HydroCision® GB US

The Leader in Hydrosurgery®

HydroCision® TenJet Devices

Symbol Description

REF Catalogue Number	Do Not Re-Sterilize
LOT Lot Number	Temperature Limit
Do Not Use If Package Is Damaged	Use-by date
Manufacturer	Do not re-use
STERILE EO Sterilized using ethylene oxide	Consult for use

℞ U.S Federal law restricts this device to sales by or on the order of a physician.

VAC Connection of the waste hose, or any container connected to it, to a vacuum source is not required and will create continuous suction at the device tip and affect device performance.

GB US

English

Instructions for Use

Please read all information carefully. Also refer to the Product Manual supplied with the HydroCision Console. The components of the HydroCision TenJet Devices are designed to be used in combination with the HydroCision Console and function as a single unit. Failure to properly follow instructions may lead to mechanical, electrical, or thermal injury and result in improper functioning of the device.

HydroCision, Inc.
267 Boston Road, Suite 28
North Billerica, MA 01862
USA
Customer Care: (978) 474-9300

EC REP
EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands
+31 (0) 70 345 8570

CE 1639

Indications

The HydroCision TenJet Device is intended for orthopedic surgical procedures where the cutting, debridement and removal of soft and hard tissue is required in a variety of open, arthroscopic, and minimally invasive surgical procedures**,** including the treatment of tendinopathy through partial of full thickness tenotomy.

Device Description

The TenJet Device consists of a disposable handpiece that is connected to the HydroCision Console through a disposable hose and a pump cartridge. The pump cartridge mounts into a nest assembly on the front of the HydroCision Console; this connection provides the power to the TenJet Device. A fluid supply hose connects via a standard bag spike to a sterile saline irrigation bag. A waste hose from the handpiece connects via a standard connector to a waste container.

Warnings

- All HydroCision TenJet Devices should not be activated in close proximity to, or come into contact with nerves or major blood vessels to avoid the possibility of injury or damage from the fluidjet cutting action, locally generated vacuum, or device edges or tips.
- Do not touch the TenJet handpiece tip while activated.
- Do not insert or withdraw the TenJet handpiece while activated.
- Inadvertent activation or movement of the TenJet handpiece outside the field of vision or without adequate assurance of device placement via ultrasound or an alternate imaging technology may result in patient injury.
- Do not reuse any system component or accessory labeled as SINGLE USE. Reuse may lead to infection or injury to the patient.
- Attempts to bend the TenJet handpiece may render the tool unusable or unsafe.
- No modification of this equipment is allowed.

Precautions

- A thorough understanding of the principles and techniques involved in ultrasound guided tenotomy is essential to avoid injury to the patient and medical personnel, and damage to the device or other medical instruments.
- Read all instructions carefully. Failure to properly follow instructions may lead to electrical, mechanical, or thermal injury and cause improper functioning of the device.
- Please refer to the HydroCision Console Product Manual for step-by-step instructions regarding the assembly and initial system check of the HydroCision Console.
- TenJet Devices are supplied as sterile, single use disposable handpieces. If the package is opened or damaged the sterility of the handpiece will be compromised.
- Ensure complete connection of the handpiece to the HydroCision Console, fluid supply and waste container prior to use.
- Avoid kinking of the high-pressure hose, which can cause leaks.
- The TenJet handpiece should be inserted, manipulated, and withdrawn carefully from the operative site to avoid possible damage to the device and/or injury to the patient or surgical personnel.
- Do not apply excessive force in any direction during the procedure to avoid patient injury.
- Particular precaution should be made to avoid unintended puncture of the tendon.

Instructions for Use

Also see the HydroCision Console Product Manual.

1. Circulating Nurse: Ensure that the sealed package is undamaged. Using sterile technique, carefully open the product outer package and present contents to sterile field personnel.
2. Scrub Nurse or Physician: Open inner pouch or lid.
3. Scrub Nurse or Physician: Clip the high-pressure hose/waste hose to the sterile drape.
4. Scrub Nurse or Physician: Pass the pump cartridge, high-pressure hose/waste hose, and coiled supply hose with bag spike to the Circulating Nurse.
5. Circulating Nurse: Insert the pump cartridge into the nest by pushing the cartridge in until it is fully seated, and locked. Attach the waste hose connector to a waste collection container – connection of the waste collection container to a vacuum source is not required and will create continuous suction at the device tip and affect device performance. The waste container must be vented to the atmosphere if not connected to a vacuum source. Remove the sterile cover from the bag spike and insert into a saline irrigation supply bag. A 1-liter bag is recommended for tenotomy procedures. Ensure that there are no kinks or external obstructions in the supply, high pressure, or waste hoses.
6. Circulating Nurse: Ensure that the foot switch is plugged into the connector on the front of the console and the power cord is plugged into the back of the console. Plug the power cord into a proper electrical outlet. Turn on the main power switch.
7. Nursing Staff: Depress foot pedal to prime system. Once the system has been primed with saline, do not allow the saline irrigation bag to empty; an empty bag will allow air into the system and reduce the system's efficiency. Therefore, always change to a new saline irrigation bag before the bag in use empties. Take care when switching bags to prevent air from entering system by closing off the supply hose with the pinch clamp.
8. Prepare the patient pre-operatively according to standard procedures.
9. After completing the procedure, disconnect the TenJet Device from the Power Console by removing the pump cartridge by pulling it straight out. Turn off the main power.

TenJet Procedure:

1. Prep the area with an antimicrobial solution and inject with a local anesthetic.
2. Place sterile sleeve over ultrasound transducer and screen anatomy to identify and visually confirm diseased tissue.
3. Under ultrasound guidance: Keeping the point end up, pierce the skin with a #11 blade scalpel. Then create a single stab track down to the pathology. DO NOT TWIST THE SCALPEL, BUT CONFIRM THAT THE SCALPEL INSERTION FOLLOWS A STRAIGHT PATH. This helps to advance the TenJet® Device to the desired anatomical position.
4. After creating a stab incision, use ultrasound guidance to direct the TenJet handpiece to the diseased tissue.
5. Activate the console by pressing down on the foot pedal. While under continuous ultrasound guidance, run the system. While the system is running, utilize a pistoning rotating motion to access and debride as much of the diseased tissue as possible. Do not apply excessive force in any direction to avoid patient injury.
6. Confirm satisfactory debridement with ultrasound and remove handpiece from the patient.
7. Follow standard surgical procedure for post-operative cleaning and closure of the percutaneous site.
8. If the device tip becomes blocked with foreign matter, it will typically be noticed by a reduction in device efficiency or the presence of spray from the tip; a) Stop the jet flow by releasing the foot switch; b) Remove the handpiece from the surgical site using care not to come into contact with vital structures; c) Remove the obstruction with forceps taking care not to touch the opening in the high-pressure jet. Once removed, depress the foot switch and check that there is a single coherent jet flow. If the obstruction is not completely removed, repeat procedure
9. The TenJet handpiece, saline irrigation bag, and waste receptacle collection container may be discarded using biohazard disposal procedures according to local regulations.

STERILE	EO

How Supplied

The TenJet Device is provided sterile.

The contents are sterile unless the package is opened or damaged. Do not resterilize.

Do not use if package is opened or damaged.

Accessory Kit (All Contents Provided Sterile)

-Qty 1, Transparent dressing 2 3/8" x 2 3/4"
-Qty 1, Wound closure strips 6'S
-Qty 4, Gauze 4" x 4" x8 PLY 2'S
-Qty 1, Probe cover w.gel 5" x48"
-Qty 1, Scalpel #11
-Qty 2, Needle, TW. "A" BEV 23 G x 1.5"
-Qty 1, Syringe, 10CC, LL
-Qty 1, Chloraprep, X. Tint 3ML Applicator

Storage

The TenJet Devices should be stored in a manner to prevent damage to the instruments prior to use.

Temperature Limit: -40°F (-40°C) to 125°F (52°C)
Humidity Range: 0% to 100%, noncondensing
Atmospheric Pressure: 500 to 1500 millibar

For further information, consult the HydroCision Console Product Manual.