FiberTape® Suture Post-Op Complaint Rate

Arthrex Research and Development

Objective

The purpose of this study is to determine the post-op complaint rate of FiberTape suture.

Methods and Materials

Arthrex compiled the complete list of all product codes using FiberTape suture. Sales data for the life of these products was obtained for the period of July 2003 to January 2016. Complaints were compiled and placed into three categories: all complaints; complaints related to FiberTape suture; and complaints potentially related to reactions to FiberTape suture.

Results

The table below lists products containing FiberTape suture and the associated complaint rates that included FiberTape suture sold between July 2003 and January 2016.[1]

Category	Complaints	Complaint Rate	Complaint Odds
1. All complaints	238	0.0150%	<15 per 100,000
2. FiberTape suture-related	41	0.0026%	<3 per 100,000
3. Potential reactions to FiberTape suture	27	0.0017%	<2 per 100,000

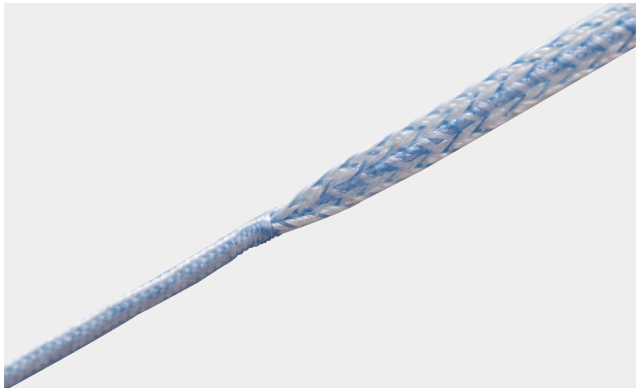

Figure 1. FiberTape Suture

Conclusion

The complaint data compiled for this review clearly demonstrates very low risk of tissue reaction associated with FiberTape suture manufactured by Arthrex, Inc. Arthrex maintains that the safety and effectiveness of our carefully selected materials contribute to successful patient outcomes.

Reference

1. Arthrex, Inc. Data on file.

arthrex.com