



Arthrex Armour

Technology Protection

Mitigating Unauthorized Repairs

The lure of cheap repairs can entice many customers to seek third-party repairs for their equipment. The reality, however, is that they will be exposing themselves to several consequences, both financial and legal. For the best quality repairs at a cost-effective rate with assurance of full compliance, all equipment should be serviced only by our expert technicians.

About Third-Party Repairs

According to the FDA, “Stakeholders have expressed concerns that some third-party entities who refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices may use unqualified personnel to perform service, maintenance, refurbishment, and device alterations on their equipment and that the work performed may not be adequately documented. Possible public health issues arising from these activities include ineffective recalls, disabled device safety features, and improper or unexpected device operation.”¹



Reference

1. FDA Reauthorization Act of 2017 (FDARA), H.R. 2430, 115th Cong. §934 (2017).

*Arthrex products modified or altered in any manner by an unauthorized third-party service provider are considered adulterated pursuant to FDA regulations and can no longer be serviced or repaired by Arthrex, Inc. Using an unauthorized third-party service provider to service or repair Arthrex products voids all warranties and/or any purchased service programs.



Impact of Using Third-Party Service Providers*

- Third-party providers servicing health care facilities currently do not fall within the FDA’s jurisdiction and do not have to comply with FDA requirements.
- Third-party providers do not have the training or expertise needed to service Arthrex devices.
 - They are not aware of the latest software upgrades.
 - They do not have access to Arthrex-certified parts, and they may choose to find third-party reverse-engineered parts or use scavenged parts.
 - They do not have the same level of expertise or training on Arthrex devices.



Financial Risks

In the event a product is returned to Arthrex and found to have unauthorized repairs, an unauthorized repair fee will be charged. This amount is the original purchase price minus any trade-out fees already paid. If the unauthorized repair fee is not accepted, return the replacement product provided by Arthrex. The unauthorized repair fee and any trade-out fees already paid will be credited when Arthrex receives the replacement product.

Frequently Asked Questions

Question: If an item is serviced via an unauthorized repair facility, does that void all service/warranties for only that device or for the entire site?

Answer: If a device is serviced by an unauthorized repair facility, the service and warranty are void on that specific device. Any devices without an unauthorized repair can still be serviced by Arthrex.

Identifying Third-Party Repairs of Optical Components



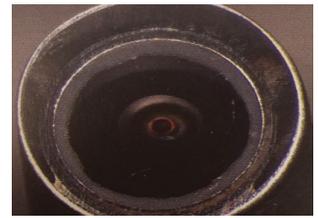
Original manufacturer
Eyepiece attached gap-free



Third-party repair
Gap formation as a result of nonoriginal component increases hygienic risks



Original manufacturer
Objective lens within specifications



Third-party repair
Copied objective lens



Original manufacturer
Precisely applied weld seams



Third-party repair
Improperly applied weld seam and/or use of adhesive resulting in poor or nonexistent sealing