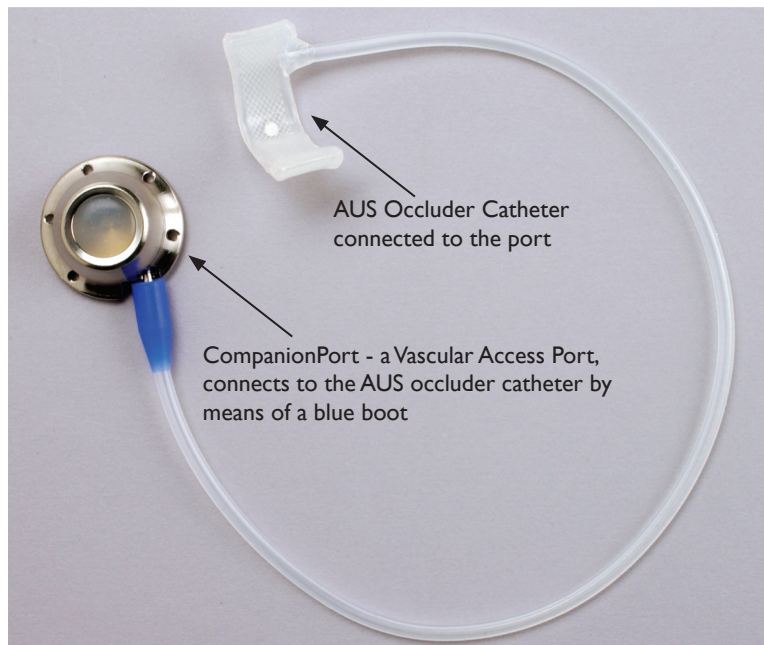




Speciality Medical Devices For The Veterinary Community

the **AUS**[™]
Artificial Urethral Sphincter Port System

SURGICAL SUGGESTIONS



Veterinary Use Only
Patent Pending

the **AUS**[™]
SYSTEM

Norfolk Vet Products Inc.
Tel: 847.674.7143
Fax: 847.674.7066
Contact: Pamela Wolf
E-mail: pwolf@norfolkmedical.com

DOCXS Biomedical Products
Tel: 707.462.2351
Fax: 707.462.2751
Contact: Rick Rizzolo
E-mail: info@docxs.net

SURGICAL SUGGESTIONS

These suggestions are meant only as a guide.

The adjustable artificial urethral sphincter port system was created by combining an inflatable silicone occluder, with a titanium subcutaneous access port. This combination of technologies has proven to be a successful system when urethral sphincter mechanism incompetence that is unresponsive to medical management occurs.

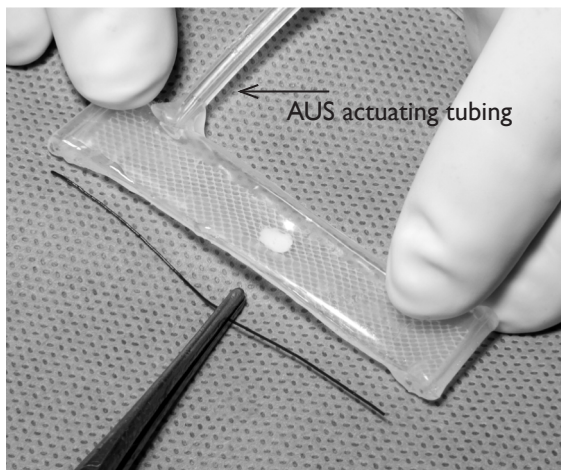
PLACING THE AUS OCCLUDER CATHETER

SURGERY IN FEMALE DOGS

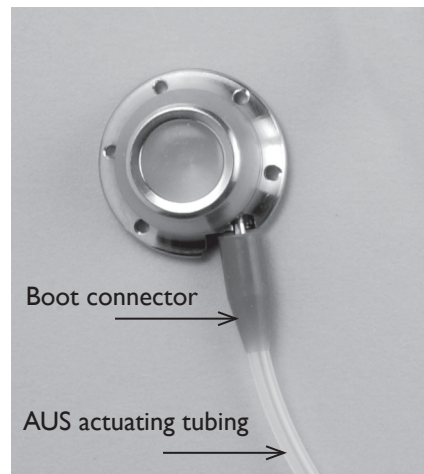
After induction of general anesthesia, a caudal midline approach to the urinary bladder is performed, continuing the abdominal wall incision to the pubic symphysis to allow maximal exposure of the urethra. The bladder is retracted cranially and a 2cm section of the pelvic urethra is isolated from the peri-urethral adipose tissue by blunt dissection, approximately 3-4cm caudal to the trigone. The urethral circumference approximated by measuring with a length of suture. A silicone AUS occluder catheter of equal or larger circumference to the pelvic urethra is selected, erring on the larger side to avoid excessive compression.

SURGERY IN MALE DOGS

Surgery is performed through a similar caudal midline approach after a para-prepuce skin incision. It is important to continue the abdominal wall incision to the level of the pubis in order to maximize exposure of the urethra. The bladder is retracted cranially and the prostate is located. A 2cm wide area is dissected around the post-prostatic urethra (caudal to the prostate) and the urethral circumference measured using a penrose drain or length of suture. A silicone AUS occluder catheter of equal or larger circumference to the pelvic urethra is selected, erring on the larger side to avoid excessive compression.



Artificial urethral sphincter occluder with side entry tubing is sized by comparing it to a piece of suture that was cut to approximate the urethral circumference



The actuating tubing of the AUS occluder is attached to the CompanionPort using the “boot” provided with each access port.

The size chart below should only be used as a guide and is based on body weights of female dogs. Measuring the circumference of the urethra with a piece of suture or ultrasound is recommended.

Device Size	6x11mm	8x14mm	10x14mm	12x14mm
Median Body Weight	3-6kg	10-20kg	20-30kg	25-40kg

Prior to placement of the AUS, all air is flushed from the lumen of the occluder and actuating tubing by retrograde filling of the system with isotonic saline, using a 21 gauge catheter. Refer to the AUS Occluder Flush and Fill Procedure below for details.

A stainless steel reusable flushing/backfill catheter (VO catheter) to assist in flushing the system can be requested when ordering the AUS-Port system.

The AUS is then completely filled, tested for leakage, and the filling volume is recorded before placing the device around the pelvic urethra, 2cm caudal to the trigone.

The cuff is closed around the urethra by placing 0-2.0 polypropylene sutures through the eyelets and tying a secure knot.

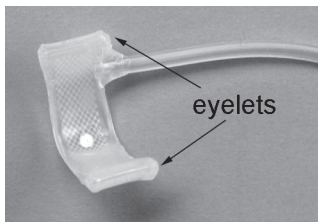
Once in position around the pelvic urethra, the actuating tubing is exited through a stab incision in the abdominal wall to be connected to the CompanionPort that is placed in the subcutaneous tissue of inner thigh.

AUS OCCLUDER- FLUSH AND FILL PROCEDURE

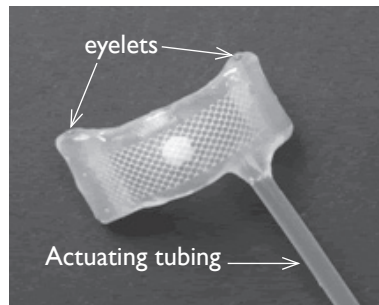
Fill with liquid and flush all trapped gasses from the system using gentle pressure. The Backfill catheter or a syringe may be used. Using the Backfill Catheter: carefully insert the Stainless Steel Catheter tube into the open end of the actuating tube/catheter of the AUS. It must extend all the way down into the diaphragm of the AUS. Use extreme caution so as not to puncture the extremely thin wall of the diaphragm with the tip of the catheter. Using a sterile syringe of the appropriate volume connected to the Backfill Catheter, slowly infuse saline into the diaphragm to force trapped air from the system. Use your fingers to help force out the air as you flush the diaphragm. Suck the diaphragm flat and empty. Clamp the tubing.

Without the Backfill Catheter: using a sterile syringe of appropriate volume, insert the syringe partially filled with saline into the open end of the catheter. Slowly infuse the diaphragm with saline to fill the diaphragm and force trapped air from the system. Use the syringe to suck all the saline and air from the device, leaving it empty and the diaphragm flat. Clamp the tubing.

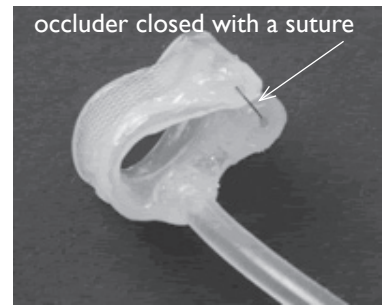
Note: the AUS diaphragm must be empty and completely deflated when it is placed around the urethra. It will be slowly adjusted to the proper occlusion later. Often, the cuff placement alone is enough to provide positive results initially.



AUS occluder catheter showing the position of the eyelets that are used to close the occluder around the urethra



AUS occluder catheter open



AUS occluder catheter is closed by placing a suture through the eyelets

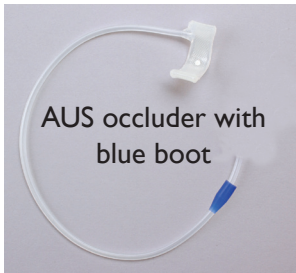
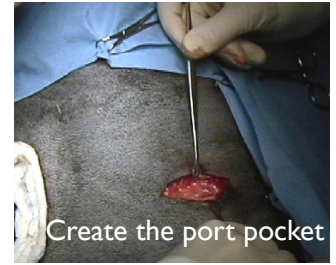
CALIBRATION OF THE AUS OCCLUDER

Calibration of the occluder is a critical step to determine the degree of occlusion attained with the addition of each 0.1ml of sterile saline. This allows you to adjust the occlusion accurately after implantation. After suturing the AUS occluder closed through the eyelets, flush the device with a syringe and saline to remove all air trapped in the diaphragm. Suck the diaphragm completely empty and flat. Then gradually introduce saline, 0.1ml at a time to gauge the degree of occlusion achieved with each 0.1ml infusion. This will serve as your guide for adjustment of the device after implantation.

PLACING THE COMPANIONPORT

Make a skin incision at the port placement site, generally the inner thigh. Create a pocket in the subcutaneous tissue large enough to bury the port - the length of this incision should be about 6cm for the medium sized CompanionPort. Place a wet sponge over this site.

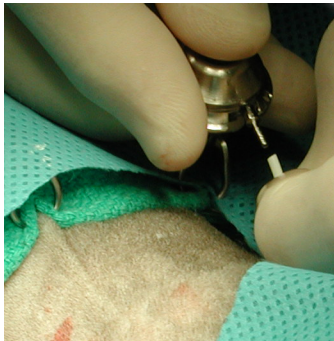
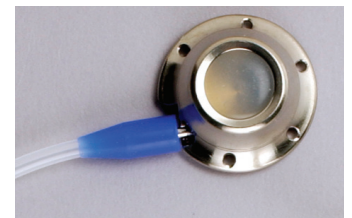
Tunnel from the port pocket incision to the site of the AUS cuff tubing. Measure the length of the catheter/actuating tubing you will need to reach from the site of the AUS cuff on the urethra to the location of the CompanionPort on the inside of the thigh easily, without creating traction or twisting. The tubing must not bind. Grasp the blue boot end of the catheter, and pull the catheter through the tunnel to the port pocket incision site.



With the diaphragm and catheter of the AUS flushed and empty of air bubbles, and the CompanionPort flushed with saline using one of the Huber needles in the kit, cut the catheter to the correct length.

DO NOT REMOVE THE BLUE BOOT.

If you removed the blue boot when cutting the tubing to length, replace it on the catheter ensuring that the wide end will facing the port when connected.



Connect the tubing from the AUS cuff to the CompanionPort by sliding the tubing over the barbed connector pin of the CompanionPort.



Slide the blue boot over the port-catheter connection.

The blue boot reinforces the connection of the port and AUS occluder catheter to prevent kinking, leakage or disconnection.

Place the CompanionPort in the subcutaneous pocket previously made off to one side so that the port septum does not lie directly beneath the skin incision line. Suture the CompanionPort to the fascia with non-absorbable sutures using all suture holes around the perimeter of the CompanionPort. This will prevent port migration and flipping.

The retraction on the skin is released and the subcutaneous tissue and skin are closed in a routine fashion.

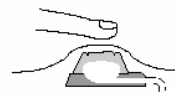
If the increased resistance provided by the AUS occluder does not control the incontinence, a small volume of saline is added to the cuff by injecting into the subcutaneous access port in the thigh using a Huber point needle.

ACCESSING THE COMPANIONPORT

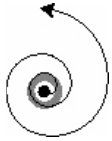
Use of an aseptic technique is mandatory when accessing the port.

A. Prepare the skin - sterile site preparation

(1) Locate the port site with your gloved hand by palpation of the perimeter.



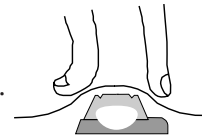
(2) Wipe the port site with a chlorohexidine based preparation or a povidone-iodine preparation three times using different swabs. Allow the site to air dry for approximately 3-4 minutes between wipes. The area prepped should extend 2" from the port center.



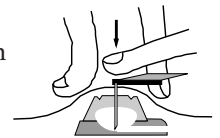
Wipe in outwardly radiating concentric circles - continuous circular direction from the inside out - beginning at the center of the port site and working away (organisms are wiped away from the access site).

B. Accessing steps

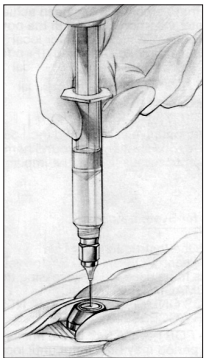
(1) Stabilize the port using your thumb and forefinger of your gloved hand.



(2) Firmly insert the Huber point non-coring needle perpendicularly through the skin and port septum into the port chamber.



(3) The needle is in the correct position when the tip touches the bottom on the port and you 'feel a click'.



(4) Attach a syringe with sterile saline to the Huber point (PosiGrip) needle hub and infuse the required volume of sterile saline into the AUS-Port system to gain continence.

GENERAL INFORMATION

CompanionPorts are available in 3 sizes to suit pets of all sizes. All sizes of CompanionPorts can be connected to an AUS occluder catheter. There is no exit site - the entire AUS-Port device is under the skin.

The CompanionPort can be left in place once the treatment is complete. It is biocompatible and will not degrade in the body over time.

Whenever the CompanionPort is accessed - for treatment or routine maintenance - sterile technique must be used.

A Huber Point needle must be used to access the CompanionPort. Huber Point needles are non-coring, & part rather than cut the silicone injection site. This preserves the integrity of the septum.

Right angle Huber Point infusions sets are available for longer infusions.

Call us at 847-674-7143 if you have any questions.