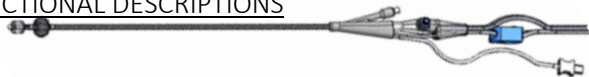


# Accuryn SmartFoley® Instructions for Use

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 with the Accuryn Sensing Urinary Catheter (SmartFoley®) – IAP UO Temp 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 SmartFoley™ is a single use device intended for short-term use (less than 30 days).

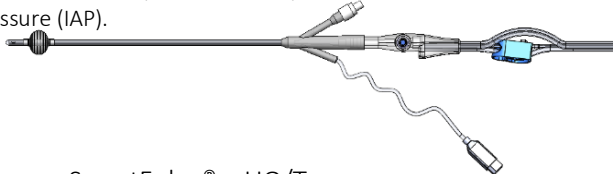
**NOTE:** The Accuryn® Monitor has its own accompanying Operator's Manual, which is provided with the Monitor. All IFUs must be referenced for proper usage of the Accuryn® Monitoring System. Refer also to the separate IFUs for additional warnings, precautions, and contraindications.

## FUNCTIONAL DESCRIPTIONS



### Accuryn SmartFoley® – IAP/UO/T

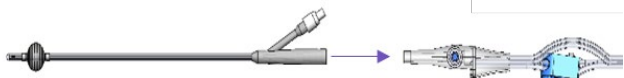
Urine flows from the patient's bladder, into the Accuryn SmartFoley™, through the drainage tube, and into the measurement cassette of the Urine Collection Set. The measurement cassette connects to the Accuryn Monitor at the cassette interface. The patented Active Drain Technology™ clears airlocks in the drainage tube on a time interval and measures urine output volume and rate. When the cassette is full, the Monitor activates a pinch valve to empty the urine from the cassette into the urine collection bag. The temperature connector from the Accuryn SmartFoley® Collection Set can be connected to the Reusable Temperature Cable, and the cable can then be connected to the Monitor Temperature Port which allows for continuous temperature measurement. Temperature is sampled once per second and updated on the Monitor display. The Accuryn SmartFoley® IAP has an additional balloon at the tip of the Foley that measures intra-abdominal pressure (IAP).



### Accuryn SmartFoley® – UO/T

Please see description above.

**NOTE** the Accuryn SmartFoley™ UO/T does not have the capability to provide intra-abdominal pressure (IAP) data.



### Accuryn SmartFoley® Adapter

A commercially available Foley between 6-24Fr must be added onto the Accuryn SmartFoley™ Adapter. Once the Foley is attached, urine flows from the patient's bladder, into the Foley, through the drainage tube, and into the measurement cassette of the Urine Collection Set. The measurement cassette connects to the Accuryn® Monitor at the cassette interface. The patented Active Drain Technology™ clears airlocks in the drainage tube on a time interval and measures urine

output volume and rate. When the cassette is full, the Monitor activates a pinch valve to empty the urine from the cassette into the urine collection bag.



**Caution:** Do not use until you have read and understood the Accuryn® Monitoring System Operator's Manual



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

Accuryn SmartFoley® is not made with natural rubber latex and comes in three configurations:

- IAP, U/O, Temp (intra-abdominal pressure, urine output and core temperature)
- U/O, Temp (urine output and core temperature)
- Adapter (has been tested with Foley catheters from 6-24Fr and is compatible with most Foley Catheters from Bard and Medline)

## CONTENTS OF THE SMARTFOLEY® TRAY

- Two anti-reflux valves built into disposable unit
- Silicone Foley Catheter if using Accuryn SmartFoley® IAP, U/O, T or Accuryn SmartFoley® U/O, T.

**NOTE:** Accuryn SmartFoley® Adapter does not include a Foley Catheter

- Securement Device
- 10 ml Sterile Water Syringe
  - 5ml Sterile Water Syringe for 8-10Fr units
- Alcohol Preparation Pad
- Fenestrated Drape
- Hand Sanitizer
- Lubricating Jelly (2x)
- Nitrile Gloves (L)
- Povidone-Iodine Swabs (3x)
- Skin Protectant Wipe
- Soap Towelette
- Specimen Container
- Waterproof Drape

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

**WARNING:** This product should never be connected to the 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 re-sterilize. Short term use only (less than 30 days).**

**Caution:** As with all temperature probes, in the presence of RF energy sources, local heating, temperature errors and probe damage may occur.

When using the Accuryn® Monitoring System with the Accuryn SmartFoley™ Adapter and the patient produces  $\leq 10\text{ml/hr}$ , flush 10cc of sterile saline upon insertion of the Foley and if the monitor has been tilted or paused.

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

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

**When using the Accuryn SmartFoley® IAP/UO/Temp or the UO/Temp do not attempt to break the junction between the catheter and the drainage tubing** – the catheter and drainage

# Accuryn SmartFoley® Instructions for Use

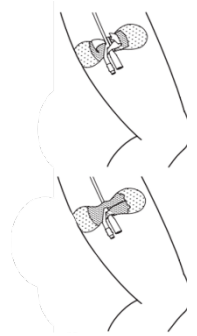
tubing are permanently bonded together.

## ACCURYN SMARTFOLEY® SET UP

**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.

1. Perform hand hygiene and put on non-sterile gloves provided by your institution.
2. Prior to use, visually inspect Accuryn SmartFoley® 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. Use hand sanitizer provided.
9. Put on nitrile sterile gloves.
10. Lift tray top to reveal lower tray components. **NOTE:** if using the Accuryn SmartFoley® Adapter, which does not come with a Foley, obtain desired commercial Foley between 6-24Fr and attach to the barbed connector of the Accuryn SmartFoley® Adapter Collection Set.
11. Pick up waterproof drape by edge without contaminating contents and place with shiny side down under buttocks.
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). Note: If using syringe other than that provided, use luer tip syringe, 10cc maximum. Do not use needle.
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.**

1. Select the area for the placement of the Grip-Lok. **NOTE:** The catheter should already be inserted.
2. Prepare the skin according to the standard hospital protocol for dressing application. Skin prep or hair removal may be required on some patients for better adhesion.
3. Hold the Grip-Lok in position while removing the paper backing from one side, then the other, to secure on the skin surface.
4. Open and separate the top fabric straps.
5. Place the drainage lumen between the foam strip and the back of the fabric straps.
6. Position the catheter so that the Y-point is centered at the keyhole in the top fabric straps.
7. Secure one of the fabric straps over the drainage lumen and the other over the catheter below the Y-point.
8. Adjust the securement of the catheter by applying the strap attachments tighter or looser as needed.



Direction: for added skin protection use skin prep pad prior to application of the securement device.

**NOTE:** replace securement device if soiled or saturated in fluid.

**NOTE:** use of an alcohol swab will ease removal of securement device from skin.

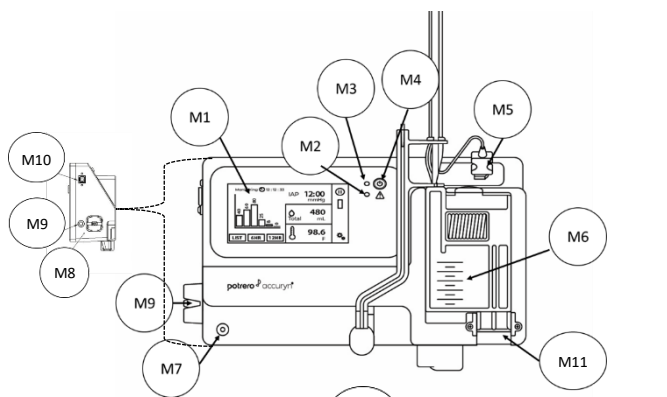
**NOTE:** re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction, or bacterial infections.

## APPLICATION INSTRUCTIONS FOR FOLEY CATHETER SECUREMENT

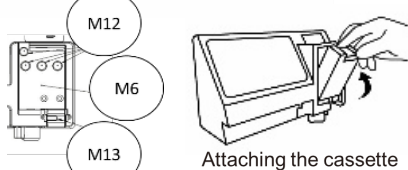
**WARNING:** Do not use catheter securement device on patients with known tape or adhesive allergies.

# Accuryn SmartFoley® Instructions for Use

## CONNECTING THE ACCURYN SMARTFOLEY® TO THE ACCURYN® MONITOR



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



Attaching the cassette

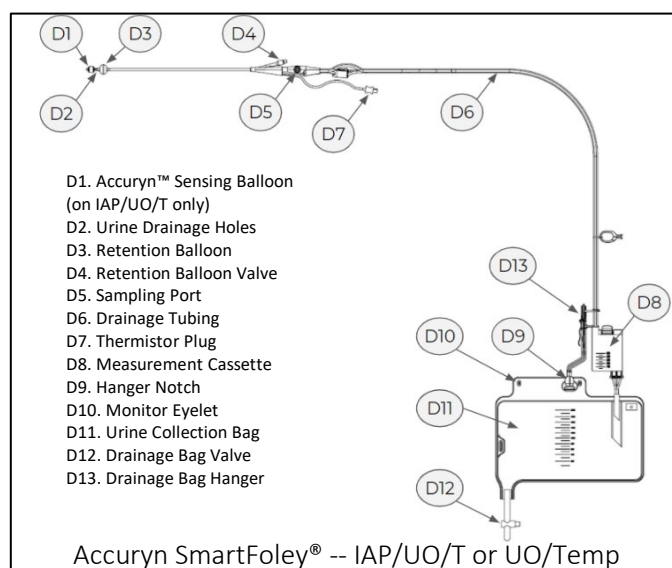
1. Ensure that tubing extends from the catheter to the measurement cassette in a smooth, uninked path.
2. Hang the Monitor on an appropriate Accuryn® mount using the mounting feature on the back of the Monitor. Adjust Monitor position to be parallel to floor as close as possible. Connect unit to Wall Power (M9).
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 (M7). Ensure that the bag hangs freely.
5. Connect the Thermistor Plug (D7) to the Reusable Temperature Cable (T1) (with Temperature Cable Adapter if needed), then connect the Reusable Temperature Cable (T2) to the Temperature Port (M5) on the Monitor.
  - a. When using a Foley catheter without temperature capabilities, the Accuryn® Monitor will alert once that there is no temperature connected. Press "OK" to clear alarm away and continue normal use.
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 (M1)).
9. Open the drainage tubing clamp to allow urine flow. Refer to Accuryn® Monitoring System Operator's Manual.
10. Catheter should be managed in accordance with the CDC guideline: <https://www.cdc.gov/infectioncontrol/guidelines/cauti/ind ex.html> At the onset or first signs of infection, catheter encrustation, or any other catheter-related adverse effect, the Accuryn SmartFoley® should be removed and replaced if necessary. Per CDC guidance the drainage system should remain sealed and closed.

## DRAINING THE COLLECTION BAG

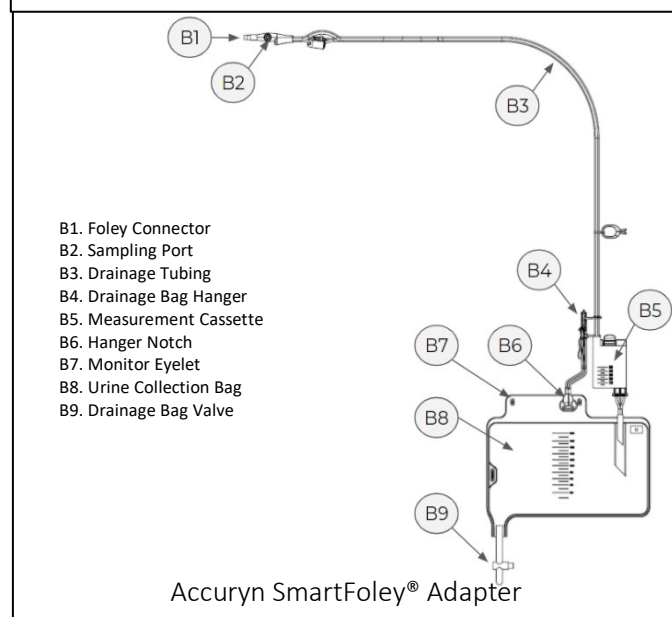
- a. Close drainage tubing clamp.
- b. Pause the Accuryn® Monitor (M1).
- c. Empty the bag per facility protocol. SLIDE the bag spout valve to open and close.
- d. Press PLAY to restart monitoring after draining (M1).
- e. Open blue drainage tubing clamp to resume normal use.

## RESET URINE OUTPUT VOLUME

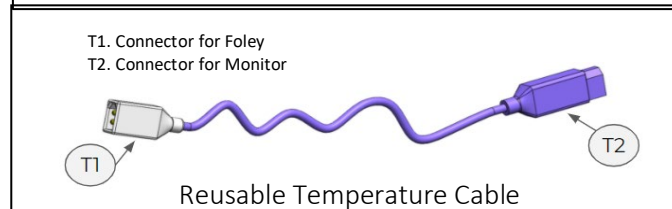
- a. Document Urine Output.
- b. Tap "UO" Symbol until UO Menu is displayed.
- c. Select "RESET".
- d. Confirm message to reset the Total UO volume back to zero.



Accuryn SmartFoley® -- IAP/UO/T or UO/Temp



Accuryn SmartFoley® Adapter



Reusable Temperature Cable

# Accuryn SmartFoley® Instructions for Use

## URINE SAMPLING

- Clamp the drainage line with the blue clamp. Wait until a sufficient sample size accumulates in the drainage tube.
- Swab surface of Sampling Port (D5) with antiseptic wipe.
- 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.
- Aspirate desired volume of urine, then twist to disengage syringe from sampling port.
- 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.
- Open the drainage tubing clamp to allow urine flow.

## FLUSHING THE CATHETER

- 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.
- Swab surface of Sampling Port (D5) with antiseptic wipe.
- 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.
- 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.**

- Ensure all data has been recorded before removal of the device.
- Pause the monitor (upper right corner of the display screen M1). Wait approximately 5 seconds until the monitor is flashing "PAUSED."
- Disconnect the Thermistor Plug (D7) from the Temperature Port(M5).
- Disconnect the Measurement Cassette (D8) from the Monitor.
- Remove Drainage Bag from bag hanger.
- Deflate retention balloon:** Gently insert a luer tip syringe into the Retention Balloon Valve (D4).

**CAUTION: Do not remove urinary catheter if resistance is felt. Check balloon status if using the Accuryn SmartFoley® IAP, U/O, Temp.**

- 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.
- Slowly remove catheter from the bladder.
- At end of device use, dispose of all materials in accordance with facility protocol.
- Power down the Accuryn® Monitor (M4) by pressing and

holding power button.

- Clean the monitor and accessories thoroughly. Follow cleaning instructions in the Accuryn® Monitoring System Operator's Manual.

## MRI SAFETY INFORMATION

(For Accuryn SmartFoleys® with intraluminal temperature cable)

Non-clinical testing has demonstrated the Accuryn SmartFoleys® are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions. Failure to follow these conditions may result in injury.

Static Magnetic Field Strength (B.)	1.5T or 3.0T
Maximum Spatial Field Gradient	81 T/m (8,100 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this device may produce an image artifact of up to 12 mm.

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.

## MRI SAFETY INFORMATION

(For Accuryn SmartFoleys® used with external Reusable Temperature Cable)

Non-clinical testing has demonstrated the Accuryn SmartFoleys® are MR Conditional. A patient with this device can be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Static Magnetic Field Strength (B.)	1.5T or 3.0T
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)

# Accuryn SmartFoley® Instructions for Use

Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this device may produce an image artifact of up to 6 mm.

Disconnect Reusable Temperature Cable (and Temperature Cable Adapter if used) from Accuryn SmartFoley® for MRI.

Additional information regarding device configuration: 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.

## CLEANING

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

## 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.

## CONTACT INFORMATION



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