**INTRODUCTION**

This value analysis brief presents information on the potential clinical and procedural benefits of using the DYNACORD™ Suture (DePuy Synthes) in soft tissue repair procedures. The DYNACORD Suture is a high-strength, orthopedic suture that minimizes suture laxity in soft tissue repair procedures in order to preserve consistent tissue approximation while improving footprint compression during the healing period. Unlike other high-strength orthopedic sutures which experience laxity, the DYNACORD Suture is uniquely designed to shorten when compression is lost, thereby minimizing micro-motion and reducing gap formation. The DYNACORD Suture design consists of an outer sheath with braided fibers of ultra-high molecular weight polyethylene (UHMWPE), polyester (PET), and nylon (or without nylon), an inner sheath with braided fibers of PET, and a co-extruded silicone core made of medical grade silicone and NaCl (Figure 1). This internal salt filled core helps the DYNACORD Suture resist laxity.

**CLINICAL UNMET NEED**

Over the past few decades, soft tissue repair techniques have evolved from an open approach to an arthroscopic approach. One of the major benefits of the arthroscopic approach is the ability to repair soft tissues without detachment or manipulation of the surrounding muscles. These procedures have been shown to reduce pain, improve motion, restore function, and improve the general health status of the patient. However, failure of soft tissue repairs is common. For example, failure of tendon healing after rotator cuff repair occurs in approximately 20-30% of cases, depending on tear size. Two common failure modes for soft tissue repairs during the healing period are knot slippage and lack of consistent tissue approximation to bone. This suggests that advances in repair techniques and surgical instrumentation are needed to optimize the healing environment after the repair in order to facilitate restoration of function.

Overall, there is an unmet need for soft tissue repair techniques and surgical instrumentation that:

- Provide high initial fixation strength,
- Maintain the ideal tissue-to-bone approximation force at the tendon-bone interface
- Permit minimal gap formation
- Minimize micro-motion due to knot/suture slippage or suture laxity
- Sustain mechanical stability until healing has been achieved.
These transformational clinical and procedural benefits have the potential to improve long-term patient outcomes during the healing period and may reduce costs by minimizing the need for revision surgery. Structural failure of the repair occurs in a substantial number of cases and can lead to an unsatisfactory result. For example, a recent meta-analysis of 8,000 rotator cuff repairs showed a mean re-tear rate of 26.6%. Additionally, the percentage of revision surgeries has been reported to be as high as 30% for isolated supraspinatus tendon tears. This suggests that advances in repair techniques are needed to optimize the healing environment after repair in order to facilitate restoration of function and minimize the risk of revision surgery. Many studies have reported that the key features of an ideal rotator cuff repair are higher initial fixation strength, greater contact area and contact pressure at the tendon- bone interface, minimal gap formation, and sustained mechanical stability until the healing has been achieved. The evidence from the DYNACORD Suture pre-clinical and biomechanical studies shows the DYNACORD Suture has many of these attributes.

Direct cost estimates (as reported in the medical literature) for a rotator cuff repair range from $10,000 to over $17,000.1,10 A recent micro-c costing analysis in the ASC setting by Bisson and colleagues (2015) estimated the direct costs of rotator cuff repair at approximately $13,000.10 From these figures, the total direct expenditure on rotator cuff repair in the United States may range from $6 billion to $8 billion. Should the use of the DYNACORD Suture yield even a small reduction in the incidence of costly revision procedures, healthcare cost savings could be substantial given the number of these types of procedures performed in the US each year. For example, a conservative 2% reduction in the current rate of revision (from 27% to 25%) for the estimated 601,000 rotator cuff repair procedures per year would yield a potential cost savings of $156.3 MM (reduction of 12,020 revision procedures at a cost of $13,000 per procedure).

CONCLUSION

Overall, the DYNACORD™ Suture is a high-strength, orthopedic suture that minimizes suture laxity in soft tissue repair procedures in order to preserve consistent tissue approximation while improving footprint compression during the healing period. These attributes have the potential to improve long-term patient outcomes during the healing period and may reduce costs by minimizing the need for revision surgery.

CITATIONS