stryker®

RemB® Electric Sagittal Saw

REF 6400-034-000

Instructions For Use

R_x ONLY

CE 0197

ENGLISH (EN)

Introduction

This instructions for use manual contains information intended to ensure the safe, effective and compliant use of your product. This manual is intended for 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, including safety information, in-service training, or current literature, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

NOTE: The RemB Electric Sagittal Saw (handpiece) is also known as the RemB Sagittal Saw.

Indications For Use

The RemB Electric Sagittal Saw is intended for use with the Consolidated Operating Room Equipment (CORE™) System.

When used with a variety of cutting accessories, the RemB Electric Sagittal Saw is intended for surgical procedures involving the cutting of bone and hard tissue. This includes but is not limited to Orthopedic, Dental, ENT (Ear, Nose, Throat), Neuro, and Endoscopic applications.

This device can also be used with the Total Performance System (TPS™).

Contraindications

None known.

User/Patient Safety

WARNINGS:

- Before using this equipment, or any component compatible with this equipment, read and understand the instructions for use. Pay particular attention to safety information. Become familiar with the equipment before use.
- Only healthcare professionals trained and experienced in the use of this medical device should operate this equipment.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique for each patient. Stryker, as a manufacturer, does not recommend surgical technique.
- ALWAYS allow the equipment to reach the specified operation temperature range before use. See the *Specifications* section.
- Upon initial receipt and before each use, clean and sterilize the equipment as indicated. See the care instructions manual supplied with the equipment.
- Upon initial receipt and before each use, inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met. 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.

For Use With

DESCRIPTION	REF
TPS Consoles with software version 4.0 and higher	5100-0XX-000 Series
CORE Powered Instrument Driver (console) with software version 5.7 or higher	5400-050-000
CORE 2 Console	5400-052-000

Accessories

WARNINGS:

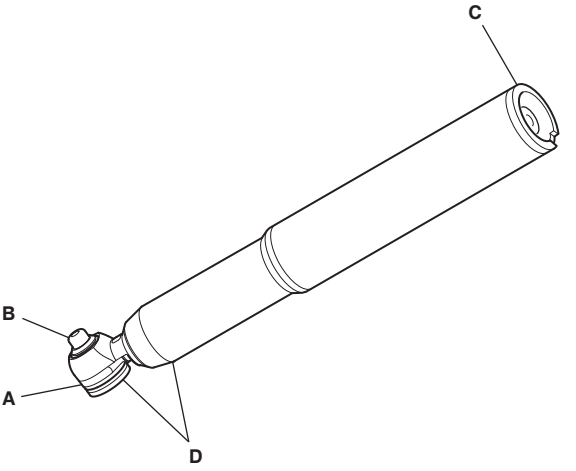
- Use only Stryker-approved equipment, unless otherwise specified.
- DO NOT modify any equipment without the authorization of the manufacturer.
- DO NOT reuse, reprocess, or repackage a single use device. A single use device is intended for a single use only. A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing. Design features may make cleaning difficult. Reuse may create a serious risk of contamination and may compromise the structural integrity of the single use device resulting in operational failure. Critical product information may be lost if the single use device is repackaged. Failure to comply may lead to infection or cross-infection and result in patient and/or healthcare staff injury.
- All cutting accessories are intended for single use only. Reuse significantly increases wear on the handpiece and attachment.

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
Blades	2296-003-XXX series
	2296-023-XXX series
	2296-033-XXX series
	5400-003-XXX series
	5400-031-XXX series
	5400-033-527
	5400-134-XXX series
Irrigation Clip	5100-034-500
Handpiece Cord	5100-004-000
Handswitches	6400-009-000
	5400-009-000

Features



A	**Blade Mount**
B	**Button**
C	**Cord Receptacle**
D	**Applied Part** – The distal end of the handpiece and the cutting accessory (as defined by the *Product Safety Certification* standards listed in the *Specifications* section of the instructions for use supplied with the console.)

Definitions

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

SYMBOL	DEFINITION
▲	Cord Alignment Mark
HANDSWITCH—●	Handswitch Alignment Mark
	General warning sign

Instructions

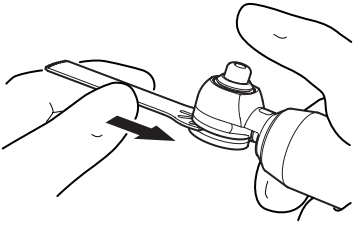
WARNINGS:

- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- DO NOT attempt to insert or remove any cutting accessory while the handpiece is operating.
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.
- DO NOT apply excessive pressure, such as bending or prying, with the blade. Excessive pressure may bend or fracture the blade and cause tissue damage and/or loss of tactile control.
- Before operating the handpiece, gently tug the blade to verify the blade is secure.
- Before operating the handpiece, attempt to rotate the blade mount to verify the blade mount is seated properly. The blade mount should not rotate, and should be fully recessed. Failure to comply may result in excessive handpiece vibration/noise.

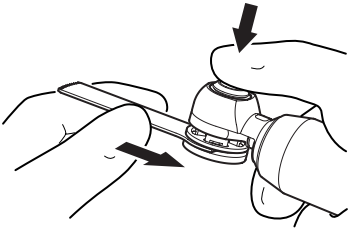
CAUTION: During an endoscopic procedure, DO NOT introduce the handpiece through the same orifice as the endoscope.

To Install a Cutting Accessory

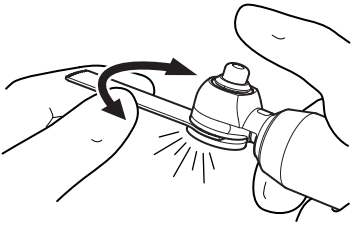
1. Insert the blade into the gap in the blade mount.



2. Fully depress the button and seat the blade against the post. Release the button.

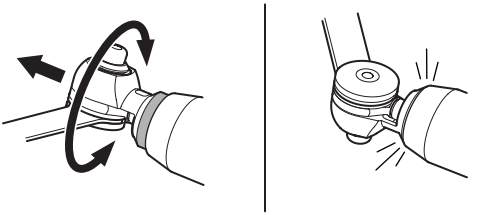


4. Rotate the blade against the post until it snaps into the desired location. If necessary, depress the button again to reposition the blade.



5. Gently tug the blade to verify the blade is secure.
6. To index the blade mount, pull out and rotate the blade mount until it snaps into the desired location.

NOTE: The blade mount will index in 45-degree increments, or eight possible locations.



Instructions (continued)

To Operate the Handpiece

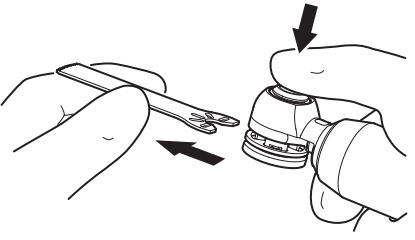
NOTE: See the instructions for use supplied with the appropriate console for additional information about handpiece operation.

1. Plug one end of the cord into the handpiece cord receptacle and the other end of the cord into the appropriate console cord receptacle.
2. Use the console to program the operational settings of the handpiece as required.
3. Use either a handswitch or a footswitch to operate the handpiece.

NOTE: Use the console touchscreen to assign different functions to the footswitch pedals as required.

To Remove a Cutting Accessory

1. Fully depress the button.
2. Remove the blade from the handpiece.



Final Disassembly

1. Unplug the cord from the console and from the handpiece.
2. Remove cutting accessory as described above.

Troubleshooting

WARNING: DO NOT disassemble or service this equipment without the authorization of the manufacturer.

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

PROBLEM	CAUSE	ACTION
The console fails to recognize the handpiece or displays a handpiece error message.	The console software is not compatible with the handpiece.	Contact Stryker to obtain console upgrade information.
	An electrical malfunction exists.	Return the handpiece for repair.
The handpiece exhibits excessive noise and vibration during operation.	The blade is not properly installed in the handpiece.	Reinstall the blade.
The blade exhibits reduced cutting action under a light cutting load.	Normal wear of internal handpiece components.	Return the handpiece for repair.
The cutting accessory will not disengage from the handpiece.	The lock collar is not turned fully enough to release the cutting accessory.	Rotate the lock collar fully counterclockwise.
Sporadic electrical interference is experienced.	Electrical noise is present.	Turn off all electrical equipment not in use in the operating room.
		Relocate electrical equipment; increase spatial distance.
		Plug operating room equipment into different operating room outlets.

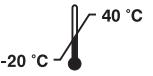
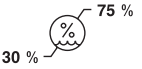
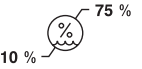
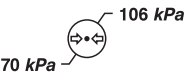
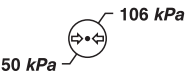
Care Instructions

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

Specifications

WARNING: ALWAYS check any documentation that accompanies attachments and/or cutting accessories for special duty cycle and usage instructions.

Model:	RemB Electric Sagittal Saw (REF 6400-034-000)
Dimensions:	5.3 inch [135 mm] length 0.79 inch [20 mm] diameter
Mass:	0.33 lb [0.150 kg]
Speed:	25000 cpm
Excursion:	5 degree arc
Mode of Operation:	Non-continuous Operation
Duty Cycle:	
Blade cutting accessory REF 5400-134-XXX	Cycle Time: 10 seconds on/10 seconds off Cycle Frequency: 3 times Rest Between Cycles: 30 minutes
All other blade cutting accessories	Cycle Time: 10 seconds on/10 seconds off Cycle Frequency: 4 times Rest Between Cycles: 30 minutes
Power Supply:	Stryker CORE 2, CORE, or TPS Console 40 V ⎓ (Direct Current)
Equipment Type:	 Type BF Applied Part
Maximum Temperature of Applied Part:	Less than 124 °F [51 °C] (Maximum surface temperature as tested to the standards listed under *Product Safety Certification* in the instructions for use supplied with the console.)
Ingress Protection:	IPX0 Ordinary Equipment

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

ES/DE/FR/IT/NL	6400-034-713
JA/ZH/KO	6400-034-720
SV/DA/FI/PT/NO	6400-034-730
PL/EL	6400-034-750

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