

HOLOGIC®

Extraordinarily powerful care

MyoSure®
tissue removal:
setup simplified

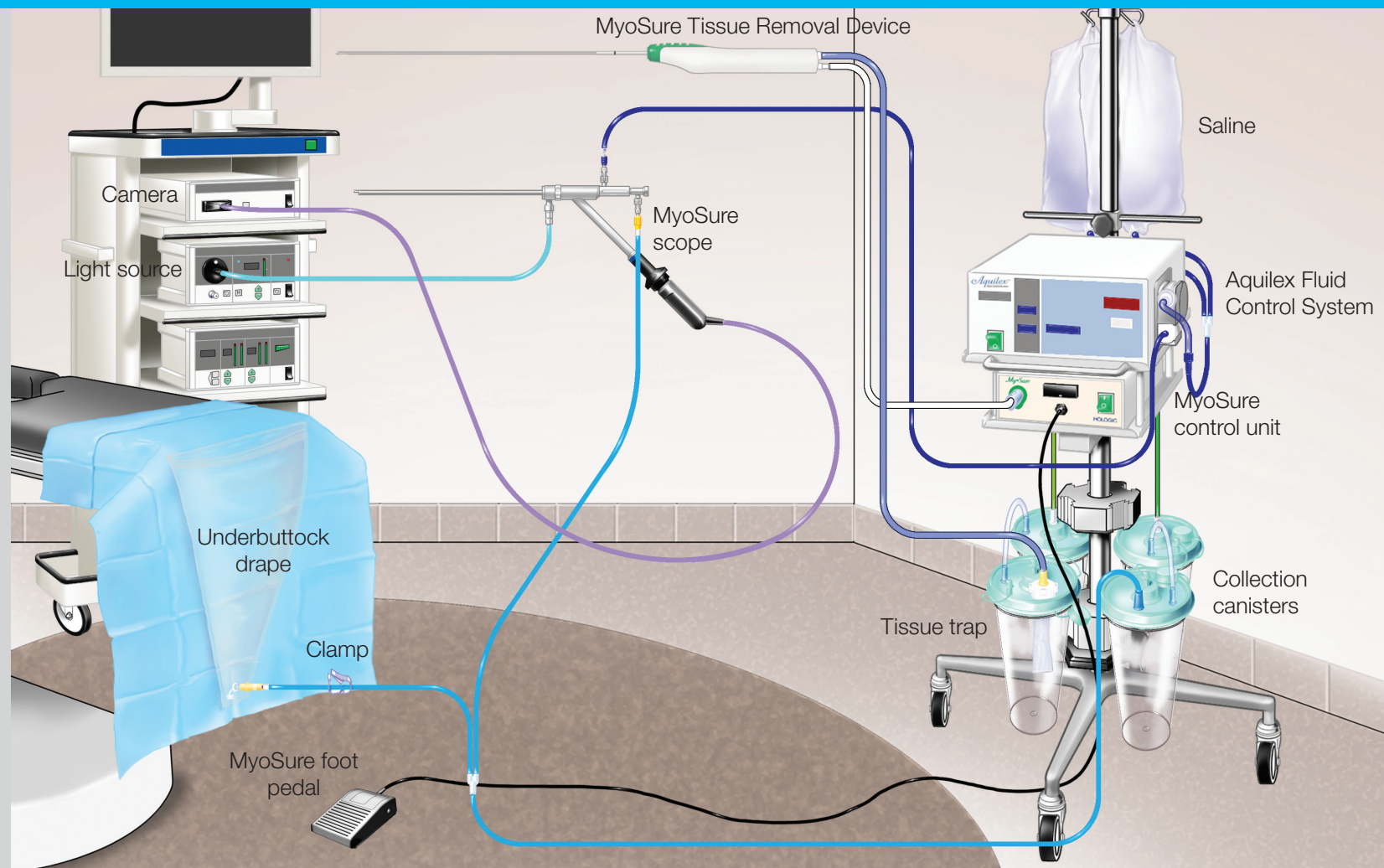


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MyoSure setup with the Aquilex® Fluid Control System

MyoSure procedure connections for use with Aquilex

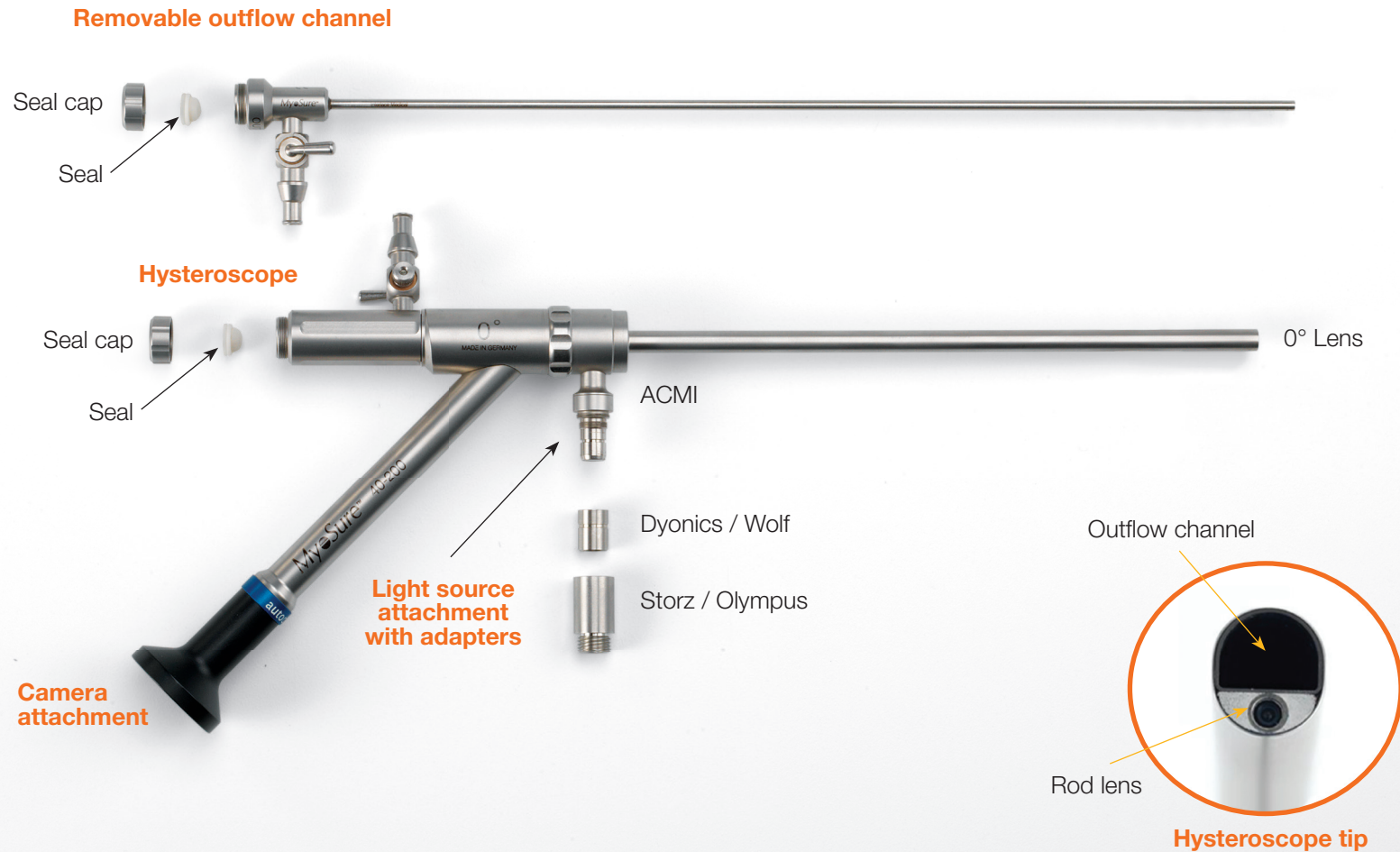




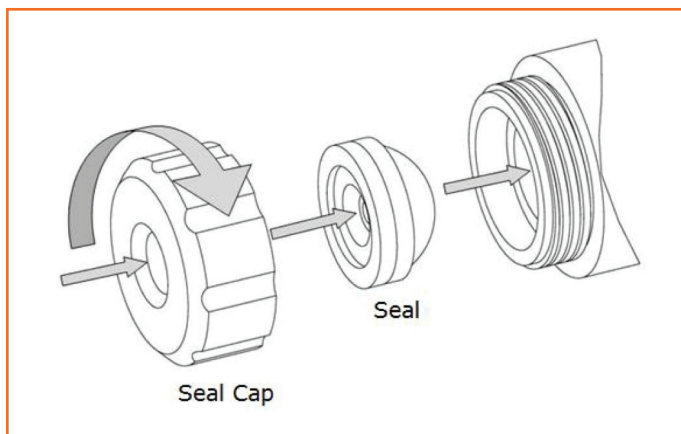
What you will need:

1. MyoSure rod lens hysteroscope with removable outflow channel
2. 2 single MyoSure scope seals
3. Light source adapter
4. 1 MyoSure control unit and foot pedal
5. 1 MyoSure tissue removal device
6. Camera, light source, and video monitor
7. Aquilex fluid control system
8. Aquilex inflow pump tubing
9. Aquilex outflow Y tubing
10. 2 Aquilex vacuum tubes
11. 4 three-liter canisters
12. 2 tandem tubes
13. 2-3 three-liter bags (0.9%) sterile saline
14. 1 tissue trap
15. 1 underbuttock drape with drainage port

MyoSure hysteroscope and removable outflow channel assembly



Seal installation



1. Remove caps from outflow channel and hysteroscope.
2. Insert sterile single-use seals into the outflow channel and hysteroscope.

Reminders:

- Remove caps and discard seals after each procedure.
- Please be sure that all accessories, hysteroscope and outflow channel are placed in instrument tray at end of procedure.

MyoSure hysteroscope specifications:

	Effective outer diameter	Working channel of hysteroscope	Outflow channel inner diameter
MyoSure	6.25 mm (19 Fr.)	3 mm (9 Fr.)	2.5 mm (7 Fr.)
MyoSure XL	7.25 mm (22 Fr.)	4 mm (12 Fr.)	2.8 mm (8 Fr.)

Canister and vacuum setup



1. Position the MyoSure control unit and the Aquilex fluid control system.

NOTE:

It is important to position the MyoSure control unit a minimum of 5 feet from the MyoSure tissue removal device, allowing the drive cable to hang in a large arc with no bends, loops or kinks.

The ideal placement of the control unit is behind the physician either to the right (if right-handed) or to the left (if left-handed).

2. Connect the color-coded reusable vacuum tubing from the High (green) and Low (white) to the vacuum ports on the back canisters.

3. Tandem-connect the front canister to back canister using the tandem ports on both the Low and High sides.

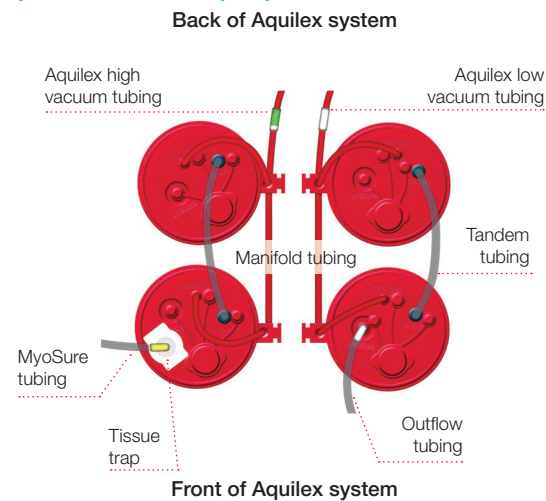
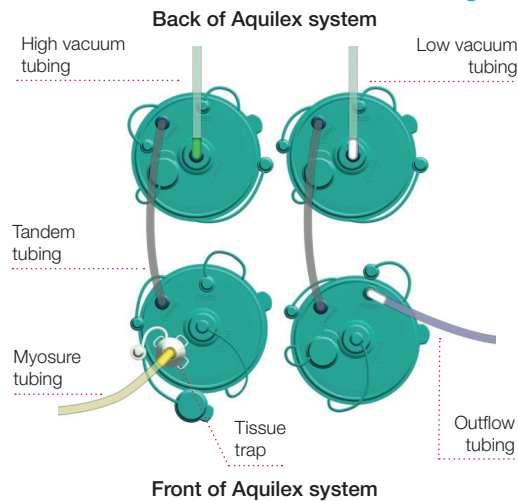
4. Place a tissue trap in the front canister on High side.

5. Ensure all canisters are sealed.

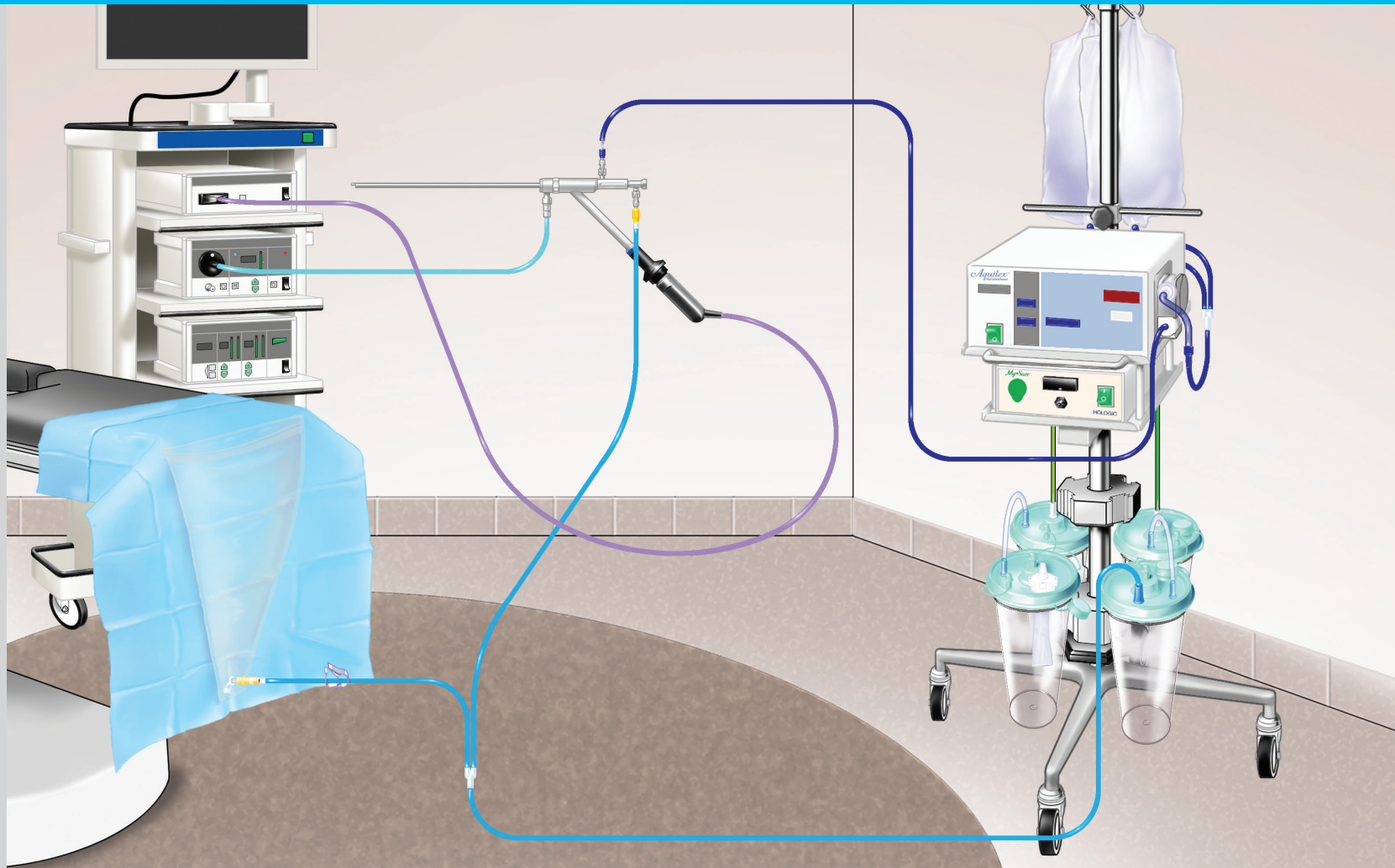
NOTE: All unused ports **MUST** be sealed to achieve required vacuum.

6. Set vacuum level on the High side of Aquilex system. Please see image above.
 - Locate the vacuum dial in the back of the pump on the High side.
 - Set vacuum to Low and adjust if necessary throughout the procedure.
7. Hang 2 three-liter bags of sterile saline.

Canister configuration - Bemis (green) and Medi-Vac (red)



Inflow and outflow setup





Inflow

1. Turn on the Aquilex system before any tubing is connected to the roller wheel. The system will perform a self-diagnostic test.
2. The system will prompt you to insert the inflow tubing into the pump roller wheel.
3. Spike fluid bags – make sure clamps are closed.
4. Connect the blue inflow luer-lock tubing onto the hysteroscope inflow port (blue).
5. Connect light source to the MyoSure hysteroscope.
6. Connect camera to the MyoSure hysteroscope.

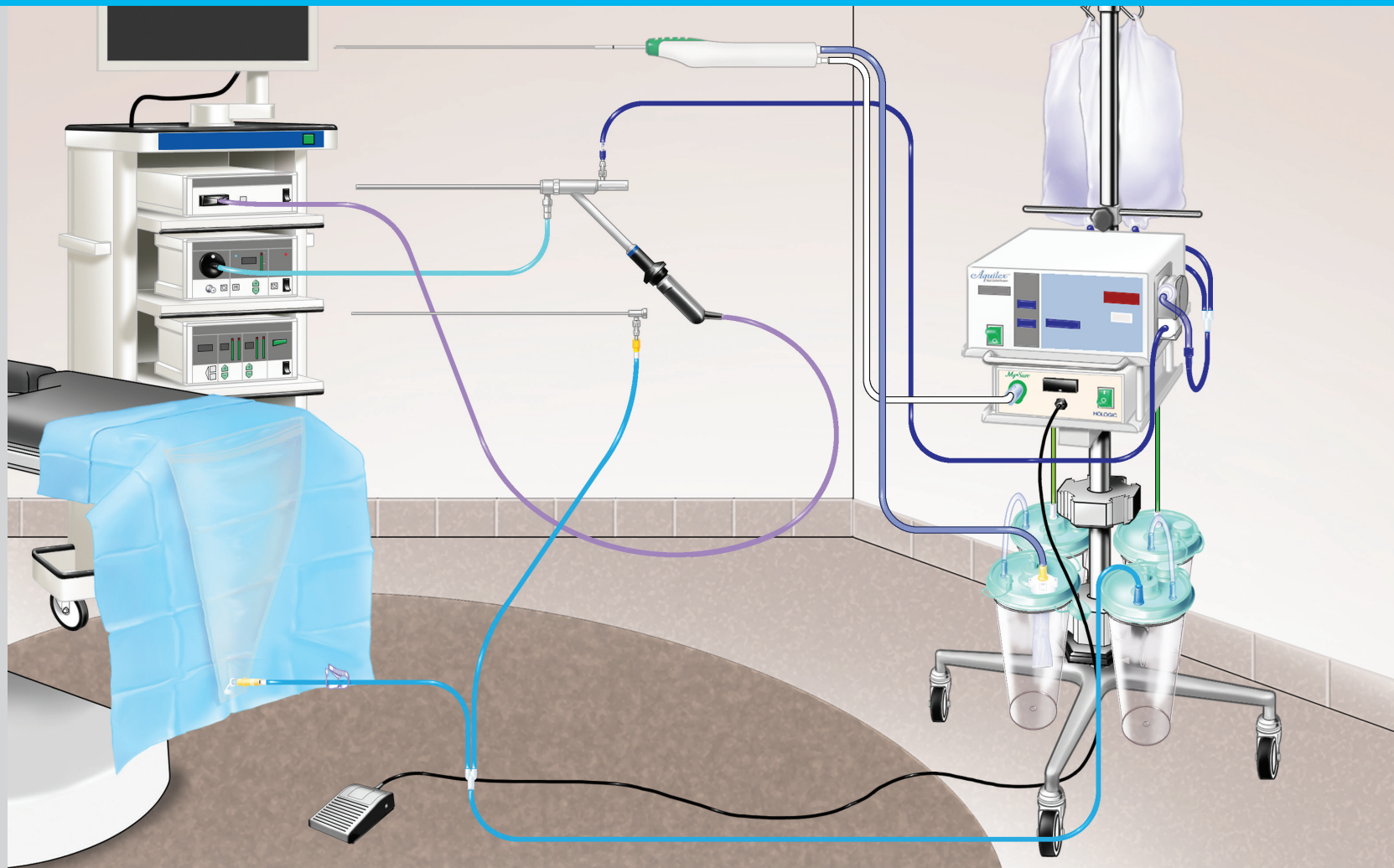
Outflow

1. Connect Y (short ends) of the outflow Y-tubing:
 - a) Attach yellow connector to underbuttock drape.
Be sure to leave clamp open.
 - b) Attach yellow luer-lock tubing to the MyoSure outflow channel.
2. Connect the long Y-tube end (white connector) to the patient port of the front low vacuum canister.

Prime the system

1. Check that the inflow stopcock is completely open and outflow stopcock is closed. Unclamp fluid bag.
2. Press the “Prime” button.
3. Prime pump and hysteroscope into a separate basin or into the underbuttock drape.
4. During the prime cycle (**CALIBRATION RUNNING**), the system will purge air from the system and perform an automatic lumen calibration.
5. Once the prime is complete, the system will beep once. The message **PRIME SUCCESSFUL CLOSE STOPCOCK** will appear and then the system will switch to **PUMP OPERATING**.
6. Close the inflow stopcock.
7. Zero out machine by holding **ZERO** button down until deficit reads 0.

MyoSure procedure setup





MyoSure setup

1. Connect foot pedal to the MyoSure control unit.
2. Connect the MyoSure tissue removal device suction tubing to tissue trap on front high vacuum cannister.
3. Connect the green end of the MyoSure tissue removal device to the MyoSure control unit.

NOTE:

Never lay the drive cable over the patient's leg.

Operative procedure

1. When ready for operative portion of the procedure, close the stopcock on the outflow channel.
2. Remove the outflow channel.
3. Insert the MyoSure tissue removal device into hysteroscope.

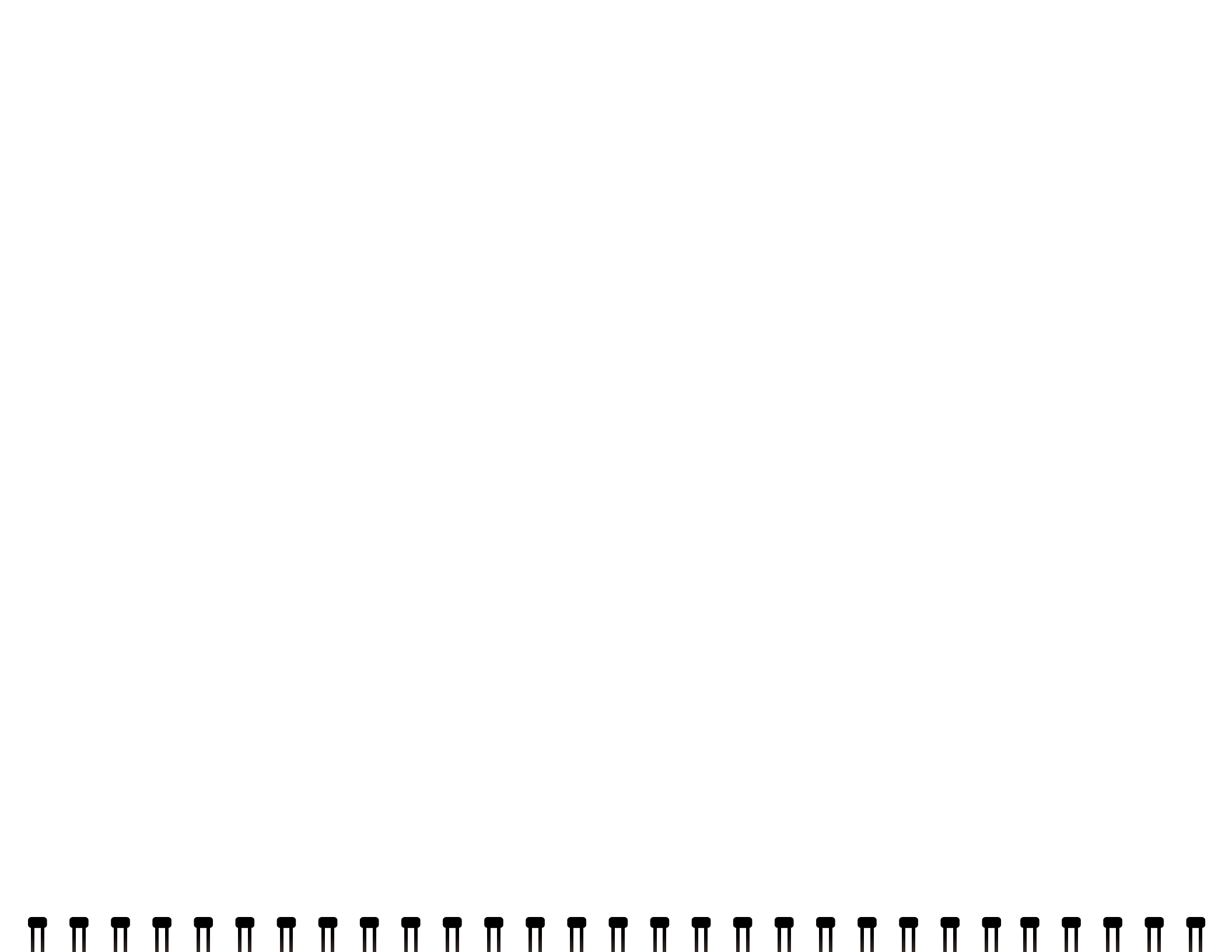
Settings

1. Set a fluid deficit. The deficit is adjustable from 700 to 2,500 ml.

NOTE:

AAGL guidelines recommend 2,500 ml for saline solution (isotonic).

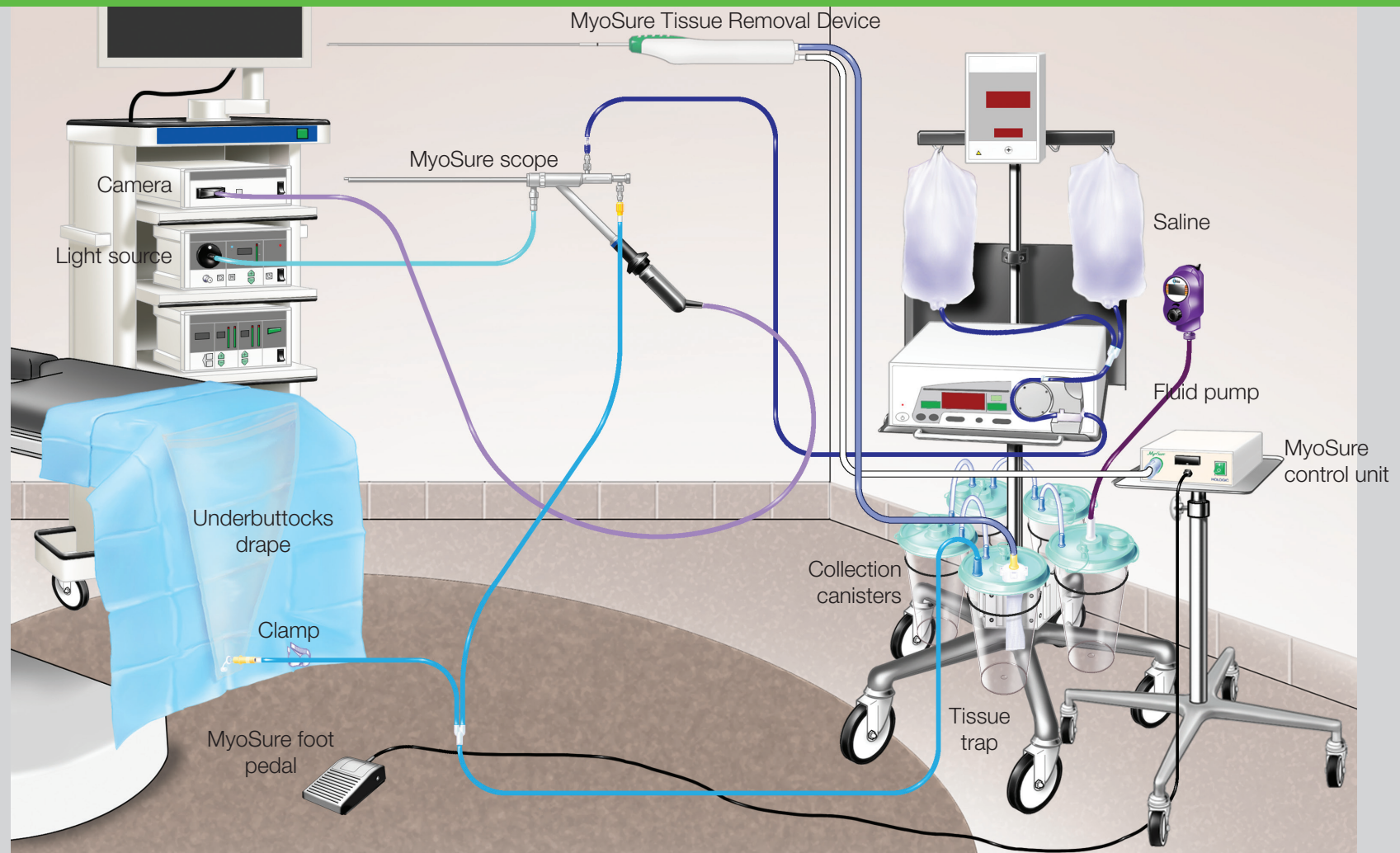
2. Appropriately set intrauterine pressure. Pressure is adjustable from 40 – 150 mmHg.
3. Intrauterine pressure and/or vacuum pressure may need adjustment during the procedure to provide maximum visualization.




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MyoSure system setup with
other fluid management systems

MyoSure procedural requirements

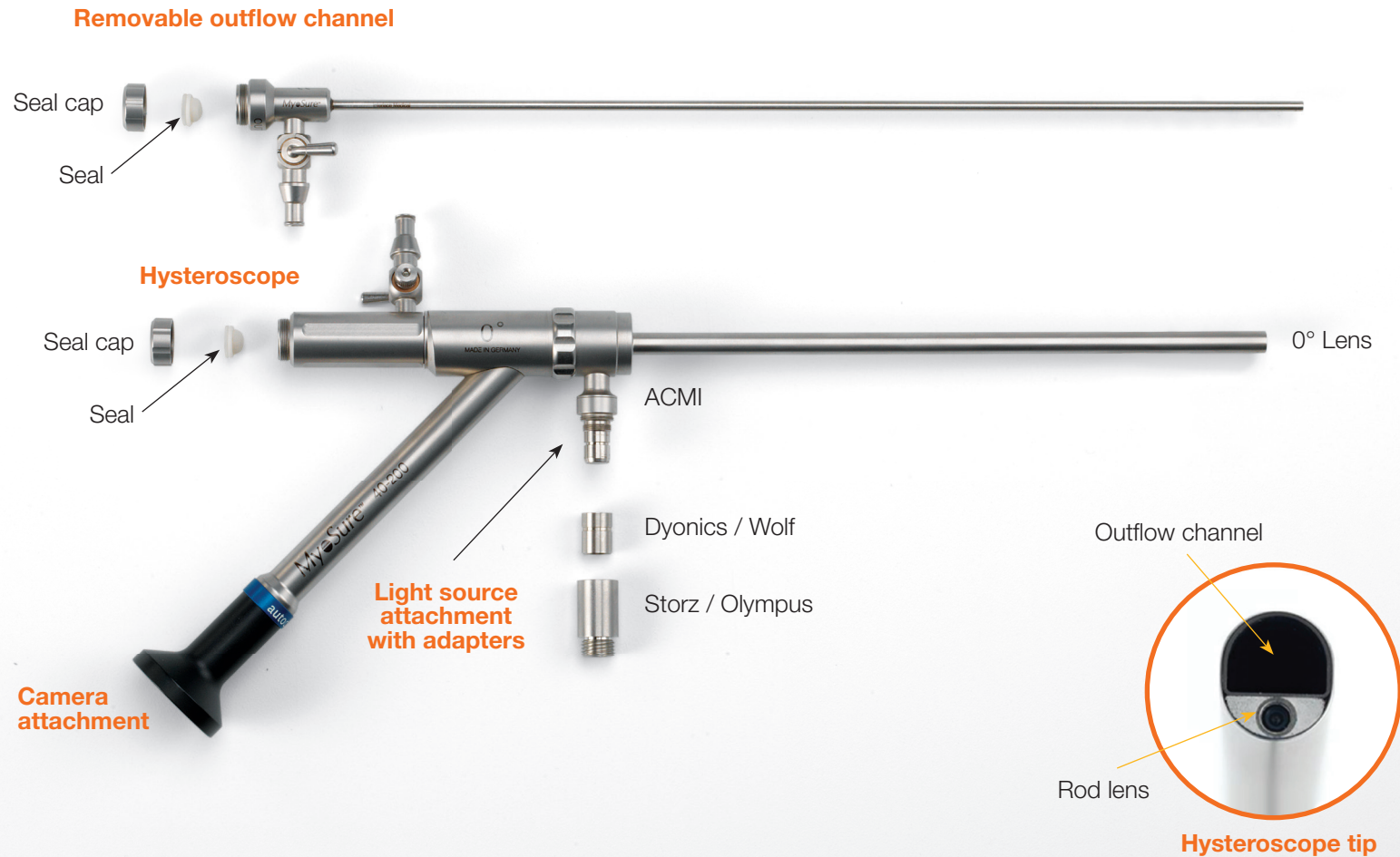




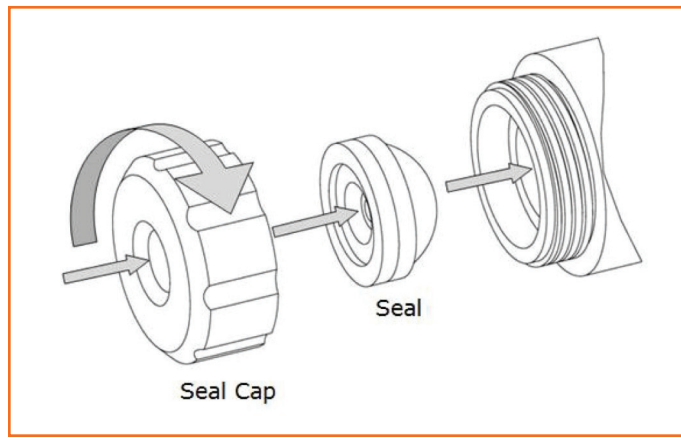
What you will need:

1. MyoSure rod lens hysteroscope with removable outflow channel
2. 2 single scope seals
3. Light source adapter
4. 1 MyoSure control unit and foot pedal
5. 1 MyoSure tissue removal device
6. Camera, light source, and video monitor
7. Hysteroscopic fluid pump
8. Inflow pump tubing
9. Outflow tubing (Y or straight)
10. 2-3 three-liter canisters and tandem tubing
11. 2-3 three-liter bags (0.9%) sterile saline
12. 1 tissue trap
13. Regulated vacuum source and tubing
14. 1 underbuttock drape with drainage port

MyoSure hysteroscope and removable outflow channel assembly



Seal installation



1. Remove caps from outflow channel and hysteroscope.
2. Insert sterile single-use seals into the outflow channel and hysteroscope.

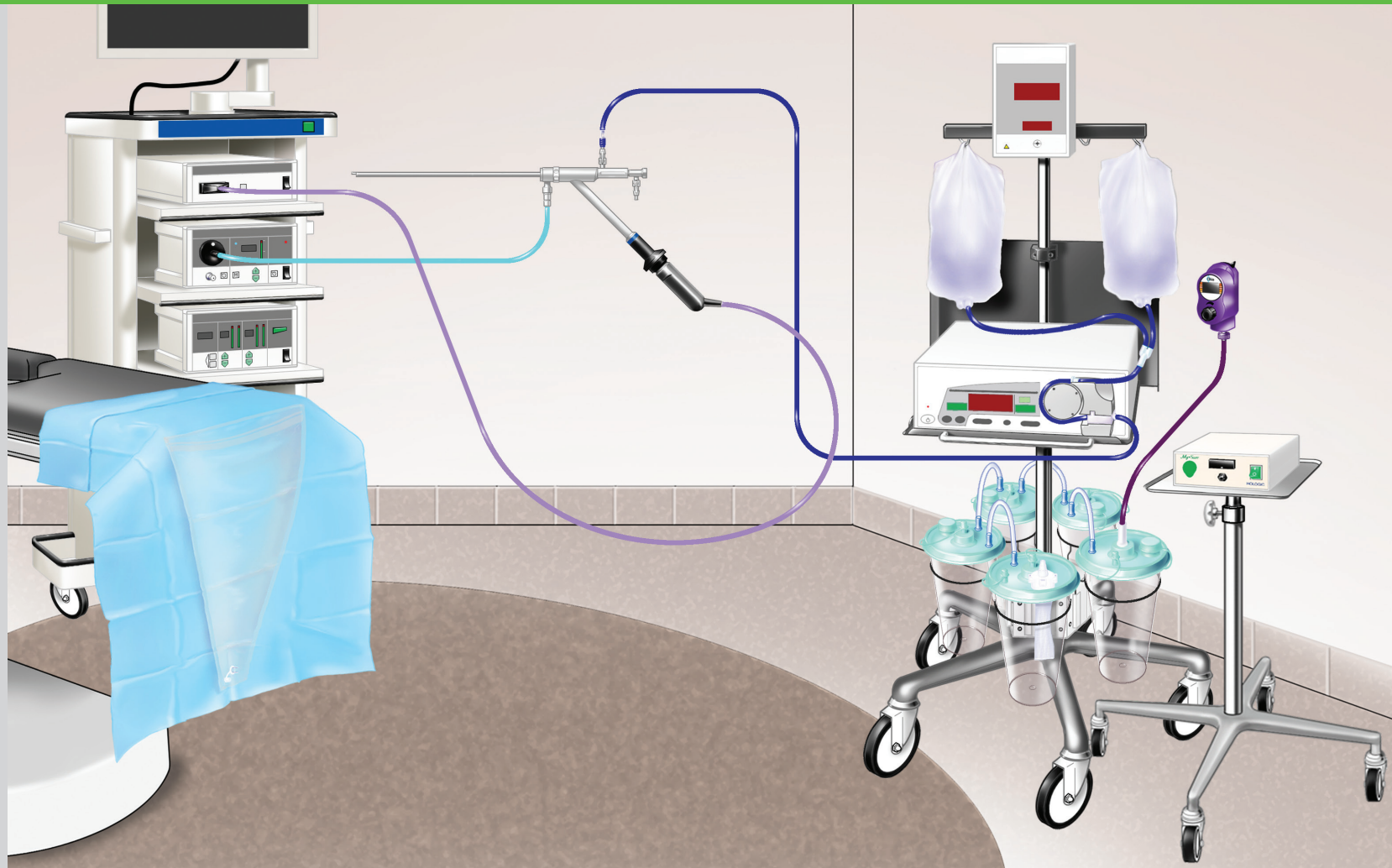
Reminders:

- Remove caps and discard seals after each procedure.
- Please be sure that all accessories, hysteroscope and outflow channel are placed in instrument tray at end of procedure.

MyoSure hysteroscope specifications:

	Effective outer diameter	Working channel of hysteroscope	Outflow channel inner diameter
MyoSure	6.25 mm (19 Fr.)	3 mm (9 Fr.)	2.5 mm (7 Fr.)
MyoSure XL	7.25 mm (22 Fr.)	4 mm (12 Fr.)	2.8 mm (8 Fr.)

Canister and inflow setup



Canister and vacuum setup

1. Connect first collection canister to vacuum source.
2. Tandem-connect first canister to next canister.
Tandem-connect additional canisters.
3. Place tissue trap in the canister furthest from the suction source.
4. Ensure all canisters are sealed.

NOTE:

All unused ports MUST be sealed to achieve required vacuum.

5. Set vacuum level:
 - Recommend use of a regulated vacuum source.
 - Recommend setting vacuum between 275 – 400 mmHg.
 - Adjust if necessary throughout the procedure.
6. Hang 2 three-liter bags of sterile saline.

Inflow

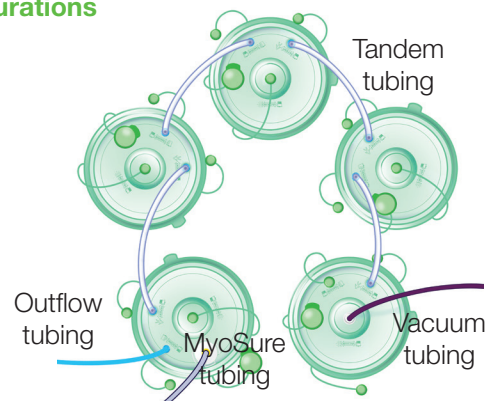
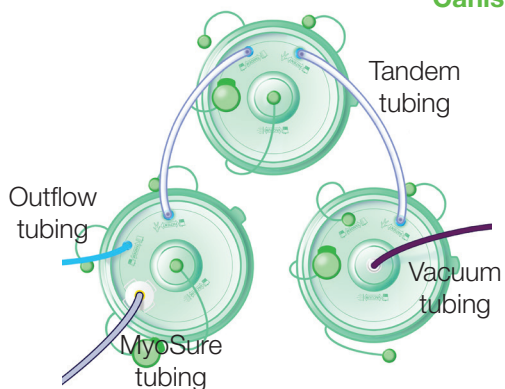
Efficient operation of MyoSure requires high pressure, high flow and regulated suction.

NOTE:

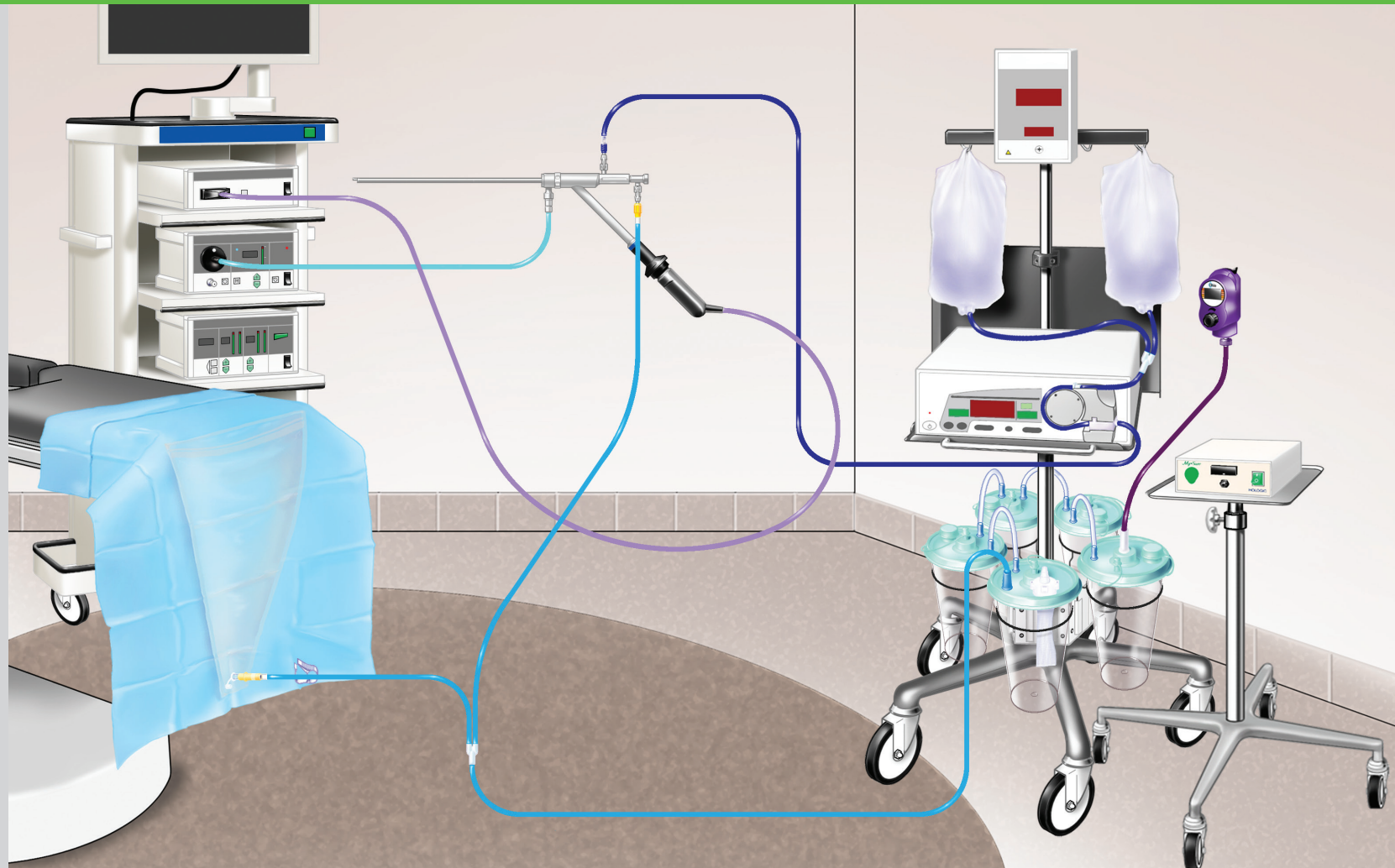
Minimum inflow rate recommended of 500 – 700 ml/min.

1. Attach the inflow tube set to pump.
2. Spike bags and clamp off.
3. Connect inflow tubing to hysteroscope inflow port.
4. Shut off inflow (close inflow stopcock).
5. Connect the light source to the MyoSure hysteroscope.
6. Connect the camera to the MyoSure hysteroscope.

Canister configurations



Outflow setup

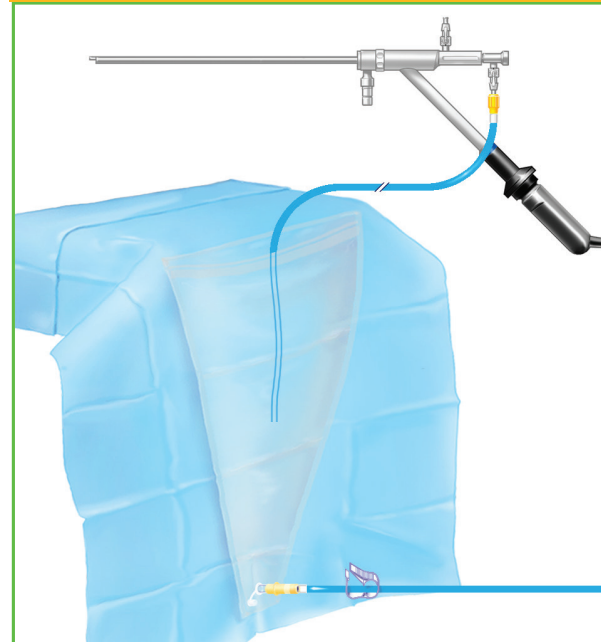


Outflow - Y tubing

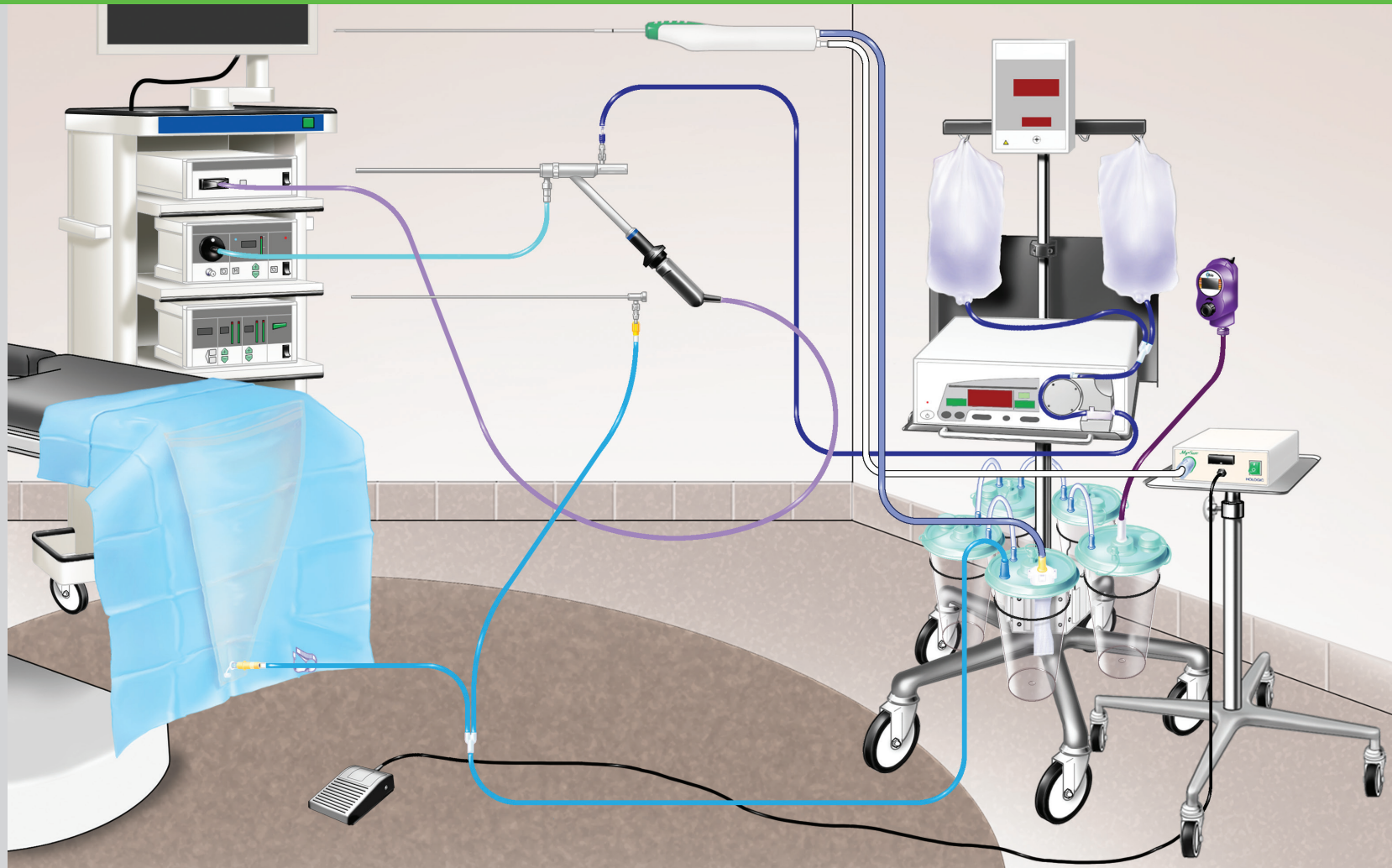
1. Connect Y (short ends) of outflow Y-tubing:
 - a) Attach yellow connector to underbuttock drape.
 - b) Attach yellow luer-lock tubing to the MyoSure outflow channel.
2. Connect long Y-tube end (white connector) to the patient port of the canister furthest away from the suction source (or canister with tissue trap).
3. Clamp off suction to underbuttock drape with clamp to reduce vacuum.
 - This is essential in order to maximize optimal performance.
4. Prime pump and hysteroscope into a separate basin or into the underbuttock drape.

Straight-tubing connections

Please see illustration below when using straight outflow tubing.



MyoSure procedure setup



Setup for use of MyoSure Tissue Removal Device

1. Position the MyoSure control unit.

NOTE:

It is important to position the MyoSure control unit a minimum of 5 feet from the MyoSure tissue removal device which allows the drive cable to hang in a large arc with no bends, loops or kinks.

The ideal placement of the control unit is behind the physician either to the right (if right-handed) or to the left (if left-handed) and on the same side as the video tower.

2. Connect foot pedal to the MyoSure control unit.
3. Connect the MyoSure tissue removal device suction tubing to tissue trap.
4. Connect the MyoSure tissue removal device drive cable to the MyoSure control unit.

NOTE:

Never lay the drive cable over the patient's leg.

Operative procedure/introduction of MyoSure Tissue Removal Device

1. When ready for operative portion of procedure, close the stopcock on the outflow channel.
2. Remove the outflow channel.
3. Insert the MyoSure tissue removal device into hysteroscope.

Settings

1. Set fluid deficit.

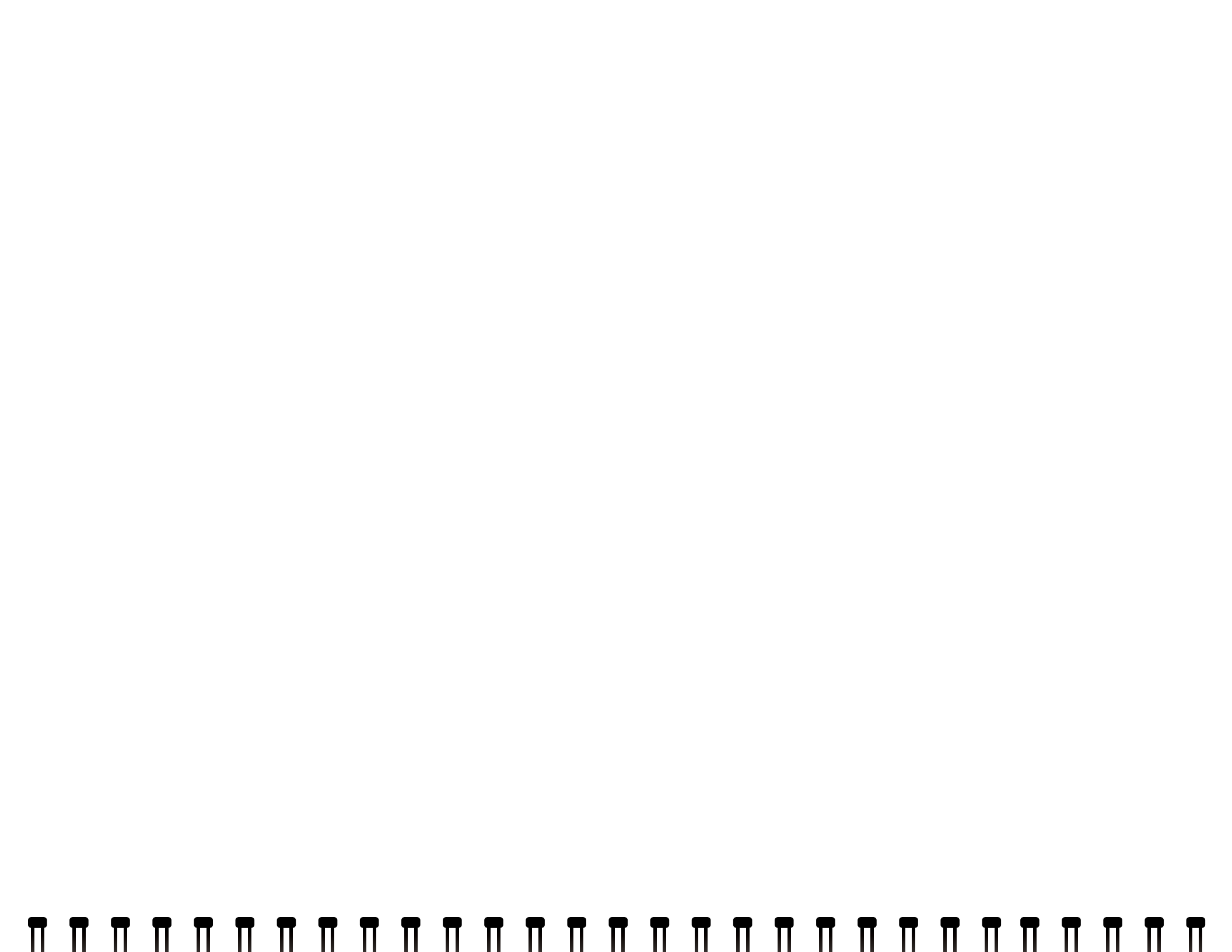
NOTE:

AAGL guidelines recommend 2,500 ml for saline solution (isotonic).

2. Appropriately set intrauterine pressure and inflow rate for fluid pump.
3. Intrauterine pressure and/or vacuum pressure may need adjustment during the procedure to provide maximum visualization.

TIP:

When a balance is created between inflow and suction, the results are improved uterine distention, optimal visualization and cutting efficiency.



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Hysteroscope and device tips

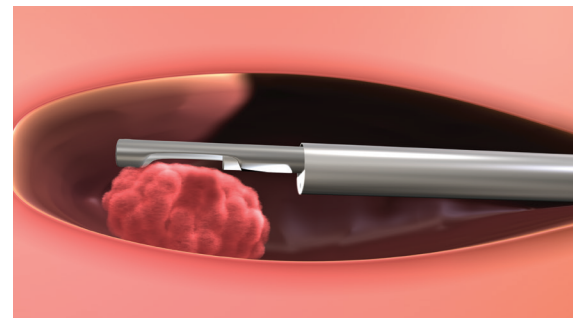
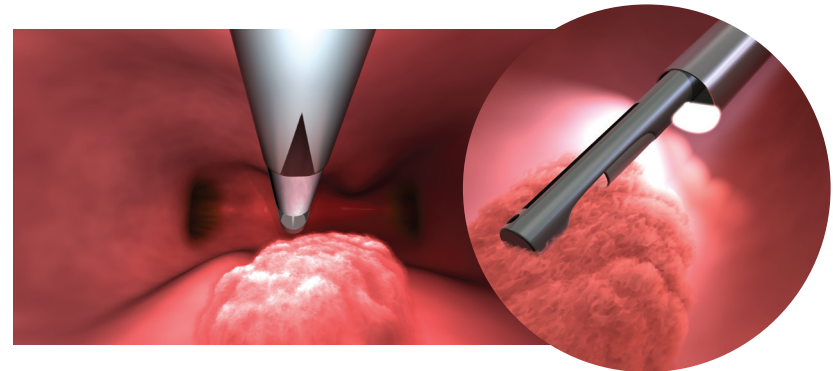
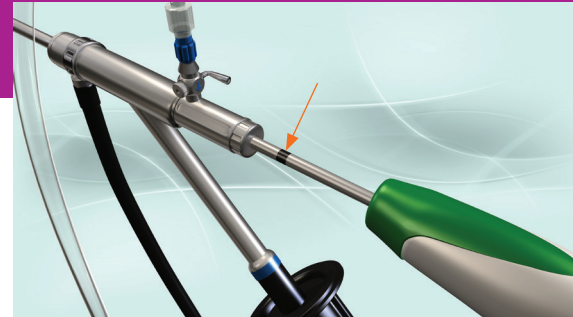
Procedural tips

Tissue removal device insertion tips

1. Insert the MyoSure tissue removal device until the black line is flush with the proximal end of the scope.
2. Once the MyoSure tissue removal device has been advanced into the cavity, the distal tip will come into view and a black line or small black arrow will be visible.

The black line is 180° opposite of the cutting window, and the small black triangle is located just below the cutting window to help orient the blade onto the tissue.

3. It is very important to always orient the cutting window directly on the tissue when the foot pedal is activated.



Hard-to-reach pathology

Initial device insertion

Insert the MyoSure device with the camera head held below the device. The cutting window should also face down (handle up).

Some pathology locations may be difficult to reach in this position due to the scope lens being positioned underneath the device.



Anterior wall pathology

To reach anterior pathology, keep the scope and camera head below the device and rotate the MyoSure tissue removal device 180 degrees until the cutting window on the device is facing up and contacts the pathology.



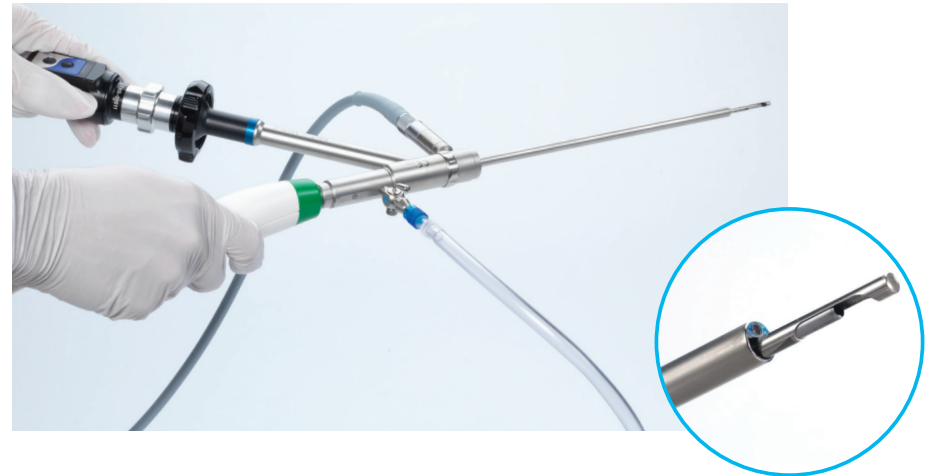
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Lateral wall pathology

For difficult-to-reach pathology on either lateral wall, you can rotate the scope and camera to better orient the cutting window against the tissue.

For example, if you have tissue on the lateral wall at 3 o'clock, you can rotate the scope clockwise to the 9 o'clock position while turning the device handle to the left at the same time.

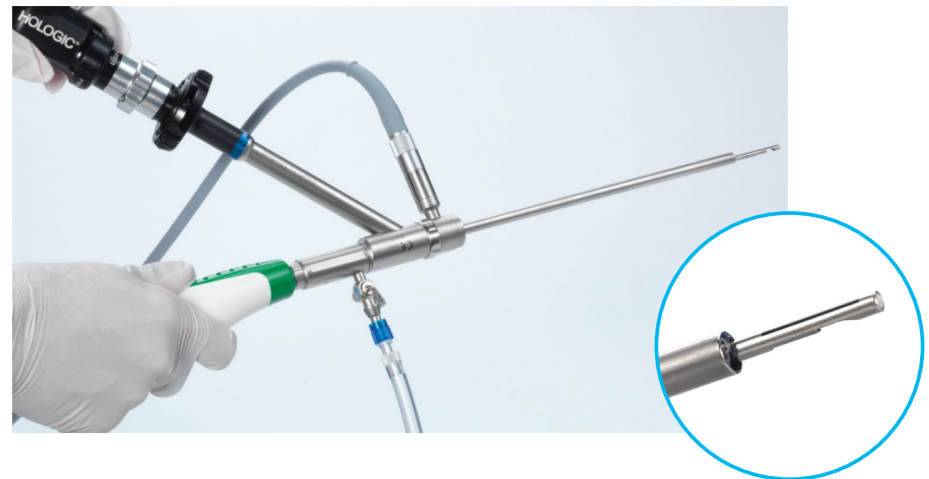
When rolling the scope, ensure that you also roll the camera head with the buttons facing up. This will maximize contact with the targeted pathology and keep the scope view in the correct orientation on the video monitor.



Posterior wall pathology

For difficult-to-reach pathology on the posterior wall, rotate the scope and camera head to the 12 o'clock position (upside down) while keeping the cutting window on the device facing down and towards the pathology.

Doing this will maximize contact between the cutting window and the posterior wall.





Troubleshooting

Troubleshooting tips



Loss of suction

- Avoid over dilation of the cervix. If over dilation of cervix, use second tenaculum to seal cervix.
- Verify saline bag clamp is open.
- Verify all canister lids are sealed.
- Verify canister filters are not wet.
- Confirm underbuttock drape is clamped off (only when using pump other than Aquilex).
- Ensure inflow tubing is on the inflow port.
- Ensure the inflow tubing is not occluded or pinched.

Visibility issues

- Advance the MyoSure tissue removal device to the fundus and allow circulation of fluid through blade to clear field.
- If, above step does not clear the field of view, retract the MyoSure tissue removal device with the leading edge of the cutting window visible and depress foot pedal for 1-2 seconds to clear field.
- Verify saline bag clamp is open.
- Intrauterine pressure may need adjustment during the procedure to provide a tamponade effect.
- May need to reduce suction to the MyoSure tissue removal device in order to minimize the amount of fluid pulled from the cavity.

Poor uterine distension

- Avoid over dilation of the cervix. If over dilation of cervix, use second tenaculum to seal cervix.
- Verify saline bag clamp is open.
- Ensure that the inflow pressure is adequate.
- When using scope, keep the outflow stop-cock lever opened only slightly – if stopcock is open all the way this can lead to pulsation of the tissue in the field of view and cause lack of distention.

Cutting issues

- Efficient operation of MyoSure requires high flow and regulated suction.
 - Minimum inflow rate recommended of 500-700 ml/min.
 - Recommend use of regulated vacuum source. Typical range of vacuum used is between 200 - 400 mmHg. Adjust vacuum if necessary throughout the procedure to provide optimal cutting of the MyoSure tissue removal device.
- Orient the MyoSure tissue removal device cutting window against tissue when foot pedal is activated.
 - If flashing from scope is seen – window is not directly over tissue.

Machine shut-off

- Avoid placing pressure on the MyoSure tissue removal device handle. If too much pressure/torque is applied, the MyoSure control unit may shut-off.
- **Leave MyoSure control unit off for 15 seconds.**
- Restart the MyoSure control unit and continue with procedure.



Changing Lives. At Hologic, we turn understanding and compassion into superior solutions for gynecologic health. We believe all women should be free of debilitating conditions that rob them of the ability to enjoy life to its fullest. We are passionate about delivering innovative products for the simple, efficient treatment of these conditions – helping you to change and dramatically improve the lives of your patients.

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Women's Health Solutions

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