

ACCURYN® URINARY CATHETER KIT

The Accuryn Monitoring System is intended for use in the drainage and/or collection of urine, and in the monitoring of urine output and core body temperature, in degrees Fahrenheit and degrees Celsius. The Accuryn Monitoring System is also intended for use in the monitoring of intra-abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS). The Accuryn Sensing Urinary Catheter is a single use device intended for short-term use (less than 30 days).

Caution: Do not use until you have read and understood the Accuryn Monitoring System Operator's Manual and the separate instructions included with the Accuryn Urinary Catheter Kit.

Caution: The Accuryn Monitoring System is only intended for use by a physician, or on the order of a physician.

*Sensing Urinary Catheter – Urinary Output, Temperature, Intra-abdominal Pressure (U/O, Temp, IAP) in Figure 1. (Sensing Urinary Catheter – U/O, Temp not shown.)

Sensing Urinary Catheter – U/O, Temp, IAP or U/O, Urine Collection Set, and Insertion Kit

Contents:

- Accuryn Sensing Urinary Catheter – U/O, Temp, IAP or U/O, Temp
- Accuryn Temperature Sensing port
- Accuryn urine drainage tube
- Drainage tubing clamp
- Urine measurement cassette
- Pre-attached 2000ml urine collection bag
- Bag hanger with string hanger
- Sheet clip
- Catheter Placement Kit:
 - 10cc syringe of Sterile Water
 - Waterproof Drape
 - Fenestrated Drape
 - Alcohol Preparation Pad
 - Specimen Container
 - Nitrile Gloves (Size 8)
 - Lubricating Jelly
 - Povidone-Iodine Swabs (3)
 - Catheter Securement Device
 - Skin Protectant Pad
 - Soap Towelette
 - Hand Sanitizer



Figure 1. Sensing Urinary Catheter – U/O, Temp, IAP

Sterile: Contents of inner wrap are sterile unless package has been opened or damaged.

WARNING: This product should never be connected to the temperature monitor or connected to a cable during an MRI procedure. Failure to follow this guideline may result in serious injury to the patient. It is important to closely follow these specific conditions that have been determined to permit the examination to be conducted safely.

Disposable. Single use only. Do not resterilize. Short term use only (less than 30 days).



WARNING: The Accuryn Sensing Urinary Catheter and Urine Collection Set is MR Conditional. It poses no known hazards in specified MRI environments with specified conditions of use. Please consult MRI Safety Instructions.

Set up procedure

CAUTION: After use this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Accuryn Sensing Urinary Catheter Set up

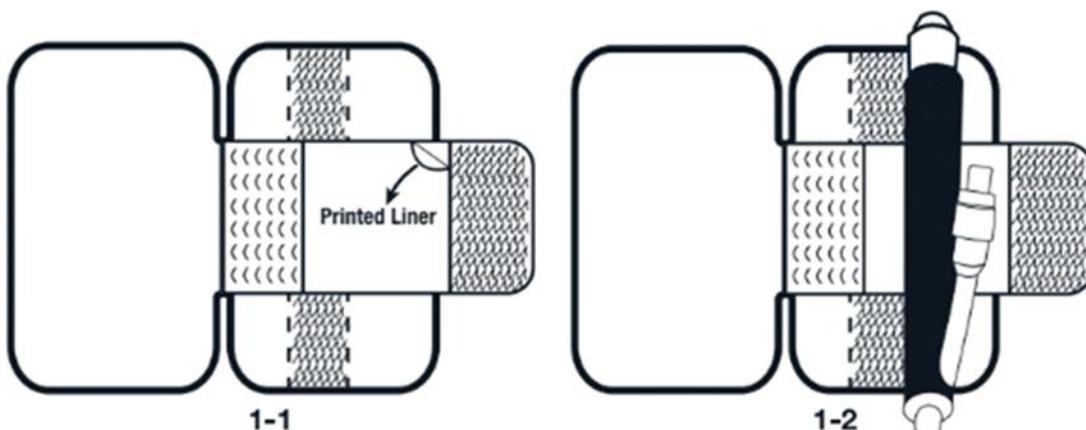
1. Perform hand hygiene and put on non-sterile gloves provided by your institution.
2. Prior to use, visually inspect Accuryn Sensing Urinary Catheter packaging to ensure no breaches. If there are breaches, dispose of product per institution guidelines and obtain a new package.
3. To open, pinch tabs on packaging and pull apart.
4. Pull tray out of pouch and place in field.
5. Using aseptic technique, unfold outer wrap to form sterile field in front of patient's peritoneal area.

6. Pinch the drainage tube closed using the attached blue drainage tubing clamp.
7. Use soap towelettes to perform perineal cleansing per facility guidelines.
8. Pick up waterproof drape by edge without contaminating contents and place with shiny side down under buttocks.
9. Use hand sanitizer provided.
10. Put on nitrile sterile gloves.
11. Lift tray top to reveal lower tray components.
12. Attach 10cc sterile water filled syringe to catheter.
13. Open lubricating jelly packet and squeeze into tray well to lubricate the catheter tip.
14. Place fenestrated drape on patient without contaminating gloves.
15. Open Povidone-Iodine swabs packet.
16. For female patient, use Povidone-Iodine swabs to clean patient's meatus from top going down. For male patients, use swabs to clean the patient's meatus per facility's guidelines. Each swab is for single use.
17. Proceed with catheterization according to facility guidelines.
18. Inflate the catheter retention balloon using the syringe provided. Instill entire amount of sterile water(10cc).
19. Confirm urine drainage by briefly opening the blue drainage tubing clamp so that urine can flow through the closed system toward the collection bag. Note: any urine collected prior to connecting to the Monitor and powering on will not be measured electronically, so re-close the blue drainage tubing clamp as soon as possible after confirmation of flow. **CAUTION: Do not use an external clamp on the drainage tubing assembly, as it may damage the catheter.**

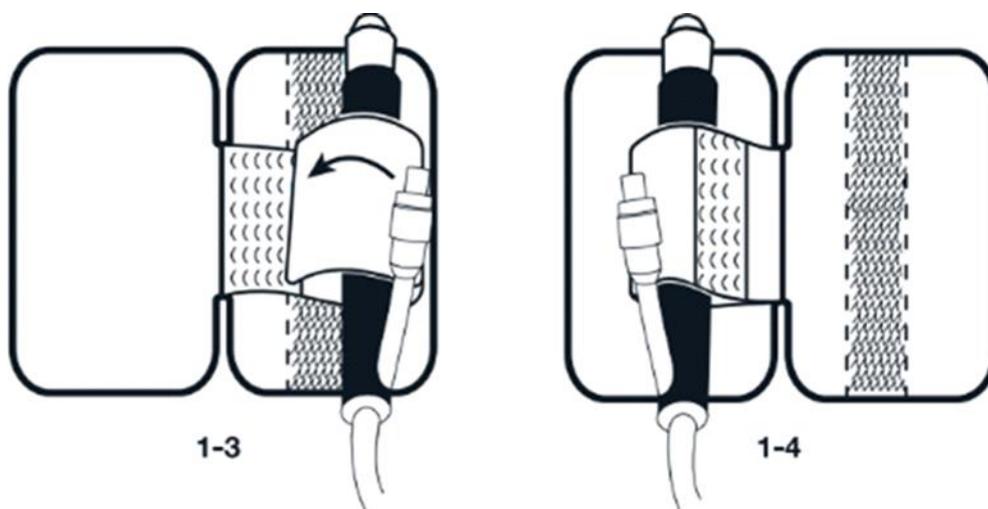
Application Instructions for Foley Catheter Securement

WARNING: Do not use catheter securement device on patients with known tape or adhesive allergies.

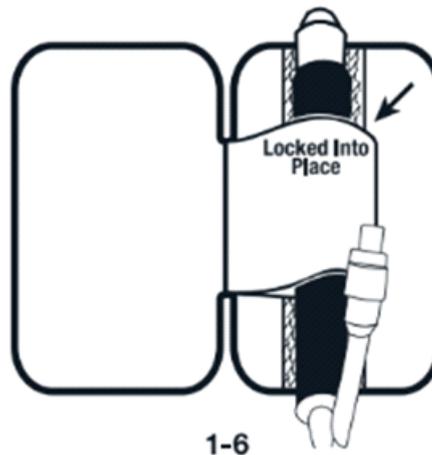
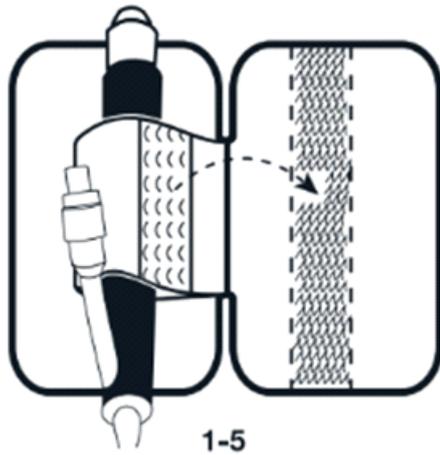
1. Clean application area with alcohol, let dry. After insertion of catheter, fully extend patient's leg.
2. Peel back printed liner (1-1). Place catheter on exposed adhesive (1-2).



3. Wrap hook & loop beyond Y lumen of catheter (1-3) and secure (1-4).



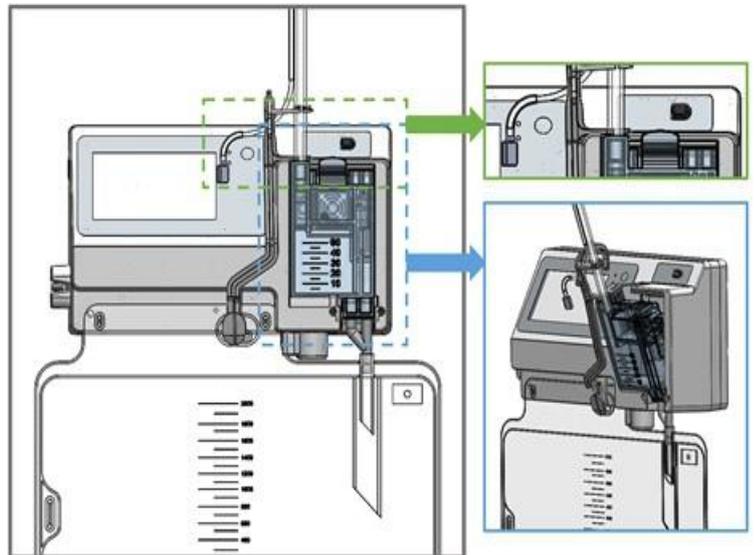
4. Locate securement site allowing for one inch of tubing slack between securement site and urinary meatus to prevent undue traction.
5. Fasten secured tab to strip on device base (1-5), locking tube in place (1-6).



6. Peel off back liner and apply catheter securement device to patient.
7. To remove: release hook and loop tab, remove Foley. Gently peel edge of securement device until completely removed. Alcohol may be used if necessary.

Accuryn Urine Collection Set and Monitor Set up

1. Ensure that tubing extends from the catheter to the measurement cassette in a smooth, unknicked path.
2. Hang the Monitor on an appropriate Accuryn mount using the mounting feature on the Monitor (M7, Refer to Figures below). Adjust Monitor position to be parallel to floor as close as possible. Connect unit to Wall Power (M10).
3. Place the Measurement Cassette (D8) securely in the Cassette Interface (M6) of the Monitor by first positioning the bottom of the cassette in the cassette interface and pivoting the cassette into place. Ensure that top latch of cassette engages with the Monitor.
4. Hang urine collection bag on Bag Hook (M8). Ensure that the bag hangs freely.
5. Connect the Thermistor Plug (D7) to the Temperature Port (M5).
6. Turn on the Monitor by pressing the Power Button (M4).
7. Follow start-up instructions in Accuryn® Monitoring System Operator's Manual to initiate patient data collection.
8. Press the start button (play icon in upper right corner of the display screen M1).
9. Open the drainage tubing clamp to allow urine flow.
10. Refer to Accuryn Monitoring System Operator's Manual for use of the Monitor.
11. Catheter should be managed in accordance with the CDC guideline, "Guideline for Prevention of Catheter-associated Urinary Tract Infections, 2009." At the onset or first signs of infection, catheter encrustation, or any other catheter-related adverse effect, the Accuryn Sensing Urinary Catheter should be removed and replaced if necessary.
12. Per CDC guidance the drainage system should remain sealed and closed. [Note: The junction between the catheter and drainage tubing is NOT breakable].
13. **To drain the collection bag:**
 - a. Close drainage tubing clamp.
 - b. Pause the Accuryn Monitor (upper right corner of the display screen M1).
 - c. Empty the bag per facility protocol.
 - d. Press play to restart monitoring after draining (upper right corner of the display screen M1).
 - e. Open blue drainage tubing clamp to resume normal use.
14. **Reset Urine Output Volume:**
 - a. Document Urine Output.
 - b. Tap "UO" Symbol until UO Menu is displayed.
 - c. Select "RESET".
 - d. Confirm message to reset the Total UO volume back to zero.
15. **Directions for urine sampling:**
 - a. Clamp the drainage line with the blue clamp. Wait until a sufficient sample size accumulates in



the drainage tube.

- b. Swab surface of Sampling Port (D5) with antiseptic wipe.
- c. Using aseptic technique, position a luer-lock syringe in the center of the sampling port. Press the syringe in firmly and twist gently to lock the syringe into the sampling port.
- d. Aspirate desired volume of urine, then twist to disengage syringe from sampling port.
- e. On the monitor click the "UO" symbol section. Select "SAMPLE" from the menu. Select volume of urine aspirated and then confirm on the next screen.
- f. Open the drainage tubing clamp to allow urine flow.

16. Direction for flushing

- a. On the monitor, click the UO volume section. Select "FLUSH" from the menu. Select volume of fluid that will be flushed and then confirm on the next screen. If there is flush volume value remaining on the display from a previous flush, the amount of the flush remaining will be indicated on both the Flush Volume section screen and the Flush Confirmation screen.
- b. Swab surface of Sampling Port (D5) with antiseptic wipe.
- c. Using aseptic technique, position a luer-lock syringe in the center of the sampling port. Press the syringe in firmly and twist gently to lock the syringe into the sampling port.
- d. Flush the catheter per facility protocol and disengage the syringe.

Removal procedure

CAUTION: Remove/replace urinary catheter after 29 days of use.

CAUTION: Disconnect Measurement Cassette (D8) from the Monitor prior to removing catheter. Failure to do so may result in urethral trauma.

1. Ensure all data has been recorded before removal of the device.
2. Pause the monitor (upper right corner of the display screen M1). Wait approximately 5 seconds until the monitor is flashing "PAUSED."
3. Disconnect the Thermistor Plug (D7) from the Temperature Port (M5).
4. Disconnect the Measurement Cassette (D8) from the Monitor.
5. Remove Drainage Bag from baghanger.
6. **Deflate retention balloon:** Gently insert a luer slip tip syringe into the Retention Balloon Valve (D4). Allow the pressure within the balloon to force the plunger back and fill the syringe with water. Use only gentle aspiration to encourage deflation if needed.

CAUTION: Do not remove urinary catheter if resistance is felt. Check balloon status.

7. Slowly remove catheter from the bladder.
8. At end of device use, dispose of all materials in accordance with facility protocol.
9. Power down the Accuryn Monitor (M4) by pressing and holding power button.
10. Clean the monitor and accessories thoroughly. Follow cleaning instructions in the Accuryn Monitoring System Operator's Manual.

MRI Safety Information

Non-clinical testing has demonstrated the Accuryn Sensing Urinary Catheter and the Accuryn Urine Collection Set is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

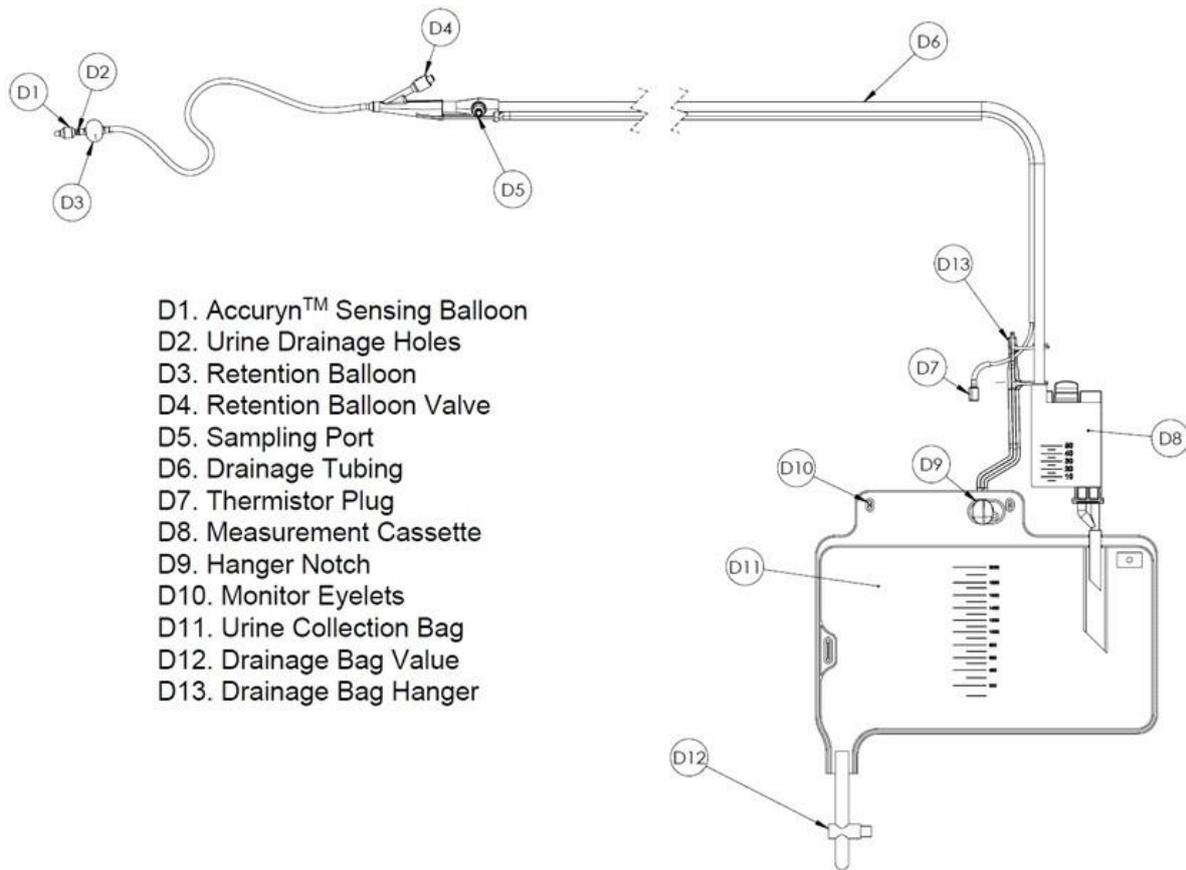
- Static magnetic field of 1.5 T or 3 T;
- Maximum spatial gradient field of 8,100 gauss/cm (81 T/m);
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Accuryn Sensing Urinary Catheter is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning at either 1.5 T or 3.0 T.

In non-clinical testing, the image artifact caused by the device extends approximately 12 mm from the Accuryn Sensing Urinary Catheter when imaged with either a gradient echo or spin echo pulse sequence and a 3T MRI system.

The position of the thermistor wire of the Foley Catheter with temperature sensor has an important effect on the amount of heating that may develop during an MRI procedure. Accordingly, the Foley catheter with temperature sensor must be positioned in a straight configuration down the center of the patient table (i.e. down the center of the MR system without any loop) to prevent possible excessive heating associated with an MRI procedure.

Accuryn[®] Sensing Urinary Catheter – U/O, Temp, IAP or U/O, Temp and Urine Collection Set



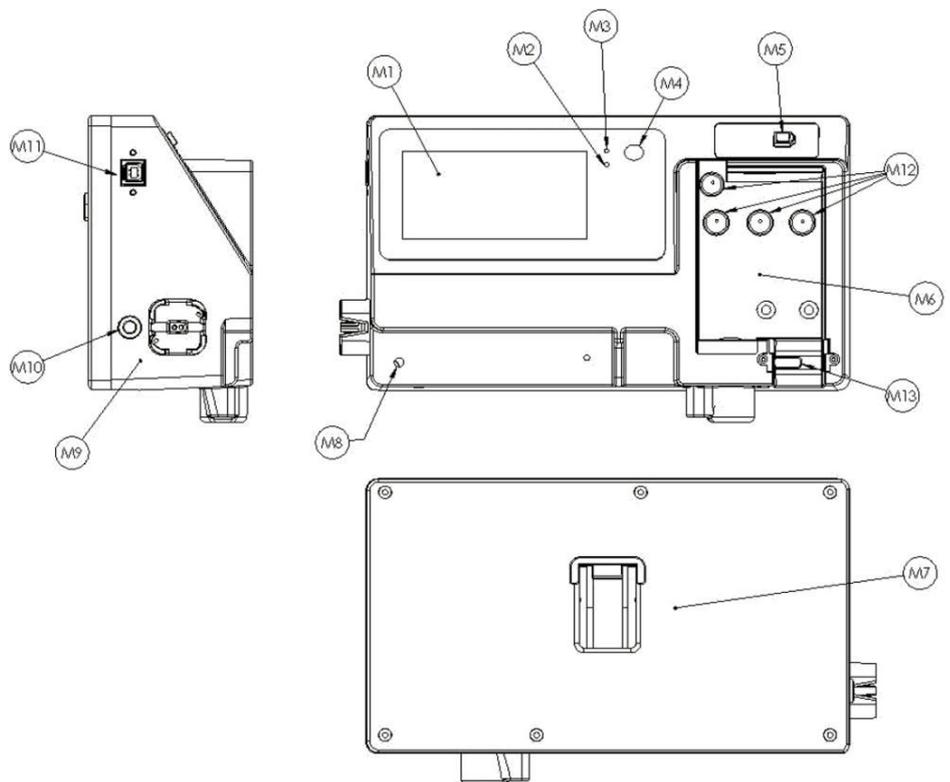
- D1. Accuryn™ Sensing Balloon
- D2. Urine Drainage Holes
- D3. Retention Balloon
- D4. Retention Balloon Valve
- D5. Sampling Port
- D6. Drainage Tubing
- D7. Thermistor Plug
- D8. Measurement Cassette
- D9. Hanger Notch
- D10. Monitor Eyelets
- D11. Urine Collection Bag
- D12. Drainage Bag Value
- D13. Drainage Bag Hanger

*D1. Accuryn Sensing Balloon – Not Applicable to U/O, Temp model

Accuryn[®] Monitor

Features

- M1. Touch Screen Display
- M2. Error Indicator Light
- M3. Power Indicator Light
- M4. Power Button
- M5. Temperature Port
- M6. Cassette Interface
- M7. Mounting Interface
- M8. Urine Collection Bag Hook
- M9. Temperature Pass-through Connector
- M10. Power Connector
- M11. USB Type B Connector
- M12. Cassette Port
- M13. Pinch Valve



Cleaning

Follow cleaning instructions in the Accuryn Monitoring System Operator's Manual.

Note: Compatible only with the Accuryn Monitor. Do not connect temperature plug with other systems.

Caution: As with all temperature probes, in the presence of RF energy sources, local heating, temperature errors and probe damage may occur. In medical use, disconnect all connections between the Accuryn Urine Collection Set and the Accuryn Monitor before activating electrosurgical or other types of direct coupled RF energy sources.

Do not stretch the catheter – will cause repositioning of the temperature probe.

Do not use stylet – will cause stretching of the catheter.

Do not attempt to break the junction between the catheter and the drainage tubing – the catheter and drainage tubing are permanently bonded together.

Cautions and Safety Information

Do not use ointments or lubricants having a petrolatum base. They will damage silicone and may cause balloon to burst.

Store catheters at room temperature away from direct exposure to light, preferably in the original box.

Aggressive traction, particularly in the presence of suturing, is not recommended for silicone balloon Foley catheters.

Should balloon rupture occur, care should be taken to assure that all balloon fragments have been removed from the patient.

Visually inspect the product for any imperfections or surface deterioration prior to use.

For urological use only.

Customer Service

Potrero Medical provides parts and technical information for servicing and repair. Before the product is sent for repair, please contact your local representative or our home office in California as shown in the information below.

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Website: www.potreromed.com

Patent: www.potreromed.com/patents

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Issue Date: May 2020