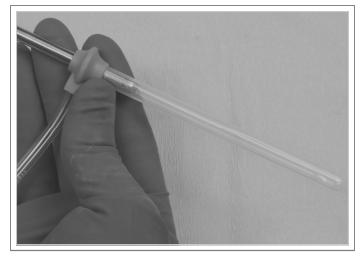
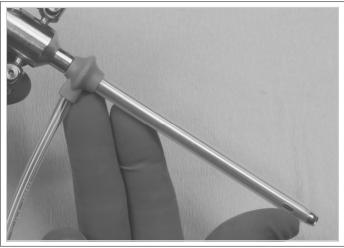
Instructions for Use

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

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



Manufactured by: Hantel Incorporated

06-030-02 Rev 2/23/06



Sterile, Irradiation



REF Catalog No.



Expiration Date



LOT Lot No.



Single use only

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

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.

The distal end of the arthroscope, with its inflow and outflow sheaths attached, should extend completely through the tissue and fat pad so that 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 tis-

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. IMPORTANT REMINDER: Moisten the distal end of the arthroscope sheath with sterile fluid so that TwoVu will slide more easily over the arthroscope sheath.
- 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.
- Make a small incision with a scalpel.
- 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.
- 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.
- 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.
- The entire assembly, arthroscope, inflow sheath and TwoVu sheath can now be manipulated as one device.
- 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.

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

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