

# BioComposite Interference Screw Post-op Complaint Rate

Arthrex Research and Development

## 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).

This is not medical advice and Arthrex recommends that surgeons be trained in the use of a particular product before using it in surgery. A surgeon must always rely on their own professional judgment when deciding whether to use a particular product when treating a particular patient. A surgeon must always refer to the package insert, product label, and/or directions for use before using any Arthrex product. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes. Products may not be available in all markets because product availability is subject to the regulatory or medical practices in individual markets. Please contact your Arthrex representative if you have questions about availability of products in your area.



## 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 |
|----------------------------------|--------------------|----------------|----------------|
| <b>BioComposite Screws Total</b> | 80                 | 0.0057%        | <6 per 100,000 |
| Original Biocomposite Screws     | 75                 | 0.0064%        |                |
| BioComposite FastThread Screws   | 5                  | 0.0024%        |                |