

Double[®] Pump



Leadership in Fluid Management

Double® Pump

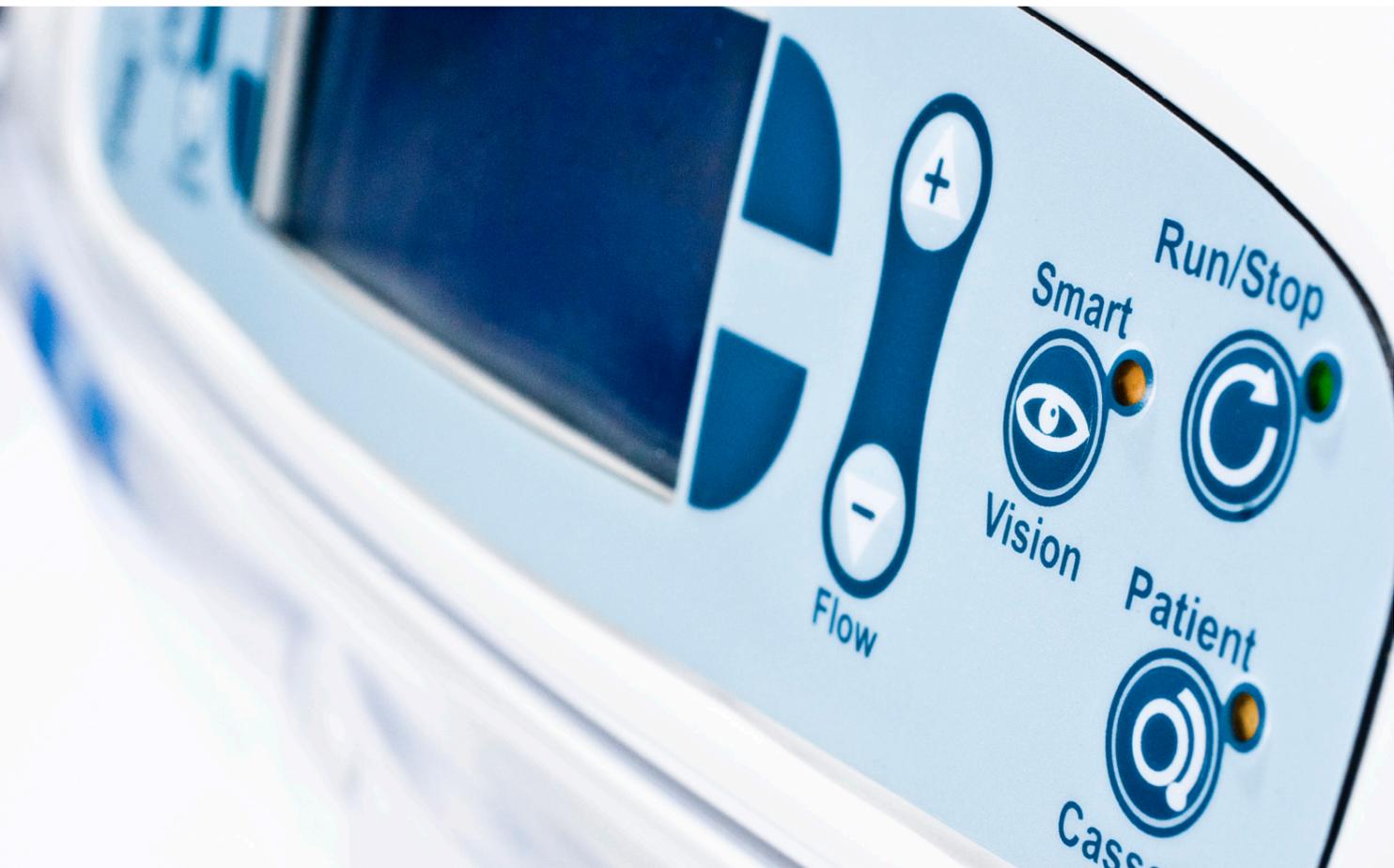
Medical Vision® leads the development in Fluid Management in endoscopic surgery, to facilitate better visualization during surgery. Through our arthroscopy pump, Double® Pump, we have the most advanced and high-tech pump on the market, which leads to more controlled and shorter procedures as well as better patient outcomes. We claim that proper fluid management is essential to perform a successful arthroscopy in any joint in the body; therefore we strive to further expand the knowledge of the fluid management segment and its importance during an arthroscopic surgery.

Double® Pump controls both in- and outflow, that is both pressure and flow in a separate fashion. The pump operates with disposable cassettes, one that controls the in-flow (Day Cassette, used for one surgical day) and one that controls the out-flow (Patient Cassette, new for every patient).

The key advantages of using Double® Pump are:

- The patented SmartVision® function.
- Interface possibility with most of the shaver systems on the market.
- Calculation and displaying of the true pressure in the joint (true IAP).
- The easy-to-use Cassette technique.
- The Outflow Tracking™ function.

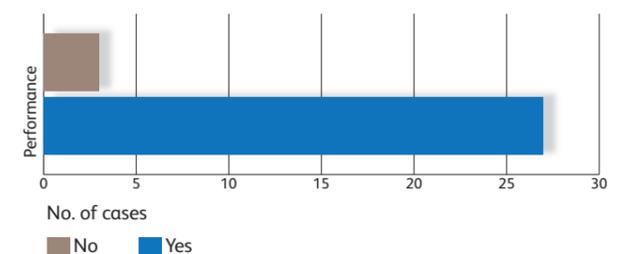
We welcome you to test Double® Pump and compare it to the pump you are using today. Through the features mentioned above we are certain that you will note the difference.



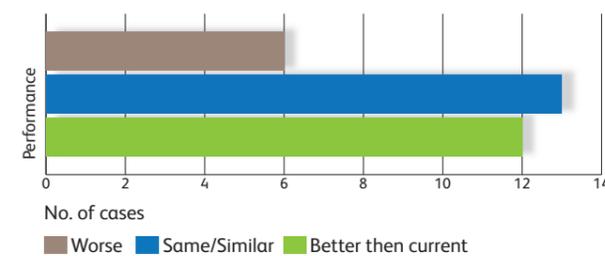
CLINICAL TRIAL AFFIRMS THE CLINICAL ADVANTAGE OF DOUBLE® PUMP

Double® Pump is not yet another arthroscopy pump. Through clinical comparisons with today's market leading pumps, we can confirm that physicians appreciate the technical advantage that Double® Pump offers. Other pumps operate through fixed pressures while Double® Pump operates through a dynamically changed pressure for any given visibility situation during an arthroscopy procedure. Especially in shoulder cases, this results in an optimal pressure level throughout the procedure and a significantly lower average pressure which leads to shorter procedures and less trauma for the patient.

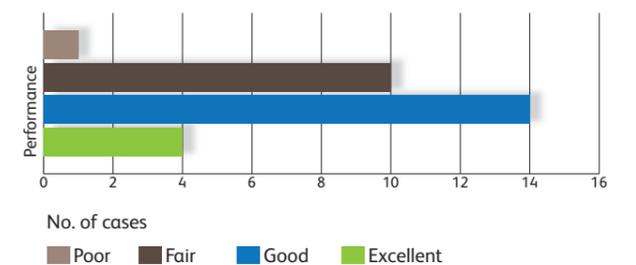
Are you likely to use this product in the future?



How did this pump compare (overall) to your current pump (FMS 4 or FMS DUO)?



Did the pump keep the view clear and free of debris?



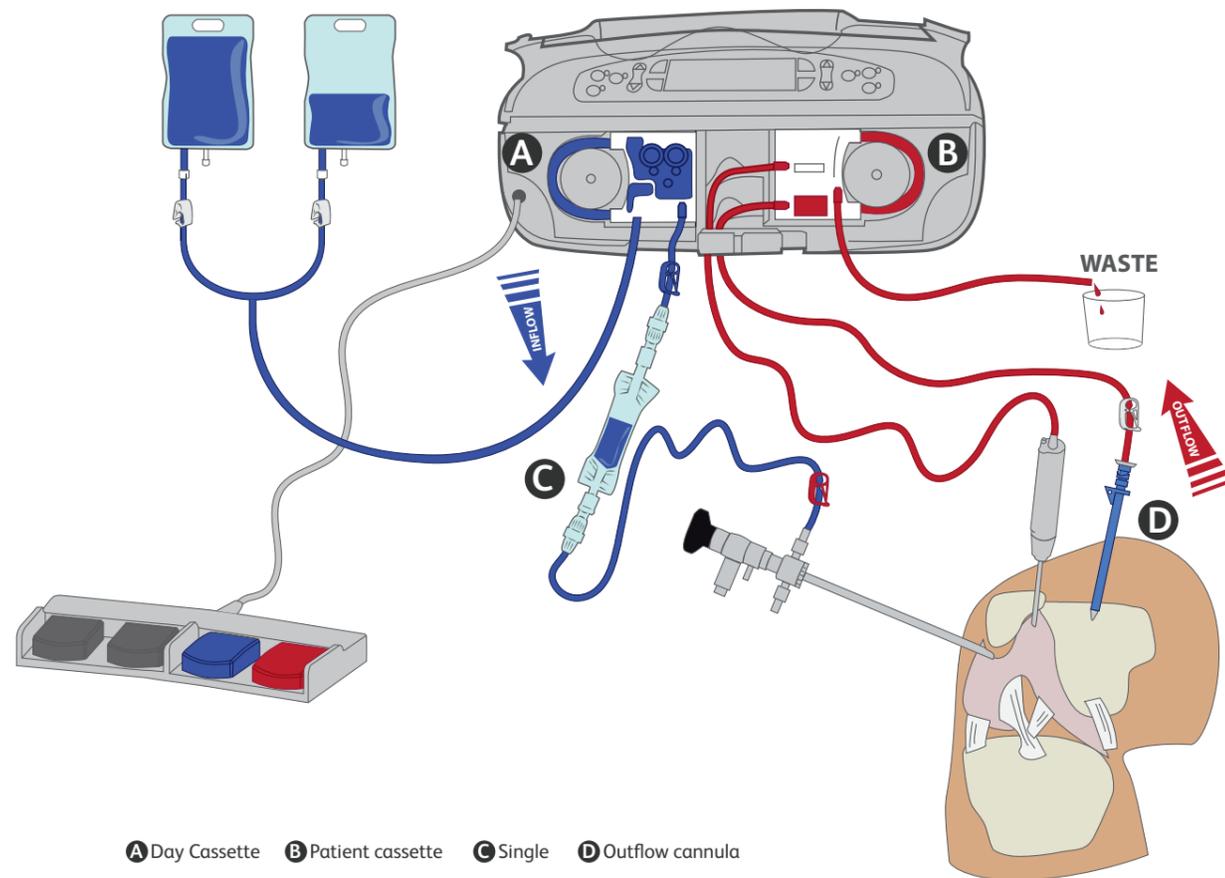
Reference. Data on file. Medical Vision.

DOUBLE® PUMP CASSETTES

Most arthroscopy pumps on the market use tubes instead of cassettes. Tubes require a more delicate setup which can result in pump inconsistency since the tube position can vary from case to case - it is normally also more time consuming. Double® Pump uses cassettes instead of tubes. The cassette house on the pump is designed to easily fit the cassette, which makes it easy and quick to mount. The cassettes snap into place with a click sound and are easily removed by unlatching the cassette with the lever. The Double® Pump cassettes have some other unique features:

- The patented algorithm which calculates the true IAP (Intra Articular Pressure).
- The Cassettes are packaged in trays instead of pouches, which both prevents from dropping on the floor, but also makes them easier to keep sterile.
- Behind the Double® Pump Patient Cassette, the Smart-Vision® optical sensor is located. With this sensor the Double® Pump can automatically adjust pressure and flow when blood or debris is detected.

Double® Pump can be operated in either single mode or double pump mode. If the Double® Pump is operated in single mode a Double® Pump Day Cassette and a Double® Pump Single is used. Double® Pump Day Cassette can be re-used during one surgical day, which significantly saves costs, while the Double® Pump Single is only used for one procedure. If the pump is used in double pump mode, a Double® Pump Day Cassette and a Double® Pump Patient Cassette is needed. The Double® Pump Patient Cassette actually consists of two (2) parts, one Irrigation tube (equal to the Double® Pump Single), and the Patient Cassette, please see drawing below.



BACKGROUND

The reason for using a pump and the whole idea with fluid management during an arthroscopic procedure is to:

- Keep the joint distended through pressurization and expansion of the operating field.
- Compress damaged blood vessels to maintain hemostasis through increased pressure.
- Maintain visibility by flushing the operating field in a controlled way.

It is fundamental to maintain an adequate pressure level throughout the surgery in order to ensure optimal visibility for the surgeon during the procedure and thereby secure better outcome for the patient. A controlled and accurate pressure will potentially also implicate a more controlled and quicker procedure. Therefore, clinically correctly measured pressure in the joint and an appropriate, case-by-case, automatic adjustment of the pressure, are features that have been proven to be crucial to get a controlled and cost-efficient end result, when performing arthroscopic procedures today¹.

One of the major concerns with the arthroscopic procedure involves the extravasation of fluid into the surrounding soft tissues. This situation occurs when the pump system used delivers a pressure that is much too high versus the pressure in the surrounding soft tissue. Particularly fluid diffusing into the soft tissues of the shoulder and periscapular region can be much more than just an inconvenience. Therefore, it is absolutely essential to control the pressure and keep it as low as possible during the procedure, while still maintaining sufficient pressure to keep the joint distended.

1) European Markets for Arthroscopy Devices 2011 and US Markets for Arthroscopy Devices 2009, Millennium Research Group.

CONTINUES FLOW

In order to keep a constant visibility during the procedure it is essential that the pump system used, can control both in- and outflow. With an irrigation-only pump system pressure is built up gradually in the joint and when fluid is evacuated, either through removal of the optic scope or via an external suction source, the pressure is dropped dramatically. This results in bleeding from damaged vessels and loss of the distention effect earlier given by the pump. It is therefore fair to state that lack of continuous flow, such as an in- and outflow pump can provide, makes the procedure much more complicated.

In order for a pump with both inflow and outflow functionalities to work as intended, there must be proper physical conditions for the fluids to move in and out of the joint. If the inflow port, e.g. the scope sheath, has a narrow space for the fluids to flow, no pump-system in the market can establish a proper and sufficient flow through the joint. Therefore, it is essential to use a high-flow scope sheath when prioritizing good visibility during the procedure. If you do not have a proper outflow the fluids have no place to go - it has to be evacuated either through the scope sheath or the Shaver suction, with a pressure influencing effect as described above.

Therefore we claim that proper fluid management is performed with an inflow and an outflow pump that dynamically controls the pressure and flow levels. Below we will explain in detail what we mean with a dynamic control.

TWO PORTAL VS. THREE PORTAL ARTHROSCOPY

Still many arthroscopies are performed with only two portals, one portal for the scope and one working portal for e.g. a Shaver. This gives a significant disadvantage when considering fluid management. With a two portal setup you either need a double flow sheath or a sheath for the working portal with a separate outflow to ensure proper fluid management. Instead we strongly advocate for a third portal, a lateral parapatellar portal, using an outflow cannula. With this setup you allow a continuous flow as described above and the Double® Pump can automatically adjust the pressure and flow through the unique SmartVision® technology.



OUTFLOW TRACKING™

Outflow Tracking™ assists in keeping the joint distended when aggressive suction is used (i.e. when using the Shaver suction). This function regulates inflow to the surgery area to precisely replace liquid removed by the outflow. The result is a constant volume of fluid in the distended joint. This is especially important when using the suction from the Shaver, resulting in an otherwise collapsed cavity. For optimal results with the Outflow Tracking™ function we advice to use a high-flow sheath to ensure that enough fluid can reach the joint. Not using a high-flow sheath can have a pressure decreasing effect.

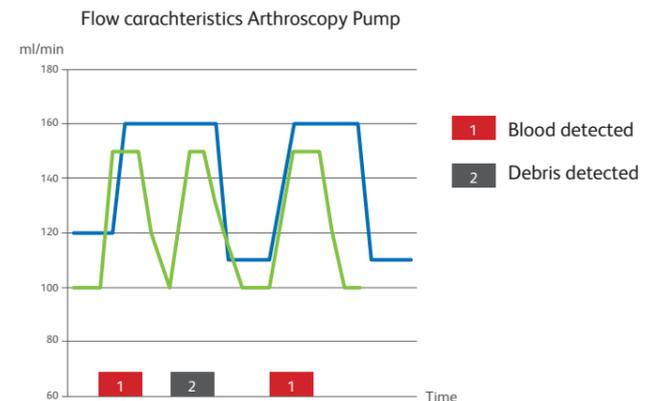
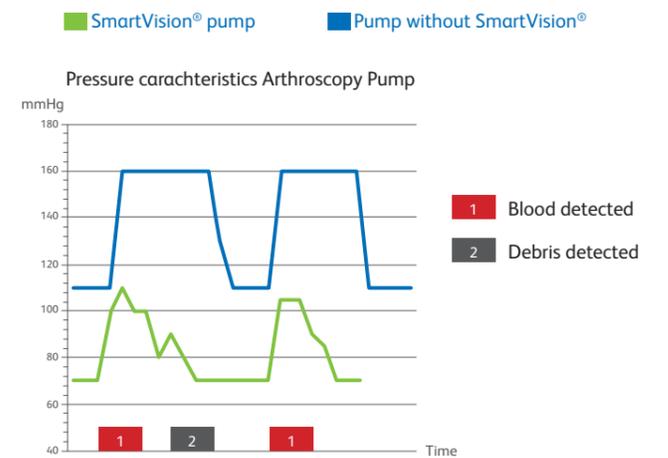
SHAVER CONNECTIVITY

Double® Pump is one of the few pumps that are compatible with most Shaver systems on the market, through CE-marked Interface Cables/Boxes. Through different types of interface cables or boxes the pump can be controlled through either the Shaver handpiece or the foot control. The Patient Cassette is therefore equipped with a special Shaver tube that evacuates fluids directly from the Shaver Handpiece. When the Shaver is operated, a signal is sent via the Interface Cable to the Double® Pump, which automatically shifts the suction from the Outflow Cannula tube to the Shaver tube.

SMARTVISION®

The technology, branded as SmartVision®, is a revolutionary solution to visibility problems during endoscopic surgery performed in conjunction with a fluid management system. When SmartVision® is in use, the pump system through an optical sensor, detects substances that have influence on the visibility during surgery. The SmartVision® adjusts flow and pressure dynamically and automatically in the operation site so that full visibility is maintained. SmartVision® is a patented technology by Medical Vision®.

SmartVision® gives the advantage of optimizing the pressure according to the visibility circumstances in the joint throughout the procedure. This result in a significantly lower average pressure and a shorter procedure time for the SmartVision® controlled pump compared to any other pump on the market.²



In the pressure diagram, it clearly shows that a SmartVision® pump works with a significantly lower average pressure compared to a pump without SmartVision®. It also shows that the SmartVision® pump adjusts the pressure according to the visibility conditions in the joint.

The flow diagram shows how the flow increases ones either blood or debris is detected. However, the flow level for the SmartVision® pump is dynamically adjusted, resulting in an optimized flow for any given part of the procedure.

2) Data on file, Medical Vision Sweden

Double[®] Pump

ORDERING INFORMATION:

Double [®] Pump	
Item number	Description
1028506S	Double [®] Pump

Double [®] Pump Cassettes		
Item number	Description	Packaging
1002053	Day Cassette	20 pcs/Box
1002059	Patient Cassette	20 pcs/Box
1002052	Single	100 pcs/Box

600003 Rev.01 2011-11