

HOW SUPPLIED

The Urethral Warming Catheter Kit is provided sterile by irradiation and is intended for SINGLE USE ONLY. Discard product after use according to hospital policy.

WARRANTY

Endocare warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of this instrument as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and others matters beyond Endocare's control directly affect the instrument and the results obtained from its use. Endocare's obligation under this warranty is limited to the repair or replacement of this instrument and Endocare shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. Endocare neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with this instrument.

Price, models and availability are subject to change without notice.

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Endocare extending life everyday™ is a trademark of Endocare, Inc.
CryoCare® is a registered trademark of Endocare, Inc.

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5,800,488; 6,074,412; 6,139,544; 6,251,105 and
other U.S. and foreign patents pending.



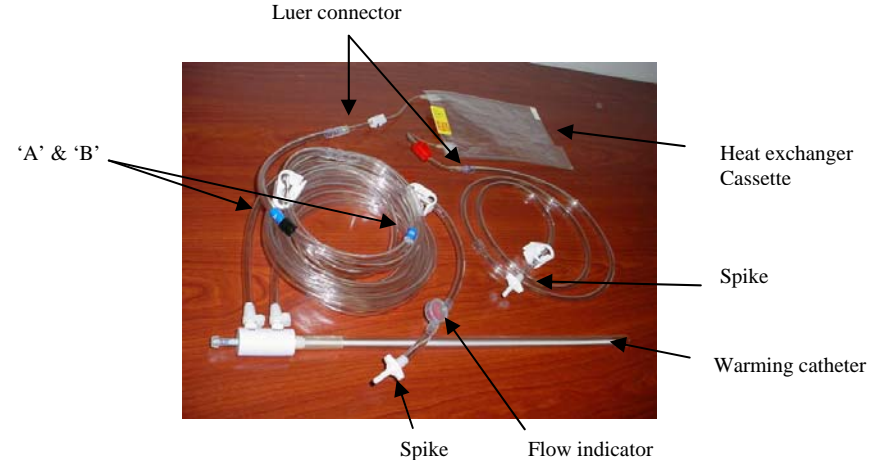
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Urethral Warming Catheter Kit

For use with the CryoCare® Surgical System™

Directions for Use



Warning: Federal (USA) law restricts this device to sale by or on the order of a physician

Urethral Warming Catheter Kit

For use with the CryoCare[®] Surgical System™

DEVICE DESCRIPTION

The Endocare Urethral Warming Catheter Kit contains a Urethral Warming Catheter, a Heat Exchanger Cassette, and tubing for completing the circuit.

INTENDED USE

The Urethral Warming Catheter Kit is intended for use with the Endocare Urethral Warming System and is designed to maintain urethral tissue temperature above 0°C during urologic cryosurgery utilizing the CryoCare[®] Cryosurgical System™ or the CryoCare[®] CS Cryosurgical System.

CONTRAINDICATIONS

Use of the Urethral Warming Catheter Kit is contraindicated in those patients with severe urethral stricture.

WARNINGS

- **DO NOT** turn off Urethral Warming System prior to removal of Urethral Warming Catheter. This may cause the catheter to freeze in the urethra, be difficult to remove and result in injury to the patient. **DO NOT** attempt to remove the Urethral Warming Catheter if Urethral Warming System has been turned off. If this occurs, turn on Urethral Warming System and circulate warm sterile water or saline through the catheter until it can be removed.
- **DO NOT** exert excessive force during advancement or withdrawal of the Urethral Warming Catheter as excessive force could result in patient injury.

CAUTIONS

- The Urethral Warming Catheter Kit should be used only by physicians and staff who have been trained and are thoroughly familiar with the instructions and safety precautions in these directions for use and the *CryoCare[®] or CryoCare[®] CS Surgical System™ Operator's Manual*.
- **For single use. Do not re-sterilize.** The components of the Endocare Urethral Warming Catheter Kit are provided sterile. Do not attempt to re-sterilize as doing so may result in damage to the device or injury to the patient or user.
- All packaging and components should be inspected prior to use. Do not use if sterile barrier has been breached. Do not use if package or components are damaged in any way.
- The Urethral Warming Catheter Kit can only be used with the Endocare Urethral Warming System. This Urethral Warming Catheter Kit will not function with other urethral warming systems.

COMPLICATIONS

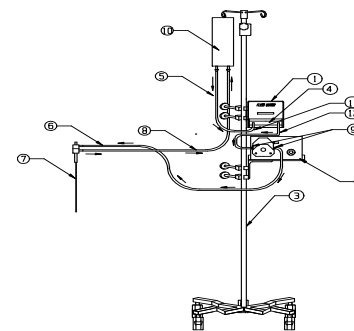
The complications which may result from urethral catheterization include:

- Tissue Trauma
- Mucosal Trauma
- Bleeding
- Creation of False Passage
- Scar Tissue Formation
- Tissue Perforation
- Urethral Perforation
- Infection
- Inability to Void

INSTRUCTIONS FOR USE

Prior to Use

- It is recommended that an additional Urethral Warming Catheter Kit be available in the event of a defect in the catheter/tubing.
- Set up the Urethral Warming System as indicated in the Endocare Urethral Warming System Operator's Manual.



Cryo-61 Warming System

Procedural Instructions

1. Open tray and remove sterile Catheter Kit from tray.
2. Close all clamps on tubing set.
3. Insert Heat Exchanger Cassette in Fluid Warmer according to the label's orientation instructions.
4. Locate label letters "A" and "B" on Urethral Warming Catheter Kit inflow tube. Place Catheter Inflow Tube in pump head so that the letter "A" are on the left side of the pump and the letter "B" is on the right. Close pump head by moving handle with black knob from left to right, thereby clamping down on the Urethral Warming Catheter Inflow Tube.
5. Insert IV bag spike of Heat Exchanger Inflow Tube into one of the access ports on IV bag. Insert the IV bag spike of the Urethral Warming Catheter Outflow Tube into the other access port on the I.V bag.
6. Open all clamps on the tubing and follow operating instructions given in the Endocare Urethral Warming System Operator's Manual.