

Cannuflow, Incorporated



Product Training Manual

rev 10/10/10a

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Overview: The Cannuflow Product Line



The Cannuflow product line is based on a few simple principles:

- Technologies that reduce or eliminate preventable complications
- Technologies that require no change in surgeon technique
- Products that pay for themselves in use
- Disposables that generate recurring revenue
- Simple well-designed solutions
- Easy to use, intuitive
- High customer retention (“sticky”)
- Affordable, clear value proposition
- Solve a real need for the patient and surgeon
- Based on real-world input from practicing professionals

Cannuflow products are simple to use, and straightforward to present. The key is to identify the surgeon's need and technique, and let the surgeon try appropriate product. When it solves their problem, then ask them to add it to their preference card, and use it in every case.

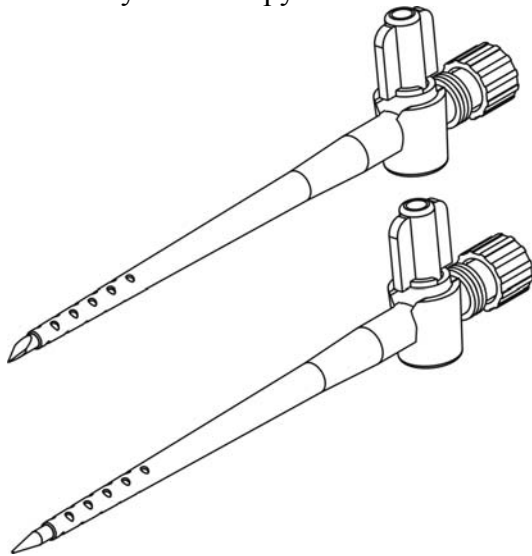
This training manual will introduce you to each product, what it is, what makes it different, what are the clinical benefits, why the surgeon should be interested, why the

facility will be interested, and how to present the product. Each section will include the product instructions for use for reference.

ClearVu®

What is it?

ClearVu is a flexible inflow-outflow fluid management cannula primarily for 3-portal knee arthroscopy. It has also been used as an accessory outflow in shoulder, and in small joint (elbow and ankle) ClearVu is also popular as an outflow cannula for small-animal veterinary arthroscopy.



Working Length 8cm

Inner diameter 2.7mm

Flow rate 0-1 liters/min, stopcock controlled

Atraumatic, flexible polymer construction

What makes it different?

Conventional inflow/outflow cannulas are rigid metal, based on a design going back to before the 1970's. It is well known that these metal cannula damage cartilage and soft tissue, clog, and are a source of post operative "third portal pain"¹

ClearVu is *progressively flexible*. It is stiffer at the proximal end for optimal control during placement, and more flexible at the distal end. The patented tapered construction prevents kinking and gives the ClearVu a super-low profile in the joint where it is needed. No other cannula has this combination of low profile, high flow, high efficiency,

and non-kinking flexibility. The ClearVu has been proven in tens of thousands of procedures.

ClearVu provides *direct flow* from the joint, and does not need to be inserted laterally into the suprapatellar pouch like metal cannulas. It is this lateral placement that makes metal cannulas clog, require repositioning, and dig painfully into soft tissue.²

What are the clinical benefits?

Metal cannulas clog, and stop flowing which causes loss of visualization in the joint, and can scrape and skive sensitive articular cartilage, especially when the knee is flexed into the figure-4 position to open up the anterior side of the knee joint.

ClearVu is the only atraumatic, progressively flexible cannula on the market that never kinks, never clogs and prevents damage to soft tissue and articular cartilage caused by rigid metal cannulas. ClearVu is also made from non-conductive polymer, and is immune to RF current shorting.

Why should the surgeon be interested?

ClearVu makes the surgeon's job easier. ClearVu is placed ONCE. No re-positioning needed. No fiddling required by the PA. It just stays put and works. Consistent flow means consistent clarity and visualization. The surgeon gets a more satisfied patient with less post-op pain and a more efficient procedure. The super-efficient ClearVu provides abundant fluid flow and clarity even during ACL reconstruction procedures. ClearVu works with any fluid inflow system, pump or gravity.

Why should the facility be interested?

Less surgical inefficiency and less wasted time means faster OR turnover and better facility utilization. Wasted time equals wasted money. Our studies show that each repositioning of a metal cannula to regain flow takes an average of 45 seconds,³ and each repositioning risks damage to the patient's cartilage and soft tissue. The average cost of OR time is \$1.50 per second, and there are an average of 3 interruptions to reposition per case or 135 seconds of interruption. This is a cost to the facility up to \$202 in wasted OR time. Using a ClearVu in place of a metal cannula can yield an average of \$167.50 in savings from increased OR efficiency. This does not include the average cost to handle and re-sterilize the metal cannula.

4 surgeons doing 4 knee cases in a day with an average of 135 seconds of interruption per case is 2160 seconds, or 36 minutes of lost, wasted OR time per day. This lost time stacks up during a surgical day and contributes to cases not starting on time. This adds up to 9360 minutes, or 156 hours lost, or nearly 4 lost working weeks of OR time per year! The facility is hit twice. Once to pay overhead on unproductive "fiddle time." The second is in the lost revenue on procedures that can't be done in that same wasted time.

Better visualization with ClearVu also means less reliance on hemostasis work-arounds such as hypotensive anesthesia that can be harmful to the patient. Metal cannulas no longer need to be stockpiled, inventoried, re-handled, cleaned sterilized and maintained. Risks of cross-contamination from reused metal cannulas and hospital-acquired infections are eliminated. All of these represent significant benefits to the facility.

How do you present the product?

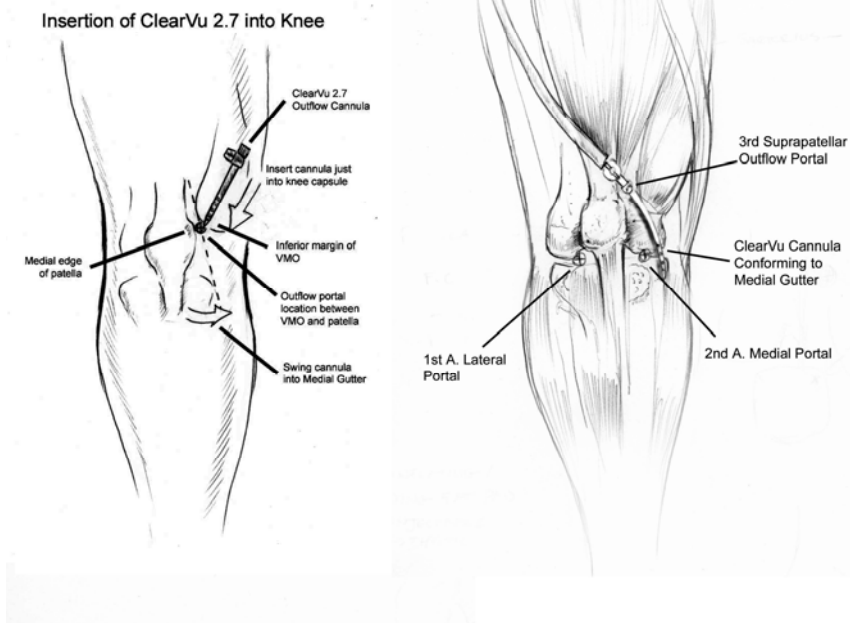
Find out if your surgeon does arthroscopy. Then find out if they are a “3-portal surgeon” meaning that they use a suprapatellar port and either inflow through the scope and outflow through a cannula, or inflow through a cannula and outflow through the scope.

The ClearVu is a drop-in replacement for a metal cannula. Be sure to instruct the surgeon to insert the ClearVu into the suprapatellar pouch, and into the joint capsule through the medial gutter. Connect to inflow or outflow depending on the surgeon preference.

ClearVu is also a great product to present surgeons doing ankle, elbow, and wrist arthroscopy. Don't insert the ClearVu laterally either suprapatellar or sub-patellar. The suprapatellar pouch shuts off in the figure-4 position. Also, the ClearVu can be crushed between the femoral condyle and tibial plateau when inserted sub-patellar (by the way, the metal cannula grinds into the joint cartilage in this position). Always use the ClearVu suprapatellar, and in the medial gutter for best results.

OR staff that will be interested in the ClearVu are the PA (physician's assistant) and the scrub staff. Often the burden of keeping clarity in the joint and repositioning the metal cannula to regain flow falls on them. The ClearVu eliminates this unnecessary burden during surgery. The PA and scrub are often very receptive to the ClearVu product.

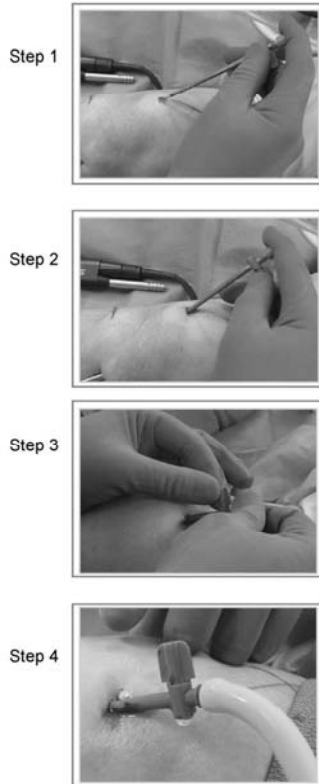
Placement of the ClearVu 2.7 Cannula in the Medial Gutter of the Knee in 3-Portal Arthroscopy



Instructions for Use



ClearVu™ 2.7 Flexible Inflow-Outflow Cannula



Federal law restricts this device to sale by or on orders of a physician.

Manufactured for:
Cannuflow Incorporated
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San Jose, California 95110 USA
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Manufactured by:
Hantel Incorporated

06-018-03
Rev 06/08/07

STERILE Sterile,
Irradiation



Expiration
Date



Single use only
Do not reuse

REF

Catalog No.

LOT

Lot No.

Description

The ClearVu™ 2.7 CV27-S (sharp trocar) and CV27-B (blunt obturator) single-use flexible inflow-outflow cannulae are compatible with most luer-lock or press-fit irrigation tubing systems in order to provide consistent fluid inflow or outflow during arthroscopic procedures. Cannulae are supplied with a sharp trocar or blunt obturator in place.

Warnings

Product supplied sterile. Do not use if package is open or damaged. **DO NOT RESTERILIZE.** Discard any open or unused product.

Precautions

The ClearVu 2.7 flexible cannula should extend completely through the soft tissue and be fully visible inside the joint cavity. This will minimize the possibility of fluid extravasation into the soft tissue due to the fenestrations of the cannula being not fully inserted into the joint space.

Normal precautions associated with arthroscopic procedures should be employed including careful attention to sterile technique and avoidance of anatomical hazards.

Instructions

For insertion:

- Step 1.** After making a small incision with a scalpel, use the trocar or obturator supplied in the cannula to penetrate a safe distance in toward the joint capsule by exerting continuous pressure inward.
- Step 2.** When the trocar or obturator is in the desired position within the joint, unscrew the hub of the trocar or obturator and withdraw it from the cannula, leaving the cannula in place. Confirmation of proper placement can be made by means of arthroscopic visualization.
- Step 3.** Carefully remove the trocar or obturator from the operative field and dispose of properly with other sharp contaminated items.
- Step 4.** Connect the inflow, gravity drainage, or suction tubing to the luer connection by twisting clockwise.

For removal:

- Step 5.** Remove the cannula from the incision site by gently pulling from the wound, rotating if necessary for a smooth exit.
- Step 6.** Dispose of properly.

Warranty

FOR SINGLE USE ONLY. This product is warranted to be free from defects in material and workmanship.

Notes

See outer package of each unit for sterilization expiration dates, method of sterilization, lot number, ordering information, reference number and patent number(s).

PRODUCT DOES NOT CONTAIN LATEX.

Patent No. 5,527,276
Patent No. 5,800,409

Surgeon testimonial quotes:

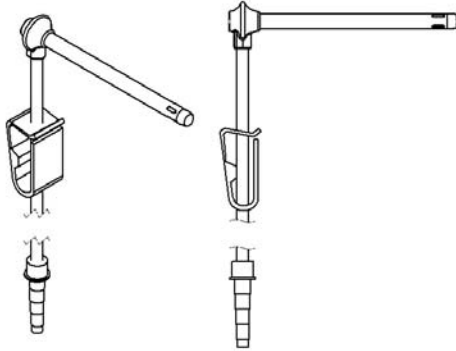
“I won’t do 3-portal knee arthroscopy without it. It’s just better for the patient”
-Tad Pruitt MD Little Rock Surgery Center, Little Rock, AR

“ClearVu allows continuous flow and does not damage the articular surfaces” –Martin Trieb, MD, Napa CA

“ClearVu in the knee is just a ‘no-brainer’ ” –Samir Sharma MD, Bascom Surgery Center, San Jose CA



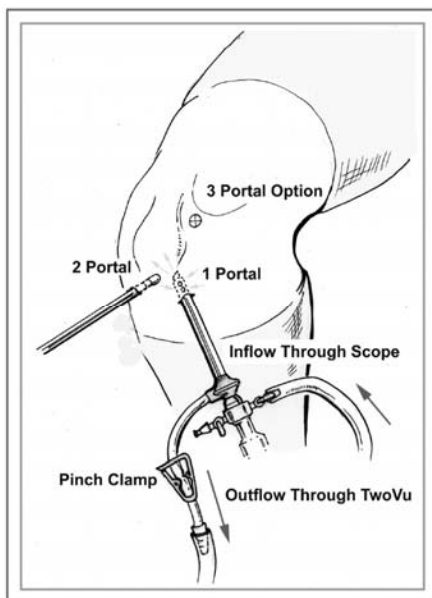
TwoVu®



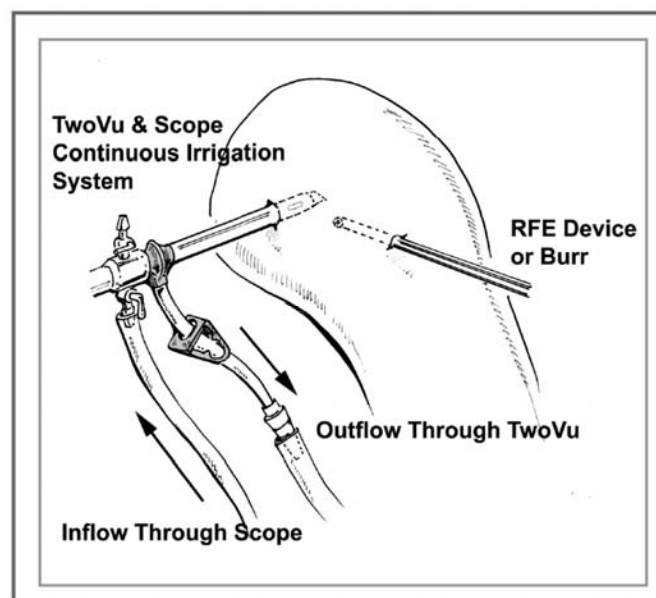
What is it?

TwoVu is a unique, patented, low-profile outflow sheath that slides conveniently over an arthroscope set used in knee or shoulder arthroscopy. It turns any conventional one-channel inflow or outflow scope into an easy to use and highly effective simultaneous inflow/outflow system. It flows easily to gravity, and distension and flow are controlled with the included pinch clamp. TwoVu is compatible with any fluid inflow system, pump or gravity.

Construction: Low-profile cannula body with expanding distal seal and outflow fenestrations, and elastomeric proximal seal with integrated drain tube and pinch-clamp flow control. There are two size ranges, the ST-5 that stretches to fit 5.5mm to 5.8mm diameter, and the ST-6 series that fits 5.8mm to 6.2mm diameter. The TwoVu comes in a range of lengths to fit most popular scopes.



TwoVu setup in two-portal knee and shoulder



Compatibility: TwoVu ST-5 fits Stryker and similar, ST6-L fits Smith+Nephew and similar, ST6-134 fits Linvatec QL and similar, ST6 fits older Linvatec T, Wolf, and some Storz and similar.

Manufacturer	Diameter	Length	Compatible TwoVu
Stryker	5.8mm	113mm	ST-5 (blue clamp)
S+N	6.2mm	122mm	ST6-L (white clamp)
Linvatec QL	5.5mm	134mm	ST6-134 (blue clamp)
Linvatec QL	5.9mm	134mm	ST5-134 (white clamp)
Other (some Storz, Wolf, Olympus, Linvatec T)	5.8-6.2mm	113mm	ST-6 (white clamp)

What makes it different?

No other arthroscopic fluid management system combines TwoVu's super-low profile, high flow rate, and exceptional ease of use. TwoVu has unique "clear pocket" flow that pulls blood and debris behind the field of view, providing brilliant "gin clear" clarity throughout the procedure, with no interruptions or "stop-cock twiddling" required. The TwoVu will move from .7 to 1.3 liters per minute, depending the scope system. Running "wide open" TwoVu is designed to remove fluid at the same rate the scope can put it in.

What are the clinical benefits?

TwoVu is the first product to make two portal knee arthroscopy practical, with the capital scope equipment the facility already has. TwoVu vastly increases clarity and efficiency in both knees and shoulders. TwoVu reduces dangerous RF heat by removing heated irrigation fluid. TwoVu reduces reliance on hypotensive anesthesia to maintain clarity in shoulder cases, which has been shown to be dangerous to patients in the "beach chair" position.

Why should the surgeon be interested?

The surgeon can finally concentrate on their surgery rather than fighting to maintain clarity, without clumsy work-arounds, even in difficult cases such as with hypertensive patients. Efficiency is greatly improved, and time-wasting "stop cock twiddling" is eliminated. Surgeons no longer need fear complications from overheating the joint or excessively low BP. "Bernoulli bleeders" stirred up in the joint due to turbulence and cross-flow are eliminated, reducing the need for excessive RF use to burn back bleeders.

Surgeons that want to convert to the two-portal knee technique now have a way to do this without losing the 3-portal quality flow that they have come to rely on. 2-portal arthroscopists can now have vastly improved vision and efficiency.

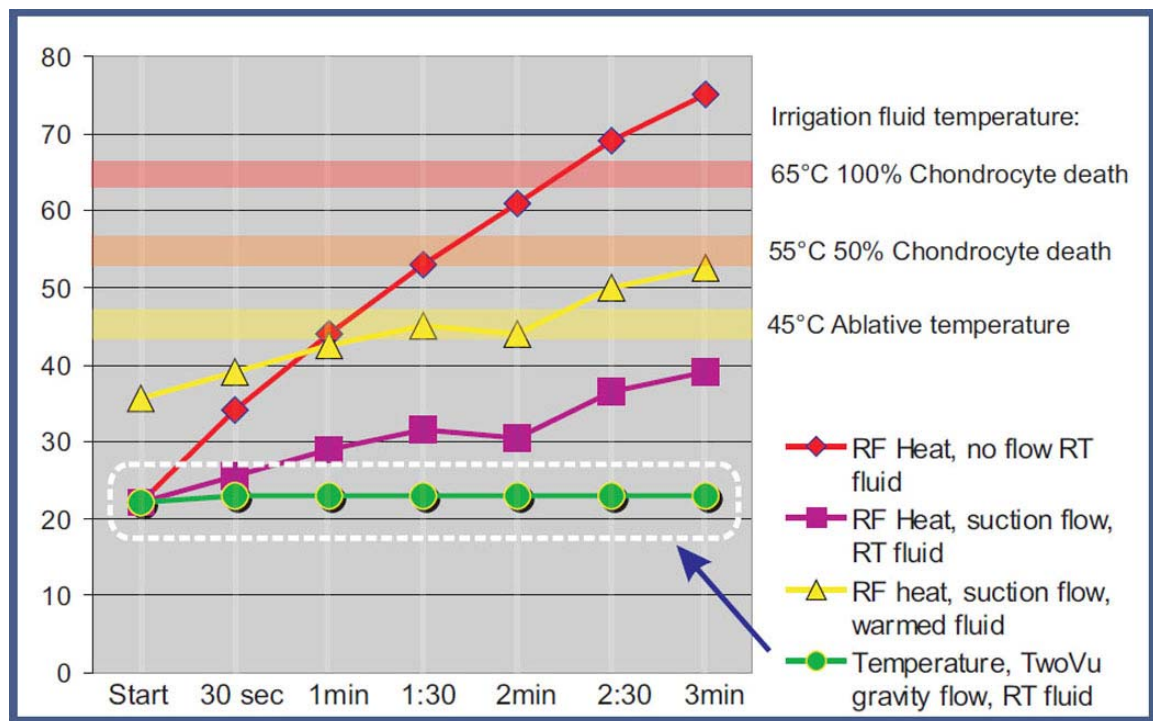
Many shoulder surgeons that do “open” shoulder procedures start with a diagnostic scope of the shoulder to confirm MRI radiology findings. Before TwoVu, getting outflow and clarity in a diagnostic scope through one portal was impossible. Now, diagnostic scoping with full inflow and outflow control and brilliant clarity is fast and easy.

Why should the facility be interested?

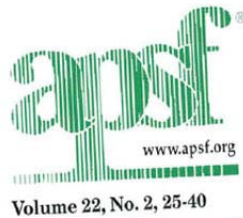
Chondrolysis due to RF overheating of the joint is a devastating and very costly complication that any facility would want to avoid even the small chance of happening.

⁴⁵Stroke due to excessive use of hypotensive anesthesia in the beach chair position is another very costly, devastating “never event.” TwoVu can help prevent both.

TwoVu makes surgery go faster, which speeds OR turnover and helps keep cases on time. TwoVu quickly pays for itself and returns efficiency dividends to the facility. At \$40 TwoVu is a very affordable way to get these significant clinical and efficiency benefits.



Typical RF heating in subacromial space *in vitro* model with no flow, wand flow, and TwoVu continuous flow, with warmed and room temperature (RT) irrigation fluid



NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

Circulation 81,489

Summer 2007

Beach Chair Position May Decrease Cerebral Perfusion *Catastrophic Outcomes Have Occurred*

by David J. Cullen, MD, and Robert R. Kirby, MD

onance imaging (MRI) 1 week later showed changes in both cerebral hemispheres suggesting cortical

resistance increase. Under nonanesthetized conditions, these effects are compensated for by an increase in systemic vascular resistance by up to 50-80%. How-

Anesthesia Patient Safety Foundation article alerting to risks of hypotensive anesthesia to control fluid clarity in the “beach chair” position

How do you present the product?

Knee: Identify the surgeon as a two-portal knee, aspiring two-portal knee arthroscopist. Let them know that they can have 3-portal quality flow in a two-portal procedure, and trouble-free, fuss-free clarity. Simply slide a TwoVu on a scope, insert into the knee, and now concentrate on your procedure, not fussing to get consistent fluid flow. TwoVu flows easily to gravity, and distention is controlled with the included pinch clamp. When the TwoVu is in the joint, close the pinch clamp one or two clicks. The TwoVu moves fluid very efficiently and this will help save irrigation fluid.

Shoulder: TwoVu is especially popular with the fast “A” class shoulder arthroscopist. These are the volume surgeons for who speed, efficiency, and fast OR turnover is paramount. Lower-volume shoulder arthroscopists also benefit from the increased efficiency and not having to fight “red-outs” during a case.

Many shoulder surgeons are concerned about RF heating and the threat of chondrolysis. Inter-articular pain pumps have been implicated in this devastating complication, however, RF overheating is also a proven cause. Studies show TwoVu effectively reduces the RF heating of irrigation fluid that can lead to cartilage death, by efficiently removing heated fluid.

Many surgeons are concerned about excessively using low blood pressure to control bleeding in the joint. This can lead to permanent brain damage from stroke in the beach chair position in rare cases. Some surgeons have even abandoned beach chair for the lateral decubitus approach. TwoVu gives the surgeon reliable, consistent clarity less risk, and without changing procedure.

Other OR staff that will be interested in the product are the PA (physician’s assistant) and the scrub staff. Often the burden of keeping clarity in the joint sometimes falls on them. The TwoVu helps eliminate this unnecessary burden during surgery. The PA and scrub staff may be interested in the TwoVu as well as the surgeon.

Instructions for Use

Cannuflow
Clearly Superior.

TwoVu™ ST Outflow Sheath

For TwoVu ST-5, ST-5L, ST-6, ST-6S, and ST-6L sizes



TwoVu ST Outflow Sheath Specifications

Scope sheath size	TwoVu size
5.5 to 5.8mm OD 110mm length min.	TwoVu ST-5
5.5 to 5.8mm OD 123mm length min.	TwoVu ST-5L
5.8 to 6.5mm OD 83mm length min.	TwoVu ST-6S
5.8 to 6.5mm OD 110mm length min.	TwoVu ST-6
5.8 to 6.5mm OD 123mm length min.	TwoVu ST-6L

Manufactured for:
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STERILE Sterile, Irradiation
REF Catalog No.
LOT Lot No.
Expiration Date
Single use only
Do not reuse
Federal law restricts this device to sale by or on orders of a physician.

06-030-03
Rev 3/07/08

Description

The TwoVu™ ST line of arthroscope outflow sheaths are designed to fit over a variety of industry standard metal arthroscope sheaths to provide continuous fluid out-flow during arthroscopy procedures. TwoVu uses gravity to evacuate fluid and debris but may also be connected to suction tubing.

Warnings

Product supplied sterile. Do not use if package is open or damaged. **DO NOT RESTERILIZE.** Discard any open or unused product.

Precautions

The distal end of the arthroscope, with its inflow and outflow sheaths attached, should extend completely through the tissue and fat pad so the fluid openings are fully inside the joint cavity. This will minimize the possibility of fluid extravasation into the soft tissue due to the fenestrations of the sheaths being erroneously positioned within the soft tissue.

Obese patients may have abnormally large anterior fat pads and are not good candidates for the optimal performance of the TwoVu device. For these patients it may be difficult to position the fenestrations within the capsule so that the fat pad does not clog the outflow sheath or cause extravasation with the arthroscope's sheath.

Instructions

1. While maintaining sterile technique, open the TwoVu sterile pack. **REMINDER: Moisten the distal end of the arthroscope sheath with sterile fluid so that TwoVu will slide more easily over the arthroscope sheath.**
2. Holding the proximal end of TwoVu, slide the TwoVu sheath over the arthroscope's sheath such that the distal end of TwoVu does not block the outflow opening(s) of the arthroscope sheath. **Make sure the TwoVu fenestrations are within 1cm of the scope sheath fenestrations.** It is important that the TwoVu sheath fenestrations are within the joint cavity and not in soft tissue. To accommodate various length scopes and sheaths, this may require that the TwoVu sheath is **NOT** pulled all the way up to the coupling.
3. Make a small incision with a scalpel.
4. With the TwoVu sheath in place over the arthroscope's metal sheath, use the trocar or obturator supplied with the surgical facility's arthroscope sheath to penetrate a safe distance in toward the joint capsule by exerting continuous pressure inward.
5. When the trocar or obturator is in the desired position in the joint, unscrew or unsnap the hub of the trocar or obturator and withdraw the trocar or obturator from the arthroscope sheath, and insert the arthroscope into its own sheath.
6. Connect the in-flow tubing to the luer connection of the arthroscope sheath.
7. Connect the outflow tubing to the slip-fit connection of the TwoVu sheath.
8. The entire assembly, arthroscope, inflow sheath and TwoVu sheath can now be manipulated as one device.
9. When no longer needed, the entire assembly may be removed from the incision site by gently pulling from the wound, rotating if necessary for a smooth exit.
10. While still moist, slide the TwoVu sheath down the arthroscope sheath and dispose of TwoVu properly.

Warranty

FOR SINGLE USE ONLY. This product is warranted to be free from defects in material and workmanship.

Notes

See outer package of each unit for sterilization expiration dates, method of sterilization, lot number, ordering information, reference number and patent number(s).

PRODUCT DOES NOT CONTAIN LATEX.

Patent Pending

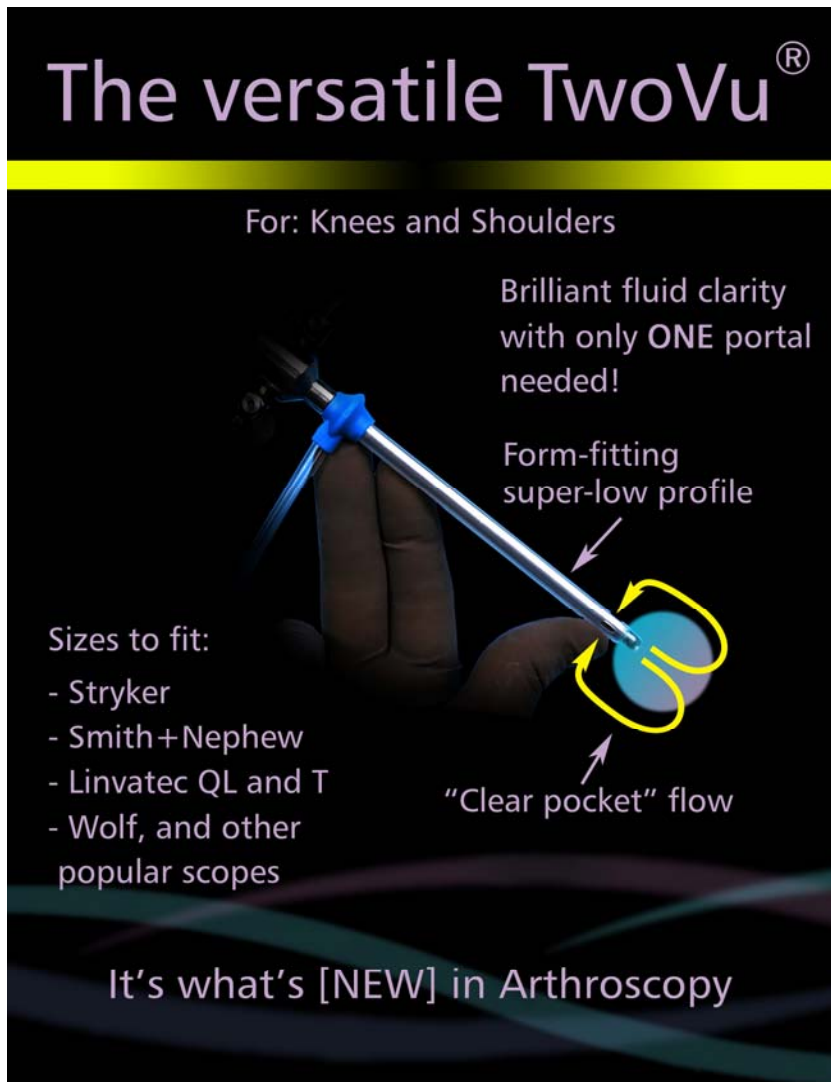
Surgeon testimonials:

"I can't imagine doing knee surgery without it!"
-Scott Forster MD San Leandro Surgery Center, San Leandro, CA

"Arthroscopy without TwoVu is like going back to the 'dark ages'!" –Gordon Levin, MD
Good Samaritan Hospital, San Jose CA

"Once you experience 2-portal arthroscopy with a TwoVu you won't want to go back to 3-portal scoping with a metal cannula again!" Paul Dossick MD

"I can't believe something this simple works so well!" William Canham, MD, Med
Center One Hospital, Bismarck ND

The image is a promotional graphic for the TwoVu arthroscopic system. It features a dark background with a yellow horizontal band at the top. The title 'The versatile TwoVu®' is in large white font. Below it, 'For: Knees and Shoulders' is written. A central image shows a hand holding the TwoVu device, which is a long, thin, blue-tipped instrument. To the right of the device, text highlights 'Brilliant fluid clarity with only ONE portal needed!' and 'Form-fitting super-low profile'. A yellow circular arrow around the tip of the device is labeled '"Clear pocket" flow'. On the left, a list titled 'Sizes to fit:' includes Stryker, Smith+Nephew, Linvatec QL and T, and Wolf, and other popular scopes. At the bottom, the slogan 'It's what's [NEW] in Arthroscopy' is displayed.

The versatile TwoVu®

For: Knees and Shoulders

Brilliant fluid clarity with only **ONE** portal needed!

Form-fitting super-low profile

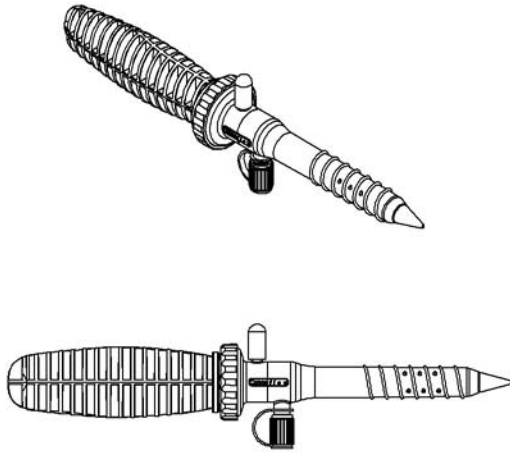
Sizes to fit:

- Stryker
- Smith+Nephew
- Linvatec QL and T
- Wolf, and other popular scopes

"Clear pocket" flow

It's what's [NEW] in Arthroscopy

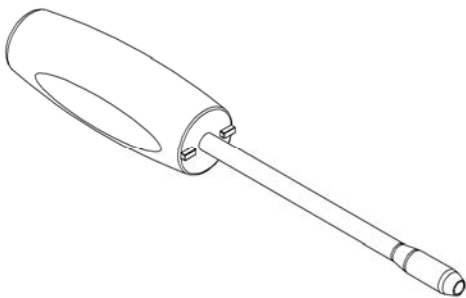
EntreVu®



EntreVu cannula with included disposable obturator

What is it?

EntreVu has all the features of a clear, high-quality twist-in cannula, with the addition of the easy-to-use, Extravastat® integrated interstitial drainage system to remove fluid extravasation. No other cannula in the world has this Extravastat technology.



EntreVu optional cannulated obturator

What makes it different?

Fluid extravasation, where irrigation fluid leaks from the shoulder capsule and subacromial space into the soft tissue causing swelling and fluid infiltration is a chronic concern, especially in longer cases, and with older and heavier patients, and where a pump is used. Until now, the only way to deal with the problem was for the surgeon to hurry up, if they could. Cannuflow exclusive Extravastat technology is the only available solution to address this swelling and fluid overload from extravasation.⁶

What are the clinical benefits?

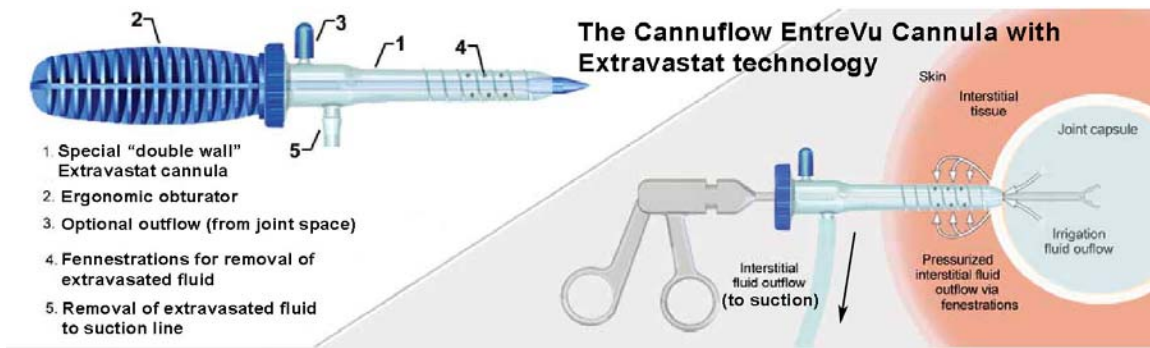
Less fluid load and swelling are better for the patient. Fluid load is a documented source of post-operative infection risk, cardiopulmonary risk, and post-operative pain. The EntreVu with Extravastat technology is the only cannula on the market proven to reduce extravasation fluid load by up to 2/3. Reduction of fluid load from extravasation can make the difference between a minimally-invasive arthroscopic procedure, or the conversion to a more invasive open procedure requiring longer post-op pain and rehab.

Why should the surgeon be interested?

Swelling from extravasation makes shoulder surgery more difficult. Cannulas lose working length as muscle tissue becomes saturated, which may require swapping out a shorter cannula for a longer one. A swollen shoulder is harder to maneuver instruments in and makes shoulder repair more difficult. Neck swelling, especially in older patients in the lateral decubitus position can be a concern. EntreVu helps solve these problems, as well as giving the surgeon other features they want, such as a high-quality leak resistant fluid seal and a crystal-clear cannula for visualizing knots and sutures.

Why should the facility be interested?

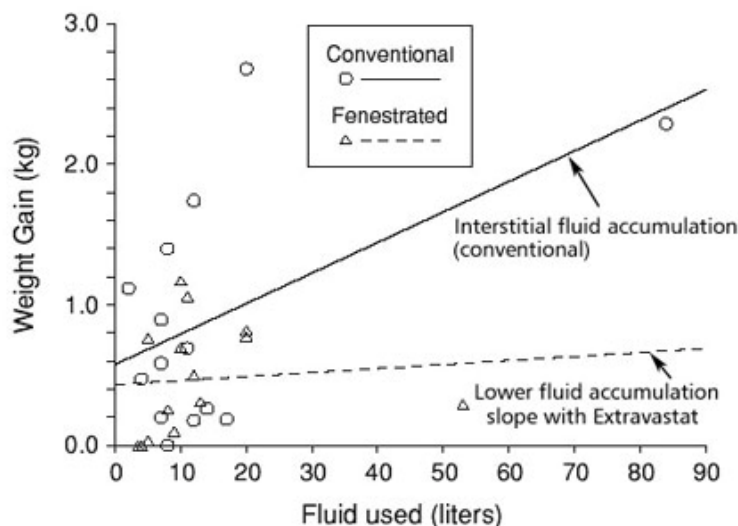
EntreVu is priced competitively with many other cannulas the facility is already using (e.g. Linvatec DryDoc \$38+, Arthrex and Mitek @ \$42.) Published complication rates due to extravasation are 5.5%. This is a total of 44,000 complications per year that may result in an expense such as an overnight stay or re-admission. So, for between \$3 and \$12 extra per cannula, the facility can avoid up to \$165.50 of costs on an average per case basis, an excellent return on a small investment. Reduction of fluid load from extravasation can make the difference between a patient experiencing a minimally-invasive arthroscopic procedure, or conversion to a more invasive open procedure, This increases patient satisfaction and avoids the costs of increased post-op pain and rehabilitation.



How do you present the product?

The surgeons most interested in controlling extravasation are those with a population of older patients (>45), particularly those with retracted, chronic tears that tend to readily leak fluid into the surrounding soft tissue, and take longer to repair. Surgeons with obese patients and smokers will be interested as well. EntreVu can improve outcomes in any shoulder surgery. EntreVu also has one of the highest quality proximal fluid seals on the market, preventing annoying leaking and squirting. EntreVu is exceptionally easy to use, only requiring the connection of a suction hose to the luer connection covered with the blue tethered cap.

An easy way to demonstrate the EntreVu is to connect the suction line to a dedicated suction bucket. Typically this will drain 1/3 to 1/2 liter of fluid or more. If a dedicated bucket is not available, an alternative is to use the bucket connected to the RF wand, and connect the EntreVu when the surgeon is done with the RF wand. Mark the bucket with a Sharpie marker, and note the level of fluid above the mark. At the end of the case, point out the amount of fluid in the dedicated bucket, or above the mark on the bucket. Point out that this extra fluid came from the patient's interstitial tissue, (NOT the joint) and this fluid would be going home with the patient had it not been removed by the EntreVu.



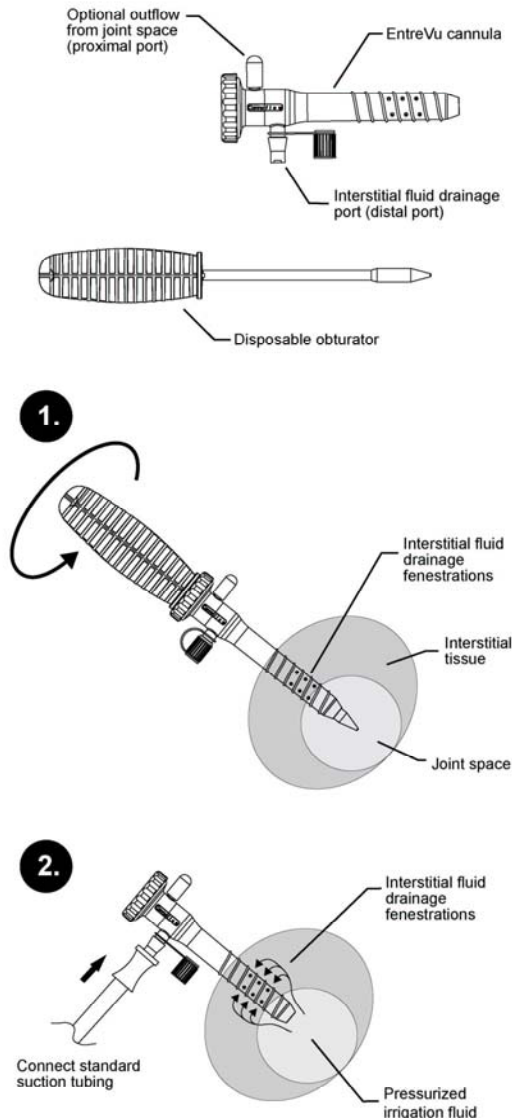
Clinical Effectiveness of Extravastat technology, CORR January 2010⁷

EntreVu™ EX

Ref: EVEX-8-7T

Instructions for Use

8.25mm ID, 7cm working length



Warnings

Product supplied sterile. Do not use if package is open or damaged.
DO NOT RESTERILIZE. Discard any open or unused product.

Description:

The EntreVu EX (Extravastat) is designed to provide both surgical access to the joint and removal of irrigation fluid from interstitial tissue in one integrated device. (Actively draining away extravasated fluid can visibly reduce shoulder swelling.) An optional outflow drainage port for draining fluid directly from the joint space is available if needed.

EntreVu EX Kit

The kit contains the single-use portal cannula and a disposable obturator. (An optional reusable cannulated obturator is available if needed.) The interstitial drainage port (distal port) connects to standard suction tubing sets via its universal connector. This port is used to drain extravasated fluid from interstitial tissue.

The second port (a smaller outflow port) is optional and is used to drain fluid directly from the joint space as needed.

Placing the Cannula

1. Insert obturator through cannula's proximal seal and place cannula into joint using standard procedure. Be sure to position cannula's interstitial drainage fenestrations so they are in contact with interstitial tissue.
2. Remove screw-on luer cap from distal port (interstitial fluid drainage port) and attach suction tubing. Then connect other end of the suction tube to fluid collection bucket or other device.

Should you need to reposition the cannula at any time, simply slip off the tubing, reposition the cannula, then re-attach the tubing.

Use of optional drainage port:

If additional drainage directly from the joint space is required, use the proximal port to drain fluid from the cannula's center lumen. The port's connector is compatible with many types of surgical drainage tubing.

For continuous irrigation of the joint, use of the Cannuflow TwoVu or TwoVu EX disposable outflow scope sheath is recommended. The TwoVu EX will also provide additional anti-extravasation capabilities.

Warranty
FOR SINGLE USE ONLY. This product is warranted to be free from defects in material and workmanship.

Notes
See outer package of each unit for sterilization expiration dates, method of sterilization, lot number, ordering information, reference number and patent number(s).

PRODUCT DOES NOT CONTAIN LATEX.
Patents Pending

Manufactured for:
Cannuflow Incorporated
1190 Coleman Avenue, Suite 250
San Jose, California 95110 USA
+1 866 484 5400

Manufactured by:
Pacific Plastics & Engineering

Federal law restricts this device to sale by or on orders of a physician
06-063-01 Rev 01/26/09



Single use only
Do not reuse



Sterile,
Irradiation



Expiration
Date



Catalog No.



Lot No.

The revolutionary EntreVu[®]

Exclusive Extravastat technology

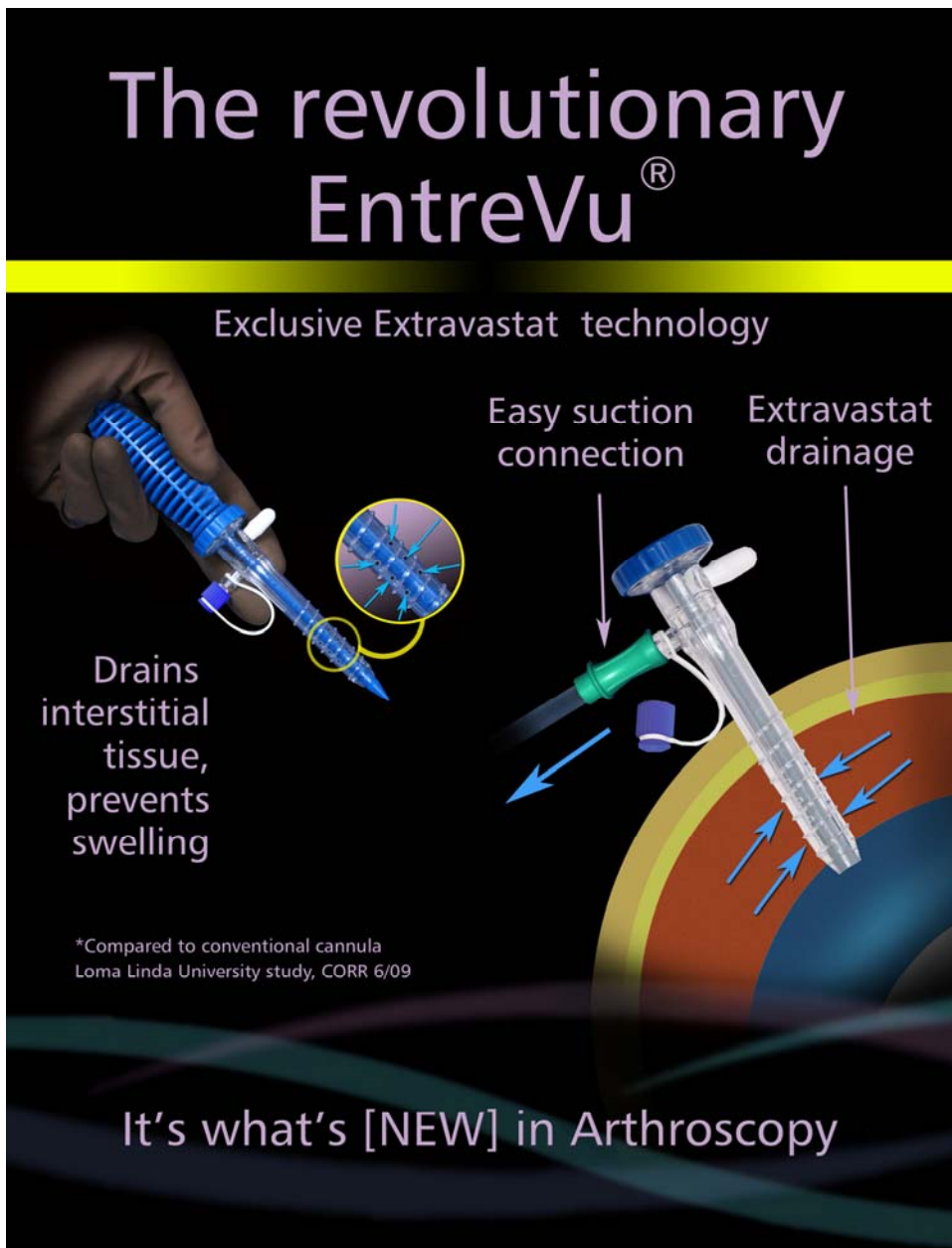
Drains interstitial tissue, prevents swelling

Easy suction connection

Extravastat drainage

*Compared to conventional cannula
Loma Linda University study, CORR 6/09

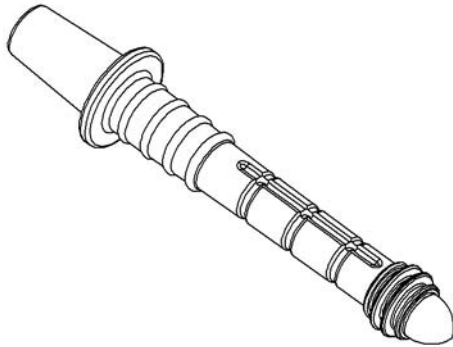
It's what's [NEW] in Arthroscopy

The graphic features a hand holding a blue and clear EntreVu cannula on the left. A circular inset shows a close-up of the cannula's tip with blue arrows indicating fluid drainage. On the right, a diagram shows the cannula inserted into a joint, with blue arrows representing fluid being drawn into the device and away from the tissue. The background is dark with a yellow horizontal band and wavy lines at the bottom.

Surgeon Testimonials

“EntreVu is especially effective with my older female patients with soft (subcutaneous) tissue where extravasation can be a problem. I no longer need to be concerned about swelling, and I have seen a reduction in post-operative pain. I use an EntreVu on every shoulder case” –Juliet DeCampos Baptist Healthcare, Pensacola FL

Extravastopper®



What is it?

Extravastopper is a unique, simple, and easy to use solution solving several annoying problems in arthroscopy: abandoned spouting portals, especially on the anterior side, fluid leakage from the joint and fluid waste on to the floor, and fluid extravasation into the soft tissue. Extravastopper easily keeps irrigation fluid IN the joint OUT of the interstitial tissue and OFF the floor.

What makes it different?

There is no other product like the Extravastopper. Current work-arounds include assistant's fingers, marking pens, and other kludges. None work very well, and all make extravasation worse. Fluid on the floor is dealt with using towels or noisy and costly suction mats that add to the annoying and possibly hazardous tangle of wires and drain lines under the surgeon and OR staff's feet. Extravastopper keeps the floor dry, saves money on irrigation fluid and gives the patient important clinical benefits by reducing fluid overload. No other product does this.

What are the clinical benefits?

Extravastopper incorporates patented Cannuflow Extravastat technology in an exceptionally easy to use and affordable device. Reducing extravasation fluid load prevents swelling and post-operative pain, and makes closure at the end of the procedure easier. Reduction of fluid load from extravasation may make the difference between a minimally-invasive arthroscopic procedure, or the conversion to a more invasive open procedure requiring longer rehab and more post-op pain.

Why should the surgeon be interested?

Bleeders stirred up by turbulence in the joint from uncontrolled spouting “abandoned” portals are a well-documented problem. This compromises visibility in the joint, and makes the repair job harder to do. Extravastopper is especially effective when the surgeon starts on the anterior side to do a subacromial decompression and subscapularis, then moves to the lateral portal to repair the supraspinatus. The work done on the anterior side tends to cause significant fluid leakage from the glenohumeral joint and subacromial from the rotator interval and subtendinous bursa toward the chest wall and neck. This limits the amount of time the surgeon has to do the supraspinatus rotator cuff repair. Extravastopper drains away this fluid, preventing swelling and giving the surgeon more time to do the repair they want. The surgeon can now “watch the case, and not the clock.”

Why should the facility be interested?

Extravastopper pays for itself in the fluid that is not wasted, the towels that don’t need to be thrown on the floor to soak up irrigation fluid, and the suction mat that is not needed. Extravastopper gives the facility a positive return in terms of surgeon efficiency, better visualization and improved workflow, and increased patient satisfaction and potentially less post-op pain. No other product is so simple, so easy to use, and generates so many benefits.

How do you present the product?

The Extravastopper is inserted into the abandoned portal with a BLUNT switching stick. The tip protrudes just into the joint capsule, and the fins on the end of the Extravastopper act as a soft, atraumatic seal to prevent leakage from the joint, and to preserve distension. The switching stick is removed, and suction connected to the proximal end of the Extravastopper. The Extravastopper will then remove extravasated fluid from the interstitial tissue (not the joint)

The Problem: Spouting, Bleeding, Swelling

From: Burkhart's View of The Shoulder, LWW 2006



Figure 1-5. Turbulence control as a means of improving visualization. A: Blood obscures the anatomic details of this subacromial view. B: Turbulence associated with free egress of arthroscopy fluid causes the bloody field.

A primitive "solution" (as long as you hold your finger over the portal, but you dramatically aggravate swelling and tie up your hands!) Holding distension a problem, wet floor, wasted fluid

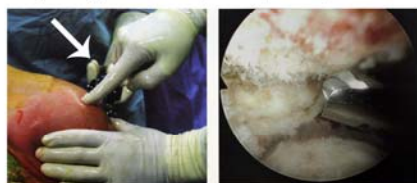


Figure 1-5. (continued) C: Digital pressure over the noncanulated portal stops the turbulent flow. D: The same field as in (A) after 10 seconds of digital pressure over the portal. Visualization has been dramatically improved.

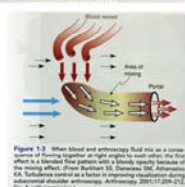


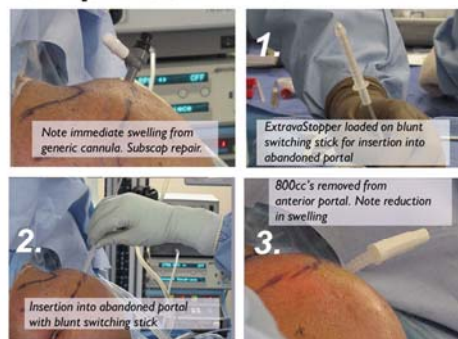
Figure 1-2. When blood and arthroscopy fluid mix as a consequence of a bursal ligament or ligament tear, the fluid flow is turbulent. The pressure and volume rapidly increase of the rising effect. (From Burkhart SJ, Simeone DM, Arthroscopic AA. Subacromial control as a fluid in improving visualization during arthroscopic shoulder arthroscopy. Arthroscopy 2001;17:209-212, fig. 4, with permission.)



Figure 1-3. A: A cannula is inserted into the joint space. B: The cannula is used to control the fluid flow and to improve visualization during arthroscopy. (From Burkhart SJ, Simeone DM, Arthroscopic AA. Subacromial control as a fluid in improving visualization during arthroscopic shoulder arthroscopy. Arthroscopy 2001;17:209-212, fig. 5, with permission.)



The Solution: Cannuflow Extravastopper Simple as 1. 2. 3.



Sealing of capsule interface

Keeps fluid IN the joint, OUT of the interstitial tissue and OFF the floor

To demonstrate the amount of fluid the Extravastopper removes, connect the suction line from the Extravastopper to a dedicated suction bucket. Typically this will drain 1/3 to 1/2 liter of fluid or more. If a dedicated bucket is not available, an alternative is to use the bucket connected to the RF wand, and connect the Extravastopper when the surgeon is done with the RF wand. Mark the bucket with a Sharpie marker, and note the level of fluid above the mark. At the end of the case, point out the amount of fluid in the dedicated bucket, or above the mark on the bucket. Point out that this extra fluid came from the patient's interstitial tissue, and would be going home with the patient had it not been removed by the Extravastopper. The shoulder may also be visibly less swollen than anticipated.

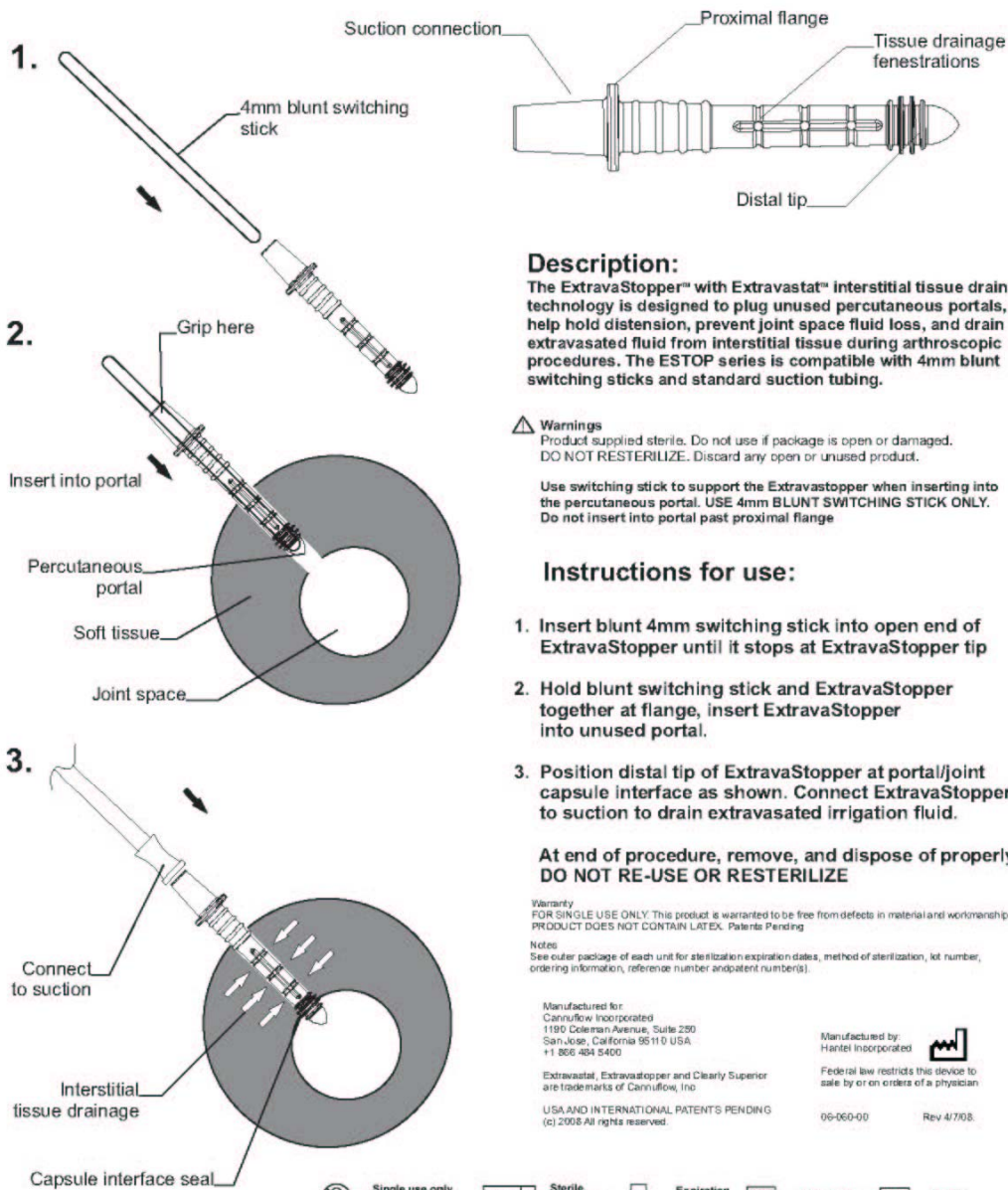
Surgeon testimonials

"I use Extravastopper on every case. It is amazingly simple and effective" –Nathaniel Cohen, MD Silicon Valley Surgery Center

ExtravaStopper™

Instructions for Use

Flexible portal plug and interstitial tissue drain



Description:

The ExtravaStopper™ with Extravastat™ interstitial tissue drainage technology is designed to plug unused percutaneous portals, help hold distension, prevent joint space fluid loss, and drain extravasated fluid from interstitial tissue during arthroscopic procedures. The ESTOP series is compatible with 4mm blunt switching sticks and standard suction tubing.

Warnings

Product supplied sterile. Do not use if package is open or damaged. DO NOT RESTERILIZE. Discard any open or unused product.

Use switching stick to support the ExtravaStopper when inserting into the percutaneous portal. USE 4mm BLUNT SWITCHING STICK ONLY. Do not insert into portal past proximal flange.

Instructions for use:

1. Insert blunt 4mm switching stick into open end of ExtravaStopper until it stops at ExtravaStopper tip.
2. Hold blunt switching stick and ExtravaStopper together at flange, insert ExtravaStopper into unused portal.
3. Position distal tip of ExtravaStopper at portal/joint capsule interface as shown. Connect ExtravaStopper to suction to drain extravasated irrigation fluid.

At end of procedure, remove, and dispose of properly. DO NOT RE-USE OR RESTERILIZE

Warranty
FOR SINGLE USE ONLY. This product is warranted to be free from defects in material and workmanship. PRODUCT DOES NOT CONTAIN LATEX. Patents Pending.

Notes
See outer package of each unit for sterilization/expiration dates, method of sterilization, lot number, ordering information, reference number and patent number(s).

Manufactured for:
Cannuflow Incorporated
1190 Coleman Avenue, Suite 250
San Jose, California 95110 USA
+1 800 484 5400

Extravastat, ExtravaStopper and Clearly Superior are trademarks of Cannuflow, Inc.

USA AND INTERNATIONAL PATENTS PENDING
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Manufactured by:
Hantel Incorporated

Federal law restricts this device to sale by or on orders of a physician

00-060-00

Rev 4/7/08

Single use only
Do not reuse

STERILE

Sterile,
Irradiation



Expiration
Date

REF

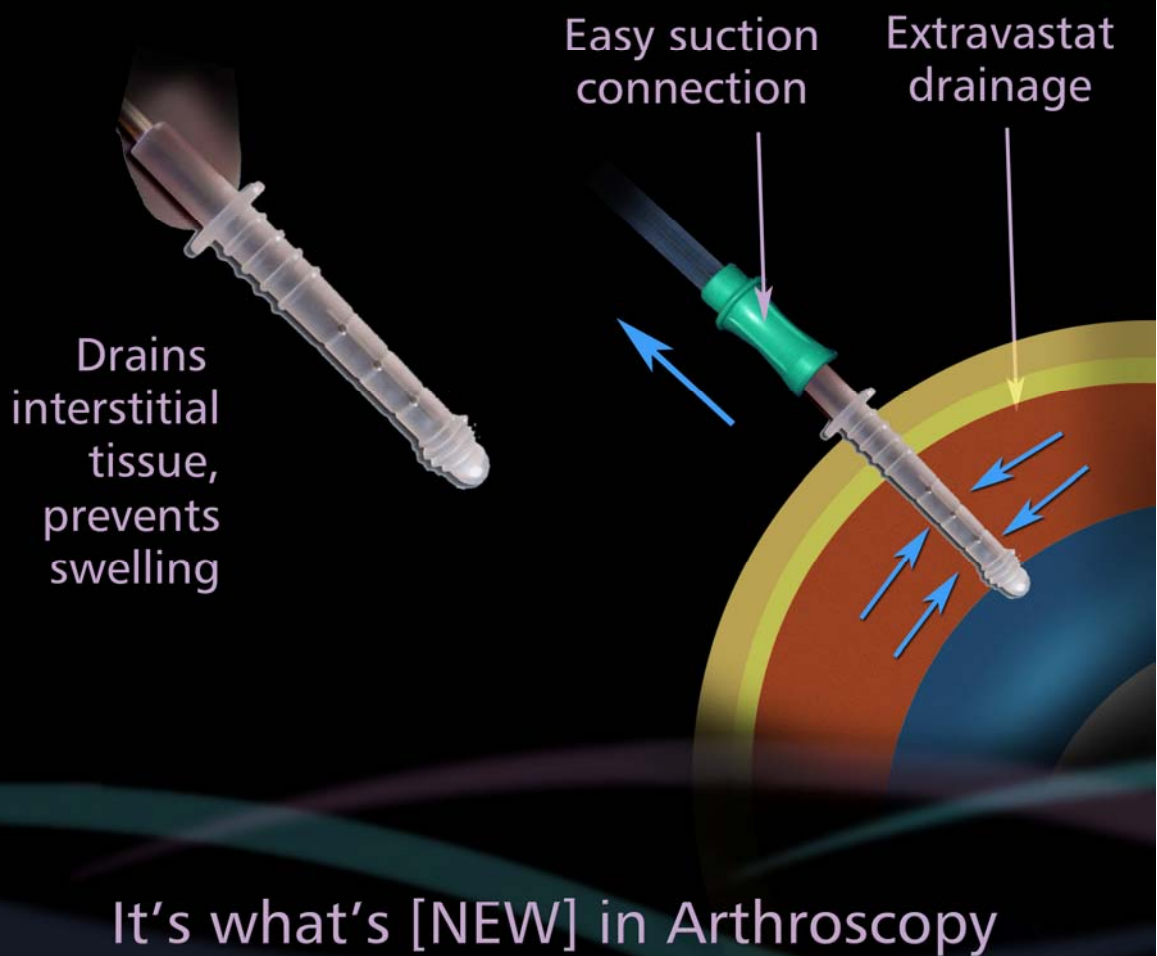
Catalog No.

LOT

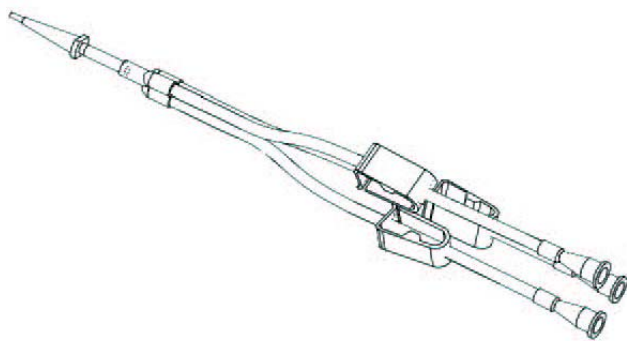
Lot No.

The amazing Extravastopper®

Exclusive Extravastat technology



The Squid™



What is it?

The Squid is the suction accessory that every surgeon wished they had, but did not have until now. It is an easy way to connect several suction devices to one drain line, and control them with pinch clamps from within the sterile field. It is another very simple and easy to use product that solves nagging problems in the OR.

What makes it different?

Typically, each suction device such as an RF wand, shaver, burr, and Extravastat device (EntreVu, Extravastopper) needs its own dedicated suction line. With the number of devices needing a line, sometimes multiple lines will need to be thrown over the patient. This can be costly, and can make a “rats nest” of tubes to manage. Also, collection systems such as the Stryker Neptune may have only limited numbers of suction connections available. Sometimes suction tube management gets to be annoying, where OR staff does not have enough tubes available, and one or two tubes are used to switch between devices. This can be hazardous to the patient, because if an RF wand is not connected to suction, the joint can overheat very quickly and can cause patient injury from overheated irrigation fluid. The easy to use Squid makes suction tube management in arthroscopy simple.

What are the clinical benefits?

With an easy way to manage suction lines with pinch-clamp control within the sterile field, the OR staff no longer need to skimp and compromise on making suction available to each device that needs suction. This can improve patient safety, especially when RF wands are used.

Why should the surgeon be interested?

When multiple suction lines are draped over a patient, keeping track of which line is which becomes impossible. Disconnected lines can drop on the floor and become contaminated. The Squid eliminates this, and gives the surgeon easy pinch clamp control of the suction lines within close reach, in the sterile field, with color-coded pinch clamps.

Why should the facility be interested?

The Squid pays for itself by replacing multiple suction lines, and reducing the volume of red bag medical waste. The Squid reduces the potential for workplace tripping hazards by reducing the number of suction lines across the OR floor. Liability from patient injury may be reduced by having a suction line available and connected to the RF wand at all times.

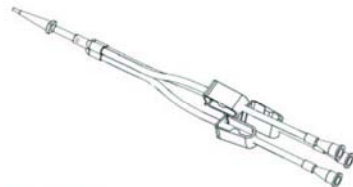
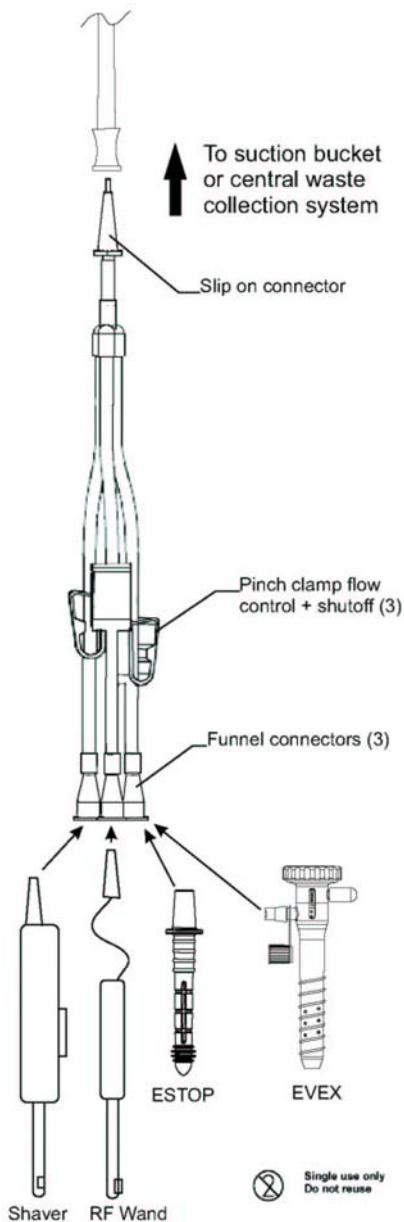
How do you present the product?

Look for a surgeon that is dealing with suction tube spaghetti, or one that wants to keep an RF wand, shaver and burr all connected at the same time. Look for a facility that uses a Stryker Neptune or other central fluid collection system and is running out of suction connections. The Squid is the fluid management accessory these surgeons have been asking for.

The SQUID™

3-into-1 Suction adapter accessory

Instructions for Use



Description:
The SQUID™ is a suction adapter that allows multiple suction devices (e.g. Shavers, RF wands, and Cannuflow Extravastat® devices (EntreVu®, TwoVu® EX, Extravastopper®) to be connected through a single suction line.

Warnings

Product supplied sterile. Do not use if package is open or damaged.
DO NOT RESTERILIZE. Discard any open or unused product.

Use switching stick to support the Extravastopper when inserting into the percutaneous portal. USE 4mm BLUNT SWITCHING STICK ONLY.
Do not insert into portal past proximal flange

Instructions for use:

1. Connect slip-on connector to suction hose
2. Connect device requiring suction to funnel connector
3. Control on/off and flow for each fluid channel with pinch-clamps. Close off un-used channels.

At end of procedure, remove, and dispose of properly.
DO NOT RE-USE OR RESTERILIZE

Warranty
FOR SINGLE USE ONLY. This product is warranted to be free from defects in material and workmanship.
PRODUCT DOES NOT CONTAIN LATEX. Patents Pending

Notes
See outer package of each unit for sterilization expiration dates, method of sterilization, lot number, ordering information, reference number and patent number(s).

Manufactured for:
Cannuflow Incorporated
1190 Coleman Avenue, Suite 250
San Jose, California 95119 USA
+1 866 484 5400

Extravastat, Extravastopper and Clearly Superior
are trademarks of Cannuflow, Inc.

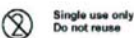
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Manufactured for:
Cannuflow Incorporated

Federal law restricts this device to
sale by or on orders of a physician

06-061-01

Rev 2/15/10



STERILE

Sterile,
Irradiation



Expiration
Date

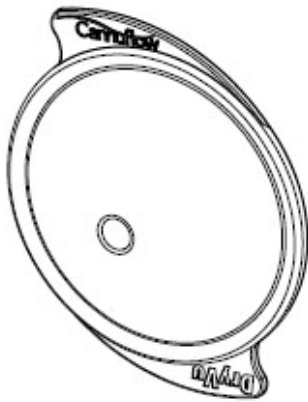
REF

Catalog No.

LOT

Lot No.

DryVu®



What is it?

DryVu is a fluid shield that prevents splashback of irrigation fluid. It is an easy to use “umbrella” like device that fits on any round-shafted instrument and will stretch to fit any diameter from 3mm to 6mm.

What makes it different?

There is no other device like it on the market. Surgeons have resorted to crude work-arounds such as tying gauze around their instrument to interrupt the flow of fluid down the shaft of a scope or other instrument. DryVu is the first and only device available to prevent splash-back and the unintended flow of fluid into the camera junction of the endoscope, which causes annoying lens fogging.

What are the clinical benefits?

Prevention of splash-back of irrigation fluid can help to protect the surgeon and OR staff from pathogens carried in the irrigation fluid, and speed OR clean up and turn-around.

Why should the surgeon be interested?

Fluid splashing into the popular “C-Mount” scope/camera junction is the main reason for fogging of the lens, and interruption of an arthroscopy procedure, particularly shoulders in the “beach-chair” position. A DryVu placed over the scope will effectively and simply keep the scope/camera junction dry, prevent fogging, and improve surgical efficiency. Some scope brands, like Storz are especially prone to this problem.

Why should the facility be interested?

In the OR time is literally money. DryVu is very affordable and pays for itself quickly in reduction of interruptions during surgeries. DryVu helps protect the surgeon and OR staff from stray fluid, and helps keep the OR floor dry, improving staff safety, and speeding OR cleanup.

How do you present the product?

Look for a surgeon who has a problem with their scope fogging, or splash-back of fluid on the floor. Have the scrub tech or PA slide the DryVu on the scope or instrument.



DryVu keeping fluid away from the “C-Mount” and camera interface, preventing fogging, and protecting the user from “splash-back”

Instructions for Use

DryVu® Fluid Shield



Step 1



Step 2



Step 3



Step 4



Federal law restricts this device to sale by or on orders of a physician.

Manufactured for:
Cannuflow Incorporated
1190 Coleman Avenue, Suite 250
San Jose, California 95110 USA
+1-866-484-5400

Plant 95073

06-017-03

Description

The DryVu® Fluid Shield anti-fogging device is designed to be compatible with most any rigid arthroscope and arthroscope sheath with an outer diameter of between 4.5 mm and 6 mm. The fluid shield blocks fluid from flowing into the coupling between the camera lens and the scope lens to prevent fogging of these lenses. DryVu is provided sterile and should be placed over the arthroscope or the arthroscope's own sheath (if used) prior to insertion into the joint during arthroscopy procedures.

Warnings

Product supplied sterile. Do not use if package is open or damaged. **DO NOT RESTERILIZE.** Discard any open or unused product.

Precautions

Normal precautions associated with arthroscopic procedures should be employed, including careful attention to sterile technique and avoidance of anatomical hazards.

Instructions

Insertion:

Once the site is prepared for insertion of the arthroscope, attach the DryVu in the following manner.

- Step 1.** Place the DryVu fluid shield flat in one hand, along the fingers such that the smooth surface is on the fingers.
- Step 2.** With your other hand slide the distal end of the arthroscope (with sheath attached, if used) slowly through the fluid shield opening until the DryVu is, as far as possible, proximal up to the fluid or light source connection.

- Step 3.** Use the arthroscope in the usual manner for the procedure.

Removal:

- Step 4.** Once the procedure is complete, remove from arthroscope and dispose of properly

Warranty

FOR SINGLE USE ONLY. This product is warranted to be free from defects in material and workmanship.

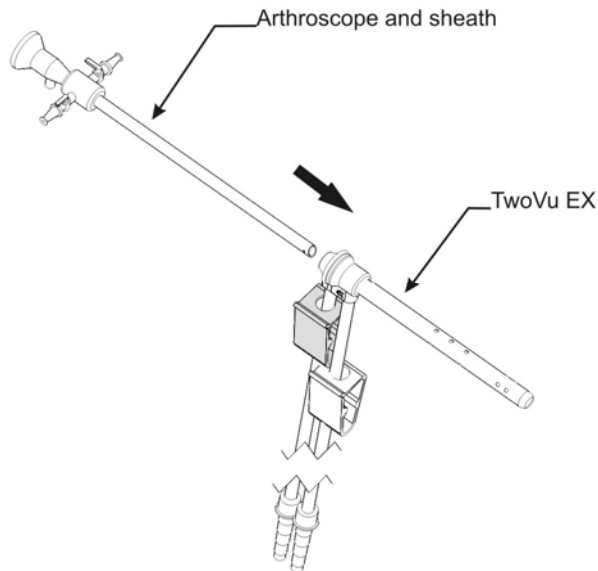
Notes

See outer package of each unit for sterilization expiration dates, method of sterilization, lot number, ordering information, reference number and patent number(s).

PRODUCT DOES NOT CONTAIN LATEX.

Patent No. 6,695,773

TwoVuEX®



What is it?

The TwoVuEX is a unique product that combines the simultaneous inflow and outflow of the TwoVu ST and patented Extravastat anti-extravasation technology in one device.

What makes it different?

TwoVuEX is completely unique. There is no other product on the market like it.

What are the clinical benefits?

The TwoVuEX provides all the benefits of TwoVu technology to provide continuous irrigation of the joint, and removes extravasation from the scope portal.

Why should the surgeon be interested?

The TwoVuEX is a more advanced product that may be of interest to surgeons who are already familiar with other Cannuflow products such as TwoVu, EntreVu, and Extravastopper, and want to more completely control extravasation at the scope portal, and want to have TwoVu continuous flow.

Why should the facility be interested?

Like other Cannuflow products, TwoVuEX markedly improves surgical efficiency and reduces complications.

How do you present the product?

TwoVuEX is an advanced product that should be presented when the surgeon is familiar and comfortable with the other Cannuflow products such as TwoVu ST, EntreVu and Extravastopper.

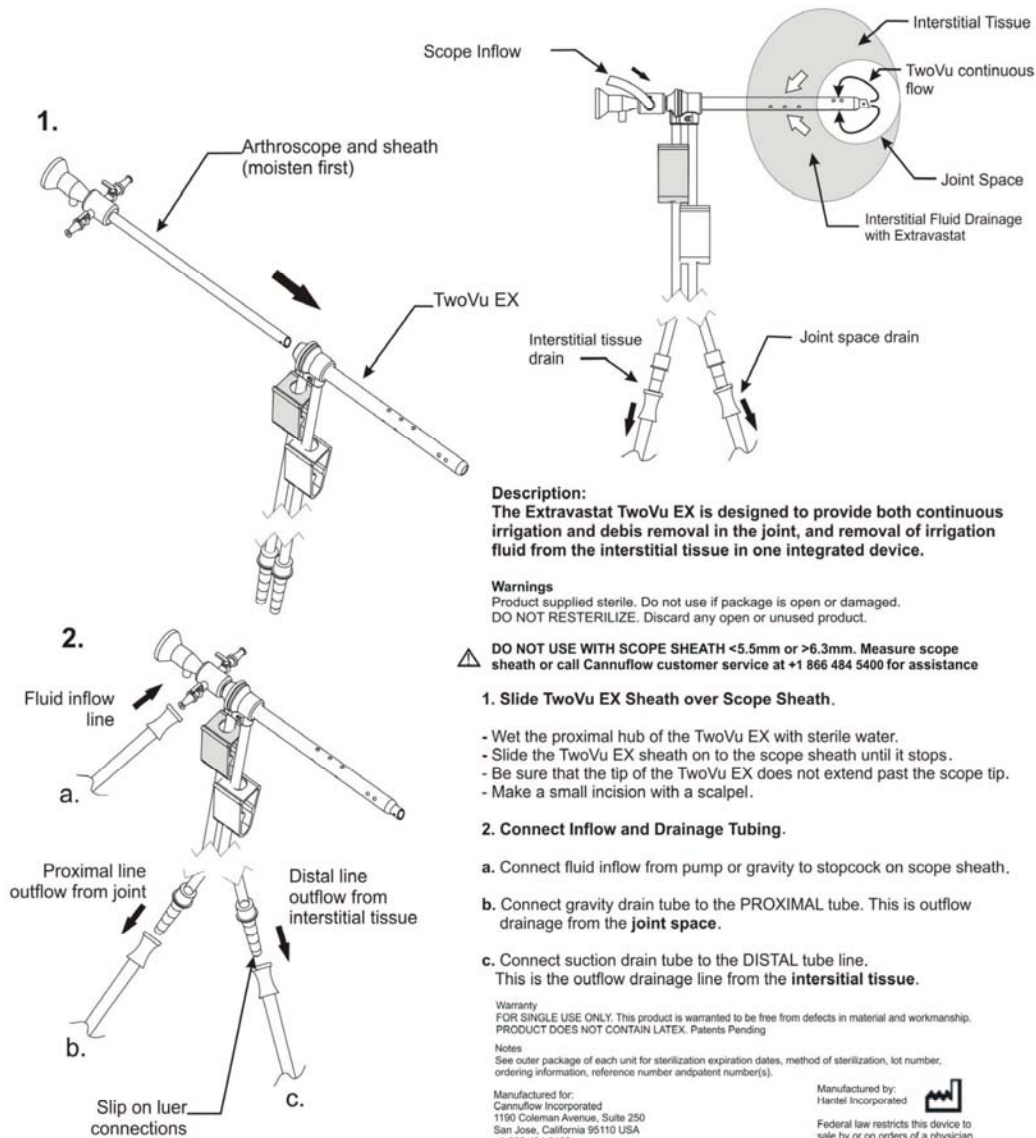


Extravastat™ TwoVu EX™ Ref: TVEX-6, TVEX-6L

Instructions for Use

TwoVu EX-6 fits 5.8mm–6.3mm OD scope sheath > 81mm working length

TwoVu EX-6L fits 5.8mm–6.3mm OD scope sheath > 123mm working length



Single use only
Do not reuse



Sterile,
Irradiation



Expiration
Date

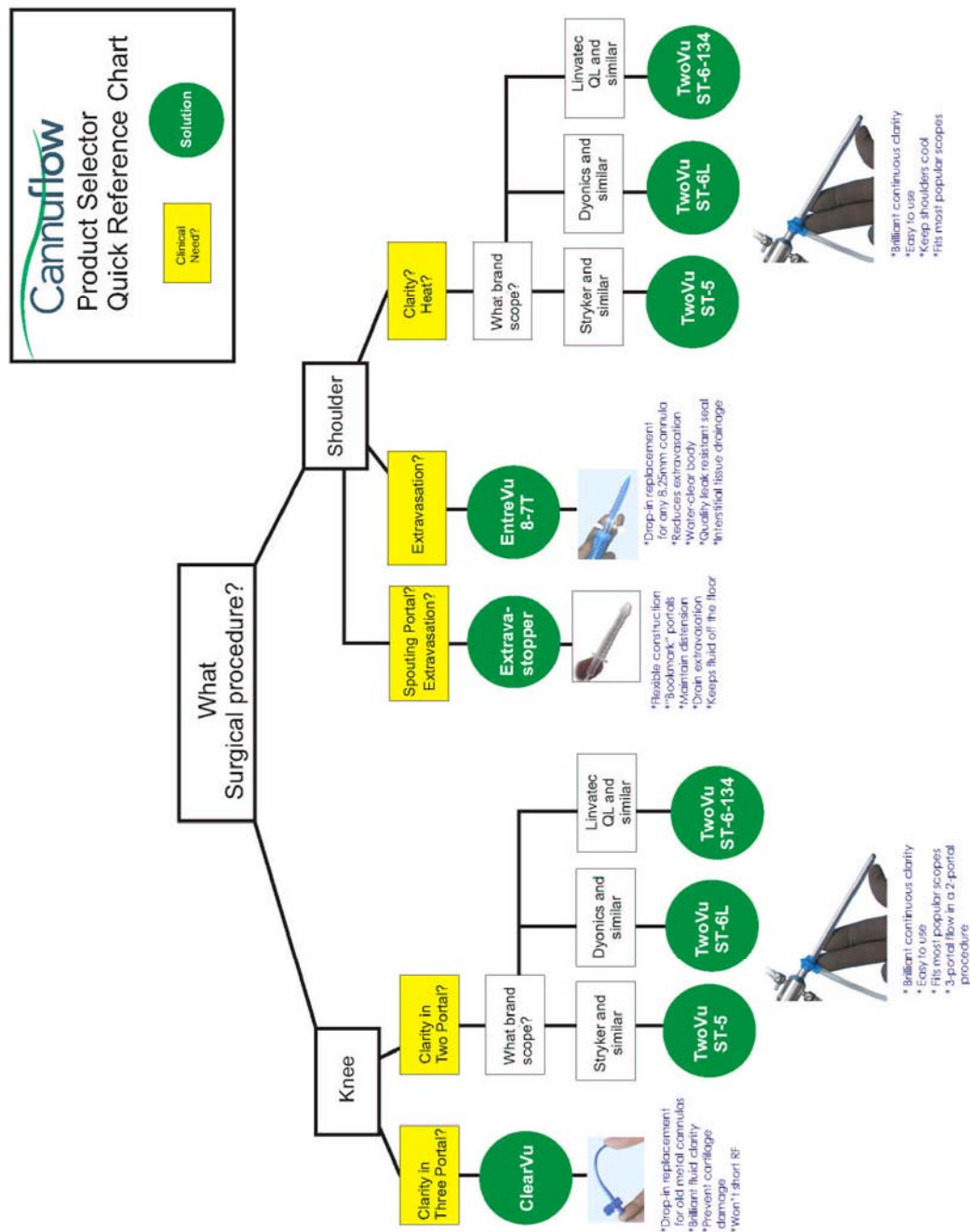


REF Catalog No.



LOT Lot No.

Appendix 1: Cannuflow Product Selector Chart



The Cannuflow Product Selector Chart allows you to easily present the Cannuflow product line to your surgeon prospect, and quickly step them through the options available to them, and find the Cannuflow product that best meets their need.

Appendix 2 On-line Training Resources

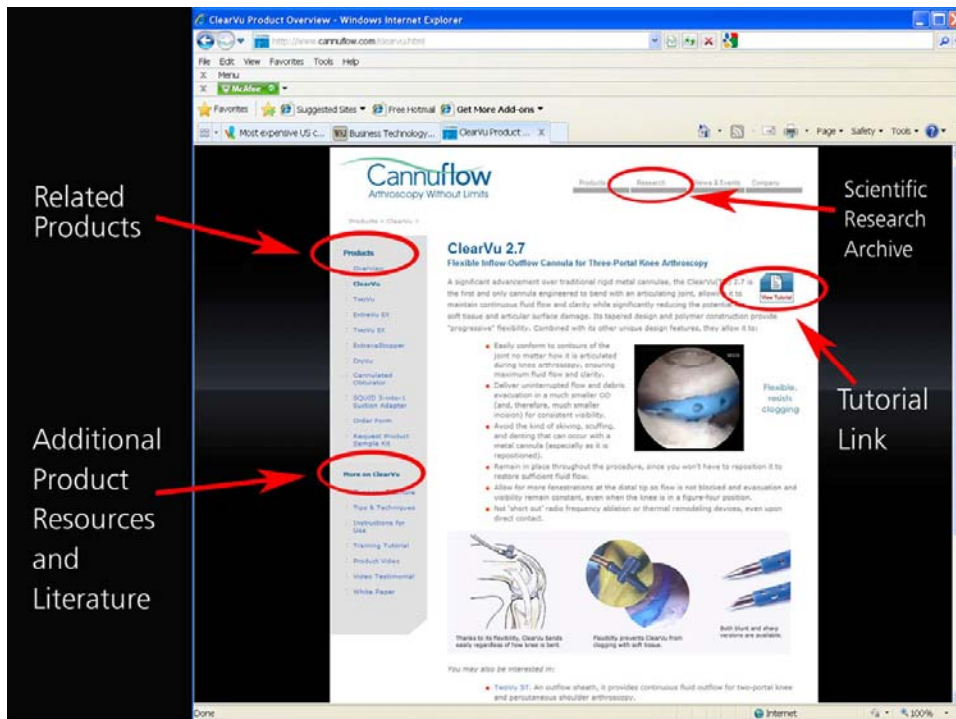
Cannuflow has a number of training resources available on the website.

www.cannuflow.com

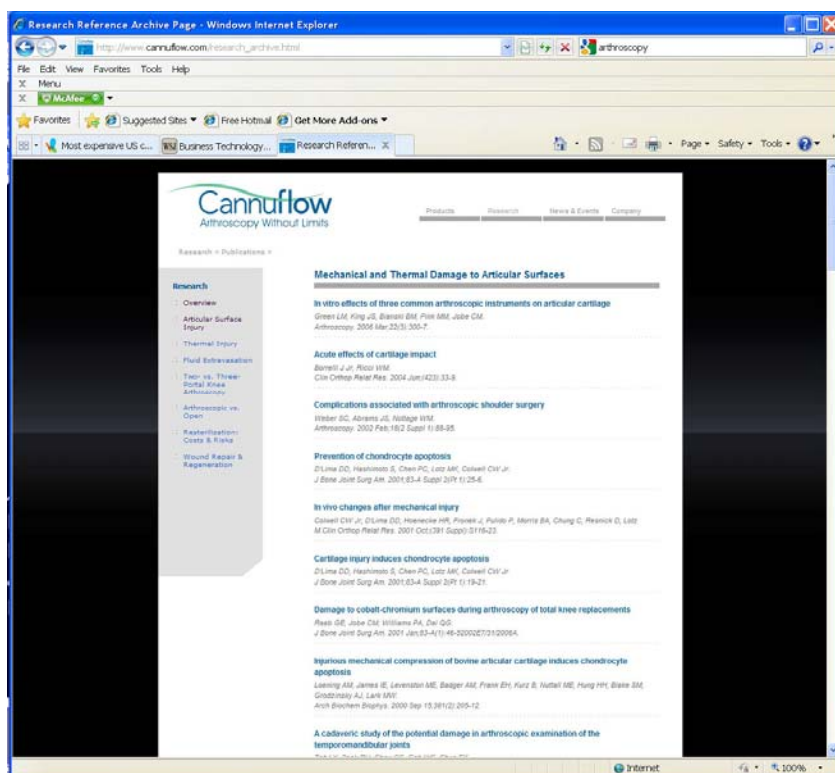
The website has a “two track” navigation structure, according to the needs of the user. You can navigate by product, or surgical area of interest.



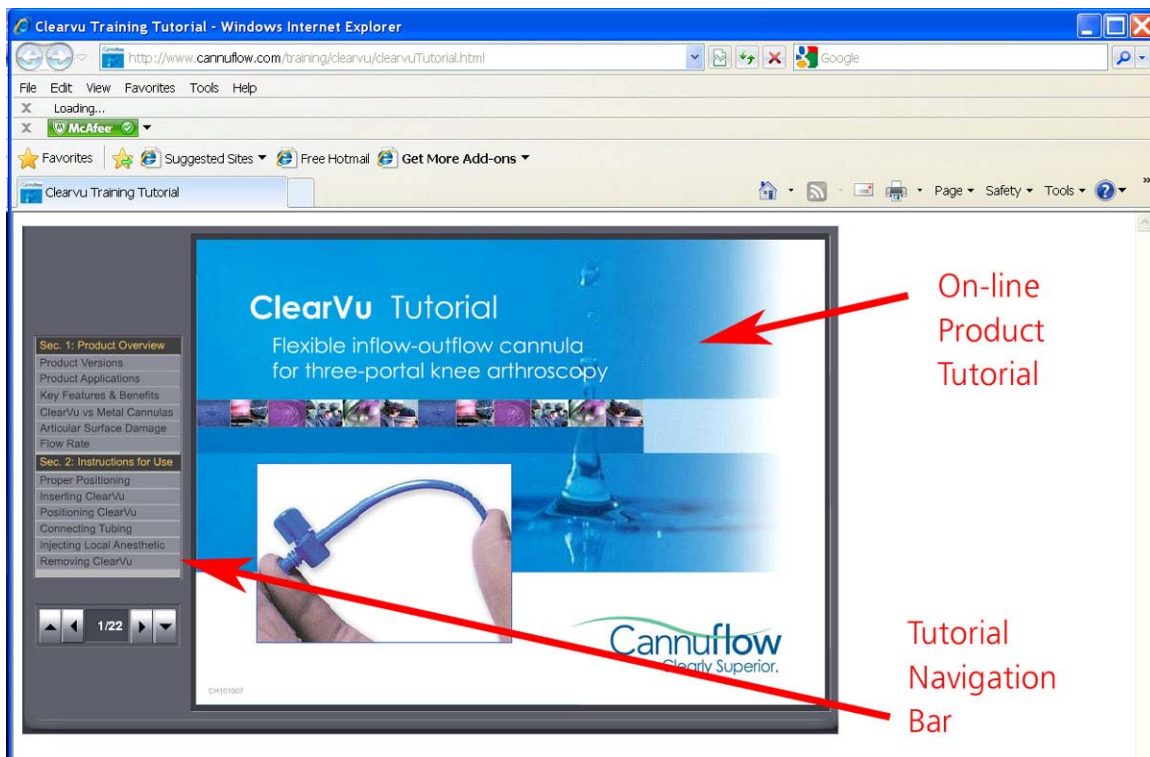
Cannuflow Home Page and navigation areas



Cannuflow product page and additional resources and navigation bars



Research archive page. Extensive scientific information supporting Cannuflow products is available



On-line tutorial page

The Cannuflow website is a rich and deep source of product information and training resources for both you and your customers. Surgeons, OR staff, buyers, and purchasers can benefit.

Take time to browse the website and become familiar with the information available and its capabilities.

Note: The Cannuflow website utilizes Adobe Flash animations and may not be compatible with Apple devices such as the iPhone Safari browser, or the iPad.

Additional Resources

Cannuflow has a number of literature resources available to you to help you effectively present the products, to the surgeon and make the case for their effectiveness and value to purchasing committees. These include white papers, journal reprints, and product-specific literature. Please check with your sales manager or Cannuflow for the latest resources available to you.

¹ Two- Versus Three-Portal Technique for Routine Knee Arthroscopy William B. Stetson, M.D., and Kevin Templin, A.T.C. American Journal of Sports Medicine. 2002 Jan-Feb; 30:108-111

² Arthroscopic arthropathy: iatrogenic arthroscopic joint lesions in animals Klein W, Kurze V. Arthroscopy. 1986;2(3):163-8.

³ Data on file

⁴ Effect of simulated shoulder thermal capsulorrhaphy using radiofrequency energy on glenohumeral fluid temperature. Lu Y, Bogdanske J, Lopez M, Cole BJ, Markel M.D.. Arthroscopy. 2005 May;21(5):592-6.

⁵ Glenohumeral chondrolysis after shoulder arthroscopy with thermal capsulorrhaphy. Good CR, Shindle K, Kelly BT, Wanich T, Warren RF. Arthroscopy. 2007 Jul;23(7):797.e1-5.

⁶ Fenestrated Cannulae with Outflow Reduces Fluid Gain in Shoulder Arthroscopy .Hasan M. Syed, Seth B. Gillham, Christopher M. Jobe, Wesley P. Phipatanakul and Montri D. Wongworawat Clinical Orthopaedics and Related Research, Springer New York, 0009-921X (Print) 1528-1132 (Online), Friday, June 26, 2009

⁷ Ibid