Methods
This value analysis brief presents information on the potential clinical and economic benefits of using the OMNISPAN meniscal repair system for all-inside meniscal repairs. A search of MEDLINE and Science Direct peer reviewed journal databases was conducted on the subject of all-inside meniscal repair. Conference proceedings and unpublished studies were also included in the analysis.

Note: The OMNISPAN meniscal repair system is the only all-inside system that contains partially absorbable suture and does not leave a hard body or knot on the surface of the meniscus.

Background
Meniscal repair devices have evolved steadily over the years allowing easier, faster and safer meniscal repairs. The goal of these devices was to improve ease of use, reduce surgical time, reduce morbidity and reduce the incidence of neurovascular injuries, while maintaining a repair consistent with the gold standard, inside-out repair.

First generation products, such as darts and arrows were shown to have significantly lower load-to-failure properties relative to inside-out repair, which led to further innovation and ultimately the development of mattress suture style all-inside meniscal repairs. Despite the improvements made device misfires, suture breakage, over-penetration issues and knot prominence continued to be challenges for the orthopaedic surgeon.

The OMNISPAN meniscal repair device improves upon other all-inside meniscal repair devices with Active Deployment, Improved Strength, partially absorbable high strength suture and a very low profile repair. In addition to these potential clinical benefits, the OMNISPAN system can offer economic benefits with large meniscal tears. The design elements of the OMNISPAN meniscal repair system translate into a number of potential clinical and economic benefits for providers, payers, and patients alike.1,2,3,4,5,6,7

Potential Clinical Benefits
The OMNISPAN Meniscal repair system is designed to provide optimized all-inside meniscal repairs. The unique design offers a truly low profile repair with the following potential clinical benefits:

Gentle on the Chondral Surface:

The unique peripherally located sliding knot eliminates the meniscal surface knot present on other devices and utilizes two low profile suture bridges on the meniscal surface (Figure 1).

Figure 1: Arthroscopic image of a meniscal repair device with a knot (blue suture shown at right) and without a knot (OMNISPAN - purple suture at left). The absence of a knot provides a very low profile repair.

The absence of a meniscal surface knot with the OMNISPAN system eliminates high pressure concentrations on the meniscal-chondral interface, which may result in chondral damage. Cadaveric testing of competitive product demonstrates a 40% reduction in surface point pressure with the OMNISPAN system (Figure 2a-b) compared with a device having a meniscal surface knot.
Figure 2a: Mean peak pressures on menisci following application of a clinically-relevant load. Pressures for the intact state (no implant), OMNISPAN (no meniscal surface knot) and Ultra Fast-Fix (meniscal surface knot) are presented.

Figure 2b: Representative pressure distributions for a single meniscus under identical loading conditions intact (left), repaired with OMNISPAN (middle), and repaired with Ultra FasT-Fix (right).

In addition to quantifying the point pressures generated by implants with and without meniscal surface knots, a custom load frame was used to simulate walking under a clinically relevant load. Knees were cycled and subsequently stained to increase visual contrast between damaged and undamaged cartilage. There were some locations of preexisting femoral cartilage damage in all specimens. However, in 50% of the cases there was a linear abrasion (Figure 2) that matched up with the direct line of motion for implant containing a suture knot.

Figure 2: Femoral condyles after 1000 cycle abrasion test: unstained (left) and stained (middle). Red ovals show un-abraded cartilage for OMNISPAN (middle) and linear abrasion for Ultra FasT-Fix (right).

The absence of a knot on the meniscal surface with OMNISPAN results in a repair that is gentle on the chondral surface, while maintaining a profile similar to the gold-standard inside-out technique.

OMNISPAN allows repairs in vertical, horizontal and oblique patterns. Testing has shown that OMNISPAN provides outstanding strength compared to competitive all-inside devices. Single pull and Cyclic pull to failure testing was conducted in porcine menisci resulting in 177N and 204N, respectively. In comparison, suture only repairs with ORTHOCORD® resulted in Single pull and Cyclic pull to failure of 124N and 222N, respectively. The robust strength of the OMNISPAN system moves all-inside repairs closer to the gold standard of inside-out repair.

The OMNISPAN Implant also consists of #2-0 ORTHOCORD™ suture, which is 55% PDS suture and 45% Ultra-High Molecular Weight Polyethylene. This offers high strength initially while offering the long-term benefit of reduced suture mass over time.

Excellent Strength and Versatility:

OMNISPAN allows repairs in vertical, horizontal and oblique patterns. Testing has shown that OMNISPAN provides outstanding strength compared to competitive all-inside devices. Single pull and Cyclic pull to failure testing was conducted in porcine menisci resulting in 177N and 204N, respectively. In comparison, suture only repairs with ORTHOCORD® resulted in Single pull and Cyclic pull to failure of 124N and 222N, respectively. The robust strength of the OMNISPAN system moves all-inside repairs closer to the gold standard of inside-out repair.

Active Deployment:

The active deployment provided by the OMNISPAN system allows the surgeon to decide when and where the backstops are deployed. Unlike passive deployment systems, this does not require over-penetration of the needles to leave the backstops behind the meniscus. Potential complications

Table 1 – Single Pull to Failure (N)¹

<table>
<thead>
<tr>
<th>Suture</th>
<th>OMNISPAN</th>
<th>Ultra Fast-Fix</th>
<th>MAXFIRE</th>
<th>CROSSFIX</th>
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<tr>
<td>#2-0 MERSILENE</td>
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<tr>
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Table 2 – Single Pull to Failure After 500 Loading Cycles (N)²

<table>
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<td>#0 ULTRABRAID</td>
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<td>95</td>
<td>204</td>
</tr>
</tbody>
</table>

Low Profile and reduced Suture Volume Post-Operatively:

The active deployment provided by the OMNISPAN system allows the surgeon to decide when and where the backstops are deployed. Unlike passive deployment systems, this does not require over-penetration of the needles to leave the backstops behind the meniscus. Potential complications
associated with over-penetration have been well
documented in the literature, such as contact with superficial
structures, injury to the popliteal artery, popliteal
neurovascular bundle, common peroneal nerve, saphenous
nerve, and the inferior lateral genicular vessels.\textsuperscript{1,3,4,5}

**Potential Economic Benefits**

**Surgical Time and Cost:**

The OMNISPAN meniscal repair system moves all-inside
meniscal repair closer to the gold standard of inside-out
meniscal repair, while reducing Operating Room time. The
time required to create incisions, position instrumentation
and pass sutures is reduced. The OMNISPAN system is also
packaged pre-sterile, obviating the need for sterilization
cycles, planning and time, which may ultimately lead to a
more streamlined procedure. This is particularly valuable
when a meniscal tear is found during the diagnostic
arthroscopy rather than with pre-operative imaging.

**Device Cost:**

Meniscal repairs require two or three implants to make a
standard repair. Large bucket handle tears may however
require a large number of implants (4-10) to make the repair.
The OMNISPAN system packages the meniscal applier and
needles separately in pre-sterile packaging. This allows the
meniscal applier device to be used multiple times during a
single surgery with multiple needles. In comparison,
competitive products package a needle and applier together,
which requires the applier to be purchased every time a
needle is required. The OMNISPAN system, depending on the
clinical situation, may be a more economical choice based on
the number of appliers purchased with competitive devices.
In addition, purchasing the needle and applier in one package
will require additional shelf space and also contributes to
additional packaging and waste for the institution.\textsuperscript{11,12}

**Deployment Accuracy:**

The OMNISPAN system is an Active Deployment system,
which allows the surgeon to choose when and where the
implants are deployed. There have been reports of
deployment complications with Passive Deployment systems
like Ultra FasT-Fix. A survey of 101 surgeons was conducted
by DePuy Mitek at the 2011 AANA and AAOS meetings.

The survey revealed that 39% of the surgeons surveyed have
had 1 or more out of 10 meniscal repair implants mis-deploy.
This results in the use of implants that do not contribute to
the repair. The survey also revealed that 57% of surgeons
have a major concern with the economic impact and waste of
meniscal repair devices. The Active Deployment features of
OMNISPAN may make deployment more reliable compared
to passive deployment systems.\textsuperscript{3,5,13}

**References**

1. Haas et al. Meniscal Repair Using the FasT-Fix All-Inside Meniscal Repair
2. Barber FA, Herbert MA, Meniscal Repair Devices, Arthroscopy: The
3. Cohen et al., Vascular Risk Associated With Meniscal Repair Using
RapidLoc Versus FasT-Fix: Comparison of Two All-Inside Meniscal
4. Abouheif et al., Determination of the safe penetration depth during all-
inside meniscal repair of the posterior part of the lateral meniscus using
the FasT-Fix suture repair system, Knee Surgery, Sports, Traumatology,
Arthroscopy; Published online: April 6, 2011.
5. Miller et al. Pitfalls Associated with Fast-Fix Meniscal Repair,
Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol. 18,
No. 8, 2002: pp. 939-943.
Containing Ultra High-Molecular Weight Polyethylene Suture,
Arthroscopy: The Journal of Arthroscopic and Related Surgery, Vol. 25,
No. 9, 2002: pp. 959-967.
containing Ultra High-Molecular Weight Polyethylene Suture including the
OMNISPAN™ Meniscal Repair System, DePuy Mitek, Inc. 2010 P/N
901096.
8. Turman et al., ALL-Inside Arthroscopic Meniscal Repair, Chapter 34, pp.
1-7 (Diduch).
9. Diduch, David R. M.D., Poelstra, Kornelis M.D., The Evolution of All-
Inside Meniscal Repair, Operative Techniques in Sports Medicine, Vol.
12. Ultra Fast-Fix is a registered trademark of Smith & Nephew.