

FiberTape Post-Op Complaint Rate

Arthrex Research and Development

Objective

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

Methods and Materials

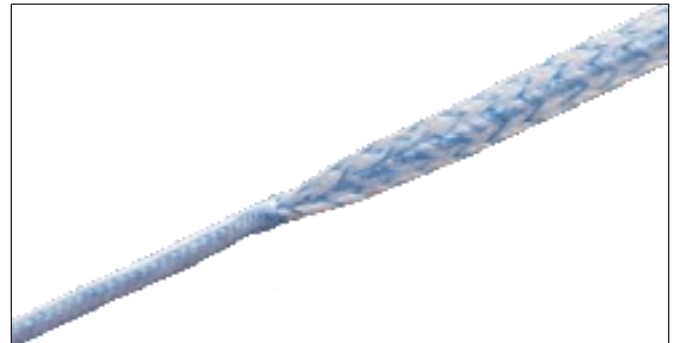
Arthrex compiled the complete list of product codes utilizing FiberTape. Sales data for the life of these products was obtained (July 2003-January 2016). From all product codes utilizing FiberTape, each complaint was compiled and categorized into (1) All complaints, (2) FiberTape related complaints, and (3) potential FiberTape complaints related to reactions.

Results

Products containing FiberTape and the associated complaint rates are provided in the table below. A total of 1,586,369 products with FiberTape were sold from July 2003-January 2016.¹

Category	Complaints	Complaint Rate	Complaint Odds
1 – All Complaints	238	0.0150%	< 15 per 100,000
2 – FiberTape Related	41	0.0026%	< 3 per 100,000
3 – Potential FiberTape Reactions	27	0.0017%	< 2 per 100,000

Figure 1: FiberTape



Conclusion

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

1. Data on file, Arthrex Inc.