HUCK MEDICAL TECHNOLOGIES®

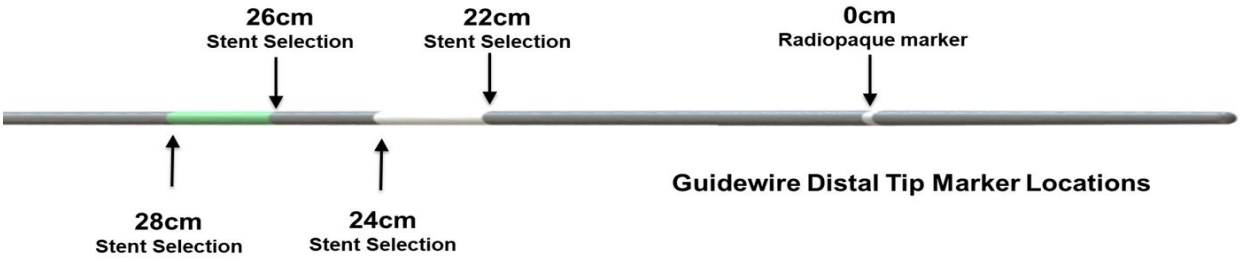
Lykins™ INDICATOR Urological Marker Stylet

Lykins Indicator Urological Marker Stylet

Instructions for Use

Package Contains

One sterile radiopaque marker stylet **0.035" (0.89mm)** by **150cm (59.0")**, with **5cm** NiTi flexible distal tip.



Intended Use/Indications for Use

The Lykins Indicator Urological Marker Stylet is intended to facilitate the placement of endourological instruments (Stents) during interventional procedures. The Indicator stylet is not intended for coronary artery, vascular or neurological use.

Caution Federal Law (USA) restricts this device to sale by or on the order of a physician.

Warning Contents supplied STERILE. Do not use if sterile barrier is damaged. For single use only. Do not reuse, reprocess, or resterilize.

Contraindications None known.

Caution

Complications of stylet placement are documented. Usage should be based upon consideration of risk-benefit factors as they apply to the patient.

Note

Prior to use, the stylet should be immersed in sterile water or sterile isotonic saline to allow the hydrophilic surface to absorb water and become lubricious. This will ease subsequent placement of the stent over the stylet under standard conditions.

Suggested instructions for usage

1. After immersing in water to make it lubricious, pass the stylet through the cystoscope into the ureteral orifice.
2. Follow stylet placement using fluoroscopy into the renal pelvis.
3. Radiopaque contrast can previously have been injected into the ureter to identify the ureteropelvic junction.
4. When the distal radiopaque marker is at the ureteropelvic junction note what marker (white, black, green) is at the ureteral orifice.
5. If the white marker is at the ureteral orifice a 22cm double J stent is placed over the stylet.
   If the black space marker is at the ureteral orifice a 24cm double J stent is placed.
   If the green marker is at the ureteral orifice a 26cm double J stent is placed.
   If the green marker is not visible a 28cm double J stent is placed.
6. After the correct length stent is placed by a pusher, the pusher is held in place and the stylet is removed, leaving the stent in the ureter.

Adverse Events

Complications which can result from the use of stylets in urological applications include:

Perforation of the Urinary Tract	Foreign Object in Body
Acute Bleeding	Infection
Hemorrhage	Hemoglobinuria
Tissue Trauma	Peritonitis
Edema	Ureter Avulsion

Warnings

• A thorough understanding of the technical principles, clinical applications, and risks associated with the use of stylets is necessary before using this product. Use of this device should be restricted to use by or under the supervision of physicians trained in urologic endoscopic procedures. Care should be exercised to prevent perforation or trauma of the linings and associated tissue, channels, or ducts.

• Failure to abide by the following warnings might result in damage to the channel or duct, abrasion of the hydrophilic coating, release of plastic fragments from the stylet, damage to or breakage/separation of the stylet that may necessitate intervention.

• Use extreme caution when using a laser, making sure to avoid contact with the stylet. Direct contact may cause damage and/or sever the stylet.

• When exchanging or withdrawing a catheter over the stylet, secure and maintain in place under fluoroscopy to avoid unexpected guidewire advancement. Otherwise, damage to the urinary channel by the stylet's tip may occur.

• Manipulate the stylet slowly and carefully in the urinary system while confirming the location of the wire's tip under fluoroscopy. Excessive manipulation of the stylet without fluoroscopic confirmation may result in perforation or trauma of the linings or associated tissues, channels or ducts. If any resistance is felt or if the tip's location seems improper, STOP manipulating the stylet and/or the catheter and determine the cause by fluoroscopy.

• Do not attempt to use the stylet if it has been bent, kinked or damaged. Use of a damaged device may result in damage to the linings and associated tissue, channels or ducts or release of wire fragments into the urinary system.

• A retrieving device, such as a gripper or basket forceps, should only be used after the stylet has been removed from the patient's channel or duct. Using a retrieving device while the guidewire is in place may cause the stylet to break.

Precautions

• The surface of the stylet is not lubricious unless it is wet. Before taking it out of its holder and inserting it through a catheter, fill the holder and the catheter with physiological saline solution.

• The stylet should be advanced through the scope using short, deliberate 2-3cm movements to prevent inadvertent damage to the device or patient.

• When reinserting the stylet back into the holder, take care not to damage the hydrophilic coating with the edge of the holder.

• After removal from the patient's urinary system, and prior to reinserting it into the same patient during the same catheterization, hydrophilic stylets should be rinsed in a bowl full of saline solution.

Caution

Intended for one time use only. Do not force stylet if resistance is encountered. Always be sure the bladder, ureter, or kidney has not been perforated before placing stent.

Huck Medical Technologies, Inc.

REF Catalog Number: **Sample**	Product/Catalog Code/Number	Use By Date: **Sample**	Use Before Date
Date of Mfg. **Sample**	Date of Manufacture	Consult Accompanying Documents	Read Instruction Prior to User
QTY Quantity: **1**	Quantity	Rx Only Prescription Only	Prescription Only
Do Not Reuse	Do Not Reuse	This product is not made with natural rubber latex	Does Not Contain Natural Rubber Latex

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PATENT PENDING

(9/22) IFU-SMT-01