stryker®

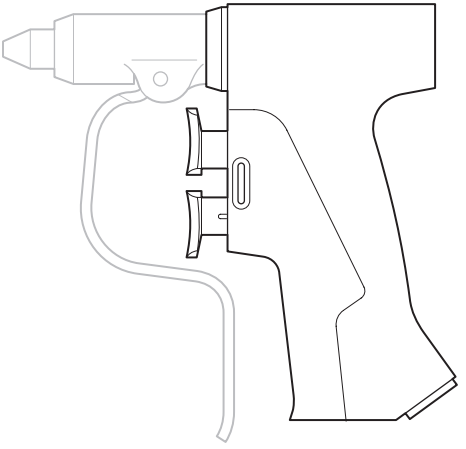
RemB® Electric Universal Driver

REF 6400-099-000

Instructions For Use

R_x 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 RemB Electric Universal Driver (handpiece) is also known as the RemB Universal Driver.

Indications For Use

The Stryker Consolidated Operating Room Equipment (CORE™) System is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to orthopedic, dental, ENT (ear, nose, throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

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

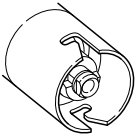
WARNINGS:

- Use only Stryker-approved equipment, unless otherwise specified.
- DO NOT modify any equipment without the authorization of the manufacturer.

Accessories (continued)

WARNINGS:

- 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.
- Wobbling may cause inaccurate wire or pin placement and/or bone or tissue damage. If wobbling occurs, see the *Troubleshooting* section.
- When using the Universal Driver, always use Stryker attachments with two J-slots. The Universal Driver will not fully retain Stryker attachments with only one J-slot.



Use attachments with two J-slots.	DO NOT use earlier versions of the Stryker Wire Collet (REF 4100-062-000) or Pin Collet (REF 4100-125-000). Both collets have only one J-slot.

A variety of specialized attachments are available for use with the handpiece. Each attachment has a specialized retainer for wires, pins, tools or cutting accessories. See the *Cordless Driver and Universal Driver Attachments Instructions For Use* for specific attachment and accessory instructions.

NOTES:

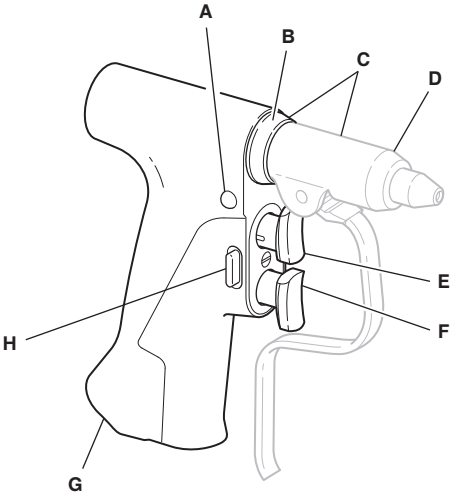
- Cutting accessories are sterilized using irradiation.
- For a complete list of accessories, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

The following Stryker-approved accessories are sold separately:

DESCRIPTION	REF
Handpiece Cord	5100-004-000

Features

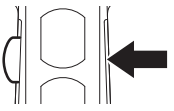
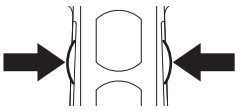
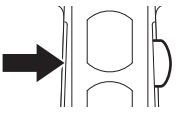
Handpiece



A	**Release Button** – Press to release an attachment from the handpiece.
B	**Attachment Connector**
C	**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.)
D	**Attachment**
E	**Reverse Trigger** – Press this pressure sensitive trigger to obtain variable speed reverse operation.
F	**Forward Trigger** – Press this pressure sensitive trigger to obtain variable speed forward operation.
G	**Cord Receptacle**
H	**Function Switch** – Adjust this switch to the desired function. Functions and switch positions are described below.

Features (continued)

Function Switch

	**SAFETY** – Fully depress the switch to lock both triggers.
	**FORWARD** – Center the switch to lock the reverse trigger. The forward trigger is functional.
	**FORWARD/REVERSE** – Fully extend the switch to unlock both triggers. Both triggers are functional.

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
R	REVERSE TRIGGER
F	FORWARD TRIGGER
S	SAFETY
F	FORWARD
F/R	FORWARD/REVERSE
▲	Cord Alignment Mark
	General warning sign

Instructions

WARNINGS:

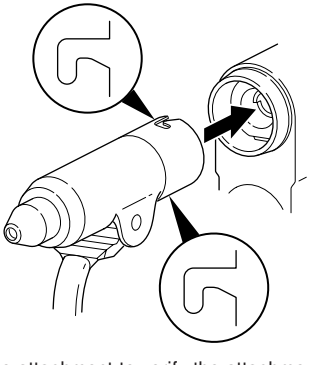
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- DO NOT attempt to insert or remove any cutting accessory while the handpiece is operating.
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.
- Use adequate irrigation during cutting to prevent heat generation.
- Before operating the handpiece, gently tug the attachment to verify the attachment is secure.
- ALWAYS set the function switch to the SAFETY position while the handpiece is idle, when passing the handpiece to another person, or before inserting or removing a cutting accessory or attachment.
- DO NOT press the pedal of a connected footswitch while the function switch is set to the SAFETY position. An accidental pedal press will override the SAFETY position and activate the handpiece.

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

NOTE: See the *Cordless Driver and Universal Driver Attachments Instructions For Use* for specific attachment and accessory instructions.

To Install an Attachment

1. Vertically align the two J-slots on the attachment with the attachment connector.
2. Insert the attachment into the attachment connector until it snaps into place.



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

Instructions (continued)

To Operate the Handpiece

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

1. Install an accessory into the attachment.

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

NOTES:

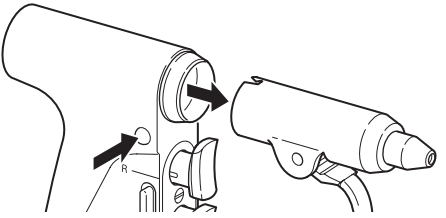
- When using the console, the Forward and Reverse buttons on the Universal Driver Screen do not function. Use the handpiece triggers or a footswitch to select the handpiece direction.
- When using the console, the Oscillate button will initiate a turn-based oscillate mode that defaults to a one-turn oscillation. Use the console touchscreen to select more turns as required.
- Depress both triggers together to operate the handpiece in the oscillate mode.
- Pressure on a trigger will also control the speed of the handpiece.

4. Use either the handpiece triggers or a footswitch to operate the handpiece.

NOTE: Use the console touchscreen to assign different functions (such as the oscillate mode) to the footswitch pedals as required.

To Remove an Attachment

1. Fully depress the release button.
2. 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 handpiece will not operate.	The function switch is in the SAFETY position.	Set the function switch to the FORWARD or FORWARD/REVERSE position.
	An electrical malfunction exists.	Return the handpiece for repair.
The handpiece operation is rough or slow.	An electrical malfunction exists.	Return the handpiece for repair.
The attachment wobbles.	The wire or pin extends too far from the distal end of the handpiece, is the wrong size, or is not properly centered in the attachment.	Reinsert the wire or pin. If the attachment continues to wobble, return the handpiece for repair.
The pin slips in Pin Collet (REF 4100-125-000).	Design limitations exist.	Use Pin Collet (REF 4100-126-000).

Troubleshooting (continued)

PROBLEM	CAUSE	ACTION
The function switch does not operate as expected.	The switch position symbols were not used to set the function switch.	Look at the switch position symbols on the side of the handpiece to properly set the function switch.
The attachment is difficult to install and/or interference is experienced during installation.	The release button mechanism needs lubrication.	See the care instructions manual supplied with the equipment.
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 Universal Driver (REF 6400-099-000)
Dimensions:	5.3 inch [136 mm] height 1.02 inch [26 mm] width 5.47 inch [139 mm] length
Mass:	1.18 lb [0.53 kg]
Speed:	1500 rpm
Mode of Operation: Duty Cycle: Rest Between Cycles:	Non-continuous Operation 20 seconds on/20 seconds off, 6 times 45 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	6400-099-713
JA/ZH/KO	6400-099-720
SV/DA/FI/PT/NO	6400-099-730
PL/EL	6400-099-750

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

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