RemB® Electric Micro Drill

REF 6400-015-000

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.

Indications For Use

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

When used with a variety of cutting accessories, the RemB Electric Micro Drill is intended for surgical procedures involving the drilling of bone and hard tissue, including the spine. This includes but is not limited to Orthopedic, Dental, ENT (Ear, Nose, Throat), Neuro, and Endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

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.

NOTES:

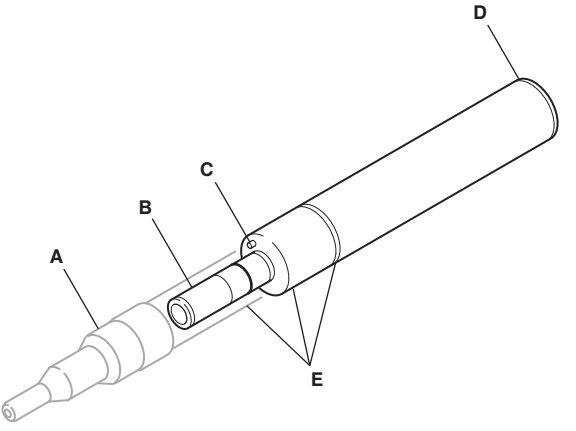
- Cutting accessories are sterilized using irradiation.
- For a complete list of accessories, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

A variety of specialized attachments are available for use with the handpiece. See the instructions for use supplied with the attachment for specific attachment and cutting accessory instructions.

The following Stryker-approved accessories are sold separately:

DESCRIPTION	REF
Attachments	0260-901-XXX series
	5100-015-XXX series
Burs	0277-010-XXX series
	1607-002-XXX series
	1608-002-XXX series
	1608-006-XXX series
	1900-010-XXX series
	1900-015-XXX series
	5300-010-XXX series
Irrigation Clips	5100-015-251
	5100-015-271
Handpiece Cord	5100-004-000
Handswitch	6400-009-000

Features



A	**Attachment**
B	**Attachment Connector**
C	**Anti-Rotation Pin**
D	**Cord Receptacle**
E	**Applied Part** – The distal end of the handpiece and the attachment (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 or 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

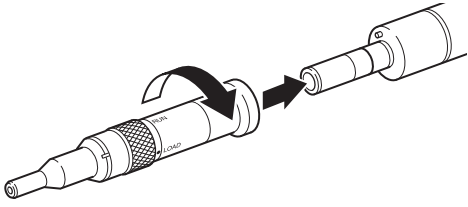
WARNINGS:

- 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.
- Use adequate irrigation during cutting to prevent heat generation.
- DO NOT apply excessive pressure with the side of the cutting accessory. Excessive pressure may cause the components to overheat.
- Before operating the handpiece, gently tug the attachment and the cutting accessory to verify the attachment and the cutting accessory are secure.
- Make sure the cutting accessory is fully locked in the handpiece to prevent friction between the cutting accessory and the handpiece. Failure to comply may cause the components to overheat.

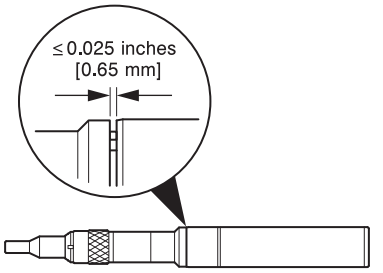
CAUTION: During an endoscopic procedure, DO NOT introduce the handpiece through the same orifice as the endoscope.

To Install an Attachment

1. Using a twisting motion, push the attachment onto the attachment connector until it snaps into place.



NOTE: When installed correctly, a small gap will exist between the attachment and the handpiece due to the anti-rotation pin. The gap should be 0.025 inches [0.65 mm] or smaller. The gap will not hinder the function of the attachment and/or the handpiece.



2. Gently tug the attachment to verify the attachment is secure.

To Operate the Handpiece

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

1. Install a cutting accessory into the attachment.

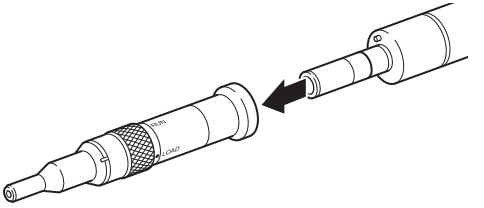
NOTE: See the instructions for use supplied with the attachment to properly install an appropriate cutting accessory.

2. Plug one end of the cord into the handpiece cord receptacle and the other end of the cord into the appropriate console cord receptacle.
3. Use the console to program the operational settings of the handpiece as required.
4. 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 an Attachment

Firmly grasp and pull the attachment from the attachment connector.



Final Disassembly

1. Unplug the cord from the console and from the handpiece.
2. Remove attachment 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 attachment is difficult to install or remove from the handpiece.	The connection between the attachment and the handpiece requires a break-in period.	Repeatedly install and remove the attachment until the connection functions smoothly.
	The handpiece and/or attachment contains a build-up of debris.	See the care instructions manual supplied with the equipment or the instructions for use supplied with the attachment.
The attachment does not retain the cutting accessory.	The cutting accessory is not installed correctly.	Reinstall the cutting accessory. See instructions for use supplied with attachment.
The handpiece will not operate.	The lock collar is not fully engaged.	Fully rotate the lock collar clockwise.
The handpiece exhibits excessive noise and vibration during operation.	The handpiece and/or attachment contains a build-up of debris.	See the care instructions manual supplied with the equipment or instructions for use supplied with the attachment.

PROBLEM	CAUSE	ACTION
The attachment and/or handpiece becomes hot.	The handpiece and/or attachment contains a build-up of debris.	See the care instructions manual supplied with the equipment or the instructions for use supplied with the attachment.
	The attachment bearings need lubrication.	Lubricate the attachment. See the care instructions manual supplied with the equipment.
The cutting accessory will not disengage from the attachment.	The lock collar is not fully disengaged.	Fully rotate the lock collar counterclockwise.
The cutting accessory seizes in the attachment.	The cutting accessory is not installed correctly.	Reinstall the cutting accessory. See the instructions for use supplied with attachment.
	The attachment is not installed correctly.	Reinstall the attachment.
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 Micro Drill (REF 6400-015-000)
Dimensions:	4.8 inch [123 mm] length 0.78 inch [20 mm] diameter
Mass:	0.29 lb [0.13 kg]
Speed:	50000 rpm
Mode of Operation: Duty Cycle: Rest Between Cycles:	Non-continuous Operation 20 seconds on/20 seconds off, 10 times 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:	10 °C – 27 °C	-20 °C – 40 °C
Humidity Limitation:	30 % – 75 %	10 % – 75 %
Atmospheric Pressure Limitation:	70 *kPa* – 106 *kPa*	50 *kPa* – 106 *kPa*

ES/DE/FR/IT/NL	6400-015-713
JA/ZH/KO	6400-015-720
SV/DA/FI/PT/NO	6400-015-730
PL/EL	6400-015-750

Stryker Instruments
4100 E. Milham
Kalamazoo, Michigan
(USA) 49001
1-269-323-7700
1-800-253-3210

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