

Description

The subcutaneous BICCS™ is to be used for complete bile collection for up to 24 hour intervals in large lab animals. It is an advanced T catheter which allows for total bile collection through the liver end of the T while occluding the intestinal end of the T. This system ensures that all bile from the liver is collected when sampling is initiated. After sampling, the intestinal end of the T may be reopened thereby allowing normal bile flow. Be aware that recanalization of the bile duct is a known phenomenon. The BICCS is available with one or two sample catheters and different catheter sizes.

| | 3 French (.020"/.5mm ID x .037/.9mm OD) | 5 French (.030"/0.7mm ID x .065"/1.7mm OD) | 7 French (.050"/1.3mm ID x .095"/2.4mm OD) |
|---------------|---|--|--|
| 2 legs | Cat.#: BICCND-3S | Cat.#: BICCND-5S | Cat.#: BICCND-7S |
| 3 legs | Cat.#: BICCNT-3S | Cat.#: BICCNT-5S | Cat.#: BICCNT-7S |

Sterilization

The T Catheter and the V-A-Ps may be steam sterilized or EtO gas sterilized.

Materials

The T Catheter is comprised entirely of silicone rubber. The V-A-Ps are fabricated from titanium and silicone rubber.

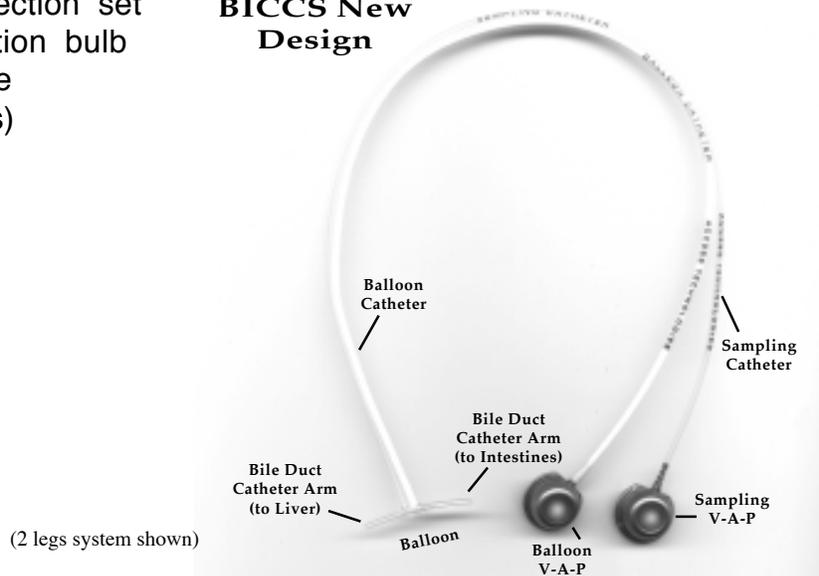
System Contents

- 1 T catheter
- 1 Balloon V-A-P Model AC
- 1 Sampling V-A-P Model AC
- 1 Flushing V-A-P Model AC (**3 legs only**)
- 1 Balloon Filler 27ga x 24"
- 1 Huber needle bile collection set
- 1 100 ml vacuum collection bulb
- 2 22ga x 3/4" Huber needle
(1 extra needle for 3 legs)

Additional Supplies Required (NOT PROVIDED)

- 1 18ga luer stub adaptor (for Sampling catheter)
- 1 3cc syringe
- 6 1cc syringes
- 1 IV sterile saline fluid bag
- 1 23ga luer stub adaptor (for Balloon catheter)

BICCS New Design

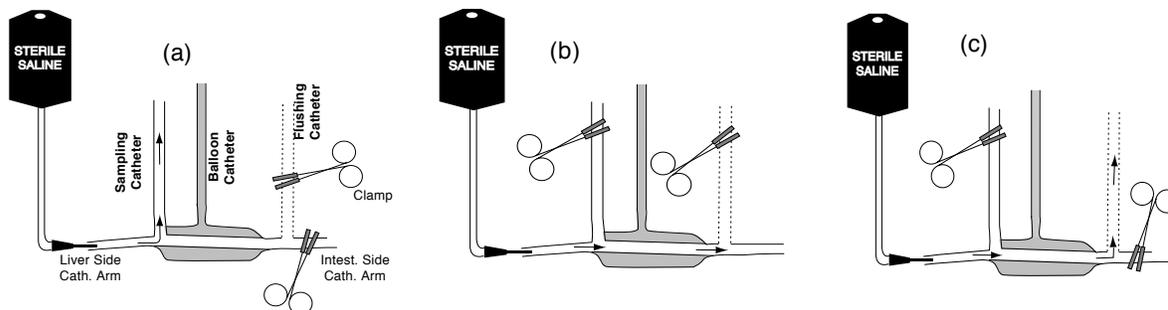


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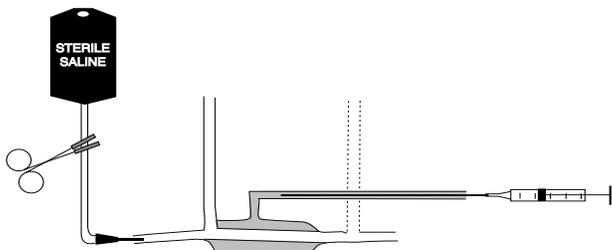
Implantation

NOTE: To the 4.5 or 6 French Balloon catheter (small ID) you will attach the Balloon V-A-P (Model CP4AC-4.5S or 6S with smaller dia. barbed pin). To the Sampling catheter (clear) you will attach the Sampling V-A-P (Model CP4AC-3S, AC-5S or AC-7S with larger dia. barbed pin). The same for Flushing catheter (3 legs only)

1. Test Patency: Attach “arm” on the liver side of T catheter to a sterile saline bag which is raised to 24” head height above the T. **a)** Clamp off opposite arm (intestinal side) and flushing catheter of T and allow saline to flow through Sampling Catheter to assess proper flow. **b)** Next, unclamp the intestinal side arm of the T, leave the clamp on the flushing catheter, and clamp off sampling catheter to assess proper flow through the T **(For 2 legs, stop here).** **c)** Last check, unclamp the flushing catheter side arm of the T, leave the clamp on the sampling catheter, and clamp off the intestinal side arm to assess proper flow.

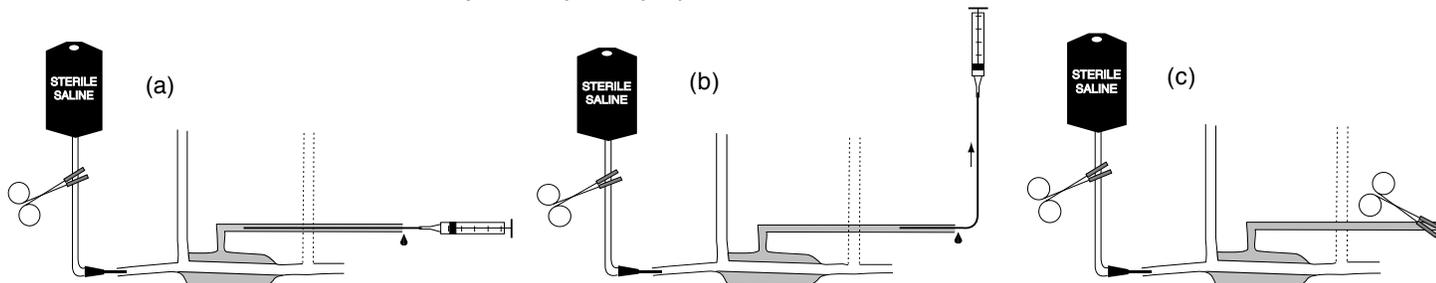


2. Insert Filler: Clamp off flow from the bag. Bend 4.5 or 6 French balloon catheter at a right angle where it meets the T section. Pass 27ga stainless steel tubing “Filler” through the 4.5 or 6 French balloon catheter to this bend. Do not pass Filler beyond this bend point as it may proceed to the balloon and damage the balloon. Attach a 3cc syringe filled with hypertonic 50% glucose solution to the PVC tubing attached to the Filler.



| Luer Stub Fitting In Catheter Arm | | | |
|-----------------------------------|----------------|----------------|----------------|
| | 3 French | 5 French | 7 French |
| Sampling | 24ga luer stub | 20ga luer stub | 18ga luer stub |
| Balloon | 24ga luer stub | 24ga luer stub | 23ga luer stub |

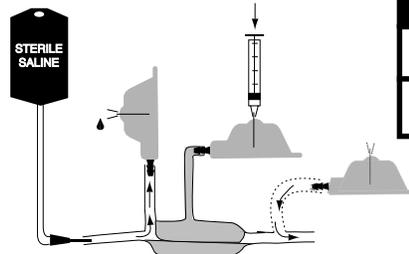
3. Fill Balloon Catheter: **a)** Using the 3cc syringe filled with hypertonic 50% glucose, infuse solution through the Filler until solution begins coming out of the proximal end of the balloon catheter. **b)** Slowly retract the Filler while continuing to infuse solution until Filler is removed from 6 French balloon catheter. This process may be thought of as a “backfilling” operation and is designed to remove air from the entire length of 4.5 or 6 French balloon catheter. **c)** Quickly clamp open end of 4.5 or 6 French balloon catheter.



4. Attach V-A-Ps: Fill Balloon V-A-P with hypertonic 50% glucose solution to remove all air, attach to 4.5 or 6 French balloon catheter, and remove clamp. Connect sampling catheter to Sampling V-A-P and *flushing catheter to Flushing V-A-P (for 3 legs only)*. Do not place sleeve yet. Simply place catheters over barbed pins.

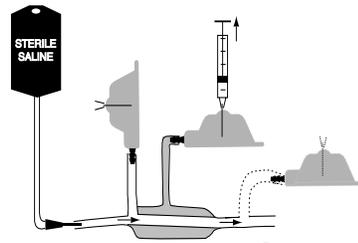
5. **Resume Flow Through T:** Resume flow from the saline bag through the T.

6. **Occlude Balloon :** Insert 22ga Huber needle into Sampling V-A-P. Draw up the exact amount of hypertonic 50% glucose solution indicated in the table below into a 1cc syringe attached to 22ga Huber needle and insert into Balloon V-A-P. Fully depress the syringe plunger to ensure that the balloon is closing off flow through the T and diverting it to the Sampling V-A-P. Remove Huber needle and syringe from port while keeping plunger depressed. Saline should be flowing through the Sampling V-A-P.



| Approx. Occlude Balloon Volume | |
|--------------------------------|------------|
| 6 French | 4.5 French |
| 0.06 cc | 0.04 cc |

7. **Unocclude Balloon:** Flush the 22ga Huber needle with air and attach to a pre-wetted (inside), empty 1 cc syringe. Leave the plunger unimpeded. Insert the needle and syringe into the Balloon V-A-P. The balloon will force an amount of the 50% glucose solution and some air into the syringe. Check the table below to determine what return volume to expect. Gently retract the plunger another .01cc. Flow of sterile saline should resume through the T.

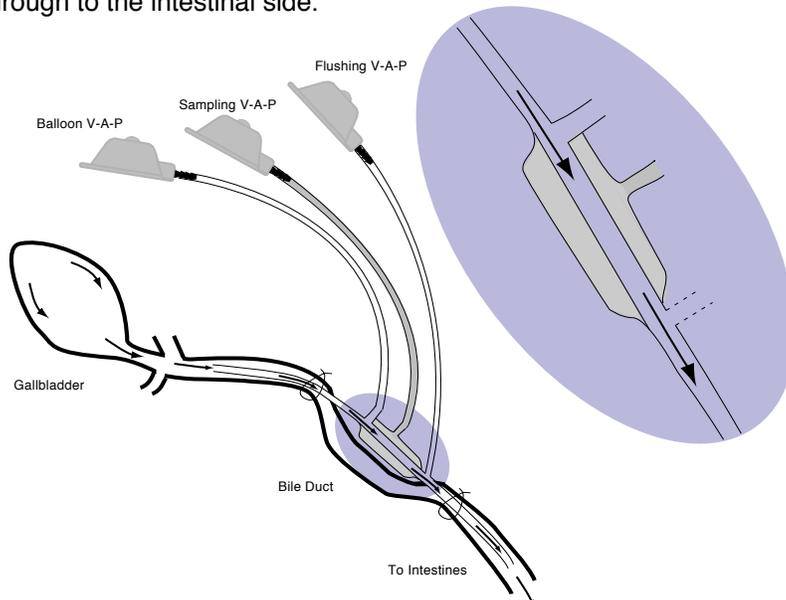


| Approx. Unocclude Balloon Return Vol. | |
|---------------------------------------|----------------|
| 6 French | 4.5 French |
| 0.04 - 0.05 cc | 0.03 - 0.04 cc |

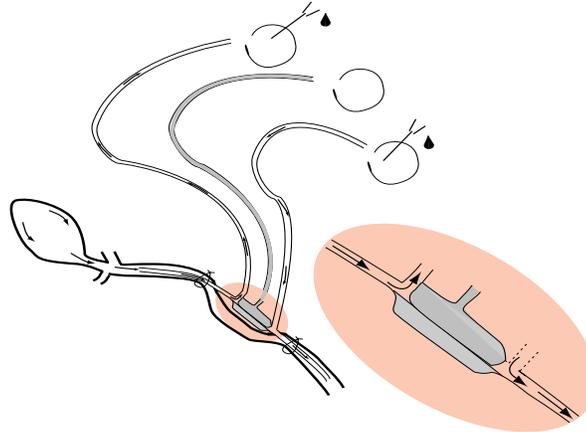
8. Repeat Step 6 and Step 7 two more times. That is “Occlude” and “Unocclude” and again “Occlude” and “Unocclude.” This is an important procedure which fully “primes” the balloon.

9. Disconnect saline bag and remove 22ga Huber needle from Sampling V-A-P. Ensure that the balloon is unoccluded.

10. **Cannulate Bile Duct:** Cannulate bile duct with the two arms of the T making sure that the side of the T with the clear bile sampling catheter is on the side of the liver. This may be done by either making two small nicks in the bile duct for each catheter arm or by transecting the bile duct. The liver side bile duct catheter tip should be distal to the hepatic duct(s). The intestinal side bile duct catheter tip should be proximal to the sphincter of Oddi. Observe for shunting flow from liver side through to the intestinal side.



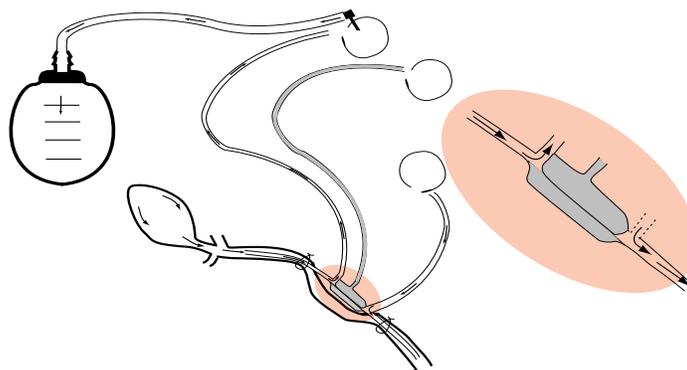
11. Insert a 22ga Huber needle into the Sampling V-A-P. Bile will probably not begin flowing through the sampling catheter while the balloon is unoccluded.
12. Occlude balloon as described in Step 6. Bile should flow through the Sampling V-A-P.



13. Unocclude balloon as described in Step 7.
14. SLOWLY flush Sampling V-A-P with sterile saline (approximately 2cc). Do not allow bile to stand in the Sampling V-A-P or catheter as it may crystallize.
15. Clamp catheters just distal to both V-A-Ps and slice catheters longitudinally over barbs to remove catheters from V-A-Ps.
16. Knot or plug both catheters and tunnel both catheters to V-A-P pocket sites. It is important that the contents of the balloon catheter do not leak.
17. Trim both catheters to appropriate lengths and attach appropriate V-A-P's.

Usage

1. When collecting bile from the Sampling V-A-P, use a 22 ga. Huber needle. Keep in mind that the needle and tubing line are restrictors in the bile flow circuit. The more this line restricts, the more pressure the balloon and biliary system will face. Thus a larger gauge needle, shorter needle length, larger tubing dia., shorter tubing lengths, and fewer luer connections, etc. will optimize bile flow and physiology as well as balloon performance.
2. The enclosed low vacuum collection bulb has a one way valve which will preclude collected bile from inadvertently infusing back into the animal. *For 3 legs system: Compounds can be simultaneously infused toward duodenum from distal Flushing3 Catheter.*



3. You should use fluoroscopy or x-ray to confirm proper function of system.
4. The balloon has been validated for inflation of up to 24 hour intervals.