooting



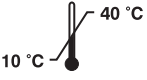
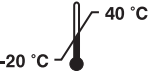
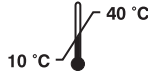

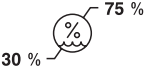
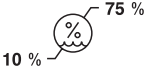

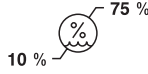
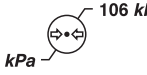
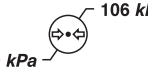
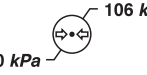
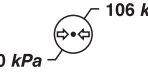




WARNING: DO NOT disassemble or service this equipment, unless otherwise specified.

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


PROBLEM	CAUSE	SOLUTION
The Cast Cutter does not operate.	The Cast Cutter is not connected to facility power.	See the <i>To Connect the Cast Cutter to a Power Source</i> section.
	The motor brushes are installed in the wrong orientation.	Remove and install the motor brushes. See the <i>Inspection, Testing, and Maintenance</i> section.
	The function switch is broken.	Return the Cast Cutter to Stryker for repair.
	The fuse is blown.	Return the Cast Cutter to Stryker for repair.
The Cast Cutter operates at a very low speed.	The motor brushes are installed in the wrong orientation.	Remove and install the motor brushes. See the <i>Inspection, Testing, and Maintenance</i> section.
The Cast Cutter does not operate smoothly, or operates with excessive noise.	The motor brushes are worn.	Replace the motor brushes and springs. See the <i>Inspection, Testing, and Maintenance</i> section.
	The roller bearing is worn.	Return the Cast Cutter to Stryker for repair.
The blade does not cut smoothly.	The blade is worn.	Replace the blade. See the <i>Instructions</i> section.
The blade slips.	The blade guide posts are worn.	Return the Cast Cutter to Stryker for repair.
When used with a CastVac, the level of suction is reduced.	The vacuum hood is blocked with debris.	Remove the debris from the vacuum hood. See the <i>Cleaning</i> section.
The equipment experiences sporadic electrical interference.	Electrical noise is present.	Turn off all electrical equipment not in use.
		Relocate electrical equipment; increase spatial distance between devices.
		Connect electrical equipment to different facility power outlets.

Specifications

Model:	Stryker Cast Cutter (REF 0940-000-000)		Stryker Cast Cutter (REF 0941-000-000)	
Electrical:	100-120 V ~, 50-60 Hz, 1.5 A input		220-240 V ~, 50-60 Hz, 0.75 A input	
Speed:	100 V ~ Nominal	120 V ~ Nominal	230 V ~, 50 Hz Nominal	
High:	12,800 CPM (cycles per minute)	15,900 CPM	15,900 CPM	
Standard:	7,700 CPM	10,700 CPM	10,700 CPM	
Power Cord:	3.1 m [10.25 ft] length, fitted with NEMA 1-15P plug		3.1 m [10.25 ft] length	
Power Source Cord:	None		2.5 m [8.2 ft] length, fitted with CEE 7/7 Schucko plug	
Dimensions:	25.4 cm [10 inch] length 7.6 cm [3 inch] height		25.4 cm [10 inch] length 7.6 cm [3 inch] height	
Mass:	1.3 kg [2.8 lb]		1.3 kg [2.8 lb]	
Excursion:	3.2 mm [0.125 inch]		3.2 mm [0.125 inch]	
Mode of Operation:	Continuous with Intermittent Loading		Continuous with Intermittent Loading	
Duty Cycle:	15 minutes on, 1 time		15 minutes on, 1 time	
Rest Between Cycles:	20 minutes		20 minutes	
Maximum Temperature of Applied Part:	Less than 48 °C [118 °F] (Maximum surface temperature as tested to the standards listed under <i>Product Safety Certification</i> .)		Less than 48 °C [118 °F] (Maximum surface temperature as tested to the standards listed under <i>Product Safety Certification</i> .)	
Equipment Type:	Class II (Double Insulation)  Type BF Applied Part		Class II (Double Insulation)  Type BF Applied Part	
Ingress Protection:	IPX0 Ordinary Equipment		IPX0 Ordinary Equipment	
Means of Isolation from Supply Mains:	Disconnection of the power cord plug from the facility power outlet or CastVac power outlet		Disconnection of the power cord plug from the facility power outlet or CastVac power outlet	
Environmental Conditions:	Operation	Storage and Transportation	Operation	Storage and Transportation
Temperature Limitation:				
Humidity Limitation:				
Atmospheric Pressure Limitation:				

Model:	Stryker Cast Cutter (REF 0940-000-000)	Stryker Cast Cutter (REF 0941-000-000)
European Conformity:	Not applicable	
Product Safety Certification:	 CSA International Canadian Standards Association (CSA) CAN/CSA-C22.2 No. 601.1-M90, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety</i> Underwriters Laboratories (UL) UL 60601-1, <i>Medical Electrical Equipment, Part 1: General Requirements for Safety – First Edition</i> ; Revisions through and including April 26, 2006 International Electrotechnical Commission (IEC) IEC 60601-1:1988, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety - Second Edition</i> ; Amendment 1 (1991); Amendment 2 (1995); Corrigendum 1 (1995) European Committee for Electrotechnical Standardization (CENELEC) EN 60601-1:1990, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety</i> ; Amendment 1 (1993); Amendment 11 (1993); Amendment 12 (1993); Amendment 2 (1995); Amendment 13 (1996)	Canadian Standards Association (CSA) CAN/CSA-C22.2 No. 601.1-M90, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety</i> Underwriters Laboratories (UL) UL 60601-1, <i>Medical Electrical Equipment, Part 1: General Requirements for Safety – First Edition</i> ; Revisions through and including April 26, 2006 International Electrotechnical Commission (IEC) IEC 60601-1:2005, <i>Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance</i> ; IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007) IEC 60601-1:1988, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety - Second Edition</i> ; Amendment 1 (1991); Amendment 2 (1995); Corrigendum 1 (1995) Canadian Standards Association (CSA) CAN/CSA-C22.2 No. 60601-1:08, <i>Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance</i> American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ANSI/AAMI ES60601-1:2005, <i>Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance</i> ; Consolidated Reprint (2009); Amendment 2 (2010) European Committee for Electrotechnical Standardization (CENELEC) EN 60601-1:2006, <i>Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance</i> ; IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010); CENELEC Amendment A11 (2011)

Guidance and manufacturer's declaration - electromagnetic emissions		
The Cast Cutter (REF 0941-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the Cast Cutter (REF 0941-000-000) should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Cast Cutter (REF 0941-000-000) 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 CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Cast Cutter (REF 0941-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the Cast Cutter (REF 0941-000-000) 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	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Cast Cutter (REF 0941-000-000), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ 150 kHz to 80 MHz $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
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 Cast Cutter (REF 0941-000-000) is used exceeds the applicable RF compliance level above, the Cast Cutter (REF 0941-000-000) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Cast Cutter (REF 0941-000-000).

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

Guidance and manufacturer's declaration - electromagnetic immunity			
The Cast Cutter (REF 0941-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the Cast Cutter (REF 0941-000-000) 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	±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	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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	95% Reduction (10ms) 60% Reduction (100ms) 30% Reduction (500ms) 95% Reduction (5s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cast Cutter (REF 0941-000-000) requires continued operation during power mains interruptions, it is recommended that the Cast Cutter (REF 0941-000-000) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m @ 50Hz CRT 1A/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 alternating current mains voltage prior to application of the test level.

Recommended separation distances between portable and mobile RF communications equipment and the Cast Cutter (REF 0941-000-000)			
The Cast Cutter (REF 0941-000-000) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cast Cutter (REF 0941-000-000) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cast Cutter (REF 0941-000-000) 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 $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	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/EL 0940-001-715
JA/ZH/KO 0940-001-725
SV/DA/FI/PT/NO/PL 0940-001-731



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