

The American Society of Plastic Surgeons (ASPS) and the American Society for Aesthetic Plastic Surgery (ASAPS) are committed to patient safety, advancing quality of care, and practicing medicine based upon the best available scientific evidence on breast implants and have issued the following joint statement on Breast Implant associated ALCL (BI-ALCL).

- In January 2016, the United States FDA provided an update to the 2011 safety communication that identified a possible association between breast implants and the development of ALCL, a rare type of non-Hodgkin's lymphoma. According to the World Health Organization, BI-ALCL is not a breast cancer or cancer of the breast tissue; it is a lymphoma, a cancer of immune cells. Women with breast implants may have a very low, but increased risk of developing ALCL adjacent to a breast implant.
- The incidence of BI-ALCL is very rare, and considering the millions of breast implants used throughout the world as of September 2015 there may be as many as 258 patients with possible BI-ALCL reported to the FDA.
- Treatment and outcomes data exist on BI-ALCL from case series, and more information is needed to fully understand risk factors, etiology, and epidemiology. An observation of reported cases indicates a predominance of textured device involvement. The association with breast implants is likely multifactorial and is currently being extensively studied.
- ASPS and ASAPS recommend educating breast implant patients on the risk of BI-ALCL and the early detection of symptoms. Women with breast implants are encouraged to contact their plastic surgeon if they notice swelling, fluid collections, or unexpected changes in breast shape (Figure 1).
- In symptomatic patients suspicious for BI-ALCL, perform an ultrasound and send suspicious peri-prosthetic fluid for CD30 immunohistochemistry, cell block cytology, and culture. Surgical treatment is essential for the management of BI-ALCL. See Figure 2 for treatment algorithm.

Breast implant associated-ALCL is very rare, and if it occurs, is highly treatable in the majority of patients. The FDA, ASPS, and ASAPS recommend that all women, including those with breast implants, follow their normal routine in medical care and follow-up, including mammography when appropriate.

The FDA as well as the Institute of Medicine (IOM) maintain that breast implants do not impair breast health or cause breast cancer, and scientific evidence continues to support that FDA-approved breast implants have a reasonable assurance of safety and effectiveness.

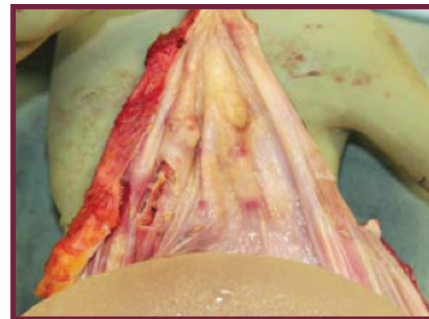


Figure 1. Example of BI-ALCL presentation with right breast swelling. Capsule appearance of BI-ALCL mass.

This joint statement was prepared by ASPS and ASAPS.

The societies are grateful to the following breast implant manufacturers for agreeing to distribute this statement to help educate surgeons and patients.

Management of Suspected and Confirmed BI-ALCL

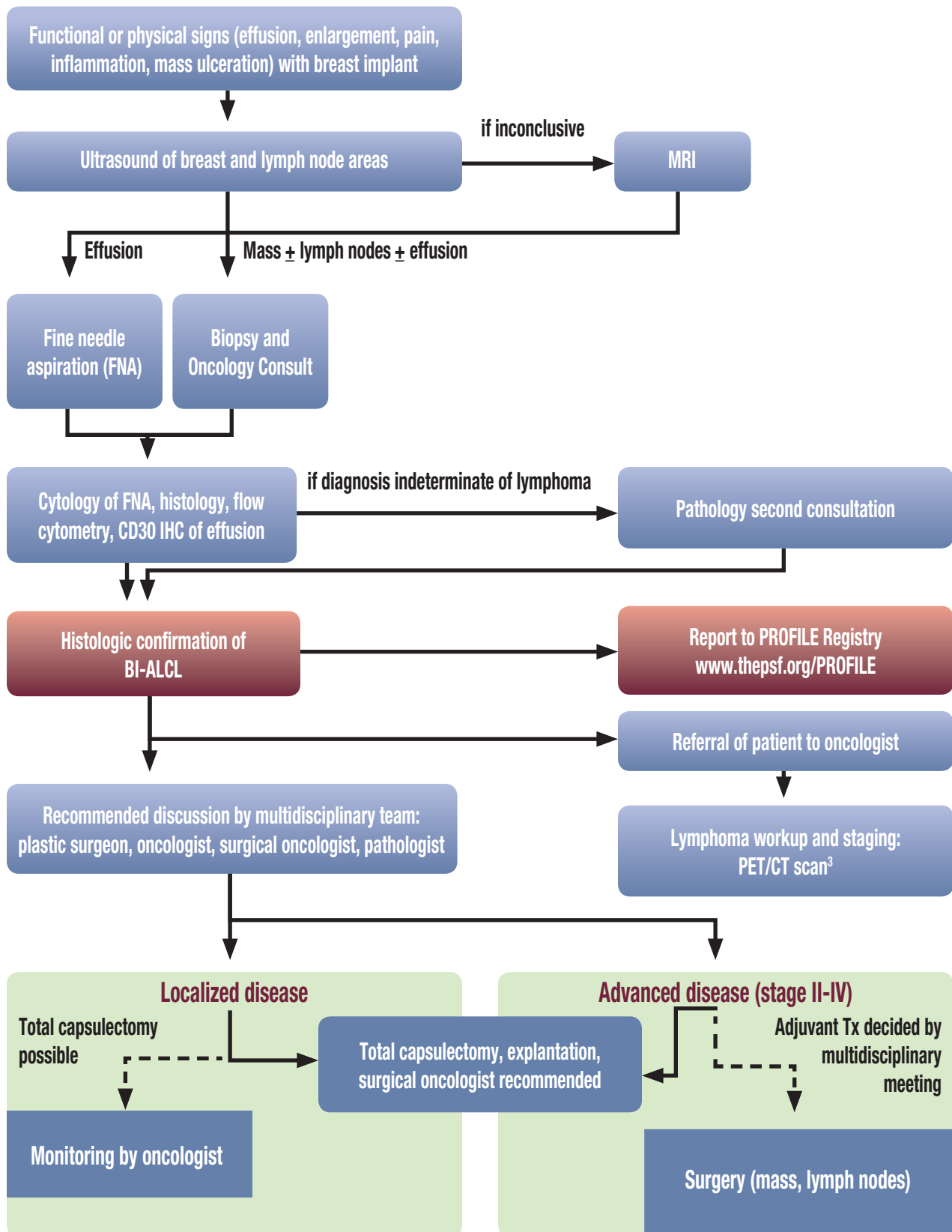


Figure 2. Treatment Algorithm