HELPFUL STEP-BY-STEP ILLUSTRATIONS ARE LOCATED IN THIS BOOKLET

DESCRIPTION
The Vet Sent –Ureter comes as a sterile stent system comprised of two components: 1) the radioopaque, double pigtail multi-fenestrated ureteral stent, made of polyurethane, and 2) a radioopaque pusher or dilator-pusher which aids in ureteral dilation and stent placement. To minimize the possibility of stent migration, both ends have a “pigtail” loop to keep one end inside the renal pelvis, the shaft down the ureteral lumen, and one end inside the urinary bladder. One end of the stent is tapered for smooth transition to the appropriately sized guide wire, and the other end has a black band that is a marker for the endoscopist to identify the transition of the ureteral stent shaft to the distal pigtail loop.

The inner lumen of the stent will accommodate various sized guide wires depending on the stent size chosen (Table 1). This stent should always be placed over a guidewire to prevent inadvertent ureteral perforation. The complete Directions for Use should be reviewed before using this system.

INDICATIONS FOR USE
The Vet Stent-Ureter is indicated for bypassing a ureteral obstruction due to various causes (ureteral stone, tumor, stricture, blood clot, ureteritis, etc). The ureteral stent has also been shown to encourage passive ureteral dilation after a few days to a few weeks, resulting in a diameter 4-10 times the starting diameter, and the potential for small stone passage, as well as increased urine drainage both around and through the stent. The ureteral stent can also be placed prior to shockwave lithotripsy (ESWL) to prevent a ureteral obstruction during nephrolith stone passage. Finally, stents have also been placed during ureteral surgery particularly if a resection and anastomosis or ureteral reimplantation is necessary or when stricture formation is a concern. It is for veterinary use only and must not be used in humans.

WARNING: The Vet Stent –Ureter is for veterinary use only and must not be used in humans.

CONTRAINDICATIONS
Contraindications associated with the use of the Vet Stent-Ureter are relative. One should be comfortable with the procedure prior to placing a ureteral stent. If guide wire access is not possible through the entire ureteral lumen, from the renal pelvis to the urinary bladder, then stent placement should be reconsidered.

WARNINGS
The Vet Stent-Ureter should only be placed using fluoroscopic guidance. It is not recommended that the stent be sutured in place, as the double pigtail design should prevent migration and suturing may prevent stent removal should problems occur.

PRECAUTIONS
Appropriate training is recommended. The stent and pusher/dilator are sterile. The stent is not designed to be resterilized or reused. The packaging and device should be inspected before use. If sterility or performance of the device is suspected to be compromised, it should not be used. The device is intended for single use only. If the guide wire or ureteral dilator-pusher cannot advance through the obstructed area, do not place the stent. The stent can be easily removed after placement if necessary by gentle traction, ideally over the guide wire.
COMPLICATIONS
Potential complications associated with the use of the Vet Stent-Ureter may include infection, ureteral disruption, stent malpositioning, stent migration, stent obstruction, tumor overgrowth or ingrowth at the stent ends or through the fenestrations, dysuria, ureteritis, cystitis, and ureterovesicular reflux.

DIRECTIONS FOR USE

1. Diagnostic Procedure

The patient should have evaluation of the kidney, ureter, bladder and urethra using ultrasound. The exact measurement of the renal pelvis is necessary prior to considering stent placement, as the pigtail of the stent must fit inside the renal pelvis. It is not recommended for a renal pelvis smaller than 5mm in size, though can be done with careful wire manipulation. The location of the obstruction and cause for obstruction should be determined prior to stent placement, as manipulation of the guide wire through the ureteral lumen is necessary. For endoscopic and surgical placement the patient is placed in dorsal recumbency. For antegrade access (trigonal neoplasia) the patient is placed in lateral recumbency (affected side up).

<table>
<thead>
<tr>
<th>Stent Size (diameter)</th>
<th>Shaft Length Options (cm)</th>
<th>Coil Diameter (mm)</th>
<th>Pusher length x diameter</th>
<th>Indication</th>
<th>Guide Wire size (diameter)</th>
<th>Ureteral Catheter Size Recommended (French)</th>
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<tr>
<td>2.5 french</td>
<td>12,14,16 cm</td>
<td>6 mm</td>
<td>45 cm long x 0.034&quot; wide</td>
<td>Feline</td>
<td>0.018&quot;</td>
<td>0.034&quot; dilator-pusher comes with stent (see instructions)</td>
</tr>
<tr>
<td>3.7 french</td>
<td>12,15,18 cm</td>
<td>6 mm</td>
<td>45 cm long x 4 french wide</td>
<td>Small dog</td>
<td>0.025&quot;</td>
<td>4 french (sold separately)</td>
</tr>
<tr>
<td>4.7 french</td>
<td>16, 18, 20 cm</td>
<td>10 mm</td>
<td>45 cm long x 5 french diameter</td>
<td>Medium or large dog</td>
<td>0.035&quot;</td>
<td>5 french (sold separately)</td>
</tr>
<tr>
<td>6.0 french</td>
<td>17, 20, 23 cm</td>
<td>12 mm</td>
<td>60 cm long x 7 french diameter</td>
<td>Tumor at UVJ (dog)</td>
<td>0.035&quot;</td>
<td>7 or 8 french sheath (see instructions) sold separately</td>
</tr>
</tbody>
</table>

Endoscopic placement: *female dogs, male dogs (>8kg), female cats (often need surgical assistance) (Figure 1)*

The patient is placed under general anesthesia and positioned in dorsal recumbency on a fluoroscopy table. For a female patient the vulva should be positioned off the end of the table for the ease of cystoscopy. The vulva is clipped, scrubbed and draped. Peri-operative antibiotics are routinely used. A marker catheter is placed per rectum and gently advanced into the terminal colon over a floppy-tipped (soft, atraumatic) hydrophilic guide wire or inside a soft rubber catheter that is advanced per-rectum. Using a cystoscope (rigid in female and flexible in male) the ureterovesicular
juncture (UVJ) is identified (Figure 2F) and the appropriate side is confirmed fluoroscopically. The fluoroscopy unit is positioned over the bladder neck and distal ureter (Figure 1A). The appropriately sized hydrophilic angle-tipped guide wire (Weasel wire) is advanced through the working channel of the cystoscope. Using endoscopic assistance the guide wire (see sizing chart) is manipulated and aimed up the UVJ and into the distal ureter. (Figure 1A, 2F, 2G) An open-ended ureteral catheter (see sizing chart) is then advanced over the guide wire to the level of the distal ureter. (Figure 1A, 2G) This is more easily accomplished when the cystoscope is situated at the UVJ and should not be moved from this position for appropriate pushability. The guide wire is removed and contrast (iohexol) diluted 1:1 with saline is infused up the catheter for a retrograde ureteropyelogram (RUPG) (Figure 2A, 2B). Be sure to fill the entire ureter and renal pelvis for mapping. The guide wire is then re-advanced up the ureter through the catheter and directed across the obstruction and into the renal pelvis. (Figure 1B, 2C) Care should be taken not to perforate the ureter at the obstruction site. Once the guide wire is in the renal pelvis the catheter is advanced over the guide wire, passing the obstruction. Using either the marks on the ureteral catheter, or the marker catheter in the colon, the ureteral shaft length should be determined from the UPJ to the UVJ. The stent length should be chosen accordingly.

The ureteral catheter should be carefully removed over the guide wire without removing the guide wire. The stent is loaded on the guide wire, through the working channel of the cystoscope (making sure you have the appropriate sized working channel to accommodate your stent diameter). The stent can be advanced over the guide wire, while the scope is situated at the UVJ and should not be moved. This allows for pushability of the stent up the ureter, as the stent is very soft compared to the catheter (2F, 2G). Using fluoroscopy the stent should be advanced over the guide wire, being sure that the wire is monitored in the renal pelvis and it remains in place (Figure 1C, 2D). Once the stent is fully inside the cystoscope the dilator-pusher catheter should be advanced over the wire to “push” the stent inside the cystoscope.
about 1 cm of the stent is seen inside the renal pelvis, or on endoscopy the “Black line” is seen, indicating the distal shaft of the ureteral stent, the wire can be slowly withdrawn (2D). If you see the line and the stent is not yet inside the renal pelvis, than the stent is too short and should be exchanged for a longer stent. One loop should be seen in the renal pelvis (2E). The wire can be withdrawn to the distal ureter, just crossing the distal stent, so that it is across the stent and pusher catheter. The cystoscope can be withdrawn into the proximal urethra while the pusher catheter is advanced to push the distal end of the stent into the urinary bladder. The wire can be removed and the distal pigtail should be inside the urinary bladder (Figure 1D, 2E).

**Surgical Stent Placement:** male cats, female cats, dogs without endoscopic access

In _dogs_ where endoscopic access is not possible the procedure is done surgically. The UVJ in dogs is in the bladder trigone and ureter access can be obtained by a distal cystotomy, where you can visually identify the appropriate ureteral orifice. The same steps are followed as above for the endoscopic procedure, though you do not need an endoscope. A guide wire is advanced up the ureteral orifice, with an open-ended ureteral catheter advanced over the guide wire into the distal ureter. Using fluoroscopy a RUPG is performed and the same steps as above are followed. For surgical placement a pusher catheter is not necessary as you can put the distal loop in the bladder manually.

In most _cats_ surgical assistance is necessary in ureteral stent placement. In female cats endoscopic guide wire access is initiated and then the abdomen is open for stent manipulation if necessary. In male cats the entire procedure is done surgically. The options for guide wire ureteral access are either antegrade (from the kidney) or retrograde (from the bladder-UVJ). It is important to remember that the UVJ in cats are located in the proximal urethra, not the bladder, so a urethrotomy is necessary, which is why antegrade access through the kidney is often performed.

**Antegrade access:** (Figure 3) The patient is placed under general anesthesia. The abdomen is clipped and aseptically prepared, including the prepuce or vulva. The animal is placed in dorsal recumbency. The entire abdomen from sternum to prepuce/vulva is draped. Via laparotomy the appropriate kidney is isolated. A 22gauge over-the-needle intravenous catheter is used to gain renal pelvic access (Figure 3A). This is done through the greater curvature of the kidney. Fluoroscopy is aligned over the kidney and proximal ureter. The catheter is prepared with a T-port, 3-way stopcock and 2 syringes (1 syringe [5cc] of contrast
[diluted 1:1 with saline] and one empty syringe [5 cc]). Once urine is seen from the catheter the needle is removed and the T-port is attached. Using the stopcock urine is withdrawn (for culture) and then contrast is infused under fluoroscopic guidance. Once a pyelogram and ureterogram are visualized the T-port is removed leaving the catheter in place and the 0.018” Weasel wire is advanced into the renal pelvis through the catheter (Figure 3B). It is manipulated down the ureter, bypassing the obstruction, and through the UVJ into the urinary bladder (Figure 3C). Once the wire is inside the urinary bladder either a small, distal cystotomy can be performed to grab the guide wire for through-and-through wire access or the wire can be passed out the urethra (Figure 3D).

The feline stent (2.5 french*) comes with a ureteral dilator-pusher** (0.034”). This is tapered to the 0.018” guide wire. This should be used to pass over the guide wire to dilate the UVJ and the small ureteral diameter distal to the obstruction. This can be done either retrograde or antegrade (through the kidney). Once this catheter is passed from the bladder to the kidney the wire should be reversed so that the soft, angled tip is on the kidney side, rather than the current bladder side. This is because the wire needs to curl inside the renal pelvis to get the proximal end of the stent curled in the renal pelvis. This should NEVER be done with the stiff end of the wire. Once the wire is reversed than the dilator-pusher catheter can be removed and the stent can be placed over the wire. Once the stent is inside the entire ureter the guide wire should be withdrawn so that the soft angled tip is inside the renal pelvis and curled. The stent should then be advanced over the guide wire until a curl is made and the wire can be withdrawn at the bladder side. The distal end of the stent can then be placed inside the bladder through the small cystotomy (Figure 3E). The cystotomy incision can then be closed and fluoroscopy should be used to confirm the stent is curled in the renal pelvis and inside the urinary bladder. The 2.5 french feline ureteral stent comes in a soft and a stiff durometer. If the ureter distal to the obstruction (normal diameter) is very difficult to bypass with the soft stent, as it is usually tight, than you can try the stiffer stent, which may have more success. The concern about the stiff stent is that it could result in more post-operative dysuria, as the material in the bladder could be irritating in some cats. The ureteral dilator-pusher that comes with the ureteral stent is 0.034” diameter. There are also 0.032” and 0.036” dilators sold separately which are often helpful in circumstances when the ureter is too tight for the stent.

**CANCER STENT***: For trigonal neoplasia induced ureteral obstruction (Figure 4)

Ureteral access for stent placement in patients with UVJ obstructions secondary to neoplasia is typically performed in an antegrade manner due to the lack of visibility of the UVJ cystoscopically. Female dogs occasionally can have placement success via transurethral cystoscopy as described above, but this is uncommon as the tumor makes the UVJ impossible to visualize.

The patient is placed in lateral recumbency with the affected kidney facing up. The dorsal paracostal and flank areas and the perineum (female) or prepuce (male) are clipped and aseptically prepared and draped. A marker catheter is placed over-the-wire or
within a red rubber catheter per rectum and advanced into the descending colon to allow for ureteral length measurement to aid in choosing the appropriate stent shaft length (Figure 4). A 3mm skin incision is made over the kidney. Using ultrasonographic and fluoroscopic guidance, an 18 gauge renal access needle is used for antegrade ureteropyelography (Figure 4A). A urine sample is obtained and cultured. Iodinated contrast material diluted 1:1 with sterile saline (approximately the same volume of the urine removed) is injected. Using fluoroscopic guidance, a 0.035” stiffened Weasel wire is advanced through the needle and guided caudally through the lumen of the ureter to the level of the ureteral obstruction at the UVJ (Figure 4B). The guide wire is manipulated gently and advanced into the urinary bladder. If the guide wire meets considerable resistance at the level of the tumor, the renal access needle is removed over the guidewire and a 5 french vascular access sheath is advanced over the guide wire into the renal pelvis allowing for contrast injection into the renal pelvis to maintain a ureterogram during wire manipulation. If necessary, a combination guide wire and 4 french angled Berenstein angiographic catheter is used to achieve access across the tumor (Figure 4C, 4D). Once urinary bladder access is achieved, the wire (and catheter if used) is directed toward the bladder trigone and down the urethra caudally until “through-and-through” wire access is obtained as it exits the urethra (Figure 4E). This wire is termed the “safety wire”. A 7 French 45 cm introducer sheath and dilator set are then advanced retrograde over the “safety wire” through the urethral lumen and across the tumor and UVJ to the level of the mid ureter (Figure 4F). This sheath dilates the ureteral obstruction. The dilator is removed over the guide wire and a second 0.035” un-stiffened angled Weasel wire is placed directly through the sheath, with the soft-angled tip advanced cranially in the ureteral lumen in a retrograde manner until it curls in the dilated renal pelvis (Figure 4F). The second wire allows the stent to be placed without losing through-and-through wire access maintained by the “safety wire” in the event the stent placement is not ideal and needs manipulation (Figure 4G). The appropriate stent length is chosen based on ureteral length measurements using the marker catheter in the colon. The 6 french Vet Stent-Ureter (cancer) is then advanced over the 2nd guide wire through the sheath in a retrograde manner to bypass the obstructed lesion. The pusher catheter is advanced over the same wire in order to advance the ureteral stent into position. Once the proximal end of the stent is advanced into the renal pelvis the 7

FIGURE 4: Percutaneous antegrade access (Canine-Tumor)
French sheath is withdrawn into the urethra and the 2\textsuperscript{nd} guide wire (over which the stent is placed) is retracted to allow a pigtail to curl in the renal pelvis (Figure 4G). The pusher catheter is used to advance the distal end of the stent into the urinary bladder. Once the stent is in place the primary through-and-through “safety wire” is carefully removed through the urethra, leaving the double pigtail stent in place (Figure 4H).

***The cancer stent is designed to have multiple fenestrations in the proximal half of the stent, and the distal loop, but not the distal shaft. This is to prevent tumor ingrowth at the UVJ, which could occlude the stent. It is important to remember this when loading the stent for placement.

**STORAGE** Do not expose this device to conditions of extreme heat and humidity or sunlight. Store the Vet Stent-Ureter in a normal room temperature environment.

**HOW SUPPLIED**
The Vet Stent-Ureter and its accessories are supplied **STERILE**. The Vet Stent-Ureter and its accessories should not be re-sterilized. The disposable, single-patient-use stents are available, pre-packaged with a pusher catheter (canine) and dilator-pusher catheter (feline). The table above lists the lengths and diameters for the currently available stents. The recommended guidelines for choosing stent length is that the stent be long enough to extend the entire ureteral length and have a curl in the bladder and in the renal pelvis. The size is measured based on stent shaft (not stent loops).

**CAUTION:** Federal law (USA) restricts this device to sale to veterinarians only. **The devices may be used in veterinary patients only. They are not for human use. The devices are for animal use only.** Each packaged unit is intended for SINGLE-PATIENT-USE ONLY. For more information or to arrange for a demonstration, contact Infiniti Medical.

**REUSE PRECAUTION STATEMENT**
Contents supplied **STERILE**. Contents intended for single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure that, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

**WARRANTY**
The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. 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 and storage of this device, as well as other factors relating to the patient, diagnosis, treatment, implant procedures, and other matters beyond the control of the manufacturer directly affect the device and the results obtained from its use. The manufacturer obligation under this warranty is limited to the replacement of this device; and the manufacturer shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. The manufacturer assumes no liability with respect to devices that are reused, reprocessed, or resterilized, and makes no warranties,
expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.