

# Value Analysis Brief— FMS DUO®+ FLUID MANAGEMENT SYSTEM

## Methods

This value analysis brief presents information on the potential clinical and economic benefits of using the FMS Duo® + Fluid Management System in arthroscopic procedures. The referenced data were obtained through a search of MEDLINE for clinical and economic studies of fluid management systems for arthroscopy and the medical resource utilization associated with these systems. Unpublished studies also were included in this analysis due to limited published economic data for the FMS Duo® + Fluid Management System.

*Note: The FMS Duo® + Fluid Management System is unique to DePuy Mitek, thus all studies referenced herein pertain directly to this system.*

## Background

Arthroscopy is a common orthopedic procedure. Surgical technique and equipment has evolved to enable increasingly complex arthroscopic surgeries. Because these minimally-invasive procedures require working within an extremely confined surgical space, visualization with effective fluid management to expand and distend the joint space is crucial.

Historically, gravity systems were used that required saline bags to be hung at different heights to provide varying pressures within the joint space. However, in a busy operating room, adjusting bag heights and measuring pressures is not practical. Therefore, mechanical systems using pumps and wall suction were an improvement but were not optimal because of the difficulty in balancing inflow and outflow and the inability to instantaneously increase/decrease these flows and pressures. State-of-the-art fluid management systems now offer a variety of features that maximize and maintain optimal visualization during arthroscopic procedures.

The FMS Duo® + Fluid Management System achieves a number of important objectives:

- Easy setup and interface with other surgical equipment;
- Consistent and predictable flow/pressure without oscillation and surges;
- Instantaneous control of flow when desired; and
- Operating room efficiencies for both facilities and staff.

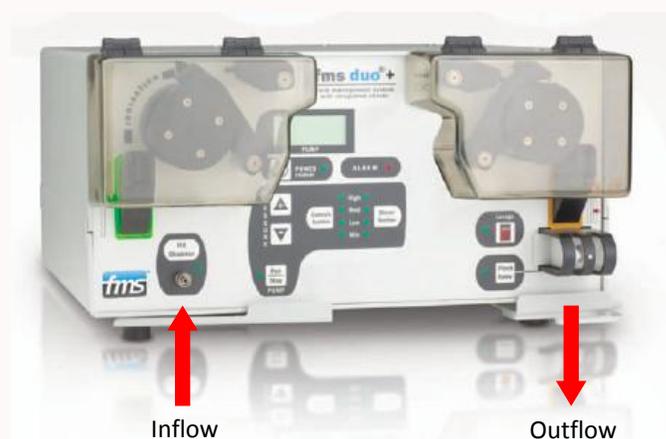
The design elements of the FMS Duo® + translate into a number of potential clinical and economic benefits to various stakeholders.

## Potential Clinical and Economic Benefits

**Optimal visualization allows *efficient and successful procedures* in confined anatomic environments.**

Today's arthroscopic procedures are increasingly complex. Simultaneous manipulation of an arthroscopy camera and instruments in a confined joint space requires skill and a clear surgical field. Bleeding and floating surgical debris further complicate the procedure. Orthopedic surgeons have been quick to recognize that visualization is key to a successful arthroscopic procedure and better clinical outcomes. A state-of-the-art fluid management system, such as the FMS Duo® +, provides optimal visualization for these complex procedures.

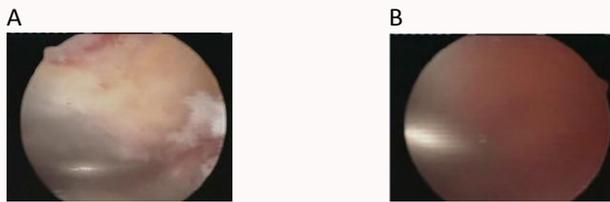
In order to effectively navigate associated anatomic structure, optimized fluid flow into and out of the joint is necessary. Older fluid management approaches (gravity flow, non-adjustable pump systems) were insufficient. The FMS Duo® + improved upon these systems by providing integrated inflow and outflow, allowing for numerous benefits that maintain a clear visual field with constant pressure within the joint.



Bleeding is one of the common problems that can instantly cloud the surgical field. Because the vessels in the typical joint space are so numerous and microscopic, increased fluid pressure is ideal for tamponade when cauterizing is difficult or impossible. By controlling inflow and outflow, the FMS Duo® + easily allows the surgeon to temporarily increase pressure in the joint to quickly control bleeding and restore visualization within the surgical space.

Circulating surgical debris also is a hindrance to surgeons. With older pumps, inflow could be changed to increase flow and flush debris. But, because outflow suction could not be simultaneously adjusted, constant pressure within the joint

could not be maintained. The integrated inflow and outflow feature of the FMS Duo® + allows temporary high flow to remove debris without a resulting change in joint pressure.



Images from a patient undergoing an arthroscopic debridement procedure for a non-repairable rotator cuff tear: visualization of the shaver in the subacromial space with (A) integrated suction from the FMS pump and (B) non-integrated wall suction

**By maintaining constant pressure throughout the surgical procedure, the FMS Duo® + system *minimizes the risk of extravasation* leading to a reduction in overall costs.**

Fluid management systems allow a surgeon to set and control pressure within the joint space. Older systems without integrated inflow and outflow resulted in oscillations in which pressure surges and drops were common. With integration comes steady pressure without extremely high pressure surges. Longer surgery times and high pressure surges increases the likelihood of extravasation or fluid leakage out of the joint space and into the surrounding tissue. At a minimum, extravasation can lead to interference within the surgical space and unwanted post-operative fluid retention. However, extravasation may lead to airway obstruction with potentially life-threatening consequences.<sup>1-10</sup> Therefore, reduction in procedure time through better visualization and the maintenance of constant pressure without high pressure surges and oscillation may reduce this type of complication.

One of the most significant advantages of using the FMS Duo® + system is the ability to maintain constant pressure throughout the surgical case. Many pumps on the market only provide inflow irrigation and thus require wall suction for outflow. This means to increase pressure, you must increase flow. This can lead to tissue extravasation into the surrounding tissues, and thereby, extensive swelling.<sup>11</sup> Additionally, longer surgery times increases the likelihood of extravasation.

The economic impact of extravasation is significant. Extravasation can lead to interference within the surgical space and unwanted post-operative fluid retention. In shoulder arthroscopic procedures, extravasation may lead to airway obstruction with potentially life-threatening consequences.<sup>8</sup> Patients will often require additional follow-up care in the ICU<sup>8</sup>. Reducing the risk of extravasation can lead to a reduction in hospital costs.

**Better visualization provided by a dual pressure and flow-control pump *reduces operating room time* leading to significant cost-savings.**

The main purpose of fluid management during arthroscopic procedures is to ensure the surgical field is clear so surgeons can concentrate on their repairs. Just a few drops of blood can create severe “red outs” which add time and frustration for the arthroscopist. The ability to manage pressure *and* flow independently is important because it allows the surgeon to capitalize on the opportunity for optimal visualization while minimizing excessive bleeding. Evidence suggests that a pressure *and* flow control pump (such as the FMS Duo® + system) provides better visualization than a pressure-control pump alone.<sup>11,12</sup> The FMS Duo® + system offers unique features to help ensure optimal visibility such as dedicated outflow, ability to eliminate bleeding (Red Pedal “Lavage” mode) and clear debris (Blue Pedal “Flow” mode), shaver interfacing to automatically control shaver suction, and the ability to eliminate the need for wall suction. Increased visualization associated with a pressure *and* flow-control pump may lead to decreased operative time when compared with pressure-control pumps alone. A recent study by Sieg and colleagues sought to compare the operative times in anterior cruciate ligament (ACL) reconstruction using these two types of pump systems; an irrigation style pump with inflow only (HydroFlex, Davol) and a pump with inflow and outflow control (FMS Duo® +, DePuy Mitek).<sup>13</sup> The authors also compared the average surgical times separating reconstruction from revision, the type of graft used, the involvement of meniscal debridement, and the surgeon performing the procedure (Table 1).

**Table 1. Surgical Time of Pressure Control Pump (Group 1) vs. FMS Duo® + Pump (Group 2)<sup>12</sup>**

|                     | Surgical Time        |                      |                            |         |                   |                  |
|---------------------|----------------------|----------------------|----------------------------|---------|-------------------|------------------|
|                     | No. of Surgeries     |                      | Average Surgical Time, min |         | Time Savings, min | P Value          |
|                     | Group 1 <sup>a</sup> | Group 2 <sup>b</sup> | Group 1                    | Group 2 |                   |                  |
| All procedures      | 21                   | 23                   | 126                        | 111     | 15                | .004             |
| Primary             | 19                   | 19                   | 126                        | 110     | 16                | .006             |
| Revision            | 2                    | 4                    | 130                        | 118     | 12                | n/a <sup>c</sup> |
| Plus debridement    | 7                    | 8                    | 130                        | 114     | 16                | .156             |
| No debridement      | 14                   | 15                   | 124                        | 110     | 14                | .009             |
| Hamstring autograft | 5                    | 4                    | 133                        | 122     | 11                | .297             |
| Allograft           | 16                   | 19                   | 123                        | 106     | 17                | .013             |
| Surgeon 1 only      | 10                   | 7                    | 126                        | 111     | 15                | .103             |
| Surgeon 2 only      | 5                    | 7                    | 126                        | 110     | 16                | .065             |
| Surgeon 3 only      | 6                    | 9                    | 126                        | 112     | 14                | .177             |

<sup>a</sup>Group 1, pressure-control pump.  
<sup>b</sup>Group 2, dual system pump.  
<sup>c</sup>Not enough information to determine P value.

The results of the study indicate that average operative time using the pressure-control pump (HydroFlex) was 126 minutes (95% CI: 118.9, 133.3) while average operative time

using the FMS Duo® + system was 111 minutes (95% CI: 104.1, 117.9).<sup>13</sup> There was an average 15-minute decrease in surgical time (P=0.004) in favor of the dual system. For each of the comparisons shown in Table 1, the use of the dual pressure-flow pump led to operative time savings ranging from 11 to 17 minutes.<sup>13</sup> Assuming the cost of operating room time is \$32 per minute,<sup>14</sup> the estimated cost savings would be about \$480 per procedure or \$21,120 if all 44 procedures were performed with the FMS Duo® + pump.

**The FMS Duo® + fluid management system provides significant *operating room efficiencies* leading to additional cost-savings.**

The FMS Duo® + fluid management system provides significant operating room efficiencies by reducing saline usage, reducing the need for outflow maintenance, and allowing for reuse of irrigation tubing. The FMS Duo® system is a low flow pump. Unlike most pumps on the marketplace, it does not have to significantly increase flow to increase pressure and does not require wall suction. As a result, the FMS Duo® system can significantly reduce saline usage and decrease operating room consumable costs over the long term.

The FMS Duo®+ system offers Sterile Zone Kit tubing with a one-way check valve. These check valves allow operating room staff to *reuse* the pump-side irrigation tubing for cases in the same operating room during the day. Additionally, the check valves decrease set-up time between cases and allow operating room staff to use partially used saline bags on the next case (instead of throwing them away) which translates into cost-savings for the facility.

**By maintaining constant pressure throughout the surgical procedure, the FMS Duo® + system *minimizes the risk of extravasation* leading to a reduction in overall costs.**

Overall, the FMS Duo® + system supplies both irrigation and suction in one unit. Because the system allows the arthroscopist to control both inflow and outflow, pressure *and* flow can be controlled independently. By maintaining constant pressure and providing better visualization than other fluid management systems, the FMS Duo® + system can provide significant operating room efficiencies, reduce operating room time, and reduce the risk of extravasation, thus leading to significant costs savings.

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