American College of Radiology
ACR Appropriateness Criteria®
Breast Implant Evaluation

Variant 1:   Evaluation of saline breast implants. Asymptomatic patient. Any age. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Not Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Not Appropriate	☢☢
US breast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 2:   Evaluation of saline breast implants. Clinical examination equivocal for implant rupture. Age younger than 30 years. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	O
Mammography diagnostic	Usually Not Appropriate	☢☢
Digital breast tomosynthesis diagnostic	Usually Not Appropriate	☢☢
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 3:   Evaluation of saline breast implants. Clinical examination equivocal for implant rupture. Age 30–39 years. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography diagnostic	Usually Appropriate	☢☢
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
US breast	Usually Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 4:   Evaluation of saline breast implants. Clinical examination equivocal for implant rupture. Age 40 years or older. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography diagnostic	Usually Appropriate	☢☢
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 5:   Evaluation of silicone breast implants. Asymptomatic patient. Any age. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Not Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Not Appropriate	☢☢
US breast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 6:   Evaluation of silicone breast implants. Suspected implant complication. Age younger than 30 years. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
MRI breast without IV contrast	Usually Appropriate	O
US breast	Usually Appropriate	O
Mammography diagnostic	Usually Not Appropriate	☢☢
Digital breast tomosynthesis diagnostic	Usually Not Appropriate	☢☢
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 7:   Evaluation of silicone breast implants. Suspected implant complication. Age 30–39 years. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
MRI breast without IV contrast	Usually Appropriate	O
Mammography diagnostic	Usually Appropriate	☢☢
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
US breast	Usually Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 8:   Evaluation of silicone breast implants. Suspected implant complication. Age 40 years or older. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
MRI breast without IV contrast	Usually Appropriate	O
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
Mammography diagnostic	Usually Appropriate	☢☢
US breast	May Be Appropriate (Disagreement)	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 9: Evaluation of unexplained axillary adenopathy. Silicone breast implants (current or prior). Age younger than 30 years. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US axilla	Usually Appropriate	O
Mammography diagnostic	Usually Not Appropriate	☢☢
Digital breast tomosynthesis diagnostic	Usually Not Appropriate	☢☢
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 10: Evaluation of unexplained axillary adenopathy. Silicone breast implants (current or prior). Age 30–39 years. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography diagnostic	Usually Appropriate	☢☢
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
US axilla	Usually Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 11: Evaluation of unexplained axillary adenopathy. Silicone breast implants (current or prior). Age 40 years or older. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography diagnostic	Usually Appropriate	☢☢
Digital breast tomosynthesis diagnostic	Usually Appropriate	☢☢
US axilla	Usually Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O

Variant 12: Suspected breast implant associated anaplastic large-cell lymphoma (BIA-ALCL) (delayed seroma, swelling, mass, pain but no erythema, warmth or skin changes that would raise concern for inflammatory breast cancer or mastitis). Any age. Breast implant of any type. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US breast	Usually Appropriate	O
Digital breast tomosynthesis diagnostic	May Be Appropriate	☢☢
Mammography diagnostic	May Be Appropriate (Disagreement)	☢☢
MRI breast without and with IV contrast	May Be Appropriate (Disagreement)	O
MRI breast without IV contrast	Usually Not Appropriate	O

BREAST IMPLANT EVALUATION

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Summary of Literature Review

Introduction/Background

Breast implants are routinely placed for augmentation and reconstruction and have been available for over 50 years. A large variety of implants are commercially available, including saline, silicone (including form-stable varieties also known as gummy bear implants), double lumen varieties using both saline and silicone, and polyacrylamide gel. Although implants have been used for many years, controversy surrounding the safety of silicone implants led the FDA to impose a moratorium on use of silicone implants for cosmetic augmentation in 1992. The ban was lifted in 2006 after studies evaluating associated malignancies, autoimmune diseases, and other problems did not show a causal relationship to implant placement. Further controversy ensued when the French manufacturer of the Poly Implant Prothese silicone implant issued a product recall in 2010 because of the use of industrial-grade silicone and substandard manufacturing, prompting recommendations for explantation.

Breast augmentation is not without risk, and implant rupture is a well-known potential complication. Rupture of saline implants is usually clinically evident, as the saline is resorbed by the body over a period of days and the patient experiences a change in breast size and shape. Rupture of silicone implants, however, may be asymptomatic, especially if the rupture is intracapsular (contained by the fibrous shell formed by the body around the implant). If the rupture is extracapsular, patients may present with palpable masses or changes in breast contour. Diagnosis of extracapsular rupture of silicone implants is often made with mammography and/or ultrasound (US), where high-density silicone is identified outside the confines of the implant shell. The diagnosis of intracapsular rupture, however, is not routinely made with mammography, can be challenging to make with US, and thus often requires magnetic resonance imaging (MRI).

In 2016, the World Health Organization provisionally classified breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL) as a newly recognized entity. Data is limited and still evolving, with most reported cases associated with textured implants. This entity is a rare T-cell lymphoma and most often presents with delayed (>1 year after surgery) peri-implant effusion. Early recognition is critical, however, as diagnosis can often be made from cytological analysis of the fluid, and patients with disease limited to the implant capsule have a much better prognosis than those with an associated mass or systemic disease [1-5].

Overview of Imaging Modalities

Imaging options for implant evaluation include mammography, digital breast tomosynthesis (DBT), US, MRI, and computed tomography (CT). Saline implant rupture is usually clinically apparent, with diagnosis made by physical examination. Silicone implant integrity is best assessed with imaging.

Mammography

A collapsed implant shell of a ruptured saline implant will be seen at mammography. The saline from the implant is resorbed by the body without significant sequelae or secondary findings in the breast.

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The diagnosis of silicone implant rupture is often more challenging, with clinical examination known to be unreliable [6]. In cases of extracapsular silicone implant rupture, the diagnosis is often made with mammography in which high-density silicone is seen outside the implant contour. Mammography does not detect intracapsular silicone implant rupture.

Both standard and implant-displaced views should be obtained.

DBT
At this time, there are no studies to show the specific efficacy of DBT in implant evaluation over and above its advantages in evaluation of the native breast tissue. Both standard and implant-displaced views should be obtained.

US
At US, extracapsular silicone demonstrates a classic 'snowstorm' appearance that is characterized by a highly echogenic pattern of scattered and reverberating echoes with a well-defined anterior margin and loss of detail posteriorly. However, most silicone implant ruptures are intracapsular. Numerous US findings of intracapsular silicone implant rupture, including the stepladder sign—a series of horizontal echogenic straight or curvilinear lines traversing the interior of the implant—have been described [7-9], but the variability in reported accuracy of sonographic findings [10-14], combined with the well-known user dependence of this technology, often makes sonographic findings somewhat equivocal.

MRI
MRI without contrast is considered the gold standard for diagnosis of intracapsular silicone implant rupture, though the reported sensitivity, specificity, and accuracy have been variable [6,10,12-19], depending on the patient population being studied (symptomatic versus asymptomatic). Pooled data from a recent meta-analysis [18] showed a sensitivity of 87% and specificity of 89.9% for MRI. Of note, most studies focused on symptomatic women, in whom the expected prevalence of rupture would be higher than among asymptomatic women. Studies of asymptomatic women have reported sensitivities and specificities of 64% and 77% [14], accuracy of 94% [13], accuracy of 92%, sensitivity of 89%, specificity of 97%, positive predictive value of 99%, and negative predictive value of 79% [15]. An incomplete intracapsular rupture has been referred to by a variety of names, including the 'inverted-loop sign,' 'keyhole sign,' 'teardrop sign,' or 'hang noose sign.' A complete intracapsular rupture occurs when the implant shell is completely collapsed within the silicone gel, has been called the 'linguini' or 'wavy-line' sign, and is the most specific sign of intracapsular implant rupture. In cases of extracapsular rupture, MRI will demonstrate extravasated silicone within the breast tissue and possibly within axillary lymph nodes.

CT
Although CT is not routinely used in breast imaging, it has occasionally been used for silicone implant evaluation in patients with a contraindication to MRI [20].

Variants discussed here range from asymptomatic patients to patients with suspected implant complications as the most severe symptom, and those with unexplained axillary adenopathy. Readers should refer to other ACR Appropriateness Criteria as needed for other specific symptoms such as pain or palpable masses (https://acsearch.acr.org/list). Additionally, asymptomatic patients with implants should pursue screening as outlined in the in the ACR Appropriateness Criteria® "Breast Cancer Screening" [21].

Discussion of Procedures by Variant

Variant 1: Evaluation of saline breast implants. Asymptomatic patient. Any age. Initial imaging.

Mammography or DBT Screening
There is no role for mammography or DBT for implant evaluation in asymptomatic patients with saline implants. However, women should follow breast cancer screening protocols as outlined in the ACR Appropriateness Criteria® "Breast Cancer Screening" [21].

US
There is no role for US for implant evaluation in asymptomatic patients with saline implants.

MRI
There is no role for MRI without contrast for implant evaluation in asymptomatic patients with saline implants [22].

There is no role for MRI without and with contrast for implant evaluation in asymptomatic patients with saline implants [22].

Variant 2: Evaluation of saline breast implants. Clinical examination equivocal for implant rupture. Age younger than 30 years. Initial imaging.

Mammography or DBT Diagnostic
Saline implant rupture is generally clinically evident [22,23]. However, diagnostic mammography or DBT may be indicated in patients with suspected saline implant rupture and equivocal clinical findings. Findings on mammography are diagnostic, where a collapsed implant shell is visible. However, for patients age <30, US should be the initial examination of choice.

US
In cases of saline implant rupture, the collapsed implant shell is visible by US. For patients age <30, US is the initial examination of choice.

MRI
There is no role for MRI without contrast in the evaluation of saline implants [22].

There is no role for MRI without and with contrast in evaluation of saline implants [22].

Variant 3: Evaluation of saline breast implants. Clinical examination equivocal for implant rupture. Age 30–39 years. Initial imaging.

Mammography or DBT Diagnostic
Saline implant rupture is generally clinically evident [22,23]. However, diagnostic mammography or DBT may be indicated in patients with suspected saline implant rupture and equivocal clinical findings. Findings on mammography are diagnostic, where a collapsed implant shell is visible. For patients age 30 to 39 years, either mammography/DBT or US may be used first.

US
In cases of saline implant rupture, the collapsed implant shell is visible by US. For patients age 30 to 39 years, either mammography/DBT or US may be used first.

MRI
There is no role for MRI without contrast in the evaluation of saline implants [22].

There is no role for MRI without and with contrast in evaluation of saline implants [22].

Variant 4: Evaluation of saline breast implants. Clinical examination equivocal for implant rupture. Age 40 years or older. Initial imaging.

Mammography or DBT Diagnostic
Saline implant rupture is generally clinically evident [22,23]. However, diagnostic mammography or DBT may be indicated in patients with suspected saline implant rupture and equivocal clinical findings. Findings on mammography are diagnostic, where a collapsed implant shell is visible. For patients age ≥40 years, mammography or DBT is the first-line examination if imaging is required.

US
In patients with suspected saline implant rupture, US may be indicated if the mammographic findings are equivocal or the patient is unable to undergo mammography. In cases of saline implant rupture, the collapsed implant shell is visible by US. For patients ≥40 years unable to undergo mammography, US may be used first. For those able to undergo mammography, US may be used for problem solving but is not the initial imaging examination of choice.

MRI
There is no role for MRI without contrast in the evaluation of saline implants [22].

There is no role for MRI without and with contrast in evaluation of saline implants [22].

Variant 5: Evaluation of silicone breast implants. Asymptomatic patient. Any age. Initial imaging.

Mammography or DBT Screening

Mammography and DBT are not indicated for implant evaluation in asymptomatic patients with silicone implants. However, women should follow breast cancer screening protocols as outlined in the ACR Appropriateness Criteria® "Breast Cancer Screening" [21].

US

The usefulness of screening for implant rupture is controversial, with scarce evidence outlining benefit. For asymptomatic women with silicone implants who are <40 years of age in whom screening for implant rupture is desired, some authors have recommended US as the initial screening tool, with MRI reserved only for patients with abnormal sonographic findings [13]. This study reported a negative predictive value of 85% for US. Sonographic findings of implant rupture are described [7-9,24], but US is hampered by interobserver variability. An economic modeling study [25] recently proposed using US in asymptomatic patients, with MRI performed only in patients with abnormal US-detected implant findings. The authors note that the low prevalence of rupture in asymptomatic patients would require a confirmatory MRI prior to proceeding to surgery in order to avoid unnecessary surgeries triggered by false-positive US findings. Given the limited data, there is no role for US in evaluation of silicone implants in asymptomatic patients.

MRI

There is currently no consensus on whether ruptured implants require surgery in asymptomatic patients, and the benefits of screening for implant rupture are controversial. Some authors [26] have advocated a patient-centered approach with shared decision making between the patient and her surgeon rather than generalized recommendations for all patients with silicone implants. In addition, numerous studies evaluating the rupture rate of more modern implants have shown this rate to be low [27-30]. Although the sensitivity, specificity, and accuracy of MRI are generally reported as much higher than any other breast imaging modality, a recent meta-analysis [18] noted that most studies evaluating MRI for detection of silicone implant rupture focus on symptomatic patients, thus introducing a selection bias. In this meta-analysis, the studies of symptomatic patients were shown to have a 14-fold higher accuracy than those of asymptomatic patients.

Studies of asymptomatic women have reported sensitivities and specificities of 64% and 77% [14], accuracy of 94% [13], accuracy of 92%, sensitivity of 89%, specificity of 97%, positive predictive value of 99%, and negative predictive value of 79% [15]. This raises questions regarding the benefits of using MRI without contrast for implant screening in asymptomatic patients. Given the limited data, there is no clear role for MRI without contrast in evaluation of silicone implants in asymptomatic patients.

MRI breast without and with contrast is not indicated for implant evaluation in asymptomatic women. In high-risk patients, cancer screening breast MRI with and without contrast may be indicated. Further details regarding screening recommendations can be found in the ACR Appropriateness Criteria® "Breast Cancer Screening" [21].

Variant 6: Evaluation of silicone breast implants. Suspected implant complication. Age younger than 30 years. Initial imaging.

Mammography or DBT Diagnostic

Extracapsular silicone implant ruptures, although only a minority of all implant ruptures, frequently present with palpable findings or other symptoms. Mammography and DBT can identify extracapsular silicone [7-9,24,31], which presents as high-density material outside the confines of the implant shell. In patients without prior explantation of silicone implants, this is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants, and comparison with priors is critical. In patients <30 years, mammography or DBT is not the initial examination of choice. Intracapsular silicone implant rupture is frequently asymptomatic and cannot be reliably diagnosed with mammography or DBT.

US

US can identify extracapsular silicone [7-9,24,31], which presents as a classic 'snowstorm' pattern, and should be the first-line examination in patients aged <30. In patients without prior explantation of silicone implants, this finding is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants.

Sonographic findings of intracapsular rupture have been described [7-9], including a 'step-ladder' appearance of the collapsed implant shell. Some authors have reported excellent agreement of US with MRI and surgical findings [10,11]. However, US is well known to be operator dependent, and other studies have reported much lower sensitivities and accuracies for US diagnosis of intracapsular silicone implant rupture [12-14], with accuracy of 72%, sensitivity of 30%, and specificity of 77%. For the assessment of appropriateness, it is assumed the procedure is performed and interpreted by an expert. Although some authors [25] have suggested that an abnormal US in a symptomatic patient with silicone implants should prompt surgery without any additional imaging, this remains controversial.

MRI

MRI without contrast is generally considered the gold standard imaging study for evaluation of silicone implant rupture. It is particularly helpful in identifying intracapsular ruptures, which are not evident on mammography and can be difficult to diagnose by US. Most implant ruptures are intracapsular, and these are most often asymptomatic. MRI findings of both intracapsular and extracapsular rupture have been described [7,9,10,22,31]. An incomplete intracapsular rupture has been referred to by a variety of names including the 'inverted-loop sign,' 'keyhole sign,' 'teardrop sign,' or 'hang noose sign.' A complete intracapsular rupture has been called the 'linguini' or 'wavy-line' sign and is the most specific sign of intracapsular implant rupture. Pooled data from a recent meta-analysis [18] showed a sensitivity of 87% and specificity of 89.9% for MRI. Of note, most studies in the meta-analysis focused on symptomatic women, where the expected prevalence of rupture would be higher than among asymptomatic women. Studies of asymptomatic women have reported sensitivities and specificities of 64% and 77% [14], accuracy of 94% [13], accuracy of 92%, sensitivity of 89%, specificity of 97%, positive predictive value of 99%, and negative predictive value of 79% [15]. In symptomatic patients [19], MRI sensitivity of 96%, specificity of 77%, positive predictive value of 90%, negative predictive value of 90%, and accuracy of 90% have been reported.

MRI without and with contrast is not indicated in silicone implant evaluation.

Variant 7: Evaluation of silicone breast implants. Suspected implant complication. Age 30–39 years. Initial imaging.

Mammography or DBT Diagnostic

Extracapsular silicone implant ruptures, although only a minority of all implant ruptures, frequently present with palpable findings or other symptoms. Mammography and DBT can identify extracapsular silicone [7-9,24,31], which presents as high-density material outside the confines of the implant shell. In patients without prior explantation of silicone implants, this is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants, and comparison with priors is critical. In patients age 30 to 39, mammography/DBT or US may be used as the initial examination of choice. Of note, intracapsular silicone implant rupture is frequently asymptomatic and cannot be reliably diagnosed with mammography or DBT.

US

US can identify extracapsular silicone [7-9,24,31], which presents as a classic 'snowstorm' pattern, and can be the first-line examination in patients age 30 to 39. In patients without prior explantation of silicone implants, this finding is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants.

Sonographic findings of intracapsular rupture have been described [7-9], including a 'step-ladder' appearance of the collapsed implant shell. Some authors have reported excellent agreement of US with MRI and surgical findings [10,11]. However, US is well known to be operator dependent and other studies have reported much lower sensitivities and accuracies for US diagnosis of intracapsular silicone implant rupture [12-14], with accuracy of 72%, sensitivity of 30%, and specificity of 77%. For the assessment of appropriateness, it is assumed the procedure is performed and interpreted by an expert. Although some authors [25] have suggested that an abnormal US in a symptomatic patient with silicone implants should prompt surgery without any additional imaging, this remains controversial.

MRI

MRI without contrast is generally considered the gold standard imaging study for evaluation of silicone implant rupture. It is particularly helpful in identifying intracapsular ruptures, which are not evident on mammography and can be difficult to diagnose by US. Most implant ruptures are intracapsular, and these are most often

asymptomatic. MRI findings of both intracapsular and extracapsular rupture have been described [7,9,10,22,31]. An incomplete intracapsular rupture has been referred to by a variety of names including the 'inverted-loop sign,' 'keyhole sign,' 'teardrop sign,' or 'hang noose sign.' A complete intracapsular rupture has been called the 'linguini' or 'wavy-line' sign and is the most specific sign of intracapsular implant rupture. Pooled data from a recent meta-analysis [18] showed a sensitivity of 87% and specificity of 89.9% for MRI. Of note, most studies in the meta-analysis focused on symptomatic women, where the expected prevalence of rupture would be higher than among asymptomatic women. In symptomatic patients [19], MRI sensitivity of 96%, specificity of 77%, positive predictive value of 90%, negative predictive value of 90%, and accuracy of 90% have been reported.

MRI without and with contrast is not indicated in silicone implant evaluation.

Variant 8: Evaluation of silicone breast implants. Suspected implant complication. Age 40 years or older. Initial imaging.

Mammography or DBT Diagnostic
Diagnostic mammography or DBT can be useful in evaluation of suspected extracapsular silicone implant rupture, which frequently presents with palpable findings or other symptoms. Mammography can identify extracapsular silicone [7-9,24,31], which presents as high-density material outside the confines of the implant shell. In patients without prior explantation of silicone implants, this finding is diagnostic of extracapsular rupture. However, in patients who have had prior silicone implants, this may represent residual silicone rather than rupture of the new implants, and comparison with priors is critical.

Intracapsular rupture cannot be reliably diagnosed with mammography or DBT.

US
US can identify extracapsular silicone [7-9,24,31], which presents as a classic 'snowstorm' pattern and may be indicated if mammographic findings are equivocal or the patient cannot undergo mammography.

Sonographic findings of intracapsular rupture have been described [7-9], including a 'step-ladder' appearance of the collapsed implant shell. Some authors have reported excellent agreement of US with MRI and surgical findings [10,11]. However, US is subject to well-known operator variability, other studies have reported much lower sensitivities, and accuracies for US diagnosis of intracapsular silicone implant rupture [12-14] showed accuracy of 72%, sensitivity of 30%, and specificity of 77%. For the assessment of appropriateness, it is assumed the procedure is performed and interpreted by an expert. Although some authors [25] have suggested that an abnormal US in a symptomatic patient with silicone implants should prompt surgery without any additional imaging, this remains controversial.

MRI
MRI without contrast is generally considered the gold standard imaging study for evaluation of silicone implant rupture. It is particularly helpful in identifying intracapsular ruptures, which are not evident on mammography and can be difficult to diagnose by US. Most implant ruptures are intracapsular, and these are most often asymptomatic. MRI findings of both intracapsular and extracapsular rupture have been described [7,9,10,22,31]. An incomplete intracapsular rupture has been referred to by a variety of names, including the 'inverted-loop sign,' 'keyhole sign,' 'teardrop sign,' or 'hang noose sign.' A complete intracapsular rupture has been called the 'linguini' or 'wavy-line' sign and is the most specific sign of intracapsular implant rupture. Pooled data from a recent meta-analysis [18] showed a sensitivity of 87% and specificity of 89.9% for MRI. Of note, most studies focused on symptomatic women, where the expected prevalence of rupture would be higher than among asymptomatic women. In symptomatic patients [19], MRI sensitivity of 96%, specificity of 77%, positive predictive value of 90%, negative predictive value of 90%, and accuracy of 90% have been reported.

MRI without and with contrast is not indicated in silicone implant evaluation.

Variant 9: Evaluation of unexplained axillary adenopathy. Silicone breast implants (current or prior). Age younger than 30 years. Initial imaging.

Mammography or DBT Diagnostic
Mammography or DBT may be indicated for evaluation of unexplained axillary adenopathy in patients age <30 if suspicious sonographic findings are identified. However, it is not the initial examination of choice for patients age <30 years. Silicone within low axillary nodes may also be seen on mammography and DBT.

US

US should be the first-line examination for patients age <30 years with unexplained axillary adenopathy. US can diagnose silicone adenitis, where a 'snowstorm' [8] appearance will be seen in the axillary nodes containing free silicone. In addition, US can identify morphologically abnormal lymph nodes that may represent metastatic disease from a previously unsuspected breast cancer or may be from a variety of other causes such as lymphoma, infection or systemic illnesses, including autoimmune diseases. If morphologically abnormal lymph nodes are identified, further evaluation of the breast parenchyma is indicated. For patients <30 years of age, this often begins with whole-breast US. US-guided core biopsy should also be considered for diagnosis of morphologically abnormal lymph nodes without characteristic findings of silicone adenitis, especially in the absence of any suspicious breast abnormality.

MRI

MRI without contrast is of limited value in evaluation of unexplained axillary adenopathy in patients age <30 years as its primary function would be to identify silicone in the lymph nodes as an explanation for the adenopathy. However, this can be more readily diagnosed with US.

MRI without and with contrast should not be used as an initial imaging study in this setting. However, MRI with and without contrast is indicated if biopsy shows axillary metastatic disease from a mammographically and sonographically occult primary breast carcinoma.

Variant 10: Evaluation of unexplained axillary adenopathy. Silicone breast implants (current or prior). Age 30–39 years. Initial imaging.

Mammography or DBT Diagnostic

Mammography/DBT or US may be the initial examination of choice for evaluation of unexplained axillary adenopathy in patients age 30 to 39 years. Silicone within low axillary nodes may be seen on mammography and DBT. When mammography/DBT is performed as the initial examination, axillary US is complementary and should also be performed at the same time.

US

US or mammography/DBT may be the first-line examination for patients age 30 to 39 years with unexplained axillary adenopathy. US can diagnose silicone adenitis, where a 'snowstorm' [8] appearance will be seen in the axillary nodes containing free silicone. In addition, US can identify morphologically abnormal lymph nodes that may represent metastatic disease from a previously unsuspected breast cancer or may be from a variety of other causes, such as lymphoma, infection, or systemic illnesses including autoimmune diseases. If morphologically abnormal lymph nodes are identified, further evaluation of the breast parenchyma is indicated. For patients 30 to 39 years of age, this often includes mammography/DBT and US. US-guided core biopsy should also be considered for diagnosis of morphologically abnormal lymph nodes without characteristic findings of silicone adenitis, especially in the absence of any suspicious breast abnormality.

MRI

MRI without contrast is of limited value in evaluation of unexplained axillary adenopathy in patients age 30 to 39 years, as its primary function would be to identify silicone in the lymph nodes as an explanation for the adenopathy. However, this can be more readily diagnosed with US.

MRI without and with contrast should not be used as an initial imaging study in this setting. However, MRI with and without contrast is indicated if biopsy shows axillary metastatic disease from a mammographically and sonographically occult primary breast carcinoma.

Variant 11: Evaluation of unexplained axillary adenopathy. Silicone breast implants (current or prior). Age 40 years or older. Initial imaging.

Mammography or DBT Diagnostic

Mammography/DBT is indicated as the initial examination for evaluation of unexplained axillary adenopathy in patient's age ≥40 years and may identify a breast cancer that has metastasized to the axilla. Silicone within low axillary nodes may also be seen on mammography and DBT. US is complementary and is done in conjunction with mammography/DBT at initial imaging evaluation, regardless of findings on mammography/DBT.

US

US is complementary to mammography/DBT and can diagnose silicone adenitis, in which a 'snowstorm' [8] appearance will be seen in the axillary nodes containing free silicone. In addition, US can identify

morphologically abnormal lymph nodes that may represent metastatic disease from primary breast cancer or may be from a variety of other causes, such as lymphoma, infection, or systemic illnesses including autoimmune diseases. If morphologically abnormal lymph nodes are identified, further evaluation of the breast parenchyma is indicated. This often begins with diagnostic mammography/DBT and may include targeted US of any suspicious findings. US-guided core biopsy should also be considered for diagnosis of morphologically abnormal lymph nodes without characteristic findings of silicone adenitis, especially in the absence of any breast abnormality on mammography and US.

MRI

MRI without contrast is of limited value in evaluation of unexplained axillary adenopathy in patient's age ≥40 years as its primary function would be to identify silicone in the lymph nodes as an explanation for the adenopathy. However, this can be more readily diagnosed with US.

MRI without and with contrast should not be used as an initial imaging study in this setting. However, MRI with and without contrast is indicated if biopsy shows axillary metastatic disease from a mammographically and sonographically occult primary breast carcinoma.

Variant 12: Suspected breast implant associated anaplastic large-cell lymphoma (BIA-ALCL) (delayed seroma, swelling, mass, pain but no erythema, warmth or skin changes that would raise concern for inflammatory breast cancer or mastitis). Any age. Breast implant of any type. Initial imaging.

Mammography or DBT Diagnostic

Mammography or DBT may detect a change in implant appearance related to a new fluid collection or an associated mass. Distinguishing between fluid and solid tissue typically requires US. One meta-analysis [1] reported a sensitivity of 73% and specificity of 50% for mammography in detection of an abnormality.

US

US will frequently identify a fluid collection or mass if present and provides image guidance for diagnostic aspiration of the fluid for cytology or core biopsy of a mass lesion. It is the initial examination of choice. Adrada et al [1] reported 84% sensitivity for detection of effusion and 46% sensitivity for detection of a mass, with corresponding specificity of 75% and 100%, respectively.

MRI

MRI without contrast may identify a fluid collection associated with the implant but is of limited value in detection of an associated mass. US provides an easier means to assess for effusion and has the added benefit of guiding aspiration for cytologic diagnosis.

MRI without and with contrast has reported sensitivity of 82% for detection of effusion and 50% for detection of a mass, with corresponding specificities of 33% and 93%, respectively [1]. This study can be considered if US is equivocal or nondiagnostic.

Summary of Recommendations

- For asymptomatic women (any age) with saline implants, no imaging is recommended for implant evaluation.
- For women <30 years with saline implants and clinical examination equivocal for implant rupture, breast US is recommended for implant evaluation.
- For women age 30 to 39 with saline implants and clinical examination equivocal for implant rupture, mammography, DBT, or breast US is recommended for implant evaluation.
- For women age ≥40 with saline implants and clinical examination equivocal for implant rupture, mammography or DBT is recommended for implant evaluation.
- For asymptomatic women (any age) with silicone implants, no imaging is recommended for implant evaluation.
- For women <30 years with silicone implants and suspected implant complication, breast MRI without contrast or US is recommended for implant evaluation.
- For women age 30 to 39 with silicone implants and suspected implant complication, breast MRI without contrast, mammography and DBT, or breast US is recommended for implant evaluation.
- For women age ≥40 with silicone implants and suspected implant complication, breast MRI without contrast, mammography, or DBT is recommended for implant evaluation.

- For women <30 years with silicone implants (current or prior) and unexplained axillary adenopathy, axillary US is recommended for evaluation of unexplained axillary adenopathy.
- For women age 30 to 39 with silicone implants (current or prior) and unexplained axillary adenopathy, axillary US is recommended for evaluation of unexplained axillary adenopathy. Mammography or DBT may also be performed as a complementary examination in this age group.
- For women age ≥40 with silicone implants (current or prior) and unexplained axillary adenopathy, mammography or DBT and axillary US are recommended for evaluation of unexplained axillary adenopathy. These procedures are complementary and should be performed together.
- For women (any age) with suspected implant-associated anaplastic large-cell lymphoma and breast implants of any type, breast US is recommended.

Summary of Evidence

Of the 32 references cited in the *ACR Appropriateness Criteria® Breast Implant Evaluation* document, 3 are categorized as therapeutic references including 1 well-designed study and 2 quality studies that may have design limitations. Additionally, 28 references are categorized as diagnostic references including 5 good-quality studies and 7 quality studies that may have design limitations. There are 16 references that may not be useful as primary evidence. There is 1 reference that is a meta-analysis study.

The 32 references cited in the *ACR Appropriateness Criteria® Breast Implant Evaluation* document were published from 2004-2017.

Although there are references that report on studies with design limitations, 6 well-designed or good-quality studies provide good evidence.

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults (see Table below). Additional

information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document [32].

Relative Radiation Level Designations		
Relative Radiation Level*	**Adult Effective Dose Estimate Range**	**Pediatric Effective Dose Estimate Range**
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv
☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies".		

Supporting Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

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