BioComposite Interference Screw Post-op Complaint Rate

Arthrex Orthopedic Research

Objective

The purpose of this study is to investigate postoperative complaint rates associated with Arthrex biocomposite interference screw products, which include BioComposite FastThread™ interference screws and first-generation biocomposite interference screws.

Methods and Materials

Arthrex analyzed sales and complaint data for all biocomposite interference screw products, including BioComposite FastThread interference screws and first-generation biocomposite interference screws for the time period from January 1, 2008, through April 30, 2022 (Table 1). All complaints associated with the listed part numbers were identified. Data collected during the complaint verification process were used to identify complaints specifically related to post-op issues. Complaints were classified as “post-op” if the complainant selected the option “After use” from a menu in response to the question asking when the incident occurred. Additionally, the open-ended, “problem statement” section was searched for the term “post-op” for all complaints and evaluated to ensure all appropriate occurrences were included. The number of “post-op” complaints was compared to the unit sales to generate a post-op complaint rate.

Results

The adjacent table outlines the total number of post-op complaints associated with the products listed above and the complaint rate compared to unit sales. There were 5 complaints associated with BioComposite FastThread interference screws, generating a complaint rate of 0.0024%. There were 75 complaints for first-generation biocomposite interference screws, generating a complaint rate of 0.0064% (Table 1).

BioComposite Screws

Product Description	Item Number
BioComposite FastThread Interference Screw, 6 mm × 20 mm to 10 × 20 mm	AR-**4020C-06–10**
BioComposite FastThread Interference Screw, 7 mm × 30 mm to 12 mm × 30 mm	AR-**4030C-07–12**
Biocomposite Interference Screw, 7 mm × 23 mm	AR-**1370C**
Biocomposite Interference Screw, 8 mm × 23 mm	AR-**1380C**
Biocomposite Interference Screw, 9 mm × 23 mm	AR-**1390C**
Biocomposite Interference Screw, 10 mm × 23 mm	AR-**1400C**
Biocomposite Interference Screw, round delta, 8 mm × 28 mm to 11 mm × 28 mm	AR-**5028C-08–11**
Biocomposite Interference Screw, delta tapered, 9 mm × 35 mm to 12 mm × 35 mm	AR-**5035TC-09–12**

Conclusion

Based on the reported complaints, the data reviewed demonstrates a very low risk of post-op complications associated with the use of the products investigated.

Table 1. Sales and Complaint Data

Time Period	Post-op Complaints	Complaint Rate	Complaint Odds
BioComposite Screws Total	80	0.0057%	<6 per 100,000
Original Biocomposite Screws	75	0.0064%	
BioComposite FastThread Screws	5	0.0024%	