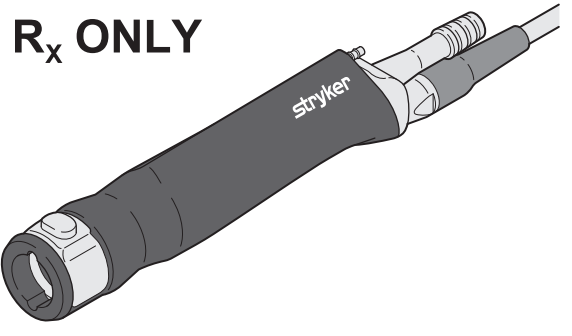
Pello™
Microdebrider

REF 6290-100-000

Instructions For Use

R_X ONLY



ENGLISH (EN)

Introduction

This instruction for use manual contains information intended to ensure the safe, effective, and compliant use of your product.

Keep and consult this reference manual during the life of the product.

Audience

This manual is intended for in-service trainers, physicians, nurses, and surgical technologists.

Conventions

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.

Contact Information

For additional information, including safety information, in-service training, or current literature, contact your Stryker sales representative or call Stryker customer service at 1-269-323-7700 or 1-800-253-3210. 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 Pello Microdebrider system is an electrically operated surgical instrument powered by the Stryker Consolidated Operating Room Equipment (CORE™ 2).

The electric motor provides power to operate removable rotating surgical cutting tools intended for the cutting and removal of soft and osseous tissue/bone in general Ear, Nose, and Throat (ENT), encompassing the areas of sinus and head and neck procedures, such as the following:

SINUS

- Ethmoidectomy/ sphenoethmoidectomy
- Septoplasty
- Endoscopic dacryocystorhinostomy (DCR)
- Frontal sinus trephination
- Transsphenoidal procedures
- Polypectomy
- Antrostomy
- Frontal sinus drill-out
- Septal spurs removal

HEAD AND NECK

- Soft tissue shaving
- Rhinoplasty
- Removal of fatty tissue in the maxillary and mandibular regions of the face

Contraindications

None known.

Description

When used with a variety of accessories, the Stryker Pello Microdebrider handpiece is used to cut and remove soft and osseous tissue/bone. The handpiece features a quick locking mechanism for accessory insertion. The handpiece is designed to provide irrigation and suction to the accessory tip.

The CORE 2 console powers the handpiece and provides irrigation to the accessories.

The footswitch provides control of the handpiece and irrigation pump.

Safety Directives

WARNINGS:

- Only healthcare professionals trained and experienced in the use of this device should use this equipment.
- 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 equipment 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 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 processing 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 processing instructions manual supplied with the equipment.
- DO NOT use this equipment in areas in which flammable anesthetic or flammable agents are mixed with air, oxygen, or nitrous oxide.

For Use With

This section identifies components intended to be used with the equipment to obtain a safe combination.

WARNINGS:

- Use only Stryker-approved equipment, unless otherwise specified.
- Use of unapproved electrical equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system. For information related to compatible software applications, refer to the user manual supplied with the respective software application.
- DO NOT modify any equipment without the authorization of the manufacturer.
- Upon initial receipt and before use, inspect the package for damage and 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.
- DO NOT reuse, reprocess, or repackage a device that is intended for 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 contamination risk and compromise structural integrity resulting in operational failure.
  - Critical product information may be lost during repackaging.

  Failure to comply may lead to infection or cross infection and result in patient and/or healthcare staff injury.
- All accessories are intended for single use only. Reuse significantly increases wear on the handpiece and accessories.

NOTES:

- Sterile accessories are sterilized by ethylene oxide (EtO).
- For a complete list of accessories, contact your Stryker sales

representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

- Depth markings on the accessories are intended as approximate reference only.

CAUTION:

- The ENT brush stylet is used to clear obstructions from the inner lumen of the accessory. See the *Clearing Obstructions* section.
- This table identifies required components used with the handpiece to accomplish its intended use. Required components and accessories are sold separately.

REQUIRED COMPONENTS

DESCRIPTION		REF
CORE 2 Console with software version 1.0 and higher		5400-052-000
Footswitch	CORE Footswitch	5402-007-000
CORE Hummer Disposable Irrigation Cassette		5290-075-000
Stryker approved accessories		See accessories below

ACCESSORIES

DESCRIPTION		REF
Shaver Blades (To be used in oscillating mode (OSC))	Pello straight 2.5 mm shaver blade (multipack)	6290-208-025
	Pello straight 2.5 mm shaver blade (single)	6290-208-125
	Pello straight 3 mm shaver blade (multipack)	6290-112-033
	Pello straight 3 mm shaver blade (single)	6290-112-133
	Pello straight 4 mm shaver blade (multipack)	6290-112-040
	Pello straight 4 mm shaver blade (single)	6290-112-140
	Pello angled 12 degree 4 mm shaver blade (multipack)	6290-112-040-12
	Pello angled 12 degree 4 mm shaver blade (single)	6290-112-140-12

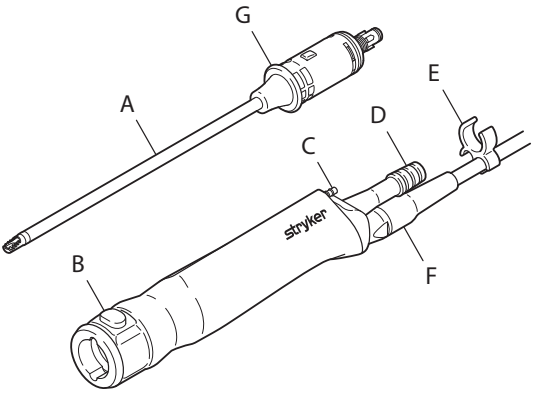
Shaver Blades (To be used in oscillating mode (OSC) continued)	Pello angled 40 degree 4 mm shaver blade (multipack)	6290-112-040-40
	Pello Angled 40 degree 4 mm shaver blade (single)	6290-112-140-40
	Pello angled 60 degree 4 mm shaver blade (multipack)	6290-112-040-60
	Pello angled 60 degree 4 mm shaver blade (single)	6290-112-140-60
Burs (To be used in forward mode (FWD))	Pello angled 15 degree 4 mm diamond bur (multipack)	6290-512-040-15
	Pello angled 15 degree 4mm diamond bur (single)	6290-512-140-15
	Pello angled 70 degree 4 mm diamond bur (multipack)	6290-512-040-70
	Pello angled 70 degree 4 mm diamond bur (single)	6290-512-140-70

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
	General warning sign
●	Cord Alignment Mark
	This symbol on the device label indicates that the device meets the stated criteria: **Contains hazardous substances** This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0 Current scientific evidence supports the position that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.
	For use with

Features



A	**Accessory** – Inserted into the distal end of the handpiece.
B	**Accessory Release Button** – Depress the spring-loaded button to release and remove the accessory.
C	**Irrigation Spike Port** – Connect the irrigation tubing to this port.
D	**Suction Port** – Connect the suction tubing to this port.
E	**Tube Retainer** – Connect the irrigation and suction tubing to this retainer.
F	**Electrical Cable** – Connect the electrical cable to the console.
G	**Hub Flange** – Flush with handpiece when cutting accessory is fully inserted.

Instructions

WARNINGS:

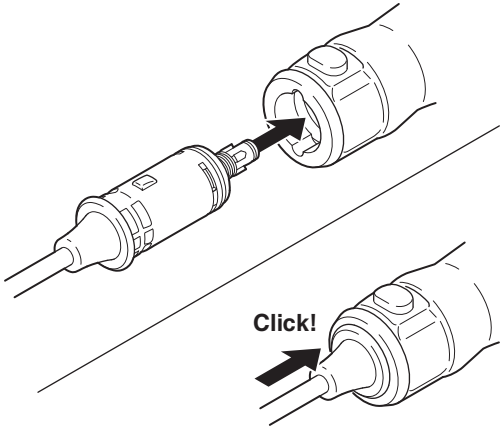
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- DO NOT attempt to insert or remove any accessory or attachment while the handpiece is operating.
- Do not apply excessive pressure, such as bending or prying with the accessory, or allow to make contact with metal objects. Excessive pressure or contact with a metal object may cause the accessory to break or shed metal, leaving pieces of metal in the wound resulting in tissue damage and injure the patient and/or the healthcare staff.

To Insert an Accessory

1. Orient the accessory to align the tabs in one of the two desired positions and insert the accessory into the handpiece. Advance the accessory until it snaps into place with an audible click.

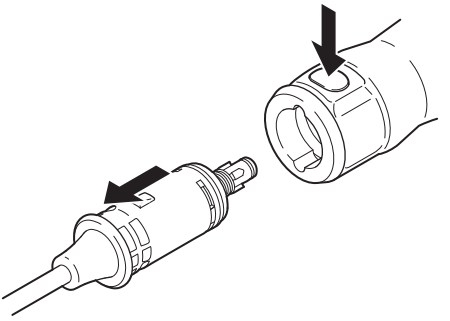
NOTE: DO NOT depress accessory release button during insertion.

2. To confirm the accessory is fully engaged, ensure the hub flange is flush with the handpiece.



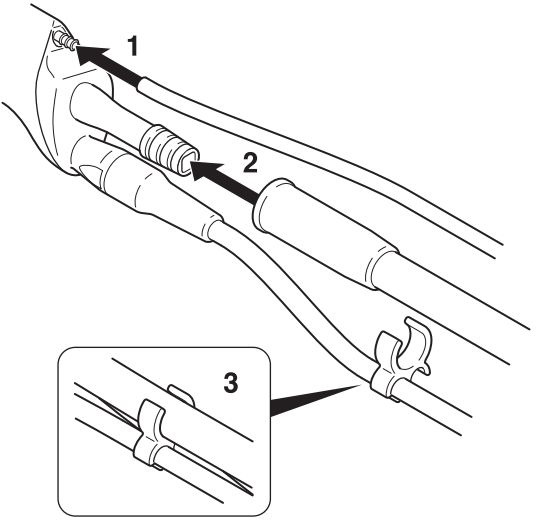
To Remove an Accessory

Fully press the accessory release button to unlock and remove the accessory from the handpiece.



To Connect the Irrigation and Suction Tubes

1. Attach the smaller diameter irrigation tube to the irrigation spike port.
2. Attach a suction tube to the suction port.
3. Snap the irrigation and suction tubes into the tube retainers located on the handpiece's electrical cable.



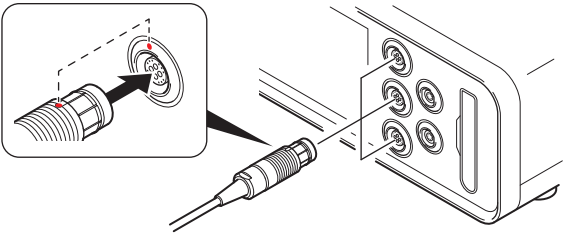
To Operate the Handpiece

WARNINGS:

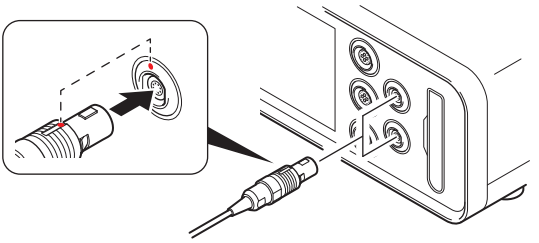
- Observe and comply with all components limitations. See the appropriate instruction booklet.
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.

NOTE: The handpiece will ONLY operate using a CORE 2 console.

1. Attach the accessory, irrigation tube and suction tube to the handpiece.
2. Use the cord alignment marks and plug the handpiece cord into the console handpiece/motor port.



3. Connect the footswitch to the console footswitch port.



4. Adjust the suction pressure to the desired level.

NOTE: When operating a handpiece with a suction source connected, ensure that the suction is ON using at least 5 InHg (127 mm Hg) vacuum.

5. Plug the console into an electrical wall outlet and turn the console ON.
6. Review and acknowledge the console's initial warning screen concerning the attachment limitations.
7. Using the console touch screen, set the desired handpiece speed, mode and irrigation setting.

WARNING: A 20% (20 mL/min) level of irrigation is required at a minimum for the handpiece. Lower levels may result in inconsistent irrigation that may lead to heat generation in the handpiece and at the surgical site, increasing the risk of clogging and abnormal wear of the accessory. Refer to the instructions for use supplied with the CORE 2 system for the procedure on how to adjust the irrigation level.

8. Using the footswitch, activate the handpiece. Depending on user preference, the footswitch pedal may be assigned different functions using the console.

WARNING: DO NOT resect tissue with the Pello Microdebrider system while actively tracking with navigation systems. The endoscopic monitor shall be used while dissecting.

9. The jog function provided by the console allows the accessory to rotate slowly and may be used to align the cutting window to the desired position.

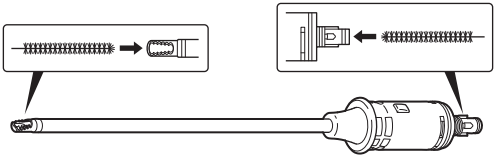
WARNING: DO NOT operate the handpiece in the jog function mode for more than one minute. Failure to comply may result in overheating.

CAUTION: DO NOT operate the handpiece if the accessory does not rotate or oscillate when power is applied to the handpiece. Failure to comply may damage the handpiece.

Clearing Obstructions

Remove the accessory from the handpiece and gently insert the ENT brush stylet (provided in the packaging) into the cutting window or the proximal opening and guide along the inner lumen of the accessory. Use light pressure to remove debris.

NOTE: Ensure the cutting tip is in the fully open position before inserting the stylet.



Final Disassembly

1. Remove the accessory. See the T*o Remove an Accessory* section.
2. Unplug the handpiece cord from the console.
3. Disconnect the suction and irrigation tubes from the handpiece.

Accessory Disposal/Recycle

- ALWAYS follow local, state and federal regulations regarding the handling and disposal of biohazardous materials.
- ALWAYS follow local, state and federal regulations regarding the disposal of sharps.

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
Handpiece is not recognized by console.	The console software is not compatible with the handpiece.	Contact Stryker to obtain console upgrade information.
Accessory does not turn.	Accessory is not seated properly.	Reinsert accessory.
	Accessory is damaged.	Remove and check accessory. Replace if not freely spinning.
Handpiece will not run.	Handpiece cable is not firmly plugged into console.	Ensure handpiece cable is firmly plugged into console.
	The electrical cable is damaged.	Return the handpiece for service.
	Footswitch electrical plug is not firmly seated into console.	Ensure footswitch plug is firmly seated into console.
Suction/Irrigation is not present.	Tubing is not securely connected to the suction/ irrigation port.	Ensure tubing is securely connected.

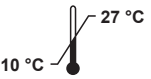
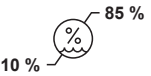
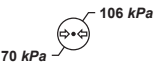
Sporadic electrical interference is experienced.	Electrical noise is present.	Turn off all electrical equipment not in use.
		Relocate electrical equipment; increase spatial distance.
		Plug equipment into different outlets.

Processing Instructions

For cleaning, sterilization, and disposal/recycle information of the Stryker Pello Microdebrider handpiece, see the processing instructions manual supplied with the product.

Specifications

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

Model:	Pello Microdebrider REF 6290-100-000
Dimensions:	7.1 inch [18.2 cm] length (handpiece only) 1.1 inch [2.8 cm] height 0.9 inch [2.3 cm] width
Mass:	0.84 lb [380 g] (including cord)
Speed:	Oscillation mode – 1400 to 5000 rpm Forward/reverse mode – 1400 to 12000 rpm
Mode of Operation: Duty Cycle: Rest Between Cycles:	Non-continuous Operation 3 minutes on/3 minutes off, 10 times 3 hours
Power Supply:	Stryker CORE 2 Console 40 V ⎓
Equipment Type:	 Type BF applied part
Applied Part:	The distal end of the handpiece as defined by the manufacturer.
Maximum Temperature of Applied Part:	Less than or equal to 48˚C [118˚F] as tested to the *Product Safety Certification* standards in the console instructions for use.
Ingress Protection:	IPX0 Ordinary Equipment
Environmental Conditions:	**Operation** / **Storage and Transportation**
Temperature Limitation:	
Humidity Limitation:	
Atmospheric Pressure Limitation:	

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